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NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, 51, 71, and 73

RIN 3150-A112

[NRC-2008-0120; NRC-2010-0194]

Physical Protection of Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to establish security requirements for the use and transport of category 1 and category 2 quantities of radioactive material. The NRC considers these quantities to be risk significant and, therefore, to warrant additional protection. Category 1 and category 2 thresholds are based on the quantities established by the International Atomic Energy Agency (IAEA) in its Code of Conduct on the Safety and Security of Radioactive Sources, which the NRC endorses. The objective of this final rule is to provide reasonable assurance of preventing the theft or diversion of category 1 and category 2 quantities of radioactive material. The regulations also include security requirements for the transportation of irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel. The final rule affects any licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material, any licensee that transports these materials using ground transportation, and any licensee that transports small quantities of irradiated reactor fuel. The rule also considers a petition for rulemaking (PRM-71-13) submitted by the State of Washington that requested that the NRC adopt the use of global positioning satellite tracking as a national requirement for vehicles transporting highly radioactive mobile or

portable radioactive devices.

DATES: *Effective Date:* This final rule is effective on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION]**.

Compliance Date: Compliance with this final rule is required on March 19, 2014.

ADDRESSES: You can access publicly available documents related to this document using the following methods:

- **NRC's Public Document Room (PDR):** The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** Publicly available documents created or received at the NRC are available online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdresource@nrc.gov.

- **Federal Rulemaking Web site:** Public comments and supporting materials related to this final rule can be found at <http://www.regulations.gov> by searching on Docket ID NRC-2008-0120. Public comments on the guidance document supporting this rule can be found by searching Docket ID NRC-2010-0194. Address questions about NRC dockets to Carol Gallagher, telephone: 301-492-3668; e-mail: Carol.Gallagher@nrc.gov.

Availability of Guidance

The NRC is issuing new guidance for the implementation of the requirements of 10 CFR part 37. The guidance document is NUREG-2155, Implementation Guidance for 10 CFR part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material" (ADAMS Accession No. ML13053A061). This guidance is publicly available as stated in this ADDRESSES section.

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I. Background.

The NRC has long participated in efforts to ensure radioactive source protection and security. The terrorist attacks of September 11, 2001, heightened concerns about the use of risk-significant radioactive materials in a malevolent act. Such an attack is of particular concern because of the widespread use of radioactive materials in the United States by industrial, medical, and academic institutions. The theft or diversion of risk-significant quantities of radioactive materials could lead to their use in a radiological dispersal device (RDD) or a radiological exposure device (RED).

The NRC's current regulations provide requirements for the safe use, transportation, and control of licensed radioactive material. Loss of control of risk-significant radioactive material, whether inadvertent or through a deliberate act, could result in significant adverse impacts that could reasonably constitute a threat to the public health and safety or the common defense and security of the United States. In the changed threat environment after the attacks of September 11, 2001, the Commission determined that certain licensed material should be subject to enhanced security requirements and safeguarded during transport, and that individuals with unescorted access to risk-significant quantities of radioactive material should be subject to background investigations.

As part of the development of the enhanced security measures, the NRC performed threat and vulnerability assessments to identify gaps or vulnerabilities in security and the effectiveness and costs of certain physical protection enhancements at various licensed facilities. The results of these assessments were used in the development of security enhancement orders that were issued to licensees using a graded approach based on the relative risk and quantity of material possessed by the licensee.

The NRC issued the first series of orders to certain panoramic and underwater irradiator licensees that possessed more than 370 Terabequerels (TBq) (10,000 curies (Ci)) of radioactive material (EA-02-249; June 6, 2003) (68 FR 35458; June 13, 2003). The next series of orders were issued to certain manufacturing and distribution (M&D) licensees (EA-03-225; January 12, 2004) (69 FR 5375; February 4, 2004). These orders require the implementation of additional security measures and the protection of the licensee's physical protection information as Safeguards Information – Modified Handling (SGI-M). The original orders are not publicly available because they contain detailed security requirements that are designated as SGI-M. However, redacted versions of these orders have been made available to the public (73 FR 33859; June 13, 2008, and 73 FR 49714; August 22, 2008). These orders were issued to both NRC and Agreement State licensees under the NRC's authority to protect the common defense and security.

Subsequently, the NRC issued Increased Control Orders (EA-05-090; November 14, 2005) (70 FR 72128; December 1, 2005) to other licensees authorized to possess certain risk-significant quantities of radioactive material (category 1 and category 2 quantities). The Increased Control Orders do not contain safeguards information (SGI) or SGI-M, and are available on the NRC's public Web site at <http://www.nrc.gov/security/byproduct/orders.html>. These orders were issued under the NRC's authority to protect public health and safety, and require licensees to implement enhanced security measures known as Increased Controls. To

effect nationwide implementation of the Increased Control Orders, each Agreement State issued legally binding requirements to impose enhanced security measures, identical to the Increased Controls, for licensees under that State's regulatory jurisdiction.

All of the orders described above specifically address the security of byproduct material possessed in quantities equal to or greater than category 1 or category 2 quantities. The orders provide for enhanced security measures for such things as license verification before the transfer of these materials, access control, intrusion detection and response, and coordination with local law enforcement authorities (LLEAs). The orders also contain requirements for the licensee to determine the trustworthiness and reliability of individuals permitted unescorted access to risk-significant radioactive materials. The determination involves a background investigation of the individual. The background investigations were originally limited to local criminal history records checks with law enforcement agencies, verification of employment history, education, personal references, and confirmation of employment eligibility (legal immigration status).

In 2005, Congress passed, and the President signed, the Energy Policy Act of 2005 (EPAAct). The EPAAct amended Section 149 of the Atomic Energy Act (AEA) to authorize the Commission to require to be fingerprinted any individual who is permitted unescorted access to radioactive material or other property subject to regulation by the Commission that the Commission determines to be of such significance to the public health and safety or the common defense and security as to warrant fingerprinting and a Federal Bureau of Investigation (FBI) criminal history records check. With this new authority, the Commission determined that individuals who have access to category 1 and category 2 quantities of radioactive material warrant fingerprinting and FBI criminal history records checks.

On October 17, 2006, the NRC issued orders to panoramic and underwater irradiator licensees (EA-06-248) (71 FR 63043; October 27, 2006), M&D licensees (EA-06-250)

(71 FR 63046; October 27, 2006), and licensees making shipments of category 1 quantities of radioactive material (EA-06-249) (71 FR 62302; October 24, 2006) to require fingerprinting and FBI criminal history records checks for unescorted access to risk-significant quantities of radioactive material at their facilities. In issuing these orders, the NRC noted that a malevolent act by an individual with unescorted access to these materials could result in significant adverse impacts to the public health and safety or the common defense and security and, thus, necessitated expedited implementation of fingerprinting requirements. The orders were issued to both NRC and Agreement State licensees under the NRC's authority to protect the common defense and security. On December 5, 2007, the NRC issued orders to all other NRC licensees that possessed category 1 or category 2 quantities of radioactive material (EA-07-305) (72 FR 70901; December 13, 2007) to require fingerprinting and FBI criminal history records checks for unescorted access to category 1 or category 2 quantities of radioactive material. These orders were issued under the NRC's authority to protect the public health and safety and are available on the NRC's public Web site at <http://www.nrc.gov/security/byproduct/orders.html>. To effect nationwide implementation, each Agreement State issued legally binding requirements consistent with the Increased Control Orders to licensees under their regulatory jurisdiction.

In 2005, the NRC issued two sets of orders to licensees transporting radioactive material in quantities of concern. The first set of transportation security orders was issued to certain licensees that might be expected to transport radioactive materials in category 1 quantities (EA-05-006; July 19, 2005) (70 FR 44407; August 2, 2005). These orders require the implementation of additional security measures and the protection of the licensee's physical protection information as SGI-M. The original orders are not publicly available because they contain detailed security requirements that are designated as SGI-M. However, a redacted version of the order is publicly available (73 FR 51016; August 29, 2008). These orders were

issued to both NRC and Agreement State licensees under the NRC's authority to protect the common defense and security.

Subsequently, the NRC issued orders (EA-05-090; November 14, 2005) (70 FR 72128; December 1, 2005) to specifically address the transportation security of byproduct material transported in quantities equal to or greater than category 2. The Increased Control Orders mentioned earlier also contain requirements for transporting category 2 quantities of radioactive material. The additional security measures contained in these two sets of orders provide for enhanced security measures during transportation that are beyond the regulations then applicable, and include: enhanced security in preplanning and coordinating shipments; advance notification of shipments to the NRC and States through which the shipment will pass; control and monitoring of shipments that are underway; trustworthiness and reliability of transport personnel; information security considerations; and control of mobile or portable devices such as radiography cameras and well-logging devices.

In November 2009, the NRC issued the Increased Control Order and the Fingerprint Order to power reactor licensees that are undergoing decommissioning (EA-09-204 and EA-09-205; November 23, 2009) (74 FR 66168 and 74 FR 66164; December 14, 2009). The orders required these licensees to implement the Increased Controls and to obtain fingerprints and criminal history records checks for individuals to have or continue having unescorted access to aggregated category 1 or category 2 quantities of radioactive material.

In December 2009, the NRC issued orders to service provider licensees that were not manufacturers or distributors (EA-09-293; December 16, 2009 (75 FR 160; January 4, 2010). The order required service provider licensees to implement specific measures to ensure the trustworthiness and reliability of their service representatives that have unescorted access to category 1 or category 2 quantities of radioactive materials.

The requirements put in place by all these above-described orders supplement the existing regulatory requirements. These additional requirements are primarily intended to provide reasonable assurance of preventing the theft or diversion of risk-significant radioactive material. These requirements provide the Commission with reasonable assurance that public health and safety and the common defense and security continue to be adequately protected.

It is the Commission's preference to implement generically applicable requirements through rulemaking rather than by orders. An order is legally binding only on the licensee or licensees receiving the order. Further, the notice-and-comment rulemaking process allows members of the public to provide comments on the proposed rule.

This rulemaking promulgates generically applicable security requirements for licensees possessing category 1 and category 2 quantities of radioactive material in the regulations. New requirements for background investigations and an access authorization program are included to ensure that individuals who have access to these materials have gone through background investigations and are determined to be trustworthy and reliable. New requirements are also included to establish physical protection systems to detect, assess, and respond to unauthorized access to category 1 and category 2 quantities of radioactive material. For transport of the radioactive materials, new requirements for recipient license verification; preplanning and coordination of shipments; advance notification of shipments; notification of shipment delays, schedule changes, and suspected loss of a shipment; and control and monitoring of shipments are included. The amendments also include security requirements for shipments of irradiated reactor fuel that weigh 100 grams (g) (0.22 pounds (lb)) or less in net weight of irradiated fuel, exclusive of cladding or other structural or packaging material, which has a total external radiation dose rate in excess of 1 Gray (100 rad) per hour at a distance of 1 meters (m) (3.3 feet (ft)) from any accessible surface without intervening shielding.

In developing this final rule, the NRC considered, among other things, the various orders, lessons-learned during implementation of the orders, the recommendations of the Independent External Review Panel and the Materials Program Working Group, and stakeholder comments received on the proposed rule and the draft implementation guidance. The Commission chartered the Independent External Review Panel to: 1) identify vulnerabilities in the NRC's materials licensing program with respect to import, export, specific, and general licenses; 2) validate the ongoing byproduct material security efforts; and 3) evaluate the apparent "good faith presumption" in the NRC licensing process that had in the past justified minimal investigation of new license applicants or inspection of their facilities before allowing their possession of radioactive material. The Panel's March 2008 report is available in ADAMS under Accession No. ML080700957. The Materials Program Working Group conducted a comprehensive evaluation of the materials program to identify short- and long-term strategies to mitigate security vulnerabilities. The Working Group report contains sensitive information and is not publicly available. However, the Group's comments on the Panel's report are publicly available in ADAMS under Accession No. ML080660424.

PRM-71-13

On July 16, 2008 (73 FR 40767), the NRC published the resolution and closure of a petition for rulemaking filed by Christine O. Gregoire, Governor of the State of Washington (PRM-71-13). The NRC indicated that the issues raised by the petitioner would be considered in an ongoing rulemaking on security requirements for the transportation of radioactive material in quantities of concern.

The petitioner requested that the NRC adopt the use of global positioning system (GPS) tracking as a national requirement for vehicles transporting highly radioactive mobile or portable

radioactive devices. As an alternative, the petitioner stated that the Commission could grant States the flexibility to impose more stringent requirements than those required under the current Increased Controls Orders. The petitioner believes that GPS technology is an effective and relatively inexpensive tool that would give law enforcement a significant advantage in locating a missing source. However, the petitioner acknowledged that requiring a GPS on these vehicles does not ensure that the radiological source will be found.

The NRC considered the issues identified by the petitioner and the petitioner's suggested approach to address those issues in the decision-making process and final determination of the rule requirements in the area of the petitioner's concern. The NRC ultimately did not include a requirement for GPS tracking in the rule. However, the rule does contain a requirement to use a telemetric position monitoring system or an alternative tracking system when transporting category 1 quantities of radioactive material. Use of GPS would be one method to satisfy this requirement. For licensees transporting category 2 quantities of radioactive material, tracking is not required. The licensee is required to maintain constant control or surveillance during transit. In addition, the rule at § 37.53 imposes additional security measures on mobile devices that includes using a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. The NRC believes that these requirements provide adequate protection for mobile devices and that GPS is neither justified nor necessary. The majority of the transportation security requirements are Compatibility Category B because there are direct and significant transboundary implications. Because the requirements are Compatibility B, Agreement States must adopt program elements essentially identical to those of the NRC and do not have the flexibility to adopt more stringent requirements. See *a/so* response to comment D29.

II. Discussion.

The NRC has determined that a new part for Title 10 of the *Code of Federal Regulations* (10 CFR) should be established for the security requirements for use and transportation of category 1 and category 2 quantities of radioactive material. Separate safety and physical protection requirements have already been established for special nuclear material in 10 CFR part 73. The establishment of a new part for security-related requirements for byproduct material would be more effective and efficient compared to interspersing the requirements with safety requirements or placing them with the part 73 security requirements for special nuclear material. A new part specifically directed to byproduct material licensees should make applicable requirements easier for both licensees and other stakeholders to locate and understand.

This discussion section has been divided into four subsections to better present information on the final rule. Each section presents information on a different aspect of the final rule. Section A provides information that is generally applicable to all aspects of this rulemaking. Section B provides information on background investigations and the access authorization program. Section C provides information on the physical protection of the materials during use. Lastly, Section D provides information on transportation security aspects.

A. General Applicability

1. *What Action is the NRC Taking?*

The NRC is amending its regulations to impose security requirements for the use and transportation of category 1 and category 2 quantities of radioactive material. The requirements establish the objectives and minimum requirements that licensees must meet to protect against theft or diversion of this material. These requirements are intended to increase the protection of

the public against the unauthorized use of category 1 or category 2 quantities of radioactive material by reducing the risk of the theft or diversion of the material. The NRC is also amending the regulations to impose security requirements for the transportation of small quantities (100 grams or less) of irradiated fuel.

2. Why Do the Requirements Need to be Revised?

Prior to September 11, 2001, the NRC requirements focused on safety and preventing inadvertent or accidental exposure of both workers and the public to these materials. These requirements also provided security for the material. The events of September 11, 2001, made the NRC take a broader look at its requirements and reevaluate what a terrorist might do to obtain these materials. From this effort, the NRC identified several areas where additional requirements were necessary to improve security. The security requirements need to be placed in the regulations so that they are generally applicable to all licensees. Publication of the proposed rule also provided an opportunity for all stakeholders to comment on the proposed requirements.

3. Why Doesn't the NRC Just Keep the Orders in Effect?

The orders issued by the NRC could stay in place indefinitely. However, the regulations would not reflect current Commission policy or requirements. Imposing long-term requirements through orders has not traditionally been the agency's preferred method of regulation. Orders, unlike rules, do not apply prospectively to applicants for new licenses. The NRC would have to periodically issue new orders to cover new and amended licenses, and perhaps reissue orders periodically to existing licensees if requirements or administrative practices change. In order to make the requirements generally applicable to all present and future licensees, the security-related requirements need to be placed in the regulations.

The NRC is now formally revising its security requirements. The orders will remain in place for NRC licensees until the final rule is implemented (1 year after publication of the final

rule). Once the final rule is implemented, the NRC will rescind the orders that were issued to its licensees. For Agreement State licensees that received an NRC order, the order will remain in place until the effective date of compatible requirements issued by the Agreement States. Each Agreement State will follow its own process for issuing these requirements. Once the State has issued its requirements and they become effective, the NRC will rescind the order.

4. Whom Would This Action Affect?

These requirements will apply to NRC and Agreement State licensees that possess an aggregated category 1 or category 2 quantity of radioactive material or that transport irradiated reactor fuel less than 100 grams net weight. This includes a wide range of licensees, including pool-type irradiator licensees; manufacturer and distributor licensees; medical facilities with gamma knife devices; self-shielded irradiator licensees (including blood irradiators); teletherapy unit licensees; radiographers; well loggers; broad scope users; radioisotope thermoelectric generator licensees; and licensees that ship or prepare for shipment category 1 or category 2 quantities of radioactive material. Nearly 1,400 licensees are implementing the various orders and are the entities that will be primarily impacted by this final rule. In addition, some fuel cycle and reactor licensees that possess sources at these levels may be impacted. Some decommissioning reactor licensees may also be impacted. Most licensees whose activities are covered under the physical protection requirements of 10 CFR part 73 are exempt from the requirements of 10 CFR part 37. For example, a reactor licensed under part 50 that also possesses a radiography source under an NRC license does not need to implement the part 37 provisions if the source is protected under the reactor security program required by part 73. Licensees that possess an aggregated quantity of radioactive waste that equals or exceeds the category 2 threshold will need to meet some requirements, but would not need to meet most of the program elements in part 37.

Aggregated quantity refers to the total quantity of radioactive material, calculated by use of the sum of fractions method discussed in question 7, that can be accessed by defeating a single physical barrier.

5. What are Category 1 and Category 2 Quantities of Radioactive Material?

Category 1 quantities of radioactive material have been called radioactive material in quantities of concern (RAMQC). Category 1 and category 2 quantities of radioactive material have been called risk-significant radioactive material and refer specifically to 16 radioactive materials (14 single radionuclides and 2 combinations). These materials are: americium-241; americium-241/beryllium; californium-252; curium-244; cobalt-60; cesium-137; gadolinium-153; iridium-192; plutonium-238; plutonium-239/beryllium; promethium-147; radium-226; selenium-75; strontium-90 (yttrium-90); thulium-170; and ytterbium-169. Irradiated fuel and mixed oxide fuel are not included even though they may contain category 1 or category 2 quantities of radioactive material; these materials are covered by other regulations. The thresholds for category 1 and category 2 quantities of radioactive material are provided in the following table. Terabecquerels is the official unit to be used for determining whether a radioactive material is a category 1 or category 2 quantity. Because many licensees use curies in their activities instead of Becquerels, the table provides the curie value at three significant figures for convenience.

Radioactive Material	Category 1 Threshold		Category 2 Threshold	
	Terabecquerels (TBq)	Curies (Ci)	Terabecquerels (TBq)	Curies (Ci)
Americium-241	60	1,620	0.6	16.2
Americium-241/Beryllium	60	1,620	0.6	16.2

Californium-252	20	540	0.2	5.40
Curium-244	50	1,350	0.5	13.5
Cobalt-60	30	810	0.3	8.10
Cesium-137	100	2,700	1	27.0
Gadolinium-153	1000	27,000	10.0	270
Iridium-192	80	2,160	0.8	21.6
Plutonium-238	60	1,620	0.6	16.2
Plutonium-239/Beryllium	60	1,620	0.6	16.2
Promethium-147	40,000	1,080,000	400	10,800
Radium-226	40	1,080	0.4	10.8
Selenium-75	200	5,400	2.0	54.0
Strontium-90 (Yttrium-90)	1,000	27,000	10.0	270
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81.0

These materials and thresholds are based on the IAEA Code of Conduct. The IAEA published these results in a document titled “Code of Conduct on the Safety and Security of Radioactive Sources.” A link to this document can be found on the NRC’s Web site at <http://www.nrc.gov/security/byproduct/enhanced-security.html>. The NRC and the international community, led by the IAEA, revised the IAEA Code of Conduct in 2003, to establish common international guidance for safety and security measures for radioactive sources. In a separate effort, the U.S. Department of Energy (DOE) and the NRC reviewed the chemical, physical, and radiological characteristics of each radioactive material that is licensed in the United States, for

its attractiveness to a terrorist. This effort identified 16 radioactive materials that could pose a serious threat to people and the environment if used malevolently. This effort further identified the different quantities or “thresholds” of materials that could be useful to a terrorist. The results of the DOE/NRC effort closely matched the Code of Conduct Category 2 quantities. The NRC adopted the IAEA Code of Conduct Category 1 and Category 2 threshold quantities to provide consistency between domestic and international efforts for security of radioactive materials that are deemed to be attractive targets for malevolent use.

IAEA Safety Series RS-G-1.9, *Categorization of Radioactive Sources*, provides the underlying methodology for the development of the Code of Conduct thresholds. Safety Series RS-G-1.9 provides a risk-based ranking of radioactive sources in five categories in terms of their potential to cause severe deterministic effects for a range of scenarios that include both external exposure from an unshielded source and internal exposure following dispersal. The categorization system uses the ‘D’ values as normalizing factors. The ‘D’ value is the radionuclide specific activity of a source that, if not under control, could cause severe deterministic effects for a range of scenarios that include both external exposure from an unshielded source and internal exposure following dispersal of the source material. Safety Series RS-G-1.9 is available on the IAEA’s Web site at:

http://www-pub.iaea.org/MTCD/publications/PDF/Pub1227_web.pdf.

6. Why Are the Requirements Limited to These 16 Radionuclides?

The Radiation Source Protection and Security Task Force, an interagency task force established by the EPAct, concluded in its 2006 report to Congress and the President (ADAMS Accession No. ML062190349) that the appropriate radioactive sources were being protected. The Task Force also concluded that the IAEA Code of Conduct serves as an appropriate framework for considering which sources warrant additional protection. For its 2010, report to Congress and the President (ADAMS Accession No. ML102230141), the Task

Force conducted a reevaluation of the radionuclides that warrant additional security and protection. The Task Force found “that the Category 1 and 2 quantities remain valid for sealed and unsealed sources as the list and threshold levels of radionuclides that could result in a significant RED or RDD event and therefore warrant enhanced security and protection.” The Task Force identified seven additional radionuclides that may be of concern when aggregated, but the Task Force did not recommend at this time that these additional radionuclides should receive enhanced protection. If in the future the Task Force revises its view and determines that additional security is necessary for these materials, the NRC would consider requiring additional security for these materials. The Task Force periodically reevaluates the list of radionuclides that warrant additional security and protection. If the radionuclides and/or thresholds change in the future, any changes would be addressed in a future rulemaking.

7. What is the Sum of Fractions Methodology or Unity Rule?

The sum of fractions methodology, also known as the unity rule, is used to determine if a licensee is required to implement 10 CFR part 37 requirements. A licensee may need to implement the requirements in 10 CFR part 37 even if it does not possess any single source or single radionuclide in excess of the category 2 thresholds. For combinations of materials (to include sealed sources, unsealed sources, and bulk or loose material) and radionuclides, a licensee must include multiple items (including bulk material) of the same radionuclide and multiple items (including bulk material) of different radionuclides to determine if the requirements apply. For the purposes of this calculation, licensees are required to consider all of the aggregated radioactive material from the list of applicable radionuclides at any location where the material can be accessed by breaching a single barrier. The following formula for the unity rule is used to determine if a licensee is required to implement the part 37 requirements:

$$[(\text{total amount of radionuclide A}) \div (\text{category 2 threshold of radionuclide A})] + [(\text{total amount of radionuclide B}) \div (\text{category 2 threshold of radionuclide B})] + \text{etc.} \geq 1.$$

If the sum is greater

than or equal to 1, the licensee has at least a category 2 quantity of radioactive material, and the 10 CFR part 37 requirements apply.

8. Does the NRC Plan To Issue Guidance on These Requirements?

Yes, the NRC plans to issue guidance on the security requirements for category 1 and category 2 quantities of radioactive materials. The draft guidance was issued for public comment (75 FR 40756; July 14, 2010) during the comment period on the proposed rule. The NRC is issuing new guidance for the implementation of the requirements of 10 CFR part 37. The guidance document is NUREG-2155, Implementation Guidance for 10 CFR part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material" (ADAMS Accession No. ML13053A061). This guidance and public comments are available as stated in the ADDRESSES section of this document.

9. Will All of the Information Considered to be Safeguards Information Under the Orders Now be Made Public?

No. The orders issued to some licensees contained detailed security information that could be useful to an adversary. To increase public awareness and participation, the NRC identified the primary security concepts behind each security measure and included these concepts in the rule to allow discussion of the security measures in a public forum. But the specific measures that a licensee puts in place may be considered SGI-M. The final rule on safeguards information became effective on February 23, 2009 (73 FR 63546; October 24, 2008), and established as SGI-M certain physical protection information related to panoramic and underwater irradiators that possess greater than 370 TBq (10,000 Ci) of byproduct material in the form of sealed sources; manufacturers and distributors of items containing source material, byproduct material, or special nuclear material in greater than category 2 quantities; and transportation of source, byproduct, or special nuclear material in greater than or equal to category 1 quantities. Physical protection information for other facilities that fall under the

requirements of 10 CFR part 37 is considered physical protection information under 10 CFR 2.390(d)(1). Licensees are also required to protect the security plan and implementing information and the list of individuals that have unescorted access from unauthorized disclosure. The rule provisions that address SGI-M or include references to the SGI-M requirements in part 73 are reserved for the NRC and are considered compatibility category NRC.

10. *What is the Authority for This Final Rule?*

As noted in the background discussion, the NRC issued some orders under its authority to protect the common defense and security and some orders under its authority to protect the public health and safety. With respect to whether the following regulations are being issued under “public health and safety” or “common defense and security,” it should be recognized that almost all regulations relating to the security of materials serve both purposes to some degree. For example, securing radioactive materials with multiple barriers protects the public health and safety by preventing the unknowing theft of radioactive materials—such as someone stealing a vehicle with material stored in the vehicle, but whose target is the vehicle—which could result in the unintentional exposure of members of the public to the material. The barriers also protect the common defense and security by preventing the theft of the radioactive material by potential terrorists or others targeting the specific material intending to use it to affect the common defense and security by exposing members of the public to the material. However, the designation of the authority being used for these regulations does have significance in determining whether Agreement States or the NRC will be responsible for overseeing the implementation of these requirements for Agreement State licensees.

Although section 274(b) of the AEA allows the NRC to relinquish its regulatory authority to Agreement States for certain radioactive materials and activities, section 274(m) of the AEA prevents such agreements from affecting the authority of the Commission to take regulatory action to protect the common defense and security. Thus, as evidenced by orders issued to

Agreement State licensees after the events of September 11, 2001, the NRC has the ability to take necessary steps to address particular common defense and security needs. If these regulations were to be issued under the NRC's common defense and security authority, only the NRC would have the authority to impose these requirements on Agreement State licensees and the NRC would be responsible for inspection and enforcement of these requirements for Agreement State licensees.

When regulations such as these complement both the NRC's public health and safety and common defense and security missions, the operative question is whether NRC oversight is necessary to fulfill the common defense and security aspects of the regulations. The NRC believes that the Agreement States can consistently and adequately implement the physical protection requirements on a nationwide basis, and as such, there will be no need for independent NRC action to protect the common defense and security. As always, the NRC retains the authority under section 274(m) of the AEA to take any necessary actions for protection of the common defense and security should individual licensees or Agreement State programs develop issues requiring immediate action. As long as all Agreement States continue to implement compatible and adequate security requirements, there appears to be no benefit to the public health and safety, or common defense and security, that would justify removing oversight of these requirements from an established regulatory program overseeing Agreement State licensees. Implementing these regulations under the NRC's public health and safety authority avoids potential complications with licensees being subject to dual regulatory authority for a single license. Thus, the NRC is issuing these regulations under its public health and safety authority, and these requirements are applicable to Agreement State licensees through the Agreement State Program.

11. *When Would the Rule be Effective?*

The final rule is effective 60 days after publication in the *Federal Register*; however, licensees do not need to comply with the rule until 1 year after publication. This provides time for licensees to put in place the necessary programs, develop procedures, and conduct training on the new requirements. While most of the provisions are similar to those contained in the orders, there are differences. The Agreement States will be required to issue compatible requirements within 3 years of the publication date of the final rule instead of 3 years from the effective date of the rule. Licensees in an Agreement State will continue to operate under the orders or other legally binding requirements until the Agreement State issues compatible requirements and these requirements take effect. The provisions put in place for the inspection of licensees in Agreement States that received the orders issued under common defense and security will remain in place until the Agreement State implements the requirements. For those Agreement States that enter into 274i Agreements, the State can continue inspections under the Agreement. For those Agreement States that did not enter into 274i Agreements, the NRC will continue to conduct the inspections until the new Agreement State requirements become effective. The NRC will rescind the orders as the regulatory requirements become effective.

12. *How Does the NRC Ensure Licensees are Following These Rules?*

The NRC and Agreement States conduct inspections to ensure that licensees are following the requirements. The NRC and Agreement State inspectors will receive training and follow inspection procedures on how to ascertain whether licensees are meeting security requirements. Potential violations that are identified will be processed in accordance with the NRC Enforcement Policy, and depending on the severity of a violation, licensees could be subject to civil or criminal penalties. Additionally, the NRC has developed enforcement guidance to ensure consistency in the enforcement process. Agreement State licensees are

subject to the State's enforcement process. Those Agreement State licensees that were issued NRC orders under common defense and security would remain subject to the NRC's enforcement process, until the Agreement State adopts the regulations with its own legally binding requirements.

B. Background Investigations and Access Authorization Program

1. *Who Is Required to Have an Access Authorization Program?*

Any licensee that possesses category 1 or category 2 quantities of radioactive materials at a facility needs to determine whether it needs to have an access authorization program. Only those licensees that permit unescorted access to an aggregated category 1 or category 2 quantity of radioactive material are required to establish and implement an access authorization program. If the material can be accessed by the breach of a single physical barrier, the licensee needs to implement an access authorization program. In addition, any applicant for a license or license amendment to possess category 1 or category 2 quantities of radioactive material at a facility is required to establish an access authorization program before obtaining the radioactive material, if it will be aggregating the material at or above the category 2 threshold.

2. *What is the Objective of the Access Authorization Program?*

The main objective of the access authorization program is to ensure that individuals who have unescorted access to category 1 or category 2 quantities of radioactive material are trustworthy and reliable and do not constitute an unreasonable risk to the public health and safety or common defense and security.

3. *Who Is Subject to the Licensee's Access Authorization Program?*

Section 652 of the EPA Act authorizes the Commission to require fingerprinting of any individual who is permitted unescorted access to "any radioactive material that the Commission determines to be of such significance to the public health and safety or the common defense

and security as to warrant fingerprinting and background checks.” The Commission has determined that the threshold that warrants fingerprinting and background checks is category 2. The Commission directed that any licensee implementing the Increased Control Orders should also have a fingerprinting and an FBI criminal records check for any individual with unescorted access to category 1 or category 2 quantities of radioactive material. Because only licensees that had aggregated quantities at or above the category 2 threshold implemented the orders, these are the licensees that need to have an access authorization program, *i.e.*, any licensee that has an aggregated quantity of radioactive material at or above the category 2 threshold. Therefore, individuals subject to a licensee’s access authorization program include anyone permitted to have unescorted access to category 1 or category 2 quantities of radioactive material. Unescorted access is defined as solitary access to category 1 or category 2 quantities of radioactive material or the devices that contain the material. The reviewing official is also included in the program to ensure that this individual is subjected to the same background check and degree of trustworthiness and reliability.

The access authorization program may also include individuals that have access to SGI-M, such as vehicle drivers and accompanying individuals for road shipments of category 1 quantities of radioactive material, movement control center personnel for shipments of category 1 quantities of radioactive material, and any individual whose assigned duties provide access to shipment information on category 1 quantities of radioactive material. Licensees may have a separate program for access to SGI or may include the program with the part 37 program for unescorted access to the material.

Those individuals who have unescorted access to certain quantities of byproduct material could pose a threat to the public health and safety or the common defense and security because they could divert or steal risk-significant radioactive material, or could aid others in the commission of such acts. The Radiation Source Protection and Security Task Force

encouraged the NRC to require fingerprinting and Federal criminal history checks of any individual with access to category 1 or category 2 quantities of radioactive material.

Certain categories of individuals are relieved from the background investigation aspect of the access authorization program (see Section II, question B20 and B21). Licensees do have the option to escort an individual and not make a trustworthiness and reliability determination. The escorts need to be approved for unescorted access.

4. What are the Key Access Authorization Program Requirements?

The key components of an access authorization program are the reviewing official, a background investigation, use of procedures, and the individual's right to correct and complete the information on which the decision to grant unescorted access is based. Each of these areas is discussed in more detail in the following questions and answers.

5. What is The Role of the Reviewing Official?

The reviewing official is the individual that makes the trustworthiness and reliability determinations for the licensee; the reviewing official determines who can be allowed unescorted access authorization. Note that the Increased Control Fingerprinting Orders referred to a trustworthiness and reliability official (or T&R official) as the individual who made determinations on a subject individual's trustworthiness and reliability. Unlike the reviewing official, the T&R official did not have to be fingerprinted. Under this rule, fingerprints of the reviewing official(s) need to be taken by either a law enforcement agency, a Federal or State agency that provides fingerprinting services to the public, or a commercial fingerprinting service authorized by a State to take fingerprints and then be submitted to the NRC. This ensures the identification of the individual submitting the fingerprints. Without this requirement the reviewing official could submit the fingerprints of another individual that is known not to have a criminal history or known terrorist ties. Reviewing officials must be permitted either access to

safeguards information or unescorted access to category 1 or category 2 quantities of radioactive material because section 149 of the AEA only authorizes the collection of fingerprints for the purposes of unescorted access to radioactive material or access to safeguards information. After the licensee has completed the background investigation for the reviewing official and determined that the individual is trustworthy and reliable, the licensee must provide under oath and affirmation, a certification that the reviewing official is deemed trustworthy and reliable. For certain licensees, the NRC may have approved reviewing officials, either under the October 17, 2006, orders (EA-06-248, EA-06-250, and EA-06-249), under the August 21, 2006, SGI-M Orders, or under other regulatory requirements. In those cases, the reviewing official may continue to act in that capacity. If the reviewing (or T&R) official has not had an FBI criminal records history check, he or she needs to be fingerprinted and undergo a background investigation and be named by the licensee before making additional trustworthiness and reliability determinations. If the individual falls under one of the categories of individuals granted relief from the background investigation, the individual can be determined to be trustworthy and reliable without going through a full background investigation. The NRC believes that it is important that the individual who is making the final determination on whether an individual is trustworthy and reliable be trustworthy and reliable themselves and have undergone the same background investigation as individuals who would be granted unescorted access, including fingerprinting and the FBI criminal records check. If the reviewing official is not fingerprinted, a gap could be created in the security program that could potentially be exploited. The reviewing official could have a criminal history or terrorist ties and allow other individuals with a criminal history or terrorist ties to have unescorted access to radioactive material in quantities of concern. This addresses the good faith presumption.

6. What is Informed Consent?

Informed consent is the authorization provided by an individual that allows a background

investigation to be conducted to determine whether the individual is trustworthy and reliable. The signed consent includes authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. An individual can withdraw his or her consent at any time. After the withdrawal, the licensee may not initiate any elements of the background investigation that were not in process at the time of the withdrawal of consent. The licensee is required to inform the individual that withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

Licensees do not need to obtain signed consent from individuals that have already undergone a background investigation that included fingerprinting and an FBI criminal history records check, been determined to be trustworthy and reliable, and permitted unescorted access to category 1 or category 2 quantities of radioactive material under the NRC orders or the legally binding requirements issued by the Agreement States. A signed consent is needed for any reinvestigation.

7. What is a Personal History Disclosure?

The personal history disclosure is the personal history required to be provided by the individual seeking unescorted access to category 1 or category 2 quantities of radioactive material. The information includes items such as employment history, education, and any arrest record. This information provides the reviewing official with a starting point for the background investigation. Failure to provide the information or falsification of any information could be grounds for denial of the individual's request for unescorted access authorization or termination of access if the individual already has access. If the individual provides false information, it could be an indication that he or she is not trustworthy or reliable.

8. What are the Components of a Background Investigation?

A background investigation includes several components: fingerprinting and an FBI

identification and criminal history records check; verification of true identity; employment history verification; verification of education; and character and reputation determination.

It is the licensee's responsibility to make a trustworthiness and reliability determination of an employee, contractor, or other individual who will be granted unescorted access to category 1 or category 2 quantities of radioactive material or a device containing such radioactive material. It is expected that licensees will use their best efforts to obtain the information required to conduct a background investigation to determine an individual's trustworthiness and reliability. Information previously obtained during the hiring process may be used to support a licensee's determination of an individual's trustworthiness and reliability without having to reverify that information. There is no particular piece of information that would automatically disqualify an individual from access. The intent is that the information is considered as a whole in determining if an individual is both trustworthy and reliable.

Fingerprinting an individual for an FBI criminal history records check is an important element of the background investigation. It can provide comprehensive information regarding an individual's recorded criminal activities within the United States and its territories and the individual's known affiliations with violent gangs or terrorist organizations.

Verification of true identity is necessary to make sure that the individual is who he or she claims to be and that the documentation matches. This check is important to make sure that someone is not posing as someone else.

Employment history, education verification, character and reputation determination; and obtaining independent information are necessary to ensure that the individual is who they claim to be, that the individual has not made false claims, has a good reputation, and conducts his or herself in a trustworthy and reliable manner.

The background investigation is a tool to determine whether individuals are trustworthy and reliable and could be permitted unescorted access to category 1 or category 2 quantities of

radioactive material. It is essential to ensure that individuals seeking unescorted access to radioactive material are dependable in judgment, character, and performance, such that unescorted access to category 1 or category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or common defense and security.

Nothing in the regulations prevents a licensee from including other elements in its background investigation. Although the NRC did not include the credit history check as a required element of the background investigation, a credit history check can provide supplemental information that could be useful to licensees, particularly in the situation where it is difficult to make a trustworthiness and reliability determination. Information from a credit history check could provide additional information that would be useful in making that final decision. To the extent that a licensee decides to use a credit history check as a measure beyond the regulatory minimum required for the access authorization program, the NRC acknowledges the merit of such use.

9. Where Does a Licensee Submit the Fingerprints for Processing?

Under the EPA Act, licensees are required to submit the fingerprints to the NRC, which forwards the fingerprints to the FBI for processing. If an individual comes under one of the categories for relief specified in 10 CFR 37.29, the licensee does not need to submit the individual's fingerprints to the NRC.

10. What Should a Licensee Do if an Individual or Entity Contacted as Part of a Background Investigation Refuses to Respond?

If a previous employer, educational institution, or any other entity fails to provide information or indicates an inability or unwillingness to provide information in a timely manner, the licensee is required to document the refusal, unwillingness, or inability to respond in the record of investigation. The licensee then needs to attempt to obtain confirmation from at least

one alternate source that has not been previously used.

11. Does an Individual Have the Right to Correct His or Her Criminal History Records?

Yes, an individual has the right to correct his or her criminal history records before any final adverse determination is made. If the individual believes that his or her criminal history records are incorrect or incomplete in any respect, he or she can initiate challenge procedures. These procedures include direct application by the individual challenging the criminal history records to the law enforcement agency that contributed the questioned information. Before an adverse determination on a request for unescorted access, individuals have the right to provide additional information.

12. Is a Licensee Required to have Procedures for Implementing the Access Authorization Program?

Yes, licensees are required to develop, implement, and maintain written procedures for implementing the access authorization program. At a minimum, procedures need to address notification of individuals denied unescorted access authorization, including provisions for review of the denial.

13. What Information Should the Reviewing Official Use to Determine that an Individual is Trustworthy and Reliable?

The reviewing official uses all of the information gathered during the background investigation, including the information received from the FBI, in making a determination that an individual is trustworthy and reliable. The reviewing official may not determine that an individual is trustworthy and reliable and grant unescorted access until the information obtained for the background investigation has been evaluated. The reviewing official may deny unescorted access to any individual based on any information obtained at any time during the background investigation. However, as required by section 149.c(2)(c) of the AEA, the licensee may not

base a final determination to deny an individual unescorted access to category 1 or category 2 quantities of radioactive material solely on the basis of information received from the FBI involving: 1) an arrest more than 1 year old for which there is no information of the disposition of the case; or 2) an arrest that resulted in dismissal of the charge or an acquittal. If there is no record on the disposition of the case, it may be that information on a dismissal or acquittal was not recorded.

14. How Frequently Is a Reinvestigation Required?

A reinvestigation is required every 10 years to help maintain the integrity of the access authorization program. This is necessary because an individual's situation may change over time in a manner that can adversely affect his or her trustworthiness and reliability. The reinvestigation includes only the fingerprinting and the FBI criminal history check.

15. Are Licensees Required to Protect Information Obtained During a Background Investigation?

Yes, licensees are required to protect the information obtained during a background investigation. The licensee is required to establish and maintain a system of files and procedures for protection of the information from unauthorized disclosure. Licensees are only permitted to disclose the information to the subject individual, the individual's representative, those who have a need-to-know the information to perform their assigned duties to grant or deny unescorted access to category 1 or category 2 quantities of material or safeguards information, or an authorized representative of the NRC.

16. Can a Licensee Transfer Personal Information Obtained During an Investigation to Another Licensee?

Yes, a licensee can transfer background information on an individual to another licensee if the individual makes a written request to the licensee to transfer the information contained in his or her file.

17. If I Receive Background Investigation Information From Another Licensee, Can I Rely on That Information?

Yes, a licensee can rely on the background investigation information that is transferred from another licensee. However, a licensee is required to verify information such as name, date of birth, social security number, gender, and other physical characteristics to ensure that the individual is the person whose file has been transferred. The licensee can also choose to verify other information that is transferred or to escort the individual and not grant him or her unescorted access.

18. What Records Are Required to be Maintained?

Licensees are required to retain all fingerprint and criminal history records received from the FBI, or a copy if the individual's file has been transferred, for 3 years after the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material. Licensees are also required to retain the written confirmation received from entities concerning a security clearance or favorably adjudicated criminal history records check and any written verifications received from service providers. A licensee is not required to retain the actual fingerprints. The licensee must keep the determination basis and the list of individuals permitted unescorted access.

19. How Does a Licensee Determine the Effectiveness of the Access Authorization Control Program?

Licensees are required to review their program annually to confirm compliance with the requirements. The review evaluates all program performance objectives and requirements, documents any findings and corrective actions, and is conducted annually. Any records need to be maintained for 3 years.

20. Are Individuals Transporting Radioactive Material Subject to the Background Investigation

Requirements?

As part of this rulemaking, the NRC considered what level of responsibility to place on its licensees regarding fingerprinting and criminal history records checks for persons involved in the transportation of category 1 and category 2 quantities of radioactive material. Licensees covered by the fingerprinting and criminal history records check requirements of this final rule may decide to transfer radioactive material away from the site or may receive radioactive material from another entity.

Such transfers or receipts may occur either as part of a shipment to or from a domestic company or an international company. Individuals involved in the shipment, in particular those employed by carriers or other organizations handling shipments, may have unescorted access to the material during the shipment process. These persons may not be employees of the licensee and thus may not be under the licensee's direct control. Section 37.29(a) grants relief from the background investigation for those individuals who are commercial vehicle drivers for road shipments of category 2 quantities of radioactive material and package handlers at transportation facilities such as freight terminals and railroad yards. Individuals that have access to SGI-M, such as drivers for category 1 shipments and movement control personnel for category 1 shipments, must undergo fingerprinting and an FBI criminal history records check as required by 10 CFR 73.21.

21. Who Would Be Relieved From the Background Investigation Requirements?

Under section 149.b. of the AEA, the NRC may, by rule, relieve individuals from the fingerprinting, identification, and criminal history records check requirements if it finds that such action is "consistent with its obligations to promote the common defense and security and to protect the health and safety of the public." The NRC issued a final rule, 10 CFR 73.61, relieving certain individuals who are permitted unescorted access to radioactive materials from the fingerprinting, identification, and criminal history records checks required by section 149.a.

of the AEA (72 FR 4945; February 2, 2007). The individuals relieved from fingerprinting, identification, and criminal history records checks under that rule include Federal, State, and local officials involved in security planning; Agreement State employees who conduct security inspections on behalf of the NRC pursuant to 274.i. of the AEA; and other government officials who may need unescorted access to radioactive materials or other property subject to regulation by the Commission as part of their oversight function. The categories of individuals relieved by the rule included the same individuals as those relieved in an earlier rulemaking from fingerprinting and criminal history records check requirements applicable to safeguards information (71 FR 33989; June 13, 2006).

Under this final rule, the Commission is using the same listing of categories of individuals with the following modifications. Emergency response personnel who are responding to an emergency are relieved from the requirements because it is impossible to predict when emergency access might be necessary. The need to provide an escort for those responding to an emergency could impede the response function. Employees of carriers that transport category 2 quantities of radioactive material and package handlers at transportation facilities are also relieved. These individuals would typically be outside the control of the licensee and the licensee would have no way of knowing or influencing who those individuals might be. The NRC will rely on the U.S. Department of Transportation (DOT) and the Transportation Security Administration (TSA) programs for background investigations of these personnel. While the background investigation may not be identical to those required under 10 CFR part 37, the NRC believes that the potential risk that a commercial driver or package handler might pose due to any difference in the background investigation is acceptably small.

Many of the individuals that are relieved from the background investigation requirements are considered trustworthy and reliable by virtue of their occupational status and have either already undergone a background investigation as a condition of their employment, or are

subject to direct oversight by government authorities in their day-to-day job functions.

Certain persons, as part of the duties of their specific occupation, may be separately or previously subject to background investigations, either as a result of NRC requirements (such as under other requirements for access to SGI or SGI-M) or as a result of requirements of other agencies. These persons are not subject to separate background investigation requirements under this final rule; individuals who have undergone a background investigation, including fingerprinting, and been found acceptable for unescorted access under provisions of other such requirements, do not need to undergo another background investigation nor would a separate determination of their trustworthiness and reliability need to be made. Individuals that have undergone fingerprinting and an FBI criminal history records check under other agency programs do not need to be fingerprinted again, but would be subject to the other elements of the background investigation. These programs include the National Agency Check, Transportation Worker Identification Credentials (TWIC) under 49 CFR 1572, Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR 555, Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR 73, Hazardous Material security threat assessment for hazardous material endorsement to commercial drivers license under 49 CFR 1572, and Customs and Border Patrol's Free and Secure Trade (FAST) Program. The individual must make available the appropriate documentation. Written confirmation from the agency/employer that granted the Federal security clearance or reviewed the criminal history records check must be provided to the licensee.

This rule does not authorize unescorted access to any radioactive materials or other property subject to regulation by the Commission. Rather, the rule makes clear that a licensee may permit unescorted access to certain categories of individuals otherwise qualified for access without performing a background investigation. Licensees still need to decide whether to grant

or deny an individual unescorted access independently of this provision. Any required training needs to be conducted before allowing unescorted access.

C. Physical Protection During Use

1. *Who Is Affected by the Requirements?*

Any licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material is required to establish, implement, and maintain a security program meeting the requirements of 10 CFR part 37 of subpart C. (The NRC considers material to be “aggregated” if an adversary could gain access to a category 2 or greater quantity by breaching a single physical barrier.) In addition, any applicant for a license or license amendment to possess category 1 or category 2 quantities of radioactive material at a facility is required to establish a security program before obtaining the radioactive material, if it will be aggregating the material at or above the category 2 threshold.

2. *What is the Objective of the Security Program and What are the Key Security Program Requirements?*

The final rule requires affected licensees to establish, implement, and maintain a security program. The objective of the security program is to monitor, and without delay detect, assess, and respond to any actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive materials. A licensee’s security program needs to include a written security plan, implementing procedures, training, use of security zones, protection of information, coordination with the LLEA, testing and maintenance of security-related equipment, security measures, and a program review. Each of these areas is discussed in more detail in the following questions and answers.

3. What Should a Licensee's Security Plan Address?

The purpose of a security plan is to establish, in writing, the licensee's overall security strategy to ensure that all of the required security measures work effectively and in an integrated way for all facilities and operations where aggregated quantities of category 1 or category 2 quantities of radioactive material will be used or stored. The plan should, among other things, include a description of the measures and strategies to implement the security requirements and identify the security resources being used to meet the requirements.

A licensee can revise its security plan to address changing circumstances. Any changes to the security plan, as well as the original plan, must be approved by the individual with overall responsibility for the security program. The security plan must be retained for 3 years after it is no longer needed. The licensee must retain any superseded portions of the security plan for 3 years.

Security plans are important for the implementation of a performance-based regulation. An adequate plan requires a licensee to analyze the particular security needs of its individual facilities and to explain how it will implement its chosen security measures to ensure that they work together to meet the applicable performance objectives.

4. Is a Licensee Required to Have Security Procedures?

Yes, licensees are required to develop and maintain written implementing procedures that document how the security requirements and the security plan will be met. These procedures must be designed to meet the individualized security needs of each location where an aggregated category 1 or category 2 quantity of radioactive material is used or stored. Procedures need to be approved, in writing, by the individual with overall responsibility for the security program. Licensees are required to keep a copy of the current procedures as a record for 3 years. Superseded portions of the procedures are retained for 3 years. Licensees should

not submit procedures to the NRC as part of the license application.

5. What Training Is Required?

As part of its physical protection program, each licensee is required to conduct training on the security plan to ensure that those individuals responsible for implementation of the plan possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The extent of the training needs to be commensurate with the individual's potential involvement in the security of category 1 or category 2 quantities of radioactive material. Individuals need to be instructed in the licensee's security program and implementing procedures, their responsibilities, and the appropriate response to alarms. Licensees with dedicated security staff are encouraged to train their security personnel in the timely notification of affected LLEAs during emergencies.

An individual subject to the training requirements of 10 CFR 37.43(c) needs to complete the training before being allowed unescorted access to category 1 or category 2 quantities of radioactive material. The licensee needs to provide refresher training annually or when significant changes have been made to the security program. The refresher training addresses any significant changes; reports on relevant security issues, problems, or lessons learned; relevant results from NRC inspections; and relevant results from the licensee's program review and the testing and maintenance program. Training records must be maintained for 3 years and need to include training topics, training dates, and the list of personnel that attended the training.

Training is essential if the licensee is to be adequately prepared for an effective and coordinated response to any effort to steal or divert category 1 or category 2 quantities of radioactive material. Adequate training is indispensable for an appropriate licensee response to an unauthorized intrusion.

6. Are Licensees Required to Protect Information Concerning Their Security Program?

Yes. To prevent unauthorized disclosure, licensees are required to limit access to their security plans, implementing procedures, and the list of individuals that have unescorted access to the material. These efforts include measures to allow access to these documents only to those individuals who have a need to know the information to perform their duties and have been determined to be trustworthy and reliable based on the background investigation requirements set forth in 10 CFR 37.25(a)(2) through (a)(7). Licensees are required to store security information in a manner to prevent unauthorized removal, such as storage in a locked office or desk drawer.

To ensure that only trustworthy and reliable individuals with a need to know are allowed access to security plans and procedures, licensees need to develop, implement, and maintain written policies and procedures to control access to their security plan and security procedures. The licensee's information protection policies and procedures need to ensure the proper handling and protection of security plans and implementing procedures against unauthorized disclosure. Licensees are required to retain copies of the policies and procedures.

Licensees that have SGI or SGI-M would remain subject to the more stringent information protection requirements of 10 CFR 73.21, including fingerprinting and an FBI criminal records check.

7. What is the Purpose of a Security Zone?

A security zone is any area established by a licensee to provide physical protection for category 1 or category 2 quantities of radioactive material. All category 1 and category 2 quantities of radioactive material need to be used and stored within a security zone.

The purpose of security zones is to isolate and control access to the material to protect it more effectively and deter theft or diversion by providing, among other things, more time for

licensees and LLEAs to respond. Isolation measures protect category 1 or category 2 quantities of radioactive material by allowing access to security zones only through established access control points. Access control measures allow only approved individuals to have unescorted access to the security zone, and ensure that other individuals with a need for access are escorted by approved individuals. A security zone effectively defines where the licensee will apply these isolation and access control measures.

To limit unescorted access to only approved individuals, licensees could isolate the radioactive materials using continuous physical barriers that allow access to the security zone only through established access control points; or licensees could exercise direct control of the security zone by approved individuals at all times.

Security zones may be permanent or temporary. Temporary security zones need to be established to meet transitory or intermittent operating requirements such as periods of maintenance, source delivery, and source replacement. A licensee could meet the requirements for a security zone at some temporary job sites (such as those involving onsite operations lasting less than a day) simply by keeping the area under “direct supervision” by authorized personnel. Similarly, when work is being done inside a temporary zone, a licensee could meet the requirements for controlling unescorted access by having the material, persons, and area within the zone under direct control of approved individuals at all times.

Because the purpose of security zones is different from the radiation safety purposes of the restricted areas and controlled areas defined in 10 CFR part 20, the security zone does not have to be the same as either of these areas. Because measures to control access are required for both radiation protection and security, however, a licensee does have the flexibility to use an area required for radiation protection purposes to fulfill the required functions of a security zone. Thus, for a temporary well-logging operation within which the licensee is required by 10 CFR 39.71 to have a “restricted area” to “maintain direct surveillance ... to prevent

unauthorized entry into a restricted area,” a licensee could define a security zone with the same boundaries as this “restricted area.” Similarly, a radiographer could choose to define a security zone with the same boundaries as the “high radiation area” over which radiography licensees are required by 10 CFR 34.51 to “maintain direct visual surveillance ... to protect against unauthorized entry.”

Because materials licensee sites are differently configured and do not lend themselves to generically defined physical areas, the security zone concept permits significant flexibility for licensees to account for a range of site-specific concerns. It also provides regulators with a well-defined and enforceable requirement keyed to performance objectives of isolation and access control.

8. When Are Special Additional Measures for Category 1 Quantities of Radioactive Material Required?

One provision of the final rule applies to category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange. Licensees are required to provide, at a minimum, an approved individual to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow the specified activities.

Due to the natural decay of their radioactivity, sources lose their effectiveness as they get older and have to be replaced or replenished periodically with new sources to maintain a device’s expected performance. Tamper-indicating devices and other intrusion detection equipment typically must be disabled to permit the device to be opened without tripping alarms. The new sources are typically shipped by an offsite supplier, who also often performs removal and exchange or reinstallation. After replacement, the removed older sources must be prepared onsite for shipment back to the manufacturer or for storage and eventual disposal.

These non-routine operations by non-licensee employees at the licensee's site, during a time when devices for detecting theft or diversion are disabled, call for additional measures to compensate for the temporary increase in vulnerability.

9. What Is Required to Monitor and Detect an Unauthorized Entry Into a Security Zone?

A licensee is required to establish and maintain the capability to continuously monitor and detect all unauthorized entries into its security zone(s). Monitoring and detection are performed by either a monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility; electronic devices for intrusion detection alarms that would alert nearby facility personnel; monitoring by a video surveillance system; or direct visual surveillance by individuals.

A licensee also needs the capability to detect unauthorized removal of the radioactive material. For category 1 quantities of radioactive material, a licensee needs to immediately detect any attempted unauthorized removal through the use of electronic sensors linked to an alarm or continuous visual surveillance. For category 2 quantities of radioactive material, a licensee needs to verify the presence of the radioactive material through weekly physical checks, tamper indicating devices, actual usage of the material, or other means.

10. What are the Requirements for Personnel Communications and Data Transmission?

Licensees are required to maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems for any personnel and automated or electronic systems used to support the site security systems. Licensees are required to have alternative capability for any system in the event of loss of the primary means of communication or data transmission and processing. The alternative means cannot be subject to the same failure mode as the primary systems.

11. What Does a Licensee Need To Do When it Detects an Intrusion into its Security Zone?

A licensee's response to an intrusion depends on the licensee's assessment of the

purpose of the intrusion, but a response is required without delay. If the unauthorized access appeared to the licensee to be an actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material, the licensee needs to immediately notify and request an armed response from the appropriate LLEA. An immediate response by the licensee permits a more timely response from law enforcement, thereby, reducing the risk that the material could be used for malevolent purposes. Immediate notification also allows for early warning to other possible targets of a simultaneous attempt to divert material from multiple locations.

A licensee's decision to call the LLEA and the NRC depends not only on the licensee's assessment of the intent of the unauthorized access but also on whether the area where the breach occurred is an area the licensee had previously determined needed to be monitored in order to meet the NRC's physical protection requirements. Thus, a licensee's assessment and response to an intrusion alarm in the business office section of its facility could be entirely different from its assessment and response to an intrusion alarm in a radioactive materials storage area.

12. Can a Licensee Use Automated Devices to Assess an Intrusion and Alert an LLEA?

Depending on the security system, the layout of controlled areas, and the design capabilities of the sensors, automated devices or systems may be programmed to automatically summon LLEA assistance in response to an intrusion alarm.

13. What Coordination is Required with LLEA?

Licensees are required to coordinate, to the extent practicable, with the LLEA to discuss the LLEA response to threats to the licensee's use of Category 1 or 2 quantities of radioactive material. An LLEA is defined as a public or private organization that has been approved by a Federal, State, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed

category 1 or category 2 quantity of radioactive material is used, stored, or transported. In the event of an actual or attempted theft, sabotage, or diversion of radioactive material, an armed response is likely to be necessary. Adversaries could be well armed, and the small unarmed or lightly-armed private security guard service typically used at byproduct material licensee sites would not be an adequate substitute for an LLEA. However, the LLEA need not be a municipal or county police force. If a hospital or university campus police force is the nearest law enforcement agency to the licensee's operation capable of providing an armed response and making arrests, that police force would meet the definition of an LLEA.

Coordination activities include providing a description of the facility, radioactive materials, and security measures and notification that the licensee will request a timely and armed response to any actual or attempted theft, sabotage, or diversion of the licensee's radioactive materials. The licensee is required to document its coordination efforts. The documentation could include such items as the dates, times, and locations of meetings or phone calls and a list of licensee and LLEA staff present at the meetings. Licensees are required to coordinate with the LLEA at least every 12 months.

Coordination with an LLEA is essential in developing an effective and efficient physical protection program. Because certain situations may necessitate an armed response, a strategy that is consistent in scope and timing with realistic potential vulnerabilities of the subject radioactive material should be coordinated well in advance with the LLEA. Another purpose of coordination is to provide the responsible LLEA with an understanding of the potential consequences associated with unauthorized use of the radioactive material of concern, so that the LLEA can determine the appropriate priority of its response. The LLEA response is needed not only to interdict and disrupt an attempted theft or sabotage onsite, but also possibly for offsite coordination to protect public health and safety and to mitigate the potential consequences of unauthorized use of the radioactive material.

14. What if the LLEA Declines to Coordinate with a Licensee?

The NRC recognizes that it cannot exercise authority over LLEAs, or any party over which a licensee has no control and the NRC has no legal jurisdiction. The NRC also recognizes that an LLEA may have good reasons for not engaging in coordination activities.

An LLEA's refusal to coordinate with a licensee does not by itself render a licensee's security plan inadequate. The NRC recognizes that in an actual emergency, State and local government officials will respond to protect the health and safety of the public. A licensee is required under 10 CFR 37.45(a)(2) to notify the appropriate NRC regional office within 3 business days if the LLEA has not responded to a request for coordination within 60 days of the coordination request, or if the LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities. The notification allows the NRC to contact the LLEA directly to ensure that the LLEA understands the importance of adequate coordination. In some cases, the NRC might contact the Department of Homeland Security (DHS) and request DHS assistance with the LLEA. If the LLEA refuses to coordinate beforehand, the licensee could still comply by making and documenting periodic good-faith efforts to elicit the LLEA's participation in planning for a timely and effective response.

15. What are the LLEA Notification Requirements for Work at a Temporary Job Site?

The final rule does not require any notification of or coordination with the LLEA for work at temporary jobsites.

16. What are the Special Requirements for Mobile Sources?

The rule requires licensees using mobile devices containing a category 1 or category 2 quantity of radioactive material to have two independent physical controls that form tangible barriers to prevent unauthorized removal of the device. For devices in or on a vehicle or trailer, a licensee is required to use a method to disable the vehicle or trailer when it is not under direct

control and constant surveillance by the licensee. Licensees are not allowed to rely on the removal of an ignition key to meet this requirement. The rule does allow for the situation where a site's health and safety procedures prohibit the disabling of the ignition. In those instances, the licensee would not be required to disable the ignition. These provisions are in addition to the other requirements in subpart C.

Mobile devices, particularly portable ones, are likely to be more vulnerable to attempted theft or diversion because an adversary could more easily remove these devices before the licensee or LLEA has an opportunity to respond. The objective of this requirement is to delay intruders long enough for a timely licensee and LLEA response.

A mobile device is defined in the rule as a piece of equipment containing licensed radioactive material that is either: 1) mounted on wheels or casters or otherwise equipped for moving without a need for disassembly or dismounting, or 2) designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location, such as an irradiator, but the definition includes radiography cameras, source changers, well logging equipment, and gauges or controllers. The definition could also include storage containers, lead pigs for holding sources during a source exchange, and onsite or offsite transportation packages, if they contained category 1 or category 2 quantities of radioactive material.

17. What Maintenance and Testing Requirements Apply to the Security Systems?

Consistent with 10 CFR 37.51, licensees are required to test intrusion alarms, physical barriers, and other systems used for securing and monitoring access to radioactive material, and these items need to be maintained in operable condition. Each intrusion alarm and associated communication system subject to the rule's requirements for monitoring, detection, and assessment needs to be inspected and tested for performance. The licensee only needs to test the equipment that it relies on to meet the requirements of 10 CFR part 37. This would include any backup equipment or systems relied upon in the event of a primary system failure.

If the licensee has additional equipment or systems that are not relied on to meet the rule requirements, the extra equipment and systems would not need to be tested and maintained.

The frequency for testing is based on the manufacturer's suggested timing. If the manufacturer does not suggest a frequency, the licensee must conduct the maintenance and testing at least annually. Licensees are required to maintain records of the maintenance and testing activities for 3 years.

18. What Events Does a Licensee Need to Report to the NRC?

A licensee is required to report any actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material as soon as possible after initiating a response, which includes notification of the LLEA. The licensee is required to submit a written report to the NRC within 30 days after the initial notification. A licensee is also required to assess any suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and notify the LLEA as appropriate. If the licensee notifies the LLEA, it must also notify the NRC. The written 30-day report is not required for suspicious activity reports.

19. How Does a Licensee Determine the Effectiveness of the Security Program?

Licensees are required to review the security program annually to confirm compliance with the requirements. The review is to evaluate the security program content and implementation. The licensee is required to document any review findings and corrective actions, and the records need to be maintained for 3 years.

D. Transportation Security

1. What Is the NRC Authority to Issue These Transportation Security Requirements?

Sections 53, 81, and 161 of the AEA, as amended, provide the NRC with the statutory

authority to issue these transportation security requirements. The NRC shares jurisdiction over the transport of radioactive material traveling over public roadways and by rail with DOT and DHS.

2. Why Is This Material Being Shipped?

In general, category 1 and category 2 quantities of radioactive material are shipped to medical institutions, companies that support medical and academic institutions, and companies that manufacture and distribute radioactive material for various industrial applications.

As radioactive sources get older, radioactive decay decreases the sources' strength and the sources lose their effectiveness and have to be replaced or replenished with new sources.

The older sources must be transported for disposal or back to the manufacturer.

3. What are the New Transportation Security Requirements?

In general, the final rule includes requirements for pretransfer checks, preplanning and coordination of shipments, advance notification of shipments, control, monitoring, and communications during shipments, procedures, investigations of missing shipments, and reporting of missing material. Each of these areas is discussed in more detail in the following questions and answers.

These requirements apply to ground transport of category 1 or category 2 quantities of radioactive material shipped in a single package or in multiple packages in a single conveyance. The category 1 requirements also apply to shipments of irradiated reactor fuel weighing 100 g (0.22 lb) or less in net weight of irradiated fuel, exclusive of cladding or other structural or packaging material, which has a total external radiation dose rate in excess of 1 Gray (100 rad) per hour at a distance of 1 m (3.3 ft) from any accessible surface without intervening shielding. Note that a licensee is not responsible for complying with these requirements when a carrier aggregates radioactive material, during transport or storage incidental to transport, for two or more conveyances from separate licensees that individually do not exceed the limits. The

shipping licensee is responsible for meeting the requirements unless the receiving licensee agrees in writing to arrange for the in-transit physical protection, including preplanning and coordination activities.

4. Is Verification of the Transferee's License Necessary?

Yes, 10 CFR 37.71 requires any licensee transferring category 1 or category 2 quantities of radioactive material to a licensee of the NRC or an Agreement State to verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. Licensees that transfer material within the same organization do not need to verify the validity of the license (*i.e.*, for companies that have licenses in several States). The licensee should know if its licenses are valid. For transfers of category 1 quantities of radioactive material, the transferring licensee is also required to verify that the licensee is authorized to receive radioactive material at the address requested for delivery. These verifications are conducted with the license issuing authority, *i.e.*, the NRC or the appropriate Agreement State, or by using the license verification system. The license verification system is a new web-based system that NRC is developing that may be used to verify the validity of a license issued by either NRC or an Agreement State. The license verification system is currently scheduled to be operational by the effective date of the final rule. If it appears that the system will not be available in time to support the rule, the NRC will change the compliance date of this provision. Licensees should contact the appropriate NRC regional office to verify the validity of NRC licensees. Information on Agreement State contacts is provided on the NRC's Web page at <http://nrc-stp.ornl.gov/asdirectory.html>. If the license verification system is non-functional and the licensee cannot reach the license issuing authority, the rule does have a provision that allows the licensee to obtain certification from the requesting licensee. Licensees are required to document any method of verification, except for use of the license verification system. Licensees exporting material need to meet the requirements in 10 CFR part 110 for

checking the documentation that the recipient has the necessary authorization under the laws and regulations of the importing country. These actions are intended to mitigate the risk that the material could be shipped to an unauthorized recipient.

5. Is Preplanning and Coordination of the Shipments Necessary?

Yes, 10 CFR 37.75(a) requires preplanning and coordination of shipment information for shipments of category 1 quantities of radioactive material. The shipping licensee (licensee sending the licensed material) is required to coordinate the departure and arrival times with the receiving licensee (licensee receiving the licensed material). This coordination reduces the risk that theft or diversion of the material would go unnoticed or unreported. The licensee also needs to preplan and coordinate the shipment information with the State(s) through which the shipment will pass. As part of the coordination activities, the licensee is required to discuss the State's intention to provide law enforcement escorts for the shipments and identify safe havens. Under the rule, safe havens are sites at which security is present or from which the transport crew can notify and wait for the local law enforcement authorities in the event of an emergency. The licensee is responsible for identification of the safe havens. The purpose of the information sharing is to ensure minimal delay of the shipment.

For shipments of category 2 quantities of radioactive material, 10 CFR 37.75(b) requires that the shipping licensee verify the shipment no-later-than arrival time and the expected arrival time with the receiving licensee.

The definitions section of the final rule defines the term "no-later-than arrival time" as the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than-arrival time may not be more than 6 hours after the estimated arrival time for category 2 shipments. Verifying that the shipment arrives on time provides the licensee with the

means to identify and immediately report an unusual occurrence that could lead to the theft or diversion of the material.

6. What does the NRC Consider to be a Safe Haven?

A safe haven is a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the LLEA. The NRC expects safe havens to be identified and designated by the licensee.

Licensees should use the following criteria in identifying safe havens for shipments: close proximity to the route, *i.e.*, readily available to the transport vehicle; security from local, State, or Federal assets is present or is accessible for timely response; the site is well lit, has adequate parking, and can be used for emergency repair or to wait for LLEA response on a 24-hour a day basis; and additional telephone facilities are available should the communications system of the transport vehicle not function properly. Possible safe haven sites include: Federal sites having significant security assets; secure company terminals; State weigh stations; truck stops with secure areas; and LLEA sites, including State police barracks.

7. Is the Shipping Licensee Required to Notify the Receiving Licensee if the No-Later-Than Arrival Time Changes?

Yes. If the no-later-than arrival time will not be met, the shipping licensee must inform the receiving licensee of the new no-later-than arrival time for shipments of category 2 quantities of radioactive material. This provision allows licensees the ability to modify departure and arrival times due to unforeseen events.

8. Whom Does the Licensee Notify When the Shipment Arrives?

The receiving licensee is required to notify the shipping licensee when the shipment of a category 2 quantity of radioactive material arrives at its destination. This requirement ensures positive communication between the shipper and recipient. Additionally, this requirement ensures that the shipper does not unnecessarily start an investigation because they are not sure

that the shipment has arrived. The receiving licensee must notify the shipping licensee if the shipment has not arrived by the no-later-than arrival time. This notification is the trigger to initiate an investigation into where the package is located.

9. *What Does the Term State Mean in the Requirements?*

As used in the definitions section of the final rule, the term “State” means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. A list of the contact information for the governor’s designees is published annually in the *Federal Register*, most recently on October 31, 2011 (76 FR 67229). An updated list is posted on the NRC’s Web site at <http://nrc-stp.ornl.gov/special/designee.pdf>. Copies may also be obtained by contacting the Director, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The NRC will work with the States to include a separate column for contacts for 10 CFR part 37.

10. *What Advance Notifications Are Required?*

The final rule requires advance written notifications for shipments containing category 1 quantities of radioactive material. The advance notifications are made to the NRC (or Agreement State which then would notify the NRC) and to any State through which a shipment is being transported. The State notification is made to the governor or the governor’s designee. The NRC shares the information with some of its Federal partners.

Advance notification provides States and the NRC with knowledge of shipments so that in the event there is an increase in the risk of theft or diversion of the material, the regulator could delay or reroute the shipment to minimize the risk. This advance notification also allows States with escort requirements to engage in planning to support the shipment.

Advance notifications are not required for shipments of category 2 quantities of radioactive material, unless the shipment falls within the scope of 10 CFR 71.97(b).

11. What Information Should Be Included In An Advance Notification?

The final rule requires that the following information be included in an advance notification for a category 1 shipment of radioactive material, if available at the time of notification: 1) the name, address, and telephone number of the shipper, carrier, and receiver of the shipment; 2) the license number of the shipper and receiver; 3) a description of the radioactive material contained in the shipment, including the radionuclides and quantity; 4) the point of origin of the shipment and the estimated time and date that shipment will commence; 5) the estimated time and date that the shipment is expected to enter each State along the route; 6) the estimated time and date of arrival of the shipment at the destination; and 7) the contact and telephone number for the point of contact. For the purpose of coordination only, the actual information in the advance notification would not be considered to be SGI-M. Any information that is not available at the time of the initial notification would be provided in a revised notification once the information becomes available.

12. What Should A Licensee Do If The Shipment Schedule Is Revised Or The Shipment Cancelled?

If the category 1 shipment schedule is revised or cancelled, the final rule requires the shipping licensee to notify the appropriate States and the NRC.

13. What Should a Licensee Do If the Shipment Does Not Arrive by the No-Later-Than Arrival Time?

The final rule requires a licensee that has shipped category 2 quantities of radioactive material to initiate an investigation for any shipment that has not arrived at the receiving licensee's facility by the designated no-later-than arrival time. The no-later-than arrival time is defined as the date and time that the shipping licensee and receiving licensee have established

as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than-arrival time may not be longer than 6 hours after the estimated arrival time for a shipment of category 2 quantities of radioactive material. A no-later-than arrival time was not included for category 1 shipments as the licensee is required to maintain continuous position monitoring and detect any unauthorized access to or removal of the material immediately. This would enable the shipping licensee of a category 1 shipment to know right away if the shipment was late or experiencing problems.

14. When Must a Licensee Make Notification That a Shipment Is Lost or Missing?

When a licensee determines that a shipment of a category 1 quantity of radioactive material is lost or missing, the rule requires the licensee to notify the LLEA in the area of the shipment's last confirmed location within 1 hour and then to notify the NRC's Operations Center. Notification to the NRC should be as prompt as possible, but not at the expense of causing delay or interference with the LLEA response to the event.

When a licensee determines that a shipment of category 2 quantities of radioactive material is lost or missing, the rule requires the licensee to notify the NRC's Operations Center within 4 hours of such determination. The licensee is also required to immediately notify the NRC's Operations Center if, after 24 hours from its determination that the shipment was lost or missing, the location of the material still cannot be determined.

Early notification provides for a more timely response from law enforcement, thereby reducing the risk of the misuse of the material.

15. Should Licensees Make Notification That a Lost or Missing Shipment has been Found?

Yes, 10 CFR 37.81(e) and (f), for category 1 shipments and category 2 shipments, respectively, require the licensee to notify the NRC's Operations Center when a lost or missing shipment has been located. This notification is considered an update on the initial notification.

Without this notification, regulatory authorities and LLEA may waste resources continuing any search for the material.

16. What Is a Licensee Required to Do If There Is an Attempt to Steal or Divert a Shipment?

For shipments of category 1 quantities of radioactive material, a licensee who discovers an actual or attempted theft or diversion of a shipment, or any suspicious activity related to a shipment, is required to notify the designated LLEA along the shipment route as soon as possible. After notifying the LLEA, the licensee is required to notify the NRC's Operations Center. The NRC's Operations Center will notify other affected States and the agency's Federal partners. For shipments of category 2 quantities of radioactive material, a licensee who discovers an actual or attempted theft or diversion of a shipment, or any suspicious activity related to a shipment, is required to notify the NRC's Operations Center as soon as possible. These security measures enhance the likelihood that the material will be successfully protected or recovered and allows for early warning of other possible victims of a simultaneous attempt to divert material from multiple locations.

17. What Types Of Procedures Are Necessary For Shipping Category 1 Quantities of Radioactive Material?

Licensees shipping category 1 quantities of radioactive material by road are required to ensure that normal and contingency procedures are developed to cover notifications; communication protocols; loss of communication; and response to an actual or attempted theft or diversion of a shipment, or any suspicious activity related to a shipment. The licensees are required to ensure that drivers, accompanying personnel, railroad personnel, and movement control center personnel have access to the normal and contingency procedures. Procedures provide reasonable assurance that these individuals are prepared for most situations and are able to act without delay to prevent the theft or diversion of shipments.

18. *What Should Be Included In The Communication Protocols?*

The final rule requires that the communication protocols include a strategy for the use of authentication and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost.

19. *What Are the Physical Protection Requirements for Road Shipments of Category 1 Quantities of Radioactive Material?*

The final rule requires that any licensee that ships category 1 quantities of radioactive material by road either establish or use a carrier that has established, movement control centers that maintain position information from a location remote from the activity of the transport vehicle or trailer. The control centers are required to monitor shipments on a continuous and active monitoring basis (24 hours a day, 7 days a week), and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies.

The final rule requires that the licensee ensure that redundant communications are in place that would allow the transport to contact an escort vehicle (if used) and the movement control center at all times. The redundant communication must not be subject to the same interference factors as the primary communication method. The same interference factors mean any two systems that rely on the same hardware or software to transmit their signal (e.g., cell tower or proprietary network).

Redundant communications provide drivers with the means to immediately report an unusual occurrence that could lead to the theft or diversion of the material. Early notification would permit a more timely response from law enforcement, thereby, reducing the risk of the misuse of the material.

The final rule also requires that the licensee ensure that category 1 shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. The movement control center is

required to provide positive confirmation of the location, status, and control over the shipment and be prepared to implement preplanned procedures in response to deviations from the authorized route or to a notification of actual or attempted theft or diversion or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures include the identification of, and contact information for, the appropriate LLEA along the shipment route.

A telemetric position monitoring system is a data transfer system that captures information by instrumentation and/or measuring devices about the location and status of a transport vehicle or package between the departure and destination locations. The gathering of this information permits remote monitoring and reporting of the location of a transport vehicle or package. GPS and radiofrequency identification (RFID) are examples of telemetric position monitoring systems.

If the driving time period is greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the DOT Federal Motor Carrier Safety Administration, the final rule requires that the licensee ensure that an accompanying individual is provided for the entire shipment. The accompanying individual may be another driver. This security measure provides reasonable assurance that the material will be protected from theft or diversion when it is stationary, as well as in emergency situations where it becomes necessary for the driver to stop or leave the vehicle.

20. Is GPS Required?

No, GPS is not required. For category 1 material, the NRC requires continuous and active monitoring for shipments. Continuous and active monitoring means that at any time while the shipment is enroute, the licensee must be knowledgeable of the shipment's whereabouts. Not specifying a particular technology provides licensees with flexibility to design a continuous and active monitoring system that meets their unique circumstances. However, GPS is considered an acceptable method of continuous and active monitoring.

21. What are the Physical Protection Requirements for Rail Shipments of Category 1 Quantities of Radioactive Material?

The final rule requires each licensee that ships category 1 quantities of radioactive material by rail to ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to a licensee, third party, or railroad communications center which meets certain criteria. The communications center needs to provide positive confirmation of the location of the shipment and its status. Rail shipment tracking provides the means for a communications center to immediately report an unusual occurrence that could lead to the theft or diversion of the material. Early notification provides for a more timely response from LLEAs, thereby reducing the risk of the misuse of the material.

22. What are the Physical Protection Requirements for Shipments of Category 2 Quantities of Radioactive Material?

The final rule requires that a licensee shipping category 2 quantities of radioactive material by road maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance. In the case of the licensee using a common carrier, the final rule requires that licensees use a carrier that has an established package tracking system. An established package tracking system means a documented, proven, and reliable system routinely used to transport objects of value. The package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control. The licensee is required to use a carrier that maintains constant control and surveillance during transit and has the capability for immediate communication to summon appropriate response or assistance. The carrier must also require an authorized signature prior to releasing the package for delivery or return.

In general, the licensee must be able to contact the shipping carrier and determine the approximate location of the shipment. Package tracking systems, such as common overnight delivery service with standard tracking, are acceptable. These requirements mitigate with reasonable assurance the risk of loss, theft, or diversion of the material.

23. How Long Do Records Related To A Shipment Need To Be Maintained?

Licensees are required to retain records for 3 years.

24. How is the Public Protected from Loss, Theft, or Diversion of These Shipments?

Regulating transport of radioactive material is a joint responsibility of the NRC and DOT. The quantities of radioactive materials being considered as part of this rulemaking are transported in packages (casks) that meet rigorous NRC and DOT safety standards. The NRC fact sheet on transportation of radioactive materials can be found at:

<http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/transport-spenfuel-radiomats-bg.html>.

The carrier transporting radioactive material must also meet DOT's requirements for shipment of the radioactive material. A link to DOT's Web site is provided on the NRC's Web site at: <http://www.nrc.gov/materials/transportation.html>.

25. What are the Requirements for Small Quantities or Irradiated Reactor Fuel?

The final rule adds a new § 73.35 to 10 CFR part 73, which provides that the requirements for shipments of irradiated reactor fuel weighing 100 g (0.22 lb) or less in net weight of irradiated fuel, exclusive of cladding or other structural or packaging material, which has a total external radiation dose rate in excess of 1 Gray (100 rad) per hour at a distance of 1 m (3.3 ft) from any accessible surface without intervening shielding. The requirements are the same as the requirements for shipments of category 1 quantities of radioactive material.

26. What Means of Transportation Are Not Addressed in This Rule?

The rule does not address air or water transport. Transport of radioactive material within

airports and by air is regulated by the Federal Aviation Administration. Transport of radioactive material within ports and by waterway is regulated by the U.S. Coast Guard.

The rule also does not address transshipments of category 1 or category 2 quantities of radioactive material through the United States. Transshipments are shipments that are originated by a foreign company in one country, pass through the United States, and then continue on to a company in another country. Transshipments are regulated by DOT and DHS.

Finally, this rulemaking does not address transport of spent fuel, except irradiated reactor fuel weighing 100 g (0.22 lb) or less in net weight of irradiated fuel, exclusive of cladding or other structural or packaging material, which has a total external radiation dose rate in excess of 1 Gray (100 rad) per hour at a distance of 1 m (3.3 ft) from any accessible surface without intervening shielding.

III. Summary and Analysis of Public Comments on the Proposed Rule.

The proposed rule was published on June 15, 2010 (75 FR 33902), for a 120-day public comment period that ended on October 13, 2010. After receiving several requests to extend the comment period, the NRC published an extension notice on October 8, 2010 (75 FR 62330), that extended the public comment period until January 18, 2011. The NRC received comments from 110 organizations and individuals. The commenters on the proposed rule included States, licensees, industry organizations, individuals, and a Federal agency.

In general, there was a range of stakeholder views concerning the rulemaking, supporting some aspects of the rulemaking, others opposing some aspects of the rulemaking. Some commenters described the new requirements as going beyond the order requirements. It is important to note that the Commission never intended to just place the orders into the regulations to make them generically applicable. The Commission always intended to consider

insights gained from implementation of the orders and any lessons learned during implementation. In addition, the Commission considered recommendations from the Independent Review Panel and the Materials Working Group, as well as a petition filed by the State of Washington.

The comments and responses have been grouped into five areas: general, access authorization program, security during use, transportation security, and miscellaneous. To the extent possible, all of the comments on a particular subject are grouped together. The Commission specifically requested input on eight subjects: 1) fingerprinting of the reviewing official; 2) background investigation elements; 3) protection of information; 4) LLEA notification at temporary jobsites; 5) reporting requirements; 6) disabling vehicle exemption; 7) license verification; and 8) monitoring plans for railroad classification yard. These eight subjects are addressed within the appropriate area grouping. A discussion of the comments and the NRC's responses follow.

A. General

Comment A1: One commenter stated that the definition for access control should be expanded to include persons with access to SGI, as such individuals are subject to the requirements in § 37.21(c).

Response: The NRC disagrees with the comment. A licensee may include the SGI component in its access authorization program, but it is not required to include SGI. The requirements for SGI are contained in 10 CFR part 73, and the licensee can choose to use the same reviewing official and process or may use a different reviewing official and process. If a licensee chooses to include SGI in its access authorization program under 10 CFR part 37, it will meet the requirements of 10 CFR part 73.

Comment A2: One commenter noted that the definition for aggregated was unclear.

Another commenter suggested including unsealed sources and bulk material in this definition. Commenters recommended either clarifying “multiple sources of bulk material” or giving it its own definition. A commenter noted it was unclear if the term bulk material aligns with DOT terminology for bulk packaging.

Response: The NRC agrees that the definition could be confusing and has revised the definition to make it clear that radioactive material in any form should be included. The definition is not related to DOT. The intent was to include all material, whether it was in the form of a source (sealed or unsealed) or was contained in a container of some sort, such as feed material, that might be used to create a source.

Comment A3: One commenter noted that the term “Aggregated” uses the term “sealed source” in its definition and that “sealed source” should be defined in 10 CFR part 37 as the use lacks clarity and safety significance. The commenter stated that the definition for sealed source should also be revised in 10 CFR parts 30 and 70. The commenter provided a suggested definition for “sealed source” as follows: “Sealed source means any radioactive material contained to minimize the spread of contamination in accordance with the presentation made in a Sealed Source and Device Registry certificate issued by the U.S. Nuclear Regulatory Commission, an Agreement State or the International Atomic Energy Agency.”

Response: The NRC disagrees with the comment. The term “sealed source” has been in the regulations for a long time and the NRC is not aware of any issues that have arisen due to a lack of clarity or safety significance. The term does not need to also be defined in 10 CFR part 37 as it is defined in the parts under which a sealed source would be licensed. Changing the definition of sealed source in 10 CFR parts 30 and 70 is beyond the scope of this rulemaking.

Comment A4: One commenter requested that the definition of “Escorted Access” be revised to delete the term “line-of-sight” as it is too prescriptive and creates compliance issues

should someone “look away” or stand in an area of the security zone where the escorted individual’s view may be blocked by some object or equipment in the zone. The commenter noted that surveillance can also be accomplished by remote video monitoring. Two commenters suggested that the term escorted access should be revised to allow for video surveillance. The commenters noted that, although the definition was a straightforward, easy way to define escorting, certain video surveillance systems provide improved security and should be allowed. The commenters suggested revising the definition as follows: “Escorted access means that the actions of the individual are observed 100% of the time while they are in the security zone.”

Response: The NRC agrees with the comment in part. The NRC has removed the term “line-of-sight surveillance” from the definition and changed it to “direct continuous visual surveillance.” The revised definition will provide greater flexibility for the licensee. The definition of escorted access was not intended to eliminate a licensee’s use of video surveillance. Video surveillance is appropriate in some, but not all cases. For example, video surveillance of patients during a treatment would be appropriate.

Comment A5: One commenter requested that the definition of license be revised as follows: “*License*, except where otherwise specified, means a license for byproduct material issued pursuant to the regulations in 10 CFR parts 30 through 36 and 39 of this chapter or a permit issued by a master materials licensee.”

Response: The NRC disagrees that the definition for license should be revised. The definition used in 10 CFR part 37 is identical to the definition used in 10 CFR part 30. No license will be issued under 10 CFR part 37.

Comment A6: One commenter requested that the definition of license issuing authority be revised to include a master materials licensee (MML) as the MML issues individual permits.

Response: The NRC disagrees with the comment. An MML is not equivalent to an Agreement State and does not issue licenses. The MML does authorize individual permits for specific locations, but cannot authorize beyond what is specified on the MML license.

Comment A7: Several commenters requested that the definition of LLEAs be revised by removing the requirement that the agency be a government entity and to broaden the definition to include private security forces that possess the authority to carry firearms and make arrests. Commenters felt that the definition was confusing and was not clear whether university police could be considered an LLEA under the definition. One of the commenters noted that some university police departments serve as the LLEA and are a fully badged and sworn police force with the authority to make arrests and provide armed response. Some of the commenters suggested revised rule language to clarify the definition.

Response: The NRC agrees with the commenters and has revised the definition of LLEA as follows: “*Local law enforcement agency (LLEA)* means a public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed category 1 or category 2 quantity of radioactive material is used, stored, or transported.”

Comment A8: Five commenters suggested revising the definition of “Lost or missing licensed material.” Commenters indicated that the definition contains subjective terms that make compliance with the reporting criteria difficult. Two commenters recommended removing “readily” from the definition as it is too subjective and could lead to inadvertent noncompliance. One commenter recommended linking the definition for lost or missing licensed material with the no-later-than arrival time definition and providing a specific criterion in regards to time to locate material in transit. The commenter suggested the following definition: “*Lost or missing licensed material*” means licensed material whose location is unknown. It includes material that has

been shipped but has not reached its destination and whose whereabouts have not been traced in the transportation system within 8 hours past the scheduled no-later-than arrival time.” The commenter noted that compliance and enforcement of the reporting criteria established in § 37.81 is difficult and that an 8-hour investigation period seems reasonable. Another commenter noted that it typically gives the carrier 24 hours to trace within their transportation cycle, before the package is declared as lost or missing, and that anything less than the 24 hours does not allow sufficient time for the carrier to do a complete document and tracking search and/or a physical search at potential locations. The commenter noted that to declare the package as lost or missing before that will result in many false positives, as 99.99% of the time the package is located within the 24-hour window.

Response: The NRC disagrees with the comment. The term “lost and missing licensed material” has been in part 20 for some time, and the definition in 10 CFR part 37 is identical. It would be confusing to have different definitions for the same term and concept in the regulations and licensees would still need to meet the 10 CFR part 20 reporting requirements. A change to 10 CFR part 20 is beyond the scope of this rulemaking. The NRC will provide additional information on the security-specific meaning of “lost or missing” in the 10 CFR part 37 guidance document.

Comment A9: One commenter stated that the definition for reviewing official should include a trustworthiness and reliability determination of an individual who has access to SGI-M.

Response: The NRC disagrees with the comment. A licensee may use the same reviewing official for trustworthiness and reliability determinations for both unescorted access and access to SGI. However, the licensee is not required to use the same reviewing official. Determining access for SGI can be a separate program.

Comment A10: One commenter stated that the definition for “sabotage” should include a definition of “security system” that is referenced in the definition.

Response: The NRC disagrees with the comment. Security system does not need to be defined in the definition of *Sabotage*. The security system will be different for each licensee as it is the system that a licensee uses to protect its category 1 and category 2 quantities of radioactive material.

Comment A11: Two commenters suggested modifications to the definition for safe haven. Another commenter noted that the provision cannot be implemented. The commenter noted that based on discussions with military and other Federal institutions, material shipments could not be diverted to them under any circumstances. The commenter suggested that safe havens be contacted, confirmed, and identified. The commenter noted that the licensee and carrier are capable of determining safe havens along the route and that past experience has shown that requesting a State to identify safe havens has been fruitless. Two commenters suggested that the NRC work with the States to identify potential safe havens and publish a list with the final rule. One commenter noted that a licensee does not need to work with the State to identify safe havens. Two commenters noted that the term “safe haven” is loosely defined by various agencies and States, and that States do not recognize, identify, or acknowledge that they have such sites. Two commenters noted that DOT removed the term from its regulations because it could not be implemented.

Response: The definition for *safe haven* has been retained in the final rule. Licensees, not States, are responsible for identifying safe havens. Identification of safe havens has been in the regulations for spent fuel transportation for a number of years and was included in the RAMQC Orders for transport of category 1 shipments, so it is not a new concept. If a licensee is having trouble identifying safe havens along a route, it may discuss possible locations with the NRC, State police, or the State’s designated contact (usually State police).

Comment A12: One commenter (a State) noted that the definition for temporary job site has a compatibility of Level B, which requires identical wording. The commenter noted that this

definition does not meet its definition which is much more restrictive in that it limits the amount of time radioactive material can be used at a temporary job site. The commenter stated that there should not be two different definitions for the same word listed in different parts of the regulations. Another commenter stated that the temporary job site definition would be more appropriate with a designation of C instead of B as it would allow States to be more restrictive.

Response: The NRC agrees with the comment in part and disagrees in part. The NRC tries to use the same definition for terms that are used in more than one part of the regulations. However, there are terms that have different meanings depending on the use. *Temporary job site* is defined in both 10 CFR part 34 and part 39 with definitions that are specific to the part. Since activities that are covered by both 10 CFR part 34 (radiography) and part 39 (well logging) may also be subject to 10 CFR part 37 security provisions, the NRC extracted the common elements of the definitions for use in 10 CFR part 37. However, the requirements related to temporary job sites have been removed from 10 CFR part 37, and the term is no longer defined in the rule.

Comment A13: Three commenters suggested revising the definition of “*Trustworthiness and reliability*.” One commenter stated that the definition is vague and subjective and that use of subjective terms in the definition such as “dependable” and “unreasonable” makes it impossible to apply. The commenter noted that a licensee cannot ensure that individuals are trustworthy and reliable and as such do not constitute an unreasonable risk to public health and safety. The commenter requested that concrete and nonsubjective criteria be provided. Another commenter requested that the definition be revised by adding “or as provided for in § 37.29” to the end of the definition. One commenter stated that the definition should be modified to include characteristics required by individuals having access to SGI-M.

Response: The NRC disagrees with the comment. The NRC does not believe that these terms make it impossible for licensees to determine trustworthiness and reliability. The

concepts of dependable and unreasonable were also contained in the orders. The determination is performance based and provides licensees the flexibility to develop programs and criteria that they are comfortable with. The definition in 10 CFR part 37 is consistent with the definition of the term in 10 CFR part 73. The NRC does not believe that it is necessary to add provisions that include access to SGI. Access to SGI is covered by 10 CFR part 73. While a licensee may use the same access authorization program for determinations for access to SGI, the licensee may have a separate program.

Comment A14: One commenter suggested maintaining the current interpretation for unescorted access that an individual having unescorted access to several less than category 2 quantity sources which are secured behind their own physical barrier would not require inclusion in the trustworthiness and reliability determination program. The commenter noted that the rule defines unescorted access to include individuals who have access to sufficient quantities of radioactive materials such that the individual could successfully accumulate lesser quantities of material into a category 1 or category 2 quantity. The commenter noted that this is a significant change and would result in a big increase in the number of individuals who will need background checks completed or require very complex source handling procedures to prevent the ability to aggregate sources. One commenter noted that the examples provided in the Statements of Consideration did not appear to apply to an individual with access to multiple licensee facilities listed on the same license or multiple separate licenses by the same organization. The commenter noted that these persons could aggregate materials just as easily as if they were at a single location under one license, but the security rules would not apply to them. One commenter stated that the NRC should reevaluate the need to include accumulation considerations for access authorization control.

Response: The NRC has reevaluated the requirement and has revised the definition for *Unescorted access*. All provisions of the rule now only apply to licensees that possess an

aggregated quantity of radioactive material that equals or exceeds the category 2 threshold.

The term aggregated contains the concept of co-location and breach of a barrier.

Comment A15: One commenter requested that the NRC add a definition for master material license to 10 CFR part 37.

Response: The NRC disagrees with the comment. Master material license is not specifically mentioned anywhere in the regulations, and the NRC does not believe that there is a need to mention it in 10 CFR part 37 as licenses are not issued under 10 CFR part 37.

Comment A16: One commenter suggested including a definition for security plan at least to the extent that 'security plan' is meant to encompass a description of a licensee's background investigation process, access control program, and physical protection measures with those specific features as identified elsewhere in the part.

Response: The NRC disagrees with the comment and does not believe that a definition of security plan is necessary. Section 37.43(a) contains the purpose of the security plan and specifies in general terms what must be included in the security plan. A definition would not add further to the understanding.

Comment A17: One commenter suggested that a limited exemption be provided to licensees who consistently meet the requirements imposed by the orders. The commenter noted that the NRC could establish criteria for the assessment of licensee's security programs and if the program was deemed inadequate, corrective action could be initiated.

Response: The NRC disagrees with the comment. The NRC believes that the requirements in 10 CFR part 37 are necessary to ensure adequate protection of category 1 and category 2 quantities of radioactive material. A licensee can always ask for relief from a particular measure and if the NRC agrees that adequate basis exists and that it is protective of public health and safety, it can grant the request.

Comment A18: One commenter, while supporting the decision to limit the rule to category 1 and category 2 sources, noted that not all category 2 sources are realistically in danger of being tampered with, particularly in large medical facilities with exhaustive security controls in place. The commenter noted that if a large medical facility's security measures are breached, sealed sources in medical devices are generally not readily accessible even by technicians with highly specialized skills and tools. Two commenters suggested exempting medical and research facilities from all of the 10 CFR part 37 requirements except for the security program or security plan. The commenters noted that the public pays for and benefits from medical and research use of these sources, and as such, should have a higher acceptable risk. The commenters noted that this is similar to the basic premise behind the patient release criteria in 10 CFR part 35 (§ 35.75), generally licensed sources, tritium exit signs, and smoke detectors, where the public can have a higher acceptable risk for the benefits which the materials bring them.

Response: The NRC disagrees with the comment. The category 1 and category 2 quantities of radioactive material possessed by a medical facility present the same risk as category 1 and category 2 quantities of radioactive material possessed by other licensees. Almost any user could argue that its use benefits society in some manner. The comparison to generally-licensed sources is not applicable, as generally licensed sources contain less than category 2 quantities of radioactive material and are considered safe for use without additional measures.

Comment A19: One commenter expressed concern that the source aggregation changes could cause additional medical facilities to come under the rule. The commenter was opposed to the rule applying to any facilities beyond those under the orders.

Response: The application of the source aggregation criteria has not changed from the orders. The concept of co-location and breaching of a common physical barrier are still factors.

While the rule may apply to licensees that were not subject to a particular order, the licensee would only be subject to the requirements if it aggregates the material. Some licensees that have an aggregated category 1 quantity may have only been subject to the Increased Control Orders and would now be subject to some additional requirements under the rule that apply to all licensees that possess a category 1 quantity of radioactive material.

Comment A20: Several commenters expressed concern about the extension of applicability for the proposed rule beyond byproduct material licensees to power reactor, research and test reactor, and fuel cycle licensees. Commenters noted that extending the requirements to large component or radioactive material storage facilities located on power reactor plant sites appears unwarranted. Commenters recommended limiting the applicability to exclude material that meet a criterion for a specific activity, surface contaminated objects, bulk packages with mass exceeding 100 pounds or limit aggregating material to a small number (fewer than 10) of discrete sources, and areas where a large number of packages containing low concentrations of radionuclides of interest are stored over a very large area, because they believe the risk is low and should not present a security concern. Commenters recommended that an appropriate threshold be developed that exempts large volume or weight of a single item or of the aggregated quantity such that exemption requests are not necessary and the security provisions of 10 CFR part 37 would not apply. Commenters noted that such materials are typically either of such large mass or volume, or of such a diffuse constitution, that they should be considered low risk for any malevolent purpose. Commenters noted that the industry is concerned that casting a wide net will present a situation whereby certain categories of facilities are regulated through exemptions.

One commenter suggested that NRC should consider using dose rates at 1 meter relative to the Appendix I definitions in IAEA TECDOC-1344 for other than sealed sources as an alternative. The commenter noted that the IAEA document acknowledges that the

categorization system may not be appropriate for waste management. The commenter noted that tables in the document are based primarily on discrete sealed sources of very high specific activity and do not apply to packages in transport. The commenter further noted that IAEA also recommends 100 rads (1 Gy) to bone marrow in 100 hours at 1 meter from sources that cannot be carried as the threshold for a “dangerous” source. With a category 2 source threshold at $10 \times D$, this also provides a practical justification for exempting low specific activity (LSA) materials, as they are restricted to dose rates of 1 rem/h at 3 meters. Using very restrictive point source consideration (*i.e.*, an inverse square relationship), LSA materials cannot result in dose rates exceeding 10 rads/h at 1 meter. The other deterministic considerations presented in the TECDOC are similarly bounded by the low specific activity of such wastes.

Commenters noted that there is a distinct difference between a given amount of activity confined in a relatively small sealed source and the same quantity dispersed around a large site in numerous containers, none of which individually contains activity approaching a category 2 amount. Commenters noted that low specific activity material, objects with low levels of surface contamination, or numerous small sources would not be attractive for theft or sabotage because of the disperse nature of the radioactivity. One commenter noted that this is recognized in the transportation arena that allows use of industrial packages for low specific activity and surface contaminated materials versus more robust Type A or Type B packages for shipping higher activity materials.

Commenters noted that the packaging of the source is relevant to potential theft and diversion. Commenters indicated that a quantity of material where the total activity exceeds a category 2 level but is dispersed in contaminated metal and other material within one or more large concrete and/or steel containers presents a different hazard than the same amount in a relatively small unshielded source. Commenters noted that large and heavy containers are difficult to move and steal without detection and that the containers themselves are

self-protecting from a sabotage point of view. The commenter noted that this is important for licensees engaged in decommissioning, processing, and shipping of bulk waste material. Commenters noted that the volume and mass required for a category 2 quantity of material renders theft an incredible scenario and that damaging and dispersing a category 2 quantity of material such that deterministic effects result from internal or external exposures are not credible.

Commenters provided examples of: 1) a commercial waste processor that could have several thousand packages in a common storage area, each containing waste forms of relatively low specific activity and each with a mass of several hundred to several thousand pounds and 2) a radioactive waste disposal facility that has a 60-car train of radioactive waste within its controlled area.

Response: The NRC agrees with the comment in part. The NRC has determined that it is appropriate to include a partial exemption in the regulation instead of treating exemptions requests on a case-by-case basis. Paragraph (c) has been added to § 37.11 to address radioactive waste materials. The provision does require that some security measures be applied to the waste, but the majority of the 10 CFR part 37 requirements would not apply. Measures include the use of continuous physical barriers, alarmed locked gates or doors, and assessment and response of unauthorized entry. The provision does not include the use of dose rates, but would cover much of the low specific activity waste addressed by the comment.

Comment A21: One commenter felt that the proposed requirements should not apply to holders of category 2 sources, particularly since the new requirements would not apply to the transshipment of category 1 and category 2 sources. The commenter noted that if the Juarez, Goiana and Mayapuri radioactive material dispersal incidents all occurred in the United States, in a single year, the annualized risk of premature death would be a small fraction of the 1E-6 probability frequently used in establishing regulatory requirements.

Response: The NRC disagrees with the comment that the security provisions should not apply to category 2 sources. The Commission has determined that category 2 sources are risk significant and, therefore, warrant additional security measures. The NRC does not regulate transshipments.

Comment A22: One commenter noted that the scope suggests that 10 CFR part 37 applies to any person who is authorized to possess or use category 1 or category 2 quantities of radioactive material at any site or contiguous sites subject to the control by the licensee. The commenter pointed out that when radioactive material is used at temporary job sites, the licensee will be in control of the quantities of radioactive material, but may not necessarily be in control of the sites. The commenter also noted that the scope does not indicate that this applies to persons who have access to SGI-M and implies it only applies to those authorized.

Response: The NRC agrees that the language may be confusing as it applies to temporary job sites and has revised the scope to clarify the intent. The requirements of 10 CFR part 37 do not apply to SGI-M. However, some of the security information developed under 10 CFR part 37 would be considered SGI-M and needs to be protected in accordance with 10 CFR part 73. The requirements for SGI-M are contained in §§ 73.21 and 73.23.

Comment A23: One commenter stated that the exemption provided in § 37.11(b) for facilities with 10 CFR part 73 security plans should be retained but offered a suggested revision to clarify who has inspection/security oversight. The commenter noted that it would be a significant paperwork task to keep records showing compliance with both sets of controls without a real increase in the security of either material. The commenter also noted that it would be an added inspection burden if the program required separate inspections by an Agreement State and the NRC. The commenter suggested adding a sentence at the end of the paragraph: “Although the NRC maintains primary oversight of these facilities, inspection by Agreement State representatives is permitted.”

Response: The NRC is retaining the exemption for licensees that possess the category 1 or category 2 quantities of radioactive material under an NRC license. For those licensees located in non-Agreement States, the licensee can choose if it wants to protect the material under the security plan required by 10 CFR part 73 and approved by the NRC or protect the material under a 10 CFR part 37 security plan. If the material is protected under a 10 CFR part 73 security plan, the licensee's records should note that the material is protected under a 10 CFR part 73 security plan. Any inspection would be against the security plan under which the material is protected. For licensees that are located in an Agreement State and possess category 1 or category 2 quantities of radioactive material under an NRC license, the licensee can choose whether to protect the material under the 10 CFR part 37 or the required and approved 10 CFR part 73 security plan. For licensees that possess the category 1 or category 2 quantities of radioactive material under an Agreement State license, it will be up to the Agreement State to decide if it will allow the licensee to protect the material under an NRC-required and approved 10 CFR part 73 security plan. The licensee would want to discuss this with its State regulator. Agreement States are not required to adopt the provision on exemptions in § 37.11(b) as a matter of compatibility. As for adding a provision to allow State personnel to inspect, the NRC disagrees with the comment. A new provision is not necessary to allow an Agreement State to inspect against a license that it has issued.

Comment A24: One commenter stated that the NRC should not promulgate the rule for licensees currently under NRC 274i Security and Fingerprinting Orders specified in EA-08-225 issued August 29, 2008. The commenter noted that these licensees are few in number, and the NRC should continue to regulate them under the existing orders. The commenter noted that this should include possession of certain isotopes greater than category 1. The commenter suggested new paragraphs for § 30.34 as follows: "30.34(m) Security requirements for licenses who possess an individual source less than category 1 but greater than or equal to category 2 of

the isotopes listed in Appendix E to 10 CFR part 20 - Nationally Tracked Sources Thresholds. Licensees or applicants must submit to NRC for review and approval of information to comply with the requirements and time frames specified in NRC Order EA-07-305 dated December 5, 2007, and its attachments titled "Table 1 Radionuclide of Concern and Attachment 3 Specific Requirements Pertaining to Fingerprinting and Criminal Records Checks" which are incorporated by reference (or listed in a new Appendix F of 10 CFR part 30). This rule is in addition to any other requirements specified in applicable 10 CFR parts." and "30.34(n) Licensees must notify NRC of their intention to possess an individual source greater than category 1 of the isotopes listed in Appendix E to 10 CFR part 20 - Nationally Tracked Sources Thresholds."

Two commenters stated that the authority to regulate the physical protection of category 1 and 2 quantities of material in transit (subpart D) should not be relinquished to the Agreement States. The commenter noted that while the adequacy and compatibility requirements of Agreement State programs would require the Agreement State regulations to be "essentially identical" to those contained in subpart D, there are several instances where Agreement State regulations include requirements in addition to those found in the analogous NRC regulations. The commenter noted that Agreement State regulations that go beyond those contained in subpart D could hinder interstate commerce and result in additional burden and expense to the licensees. Another commenter stated that there is value to Federal preemption in regulating the transportation security of category 1 and category 2 quantities of radioactive material as this would ensure uniformity of the administration of the requirements. One commenter suggested that the authority be transferred to DOT and not the States.

Two commenters stated that the NRC should retain authority for the security of category 1 licensees under common defense and security unless the States are given authority to regulate all aspects of category 1 sources. The commenters noted that the rule does not give

the States authority to regulate the safeguards information and, therefore, the regulatory authority would be split. Commenters suggested removing the SGI designation. One commenter noted that under Supplementary Information Item II.(A)(10), it states, "Although the NRC relinquishes authority to States for certain materials, under section 274(m) of the AEA no such agreement will affect the authority of the Commission to take regulatory action to protect the common defense and security." The commenter noted that Item 11 states, "The provisions put in place for the inspection of licensees that received the orders issued under common defense and security would remain in place until the State implements the requirements." The commenter stated that this contradicts Item 19 which states the NRC will not enter such agreement for common defense and security. The commenter indicated that category 1 materials must be considered under the terms of common defense and security and should remain under NRC jurisdiction for security. The commenter noted that the proposed rule states "licensees who activities are covered under part 73 would be exempt from part 37." The commenter stated that most of the irradiator requirements (SGI-M) are based in 10 CFR part 73 and therefore indicates that there are no category 1 licensees that are subject to State purview. The commenter noted that there are references to SGI-M in the proposed rule which further leads to the need for clarification.

One commenter noted the drafted document appears to be inconsistent in this regard and that the issue of jurisdiction and responsibility for these licensees must be clearly made and the necessary inclusions and exclusions to the rules made accordingly.

Response: The NRC disagrees with the comment. The NRC believes that it is appropriate for the Agreement States to regulate the physical protection of category 1 and category 2 quantities of radioactive material. Although some of the security information is considered to be SGI-M under 10 CFR part 73, the NRC does not believe that this prevents the Agreement States from regulating the security aspects for those facilities. While the State could

not inspect the SGI provisions for protection of the material unless it entered into a 274i Agreement with the NRC, the State could inspect and enforce the provisions of 10 CFR part 37. The exemption provided in § 37.11 was intended to only cover facilities that had a security plan under 10 CFR part 73 and not the information protection aspects. The NRC has clarified the exemption. See *also* the responses to comments A23, A46, and A47 and the response to question 10 in Section II.A of the Statement of Considerations.

Comment A25: One commenter noted that the rule should adopt the entire categorization of radioactive sources from the IAEA Safety Guide No. RS-G-1.9 - Categorization of Radioactive Sources. The commenter pointed out that the IAEA Safety Guide provides a more robust, risk-based categorization of quantities than the categorization provided in the proposed rule as it describes five different categories that differentiate sources possessed by various licensees based on quantity as well as use. The commenter also stated that the rule should be limited to source quantities characterized as category 1 and category 2 in the IAEA Safety Guide. The commenter noted that the types of sources used in refineries and petrochemical plants are considered category 3 and according to the IAEA Safety Guide, the types of sources used in refineries and petrochemical plants present less risk than the source quantities in category 1 and 2.

Response: While the NRC agrees that category 3 sources present less risk individually than category 2 sources, the NRC disagrees with the remainder of the comment. Unlike RS-G-1.9, the NRC and the IAEA Code of Conduct do not consider use (e.g., fixed gauges, well logging, and radiography) in the determination of source categorization. Regardless of its intended use, any category 2 quantity may pose a significant risk to individuals, society, and the environment. Additionally, 10 CFR part 37 applies not only to sources, but also to bulk material. The rule also addresses aggregation of radioactive material at or above the category 2 threshold. If several sources are stored together that individually are considered to be category

3 sources, but together form an aggregated category 2 quantity, the attractiveness of the material as a group would be the same as if there were only one category 2 source. If the sources used in the refineries and petrochemical plants are not aggregated, 10 CFR part 37 would not apply.

Comment A26: One commenter indicated that for facilities covered under the Maritime Transportation Security Act, the rule would mean additional burdens, redundancies and confusion. The commenter recommended that for facilities regulated under DHS/DOT Personnel Surety programs, the rule should allow a program of reciprocity to reduce redundancy. The commenter noted that at National Petrochemical & Refiners Association (NPRA) member facilities, the Radiation Safety Officer (RSO) and technicians have intimate contact with source holders and the rule would be best implemented by the RSO and technicians and not the entire facility population.

Response: The NRC disagrees that the rule imposes additional burdens, redundancies, and confusion. The Maritime Transportation Security Act, which amends the Merchant Marine Act of 1936, establishes a program to ensure greater security for United States seaports and provides requirements pertaining to personnel whose duties are related to import and export activities at the ports. Part 37 transportation requirements only apply to the domestic portion of an import or export. For an import, the provisions would apply once the shipment clears customs and for exports, up to the point the shipment crosses the border. Holders of the TWIC do not need to undergo fingerprinting and the FBI criminal history records check again as § 37.29 relieves them from the requirement. However, the individuals would need to undergo the remaining elements of the background investigation.

As for the NPRA member facilities, the provisions for access authorization under 10 CFR part 37 would only apply if the facility allows unescorted access to category 1 or category 2

quantities of radioactive material. The licensee decides who is in charge of the security program as the regulations do not specify any specific position.

Comment A27: One commenter asked for clarification whether the provisions apply to those licensees authorized to possess the material or those that actually possess the material. The commenter noted that the language discrepancy occurs throughout the rule and must be corrected. Another commenter asked that the requirements be spelled out separately to avoid confusion.

Response: The proposed rule contained some provisions that pertained to licensees that were authorized to possess category 1 or category 2 quantities of radioactive material. The final rule contains provisions that apply only to those that actually possess and aggregate the material to a category 1 or category 2 quantity.

Comment A28: Some commenters objected to the need to submit compliance information. The commenters felt that this is an unnecessary burden to both the licensees who have already implemented a program and the regulatory agency. The commenters noted that the licensees subject to this part have already been inspected multiple times and have established a compliance history, and therefore these licensees should be exempted from having to resubmit existing information. One commenter thought that the provision was vague as written and requested clarification that compliance with the provision would be achieved by submitting a letter to the NRC indicating that the licensee has successfully implemented the program. One commenter noted that the NRC must identify in the regulation what essential elements are to be included because placing the information in guidance is unacceptable. One commenter thought the provisions should be removed from the rule but if retained offered suggested language. One commenter stated 30 days did not provide adequate time. Commenters noted that requiring a licensee to report compliance was an unnecessary burden as licensees are expected to comply and that the normal terms of implementation for

rulemaking are adequate. One commenter suggested deleting § 37.41(d) as unnecessary since current implementation of the Increased Control Orders is an adequate basis to conclude the current licensees will transition to compliance with the new regulations.

Response: The NRC agrees that the submittal of compliance information is not needed and has removed the requirement from the rule. The NRC and the Agreement States already know which licensees will need to implement 10 CFR part 37. A provision has been added in § 37.41 to require a licensee that has never implemented the orders or 10 CFR part 37 to notify the NRC 90 days before aggregating material to a category 1 or category 2 quantity of radioactive material.

Comment A29: One commenter stated that in § 30.32 the wording implies the application must include an affirmation that the proposed security program meets the requirements in 10 CFR part 37. The commenter stated that instead the application should include a proposal as to how the requirements will be satisfied and be subject to evaluation for sufficiency. The commenter suggested the following language: “(1) An application for a specific license to use, store, or transport category 1 or category 2 quantities of radioactive material must include information outlining the applicant’s security program designed to satisfy the requirements in part 37 of this chapter.”

Response: The NRC has reevaluated the need for the requirement and has decided that it is unnecessary. A new applicant will be evaluated on the need to implement 10 CFR part 37 as part of a prelicensing review and inspection. If the licensee will be aggregating the material to a category 1 or category 2 quantity of radioactive material, the licensee will be expected to implement the provisions of part 37 before receiving a license.

Comment A30: One commenter noted that institutions that have aggregated material may require significant time to implement the provisions as it will require a financial investment. The commenter did not suggest an appropriate timeframe. Several commenters noted that

30 days for implementation was not sufficient for the changes that need to be made. Two commenters suggested a 1-year effective date. Commenters supported terminating the orders on the effective date of the rule to avoid confusion and noncompliance. One commenter stated that the rule should be clarified as to the compliance date and asked what happens if a licensee is not in compliance by that date. One commenter noted that it would be difficult to comply with the 30-day timeframe for preparing and implementing the security plan and implement the security program at least 90 days before it "...aggregates radioactive material to a quantity that equals or exceeds the category 2 thresholds." The commenter further noted that work varies significantly from project to project and that security plans that are sufficiently robust to be effective also would vary significantly. The commenter noted that it is not possible to prepare or implement a project-specific security plan without knowing the details of the project and that frequently licensees need to mobilize and initiate work within a matter of a few days, which would not be possible if a 90-day advance notice was required.

Response: The NRC notes that the proposed rule indicated that the final rule would be implemented 270 days after publication in the *Federal Register*. The 30-day timeframe was for the licensee to submit compliance information. The NRC has removed the requirement to submit the compliance information. In addition, the NRC is providing a 1-year implementation period for the final rule. This should allow ample time for licensees to implement the requirements, including the development of any new procedures and the conduct of necessary training. Agreement States will be given 3 years from publication of the final rule to adopt the rule provisions instead of from the effective date. This will still provide the States with a 3-year window to adopt the regulations.

Comment A31: One commenter noted that its business depends on the ability to not co-locate or aggregate its radioactive material and that it manages its radioactive material through quantity control and physical separation of material not in use at any one time. The commenter

noted that, if it was required to aggregate all of its material, which includes the standard, returned sources, sources packed and ready to ship, cell waste (cell sweep, dust, chips), plus isotope material, it would be continuously above the category 2 threshold, and the additional requirements would be a significant economic hardship on the company.

Response: The rule does not require co-location or aggregation of radioactive material. If a licensee does not aggregate the material above a category 2 threshold, the licensee will not need to implement the provisions of 10 CFR part 37. The final rule only applies to those licensees that possess aggregated quantities at or above the category 2 threshold.

Comment A32: Several commenters objected to the change from a 3-year retention period for records to a 5-year retention period. One of the commenters believed that the change from the standard practice where most documents in the industry have a mandated 3-year retention period is redundant and unnecessary and will add a potential for confusion where none need exist. One commenter questioned why there was a need to keep superseded portions of procedures and the security plan for 5 years. The commenter stated that this was an added burden and does not add to the security of the material or to the protection of the health and welfare of the general public. The commenter also questioned the need to keep training records for 5 years stating that it should be adequate for a licensee to show that it is conducting annual training and suggesting a 1-year retention period.

Response: The NRC agrees with the comment on the retention period and has changed the record retention period for most records to 3 years. Safety records are maintained for 3 years, and the NRC agrees that there is no benefit to keeping only the security records for 5 years. There are a few licenses that have an inspection frequency of 5 years; however, the majority of the licensees impacted by 10 CFR part 37 have a 3-year inspection frequency. Superseded procedures and training records are necessary from an inspection and enforcement aspect.

Comment A33: One commenter questioned how long to hold on to the old security plan once it is updated and how long the documentation of the coordination activities is to be maintained. Another commenter recommended changing the record retention period for the security plan so that the record could be destroyed 5 years after it is no longer needed. The commenter noted that there was no value in keeping the security plan once a licensee was no longer allowed to possess materials that would require a security plan.

Response: Section 37.43(a)(4) specifies that the superseded portions of the security plan be retained for 3 years (note the proposed rule specified 5 years). For any record where a retention period is not specified, § 37.103 specifies that the record be retained until the Commission terminates the license. The NRC has added a retention period of 3 years for the documentation records. The NRC agrees with the comment and has changed § 37.43(a)(4) to indicate that the security plan must be retained for 3 years after it is no longer required.

Comment A34: One commenter requested clarification in § 37.101 on the concept of “safeguards against tampering with” to preclude unwarranted interpretations during a regulatory inspection about the requirements for records. The commenter offered suggested language as follows: “the licensee shall maintain adequate safeguards against tampering with and loss of records. The requirements in § 37.43 for protection of information are not applicable to this section.” Another commenter recommended replacing the term “safeguard” with “protect” in § 37.101. The commenter felt that safeguard should be only used when referring to safeguards.

Response: The NRC disagrees with the comment. The records provision in § 37.101 is identical to provisions in other parts of the regulations. The NRC is not aware of any issues that have arisen over interpretation. The provisions of § 37.43 would apply if the records were the security plan, implementing procedures, or the list of individuals allowed unescorted access.

Comment A35: One commenter stated that the enforceability in regulations of records retention for reporting suspicious activities is unduly burdensome on the licensee. The

commenter stated that due to the clandestine nature of reporting suspicious activities to LLEAs, the licensee may not have the LLEA's or NRC's fluid responses to these reports for security reasons and that ongoing investigations can encompass years, so the recordkeeping requirement is inconsistent and can be inconsistent with other recordkeeping requirements depending on the incident nature of the reporting.

Response: The NRC does not understand the commenter's concern. There are no record retention requirements associated with reporting suspicious activities. The 30-day written report is not required for suspicious activity reporting. The licensee is required to assess the suspicious activities and notify the LLEA, only if the licensee believes it is appropriate to do so. The licensee is only required to notify the NRC if the LLEA is notified. The NRC acknowledges that there is some subjectivity involved in determining what is considered to be suspicious.

Comment A36: One commenter questioned who was authorized to authenticate reproduced records in § 37.101.

Response: "Authorized personnel" in § 37.101 are those authorized by the licensee to authenticate duplicated documents.

Comment A37: In the proposed rule, the NRC specifically requested comment on the reporting requirements. Commenters were requested to provide information on: 1) whether the proposed rule contained the appropriate items and thresholds to be reported to the LLEA; 2) whether the proposed rule contained the appropriate items and thresholds to be reported to the NRC; 3) whether suspicious activities should be reported and if they are reported, what type of activities should be considered suspicious; and 4) whether the timeframe for reporting was appropriate. Fifteen commenters provided responses to the specific questions on this subject.

Of those that provided responses to the questions on the reporting requirements, the majority agreed that the reportable items and thresholds were appropriate, and five commenters

felt the items and/or thresholds should be changed. One of the commenters indicated that the NRC and/or FBI should be notified of any denial for cause of a request for unescorted access as this might be domestic intelligence information of interest to the FBI or DHS. The commenter also felt that the NRC/FBI should be notified of activities determined to be suspect by the LLEA. Three commenters stated that actual and attempted theft were appropriate reportable actions but that suspicious activities should be removed from the rule. Of the commenters that supported reporting of suspicious activities, no commenter offered suggestions as to what type of activities should be considered suspicious. A couple of the commenters stated that the licensee is the best judge of what type of activities would be considered suspicious at its facility. Other commenters just suggested that the NRC should provide guidance to assist the licensee. Most of the commenters indicated that the reporting timeframes were appropriate. One commenter stated that the timeframes did not allow for a realistic period of assessment. The commenter noted that classifying some of these events will be very subjective and some may be impossible to distinguish from events that are not malicious or not related to a category 1 or category 2 quantity of radioactive material. Another commenter stated that a specific timeframe should be specified instead of immediate and upon discovery. The commenter stated that failure to set specific time limits will result in delay in implementing the Federal response framework.

In addition to those that provided responses to the specific questions, seven commenters addressed this subject in their comments. Two commenters noted that classifying some of these events will be very subjective and some are likely to be impossible to distinguish from events that are not malicious or are not related to category 1 or category 2 quantities of radioactive material. The commenters noted that reasonable persons could interpret the expectations of the NRC and the details of a specific event very differently. The commenters further noted that these events will require a period of assessment, and sometimes a lengthy

period of assessment, to determine the nature of the event and that the timeframes for reporting do not anticipate a period of assessment. As an example the commenters provided the situation where a discrepancy in the inventory is discovered without any evidence of an “actual theft” (e.g., locks that have been cut), requiring a period of assessment to determine the nature of the event. Two commenters stated that the requirement for sabotage reporting should be removed. The commenters noted that it would not be possible for a licensee to determine the “intent” of the person causing any damage and whether his or her “intent” is malevolent. One commenter noted that § 37.57(b) requires NRC notification when there is “suspicious” activity related to “possible” theft, sabotage, or diversion. The commenter stated that it would only be appropriate to notify the NRC if the licensee, in conjunction with the LLEA, determines that there is some validity to the suspicion. The commenter noted that the NRC should encourage open communication between the licensee and LLEA, and licensees should feel free to express even minor concerns, uncertainties, etc. to LLEAs for their assistance without having to notify the NRC in each instance. One commenter agreed with the reporting requirement for suspicious activities but noted that it would be dependent on the licensee’s judgment based on its circumstances. The commenter noted that it would be difficult to quantify what suspicious activity is ahead of time, and the licensee should not be second guessed on whether or not it made this type of notification. One commenter noted that suspicious activities should continue to be reported on a voluntary basis as it is very subjective and would be difficult to enforce. One commenter recommended defining suspicious activity. One commenter expressed concern over the requirement to report suspicious activities asking how it could be enforced as individual judgment may differ as to what constitutes a suspicious action. The commenter also questioned why, if the LLEA provides an immediate assessment and determines that the event is completely harmless, the NRC needs to be notified. The commenter suggested language for § 37.57(b) to increase the clarity and to allow for some local interpretation. The suggested

language is as follows: “The licensee shall notify the LLEA upon the discovery, of any security-related events involving suspicious activity that may indicate preoperational surveillance, reconnaissance, or intelligence-gathering activities directed against licensees, or their facilities related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material. If the event is not found to be harmless, the licensee should notify the NRC’s Operations Center (301-816-5100) as soon as possible, but not later than 4 hours, after notifying the LLEA.”

Response: The NRC has revised the reporting requirement to make it clear the licensee does not need to contact the LLEA when it has determined that an alarm was not the result of an attempted or actual theft, sabotage or diversion. The NRC does not believe that it is necessary for the licensee to report to the NRC the denials for unescorted access. The NRC has access to the information during inspections. The NRC has retained the reporting requirement for sabotage. If an individual has caused damage and placed the radioactive material at risk, the NRC wants to know regardless of the individual’s intent. The NRC disagrees that it is necessary to establish a set timeframe for reporting attempted theft, diversion, or sabotage as the terminology is consistent with other similar reporting requirements. The NRC agrees that it is good practice to have open communication between the LLEA and the licensee.

On the question of reporting suspicious activities, the NRC has decided to retain a requirement on suspicious activities. The reporting of suspicious activities is an important component of evaluating the threat against licensed facilities and material. The NRC reviews individual notifications of suspicious activities to evaluate whether potential preoperational activities (*i.e.*, multiple events at a single site or multiple events at multiple sites) may be part of a larger plan and to integrate this information with other agencies in the homeland security and intelligence communities. The NRC is not requesting that the licensees actively gather

intelligence but rather that they report information they believe is relevant to the security of their facility or activity. The reporting requirements provide a consistent means of communicating this information to the NRC. The requirement has been revised to require the licensee to assess suspicious activities and to only contact the LLEA if the licensee believes it is appropriate to do so. The licensee is required to notify the NRC only if notifying the LLEA. Some suspicious actions may be successfully handled by the licensee without the need to involve law enforcement or the NRC. The NRC believes that the revision will provide the licensee more flexibility in determining how to address any situation that involves what might be considered suspicious activities. The NRC does recognize that what is considered to be suspicious is subjective and not all licensees will handle the same situation in the same way. On balance, the NRC believes that it will receive information on the more serious instances, but not the trivial instances.

Comment A38: One commenter noted that in the absence of any suspicious or known mitigating factors, it has typically given the carrier 24 hours to trace within their transportation cycle, before the package is declared as lost or missing. The commenter noted that this has proven to be the most effective time period and that anything less than the 24 hours does not allow sufficient time for the carrier to do a complete document and tracking search and/or a physical search at potential locations. The commenter noted that to declare the package as lost or missing before that will result in many false positives, as 99.99% of the time the package is located within the 24-hour window which will result in significant resources of both the regulatory agencies and licensees involved, trying to get useful information that just isn't available.

Response: Part 37 requirements would not change this practice. The reporting requirement in § 37.81(b) is similar to the requirement from the orders. The licensee is not required to notify the NRC when the material has not arrived by the no-later-than arrival time, rather it is to notify the NRC once it has been determined that the material is lost or missing.

This allows some time for investigation before the first phone call to the NRC. Similar to the order requirement, the licensee is required to notify the NRC a second time if the material is still missing after 24 hours of investigating. The rule should not result in a change in practice and in fact gives the licensee additional time before starting an investigation.

Comment A39: Several commenters requested information on how diversion differs from a theft as in both cases the material is removed and the movement is unauthorized. The commenters felt that the requirements for reporting diversion and suspicious activities were subjective and that the NRC's expectations concerning diversion and suspicious activities were not clear.

Response: *Diversion* means the unauthorized movement of radioactive material subject to this part to a location different from the material's authorized destination inside or outside of the site at which the material is used or stored. As an example, a source purchased using a legitimate license may be shipped to an unauthorized location. Diversion does not require the adversary to defeat the licensee's physical security system. Theft is the act of taking material from a facility, vehicle, or temporary job site and requires the adversary to defeat the licensee's physical security system.

What constitutes a suspicious activity can be subjective and may vary from one licensee to another. Examples of suspicious activities are provided in the guidance. The reporting of suspicious activities is an important component of evaluating the threat against licensed facilities and material. The NRC reviews individual notifications of suspicious activities to evaluate whether potential preoperational activities (*i.e.*, multiple events at a single site or multiple events at multiple sites) may be part of a larger plan and to integrate this information with other agencies in the homeland security and intelligence communities. The NRC is not requesting that the licensees actively gather intelligence, but rather that they report information they believe is relevant to the security of their facility or activity. The reporting requirements

provide a consistent means of communicating this information to the NRC.

Comment A40: One commenter recommended placing the reporting requirements in §§ 37.57 and 37.81 in subpart M of 10 CFR part 20 to avoid duplicative regulations. The commenter stated that the notifications in § 37.81 should be the same as 10 CFR part 20 and should be immediately after discovery, but only after initially notifying the LLEA. The commenter noted that immediate notifications of theft should be made to the LLEA, not as soon as possible as the proposed rule would allow. Another commenter noted that the reporting requirements should be consistent to ensure that multiple reports for the same event are not an unintended consequence.

Response: The NRC disagrees with the need to move the 10 CFR part 37 reporting requirements to 10 CFR part 20. The NRC has revised § 20.2201(c) to include a reference to 10 CFR part 37 so that duplicative reports are not required. The NRC disagrees with the comment to change as soon as possible to immediate in § 37.81(c) and (d). The historic interpretation of immediate reporting has been up to 4 hours. The NRC does not believe that 4 hours is the appropriate timeframe for the notification; notifications need to be made promptly. For this reason, the NRC has used “as soon as possible” in both the orders and the rule language.

Comment A41: One commenter questioned the difference between the requirements to report no later than 4 hours after the discovery of any actual theft or diversion in § 37.57 and the requirement in § 37.81 to report within 1 hour of lost or missing material.

Response: Under § 37.57, the licensee is to immediately notify the LLEA and then to contact the NRC as soon as possible. If contacting the NRC would somehow interfere with or delay the LLEA response, the licensee can take up to 4 hours to notify the NRC. The LLEA would be in charge of any response as the occurrence was at a fixed location. It is the NRC’s expectation that the notification would occur very quickly after the LLEA is notified. Under

§ 37.81, the licensee is required to contact the NRC within 1 hour because the NRC may need to initiate a response as the occurrence was during transit.

Comment A42: One commenter noted that the rule should not require the licensee to provide a copy of the reports required under § 37.81(g) to the Office of Nuclear Security and Incident Response (NSIR). The commenter believes that the NRC should provide the copy to NSIR. One commenter recommended that the written follow-up report for event reporting be submitted within 60 days instead of 30 days. The commenter noted that 30 days is insufficient time for licensees to complete an investigation, prepare, and submit a written report and that the 30 days is inconsistent with the timeframe for submittal of written follow-up reports that are required elsewhere in 10 CFR Chapter I. One commenter objected to the wording of the requirement in § 37.81(g) to “include sufficient information for NRC analysis and evaluation” as it is too open-ended and the commenter felt that further explanation is necessary. The commenter stated that the NRC is doing a disservice to licensees if it wishes to claim that such items are difficult or impossible to predict for all cases or would be more fully addressed in guidance.

Response: The NRC agrees with the comment in part and disagrees with the comment in part. The NRC often specifies that a copy of a report should be submitted to a specific office and does not believe that it presents a large burden on the licensee. While some of the follow-up reports contained in Title 10 Chapter I are submitted within 60 days, some are submitted within 30 days. The 30-day timeframe for a written follow-up report is consistent with the requirement for the follow-up report for reporting lost and missing material contained in 10 CFR part 20. If the investigation is not complete, a final report can be submitted upon completion. The NRC agrees with the comment on sufficient information and has added language similar to the provisions in § 20.2201(b).

Comment A43: One commenter requested that a subsection be added to § 37.57 to clarify requirements for reporting by a licensee or permittee under a master materials license that has an onsite LLEA in order to preclude unwarranted interpretations during a regulatory inspection about reporting to NRC. The commenter offered suggested language as follows: “(d) For a licensee or permittee under a master materials license with an on-site LLEA, reporting in this subsection is required only after the on-site LLEA has confirmed the attempted, actual, or actual activity related to theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material.”

Response: The NRC disagrees with the comment. The reporting requirements remain the same whether the LLEA is on site or off site. The NRC does note that the LLEA does not need to be contacted until after the licensee has assessed the situation. The LLEA needs to be notified only if the licensee has determined that an attempted or actual theft, diversion, or sabotage act has occurred or is taking place, or, as appropriate, if the licensee has identified suspicious activities.

Comment A44: One commenter recommended defining substantive information in § 37.81(h). The commenter noted that the term substantive information indicated a higher priority notification than 30 days.

Response: The NRC disagrees with the comment. The provision is identical to the provision in § 20.2201(d). A licensee should use judgment on whether the information should be provided sooner than 30 days.

Comment A45: One commenter stated that certain provisions of the proposed rule would be matters of mandatory compatibility between the NRC and the Agreement States. The commenter stated that the NRC has no statutory basis requiring an Agreement State to maintain regulations compatible with those of the Commission. The commenter believes that the Commission may request compatibility by the State, but cannot require it.

Response: Section 274, "Cooperation with States," of the AEA provides for cooperation with States, authorizing the Commission to enter into Agreements with States for certain materials provided that certain conditions are met. Two specific sections of the AEA provide for compatibility requirements: 1) subsection 274d. gives the Commission the authority to enter into an Agreement with a State if the Commission finds that the State program is compatible with the Commission's program for regulation of such materials (subsection 274d(2); and 2) under subsection 274g. of the AEA, the Commission is authorized and directed to cooperate with the States in the formulation of standards for protection against hazards of radiation to assure that the State and Commission programs for protection against hazards of radiation will be coordinated and compatible.

In the Commission's policy statement, "Policy Statement on Adequacy and Compatibility" (62 FR 46517; September 3, 1997), the Commission addressed a similar comment. At that time, it was the Commission's view that, pursuant to section 274, an Agreement State's program should be compatible with NRC's program for the duration of the Agreement for the following reasons, set forth in the policy statement:

Subsection 274g. authorizes and directs the Commission to cooperate with the States in the formulation of radiation protection standards "to assure that the State and Commission programs for the protection against hazards of radiation will be coordinated and compatible." This provision demonstrates Congress' intention that the compatibility between the NRC and Agreement State programs should be maintained on a continuing basis.

Subsection 274j.(1) calls on the Commission to suspend or terminate an Agreement State's program if "the State has not complied with one or more of the requirements" of Section 274. The Commission believes that this phrase "one or more of the requirements," encompasses all requirements of Section 274, including the requirement for compatibility in Subsection 274(g).

Under Subsection 274d.(2), the Commission is authorized to enter into an agreement with a State if the Commission makes both requisite findings that the State program is compatible with the NRC's program and adequate to protect public health and safety. Absent a continuing compatibility requirement, an Agreement State could divert from having a compatible program the day after any agreement is signed with NRC. This

would render the Commission's initial compatibility finding required by Subsection 274d.(2) meaningless.

In addition, the NRC has an obligation, pursuant to section 274j. of the AEA, to periodically review existing Agreement State programs to ensure continued adequacy and compatibility. Section 274j. of the AEA also provides that the NRC may terminate or suspend all or part of its agreement with a State if the Commission finds that such termination is necessary to protect public health and safety or that the State has not complied with the provisions of section 274j. In fulfilling this statutory responsibility, NRC provides oversight of Agreement State radiation control programs to ensure that they are adequate and compatible prior to entrance into a section 274b. agreement and that they continue to be adequate and compatible after an agreement is effective. The NRC, in cooperation with the Agreement States, established and implements a performance evaluation program to provide NRC and Agreement State management with systematic, integrated, and reliable evaluations of the strengths and weaknesses of their respective radiation control programs and identification of areas needing improvement, the Integrated Materials Performance Evaluation Program (IMPEP).

There have been no changes to the AEA or to Commission policy that would render a different interpretation of these sections of the AEA. Therefore, no changes were made to the rule in response to this comment.

Comment A46: Two commenters stated that it was unclear if the rule can be implemented under a public health and safety basis. The commenters noted that the performance objective in § 37.21(b) is to prevent an unreasonable risk to public health and safety or the common defense and security, but that the basis for the rule is health and safety and not common defense and security.

Response: This rule can be implemented under the NRC's authority to protect the public health and safety. The rule amends NRC's regulations to impose security requirements for the

use of category 1 and category 2 quantities of radioactive material. The proposed security requirements set forth the objectives and minimum requirements that licensees must meet to protect against theft or diversion of category 1 or category 2 quantities of radioactive material. Accordingly, these requirements increase the protection of the public from harm resulting from the unauthorized use of these materials.

As discussed in the Statements of Consideration for the proposed rule (75 FR 33902, 33907 (June 15, 2010)), when regulations such as these address both the NRC's public health and safety and common defense and security missions, the operative question is whether NRC oversight is necessary to fulfill the common defense and security aspects of the regulations. The NRC believes that the Agreement States can consistently and adequately implement the physical protection requirements, and as such, there is no need for independent NRC action to protect the common defense and security. However, the NRC retains the authority under section 274(m) of the AEA to take any necessary actions for protection of common defense and security should individual licensees or the State program develop issues requiring immediate action.

Implementing these regulations under the NRC's public health and safety authority avoids potential complications with licensees being subject to dual regulatory authorities for a single license. Agreement States can impose these security requirements because they provide a reasonable assurance of preventing the theft or diversion of category 1 and category 2 quantities of radioactive material that has a potential to result in significant adverse health impacts and reasonably constitutes a threat to public health and safety. In addition, making these requirements applicable to Agreement State licensees through the Agreement State Program allows Agreement States to impose these requirements on its licensees and makes Agreement States responsible for enforcement of these requirements on its licensees.

Comment A47: One commenter noted that while the NRC has regular oversight of individual Agreement State programs through its Integrated Materials Performance Evaluation Program (IMPEP), the NRC should evaluate its authority under IMPEP against the authority granted to the Secretary of Transportation under U.S.C. Title 49 Section 5125 – Preemption. Prior to relinquishing its regulatory authority to the Agreement State, the NRC should ensure that it is authorized and capable of preempting an Agreement State regulation pertaining to the physical protection in transit of category 1 and category 2 quantities of radioactive materials if the Agreement State regulation does not comply with the general criteria provided in 49 U.S.C. 5125. The commenter stated that if the NRC concludes that it is indeed appropriate for the Agreement States to regulate the physical protection of category 1 and 2 quantities of radioactive material while in transit then a mechanism has to be in place to ensure these Agreement State regulations cannot add requirements in addition to those provided in 10 CFR part 37.

Response: The NRC in its Policy Statement on *Criteria for Guidance of State and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement*, developed criteria to implement the Agreement State program, authorized by Pub. L. 86-373 which was enacted in the form of a new section to the AEA (section 274) and approved by the President on September 23, 1959 (46 FR 7540-7546; January 23, 1981). Criterion 10 of the Policy Statement, *Regulations Governing Shipment of Radioactive Materials*, provides that the State shall to the extent of its jurisdiction promulgate regulations applicable to the shipment of radioactive materials, such regulations to be compatible with those established by the U.S. Department of Transportation and other agencies of the United States whose jurisdiction over interstate shipment of such materials necessarily continues. Therefore, State regulations regarding transportation of radioactive materials must be compatible with 10 CFR part 71.

The NRC believes that it is indeed appropriate for the Agreement States to regulate the physical protection of category 1 and category 2 quantities of radioactive material while in transit under the provisions of the 274b. Agreements and the continued oversight provided by the NRC. Many of the transportation requirements fall within the Compatibility Category B, Program Elements with Significant Transboundary Implications. Agreement State program elements under Compatibility Category B should be essentially identical to those of the NRC. The NRC evaluates these program elements under IMPEP and can take actions when a State has a program that is not compatible including termination or suspension of an agreement. We believe that this mechanism appropriately addresses the concern that a mechanism be in place to address the scenario of Agreement State regulations, adding requirements beyond those provided in 10 CFR part 37 where the additional requirements would not meet the compatibility designation for a given provision.

Comment A48: Numerous commenters stated that the requirements created too much burden with little, if any, improvement in security and are not necessary or justified and are a waste of taxpayer money. Some commenters felt that the requirements were not commensurate with the risk of the material and were unnecessarily complex, complicated, and long. Some commenters noted that there were no quantifiable benefits, only qualitative benefits and, therefore, there is no evidence that additional measures are necessary. One commenter noted that there must be a balance between the real benefit of providing the services that the category 1 and category 2 sources provide, against a hypothetical malevolent act that may involve one of these sources. Some commenters felt that implementation of the new requirements would financially cripple small companies and would limit funding for new, safer technologies. Some commenters indicated that the burden could result in some medical facilities not offering radiation therapy services, a reduction in research, and will negatively impact patient care. One commenter was of the opinion that the number of licensees would

drop by 25 to 30 percent. Commenters felt that the original order requirements are adequate and should be maintained with no additions as they were sufficient to ensure security. Commenters felt that additional requirements should be based on documented deficiencies in the orders and not on the very low likelihood of a terrorist event. One commenter noted that inspections insure that licensees are performing operations in such a manner as to meet regulatory requirements as they stand. One commenter noted that the NRC has not conducted a national performance-based assessment of the current orders. Commenters stated that the rule was overly prescriptive. Several commenters stated that the requirements should be graded for different types of facilities and material and fixed versus portable material. Some commenters felt that the NRC has lost touch with the way the industry operates or wouldn't suggest unnecessary changes.

Commenters noted that monetary burden of compliance with the orders has required industry to reduce the amount of resources allocated for other aspects of its business and has made it challenging to compete in the global market. Some commenters expressed concern over the cumulative impact noting the implementation of the National Source Tracking System and the license verification system. One commenter noted that it wasn't just the initial outlay, but also the annual burden that needed to be considered. One commenter noted that the rule would impact licensees who have previously not been impacted by the orders. The commenter noted that educating and inspecting these new licensees will impact the NRC staff resources, and could diminish their focus on ensuring security compliance for existing category 1 and category 2 sources. One commenter noted that the rule would be burdensome on the regulatory agency and LLEAs, as well as licensees.

One commenter suggested placing generic requirements in the rule and then address subsets of licensees in the NUREG-1556 series. One commenter suggested that the proposed rule should be renoticed after making changes with more detail provided as to the actual safety

and security benefits to be obtained. One commenter noted that the rule does not conform to the recent draft policy statement on the Protection of Cs-137 Chloride sources.

Response: The NRC understands the concerns of the commenters and has tried to limit the burden while continuing to ensure the adequate safety and security of sources of concern. The security orders were issued based on the specific knowledge and information available to the Commission at the time the orders were issued. The NRC never intended to simply make generically applicable security requirements identical to the orders. The NRC always intended to consider insights gained from the implementation of the orders and implementation of the inspection program, as well as other factors. A number of changes have been made based on specific public comment. The result of these rule changes significantly reduces the burden of the final rule as compared to the proposed rule. The NRC believes that the provisions in the final rule are necessary to protect the public health and safety and ensure security. There could be some facilities impacted by the rule that were not impacted by the orders. Some facilities, such as reactors and fuel facilities, may be impacted by 10 CFR part 37. There should not be any byproduct material facilities newly impacted by 10 CFR part 37 that were not impacted by the orders.

Comment A49: A couple of commenters stated that the NRC should only include the order provisions in the rule and then start work on developing a strategic rulemaking, which may need to include changes in legislative authority, to develop a 10 CFR part 37 with a more risk-informed and performance-based model. The commenters noted that this effort should include evaluating requirements for different types and quantities of radioactive material and different uses, working with States and law enforcement groups to determine effective ways to transport material and working with law enforcement groups to determine effective ways that an LLEA can know and provide emergency response support to licensees. Another commenter suggested using subparts based on the type of business and security risks commensurate with

each type. One commenter noted that the two-part approach would be a major accomplishment for the NRC and would be consistent with NRC's "Principles of Good Regulation." The commenter noted that this approach would reflect the Commission's Staff Requirements Memorandum (SRM) on the draft policy statement on the protection of Cesium-137 Chloride sources (SRM for COMSECY-09-0029) which states: "any additional efforts to enhance security for these sources should consider whether there are benefits of further risk reduction given the NRC's actions to date and the current threat environment."

Response: It was never the NRC's intent to include in the rulemaking only the order provisions. While there are differences from the orders, the NRC believes that the requirements contained in the final rule are necessary. As a general principle, the NRC prefers to construct performance-based regulation rather than explicit, prescriptive regulation where possible. The rule does not dictate what measures each licensee must use to protect the radioactive materials under its possession and control, rather the rule allows the licensee to choose those measures that best meet its needs. The NRC believes that the rule is risk informed and contains an optimized mix of performance-based and prescriptive requirements. A two-step process to conduct two rulemakings would be a waste of not only to the NRC and Agreement State resources but also those of licensees. The basic requirements in the orders were the same for all licensees. The NRC is aware of the areas that need enhancements and these areas are addressed in the rule. The NRC did add a new option to the regulatory analysis for the final rule that addresses only including the order provisions in the rule.

Comment A50: One commenter stated that the total cost of the 10 CFR part 37 revision should include the costs that the licensees incurred to meet the orders and that the estimate and burden on licensees is out of proportion to the actual risk. Another commenter stated that the option 1 cost analysis was inappropriate because it assumed no security measures had been implemented, and it should have considered that the orders were in place. The

commenter stated that an additional cost option determining the cost of implementing a new 10 CFR part 37 with requirements equivalent to the orders would be helpful. Several commenters stated that the cost estimates were underestimated but did not offer better cost estimates. One commenter stated that the annual recurring licensee cost was underestimated by at least a factor of 2. One commenter estimated that it would cost about \$30,000 to implement the provisions and about \$20,000 every year to maintain the plan and that the reinvestigation would cost between \$10,000 and \$20,000 depending on the number of users that need to be rechecked. One commenter noted that the regulatory analysis did not specifically describe the average licensee on which the analysis is based. One commenter (a research facility) noted that it would need to process an additional 60 individuals per year and that the rule would cost approximately \$23,000 per year and an initial outlay of \$30,000. One commenter noted that it had added one additional employee to address the order requirements and that the rule would add yet more burden. One commenter stated that the regulatory analysis does not provide any technical data to support the statement that the qualitative benefits outweigh the costs of the rule. One commenter noted that a major medical facility could have hundreds of individuals in its access authorization program. One commenter noted that it had spent about \$250,000 on physical site upgrades alone and has recurring costs of \$50,000 annually for the alarm system to support the existing orders. One commenter stated that it spends approximately \$100,000 a year for the transportation of category 1 and category 2 sources under the orders. The commenter noted that the amount of employee resources to implement and support the orders has been approximately 400 man days initially and 75 man days annually with total costs to date of approximately \$1.5 million. The commenter estimated that to implement the additional requirements in the rule, it would cost \$250,000 initially which includes 100 man days to set up all the programs and procedures and an ongoing annual cost of \$100,000 to \$200,000 for hiring at least one to two individuals as a technical/ administrative

resource to implement all the procedural and documentation requirements. The commenter stated that the costs assumed in the regulatory analysis (\$25,000 initially and \$27,000 annually) to be substantially underestimated. Some commenters noted that the regulatory analysis did not identify any quantifiable values and that the qualitative benefits were identical to the program in place today. One commenter noted that National Nuclear Security Agency (NNSA) is spending \$26 million to implement voluntary enhancements at certain facilities. One commenter noted that it was not clear that NRC had considered the potential impacts to licensee safety programs, research, and an increase in disused sources due to "deteriorating financial circumstances" (mentioned in SECY 10-0164) that may result from the rulemaking.

Response: The NRC appreciates the information provided on cost and considered that information when estimating the costs in the final regulatory analysis, increasing the annual cost of implementing the measures, increasing the number of individuals requiring a background investigation, and using different values for a small, medium, and large facility. The regulatory analysis prepared to support the proposed rule did contain the cost information on the orders. As the cost has already been expended, it is considered a sunk cost and is not included in the main analysis. The cost is provided for informational purposes. Many attributes considered in a regulatory analysis can only be expressed in a qualitative way and cannot be quantified. Differences in quality cannot be easily assessed or expressed. While it is possible that some licensees may decide to go out of business and there could be additional disused sources, the NRC is not able to predict how many, if any, companies might decide to go out of business.

Comment A51: One commenter noted that the regulatory analysis and regulatory flexibility analysis did not reflect the actual number of licensees impacted (closer to 2,900) versus the number actually implementing the orders (about 1,400).

Response: The regulatory analysis did reflect the 2,950 licensees that would be impacted by the proposed rule. Section 3.2.3 lays out the assumptions used in the analysis.

The analysis assumed that 1,400 licensees would need to fully implement the security provisions and that another 1,550 licensees would need to conduct some activities. The commenter is correct that the regulatory flexibility analysis only addressed those that fully implemented the provisions.

Comment A52: Two commenters noted that the regulatory analysis does not address how harmonization between the NRC proposed rule and eventual Agreement State regulations will be assured; specifically in regards to the requirements contained in subpart D. The commenter noted that inconsistencies between Agreement State transport security requirements could greatly hinder the ability to transport category 1 and 2 quantities of radioactive materials in commerce and could also serve as barriers to transporting category 1 and 2 quantities of materials through an Agreement State. The commenter noted that it is also unclear if the NRC considered what fees Agreement States may impose to fund the cost of regulating the physical protection of material in transit. The commenter noted that the State of Iowa currently has what Industry considers excessive fees to transport category 1 quantities of materials through the State.

Response: The commenter is correct that harmonization of the requirements between the NRC and the Agreement States is not addressed in the regulatory analysis; the cost for the States to adopt the regulations is addressed. The final rule is a matter of compatibility between the NRC and the Agreement States. The NRC analyzed the final rule in accordance with the procedure established within Part III, "Categorization Process for NRC Program Elements," of Handbook 5.9 to Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs." Most of the provisions in subpart D are Compatibility Category B because there are significant transboundary implications. The Agreement States must adopt Category B program elements in an essentially identical manner. The Agreement States do have 3 years to adopt the regulations. For transportation of category 1 quantities of radioactive material, an

Agreement State licensee will continue to follow the NRC order on transportation until the State adopts the regulation. The order would then be withdrawn and the transportation would occur under the Agreement States' regulations. For category 2 shipments, an Agreement State licensee will follow the Increased Control provisions on transportation until the State adopts the regulations. As for the fees that a State may charge, the NRC does not have any control as this is not a matter of compatibility. A State could choose to charge a fee whether the transport occurred under NRC or State requirements. The fees aspect is beyond the scope of this rulemaking.

Comment A53: One commenter noted that because Agreement States have 3 years to adopt regulations compatible with the final rule, provisions need to be made so licensees with both NRC and Agreement State licenses who modify their programs to comply with the NRC requirements are not cited as noncompliant with the Agreement State license.

Response: A licensee must be in compliance with the regulations for the jurisdiction in which it operates. Part 37 is no different than any other regulation in that regard. A licensee that has implemented the 10 CFR part 37 requirements should be in compliance with the majority of the provisions in the orders. The licensee can have discussions with its Agreement State regulator about adopting the provisions before the State has issued compatible requirements.

Comment A54: One commenter addressed the questions related to small businesses. The commenter indicated that the rule needs to be more risk informed and better recognize the actual risk associated with category 2 sources by providing more flexibility. The commenter indicated that the annual risk from a category 2 radioactive material dispersal device is between 10,000 and 100,000 times less likely than many other sources of premature death that the United States population commonly accepts from smoking, obesity, medical accidents, and auto accidents.

Response: The Commission has determined that category 1 and category 2 quantities of radioactive material warrant additional security measures. In addition, the Radiation Source Protection and Security Task Force found that the category 1 and category 2 quantities warrant enhanced security and protection. See *also* QA5 and QA6 in Section II of this document.

Comment A55: Two commenters provided input on the specific questions related to information collection. On the question of whether the proposed information collection is necessary for the proper performance of the functions of the NRC and the information has practical utility, one commenter agreed with the need for signed consent but questioned the usefulness of the credit history review and the FBI criminal history records check. The commenter agreed that a licensee needs to have an individual's employment and education history, but questioned the need to require the individual to provide the information multiple times if the licensee already has the information in the individual's employment record. The commenter did not address the utility of any other aspects of the information collection. Two commenters did not agree with the burden estimate. One commenter stated that the estimate of the number of individuals who would need to have a background investigation was low; but provided no other estimates. The commenter also indicated that the cost of the background investigation was underestimated, and estimated that a background check would cost from \$60 to \$250 and higher. The commenter noted that it would take licensee personnel 10 hours to gather, submit, and review background information for a normal background check, to more than 20 hours if the individual had resided in multiple State and foreign jurisdictions. The commenter estimated that it would take an individual 2 hours to complete a personal disclosure history, and that this was not included in the analysis. The commenter noted that a licensee would have to develop a compliance program required by the Fair Credit Reporting Act to obtain credit history and arrest records. A second commenter stated that the current labor rate for nonroutine technical support is \$149 per hour. The commenter stated that first-year

implementation would be about 320 hours, or \$47,000 and about \$30,000 a year thereafter. On the question of whether the burden of the information collection could be minimized, one commenter noted that a more prudent and efficient method of checking background and overall status of an employee is to use the federal database “E-verify.” The commenter stated that the NRC could rely on the E-verify check as one of the background check tools for a licensee’s access authorization program. The commenter also requested that guidance be given on FBI criminal background reports to assist a licensee’s understanding of what the information in the report means.

Response: The NRC notes that the FBI criminal history records check is required by the EPAct. The NRC has removed the requirement for a credit history evaluation as part of the background investigation. See response to Comment B67 for further discussion on credit history. There is no requirement for an individual to provide employment and education history multiple times. If the licensee already has that information, it does not need to go back to an individual to obtain the information a second time. Effort for the personal history disclosure was not included because it was viewed as information that would be provided when seeking employment and completing an application for employment. The information on cost and time was factored into the regulatory analysis for the final rule. As for the E-verify system, a licensee may use it as one tool for completing a background investigation, but use of E-verify alone would not meet the requirements for the background investigation. Guidance on the background investigation is available in the implementation guidance.

Comment A56: Commenters requested guidance for various provisions of the rule, noting that the guidance was necessary for both the licensees and the regulatory agency. Commenters were specifically interested in guidance for both the determination on the reviewing official that would be used by the regulator and for the determination for those to be allowed unescorted access to the material that could be used by the reviewing official.

Commenters felt that the lack of criteria or guidance will result in inconsistent approval or denial of the individuals. Commenters noted that compliance determinations are performance based and that the regulatory agency would have no recourse but to deem a licensee's determination appropriate as long as the licensee documented the basis. Several commenters agreed that licensees should be allowed flexibility in conducting the background reviews. One commenter suggested that the NRC should review 49 CFR 73.8 for specific guidance for denying an individual access.

Response: Guidance on the rule is available in the document "Implementation Guidance for 10 CFR part 37 Physical Protection of Byproduct Material Category 1 and Category 2 Quantities of Radioactive Material," which will be published at approximately the same time as this final rule. Guidance on what should be considered in evaluating the results from the background investigation is in the document. The document does not contain a checklist, but provides general guidelines for making the determination on whether to grant an individual unescorted access. The determination basis is performance based; each licensee is responsible for making its own determination. Under the orders, the trustworthiness and reliability official made the determinations of who was granted access and that official is now called the reviewing official. Although there will be additional factors to consider, the decision-making responsibility remains unchanged.

Comment A57: One commenter stated that the sections for the Paperwork Reduction Act Statement and Regulatory Flexibility Certification do not appear to have included pool irradiator and manufacturer/distributor licensees with category 1 quantities of radioactive material in their scope, and the documents will need to be augmented.

Response: Pool irradiator and manufacturer/distributor licensees were included in the analysis conducted for the Paperwork Reduction Act Statement and the Regulatory Flexibility Certification.

B. Access Authorization Program

Comment B1: One commenter stated that § 37.21(a) did not address the requirements for currently approved access authorization programs or the actions that must be taken by the licensee within a specific timeframe. Another commenter noted that it was not clear what licensees that implemented the orders needed to do.

Response: The NRC did not approve access authorization programs under the orders. The NRC approved them in the sense that we inspected and did not cite them if their programs were adequate. All licensees that allow unescorted access to an aggregated category 1 or category 2 quantity of radioactive material must have an access authorization program that meets the requirements of subpart B on the date that the rule is effective in the State in which the licensee conducts its operations. The NRC is providing a 1-year implementation period for the final rule.

Comment B2: One commenter requested clarification as to whether § 37.21(a)(2) is based on possession or authorized possession.

Response: The proposed rule contained several provisions that were based on authorization to possess. These provisions are not contained in the final rule. The NRC has revised the text to make clear that the provisions apply only to those that actually possess the material.

Comment B3: One commenter stated that in § 37.21(b), the term “unreasonable risk” should be defined.

Response: The NRC disagrees with the comment. The NRC acknowledges that implementation is dependent on the judgment of the reviewing official; however, this is a performance-based requirement and provides the licensee with flexibility in the implementation of its program. Although, the NRC has removed the term “unreasonable risk” from the

requirement, the concept remains because the concept is inherent in the definition of trustworthy and reliable.

Comment B4: One commenter stated that § 37.21(c) should be deleted as being redundant to previous sections about who is approved for unescorted access.

Response: The NRC disagrees that § 37.21(c) is redundant. The section establishes the individuals that are subject to the access authorization program.

Comment B5: One commenter stated that § 37.21(c)(1) introduces new criteria for approval (individuals with job duties that require unescorted access) that are not otherwise used in the regulations. The commenter indicated that if it was considered necessary to limit approvals, the section should be modified by inserting the word “only.”

Response: The NRC disagrees with the comment. Section 37.21(c)(1) establishes the individuals who are subject to the access authorization program and, therefore, need to undergo a background investigation and be determined to be trustworthy and reliable.

Comment B6: One commenter asked if the shipper or the carrier was responsible in § 37.21.

Response: The licensee is responsible for assuring that all individuals who have unescorted access to the category 1 or category 2 quantities of radioactive material have undergone a background investigation (or fall under one of the categories for relief) and been determined to be trustworthy and reliable. A commercial carrier is subject to separate State and federal transportation security requirements, and is not a licensee under 10 CFR part 37.

Comment B7: One commenter noted that movement control center personnel were included in the list of individuals who were to be subject to an access control program. The commenter noted that the licensee may not have direct oversight of these centers and the center may be monitored by LLEA or other security or emergency personnel which could make enforcement difficult or impossible as these individuals would likely not be responding to an

emergency. One commenter noted that the vehicle driver and accompanying individual(s) and movement control center personnel are typically employed by the carrier, and the access authorization program should be under the carrier's responsibility. One commenter stated that licensees can't implement the requirement of § 37.21(c)(1)(ii) and (iii) when carriers are used for shipments of category 1 quantities.

Response: The movement control center personnel were included because they have access to SGI-M. The vehicle driver and accompanying personnel were included, in part, because they have access to the SGI-M information. Whether these individuals come under 10 CFR part 37 access authorization program or not, they would still need to be fingerprinted and determined to be trustworthy and reliable under the requirements of 10 CFR part 73. The NRC has revised § 37.21(c) to reflect that those with access to SGI may be placed under 10 CFR part 37 access authorization program or they may be part of a separate program that meets the requirements of 10 CFR part 73. Law enforcement personnel are relieved from the fingerprinting and background check that are required for access to SGI and are relieved from the background investigation required under 10 CFR part 37.

Comment B8: One commenter stated that § 37.21(c)(3) conflicts with the requirements of § 37.21(c)(1)(ii), (iii), (iv), and (v) as none of those personnel require unescorted access to radioactive material.

Response: The NRC disagrees that there is conflict with the requirements. Some of the personnel referenced in § 37.21(c)(1) were part of the access authorization program because they required access to SGI information which also requires a determination of trustworthiness and reliability. However, the requirements for the background investigation required for SGI and unescorted access are not identical, so the NRC has revised § 37.21(c) to reflect that those requiring access to SGI may be included in the access authorization program, but are not

required to be included. The licensee can choose to have a separate program to provide access to SGI information.

Comment B9: One commenter noted that the specific requirement for access to materials included transport of category 1 and category 2 materials and that the requirements should be consistent with 10 CFR part 71 and 49 CFR 171 through 180.

Response: Part 71 does not contain requirements related to access of materials. The referenced DOT regulations do not contain requirements for access to materials, except for a driver who needs a hazardous material certification which includes fingerprints and an FBI criminal history check. Part 37 provides relief from the fingerprinting aspects of the background investigation for individuals that have undergone the DOT check.

Comment B10: Two commenters requested clarification whether an engineer designing the security systems for an irradiator room would need unescorted access. The commenters noted that it would be beneficial if the requirements for individuals with access to sensitive information were clearly described.

Response: Whether to grant unescorted access to an engineer designing the security systems would be up to the licensee. The licensee could arrange for the engineer to be escorted while in the irradiator room or could conduct a background investigation and grant the engineer unescorted access if the licensee believed it was warranted. The requirements for individuals with access to sensitive information are contained in § 37.43(d).

Comment B11: One commenter asked what shipping information requires an access authorization program.

Response: The shipping information related to shipments of category 1 quantities of radioactive material is considered to be SGI-M. Part 73 contains requirements for individuals to undergo a background check and be determined to be trustworthy and reliable before being allowed access to SGI. A licensee can include those individuals needing access to SGI-M in its

access authorization program under 10 CFR part 37 or in a separate program under 10 CFR part 73. If a licensee has an access authorization program that meets the requirements of 10 CFR part 37, the program will also meet the requirements of 10 CFR part 73 for access to SGI-M.

Comment B12: One commenter noted that a licensee's access authorization program expands beyond those permitted to have unescorted access to category 1 or 2 sources and, therefore, the rule text must accurately reflect the need to include such individuals without requiring them to have unescorted access to the sources.

Response: The access authorization program may also apply to those that require access to SGI, such as personnel involved in transportation of category 1 quantities of radioactive material. The rule has been clarified to reflect that those with access to SGI may be part of the access authorization program for materials unless the licensee chooses to have a separate program. Although the comment is not clear, the NRC believes that the commenter was referring to the reviewing official as someone that should not be required to have unescorted access to the sources. The NRC believes that it is important that the reviewing official undergo the same background investigation as those being reviewed and approved by the reviewing official. Therefore, the reviewing official is included in the access authorization program. See *also* the responses to B14 and B15.

Comment B13: One commenter noted that if the radioactive material is in a secured area within a room, then a trustworthiness and reliability determination shouldn't be required for personnel who need access to that room.

Response: Secured area can mean different things. If the material is accessible by breaching a common barrier, then the individuals would need to undergo a background investigation and be determined to be trustworthy and reliable. See the implementation guidance for examples.

Comment B14: In the proposed rule, the NRC specifically invited comment on the issue of fingerprinting the reviewing official. Commenters were specifically requested to provide information on: 1) whether the reviewing official needs to be fingerprinted and have an FBI criminal records check conducted; 2) whether the other aspects of the background investigation are adequate to determine the trustworthiness and reliability of the reviewing official; 3) whether there are other methods that could be used to ensure that the reviewing official is trustworthy and reliable; 4) whether the requirement to fingerprint the reviewing official places too large of a burden on the licensee; and 5) whether the Agreement States have the necessary authority to conduct reviews of the nominated individual's criminal history record. Twenty commenters provided responses to the specific questions on this subject.

Of those that provided responses to the questions on fingerprinting of reviewing officials, the commenters were evenly split on whether the reviewing official should be fingerprinted. Of those that responded no on the fingerprinting, most did not support the concept of a reviewing official at all and stated that the trustworthiness and reliability official established under the Increased Control Orders should remain in place. One of those opposed to the fingerprinting of the reviewing official stated that the official should be approved by the licensee as did a couple of the commenters that indicated support for fingerprinting. One of those supporting fingerprinting was opposed to requiring the individual to have access to radioactive material. The commenter suggested that the NRC table this element until NRC is granted authority to require fingerprinting of the reviewing official. The majority of those responding indicated that the other aspects of the background investigation were adequate to determine the trustworthiness and reliability of the reviewing official, including several commenters that supported the fingerprinting requirement. Several responded that specific guidance and acceptance or rejection criteria must be made available. Several commenters indicated that the reviewing official should meet all of the requirements for unescorted access. Three commenters

stated that other aspects of the background investigation were not adequate but also indicated that they did not support the concept of a reviewing official. Based on its experience with the orders, one commenter stated that the criminal history derived from the FBI should serve as the sole basis. Most of the commenters did not think that the fingerprinting placed too large a burden on the licensee. Of the two commenters that felt that fingerprinting did place too large of a burden on the licensee, one of the commenters did not explain its rationale and the other stated that it was unnecessary for the reviewing official to have access to the material. One commenter indicated that this placed too large a burden on the States. On the question of whether the States have the authority to conduct reviews of the nominated individual's criminal history record, the response was inconclusive, with many commenters noting the authority was undetermined or not clear whether the State had authority. One State indicated that it did have the authority, two States that they probably had the authority, and one State indicated that it did only if specific disqualifying criteria are put in the regulations. Suggestions for other methods that could be used to ensure that the reviewing official is trustworthy and reliable included deferring the decision to licensee management using best business practices; using a background investigation by a professional such as a police investigator, private security clearance contractor, or human resource professional; and use of employment history with the licensee.

In addition to those that addressed the specific questions, 33 commenters addressed this subject. The Conference of Radiation Control Program Directors (CRCPD) conducted a survey of the Agreement States, and 69 percent of those that responded disagreed with the requirement for the regulatory body to approve the reviewing official. However, 62 percent did support the requirement that the reviewing official be fingerprinted. Some commenters noted that there may be some States that may not have the authority to adjudicate fingerprints for approval. CRCPD reported that 69 percent of the responders to its survey indicated that they

do not have the necessary authority to conduct the criminal history reviews without legislative action. Some of the States noted that they have the authority but do not want to conduct fingerprint reviews. One State indicated that it may not have the statutory authority to write a rule to approve the reviewing official, and another noted that it did not have the authority unless there were clear criteria. At least one State noted that it may not be able to completely protect the findings of the criminal history records check from public release. Several commenters expressed concern that the regulatory body (NRC or the Agreement State) would be basing the regulatory approval of the reviewing official on only the results of the fingerprints for a criminal history records check, and the other elements of the background investigation would not be part of the approval process. Commenters noted that neither the regulatory body nor the licensee would have the benefit of the complete information on an individual in order to make an informed determination. Commenters felt that the approval of the reviewing official should remain with the licensee and not the regulatory body because the licensee has more direct personal knowledge and experience with the individual, and the licensee has much more to lose by approving an incompetent reviewing official. Some commenters supported the approval of the reviewing official to be an outside agency such as the NRC as a logical methodology.

Some commenters noted that the regulator should not deny someone based only on the fingerprint results. Several commenters noted that this would put additional resource burden on the regulatory body and that there is no compelling evidence of threat to public health and safety or security or that the current system is not working. Some States expressed concern over the possible liability for approving a reviewing official. Some commenters objected to the need to submit or remove the background check results outside of their offices and send them to the regulatory body. Commenters questioned how the Agreement State will be able to review the fingerprint results when the fingerprints are sent to the NRC. One commenter stated that the rule should specify who evaluates all of the information for the reviewing official, as a

licensee is required to have the information reviewed before submittal of the fingerprints. The proposed rule puts the burden of review of fingerprint results on the regulatory body which will result in a resource burden. Commenters noted that it is unknown what the impact on Agreement States' resources will be to begin approving reviewing officials.

Response: After considering the comments, the NRC has decided to change the approval for the reviewing official. The NRC (or Agreement State) will no longer approve the reviewing official. The final rule adopts a similar process to what was in the Increased Control Orders. Each licensee will be required to provide the name of the reviewing official(s) to the NRC (or Agreement State) and certify, under oath or affirmation, that the reviewing official is trustworthy and reliable. By the licensee certifying under oath and affirmation that the individual is trustworthy and reliable, the NRC believes that it adequately addresses the good faith presumption concern. This certification occurs after the licensee has completed the background investigation for the reviewing official. The determination basis for the reviewing official is subject to inspection. If the individual has undergone fingerprinting and an FBI criminal history records check, a licensee can continue to use the trustworthiness and reliability official or the reviewing official used under the orders.

Comment B15: Many commenters objected to the need to grant the reviewing official access to the radioactive material or SGI. Many licensees have used Human Resources (HR) personnel to conduct the background investigations under the orders as they are the hiring experts for their companies. It was further noted that HR personnel would not have a need for unescorted access to category 1 and category 2 quantities of radioactive material. Licensees noted that this means that HR personnel are either prohibited from doing the access authorization or must be permitted access to the material or SGI. Further, commenters note that permitting HR personnel access creates possible radiation safety/security issues or creates an untenable business model for Increased Controls licensees with no evidence that the current

system under the orders is flawed in any way. Some commenters noted that if it is the intent simply to have this person undergo the same level of scrutiny as those who would be given unescorted access, then the regulation should be amended to state as much. One commenter noted that the orders were quite emphatic that no individual should be granted access unless the individual actually needed access and that requiring the reviewing official to have access appears to reduce security. Several commenters noted that the workaround needed to require fingerprinting was an inappropriate approach and that NRC should complete the process of obtaining from Congress the authority to fingerprint the reviewing official. Commenters noted that the requirement is unduly restrictive on management options and an invasion of the rights to operate a business as they see fit. Commenters also noted that there may be other requirements surrounding unescorted access that could be implemented in the future and may not apply to the reviewing official that could cause hardships for licensees. While a few commenters were opposed to the requirement to have the reviewing official fingerprinted, most of the commenters did not object. One commenter noted that relying on someone to compile the information and have the reviewing official make the final decision also introduces the possibility of the individual compiling the information to act in a malevolent manner. One commenter suggested the following language: "Reviewing officials must meet the necessary requirements to have unescorted access to category 1 or category 2 quantities of radioactive material." Two commenters noted that, if a reviewing official is granted unescorted access as a routine job requirement, the individual receive and satisfactorily complete radiation safety training required by the licensee.

Response: The NRC believes that it is essential that the individual that approves others for unescorted access to radioactive material undergo the same background investigation before approving individuals for unescorted access. The NRC needs to have confidence in the integrity of the reviewing official. The reviewing official is one of the layers for defense-in-depth

of the security program. If the reviewing official exercises the permission for unescorted access to the material, the individual would need to undergo any required training, including any safety training, before actually having unescorted access. There are often individuals at facilities that have unescorted access permission but seldom exercise the permission. The language has been revised slightly to note that the reviewing official must be permitted unescorted access, and the phrase “as part of their job duties” has been removed. However, these individuals are not being required to physically access the material. The changes were made to better match the language in the AEA. The compatibility of § 37.23(b)(3) was changed to Category C to allow States to be more restrictive as it relates to access to the material. Some States may have authority to require fingerprinting by use of other mechanisms than the AEA.

Comment B16: Several commenters suggested allowing a reviewing official approve others to be a reviewing official as this would provide the licensee with more flexibility in assigning individual duties. Commenters noted that the restriction seemed arbitrary. One of the commenters noted that there was no reason why a reviewing official couldn’t approve someone as there is no difference in the determination for a reviewing official and someone for unescorted access. Commenters noted that if this requirement was an attempt to maintain a list of reviewing officials it could be accomplished in a different manner.

Response: The NRC does not believe that the reviewing official should be allowed to approve another individual to be a reviewing official. While the background investigation is identical, the responsibility for the reviewing official is greater. However, under the final rule, a licensee is able to name its own reviewing officials. The existing reviewing official could be involved in the background investigation evaluation. *See also* response to comment B14.

Comment B17: One commenter suggested adding the word “nominated” before reviewing official in § 37.23(b)(5) because the person is not a reviewing official until approved by the NRC.

Response: The requirement for nominating a reviewing official has changed in the final rule. A licensee now names the reviewing official and certifies under oath and affirmation, to the NRC, that the reviewing official is trustworthy and reliable. See *also* response to Comment B14.

Comment B18: Two commenters objected to the wording in § 37.23(b)(4) and (5) that implies that the reviewing official permits unescorted access. The commenters agreed that the reviewing official should be the individual who makes the trustworthiness and reliability determinations but asserted that the reviewing official should not be the individual who gives permission for unescorted access. The commenters noted that after a positive determination is made, the actual determinations for unescorted access should be controlled by someone else such as the RSO. The commenters suggested that the two sections be revised to remove the permit unescorted access language. The commenters also suggested that § 37.23(e)(2) be modified by changing the word “permit” to “authorize.”

Response: The NRC agrees with the comment. The NRC has revised the language in § 37.23(b)(1) (formerly paragraph (b)(4)) to read: “Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 quantities of radioactive materials possessed by the licensee.” The NRC has removed the provision in § 37.23(b)(5) as it was duplicative of paragraph (b)(4) (now paragraph (b)(1)). The NRC has not revised the language in § 37.23(e)(2) because permit is the term used in the AEA.

Comment B19: One commenter noted that § 37.23(b)(5) is redundant as § 37.23(b)(4) conveys the same requirement.

Response: The NRC agrees with the comment and has removed § 37.23(b)(5) from the rule.

Comment B20: Two commenters recommended that the reviewing official be allowed to authorize access to SGI.

Response: The reviewing official may approve individuals for access to SGI. Part 73 requires that a reviewing official conduct the background check review, but does not specify who that individual is or specify any qualifications for the position. A licensee can choose to use the same individual for both the SGI access under 10 CFR part 73 and unescorted access under 10 CFR part 37.

Comment B21: One commenter noted that licensees were allowed fingerprint exemptions based on submittal to other governmental programs, such as those to access Select Agents or government clearances. The commenter noted that these programs allow for licensee personnel to be trained to take the fingerprints but that the rule does not allow the reviewing official to be fingerprinted by the licensee personnel which will result in additional cost to travel to an authorized agency and fees to have the authorized agency take fingerprints. Two commenters noted that the requirement for the fingerprints of the reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a State to take fingerprints and that this seemed arbitrarily restrictive and was not a similar requirement for other individuals. The commenters also noted that 10 CFR part 73 did not contain a similar provision.

Response: The NRC disagrees with the comment. Because the reviewing official has extra responsibility in the access authorization program and will be making the determinations to allow access, the NRC believes that it is necessary for the reviewing official's fingerprints to be taken by an entity that will verify that the identification matches the person being fingerprinted. This ensures the identification of the individual submitting the fingerprints. Without this requirement the reviewing official could submit the fingerprints of another individual that is known not to have a criminal history or known terrorist ties.

Comment B22: Two commenters asked how a licensee will know if an appointed reviewing official has been approved. Commenters also asked how long the review would take. One commenter asked the NRC to describe the controls that will be in place to protect the personal information provided to the NRC on behalf of the prospective reviewing official. One commenter noted that the regulation does not indicate what the NRC will do with the fingerprints and how long the NRC retains personal information and the FBI data. The commenter wanted to know how long the FBI and NRC retain the fingerprints and personal information and who they can or will share that information with. Commenters were concerned how the transition period, before a reviewing official is approved, could impact a program. Some commenters questioned the length of time for NRC review.

Response: The final rule does not contain the provision for the NRC (or Agreement State) to approve the reviewing official. The only information provided to the NRC is the name of the individual and the fingerprints. The NRC typically does not retain the fingerprints and FBI results beyond 30 days. Either the cards are destroyed or the electronic file is deleted in accordance with Federal guidelines.

Comment B23: A few commenters indicated that the T&R officials under the orders would be grandfathered and become reviewing officials under the rule. Another commenter wanted to know what is meant by the statement that the already deemed reviewing official may continue to act in that capacity for an expanded set of persons, *i.e.*, what is classified as an expanded set of persons. One commenter recommended revising the rule to relieve reviewing officials who already have fingerprints on file from submitting fingerprints again.

Response: The NRC disagrees with the comment in part. The commenters have misunderstood the grandfather clause. The T&R officials would only be grandfathered if they had been fingerprinted under the orders for either unescorted access to the radioactive material or to SGI. If the T&R official has not previously undergone the fingerprinting and criminal history

records check, he or she would need to complete the fingerprinting before making any additional determinations for access to material. The expanded set simply referred to those individuals, including new employees, who might newly require a background investigation.

Comment B24: Several commenters noted that both the NRC-Agreement State working group and the NRC staff steering committee developing the fingerprinting orders discussed at great length whether to require fingerprinting and background checks for T&R officials. Under the orders, T&R officials were not subject to the requirements. Commenters noted that they were not aware of any subsequent developments that would change the situation and now warrant requiring fingerprinting and background checks for reviewing officials now required under part 37. The commenters objected to what they called the appearance of an attempt to incorporate in rule a concept that did not have consensus and was not incorporated after going through the previous security orders working group process. They are opposed to requiring the reviewing official to undergo fingerprinting and a background check because in their opinion the requirements provide no plausible added benefit to the existing structure under the orders.

Response: The 10 CFR part 37 working group considered the order requirements, lessons learned, implementation issues, inspection issues, recommendations from other reviews, as well as the comments on the preliminary rule language. The 10 CFR part 37 working group determined that there was a potential gap with the individual approving others for access without undergoing the same background investigation. Requiring the reviewing official to undergo a background investigation addresses the good faith presumption. *See also* the response to question B5 in Section II.

Comment B25: One commenter objected to the timing of the submittal of the fingerprints for the reviewing official, noting that the approval process would be timelier if the fingerprints were processed at the same time the licensee is conducting the other elements of the background investigation.

Response: The requirement for NRC approval of the reviewing official has been removed from the rule. The rule requires the licensee to certify that the reviewing official is trustworthy and reliable and to then provide the name of that individual designated as the reviewing official to the NRC. See *also* response to Comment B14.

Comment B26: One commenter noted that many of the items in subparts A through D do not reference SGI, but the requirements in this rule apply, and the inconsistencies must be corrected.

Response: The NRC disagrees with the comment. Requirements for protection of SGI are contained in 10 CFR part 73, not 10 CFR part 37. Part 37 contains appropriate references to the requirements for SGI that are contained in §§ 73.21 and 73.23.

Comment B27: One commenter requested that a section for a master materials licensee to approve reviewing officials at the permittee level facilities be added.

Response: The licensee is now responsible for approving the reviewing official. See *also* the response to comment B14.

Comment B28: One commenter noted that it was not clear how the licensee would comply with the requirement in § 37.25(a)(1) to complete fingerprinting and an FBI identification and criminal history records check for reviewing officials before granting them unescorted access inasmuch as NRC (or the Agreement State) would have the responsibility of reviewing the FBI identification and criminal history records check information, in lieu of the licensee doing so.

Response: The NRC (or the Agreement State) is no longer involved in the approval of the reviewing official. See *also* response to comment B14.

Comment B29: One commenter raised the issue of how individuals denied approval for reviewing official duties will be tracked to avoid going to another jurisdiction for approval.

Response: The final rule does not require the NRC to approve the reviewing official. The NRC does not plan a tracking system to track reviewing officials.

Comment B30: Two commenters requested information on what happens if the company appointed reviewing official is denied, particularly in smaller companies where the owner, manager, or RSO may be the appointed reviewing official and how such a denial might affect the operation of the company.

Response: The licensee is now responsible for approval of the reviewing official. The NRC is not involved in the decision. *See also* response to comment B14.

Comment B31: One commenter suggested changing the characteristics derived from the background Investigation. The commenter stated that for the reviewing official to state that an individual is “trustworthy and reliable” implies more of an intimate knowledge of the characteristics of a person than would be gained from simply running the required checks. The commenter suggested that defining an individual as “low-risk” may be more appropriate.

Response: The NRC disagrees with the comment to change the rule. The NRC recognizes that determining that an individual is considered to be trustworthy and reliable is subjective, and not a guarantee that the individual won’t ever commit, or conspire to assist others in committing, a malevolent act. The trustworthy and reliable concept is in the orders and is in other locations in the regulations.

Comment B32: One commenter suggested that, for those individuals who are relieved from the fingerprinting, identification, and other elements under § 37.29, the licensee should be exempt from the requirement in § 37.23(c) to provide informed consent and obtain a signed consent form. The commenter noted that it conducts a background investigation on all badge-holders (employees, fellows, contractors, etc), the vast majority of whom have no intent of applying for purposes of unescorted access and that there is no opportunity, or it is a misplaced opportunity, to request an individual's signed consent under this regulation at the

point of background investigation initiation. The commenter stated that there should also be an exemption for this situation as there is no need to repeat the background investigation just because an Individual later determines a need to request unescorted access. Other commenters questioned why an individual that has already been subject to fingerprinting now needs to provide consent.

Response: Section 37.23(c) states that the licensee does not need to obtain signed consent from those individuals who have undergone a background investigation under the orders or 10 CFR part 73. A signed consent is not necessary until the reinvestigation occurs. A licensee would not need to obtain a signed consent from an individual subject to § 37.29, unless the licensee conducted one or more of the elements of the background investigation.

Comment B33: One commenter questioned whether the NRC would develop a standard consent form and background questionnaire form so that everyone asks the same questions and evaluates on the same basis.

Response: The NRC has included a consent form in the guidance that could be used by licensees. A standard background questionnaire was not included as this would be similar to the information included in applications for employment. Information would include job history, education history, and a list of references.

Comment B34: One commenter stated that § 37.23(e) was improperly named as no basis for making a determination was included, only a requirement for licensees to develop, implement, and maintain written procedures with the determination basis that they deem appropriate.

Response: The NRC disagrees with the comment. The section contains the requirement for the reviewing official to make determinations on authorizing unescorted access, and the NRC believes that it is appropriately named. The licensee is provided flexibility in the criteria that it uses to make a determination.

Comment B35: One commenter stated that NRC should provide the specific and detailed adjudication criteria that will be used to approve the reviewing official.

Response: The guidance document contains the general criteria that the NRC used in approving reviewing officials under the orders. The specific criteria to be used are up to each licensee.

Comment B36: One commenter stated that licensees are not in a position and do not have the knowledge and skill to ensure that personnel are trustworthy and reliable and that all that licensees can be expected to do is to follow the NRC rule that was presumably written to provide licensees with methods to screen personnel.

Response: Licensees are required to follow the requirements in 10 CFR part 37 to acquire information about personnel and to make their own judgments of the trustworthiness and reliability of their employees. These determinations do not require specialized knowledge or skill and are similar to the determinations that licensees make in hiring decisions.

Comment B37: One commenter requested that § 37.23(e)(1) and (2) be revised to remove the requirement to review all of the background investigation information required in making a determination on trustworthiness and reliability. The commenter felt that some of the information would be impossible to obtain and therefore, if you are required to review all information, a licensee could never approve some personnel. The commenter suggested that the language be changed to “collected background investigation information.” Several commenters suggested removing the term “disqualifying” from the paragraph as the NRC has not provided a list of disqualifying factors.

Response: The NRC agrees with the comment and has revised the rule to specify that the evaluation is of the information collected to meet the requirements. The NRC has also removed the term “disqualifying” from § 37.23(e)(2).

Comment B38: Two commenters noted that in § 37.23(e)(3) “reasonable assurance” is not defined. One of the commenters felt that the lack of clarity in this requirement and in what documentation should consist of will result in disputes with NRC inspection findings. One commenter objected to the need to document the determination basis for granting someone unescorted access. The commenter felt that only the reasons for denial should be documented.

Response: The NRC does not believe that “reasonable assurance” needs to be defined in the regulations. The determination basis is a performance-based requirement, and licensees are provided flexibility to develop criteria that best meet their needs. The NRC believes that documentation of the determination basis is essential. The documentation does not need to be extensive. It can consist only of an indication that no negative information was found during the investigation or an explanation of why negative information did not disqualify the individual. Without documentation an inspector could not be assured that the individual had actually undergone the required background investigation. Documentation of the basis is also beneficial to the licensee if it needs to reevaluate whether an individual should continue to have unescorted access.

Comment B39: Several commenters objected to the requirement in § 37.23(e)(3) to immediately remove the person from the approved list once he or she no longer require access. One commenter noted that “immediately” is not defined and that it is not realistic for routine terminations such as student graduations and deaths. The commenter indicated that the only justification for immediate removal would be demonstrated unreliability that would result in withdrawal of the person’s trustworthiness and reliability status. The other commenter stated that immediate removal was not warranted but should be done in a timely manner. The commenter suggested replacing “immediately” with “as soon as practical.” Another commenter suggested removal from the list in a timely manner not to exceed 30 days after the determination.

Response: The NRC agrees with the comment in part. An immediate removal from the list is probably not necessary. However, prompt actions do need to be taken to prevent access, such as deactivating his or her access code. The NRC has revised the language to reflect that the action should occur as soon as possible but no later than 7 working days. The NRC believes that it is important to maintain a current list of those individuals that are allowed unrestricted access to the material.

Comment B40: One commenter questioned whether § 37.23(e)(3) means that the licensee must document its basis for approval of the trustworthiness and reliability determination as a written policy. The commenter noted that an alternate interpretation could be that the licensee must document a rationale for each individual's trustworthiness and reliability approval, as opposed to a generic basis for approval for all applicants.

Response: The licensee must document the rationale for each individual's trustworthiness and reliability determination. The documentation does not need to be extensive. The NRC notes that the orders also required the licensee to document the basis for concluding that there is reasonable assurance that an individual granted unescorted access is trustworthy and reliable.

Comment B41: One commenter stated that the access authorization program requirements were overly prescriptive, particularly the number of required procedures and amount of associated documentation. The commenter noted that the licensee should be allowed to determine the level of detail of its program as appropriate depending on the size and complexity of the program.

Response: The NRC agrees with the comment, in part, and has made some changes to the access authorization program. Section 37.23(f) has been revised to remove some of the specificity in the types of required procedures.

Comment B42: Two commenters noted that the requirement to have procedures to ensure that individuals who have been denied unescorted access authorization are not allowed access was redundant. The commenters stated that a person denied unescorted access would not be provided with a key or codes to access the sources, and a procedure is not needed.

Response: The NRC believes that procedures are necessary to implement the access authorization program. Not all licensees use keys or codes to control access to the material.

Comment B43: Two commenters stated that for licensees subject to 10 CFR part 73 with additional radioactive materials not covered by the 10 CFR part 73 security plan, the procedures used for 10 CFR part 73 background investigations and updating of background investigations, etc., should be considered adequate to meet the intent of 10 CFR part 37. One of the commenters suggested adding a new paragraph (5) to § 37.23(f) to read as follows: “Procedures and policies meeting the requirements of the security plans required by part 73 meet the requirements of this subpart B of this chapter.”

Response: The NRC agrees that a licensee does not need to maintain two sets of procedures; however, a provision is not needed in the regulations. As long as 10 CFR part 73 procedure addresses the content of the required procedures under 10 CFR part 37, additional procedures are not necessary.

Comment B44: One commenter suggested that NRC develop a generic set of procedures for the conduct of background investigations as guidance for licensees.

Response: The NRC has not included generic procedures for conducting a background investigation. Implementation of background investigation requirements will vary with the circumstances of individual licensees. Guidance is available on the various elements.

Comment B45: One commenter stated that in § 37.23(g) at least 10 days should be allowed for an individual to correct, complete, or explain other components of the background investigation.

Response: The NRC has not specified a timeframe in order to allow licensees flexibility to choose a timeframe that they believe is appropriate for their program. The NRC has provided a 10-day timeframe to challenge the FBI criminal history records, and 10 days would be an appropriate timeframe for allowing a challenge of other aspects of the background investigation results. The licensee may choose the timeframe that works best for it.

Comment B46: One commenter noted that since § 37.23(g)(2) specifies that the licensee can't act on challenged information until the FBI goes through their due process, the FBI needs to be on board. The commenter suggested adding a requirement to allow the licensee to make a final determination if nothing is heard from the FBI within 30 days.

Response: The rule contains procedures for an individual to correct background check information that are identical to the procedures in § 73.57(e)(2). The NRC disagrees that a 30-day cut-off period is needed because such a provision would circumvent an individual's right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Further, the 30-day cut-off period may be unreasonably short. The FBI has indicated that once it receives a formal challenge to an individual's record, a recheck is completed within approximately 3-4 weeks (52 FR 6310; March 2, 1987). Given the rule's 10-day window for an individual to initiate a challenge, the timeframe for resolution of challenges could potentially be greater than 30 days. Accordingly, the NRC declines to impose a 30-day time limit for challenges to an individual's background check information.

Comment B47: One commenter stated that § 37.23(h)(2) requires the licensee to retain a list of persons approved for unescorted access for 5 years after the list is superseded and noted that the word "list" implies a written document. The commenter asked if the "list" may include database records that contain unescorted access approval and removal dates and thus would allow discarding printed copies that are no longer useful. The commenter noted that other NRC regulations (*e.g.*, §§ 20.2110 and 37.51) allow records to "be stored in electronic

media with the capability for producing legible, accurate, and complete records during the required retention period.” The commenter recommended changing the wording to add similar wording as in other NRC regulations making it clear that the “lists” do not need to be printed copies.

Response: Section 37.101 already allows records to be maintained in electronic media. The language is similar to that provided in § 20.2110 and applies to all records that are required by 10 CFR part 37.

Comment B48: Two commenters objected to the requirement in § 37.23(h)(3) to maintain a list of individuals not approved for access. Two commenters objected to the need to maintain every change to the list for 5 years. One commenter felt that it would seem reasonable to ask that a list of all persons currently granted unescorted access be maintained (+ a month) and that a list of all persons denied or removed from the unescorted access list be maintained (\pm a month). Another commenter noted that maintaining a list has no value as a licensee may develop a badge system that indicates a person’s level of access. Another commenter noted that there was no value in keeping a list since the determination basis has to be documented.

Response: The NRC agrees, in part, and disagrees, in part, with the comment. The NRC agrees that it is not necessary to maintain a list of those individuals not approved for access and has removed the provision. The fact that someone is not included on the access list means that they should not be granted unescorted access to the material, and a second list is not needed. There is currently no mechanism in place to share information among licensees, so there is no benefit in maintaining a list of those not approved for access. The NRC disagrees with the comment to remove the requirement to maintain every change to the list; however, the NRC has changed the retention time to 3 years. The superseded lists are necessary for inspections. If an inspector discovers something during an inspection, the superseded list could be reviewed to determine who had unescorted access during a given time period.

Comment B49: One commenter requested clarification whether the notification required by § 37.27(a)(2) is different from the informed consent required by § 37.23(c)(1).

Response: The informed consent under § 37.23(c)(1) is consent to conduct the background investigation. The notification required by § 37.27(a)(2) is specifically for the FBI criminal history records check. The licensee may develop one consent form that covers both aspects.

Comment B50: In the proposed rule, the NRC specifically invited comment on the appropriate elements for a background investigation. Commenters were requested to provide information on: 1) whether a local criminal history review is necessary in light of the requirement for an FBI criminal history records check; 2) whether a credit history check provides valuable information for the determination of trustworthiness and reliability; 3) whether the Agreement States have the authority to require a credit history check as part of the background investigation; 4) the appropriate elements of a background investigation and why any suggested elements are appropriate; 5) whether the elements of the background investigation are too subjective to be effective; and 6) how much time a licensee typically spends conducting a background investigation for an individual. Twenty-seven commenters provided responses to the specific questions on this subject.

Of those who provided responses to the questions on the background investigation elements, no one supported inclusion of the local criminal history check as part of the background investigation elements and only one commenter indicated that the credit history check added any value. Most commenters indicated that the FBI criminal history records check was sufficient, and that requiring a local criminal history check was redundant and overly burdensome. Many commenters noted that conducting a local criminal history check would be very difficult for foreign nationals and those who have moved frequently. Most commenters stated that the credit history evaluation was not useful, and that poor credit and

untrustworthiness do not go hand-in-hand. Commenters were also concerned that there were no clear guidelines on what credit score would be cause for concern. Many commenters expressed concern over the accuracy of information in credit histories. Some commenters questioned whether requiring a credit history check was legal in some States, noting that the requirement was an invasion of privacy. One commenter suggested Social Security number (SSN) validation instead of the credit history check.

In response to the question of whether the Agreement States have the legal authority to require a credit history check, most commenters indicated that they did not know. One State responded that recent legislation prohibits discrimination based on credit history, but did note that the law provides for exceptions. One State indicated that it did have authority, and another noted it did if specific criteria were provided.

The majority of commenters indicated that the current background investigation elements from the orders were adequate. One commenter suggested as appropriate elements: verification of legal citizenship, personal references, former employers, education, fingerprinting and FBI criminal background investigation, and personal knowledge. Another commenter noted that the elements should be employment history, education history, reference check, and FBI history check. Two commenters noted that the background investigation should be limited to the fingerprint-based criminal history check, and that an adverse criminal history could be mitigated by satisfactory employment history with the licensee. One commenter suggested a two-person rule for truly significant sources instead of a background check. One commenter indicated that the area that needed review is the background investigation for foreign nationals and students because the required information is troublesome to obtain.

Most of the commenters felt that the elements of the background investigation were too subjective, and that guidance or criteria were needed so that the elements could be consistently applied across the country with minimum second guessing by auditors and inspectors. Other

commenters stated that while the elements were subjective, this did not mean that they were ineffective. Commenters stated that there is a good mixture of subjectivity and objectivity for the reviewing official to use in making a determination of a person's trustworthiness and reliability. One commenter noted that some subjectivity is necessary to evaluate the situation and the individual, as strict adherence to guidelines could lead to rejection and a serious impact on an applicant's career.

NRC also requested information on how much time a licensee spends conducting a background investigation. Responses varied from a few hours to months; the longer times typically included wait times and not actual effort.

One commenter suggested centralization of the background investigation process, suggesting that the security clearance process performed by the Defense Industrial Clearance Security Offices for various Federal agencies could be tailored to meet the 10 CFR part 37 requirements. The commenter indicated that this could be more efficient than requiring each licensee to develop a process.

In addition to those who provided responses to the specific questions, 70 commenters addressed this topic. Several commenters felt that the current background investigation elements were sufficient and questioned the value of the proposed additional elements (credit history evaluation, verification of true identity, military history verification, and criminal history review from local criminal justice resources). Some commenters felt that specific justifiable evidence that current trustworthiness and reliability programs aren't working is needed to justify any new requirements, and that a cost-benefit analysis should be used to justify inclusion of any new elements. Several commenters noted that the cost of obtaining the necessary information may be burdensome in time and money, and that the requirements are overly prescriptive. Commenters expressed concern that the required checks could result in lost jobs if individuals did not meet the standards set forth by the licensee. One commenter

noted that a licensee would probably investigate the individual before hiring, which would result in multiple expenditures for one eventual employee. One commenter noted that the background investigation could deter some talented and knowledgeable professionals from applying due to the potential invasion of privacy. One commenter noted that the NRC needs to find the fine line between cautious and correct and overly cautious and burdensome.

Some commenters felt that the FBI criminal history checks and work history are sufficient. Two commenters felt that the background investigation should only require a fingerprint-based criminal history check and that adverse criminal history may be mitigated by the employment history of an employee with more than 3 years employment with the licensee. Commenters noted that employment history is far more accurate for determining trustworthiness and reliability than any other check proposed. One commenter suggested allowing licensees to use a graded approach taking into consideration multiple variables, such as: whether the activity is category 1 or category 2; the desirability of the source to an adversary; the physical security present; how quickly the radioactivity could be removed from the device and readily dispersed or used to cause serious harm; the mobility of the source or device, and the frequency of physical inspection/observation by more than one individual. One commenter suggested revising the requirement so that the licensee could use either employment history evaluation, verification of employment, or military history evaluation. At least one commenter noted that the insider threat would be best controlled with monitoring and detection.

Sixty commenters objected to the inclusion of the credit history element in the background investigation. Commenters noted that, in the current economic environment, a credit history evaluation could reflect an inaccurate and erroneous assessment of a person's trustworthiness and reliability and could result in some skilled individuals being removed from employment consideration. Commenters felt that the credit history check was an unnecessary invasion of privacy, and that most individuals would choose not to pursue unescorted access if

faced with a credit history check. One commenter noted that when implementing the orders it had initiated a credit history evaluation that created a significant uproar and resulted in several researchers withdrawing their irradiator access privileges. The commenter noted that this created an atmosphere of distrust. Commenters felt that the information was not relevant when attempting to determine trustworthiness and reliability and was unjustified and not a valid gauge of trustworthiness and reliability. Commenters noted that having a bad credit history did not make the individual untrustworthy and that a good credit history did not define an individual as trustworthy and reliable. Some commenters requested that the NRC provide some study or peer reviewed document that demonstrates that persons with poor credit may be more easily coerced into helping terrorists. Some commenters stated that the requirement could potentially be viewed as discriminatory by workers. One commenter questioned how to deal with identity theft.

Commenters noted the difficulty of obtaining a credit history of individuals who have lived outside the United States, such as foreign nationals. Commenters noted that in some cases it was impossible to obtain the information. Commenters noted that many countries do not have a combined credit history reporting agency. One commenter expressed concern that individuals who have established a credit history in the United States and whose credit history is poor will be at a disadvantage over individuals with a similar but undocumentable credit history in another country, as an employer may choose to allow access to the foreign national based on incomplete information and deny access to a United States citizen based on more extensive but unfavorable information.

One commenter noted that Title 11 of the United States Code, Section 525, makes it illegal to discriminate against employees or job applicants solely because of filing for bankruptcy. Another commenter noted that the Equal Employment Opportunity Commission has been cracking down on efforts to disqualify potential hires with bad credit history as the

practice can be discriminatory. Several commenters noted that some States have laws that prohibit employers from discriminating against employees on the basis of credit history and prevent employers from inquiring about credit history. One commenter stated that if Congress, in consultation with the NRC, had deemed credit history checks significantly useful to provide for the common defense, the checks would have been included within the most recent amendments in section 149 of the AEA. Another commenter noted that Congress has considered passing an act to make it unlawful to base adverse employment decisions on consumer credit reports.

In a CRCPD survey of Agreement States, 70 percent of those responding indicated that they did not have the authority to require a credit history check as part of a background investigation. Some Agreement States indicated that they were not sure if they had the authority to require a credit history check. One State indicated that (assuming it has authority) its administrative procedures would require specific criteria for pass/fail. One commenter noted that there are State laws that prohibit “discrimination” against employees due to credit history and asked how this would affect the credit history check requirement. The commenter noted that a Google search indicated that States that have and/or are considering such laws include: Connecticut, Wisconsin, Hawaii, Illinois, Missouri, New York, Oregon, Washington, and Texas.

One commenter felt that much of the information obtained from a credit history report would already be included in the personal history disclosure. Two commenters stated that for category 2 sources it should be up to the reviewing official to decide if they have enough information to grant unescorted access to a category 2 source without the need for a credit history check. One commenter noted that individuals relieved from the background investigation elements were just as likely to have negative credit history but will not be subject to the same scrutiny. One commenter recommended defining “full credit history,” as a licensee can’t comply with open-ended requirements. Two commenters noted that this concept had

been considered in the working group for the orders but was rejected, and, therefore, should not have been included in the proposed rule.

Several commenters opposed the inclusion of the criminal history check in the background investigation. They questioned why a criminal history check from local sources was necessary if a national check through the FBI was conducted. One commenter stated that the local check would be an added benefit if the FBI check was somehow inadequate. Commenters stated that the information would be difficult to obtain in many locales and would be an increased burden to both the licensee and local law enforcement without a corresponding benefit. Commenters also noted that the information would be impossible to obtain for foreign nationals, and that a provision must be provided that allows less-than-absolute compliance. One commenter noted that licensees in rural areas may have limited access to local resources, and that some local resources may have limited capabilities to respond to such requests. Commenters asked how to determine the appropriate local law enforcement agency and what constituted local.

Several commenters objected to the inclusion of a character and reputation element in the background investigation. Commenters felt that the determination would be very subjective, added little value, and unnecessarily added to the licensee's burden. Commenters noted that an adverse judgment about an employee's character and reputation could be perceived as discriminatory. One commenter suggested removing the term "trustworthy and reliable" from the character and reputation element and thereby removing the connotation that a personal reference can attest to the present state of an individual's trustworthiness or reliability. The commenter noted that including a character and reputation check would require references to be knowledgeable about that definition, and very few references can attest to the present status of an individual, as required by the words "continues to be." Some commenters expressed concern over possible invasion of privacy. One commenter recommended requiring

a minimum of three references. One commenter noted that, for a reference to provide a worthwhile evaluation of the applicant, a minimum time frame for contact with the individual should be established in the rule. The commenter also cautioned that the reference should not be from someone, such as a supervisor, who may benefit from the applicant's unescorted access.

Several commenters objected to the requirement to obtain independent information to corroborate the information provided by the individual. Commenters stated that the provision was vague and unreasonable, and they did not understand how it could be accomplished. Commenters stated that it was unreasonable to expect licensees to track down independent information, as they are not investigative agencies. Commenters noted that many entities cannot or will not provide background information, and licensees do not have the resources to obtain information elsewhere. Commenters noted that the cost would be prohibitive in many cases. One commenter recommended removing the phrase "to the extent possible" because it made the section meaningless. One commenter asked what he or she should do if it is not practicable to confirm information. Another commenter stated that the documentation would be excessive and time consuming. One commenter suggested requiring independent information only in situations where the accuracy or completeness of information provided by the applicant is in doubt, or where the licensee can't confidently make an evaluation based on an analysis of all of the gathered information. One commenter suggested changing the phrase "to the extent possible" to "to the extent practicable." Three commenters objected to the need to obtain information from an alternate source when a previous employer or other entity does not respond. One commenter noted that where a company has gone out of business, it would be impossible to obtain confirmation that the individual worked at the company. The commenters felt that it was unclear how a licensee could obtain this information in some cases. One

commenter noted that it doesn't have the resources to confirm an applicant's information independently, particularly if the person's family is excluded.

Commenters noted that obtaining the information for some groups of people, (e.g., foreign nationals, research students, and citizens who have resided outside the United States for long periods), is difficult or impossible. Some commenters noted that licensees with a high turnover, such as universities and research facilities, would incur substantial cost and would have difficulty implementing the provisions. One commenter provided some cost information, noting that the current cost is \$131 per applicant, excluding the \$100 average cost for processing new employees. The costs included \$25 for fingerprinting, \$26 for fingerprint processing through the NRC and FBI, and \$80 for a WorldScan. The commenter noted that adding the credit history and military history would increase the cost per approved person to \$155 for United States records, and even if the credit history and military records were obtainable and reliable, getting this information on foreign applicants would be prohibitively expensive. Two commenters noted that a foreign credit history check costs \$170, and one commenter noted that that a credit check would cost \$1,000 per individual for a foreign national, and another said that the cost of military verification was \$80 per person. Another commenter noted that the current cost of conducting background investigations was \$125, and adding a credit check and military records check would increase this to \$400 per person (assuming that half the individuals require foreign credit checks). One commenter noted that it would take 2 to 3 person-days to perform the different checks.

Several commenters recommended that NRC consider using the same background check process used by the Centers for Disease Control (CDC) for select agents because centralized NRC coordination would probably result in more consistent evaluations at reduced cost. Other commenters suggested that the NRC authorize unescorted access using a method

similar to the Transportation Safety Administration's TWIC program. They noted that the CDC and the U.S. Department of Agriculture programs for select agents and the DOT system for issuing hazardous material certifications for Commercial Driver's Licenses, all have the applicable Federal government agency perform the reviews and grant the approvals. The commenters stated that this approach would provide consistency in the conduct of the reviews and would best assure that all needed information is collected and reviewed by well-trained individuals. One commenter suggested that the NRC review the visa process to see if any of the requirements could be replaced with a verification of visa, since foreign nationals must go through a Homeland Security review to get a visa. One commenter noted that it has reviewed 3,182 persons since the Fingerprint Order was implemented and has determined that 38 could not be judged trustworthy and reliable based only on the FBI criminal history report and not because of any other background investigation elements. The commenter noted that more than 90% of the persons it judged to be trustworthy and reliable were also judged trustworthy and reliable by the U.S. Bureau of Alcohol, Tobacco, Firearms, and Explosives (BATFE), and that this experience appears to validate why all other federal agencies that perform similar checks do so solely on the basis of the FBI criminal history.

One commenter noted that his or her industry is subject to three different Federal background check programs (BATFE, DOT, and NRC), and recommended that the agencies come up with one background check that would satisfy all three.

Response: The NRC has determined that the appropriate elements of the background investigation include: fingerprinting and an FBI criminal history records check, verification of identity, employment history verification, education verification, and a character and reputation determination. Many of these items are part of routine employment checks that an individual may go through before being hired by a company. The NRC has removed military history verification from the elements as it is considered part of the employment history and does not

need to be a separate element. The NRC has also removed the provision to conduct a local criminal history check as part of the background investigation. The NRC determined that while the local criminal history check would provide some beneficial information, the burden of obtaining the information is not justified by the limited benefit. The NRC recognizes that conducting the background investigation for some individuals, such as foreign nationals, may be difficult. If there was no education or military service in the 7-year period preceding the need for unescorted access to the material, the investigation would not need to include these items.

After careful deliberation and consideration of all the comments received on including credit history as a background investigation element, the NRC has decided not to include credit history as a required element for the background investigation or reinvestigation. The credit history can provide information that is useful in making a determination that an individual is trustworthy and reliable. Credit history can add an extra layer of defense in mitigating the insider threat and can provide some information that is not easily available from other sources. Credit history was never intended to be the determining factor for trustworthiness and reliability but simply one more piece of information in making that determination. However, as many of the commenters pointed out, there are issues with the accuracy of credit reports, and a poor credit history is not necessarily an indicator that an individual is not trustworthy or reliable, particularly in these tough economic times. Although NRC disagrees, some of the commenters indicated that there is the potential that some Agreement States might not be able to implement the provision due to State laws. These things could result in uneven implementation of the provision across the country. As pointed out by the commenters, it is harder and more expensive to obtain a credit history for those that have resided in other countries for long periods of time. This could lead to an imbalance in the information collected and used in making the trustworthiness and reliability determination. In addition, some licensees may decide not to grant unescorted access to fully qualified individuals because of the lack of

information or the difficulty in obtaining the information. Many smaller licensees may not have staff and/or knowledge to be able to fully utilize the information obtained from the credit history. The NRC has determined that the potential benefit of the credit history is not justified by the cost and, therefore, the NRC has not included credit history as a required element of the background investigation. While not requiring a credit history, the NRC does note that information obtained from the credit history could be useful to licensees, and nothing in the NRC regulations prohibits a licensee from conducting a credit history. In situations where a trustworthiness and reliability determination is difficult, the information from a credit history could provide the determining information. A licensee can always use measures beyond the regulatory minimum that is required by the access authorization program.

The NRC is not providing specific criteria that would disqualify an individual from obtaining unescorted access to the material. There is no checklist. Because the individual circumstances of each applicant may vary significantly, each licensee needs the flexibility to establish its own program. The implementation guidance document does provide general information and items for consideration, but no specific disqualifying information. A licensee should consider any negative information together with all of the other information in making a final determination.

At this time, the NRC has no plans to establish a new program to conduct background investigations similar to the TSA or CDC programs. The NRC does relieve individuals who have been approved under these programs from the fingerprinting element of the background investigation.

Information provided by the commenters on the burden of conducting a background investigation has been factored into the final regulatory analysis, as appropriate.

Comment B51: One commenter expressed concern that the new requirements could force employment decisions based on incomplete information and that this could lead to

significant legal implications for the facility. The commenter noted that the intersection of these requirements with the Equal Employment Opportunity Act should be investigated.

Response: The NRC does not agree that the background investigation requirements force licensees to make employment decisions based on incomplete information. Individuals who are granted unescorted access to category 1 or category 2 quantities of radioactive material must be deemed trustworthy and reliable. The background investigation is one component designed to provide the licensee with sufficient relevant information before making this determination. It is the licensee's responsibility to evaluate the information received as a result of the background investigation and all other relevant information to make its trustworthiness and reliability determination. These requirements do not relieve a licensee from its obligation to comply with all applicable Federal and State labor laws. Further, the NRC does not believe that fulfillment of these trustworthiness and reliability determination requirements would cause the licensee to violate any labor laws. Accordingly, the NRC does not believe that it is necessary to develop guidance on this issue.

Comment B52: Two commenters questioned the 10-year period for the background investigation versus the 3-year period contained in the orders. The commenters felt that 10 years is an arbitrary timeframe and that 3 years is sufficient. One of the commenters noted that going back 10 years is more expensive and that it is more important what happened in the last few years of the person's life and not distant history. Another commenter suggested changing the timeframe to 7 years as the standard criminal history and credit checks only go back 7 years. The commenter noted that many States charge an extra fee to extend the check beyond 7 years. One commenter noted that there could be a problem when attempting to use the 10 year criteria for students. Another commenter asked for clarification for how far back the investigation should go and what sources could be used. One commenter noted that the employment history evaluation period of 10 years was not consistent with 10 CFR parts 26 and

73 which only cover the most recent 3 years and that justification should be provided for going with 10 years. One commenter suggested going back the last two employers or 10 years whichever is less restrictive. One commenter stated that the timeframe should be left to the discretion of the licensee based on the situation of the applicant. One commenter felt that 10 years was too long an evaluation period and that there was no stopping point to the 18th birthday. The commenter recommended changing the 10 years to 3 years or until the person's 18th birthday, whichever is shorter. One commenter requested that NRC clarify the date used to determine the 10-year reinvestigation. One commenter noted that the rule needs to be clear that the expectation for the review is to go back 10 years or to such time as the individual was a minor.

Response: The NRC has reconsidered the time frame for the initial background investigation and has changed the timeframe to 7 years as suggested by the commenters. This may reduce the cost of the investigation. The rule does provide that the investigation only goes back to the individual's 18th birthday.

Comment B53: One commenter noted that the rule did not provide a tiered approach for individuals who had been with the licensee for greater than 3 years. The commenter noted that under the orders the licensee could review the individual's employment history (*i.e.* personnel files) and obtain the supervisor's standardized recommendation. The commenter recommended retaining this system for the initial and reinvestigation for individuals who have been with the licensee for a long period of time (*i.e.* 10 years).

Response: The NRC disagrees with the comment. The NRC believes that the longer timeframe is appropriate. If the individual has been with the company for 7 years, the licensee would not need to check with previous employers. The reinvestigation does not include all of the elements of the initial background investigation.

Comment B54: One commenter requested clarification on whether the licensee verified the true identity of individuals or the licensee's reviewing official. The commenter also objected to the language in the rule to verify "true identity" and "ensure" the individual is who he or she claims to be. The commenter felt that making it the licensee's responsibility to establish anyone's "true identity" is not always possible as identification documents (IDs) can be forged, and very few licensees are experts at identifying forged documents. The commenter felt that the language is too strong, cannot be guaranteed, and needs to be rewritten to just state that the licensee is responsible to review the identification documents. The commenter also stated that the requirement to compare the personal information data to identify any discrepancy in the information is too vague. The commenter asked what personal information and what should be done when discrepancies are discovered. The commenter suggested that the language be revised to require that the licensee review available information from an ID that is provided to the licensee by the applicant, and resolve any discrepancies. One commenter asked how verification of true identity was supposed to be done and questioned the expense and value. One commenter noted that it already performed an I-9 or E-verify for employees but not in the case of students at universities.

Response: The licensee is not expected to determine that an ID has been forged. Section 37.25(a)(2) states that the licensee is to review the identification documents provided, such as a driver's license or passport, to make sure that the information matches what was provided by the individual. If the information such as the name of the individual or social security number doesn't match, the licensee should investigate further. E-verify is one tool that can be used. The guidance document on the rule contains information on how this provision should be addressed.

Comment B55: One commenter suggested that the requirements to verify employment history, education history, and military history were too rigid and that the language should be

revised to “the licensee shall attempt to verify...” The commenter noted that this would recognize that businesses fail and overseas employers and schools may be impossible to contact. The commenter indicated that the unsuccessful attempts should then be documented. Another commenter noted that it could be very expensive to verify foreign employment.

Response: The NRC agrees in part with the comment. Section 37.25(a)(7) (previously (a)(10)) already contains a provision for when an employer or other entity doesn’t provide any information. The provision had been modified to provide additional clarification and to add a requirement that the licensee document the actions taken when it is unsuccessful in verifying the history.

Comment B56: One commenter questioned the relevance of obtaining military history and how the results would be used. The commenter stated that NRC should perform this service for foreign nationals. Another commenter noted that military history verification can be a lengthy and difficult process. The commenter noted that obtaining records from the Department of Veterans Affairs was difficult, particularly for Korean and Vietnam era veterans, and compliance is dependent on another Federal agency. One commenter noted that in some countries military service is a requirement of its citizens so verification has little bearing on an individual’s trustworthiness and reliability. Another commenter noted that the return rate for requests on military history has been about 20 percent and takes between 3-6 months. Commenters do not believe that this adds any value. Another commenter questioned how to obtain military history verification.

Response: Military history is considered part of the employment history. The rule text has been revised to include military history as part of the employment history instead of a separate element. For some individuals, military service could be their only employment. The licensee only needs to verify the service if the military service occurred in the last 7 years. Information on foreign nationals can be more difficult to obtain. The NRC notes that licensees

always have the option of escorting the individuals. Additional guidance on foreign nationals is provided in the implementation guidance.

Comment B57: One commenter questioned the value of verifying education history and questioned how the verification should be accomplished. Another commenter questioned how far back a company needed to go for someone employed at the company for 10 years. One commenter noted that the verification should be for the degree and not the time period of attendance. The commenter noted that it would be a huge burden to verify every time period at every institution for those who completed their education over numerous years at various institutions.

Response: Education history is similar to employment history and helps to validate what the individual was engaged in during the noted timeframe. Education history would typically be verified by checking with the educational institution. Education history only needs to be verified if it occurred in the last 7 years.

Comment B58: Two commenters felt that the employment history was completely ignored as the rule did not provide for limiting the background investigation to the FBI criminal history check for employees with more than 3 years with the licensee. The commenter noted that employment history is a factor that can be used when determining whether an employee with a criminal history is trustworthy and reliable. One of the commenters felt that employment history is a far more accurate set of data for determining trustworthiness and reliability than any other check proposed and that the employment history should not be ignored.

Response: Employment history was not ignored by the NRC and it is one of the elements of the background investigation. The NRC agrees that employment history can and should be used when considering the information obtained during the background investigation. The licensee has the flexibility to determine how much weight to give each element of the background investigation.

Comment B59: One commenter noted that it was impossible to verify employment if the individual has never worked before.

Response: Part 37 specifically requires that the licensee verify the individual's employment with each previous employer for the most recent 7 years before the date of application. If an individual has never worked before, there is no previous employer and no employment to verify. For this individual, no employment verification would be required.

Comment B60: One commenter questioned what was meant by the claimed period and indicated it should be defined in the rule.

Response: The NRC disagrees that claimed period needs to be defined in the rule. The claimed period is simply the period of time for which the individual indicates that they were engaged in a particular activity such as attending college, being a member of the military, or working for a company.

Comment B61: One commenter asked for the definition of "timely manner" for when an entity refuses to respond during a background investigation.

Response: The rule itself does not use the term "timely manner." The rule indicates that within a timeframe deemed appropriate by the licensee but at least after 10 business days of the request.

Comment B62: One commenter objected to the language in response B8 in the Statements of Consideration indicating that licensees should use their best efforts to obtain background information. The commenter noted that best efforts can't be enforced and must be clearly defined. The commenter also objected to the concept of dependable in judgment, character, and performance and noted that this must be reduced to something quantifiable and enforceable and not subject to disparate interpretations.

Response: The NRC disagrees with the comment. The NRC believes that the concept of best efforts in this context is necessary because sometimes it is impossible to obtain information. Companies going out of business and entities refusing to provide information or not getting back to the licensee are examples of situations where the licensee's best efforts will suffice, as long as the licensee documents the efforts taken to obtain the information. The NRC understands that judgment and character are subjective items. Licensees make determinations on judgment and character every time they hire someone or trust an individual with company assets.

Comment B63: One commenter stated that the NRC should ensure that the FBI check includes checks against known terrorists or denied entity lists.

Response: In addition to a criminal history records check, the names and fingerprints sent to the FBI are checked against various terrorist watch lists.

Comment B64: One commenter requested clarification on whether the fingerprints and associated criminal history records check was part of the background investigation conducted by the licensee since the FBI does the check and not the licensee.

Response: The background investigation includes the collection and review of all the information submitted by the applicant and any information provided by outside sources upon the licensee's request. While the actual criminal records check is conducted by the FBI upon receipt of an applicant's fingerprints, the results of the FBI's check are returned to the licensee, and that information should be reviewed as part of the licensee's determination of an individual's trustworthiness and reliability.

Comment B65: One commenter requested clarification on whether the background investigation elements could be outsourced by licensees to a third-party verification service. Another commenter requested clarification on whether some elements of the background

investigation could be performed by HR personnel and have them certify what steps had been taken.

Response: The background investigation elements could be outsourced. However, the final determination must be made by the licensee's reviewing official. If the investigation elements were outsourced, the licensee would need to assure that the information was properly protected and controlled.

Comment B66: One commenter expressed support for grandfathering individuals already allowed unescorted access under the orders. One commenter recommended that the grandfathering provision also include those individuals determined trustworthy and reliable under 10 CFR part 73.

Response: The NRC agrees that those individuals deemed trustworthy and reliable under 10 CFR part 73 should be grandfathered or relieved from the fingerprinting and background investigation elements. Those individuals who have been deemed to be trustworthy and reliable under other security fingerprinting orders (such as those for fuel cycle facilities and independent fuel storage installations) should also be grandfathered. The NRC has revised the rule to provide grandfathering for those individuals.

Comment B67: Two commenters questioned the value of the 10-year reinvestigation. They felt that conducting a complete check again makes no sense if the employee has worked for the licensee that long. One commenter recommended removing the reinvestigation, or if it is retained, making it simpler, such as a local criminal history check and supervisor evaluation. One commenter stated that the reevaluation needed to include character and reputation determinations. The commenter noted that changes in a person's attitude or demeanor can indicate a change in circumstances that warrants restricting access, whereas there may have been no change in a credit or criminal history. Two commenters recommended using the FBI background check for the 10-year reinvestigation. One commenter asserted that, if there are no

indicators that something has changed, the FBI check should be adequate for a reinvestigation. The commenter noted that employees are typically evaluated by their employer at least annually, and this provides ample opportunity to ensure that there have been no changes negatively affecting security concerns. One commenter noted that § 37.25(c) suggests that only a criminal history records check and credit history check are needed, and this implies that trustworthiness and reliability is not sufficiently demonstrated by 10 years' worth of access without an incident to revoke the individual's unescorted access. The commenter stated that the reinvestigation requirement seemed overly draconian, given that the federal Office of Personnel Management (OPM) standard for background investigations only requires a reinvestigation for a security level higher than even an NACIC - and the OPM reinvestigation is required only every 15 years. The commenter also asked for clarification on whether the relief provided by § 37.29 applies to the reinvestigation. The commenter also requested clarification on when the 10-year reinvestigation is triggered. One commenter stated that reinvestigation requirement does not make sense as there would be insufficient information on whether the criminal history will really be the criminal history or just an arrest record.

Response: The NRC believes that periodic reevaluation of an individual's trustworthiness and reliability is important. The reinvestigation is not a complete check. The reinvestigation is limited to the FBI criminal history records check. The relief provided by § 37.29 does apply to the reinvestigation. The licensee would need to check that the individual still meets the relief category.

Comment B68: One commenter questioned whether the reviewing official was subject to the reinvestigation requirement.

Response: The reviewing official is subject to the reinvestigation. The rule text has been revised.

Comment B69: One commenter stated that §§ 37.25 and 35.27 have some duplication of information and that sections should be reviewed to avoid duplication.

Response: There is some overlap in the requirements. However, the provisions of § 35.27 apply solely to the fingerprints and FBI criminal history records checks. The provisions of § 37.25 apply to the complete background investigation.

Comment B70: One commenter noted that there is potential for discrepancy between different licensees' basis determination for unescorted access and questioned the wisdom of allowing transfer of an individual's trustworthiness and reliability determination under § 37.27(a)(4).

Response: The commenter is correct that there may be differences between licensees' determination bases for unescorted access. The NRC still believes that there is merit in allowing licensees to transfer information and accept another licensee's determination on an individual. The individual has undergone a background investigation (or met one of the categories for relief) and been determined to be trustworthy and reliable. If the second licensee has reason to doubt the determination or does not feel comfortable relying on the first licensee's determination, the licensee is not obligated to allow the individual unescorted access. The licensee could also decide to conduct its own background investigation before allowing the individual unescorted access.

Comment B71: One commenter questioned the language in § 37.27(a)(6) that limits use of information obtained as part of the criminal history records check (from the FBI) to determining an individual's suitability for unescorted access to the material or SGI. The commenter felt that if the information indicated that an employee lied on an employment application, the licensee should be able to fire the individual based on this information.

Response: The NRC disagrees with the commenter's suggestion that § 37.27(a)(6) be deleted. The language in § 37.27(a)(6) of the proposed rule implements the statutory

requirement set forth in section 149c.(2)(B) of the AEA, 42 U.S.C. 2169(c)(2)(B). Information obtained from an FBI criminal history check shall be used by licensees solely to make suitability determinations for unescorted access to category 1 or category 2 quantities of radioactive material, or access to SGI. Information which pertains to the trustworthiness of an employee obviously is pertinent to a suitability determination. With that said, the NRC does not make employment decisions for the regulated community.

Comment B72: One commenter stated that the requirement in § 37.27(b)(1) prohibiting a licensee from basing a final determination to deny an individual unescorted access solely on information received from the FBI is inconsistent with the intent of the rule to protect the public from category 1 and category 2 radioactive sources. The commenter questioned how a responsible licensee could not use information provided by the FBI to restrict a terrorist from access to these sources.

Response: The prohibition on using information received from the FBI only involves information on an arrest more than a year old for which there is no information on the disposition of the case or an arrest that resulted in the dismissal of a case or an acquittal. The licensee may still consider the information, but it cannot base its decision solely on the information. If there is no disposition of the case in the file, the individual may have been acquitted of the charge, and an acquittal is information that would be pertinent to the decision to grant unescorted access.

Comment B73: One commenter stated that a licensee would need to have in-depth knowledge of constitutional law to understand the requirement in § 37.27(b)(2) that prohibits a licensee from using the information from a criminal history records check obtained under 10 CFR part 37 in a manner that would infringe upon the rights of any individual under the first amendment of the Constitution. The commenter noted that NRC should not be proposing any regulation that will be unconstitutional or be apt to be used to infringe on the rights of workers.

Response: The NRC disagrees with the commenter's suggestion that § 37.27(b)(2) be deleted. The NRC is not proposing a regulation that is unconstitutional or that infringes on the rights of any individual. This provision implements section 149c.(2)(D) of the AEA, 42 U.S.C. 2169c.(2)(D), which provides that the NRC is to protect individuals subject to fingerprinting from misuse of criminal history records. The onus is on the licensee, not the NRC, to ensure that the information it obtains as a result of an FBI criminal history records check will have limited use, and be used in accordance with all applicable Federal and State laws.

Comment B74: One commenter stated that the licensee should be allowed to submit fingerprint cards to the FBI. The commenter noted that submittal of fingerprint cards to the NRC is cumbersome, time-consuming, and apparently done only to provide an additional revenue source to the NRC. The commenter noted that it had experienced NRC losing one set of fingerprint cards. Another commenter noted that the rule does not allow licensees with a fully-accredited program to do their own collection and transmission of fingerprints to the FBI. The commenter requested an exemption to this restriction for licensees who possess a fully-accredited program.

Response: The NRC cannot exempt a licensee from the statutory requirement to submit fingerprint cards to the Attorney General of the United States through the Commission, even if that licensee possesses a fully-accredited program to collect and transmit fingerprint cards to the FBI. Section 149 of the AEA states that fingerprints obtained by an individual or entity must be submitted to the Attorney General of the United States through the Commission for identification and a criminal history records check. Consistent with the statutory requirements, a licensee is required to submit fingerprint cards to the NRC. The NRC will then submit the fingerprint cards to the FBI for processing and transmit the results received back from the FBI to the licensee.

Comment B75: One commenter stated that the fees for fingerprint processing should be placed in the regulations instead of a reference to the Web site.

Response: The NRC disagrees with the comment. The fees change based on what the FBI charges. If the fee was placed in the regulations, it would require the NRC to conduct a rulemaking every time the fee changed. By placing the current fee information on the Web site, it can be changed quickly when necessary.

Comment B76: Two commenters stated that § 37.29 should be deleted and that there should not be any categories of individuals that are provided relief from the background investigation elements. One of the commenters noted that any person entering a facility and having unescorted access to or transporting category 1 or category 2 quantities of radioactive material should be fingerprinted, without exemption or relief. The commenter stated that given the significance of theft of such material and the cost of dispersal of such radioactive material outside a controlled area, the cost and very minor use of time for fingerprinting is totally insignificant. The commenter noted that there are many examples of Congress or other persons who have been fingerprinted and who have broken criminal or other law and, therefore, should not be exempted. The commenter noted that fingerprinting is required in many situations not involving threats to national security or dispersal of radioactive material in public places and that the process is inexpensive, unobtrusive, and, if the person being fingerprinted has no reason to fear the process, insignificant and irrelevant. The commenter noted that most of the individuals covered by the relieved categories would be escorted and that providing relief causes confusion and makes the process more complicated. The commenter further noted that there is no more guarantee that these persons are more reliable than other workers; therefore, why proceed with exemptions that weaken the regulation.

Response: The NRC disagrees with the comment. NRC continues to believe that these categories of individuals should be provided relief. Many of these individuals have undergone

equivalent background investigations or by the nature of their positions are considered to be trustworthy and reliable as a matter of policy. Just because an individual is relieved from the background investigation elements, a licensee is not required to provide unescorted access to the material. For example, if a member of Congress were to visit a facility, the licensee would likely escort the individual and not allow him or her to wander the facility unescorted. An individual would still need to receive security and radiation protection training before being granted unescorted access.

Comment B77: One commenter disagreed with providing relief from the background investigation elements other than the fingerprints and criminal history check. The commenter noted that the relief is inappropriate for certain categories of individuals, in particular those covered under § 37.29(k). As an example, the commenter noted that a favorably adjudicated Security Risk Assessment under the Select Agent program does not assess the depth and breadth of information required under the full background checks specified either by existing orders or the proposed regulations. The commenter noted that the risk assessment only includes those checks specified under the Patriot Act and that character determination, credit history, verification of education, verification of employment, and the gathering of corroborating information are not explicitly included. The commenter noted that the acceptance of a Security Risk Assessment in place of the more extensive checks creates a double standard and introduces potential vulnerability into the personnel reliability process. The commenter noted that the information that would be analyzed for personnel under § 37.29(k) does not provide sufficient basis to assess whether an individual is trustworthy and reliable under the requirements set forth under either the NRC orders or under the proposed background check requirements.

Response: The NRC agrees with the comment and has revised the rule. The relief provided for individuals that come under § 37.29(b) (formerly § 37.39(k)) only applies to the

fingerprints and FBI criminal history records checks; the other elements of the background investigation must still be completed. For the other categories of individuals in § 37.29(a), relief is provided from all the background investigation elements.

Comment B78: One commenter objected to exempting commercial vehicle drivers for road shipments of category 2 quantities of radioactive material. The commenter felt that devices and sources are more vulnerable during shipment by a nonlicensee carrier than under licensee or manufacturer control and, therefore, carriers must require a background investigation for their staff with unescorted access to category 2.

Response: While understanding the commenter's concern, the NRC believes that the relief is appropriate. The licensee does not control the carrier or whom the carrier employs. However, the carriers are subject to DOT. Title 49 CFR 172.800 requires that each person who offers for transportation in commerce or transports in commerce category 1 or category 2 quantities of radioactive material to develop and adhere to a transportation security plan. The components of the transportation security can be found in 49 CFR 172.802.

Comment B79: One commenter requested that information be provided on what elements of the background investigation each category of individual relieved from the background investigation under § 37.29 go through.

Response: The NRC acknowledges that the background investigation conducted for individuals in the relieved categories contained in § 37.29 may not contain all of the aspects of the background investigation required under part 37. In some cases, the background investigation is more exhaustive, such as the Federal background investigation for access to classified information, and some may contain fewer elements. The licensee is not required to allow these individuals unescorted access to radioactive material and can choose to escort them. The licensee can also choose to conduct an investigation that included some or all of the

background investigation elements before allowing such an individual unescorted access to the material.

Comment B80: Two commenters recommended that the relief from the background investigation elements for individuals with a Federal security clearance be extended to include other aspects of the authorized individual process such as NRC approval of the reviewing official. One commenter requested clarification as to whether the relief granted by this regulation may be extended to individuals who will serve as the licensee's reviewing official.

Response: The NRC agrees with the comment that if the potential reviewing official meets one of the relief categories of § 37.29, the individual would not need to be fingerprinted and undergo a new background investigation. The rule has been clarified.

Comment B81: One commenter requested that § 37.29(g) be revised to include master materials licensee employees conducting inspections under their license authority. The commenter also requested that subparagraph (k) be revised to contain an explicit statement about whether persons approved under a government program have to be reapproved after a specified time interval.

Response: The NRC disagrees with the comment. A licensee employee conducting an inspection on the licensee's own program is not the same thing as an NRC or Agreement State inspector. The NRC disagrees that the individual should be relieved from the background investigation elements as the individual is still a licensee employee. The individuals who were granted relief would be subject to the 10-year reinvestigation. If the individual still fell under one of the categories, such as § 37.29(l), he or she would continue to be relieved. However, the licensee would need to document that the relief category still applied.

Comment B82: One commenter requested that the relief provided by § 37.29(i), from background investigations for emergency personnel responding to an emergency, be extended to emergency response personnel who are not responding to an emergency. The commenter

pointed out that these individuals need frequent access for smoke detector checks, safety inspections of fire walls, assessment of and response to false alarms, etc.

Response: The NRC disagrees with the comment. Fire department personnel who need to check smoke detectors and conduct safety inspections can be escorted. The NRC does not see why these individuals would need unescorted access to radioactive material. Someone responding to an alarm would be considered responding to an emergency, even if the alarm turned out to be false.

Comment B83: One commenter suggested expanding § 37.29(j) to include handlers at the transportation facilities, *i.e.*, the people who physically handle the package at the freight terminals and move the packages from one location to another. The commenter noted that licensees cannot perform checks for these nonemployees.

Response: The NRC agrees with the comment and has added a new category to include handlers at transportation facilities such as freight terminals and rail yards.

Comment B84: One commenter noted that there is a gap whereby § 37.29(m) does not cover self-employed service provider licensees who are small business owners, for example, independent service technicians who are licensed to perform maintenance and repairs on sealed source irradiators. The commenter noted that these individuals are qualified in a similar way for the applicability of § 37.29, yet the wording of this regulation does not appear to extend to them.

Response: The NRC believes that § 37.29(a)(13) (formerly § 37.29(m)) does cover a self-employed service provider. The access authorization program would not be required of a service provider that does not possess material; however, there is nothing in the regulation that would prevent the service provider from conducting background investigations that meet the requirements of § 37.25. The service provider would need to provide written verification that the

individual has been determined to be trustworthy and reliable under a subpart B program. Additional information has been added to the implementation guidance to address this situation.

Comment B85: One commenter indicated that § 37.29 should include exemption provisions for reputable security system vendors. The commenter noted that these vendors perform extensive background checks as part of their hiring process and it seems reasonable to consider the service providers, software engineers, etc. who work at or with a licensee's institution to be authorized to access the controlled areas. The commenter noted that it is unreasonable to expect the licensee to conduct its own background checks on all employees of the company who may be involved in the security system at the particular institution. The commenter noted that by not allowing this exemption, the licensee may be less inclined to use the state-of-the-art security systems available and this may be detrimental to the overall security of the material. The commenter noted that although security service providers are addressed in the "protection of information" section (§ 37.43(d)), they should be included here as well, since they not only have knowledge of the security program but may also have the ability to grant access.

Response: The NRC disagrees with the comment. It is not clear why security system vendors, particularly software engineers, would need to have unescorted access to the radioactive material. These individuals would need to have access to some of the licensee's security information, which is why they were included in § 37.43(d). Security system vendors may or may not conduct fingerprinting and an FBI criminal history records check as part of their investigation during the hiring process. Licensees may accept documentation from vendors that vendor employees have undergone a background check meeting the requirements of this part, but in the absence of evidence that all vendors' employment checks meet part 37 requirements; vendor employees should not be exempted by rule. Licensees also retain the prerogative to escort such employees when they are onsite.

Comment B86: One commenter, while noting that several State employees listed by job duties are listed as being relieved from the background investigation requirements, suggested that State licensing staff, information technology staff, and legal staff be included. The commenter noted that these individuals may also have access to such information.

Response: The NRC believes that the provisions in § 37.29 are broad enough to include other State employees that may require access.

Comment B87: The Nebraska Emergency Management Agency stated that it believes that it is exempt from the fingerprinting, identification, and criminal history records check requirements and only needs to provide physical security for its one category 2 quantity source until such time as the source is collected under the DOE source recovery program.

Response: No licensee is exempt from the provision of 10 CFR part 37. Section 37.29 does provide relief from the fingerprinting and background investigations for individuals that fall under one of the categories. State employees would likely come under the provision of § 37.29(a)(4) or (6) and would be relieved from the background investigation elements.

Comment B88: One commenter asked what “other property” refers to in § 37.29.

Response: The term “other property” comes from the AEA. The NRC has removed the term as it has no meaning in the context of 10 CFR part 37.

Comment B89: One commenter suggested that the regulation itself makes it clear that a licensee has the option of escorting the category of individuals provided relief from the background investigation (§ 37.29), and that granting unescorted access to these individuals is not required. The commenter also noted that it should be made clear that the security training must be provided before granting unescorted access.

Response: The NRC does not believe that the regulation needs to specify that the licensee has the option of escorting the individuals. It is always up to the licensee to decide whom it allows to have unescorted access. The provision in § 37.29 only provides relief from

the background investigation elements and does not require granting unescorted access to designated categories of individuals. Any individual allowed unescorted access to the material must meet all of the licensee's applicable training requirements before having unescorted access to the material.

Comment B90: One commenter requested that each subsection in § 37.25, "Background investigations," be revised to explicitly state if the subsection is applicable and must be followed for those who are relieved from elements of the background investigation under § 37.29.

Response: The NRC does not believe that it is necessary to make the requested revisions. Section 37.29(a) relieves the licensee from conducting the fingerprinting and all other elements of the background investigation. However, the licensee can still choose to conduct all or some of the elements before providing unescorted access to an individual who is covered by one of the categories listed in § 37.29. The licensee will still need to verify identification.

Comment B91: One commenter, while supporting the transfer of background information to outside entities allowed by § 37.31(c) felt that it would create additional legal issues and burdens on the HR department that they would not be able to meet. The commenter was concerned about the ability to authenticate the documentation presented and avoid fraudulent documentation. The commenter is concerned that there is no legally proper way to transfer such private information in a secure manner that would not create legal failure points and possible violations, as such, they would neither request nor offer such information.

Response: The language in the rulemaking under § 37.31(c) states that the personal information obtained on an individual from a background investigation may be provided to another licensee. While an individual may request that this information be transferred or shared, the licensee is not required by these regulations to do so, thereby minimizing or eliminating additional legal issues or burdens on the HR department that could arise from such

requests. Any decision to request or provide such information should be made at the licensee's discretion. The rule merely states that NRC considers it an acceptable practice, provided that the stipulations in § 37.31(c) are met.

Per the language provided in § 37.31(c)(2), the recipient licensee must verify information such as name, date of birth, social security number, gender, and other applicable physical characteristics, which should aid in authentication and the avoidance of utilizing fraudulent documentation.

Comment B92: Two commenters noted that the proposed rule has no mention of safeguards of the privacy of this background information, or of the method of review. One commenter requested clarification on whether the licensee needed to retain the fingerprints or just the records returned from the FBI.

Response: Information protection provisions for the background investigation are located in § 37.31. The licensee is only required to retain the records returned from the FBI and not the actual fingerprints. The NRC is not sure what the commenter meant by method of review.

Comment B93: Two commenters suggested revising the language for the timing of the program review to "periodically (at least annually) review" similar to what is contained in § 20.1101. The commenters stated that the proposed wording is onerous and unnecessary. Another commenter suggested adding the access authorization program review to the security program review. Several commenters suggested a 36-month timeframe or after changes to the program. The commenter noted that the program should see little revision once it is put in place and that an annual review seems excessive. One commenter indicated that NRC should specify those essential program elements for inclusion in the program review noting that placing such information in the guidance would not be enforceable and would be a disservice to licensees. Another commenter stated that there were too many criteria and it could lead

someone to think that the annual security review was more important than the safety review. Another commenter suggested every 3 to 5 years for the program review. One commenter noted that the program review could take from 1 to 3 man days.

Response: The NRC agrees with the comment in part and has revised the language for the program review to be consistent with § 20.1101. The use of consistent terminology between the safety and security programs should enhance the licensee's understanding of the requirement. The content of the program review has not been revised.

Comment B94: Two commenters recommend that facilities utilizing Federal security clearances should be exempted from the program review.

Response: The NRC disagrees with the comment. While the actual background investigations and protection of information would be covered by the Federal program, other aspects of the access authorization program would not necessarily be included in the Federal program. For example, the licensee would still need to have a program in place to document the information on who has access.

Comment B95: One commenter stated that the reviewing official and the individual with overall responsibility for the security program should be required to review the access authorization program review findings. The commenter felt that it was logical for the individual with overall security responsibility to be involved in the review; otherwise, the program could result in split responsibility for the security program.

Response: The NRC disagrees that a rule change is warranted. The rule provides the licensee with flexibility as to who should be designated to review the program review findings. The NRC does agree that it would be appropriate for both the reviewing official and the individual with overall responsibility to conduct the review.

Comment B96: One commenter questioned whether licensees should be obligated to provide unescorted access to any inspectors. The commenter asked whether Agreement State

inspectors are required to present credentials indicating that they are in compliance with the background investigation.

Response: Licensees are not obligated to provide unescorted access to an inspector. A licensee always has the option of accompanying the inspector. The regulations only require that the licensee “shall afford to the Commission at all reasonable times opportunity to inspect category 1 or category 2 quantities of radioactive material and the premises and facilities wherein the nuclear material is used, produced, or stored.” This means that the licensee must allow the inspector to go anywhere in the facility but can choose to accompany the inspector. A licensee has the right to request that an inspector present his or her credentials (*e.g.*, an agency issued badge) and to confirm with the inspector’s home office that the individual is indeed an employee of the agency. However, the inspector is relieved from the background investigation elements and does not need to present any documentation of compliance with the background investigation.

Comment B97: One commenter recommended adding language that states that the licensee is not prohibited from revoking previously granted authorizations at any time.

Response: The rule contains language in § 37.23(e)(4) that allows the reviewing official to terminate or administratively withdraw an individual’s unescorted access authorization based on information obtained after the individual has obtained unescorted access.

Comment B98: One commenter noted that language needs to be included to allow access to SGI-M and other security related information identified in the part in addition to unescorted access privileges for category 1 and category 2 materials.

Response: The NRC disagrees with the comment. Provisions for the protection of SGI, including access restrictions, are located in §§ 73.21 and 73.23. The requirements do not need to be repeated in 10 CFR part 37. Part 37 contains appropriate references to the 10 CFR part 73 SGI requirements.

Comment B99: One commenter noted that language is necessary to include the phrase ‘unless otherwise suspended or revoked’ to address those situations where such restrictive actions became necessary in regard to access to information or the material.

Response: The NRC disagrees with the comment. Section 37.23(e)(4) contains language that permits the reviewing official to terminate or revoke an individual’s unescorted access authorization. The NRC does not believe that additional language is necessary.

Comment B100: One commenter indicated that the rule should include a limitation on escorted access to only those needing such access to perform a job function or assist in educational activities.

Response: The NRC disagrees with the comment. The licensee should be allowed to determine who should be provided escorted access to the facility and materials. While there should be a need for the escorted access, there could be reasons other than to perform a job function or for educational activities.

C. Security During Use

Comment C1: One commenter stated that § 37.41(a) did not allow for the concept of co-location of sources, only addressing aggregated sources. The commenter noted that it was not cost effective to require increased controls on fixed gauges that are scattered throughout a facility.

Response: The concept of co-location is built into the definition for aggregated. Fixed gauges that did not fall under the orders do not fall under 10 CFR part 37.

Comment C2: Several commenters stated that the provisions in § 37.41(a)(2), providing for a 90-day notice before aggregation of material, were confusing and unnecessary and that aggregation would be detected during routine inspections. The commenters felt that the provisions would lead to unintentional noncompliance. Another commenter questioned how the

agency would know when a licensee aggregated the material, indicating that it would be time consuming and costly to coordinate and track. Another commenter suggested adding language to address the permittee system under master materials licenses. One commenter noted that § 37.41(a)(4) required implementation before possession. One commenter noted that it should be assumed that licensees are implementing the measures if they aggregate. One commenter disagreed with the notification for activation of the security plans.

Response: The NRC agrees in part and disagrees in part. The provision was added to help licensees that do not routinely possess an aggregated category 2 quantity, but may on occasion. The provision was intended to provide some relief from the need to always meet the requirements. However, since the wording has caused confusion, the NRC has revised the provision to simplify and clarify the requirement. A licensee only needs to provide a 90-day notice before aggregating the material if the licensee has never implemented either the orders or the 10 CFR part 37 provisions.

Comment C3: One commenter suggested adding a provision in § 37.41(2) to note that the NRC or Agreement State may prohibit the transfer of radioactive material in quantities of concern should an evaluation of the security plan be found lacking until corrective measures are taken and verified.

Response: The NRC disagrees with the comment. The NRC or State may take action to prohibit the transfer of material in such a situation; however, a provision in the regulations is not necessary. NRC would typically issue an order to the licensee or issue a confirmatory action letter documenting the licensee's agreement not to ship material until the issues have been resolved.

Comment C4: One commenter recommended that the general performance objective in § 37.41(b) be revised to remove the phrases "without delay" and "an actual or attempted." Two commenters noted that this objective is unrealistic during normal business hours as

unauthorized access, whether actual or attempted, would only be detected “without delay” if individuals were in the vicinity and could witness the access or attempt to access. One of the commenters stated that “without delay” is unrealistic during normal business hours as a business’ security system will not be set to alarm. One of the commenters noted that areas that may contain category 1 or category 2 quantities may be locked and unoccupied but not monitored. The commenters further noted that, after business hours, an armed security system could detect (without delay) unauthorized access to an area that contained a category 1 or category 2 quantity of material but may not be able to detect an “attempt” to access the area as the attempt may have failed without compromising a security measure or triggering an alarm. One commenter suggested revising the performance objective in § 37.41(b) as follows: “Each licensee shall establish, implement, and maintain a security program that is designed to monitor, detect, assess, and respond to unauthorized access to category 1 or category 2 quantities of radioactive material.” One commenter recommended defining “without delay” in § 37.41(b), particularly with regard to the assessment of an access incident. One commenter suggested the following language for § 37.41(b): “Each licensee shall establish, implement, and maintain a security program that is designed to monitor, and without undue delay detect, assess, and respond to an actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive material as outlined in their security plan.”

Response: The NRC disagrees with the comment. The purpose of the security program is to prevent unauthorized access and to detect unauthorized removal of the material. The sooner material is discovered to be missing, the more quickly a response can be started that includes trying to apprehend those who stole the material and to recover the material before it can be used for malevolent purposes. The NRC agrees that the licensee is not expected to respond to events that do not trigger the security system. The threshold for the security systems should not be set so high that actual attempts, such as someone trying to pry open the

door, are not detected or so low such as someone casually brushing a doorknob sets off the alarm. The NRC does not see any benefit to adding “as outlined in their security plan” to the rule text. The security plan must meet the requirements, and the licensee must follow the security plan.

Comment C5: One commenter recommended that a provision be added to require the licensee to appoint an individual with overall responsibility for the security program. The commenter noted examples where no one individual had responsibility to implement the security measures and noted that a default person such as the RSO may not have the necessary authority or ability to ensure that the program is working. The commenter noted that having the licensee specifically designate an individual will clarify responsibility and provide some authority. Another commenter noted that the individual should be placed on the license as is done for the RSO.

Response: The NRC, while agreeing that it is good practice to have an individual with overall responsibility for the security program, does not believe that the requirement needs to be in the regulations. If there were a requirement most licensees would likely name the individual on the license and then it would take a license amendment to change the named individual.

Comment C6: Several commenters objected to the requirement to develop a security plan if they are authorized but never possess a category 2 quantity or never aggregate the material above a category 2 threshold. Commenters felt that the exercise to develop a plan was a waste of time and manpower and questioned the value of preparing for an eventuality that will never occur. Some commenters noted that the material was in different buildings or scattered throughout a facility. One commenter stated that physical protection requirements during use have already been met and there isn't any evidence that requiring licensees to try and track locations of small amounts of source material so as not to aggregate to a threshold quantity is unnecessary to protect the security of the general public. One commenter asked what the

security plan should contain if a licensee doesn't possess category 2 quantities of material.

Two commenters stated that a licensee must implement a full security program based on authorization and not possession and that this is inconsistent and places an undue burden on licensees. One commenter requested clarification on whether the security plan would need to be implemented if the licensee was authorized for sources above the category 2 threshold but the sources were located at different sites.

Response: The NRC agrees with the comment and has revised the rule. Licensees will only be required to develop and implement a security plan if it aggregates the material to a category 1 or category 2 quantity of radioactive material at a specific location.

Comment C7: Several commenters felt that the specified contents for the security plan were too prescriptive. Commenters felt that each facility needs to have the flexibility necessary to develop a security plan that works best for them and that every security plan may not need all the prescriptive requirements specified in the proposed rule. Commenters noted that licensees have already developed their programs to implement the orders and that the programs have already been inspected and compliance verified. Commenters felt that the specificity of the rule was in conflict with the concept of a performance-based regulation. One commenter noted that the blind "broad brush" application of arbitrary requirements is not how to increase security; it should be based on each licensee's unique requirements. One commenter noted that there should be an exemption for licensees that already have a security plan in place.

Response: The NRC does not agree with the comment that the security program is too prescriptive. The licensee is free to choose the methods that work best for its facility; the exact security measures to be used are not prescribed. The content of the security plan is based on the measures that the licensee chooses to use. The NRC has made changes to § 37.43(a) to clarify that the security plan is specific to a facility and its operation and to remove the requirement to address site-specific conditions that affect implementation. The NRC has

determined that the site-specific aspects would be addressed by the measures used by the licensee and could not be addressed for temporary jobsites without creating a security plan for each site. It was not the NRC's intent to require a unique security plan for each temporary jobsite. The NRC has also removed the requirement to include a description of the training program. There is a separate requirement that addresses training, and it is not necessary to describe the program in the security plan.

Comment C8: One commenter noted that the original security plan must be reviewed and approved by the individual with overall security responsibility but that any revisions to the plan must also be reviewed by licensee management. The commenter questioned the different review and approval requirements. The commenter further noted that licensee management may not have a need-to-know and may not wish to go through the background investigation process just to review a plan, particularly if the authority and responsibility have been delegated. Another commenter noted that this also contradicts the requirement to limit access to the security plan.

Response: The NRC agrees with the comment and has removed the requirement for licensee management to review the revised plan.

Comment C9: One commenter stated that the phrase "measures and strategies" in § 37.43(a)(1)(i) is meaningless and unenforceable even as a performance-based goal. The commenter stated that the phrase should either be removed or the intent made clear by measurable, quantifiable, or otherwise objective expectations.

Response: The NRC disagrees with the comment. The licensee is required to describe the overall approach, methods, and equipment that it uses to meet the security requirements. Additional information has been added to the guidance.

Comment C10: One commenter indicated that the present security plan (from the orders) is sufficient and that a more stringent security plan is unnecessary.

Response: The NRC disagrees with the comment. The orders did not require licensees to even develop a security plan. The NRC does not believe that the requirements for the security plan are overly stringent. In fact, the licensee has the flexibility to include in the plan the site-specific measures that the licensee employs.

Comment C11: One commenter requested clarification in the situation where there is a high-level corporate security plan in place. The commenter's interpretation is that the security plan is not required to apply exclusively to the security of category 1 and 2 radioactive materials but can be an adaptation of a preexisting site or corporate-wide plan as long as the required elements are met.

Response: The NRC agrees with the comment. As long as a preexisting site or corporate-wide plan meets the requirements of subpart C as to the content of the security plan, the plan would be acceptable and a new plan would not need to be developed.

Comment C12: One commenter asked whether the written security plan must be a separate document in addition to the Standard Operating Procedures (SOPs) that pertain to security. The commenter felt that it is acceptable for a set of written SOPs to constitute a "written security plan" and would like the regulation to confirm that. Another commenter requested that a subsection be added to § 37.43 to allow the security plan and procedures to be the same document or a group of documents.

Response: Each licensee must determine what information is applicable to its facility and must be included and documented in its security plan. If a licensee already has a security plan developed to meet the requirements of an order or for other purposes, and this plan meets all the requirements in 10 CFR part 37, there is no need to develop a new plan. However, it is unlikely that many licensees will already have all the required information in place in existing procedures.

If a licensee has existing written procedures and policies in place that will be incorporated as part of its security plan under 10 CFR part 37, these may be referenced in the security plan as such; however, if these existing procedures contain information which would require marking and handling as SGI-M, then the licensee must ensure that all copies of the existing documents are appropriately marked and handled.

Comment C13: One commenter proposed that for mobile licensees the rule be modified to allow the preparation and submittal of a generic security plan that would be supplemented by a project-specific security plan prior to initiating work on any given project. The commenter proposed that the submittal of the generic security plan be required within 30 days of publication of the final rule as proposed by NRC; however, the 90-day requirement would not apply.

Response: It was not the intent of the NRC to require the development of a site-specific security plan for each temporary jobsite. Development of a general security plan that addresses how security will be applied at temporary jobsites will meet the requirement for having a security plan. The security plan is not submitted to the NRC for approval but would be available at a facility or temporary jobsite during inspection. The NRC has removed the requirement that the security plan address site-specific conditions.

Comment C14: One commenter noted that, since the security plan is to include a description of the environment, buildings, or facility where the material is used or stored, this would require companies that work at temporary jobsites to develop a separate plan for each jobsite. The commenter noted that this would be extremely costly and would require at least one additional employee per crew to follow the workers around, assess the surrounding environment, write a security plan, and train the crew in the new security plan prior to any work being performed each day. The commenter stated that this would cause undue burden on the licensee with no evidence that it would in any way stop an attack or protect the general public.

Response: The NRC agrees with the comment and has removed the requirement for the security plan to address site-specific conditions. It was not the intent of the NRC to require the development of a site-specific plan for each temporary jobsite. Development of a general security plan that addresses how security will be applied at temporary jobsites will meet the requirement for having a security plan. For those temporary jobsites that may be considered permanent (*i.e.*, pipe yards), the licensee should develop a more specific security plan.

Comment C15: One commenter noted that references to the security plan should be more specific to avoid security plans required by other parts.

Response: The NRC disagrees with the comment. The term, as used in 10 CFR part 37, refers to the security plan required by 10 CFR part 37, and there should be no confusion. Anywhere in this *Federal Register* notice or in the guidance for the rule where a different security plan is being referred to, language has been added to make clear that it is a 10 CFR part 73 security plan.

Comment C16: One commenter stated that the security program is too prescriptive and suggested using language similar to § 20.1101 to implement a program commensurate with the scope and extent of licensing activities and sufficient to ensure compliance with the provision of this Part. The commenter stated that this would allow the licensee the necessary flexibility in documenting its specific program but would not be prescriptive.

Response: The NRC disagrees with the comment. The NRC believes that the 10 CFR part 37 requirements provide the licensee flexibility. The rule does not specify what specific measures that a licensee must use; a licensee can choose those methods that fit its facility. The security plan, procedures, and training would address the measures that the licensee has chosen to use to protect the material.

Comment C17: One commenter suggested deleting § 37.43(b) on implementing procedures because separate procedures for the implementation of the security program are

unnecessary since they should be incorporated into the security procedures. Another commenter stated that many implementing procedures will be developed that do not include specific security measures designed to protect the sources and that do not need to be protected under this section. As examples the commenter offered procedures and forms on how to apply for unescorted access, how to add people to Radiation Use Authorizations involving irradiators, or procedures on record destruction.

Response: The NRC disagrees with the comment in part and agrees in part. Implementing procedures are a necessary component of both safety and security programs. If a licensee already has security procedures, it is acceptable to continue using those procedures and update the procedures to reflect any changes to the program. The licensee is not required to protect all of its procedures under this provision. The only procedures that require protection are procedures that document how the security program is implemented. This would include procedures on alarm response, security guard checks, and procedures that describe actual security measures. It would not include the types of procedures mentioned by the commenter. Examples have been added to the guidance document.

Comment C18: One commenter noted that § 37.43 does not mention that the requirements apply to individuals who have access to SGI.

Response: Section 37.43(d)(8) does contain a reference to the protection of SGI. The requirements for access to and protection and handling of SGI are contained in 10 CFR part 73.

Comment C19: Several commenters stated that there was no need for the refresher training unless something specific about the program changes. Commenters felt that only those individuals with a need-to-know should receive training on specific changes and that not everyone should be trained on the security plan. One commenter noted that those who just use the device do not need to be trained on the security of the device. Two commenters felt that refresher training every 12 months would be burdensome, particularly if you have many

employees needing the training. One commenter suggested that the periodicity of the refresher training be based on licensee's expectations and assessments for a need for refresher training. One commenter noted that the inclusion of training on the security program just added to the overhead. Another commenter expressed concern with the probable cost of the training program and noted that it could require a staff member to be assigned to the task full time to keep up with the training, refresher training, and testing for large numbers of diverse individuals with frequent turnover such as at a university. One commenter requested cost estimates specific to the training requirement.

Response: The NRC disagrees with the comment. The NRC believes that training is an essential element of any program. If employees are not trained, how will they know what to do if an alarm sounds or material is determined to be missing? The training needs to be commensurate with the individuals' responsibilities. The estimated cost for the training is included in the regulatory analysis prepared to support the rule.

Comment C20: One commenter stated that the training program requirements were too prescriptive and go well above what is in the existing orders. One commenter wanted to know what the training entails and requested a definition of the term "adequate training."

Response: The NRC disagrees with the comment that the training program requirements are too prescriptive. The NRC believes that training is an essential element of any program and should be required. The orders did not require any training to be conducted. The training must address the licensee's security program and procedures and the security measures employed by the facility. Individuals do not need to be trained on the complete security plan; the training should be commensurate with their responsibilities. The provisions in § 37.43(c)(1)(ii), (iii), and (iv) are also general and are similar to the training provisions of § 19.12.

The term “adequate training” is not used in the rule language. However, the training must cover the information for an individual to carry out his or her assigned duties and responsibilities.

Comment C21: One commenter stated that § 37.23(a)(2) requires users to be trained in all aspects of the security plan and that this conflicts with § 37.43(c)(2) which notes that the training should be commensurate with the individual’s responsibilities.

Response: The NRC disagrees that there is a conflict between the sections. Section 37.23(a)(2) requires the training required by § 37.43(c) to be completed before allowing the individual to have unescorted access. It does not state that the individual must be trained on all aspects of the security plan.

Comment C22: One commenter recommended defining “relevant results” in § 37.43(c)(3).

Response: The NRC disagrees with the comment. The term relevant is a common term and in this case simply refers to items that are related to security. Examples of some items that would be included are areas where staff has had trouble following the security requirements, violations of the security requirements that have been discussed in an inspection report, and measures taken to fix any identified security issues. Additional information has been added to the associated implementation guidance.

Comment C23: Two commenters requested clarification on the timing of the refresher training. The commenters noted that their understanding was that refresher training could be taken more than 365 days after the previous training, as long as it is taken within the same month of the succeeding year.

Response: The commenter is correct in its understanding that the training is to be provided at a 12-month frequency and be conducted within the same month of each succeeding

year. This allows licensees greater scheduling flexibility to accommodate the needs of their operations, instead of holding them to a strict 365-day time constraint.

Comment C24: One commenter did not think that the licensee should be training the LLEA on rules of engagement, such as the proper response to an alarm. The commenter also asked whether it would be considered self defense to shoot a perpetrator that holds a category 2 source up as to expose the responder. Another commenter noted that the LLEA does not have the time or the inclination to undergo licensee training. One commenter requested clarification on whether the training program included LLEAs.

Response: The training is not for the LLEA but for the licensee's staff that would be responding to the alarm. The licensee is not required to conduct any training of the LLEA, although providing the LLEA an overview of the facility is a good practice. The rule does not authorize lethal force or arming of licensee personnel.

Comment C25: In the proposed rule, the NRC specifically invited comment on the requirement to protect security-related information. Commenters were requested to provide information on: 1) whether the Agreement States have adequate authority to impose the information protection requirements in this proposed rule; 2) whether the Agreement States can protect the information from disclosure in the event of a request under a State's Freedom of Information Act or comparable State law; 3) whether the proposed rule is adequate to protect the licensee's security plan and implementing procedures from unauthorized disclosure, whether additional or different provisions are necessary, or whether the proposed requirements are unnecessarily strict; 4) whether other information beyond the security plan and implementing procedures should be protected under this proposed requirement; and 5) whether the background investigation elements for determining if an individual is trustworthy and reliable for access to the security information should be the same as for determining access to category

1 and category 2 quantities of radioactive material. Nineteen commenters provided responses to the specific questions on this subject.

Of those that provided responses to the questions on the protection of information, the commenters were divided in their views. Some felt that the proposed provisions were sufficient, some felt that they were unnecessarily strict, and some felt that the current provisions from the Increased Control Orders were sufficient. One commenter stated that with the proposed provisions, there was no continued need for any of the security information to be considered SGI or SGI-M. One commenter stated that the requirements should be clarified to indicate that only written copies of the plan and procedures will be protected. One commenter stated that the rule was unnecessarily strict by requiring that persons with access to the security plan and procedures also be permitted unescorted access to the sources. Two commenters suggested that the list of individuals granted unescorted access to the security zone should also be protected. Most of the commenters agreed that the background investigation elements for determining whether an individual has access to the information and radioactive material should be the same. Two individuals stated that a criminal history records check should be part of the background investigation for access to the information. Two commenters stated that the elements should be different but did not indicate what should be different. On the question of whether the States have adequate authority to impose the information requirements, many commenters indicated that the States do have the authority or that they thought the States did. On the question of whether the States can protect the information from disclosure in the event of a request under a State's Freedom of Information Act, most of the responses were not definitive. Several commenters indicated that an opinion from the State Attorney General's Office would be necessary; four States indicated that they did have the necessary authority.

In addition to those that provided responses to the specific questions, 8 commenters addressed the information protection provisions. One State noted that it did have authority to

impose the information protection requirements and could protect the information from disclosure. One commenter noted that there are already processes in place under SGI and/or official use only (OUO) to protect security information.

One commenter recommended adding the list of individuals approved for unescorted access authorization to the information that must be protected from unauthorized disclosure, noting that if the names become public, the individuals could potentially be targeted to gain unabated access to sources. One commenter requested that § 37.43(d)(1) be revised to clarify that the protection of information refers to the written security plan or procedures only, so as to preclude unwarranted interpretations during a regulatory inspection about what information or discussions to restrict. The commenter offered suggested language as follows: “(1) Except as provided in paragraph (d)(8) of this section, licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to copies of their written security plan and implementing procedures and unauthorized disclosure of substantive details of the plan or procedures that facilitate unauthorized access.”

Commenters noted that the fingerprinting element was not included in the background investigation elements for access to security information, and several commenters stated that it should be included. Other commenters requested clarification whether fingerprints were prohibited for this purpose. Commenters requested that the NRC make the requirements for background checks consistent throughout the rule. One of the commenters noted that a licensee is left either to perform incomplete checks on individuals with whom information is shared, or to grant unrestricted access to individuals who truly do not need the access, just to allow the licensee to conduct the main element of the background check (*i.e.*, the FBI identification and criminal history records check). One commenter stated that the response discussion for C6 in the Statements of Consideration should be modified to include the requirement that anyone seeking information on category 1 quantities of radioactive material

must also have undergone the access authorization process, including the FBI criminal history review and fingerprint identification verification. The commenter stated that this would be a practical threshold for States to have equivalent rules in place that mimic the NRC's SGI-M requirements in 10 CFR part 73.

One commenter stated that the phrase "security service provider employees" as used in paragraph § 37.43(d)(4)(ii) is too general. The commenter indicated that it didn't appear that the intent of the NRC was to require background checks on individuals who do not access the facility and simply monitor the facility's security system from an offsite location, such as alarm service providers. The commenter further asked if the requirement is intended to address security guard service employees who work on the licensee's premises that contain category 1 and category 2 quantities of materials. Another commenter requested clarification and suggested revised language. One commenter noted that the exemption to performing background investigations for employees of security service providers requires written verification from the provider for each employee. The commenter stated that it may be more appropriate to approve the security service provider as a whole since it may be difficult for the licensee to maintain a current list of all employees of the vendor who may have intimate knowledge of the security system at the licensee's location(s). The commenter noted that it would be burdensome for the licensee to track individual employees of these companies. The commenter stated that a letter documenting the background investigation procedures of the security vendor could be provided to the licensee to allow it to forego the access authorization procedures for the security vendor employees. One commenter stated that each subsection on the protection of information (background investigation information) should be revised to state explicitly which subsections are applicable and must be followed for individuals provided relief in § 37.29.

One commenter stated that there should be no need to have another documented basis for an individual to have access to the security plan if it has already been documented that the individual has unescorted access to material as it is redundant and create additional burden. One commenter also requested that a table or flow diagram be added to the guidance document to show when the background investigation elements apply.

Response: All aspects of the information protection requirements apply to all of the background investigation information possessed by the licensee whether the information is the full background investigation or information on how the individual met a category in § 37.29 for relief from background investigation requirements. The NRC agrees that the list of individuals that have been approved for unescorted access should be protected and has added it to the list of items for protection. Individuals do not need to have unescorted access to the radioactive material in order to have access to the protected information. An individual who has been granted unescorted access to the radioactive material would not need to undergo another background investigation to have access to the security information. The licensee would need to document that the individual has a need-to-know the information. The rule has been clarified that a second background investigation is not necessary.

On the issue of protecting only written copies of sensitive information, the NRC disagrees with the comment. The licensee must protect against any form of unauthorized disclosure of the protected information, including verbal or electronic disclosure.

On the issue of the security service provider, the NRC disagrees with the suggested change as a security service provider may not be a guard and could include other occupations. Language in § 37.43(d)(4)(ii) allows the licensee to accept a security service provider's determination of trustworthiness and reliability based on a full background investigation. Additional information has been added to the implementation guidance.

On the issue of requiring fingerprints and FBI criminal history records for access to the information, the NRC does not have the authority to require fingerprints for access to this type of security information. The NRC can only require fingerprints for access to SGI and unescorted access to radioactive material. The NRC has added a table to the guidance document on the background investigation elements.

Comment C26: One commenter requested clarification of § 37.43(d)(3) as to whether individuals, who by nature of their job position have knowledge of critical components of the security plan, would be required to undergo a background investigation unless they have access to the security plan document or any of its implementing SOPs. Examples include a security guard with access to an alarm-response schematic or an IT specialist who supports an IT system responsible for alerting security personnel of adverse indicators in the area of category 1 or category 2 radioactive sources. In each case the individual has knowledge of security plan components but would not have access to the plan itself or implementing SOPs.

Response: Employees or service providers with limited knowledge of the security plan but without access to the plan or the implementing procedures would not necessarily need to undergo a background investigation. The licensee would have to decide in some cases how much knowledge of the plan the employee has; if the employee is familiar with the plan and procedures, even if he does not have access to the document, it may be necessary to conduct a background investigation and make a determination of trustworthiness and reliability. Note that new language in § 37.43(d)(4)(ii) allows the licensee to accept a security service provider's determination of trustworthiness and reliability based on a full background investigation.

Comment C27: One commenter requested that the language in § 37.43(d)(5) requiring that "...the licensee shall immediately remove the person..." be revised to remove the word "immediately" and to substitute "as soon as practical." The commenter noted that the person

won't immediately forget the information in the plan and that there is no need for immediate removal.

Response: The NRC agrees with the comment. An immediate removal from the list is probably not necessary. The NRC has revised the language to reflect that the removal should occur as soon as possible but no later than 7 working days.

Comment C28: One commenter objected to the phrase "in a manner to prevent removal" in § 37.43(d)(6). The commenter felt that the phrase was exceedingly vague. The commenter suggested a change to "secure the plan to prevent unauthorized access."

Response: The NRC agrees with the comment and has revised the rule text to read: "When not in use, the licensee shall store its security plan and implementing procedures in a manner to prevent unauthorized access."

Comment C29: One commenter requested clarification on whether a reinvestigation is required for individuals who have access to sensitive information only, and if so, the procedure that should be followed.

Response: Yes, the reinvestigation applies to individuals who have access to sensitive information. The rule has been clarified to make the requirement clear.

Comment C30: One commenter requested that language from the orders addressing marking and transmission of security related documents be added to the rule.

Response: The NRC disagrees with the comment and does not believe that the marking and transmission measures need to be added to the rule. Licensees are not required to submit either the security plan or implementing procedures to the NRC. The NRC reviews these documents during inspections at the site. The transmission portion is therefore not necessary. The necessary elements from the orders on access to and protection of the information are in the rule. The other elements are good practice, but the NRC does not believe that they are essential for the adequate protection of the information. However, if a licensee believes that

information submitted to the NRC should be withheld from public disclosure, the licensee should follow the requirements in § 2.390.

Comment C31: One commenter suggested that the terms “Safeguards information” and “Safeguards information modified handling” be defined in 10 CFR part 37.

Response: The NRC disagrees with the comment. Safeguards information and safeguards information modified handling are defined in 10 CFR part 73 where the requirements for handling such material are located. The reference in 10 CFR part 37 is merely a pointer to the requirements and does not establish any new requirements; therefore, the NRC does not believe that a definition for these terms is necessary in 10 CFR part 37.

Comment C32: One commenter asked that the NRC define “to the extent practicable” for coordination with LLEAs.

Response: This provision was added to the rule to provide the licensee with some flexibility. Some LLEAs may be reluctant to engage in coordination activities with a licensee. The provision “to the extent practicable” allows the licensee to remain in compliance with the rule when an LLEA will not participate in any coordination activities. The NRC does not believe that phrase needs to be defined. Guidance is available on this topic and other aspects of the rule in the associated implementation guidance.

Comment C33: Two commenters recommended deleting paragraph § 37.45(a)(1)(ii) as this information would be classified as SGI or SGI-M for some licensees and would require handling and control in accordance with § 73.21. The commenter indicated that there appears to be little if any benefit in providing this information to the LLEA that would warrant the dissemination of SGI or SGI-M. Another commenter felt it was unnecessary to describe specific security measures such as alarm types and locations unless the LLEA is actually monitoring these alarms. The commenter asserted that a generic description would be adequate for the purpose of LLEA situational awareness.

Response: The NRC disagrees with the comments. The NRC believes that the information on the facility can be useful to the LLEA. In an event where someone is trying to steal the material, the LLEA can mount a more informed response if information about the facility is available to the responders. When NRC staff has met with LLEA representatives, the representatives have indicated interest in the coordination activities. LLEAs are deemed trustworthy and reliable for access to sensitive security information as well as SGI.

Comment C34: One commenter noted that an LLEA is not going to tell every licensee whether the initial response to an emergency involving radioactive materials must be provided by other than armed LLEA personnel and questioned how a licensee would know this information. The commenter suggested removing the provision as it was a nonsense requirement. One commenter stated that the NRC should coordinate with the States to be notified instead of requiring the licensee to notify the NRC after the licensee becomes aware of any State or local requirements that an initial response to an emergency involving radioactive material must be provided by other than armed LLEA personnel. Another commenter recommended removing the requirement. One commenter asked what the NRC would do after such notification.

Response: The NRC agrees that there may be some reluctance on the part of the LLEA to provide the information. The provision is not included in the final rule.

Comment C35: One commenter questioned the need for a specific written agreement for response. The commenter also requested clarification on what must be included in the agreement. Some commenters questioned the benefit of requiring coordination with the LLEAs and questioned whether this was the best use of LLEA resources given the low probability of an actual threat to sabotage or steal a category 2 source. Commenters indicated that, based on their experience to date with the orders, the LLEA coordination was not beneficial, noting that at best the LLEAs would acknowledge the coordination attempts with no commitments, other than

to respond in the manner they believed was proper, and that most LLEAs were completely disinterested and did not acknowledge any information provided by the licensee. They noted that in their discussions with those LLEAs where feedback was provided, the LLEAs were unwilling to discuss the manner in which they planned to respond and unwilling to commit to any specific action as each decision to respond must be based on their judgment of the circumstance. One commenter indicated that LLEAs would not want to disclose their capabilities. One commenter noted that the LLEA is not required to comply with the request. At least one commenter questioned whether it would be more efficient to inform/train only the LLEA involved when the billions we spend on intelligence indicate a credible threat. Commenters felt that adding a requirement does not address the root cause. One commenter expressed concern that security could be reduced if the LLEA failed to protect the information or had to release the information under a FOIA request. The commenter suggested a reevaluation of the information provided to the LLEA such that release of information would not cause a breach in security. Two commenters noted that they had successfully coordinated with their LLEA under the orders and do not believe that any additional requirements are needed. One commenter indicated that the coordination process should be a clearly defined process. One commenter stated that LLEA coordination requirements were overly prescriptive and difficult to implement. The commenter stated that, if NRC feels this is necessary, NRC should take the lead and identify contacts and provide training. A commenter noted that the use of 911 is effective for all kinds of emergencies and should be used by licensees. One commenter agreed that there is value in a coordinated response from an LLEA and that such a response should include the capability of bringing armed force; however, the commenter stated that it was inappropriate to place the requirement on the licensee. The commenter stated that the extent of the response should be left to the discretion of the LLEA. The commenter noted that the requirement for a written agreement with the LLEA was unenforceable and outside the State's

jurisdiction. Two commenters noted that the LLEA coordination was one of the most difficult areas to implement from the orders and places responsibility on licensees for activities they cannot control.

Response: While the orders contained a requirement for a prearranged plan with the LLEA, the proposed rule only contained a provision to request that the LLEA enter into a written agreement. After evaluation of all of the comments on the LLEA coordination, the NRC has simplified the requirement. The NRC continues to believe that coordination with the LLEA is important, and the rule contains a requirement for coordination. However, the decision was made that several of the items, while good ideas, were better addressed in the guidance document and not in the rule itself. A written agreement and several of the coordination activities are not included in the final rule. Even if a written agreement had been reached, an LLEA will respond as it feels is appropriate to the particular situation.

Comment C36: One commenter objected to requesting the LLEA to provide updated contact information as it places a burden on the LLEA. Two commenters suggested that this only be a requirement if a facility is not served by a 911 system.

Response: The NRC agrees that it is not necessary to request contact information or updated contact information. Most licensees in the case of an actual threat would call 911 and not the contact. Additionally, no contact would be available 24/7. The provision is not included in the final rule.

Comment C37: Many commenters objected to the requirement that a licensee request the LLEA to notify it of degraded capabilities as unrealistic, unnecessary, unenforceable, and would probably violate LLEA “need-to-know” procedures. Some commenters felt that the requirement that the LLEA notify licensees of a degradation of their response capabilities was clearly outside the purview of the regulating agencies. Others noted that licensees have no authority over nonlicensed entities such as LLEAs. Commenters felt that the LLEA is better

equipped to arrange for alternative response capabilities than would the licensee and that this would be an inherent part of LLEA organizational framework; some commenters asked what the direction was if a licensee was notified of a degraded LLEA response capability. Another commenter asked what the State was to do if notified that the LLEA was not cooperating in providing the degraded capability information. Commenters noted that it is inconceivable to believe that the LLEA would notify a licensee that their response capabilities have become degraded, not only because that would appear to be an open invitation to the criminal sector, but also, if capabilities are degraded, logically the LLEA would not have the capability to notify licensees. Commenters asked what they would do with the information if provided. One commenter suggested as an alternative that the licensee request the LLEA to confirm that it has a contingency plan in case of compromised response capabilities. Another commenter noted that it was more important for the licensee to discuss this issue with the LLEA during the coordination meetings. Another commenter noted that there is not prescribed action for the licensee to take if notified and questioned the purpose of the notification.

Response: The NRC agrees that many LLEAs may not want to provide information on degraded capabilities. The provision is not included in the final rule.

Comment C38: One commenter stated that the participation of licensees and LLEAs in drills and exercises was an unfunded mandate and should not be required. The commenter also questioned whether drills and exercises contribute to the security of the sources or the public health and safety. Two commenters suggested removing this requirement as there is no requirement to conduct such drills.

Response: The NRC agrees in part and disagrees in part. The proposed rule did not require that drills and exercises be conducted. The rule did contain a provision that required the licensee to ask whether the LLEA would be willing to participate in drills and exercises. As there is no requirement to conduct drills and exercises, the NRC has removed this provision as

suggested by the commenters. The NRC does note that drills and exercises can contribute to the public health and safety and the security of the material.

Comment C39: Several commenters felt that the requirement for a licensee to notify the regulatory agency if an LLEA declines to participate in coordination activities creates an unnecessary burden for the regulatory agencies that will now be required to notify the Department of Homeland Security or contact the LLEA directly to explain the importance of cooperating. Some commenters suggested that if NRC believes this is truly a critical issue, NRC should coordinate with the Federal Department of Homeland Security's Nuclear Sector Government Coordination Council to engage law enforcement from a broader perspective. One commenter asked what actions the NRC would take when notified and what the NRC would do if the NRC did not gain confidence that the LLEA would respond in an actual emergency.

Response: The NRC disagrees with the comment. The NRC believes it is vitally important for the licensee to coordinate with the LLEA, and the agency wants to know if the LLEA won't participate. There were instances during implementation of the orders where the NRC met with the LLEA to explain the importance of LLEA cooperation with the licensee. The State is not required to contact DHS or the LLEA if the LLEA does not want to participate in coordination activities. DHS does have training programs to educate LLEAs.

Comment C40: Two commenters objected to the requirement to coordinate with the LLEA every 12 months, noting that it took several months to set up a meeting for the coordination required by the orders. The commenter felt that, as there had been no events requiring contact with the LLEA and no changes to the security program, there was no need to meet annually. The commenter noted that both parties have plenty of work and are not just sitting around and focusing on this one agenda item. The commenters asked whether the licensee would be cited if the LLEA refused to meet on an annual basis.

Response: The NRC disagrees with the comment. The NRC believes that it is important to maintain contact with the LLEA. Turnover at both the LLEA and the licensee occurs over time and if contacts are not maintained, the knowledge obtained during the initial coordination is lost. The annual follow up does not need to be extensive. If the LLEA refuses to participate, the licensee should document the attempt. The licensee would not be cited as long as it had documented the attempt(s).

Comment C41: One commenter noted that the requirement to document coordination activities with the LLEA would now require regulatory agency inspectors to visit LLEAs to determine licensee compliance, resulting in longer inspection times and possibly creating a situation that may be interpreted by the LLEA as intrusive.

Response: It is not clear why the commenter feels that an inspector would be required to visit the LLEA to determine a licensee's compliance with the rule's coordination requirements under § 37.45. The licensee is required to document the coordination activities, and an inspector would be expected to review the documentation. An inspector may choose to contact the LLEA to gain a greater understanding of the nature of the coordination efforts. However, this rule does not require that an inspector contact the LLEA to determine licensee compliance with § 37.45.

Comment C42: Two commenters noted that the goals and objectives for coordination activities with LLEAs are admirable, but the commenters stated that this is an area where the NRC should consider taking concerted efforts to engage law enforcement communities to improve situational awareness now, rather than waiting for feedback from licensees regarding potential LLEAs refusing to cooperate. The commenters suggested that the NRC consider an outreach campaign aimed at direct communications with LLEAs to better understand their perspectives regarding these issues. Another commenter suggested a Federal outreach

training program to LLEAs for radioactive materials incident response. The commenter noted that DOT has an outreach program for transportation incident response.

Response: During the security inspection process, the NRC inspectors have been contacting the LLEAs to both ensure that licensees have been coordinating and to improve the LLEAs understanding of the importance of providing a timely response. At this time, the NRC is not planning any additional outreach to LLEAs. However, the DOE has a program to provide LLEAs with additional training for responding to the attempted or actual theft of category 1 or category 2 quantities of radioactive material. The Global Threat Reduction Initiative (GTRI) program provides security personnel and local law enforcement with tools (e.g. radios, repeaters, and personal detection devices) and additional training to respond to a security incident. To ensure that both onsite and offsite responders understand how to respond to enhanced security system alarms, GTRI developed an alarm response training course, which is held at the Y-12 National Security Complex in Oak Ridge, Tennessee. This alarm response training also prepares responders to protect themselves and the public when responding to events involving radiological materials. The participants conduct hands-on training in a realistic setting using actual protection equipment and real radioactive sources. The courses include operational exercise scenarios that build on classroom instruction and allow response forces to exercise their own procedures during realistic alarm scenarios.

Comment C43: One commenter noted that not all events that occur are of a nature that an LLEA would have to be involved and questioned why it should be mandatory that an LLEA respond to events that could be handled by internal security.

Response: It is not mandatory that the LLEA respond to all events. The licensee is suppose to assess the event and contact the LLEA only if there has been an actual or attempted theft, diversion, or sabotage attempt. The language has been clarified.

Comment C44: One commenter questioned how the failure of the LLEA to coordinate fully with the licensee would impact the status of a license. The commenter noted that licensees should not be held accountable for noncooperation or lack of resources on the part of the LLEA. The commenter stated that it should be under the purview of the NRC or Agreement State to ensure that the LLEA works with the licensee in the requested manner.

Response: Failure of the LLEA to coordinate does not affect the status of the license, and licensees will not be held responsible if the LLEAs do not coordinate. Under § 37.45(b) and (c), licensees are only required to document their coordination efforts and notify their appropriate NRC regional office if the LLEA does not wish to coordinate. The NRC will contact the LLEA to explain the potential consequences of the theft of category 1 or category 2 quantities of radioactive material and encourage the LLEA to participate in coordination activities with the licensee.

Comment C45: One commenter requested that the NRC add a subsection to clarify requirements for coordination by a licensee or permittee under a master materials license that has an onsite LLEA that would preclude unwarranted interpretations during a regulatory inspection about the extent that coordination must be documented. The commenter offered suggested language as follows: “For a licensee or permittee under a master materials license with an on-site LLEA, coordination requirements in this subsection are considered to have been completed if the security plan and implementing procedures establish methods for LLEA response at the facility.” Another commenter raised the issue of unnecessary documentation of coordination activities when the LLEA is part of the same organization that owns the radioactive material. The commenter noted that the lack of documentation activities should be seen as good news unless the LLEA refuses to respond to appropriate requests for assistance. The commenter also notes that burdening the police with detailed paperwork is an “insult to their understanding of the risks inherent to their mission.” This commenter also suggested adding a

new subparagraph as follows: “When the LLEA is part of the organization that owns and controls the Category sources, the documentation in § 37.45(a)(2)” {was (a)(1)} “is not required provided all the elements of good willful coordination are clear.”

Response: Even when the LLEA is on site, the licensee should conduct coordination activities. The coordination would likely be simplified but still needs to occur. The coordination activities to meet the requirements of § 37.45 need to be documented even if the LLEA is part of the same organization. The licensee would not need to document all interactions with the LLEA, only those necessary to meet the requirements. Note that it is not the LLEA that is required to document the coordination activities.

Comment C46: One licensee asked whether a written agreement with a third party service that provides off-duty local law enforcement agents on site at all times would be acceptable to demonstrate compliance with the LLEA coordination requirement.

The commenter stated that the agents have full response and arrest capabilities while working at the facility.

Response: If the third-party service provides individuals that meet the definition of LLEA and the third-party service can provide a timely armed response 24 hours per day, then the third party service providers meet the requirement for LLEA coordination.

Comment C47: One commenter questioned what would be expected of the State if the LLEA did not respond to an event?

Response: The expected response would depend on the circumstances and would be up to the State. The NRC believes that it would be highly unlikely that the LLEA would not respond to an actual or attempted theft of radioactive material.

Comment C48: In the proposed rule, the NRC specifically invited comment on the requirement to contact the LLEA for work at a temporary jobsite. Commenters were requested to provide information on: 1) whether there is any benefit in requiring that the LLEA be notified

of work at a temporary jobsite; 2) whether notifications should be made by licensees for work at every temporary jobsite or only those where the licensee will be working for longer periods, such as the 7 day timeframe proposed in the rule; 3) whether 7 days is the appropriate threshold for notification of the LLEA or should there be a different threshold; 4) whether licensees can easily identify the LLEA with jurisdiction for temporary jobsites or whether this imposes an undue burden; and 5) whether LLEAs are interested in receiving these notifications. Eighteen commenters provided responses to the specific questions on this subject.

Of those that provided responses to the questions on LLEA notification at temporary jobsites, the majority indicated that there was no benefit to notifying the LLEA of temporary jobsites. Only one commenter indicated that there is some benefit for notification of work using category 1 materials and one noting some benefit for a temporary jobsite lasting longer than 30 days. Commenters indicated that temporary jobsites are unpredictable in nature and therefore unlikely to be a primary target. Commenters noted that in most cases the licensee does not know 3 days in advance where work might occur and that due to the nature of the job it is often not possible to determine the length of the job in advance. Commenters noted that the notifications may cause confusion for the LLEA and would likely be intrusive. Commenters indicated that the emergency 911 system is adequate in the case of a security event. One commenter noted that the LLEA would also need to be notified when the job ended. One commenter suggested that notifications go to a central location, such as the NRC or Agreement State, and then the central organization could coordinate with State and local police. The commenter indicated that this would reduce the confusion and workload on both the licensees and the LLEA and help to maintain a healthy working relationship and be more effective. Some commenters noted that clarification would be needed to address cumulative time where 7 days are not consecutive and to better define the boundary of a temporary jobsite for jobs along pipelines. Commenters indicated that it would be difficult to identify LLEA with jurisdiction over

temporary jobsites, noting issues with overlapping jurisdictions, moving jobsites, offshore locations, etc. Commenters stated that this would impose a huge burden without meaningful benefit. Most commenters indicated that the LLEA would not be interested in receiving temporary jobsite notifications. Commenters indicated that LLEAs would respond in the case of an emergency whether there was an advance notification or not. No LLEAs provided comments.

In addition to those commenters that provided responses to the questions, 32 commenters provided comment on the issue of LLEA notification for temporary jobsites. Most of the commenters objected to the requirement to notify LLEA for work at temporary jobsites. Commenters thought that the requirement was unrealistic and created an unnecessary burden, both in personnel and operations. One licensee noted that its company had over 5,000 jobs a year that would meet the requirement and that in addition many jobs, that were to be less than 7 days, experience delays that are beyond the control of the company. Commenters noted that the paperwork for the notifications will be time consuming to produce and, if it is to be valuable, time consuming for LLEAs to read and comprehend. Many noted that there is no practical means to identify the appropriate LLEA, particularly in areas that the licensee is not familiar with, and in some cases a temporary jobsite might cover a very large area with several overlapping jurisdictions, and it can be difficult to determine which agency is the first responder. Commenters noted that many times licensees are notified of the necessity of work on the same day the work is required and don't know 3 days in advance, with one commenter noting that only about 3 percent of its jobs are known 3 days in advance. Commenters noted that these jobs often involve repair of critical oil and gas infrastructure which could be delayed while attempting to determine which LLEA has jurisdiction and coordinating with them, creating significant cost to the industries with no benefit. One commenter suggested that, if the provision was retained, it be modified to require the notification be made within three business days

subsequent to beginning work as this would alleviate some of the problems created by advance notifications.

Some commenters noted that the LLEAs do not want to receive these notifications and would be unprepared to receive the notifications. Some commenters thought that the contacts with the LLEA without possible response from the LLEA may accomplish nothing but aggravation and frustration for the LLEA. One commenter (a State) indicated that, based on a survey of LLEAs, the LLEAs want to know about a temporary jobsite, no matter how long the site will be used, so they can plan for emergencies. The commenter indicated that the LLEA would like a standardized form to be used by States that clearly indicates the high priority of the information. Many commenters noted that the 911 system is the best tool if there was an attempted theft and that responders would quickly respond once they realized that radioactive material was involved. Commenters noted that it is expected that the LLEA will respond to a security event in fulfillment of their responsibility to protect life and property and that in many jurisdictions LLEA resources are somewhat limited. Commenters felt that the NRC lacked a true understanding of the nature of the temporary jobsite work that is done or the concept of using the 911 system when law enforcement is needed. At least one commenter felt that the NRC was placing the licensee in a position that would likely result in unintentional violations to the rule. Commenters felt that due to the itinerant nature of temporary jobsites and being constantly on the move, it would be very difficult to plan a theft in the field setting. One commenter noted that licensees are already required to negotiate and pay for reciprocity, as well as inform the applicable State agency as to when and where operations are planned and the duration of the project and that expansion of this requirement to include local authorities was asking a lot.

One commenter suggested an alternative of requiring daily contact with the home office and noted that failure to contact would prompt an investigation by the home office which would

lead to LLEA notification as appropriate. Commenters asked who will offer training to every jurisdiction and who will subsidize those jurisdictions, current local budgets being what they are.

Response: After reviewing the comments received on this issue, the NRC has decided not to include the LLEA notification for work at temporary jobsites in the final rule. While there is some limited benefit in receiving the notifications, the benefit does not outweigh the burden that the requirement would impose. Identification of the appropriate LLEA would not be easy. The notifications could also cause confusion among the LLEAs as to what they should do with the information. In the event of a theft, the licensees will likely call 911, and the LLEA will respond as appropriate to the call. Also, as pointed out by the commenters, companies often don't know where they will be working in advance. Locations, particularly along pipelines, shift consistently making it difficult to know who to contact.

Comment C49: One commenter suggested that instead of mandating the licensees to take on this burden, the Commission's approach should be to encourage licensees to offer LLEAs their expertise and offer some form of training to the local departments. The commenter noted that the Increased Control Orders require the licensees to establish their presence with LLEAs as the facilities clearly are a much more attractive target to an attack than the mobile fleets. The commenter suggested that an adjustment in the rule encouraging a closer relationship in this area would be more accepted by all parties involved and would not overly impact said parties financially or on a personnel basis. Creating a program that encourages and supports licensees and LLEAs working together would or could create close relationships that will have far more impacting and lasting results than calls to the departments advising them of work that is proposed to last more than 7 days.

Response: The NRC has not included the notification provision for work at temporary jobsites in the final rule, and there are no requirements for training affected LLEAs. See the response to comment C48. The NRC recognizes the benefits to licensees of having a close

working relationship with the LLEA for the security of any jobsite, permanent or temporary. Licensees are free to take whatever actions they feel are appropriate to develop this type of working relationship.

Comment C50: One commenter noted that the temporary jobsite notification could be via e-mail and that e-mail is generally unsecured unless it is encrypted or sent as password protected attachments. The commenter noted that the rule does not contain any restrictions as outlined in Regulatory Issue Summary 2005-31.

Response: The provision for LLEA notification for temporary jobsites is not included in the final rule. See the response to comment C48.

Comment C51: Some commenters objected to the concept of a security zone because they believe it is abstract, nebulous, and unworkable in actual work environments of the types of licensees who must comply with the regulation, and unnecessary and burdensome with no benefit. Commenters felt that the concept would cause confusion. Commenters stated that it would add an unneeded term and concept that would likely lead to confusion and would add burden with little intrinsic benefit. The commenters noted that the licensees' procedures that have been put into place to meet the current orders create security and have been verified through inspections and that no change is necessary. Two of the commenters stated that the security zone concept was discussed during the orders working group process and that the concept was not incorporated in the orders. The two commenters indicated that this had the appearance of an attempt to incorporate in rule a concept that did not have consensus and was not incorporated after going through the orders working group process. One commenter noted that the industrial use of radioactive materials when used at its facility is essentially a security zone because facility access is restricted due to ITAR requirements. This commenter said it should be sufficiently secure to set up restricted areas based on the radiation level and monitor the material until it is secured in storage. One commenter noted that the increased controls are

in place, and it was not aware of any situations that have occurred that now warrant the inclusion of a security zone designation.

Response: While working groups for the orders may not have been able to reach a consensus on an issue, this does not mean that the working group for the rule was unable to reach consensus. The 10 CFR part 37 rule working group had information available that was not available to the orders working group. The 10 CFR part 37 working group considered the orders, lessons learned, implementation issues, inspection issues, recommendations from other reviews, as well as the comments on the preliminary rule language and proposed rule. The purpose of security zones is to isolate and control access to category 1 and category 2 quantities of radioactive material to protect them more effectively and deter theft or diversion. A security zone effectively defines where the licensee will apply these isolation and access control measures. It is thus a logical extension of the requirement in the Increased Control Orders that licensees “control access at all times to [category 1 and category 2] radioactive material quantities ... and limit access to such radioactive material and devices to only approved individuals who require access to perform their duties.”

Because the purpose of security zones is different from the radiation safety purposes of the restricted areas and controlled areas defined in 10 CFR part 20, the security zone does not have to be the same as either of these areas. Because measures to control access are required for both radiation protection and security, however, a licensee does have the flexibility to use an area required for radiation protection purposes to fulfill the required functions of a security zone.

Comment C52: One commenter noted that the security zone concept potentially has serious operational and financial repercussions and is expensive overkill. The commenter noted that adding continuous barriers could be extremely expensive and may introduce scattered radiation into labs that have very specific operational requirements. The commenter

noted that isolating and controlling access does not appear to comply with the requirements for the physical barriers and that locks, cables, etc. would not isolate the same radioactive material in a security zone as required. The commenter noted that individuals could frequent the security zones but still be separated from the radioactive material due to the lock but that the rule requires that only authorized individuals have access to the security zones. The commenter stated that these two concepts seem to conflict with each other and if the common physical barrier concept is not acceptable, then many more licensees will fall under these requirements due to the aggregation of radioactive material. The commenter noted that it would cost over \$200,000 to develop continuous barriers and redo calibrations, procedures, etc., if it can be done at all. The commenter suggested allowing the licensee to propose measures to compensate for the lack of a continuous barrier when that barrier would obstruct the use of the radioactive material for its intended purpose and when there is no available alternative.

Response: A continuous barrier is not the only method that a licensee can use to meet the requirement. Direct observation is also allowed, as is a combination of barrier and direct observation. A continuous barrier does not have to be expensive; it can be a metal cage or walls. The commenter seems to believe that unauthorized individuals cannot be in a security zone. This was not the intent of the rule. Unauthorized individuals can have access to the security zone as long as they are escorted by an approved individual. The rule language has been clarified, and additional information has been added to the implementation guidance. The licensee can establish the boundaries of the security zone as appropriate for a particular facility; the rule does not dictate where the security zone is located. In most cases, whatever a licensee used to meet the orders will also meet the 10 CFR part 37 requirements. The Increased Control Orders did not use the term “security zones” but the concept was a factor.

Comment C53: One commenter expressed concern with the security zone concept at temporary jobsites. The commenter noted that implementation would require additional

personnel and expense, and the security zone will require areas that will be larger than the radiation areas. Another commenter noted that the concept could cause confusion in certain types of jobsites where aggregation of multiple low level sources would constitute a security zone. The commenter provided the example of petrochemical plants that use low level sources to monitor product levels, noting that aggregation of these sources will constitute a security zone which would require direct control by approved individuals at all times and/or intrusion detection systems and physical barriers. The commenter felt that this could mean that the entire plant would be a security zone, and only trustworthy and reliable employees could enter.

Response: The NRC disagrees with the comment. It is not clear why the security zone concept would result in additional personnel and expense, or why it will require security zones larger than the radiation areas at either temporary or permanent jobsites. A security zone effectively defines where the licensee will apply the isolation and access control measures required under the Increased Control Orders. The NRC is unaware of any operating conditions that would require more space for compliance with any of the additional measures required by this rule. The licensee establishes the security zone, and because measures to control access are required for both radiation protection and security, a licensee has the flexibility to use an area required for radiation protection purposes to fulfill the required functions of a security zone. The NRC is unaware of any petrochemical or other industrial plants that have designated the entire plant as a radiation safety area for their radiography or other sources, and the NRC sees no reason why such licensees or licensed service providers would need to designate the entire plant a security zone for the purposes of this rule. A licensee could of course choose to do so.

Because the concept of aggregation is no different from the concept of aggregation and co-location under the orders, it is not clear why the application of security zone requirements would result in confusion at jobsites where multiple low-level radiation sources are aggregated.

Comment C54: Several commenters requested clarification on what constitutes a physical barrier and recommended that physical barrier be either defined or guidance provided. Another commenter suggested changing the term to physical security barrier to avoid confusion with the definition of physical barrier in 10 CFR part 73. One commenter suggested the physical barrier is where the security zone has been established.

Response: The NRC has revised § 37.47(c)(1) to provide additional clarity. This provision now notes that a physical barrier is “a natural or man-made structure or formation sufficient for the isolation of the category 1 or category 2 quantities of radioactive material within a security zone.” Additional information has also been added to the implementation guidance.

Comment C55: One commenter asked how many security zones needed to be designated and noted that the rule is unclear for those licensees within fixed facilities.

Response: The licensee is responsible for establishing security zones. The number of security zones established by a licensee is dependent on the needs of the licensee. A licensee may have only one security zone or may have several.

Comment C56: One commenter recommended including a provision in § 37.47 that exempts the security zone requirements for category 1 or category 2 quantities of material stored in casks or packages that require specialized equipment to move, open, or access, if the equipment needed to access the material is unavailable. One commenter noted that the continuous monitoring of security zones and detection capability is a significant additional cost without any benefit for category 1 and category 2 materials that may be stored at a nuclear facility in a concrete mausoleum or within individual concrete vaults that require heavy equipment, such as a crane, to access. One commenter stated that clear criteria for applicability would be needed to implement security zones. The commenter offered the example of multiple high integrity containers with lids weighing 10 tons, each inside a shield, stored inside a fenced common area which contains, in the aggregate, a category 1 or category

2 quantity of radioactive material and no crane in the area to lift the shield container lid. The commenter stated that establishing a security zone for the common storage area is required and that this is excessive.

Response: A licensee can always request an exemption for material or items that it believes should be exempt from all or some of the 10 CFR part 37 requirements. Exemptions are handled on a case-by-case basis. Some of the material addressed by this comment is covered by the partial exemption in § 37.11(c). *See also* response to comment A20.

Comment C57: One commenter noted that large manufacturing and distribution facilities will have several security zones with significant quantities of category 2 sources in storage and that it would be impossible to perform an effective physical check on a weekly basis. The commenter also noted that a weekly check is not consistent with the ALARA principle. The commenter noted that putting tamper indicators on each source/device would be cost prohibitive and require a significant amount of time and personnel dose to install, monitor, and subsequently remove. The commenter noted that sources are constantly transferred from one container to another in the course of manufacturing, storage, and preparing for shipment and receiving. The commenter requested clarification as what “other means” would cover and/or be acceptable in § 37.49(a)(3)(ii). The commenter noted that under the orders it has a method approved by the Regulatory Authority to ensure that the category 2 radioactive material is present and that the process is considered SGI-M information. The commenter wanted to know how such pre-existing compliance agreements would be handled under the rule. The commenter also requested clarification on the situation where there are individual sources that are each less than category 2 but when they are collocated/aggregated the total quantity exceeds category 2, whether the individual sources need to have this physical check performed. The commenter noted that depending on the answer, the quantity of sources affected at a large facility could be more than a thousand and that this would affect many smaller facilities including

medical institutions, universities, and gauging. The commenter noted that the requirement has significant implication and needs to be carefully considered to avoid unintended adverse consequences.

Response: The licensee is not required to conduct a weekly physical inventory of the category 2 quantities of radioactive material; other methods can be used. The other means allowed by the rule are intended to provide the licensee with the flexibility to use the method that works best for its facility. A licensee could use methods to detect removal of the material from the security zone. If a licensee is currently using an agreed on method, the method should continue to meet the intent of the requirement. Any of the methods deployed for category 1 materials could also be used for category 2 materials. Additional information is available in the implementation guidance.

Comment C58: One commenter requested clarification on where an NRC security zone at a licensee site and a DOT security zone for transport take effect for shipments leaving a facility. One commenter noted that the NRC should clarify at what point the shipment is under DOT rules and not under 10 CFR part 37. The commenter asked if this occurs once a shipment of category 1 or category 2 radioactive material is prepared (DOT paperwork in possession of the driver) but still on a licensee's site. The commenter noted that a temporary security zone cannot accompany the shipment until it physically exits the licensee's property or jobsite.

Response: It is the licensee's responsibility to implement the requirements of 10 CFR part 37 throughout the shipment regardless of the location.

Comment C59: One commenter noted that § 37.47(d) is not clear whether the regulation requires a physical presence for maintaining continuous surveillance, or whether the continuous surveillance may be by remote monitoring. The commenter also noted that the wording implies that the licensee must provide an approved individual and questioned whether

the service provider approved under § 37.29(m) is permitted to provide the continuous surveillance while working.

Response: The continuous surveillance may be by remote monitoring. If a service provider has been approved for unescorted access, then the individual can provide the surveillance. It is noted that if that individual is conducting work of some sort, it may be difficult for that individual to also maintain continuous surveillance.

Comment C60: One commenter noted that § 37.47(d) requires additional measures for security zones for category 1 radioactive material during maintenance, source receipt, etc. when security zones are compromised and that permanent security zones are required in § 37.47(c) for both category 1 and 2 radioactive material. The commenter questioned why the additional measures are required only for category 1 radioactive material if the security zones are compromised during certain times. The commenter noted that it appears that the isolation requirements for radiation protection under restricted, radiation, high radiation and very high radiation areas provide the same or better levels of security than those described (*i.e.*, continuous physical barriers that allow access to the security zone only through established access control points; or licensees could exercise direct control of the security zone by approved individuals at all times). The commenter noted that you do not need to have duplicate regulations that apply to category 1 and category 2 quantities of radioactive material.

Response: The additional measures are only required for the category 1 material because these materials are considered higher risk than the category 2 materials. A security zone can be the same as the area used for radiation protection if it meets the requirements of part 37. The measures in part 37 are intended to prevent/detect theft of the material and not to protect an individual from radiation exposure.

Comment C61: One commenter noted that § 37.47(d) indicates that during those identified periods an approved individual must be provided to maintain continuous surveillance

of the sources. The commenter noted that “approved individual” is not defined. The commenter also noted that depending on the design of the facility, multiple approved individuals may be necessary to adequately monitor activities throughout a site, which does not appear to be clearly required by the rule.

Response: The NRC agrees with the comment and has revised the rule to clarify that an approved individual is someone approved for unescorted access and to reflect that more than one individual may be necessary.

Comment C62: One commenter recommend deleting the phrase “without delay” from § 37.49(a)(1) as the phrase is unrealistic during normal business hours. The commenter noted that unauthorized access whether actual or attempted would only be detected “without delay” if individuals were in the vicinity and could witness the access or attempt to access. One commenter stated that the monitoring, detection and assessment requirements in § 37.49 are unduly onerous. The commenter indicated that the requirement to maintain the capability to detect without delay attempted unauthorized entry into the security zone should be eliminated or defined in a more concrete manner for the sake of clarity in enforcement. One commenter asked how much time is allowed for response when an unauthorized entry into the security zone is discovered. The commenter also asked for clarification on the meaning of without delay. One commenter requested clarification on what is meant by detect without delay all unauthorized entries into a security zone. The commenter asked if the licensee was to respond immediately and also asked how this could be accomplished when using an alarm monitoring service. The commenter recommended removing “without delay” from § 37.49(a)(1). The commenter stated that “without delay” is unrealistic during normal business hours as a business’ security system will not be set to alarm. The commenter noted that areas that may contain category 1 or category 2 quantities may be locked and unoccupied but not monitored. The commenter noted that unauthorized access whether actual or attempted would only be detected

“without delay” if individuals were in the vicinity and could witness the access or attempt to access.

Response: The NRC disagrees with the comment. The NRC notes that the orders contain a similar provision to immediately detect, assess, and respond to unauthorized access. “Without delay” means promptly or immediately. The purpose of security provisions is to quickly detect and respond to any potential theft of the material. The NRC further notes that, if a licensee is merely locking the material in a room and not implementing any other security provisions, they would not be in compliance with the orders or the rule. No change has been made to the rule.

Comment C63: One commenter noted that the intent of § 37.49(a)(1), in the event of a power failure or tampering that affects the monitoring and detection system, should be to provide 1) a reliable power back up or 2) prompt notification of the power failure/tampering such that the licensee will take immediate corrective action to restore the power and provide for alternate monitoring and detection that meets the requirements of the part until the system is repaired. One commenter asked what the NRC’s expectations were for implementation of the security requirements in an emergency, including the expectation as to how long backup systems were required to operate. The commenter asked how a licensee is supposed to implement these requirements when there are no provisions for individuals to even reenter a disaster area.

Response: The backup power for the monitoring and detection system needs to be available until power is restored or other measures need to be used such as direct surveillance. Disaster situations such as flooding or earthquakes that prevent entry to the facility would be addressed on a case-by-case basis.

Comment C64: One commenter stated that § 37.49(a)(2)(ii) should contain a more accurate description such as “...alert personnel within audible range of the alarm.” Another

commenter noted that “nearby” needed to be clarified as NNSA representatives recommended only silent alarms in the area immediately surrounding category 2 sources.

Response: The NRC believes that the language is appropriate and has not revised the rule. Additional information is provided in the implementation guidance document.

Comment C65: Two commenters recommended adding a 4th method to § 37.49(a)(3)(i) to allow security zone intrusion detection alarms. The commenter explained that when the intrusion detection system is monitoring the security zone, an attempt to gain unauthorized access into the security zone results in an alarm that is equated to an attempt to remove or sabotage the material. The commenter noted that during normal business hours when an intrusion detection alarm to a security zone is disabled the licensee prevents unauthorized access into security zones with locks, physical barriers, and surveillance or some combination of each. The commenter stated that it is during these periods that a tamper-indicating alarm or radiation detection alarm or video surveillance could alert the licensee of an unauthorized attempt to remove radioactive material from the security zone. The commenter stated that, if the method is not added, revision is needed in the implementation guide that allows the licensee to rely on its main site wide intrusion detection system when the intrusion detection system is activated, the facility is not occupied by the licensee, AND the intrusion detection system can detect access to the security zone.

Response: The NRC disagrees with the comment that a 4th method needs to be added to the rule. Although this is not the preferred method, the situation described in the comment is not prohibited under the rule. Additional information has been added to the implementation guidance.

Comment C66: One commenter asked whether a tamper device was sufficient to verify the presence of material or would a weekly check still be necessary. One commenter noted that a weekly verification should only be performed for sources/devices that do not have

tamper-indicating devices. Another commenter stated that the weekly check was too prescriptive and asked about the basis for the timeframe. Another commenter stated that a weekly check was not adequate. The commenter noted that the orders require the licensee to respond immediately to any actual or attempted theft, sabotage, or diversion and that a weekly check would allow the material to be missing for up to a week before it is discovered. The commenter suggested that § 37.49(a)(3)(ii) be revised to read: “For category 2 quantities of radioactive material, the licensee must maintain control of licensed material, secure it from unauthorized removal or access, and without delay, detect and recover all stolen, missing or lost licensed material.” One commenter stated that verification of the radioactive material may not be appropriate for sources housed in devices. The commenter suggested requiring verification “to ensure that the source/device is present” and suggested that this verification could be made by means of a camera in the room housing the device/source.

Response: Category 2 quantities of radioactive material are considered risk-significant and if not in use, the material needs to be checked to make sure it is still present. Contrary to the comment, the rule is not prescriptive. The rule does not require that a licensee conduct a physical check. The rule allows the licensee to pick a method that best fits its needs; a physical check is one of the methods that could be used. There are many other methods that could be used to conduct the verification. Tamper indicating devices are considered adequate to meet the requirement. The licensee can also use methods to detect removal of the material.

Comment C67: One commenter suggested deleting the weekly verification for category 2 quantities in § 37.49(a)(3)(ii) and include the category 2 material in the category 1 material requirement for continuous surveillance. The commenter noted that the provision implies that it may be acceptable for a missing category 2 quantity of material to go undetected for up to a week when this is clearly not the case.

Response: Category 1 quantities of radioactive material are considered higher risk than category 2 quantities of radioactive material. Therefore, there are more requirements on the category 1 material. The commenter is correct, however, that the NRC does not mean to imply that it is acceptable for missing category 2 materials to go undetected for a week. A weekly verification is just one of several acceptable methods to make sure that unauthorized removal of the material has not occurred. Each licensee must determine its own compliance strategy to meet the security requirements of this rule, but the rule provides significant latitude for each licensee to comply in a way that optimizes its individual operating requirements.

Comment C68: Two commenters stated that the monitoring and detection requirements of the security program need to be more prescriptive, with a minimum requirement for electronic sensors and a detection system linked to an onsite or offsite monitoring facility. The commenters did not believe that allowing monitoring and detection to be performed only by visual inspection or direct visual surveillance was adequate. The commenters noted that the concepts of detection, delay, and deterrence are best implemented through multiple tiers of security. The commenters stated that in the scenario of armed terrorists with explosives attacking a facility, reliance on individuals to be the sentinels would allow the security program to be defeated rather easily.

Response: While the NRC agrees that defense in depth is always a good practice, the NRC believes that allowing direct visual surveillance is appropriate. The NRC attempts to balance the burden of imposing additional requirements against the risk of the material and the added protection a measure provides.

Comment C69: One commenter stated that the requirement to have a means to detect unauthorized removal of the radioactive material from the security zone was unnecessary and would create a huge burden to establish. The commenter also noted that the requirement does not even account for the fact that the alarm has to be monitored or by whom.

Response: The purpose of the security program is to detect and prevent unauthorized removal of the category 1 and category 2 quantities of radioactive material. The provision in question does not require an alarm. If alarms are used, the licensee has flexibility in determining who conducts the monitoring and who responds.

Comment C70: One commenter asked what the NRC's expectation was for implementation of the requirement to immediately detect any attempted unauthorized removal through the use of electronic sensors linked to an alarm. The commenter wanted to know if the electronic sensors are to be mounted to the actual source, hot cell, or storage area. The commenter noted that there are numerous ways to shield radioactive material, therefore, the method has to be able to detect an unauthorized removal of a shielded container, and using a building or area alarm is specifically not allowed.

Response: The NRC assumes the commenter is referring to the requirements in § 37.49(a)(3). This requirement is in addition to the requirements in §§ 37.49(a)(1) and 37.49(a)(2). Licensees must be able to detect the unauthorized removal of a category 1 source. Licensees can choose any method to detect unauthorized removal. Some methods that the licensee may use to meet this requirement include, but are not limited to, the following:

- Alarming electronic tamper-indicating device;
- Alarming radiation detector; or
- Visual surveillance by an approved individual.

If a licensee uses electronic tamper-indicating alarms, the alarm should be capable of alarming either when an attempt is made to remove a category 1 quantity of radioactive material from a device, or when an attempt is made to remove the device itself. The tamper-indicating alarms should be armed at all times, except during periods of maintenance.

Comment C71: One commenter stated that it is an unreal expectation that licensees can assess an attempted unauthorized entry and that the requirement should be removed as

there is no resulting gain in security. The commenter noted that this increases the surveillance burden on licensees to monitor not just access but attempted access. As an example the commenter noted the situation where someone walking by tries to open the door and the licensee would be required to be able to detect that and assess. For the same reasons, the commenter stated that the requirement to respond to attempted unauthorized access should also be removed. Another commenter felt that the requirement was too broad. This commenter also noted the situation where someone (including an inspector) tries a locked doorknob of a secured area. The commenter noted that there is no point in responding to this sort of challenge to the system as long as the door remains locked as there is no security benefit gained by responding to this type of situation. The commenter stated that to prevent and reduce unnecessary responses to this sort of trivial challenge, a continuous watchman would be needed or a locked door outside the security zone to prevent access to the boundary of the security zone to keep individuals away from the security zone. The commenter suggested the following change to the rule text: "The licensee shall immediately respond to any action that breaches the perimeter of the Security Zone." One commenter noted that § 37.49(d) requires the licensee to immediately respond to any actual or attempted unauthorized access in addition to requesting an armed LLEA response. The commenter noted that presumably this means the alarm service will notify the LLEA on behalf of the licensee as requiring the licensee to physically respond could put them in harm's way should the intruder be armed. The commenter also asked what other actions the licensee should take (*i.e.*, do surveys, inventory material, etc.).

Response: The NRC disagrees with the comment. The NRC believes that it is important to assess the attempts to gain unauthorized entry. An individual could test the system before an actual break-in to steal the material.

Comment C72: One commenter pointed out that the NRC supported and recommended that licensee's volunteer to participate in the NNSA GTRI program. The commenter noted that the rule does not acknowledge or differentiate its requirements for fixed facilities which have completed or are in the process of completing participation in the GTRI and that the NRC should acknowledge the differences between facilities that merely meet the NRC requirements and those that have the robust security provided by the GTRI. The commenter stated that licensees will be unable to meet specific requirements prescribed in proposed part 37.

Response: The NRC does support the GTRI program that provides security upgrades to licensee facilities. However, all licensees are required to meet all of the requirements of 10 CFR part 37 regardless of participation in the GTRI program. Licensees that participate in the GTRI program may take credit for those upgrades that meet the 10 CFR part 37 requirements.

Comment C73: One commenter asked how long the continuous (primary or alternative) communication capability must continue to be operable. The commenter asked what arrangements need to be made to maintain the capability in any emergency. The commenter noted that there is no practicable means to implement this requirement as no communications systems work reliably for many hours or days, particularly if there is no power available, nor personnel allowed in the area to start a generator.

Response: During most emergencies, the licensee would be expected to maintain operability of either the primary or alternative system throughout the emergency. Disaster situations such as flooding or earthquakes that prevent entry to the facility would be addressed on a case-by-case basis.

Comment C74: One commenter noted that guidance on allowable dose limits should be added to § 37.49(d) for LLEA first responders. The commenter noted that most licensees are probably following the EPA's Protective Action Guidance of 25 rem whole body dose for

life-saving actions and protection of large populations and that it would be helpful to have guidance on what to plan for, as part of LLEA training.

Response: The NRC disagrees with the comment and notes that guidance does not belong in the regulations. First responders are subject to the dose restrictions in State or Federal occupational safety regulations.

Comment C75: Several commenters suggested revising the frequency of the testing, maintenance, and calibration requirement. One commenter questioned the technical basis to require operability and performance testing of intrusion alarms and communication systems every 3 months and asked if the frequency was supported by industry data or a probabilistic risk analysis from the nuclear power industry. Another commenter stated that the test frequency for a device should have a relationship to the device's known failure rate. Another commenter stated that the requirement was extremely vague, questioned what standard things are to be tested and calibrated, what performance standard should be used, and noted that the timeframe was arbitrary. The commenter suggested that annual testing would be more consistent with other requirements. One commenter suggested every quarter at intervals not to exceed 5 months. The same commenter also suggested adding "Equipment without a known failure mechanism shall be tested after initial installation and at a frequency not to exceed 10 years." One commenter suggested a monthly frequency, another suggested an annual frequency. One commenter stated that testing should be more frequent than quarterly but did not specify a timeframe. One commenter suggested testing every 6 months and noted that testing required 40 man-hours to complete. One commenter stated that any testing should include verification of the notification process to the responding individuals, including the LLEA, on at least an annual basis. One commenter recommended an annual requirement to exercise the assessment and response portions of the physical protection systems including an invitation to the LLEA to participate if reasonable to do so. One commenter stated that an annual requirement should be

included that exercises the assessment and response portions of the physical protection systems.

Response: The NRC reevaluated the testing frequency. The requirement has been changed to allow the licensee to conduct the maintenance and testing at the manufacturer's suggested frequency. The manufacturer's suggested frequency would presumably account for known failure rates. If the manufacturer does not suggest a frequency, the testing must not exceed 1 year.

The NRC agrees that exercising the response portion of the security plan is a good practice, and we encourage licensees to exercise their plans with the LLEA. However, requiring licensees to exercise their response plans may be too burdensome for small licensees with less complex security plans.

Comment C76: One commenter stated that the rule and guidance should allow licensees to limit testing of alarms, associated communication systems, and other physical components of the security system to those alarms, systems, and components necessary to meet the requirements. The commenter pointed out that testing all alarms, systems, and components quarterly is a long-term financial burden and could result in licensees removing all unnecessary alarms, systems, and components. The commenter noted that requiring only testing of necessary equipment leaves the requirement open for interpretation but that performance-based regulations should allow for a risk-based analysis. The commenter stated that testing of all alarms places an unnecessary burden on licensees and will encourage licensees to minimize the number of alarm points in a system which is counter to the intent of this regulation. Testing of necessary alarms will show that the system is functioning appropriately. Another commenter noted that some devices may require partial disassembly of the equipment for testing and that repeated disassembly and reassembly for testing purposes could lead to premature failure or wear on components. The commenter suggested that

internally installed detection devices be allowed to be tested on an annual basis, which could coincide with an annual preventive maintenance of the equipment. One commenter noted that the rule needs to be modified to indicate what testing is required. One commenter requested that the following be addressed in the discussion when the final rule is published. If an alarm system/device is removed/de-energized from service because the “individual with overall responsibility for the security program” deemed the device unnecessary, obviously there are no testing/maintenance requirements; however, if the device is deemed unnecessary, but remains energized, must testing/maintenance be performed and documented?

Response: The NRC agrees with the comment. The licensee is only required to maintain and test those components that it relies on to meet the security requirements of 10 CFR part 37. *See also* the response to C75.

Comment C77: Three commenters recommended removing the requirement for calibration from § 37.51. One commenter noted that there are procedures to test and maintain these systems, but the term calibration seems out of place. Another commenter questioned how you calibrate an intrusion detection system. Several commenters requested clarification on what is expected beyond maintenance and testing. One commenter suggested changing calibration to appropriate operational checks. The commenter noted that true calibration of radiation monitors would expose staff to unnecessary radiation dose.

Response: The NRC agrees with the comment and has removed the calibration requirement. Testing the operability of a system is sufficient to ensure that the equipment is operational and able to serve its function. Some of the equipment, such as meters, relied on for safety may be calibrated, but some equipment would not be calibrated as the term is typically considered.

Comment C78: One commenter stated that it was not clear what is expected for compliance for the maintenance, testing, and calibration requirement. Another commenter asked what was considered acceptable maintenance, testing, and calibration.

Response: The licensee must ensure that the intrusion detection system (IDS) is operational and capable of performing its required function. To maintain functionality, licensees must periodically test the IDS and perform maintenance on malfunctioning components. The testing program is considered acceptable if the IDS operates in a manner consistent with the licensees' physical security plan. Licensees will be required to test the entire IDS or components of the IDS at the frequency specified by the manufacturer or at least annually. The licensee may choose to test the entire IDS or components of the IDS throughout the 12 months.

Comment C79: In the proposed rule, the NRC specifically requested comment on whether an exemption for disabling vehicles should be provided in certain hazardous situations. Commenters were requested to provide information on: 1) whether relief from the vehicle disabling provisions should be provided; 2) any problems experienced in implementing this aspect of the Increased Controls; 3) whether there should be an exemption written into the regulations or should licensees with overriding safety concerns be required to request an exemption from the regulations to obtain relief from the provision; 4) whether any exemption should be a blanket exemption or a specific exemption for the oil and gas industry; and 5) whether the disabling provision conflicts with any Occupational Safety and Health Administration (OSHA) requirements or any State requirements. Fourteen commenters provided responses to the specific questions on this subject.

Of those that provided responses to the questions on the exemption for disabling vehicles when a mobile source is in or on the vehicle, the majority supported providing some sort of relief from the vehicle disabling provisions where there is a potential threat due to the work environment, such as a refinery or oil field. Only one commenter opposed providing relief.

A couple of commenters did indicate that they had had problems in implementing the vehicle disabling requirement under the Increased Controls, some commenters noted that the provision was in opposition to the facility safety rules. A couple of commenters noted that the requirement was in conflict with OSHA and/or State requirements. On the question of whether an exemption should be written into the regulations or handled on a case-by-case basis, the commenters were split, but a slight majority favored writing the exemption into the regulations. Those supporting the exemption being written into the regulations noted that providing an exemption on a case-by-case basis creates a burden on the licensee to prepare the request and on the regulatory agency to review the request. One of the commenters supporting the regulatory exemption still felt that the licensee should provide adequate justification for claiming the exemption. Those not supporting the regulatory exemption felt that the case-by-case review would allow the regulator to review whether the exemption was actually warranted. Two of the commenters stated that the requirement should be removed as the requirement to remove the ignition key is not warranted and unnecessary. On the question of whether an exemption should be specific for the oil and gas industry or be broader, most commenters supported a blanket or broader exemption. One commenter suggested a blanket exemption for all category 2 sources. On the question of whether the disabling provision was in conflict with OSHA or any State requirements, three commenters indicated a possible conflict but did not provide any specifics.

In addition to those that responded to the specific questions, five commenters provided comments on this topic. One commenter noted that the requirement for disabling mobile sources presents safety concerns within a refinery or petrochemical plant. The commenter noted that individuals must be able to quickly evacuate the site in the event of an emergency and that unoccupied vehicles must be able to be moved by other evacuees or emergency responders. The commenter noted that requiring a secondary securing device other than the

key from a vehicle prevents the easy movement of the vehicle and compromises safety in the event of an emergency. One commenter indicated that relief should be provided on an as-needed basis. Another commenter noted that there is a possibility that an individual using a mobile device needs to evacuate an area quickly and that using a disabling device could jeopardize the health and safety of the individual. The commenter suggested the following language: "For devices in or on a vehicle or trailer, the licensee shall secure the vehicle or trailer containing the device from theft when not under the direct control of the licensee. This may be accomplished by removing the ignition key and arming a vehicle alarm system, or through the use of disabling device or by the removal of component that would result in the inability to operate the vehicle or trailer." One commenter stated that further guidance was necessary on what was meant by disable and that the commenter assumed that the disabling was temporary. One commenter indicated that any exemption should be broader than just for the oil and gas industry. One commenter recommend revising § 37.53(b) to allow credit for removing the key from the ignition and maintaining the key with the individual. The commenter noted that a disabling device could add additional risks to the worker; for instance, if the device fails, the individual may become stranded, or it may slow emergency egress.

Response: After consideration of the comments on this issue, the NRC has decided that an exemption should be added to the regulations instead of doing reviews on a case-by-case basis. Requiring licensees to submit an application for an exemption that would in most cases be approved imposes unnecessary burden on both the licensee and the agency staff. The NRC has also decided that the exemption should be broader than for just the oil and gas industry as there are other situations where a similar health and safety issue may arise. The NRC has revised § 37.53(b) to provide flexibility for situations where the health and safety requirements for a site prohibit the disabling of the vehicle.

Comment C80: One commenter indicated that the terms “mobile” and “portable devices” are used differently in 10 CFR part 37 than elsewhere in the regulations. The commenter stated that the NRC should change the terminology or the requirements be changed to be applicable to already defined mobile and portable devices.

Response: The NRC disagrees with the interpretation that the terms “mobile” and “portable devices” are used differently in 10 CFR part 37 than elsewhere in the regulations. The usage of the terms in 10 CFR part 37 is in agreement with previously issued NRC guidance. Specifically, the Increased Controls Question and Answer #159, provides guidance for definitions for “portable” and “mobile” as provided by the American National Standard for Gamma Radiography.

Comment C81: A few commenters suggested a change to the timing of the program reviews. Commenters suggested an annual frequency not to exceed 14 months between the dates of the reviews, a timeframe of 15 months, a timeframe of 8 to 15 months, and language similar to § 20.1101 of periodically (at least annually). The commenters noted that this would provide some flexibility to allow for circumstances beyond the control of the workforce. One commenter noted that the program review could be eliminated and included under § 20.1101(c). One commenter stated that the review should include a requirement for the licensee to summarize those occasions where an unauthorized access resulted in activation of the monitoring and detection systems, but the licensee’s assessment showed no actual or attempted theft or diversion of radioactive material as such alarms could be indicative of a ‘probe’ to test or evaluate a licensee’s response by a potential intruder.

Response: The NRC agrees with the comment and has revised the language for the program review to be consistent with § 20.1101. The use of consistent terminology between the safety and security programs should enhance the licensee’s understanding of the requirement.

The NRC does not believe that it is necessary to add additional detail on what must be included in the program review.

Comment C82: One commenter noted that § 37.55 introduces the term “radioactive material security program” which should be clarified and consistently used in the regulations.

Response: The concept of the security program is introduced in § 37.41. The NRC believes that the term has been used consistently in the regulations and that the concept is clear. The implementation guidance contains information on the security program.

Comment C83: One commenter requested clarification on what radioactive materials should be included in the security program review.

Response: Part 37 only applies to category 1 and category 2 quantities of radioactive material. The security program review would only address the security of the category 1 and category 2 quantities of radioactive material.

Comment C84: One commenter indicated that the LLEA required it to file Non-Residential Burglary Alarm Registrations for each room in which an irradiator is housed (and to which they are expected to respond in the event of an alarm). The commenter noted that the LLEA has indicated that an LLEA response is deemed false if no evidence of criminal activity is found, in which case a “False Alarm Notice” will be served, including penalties escalating up to \$4000 for requested LLEA responses that are judged to be false. The commenter noted that this places the licensee in a very bad position to attempt compliance with this regulation and risk fines from the LLEA. The commenter noted that there does not need to be evidence of criminal activity for the licensee to perceive a threat to its facility, and appropriately request LLEA response. The commenter requested that NRC conduct outreach to the LLEA community with the intent of clarifying NRC’s expectations on this topic.

Response: Section 37.57 states that the licensee shall immediately notify the LLEA after determining that an unauthorized entry was an actual or attempted theft, sabotage, or diversion

of a category 1 or category 2 quantity of radioactive material. The NRC believes that such an unauthorized entry would likely constitute criminal activity. Furthermore, suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material would also constitute suspicion of criminal activity. When coordinating with the LLEA, the licensee must explain that it will request a timely armed response to any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of material.

Comment C85: One commenter requested that §§ 37.41 and 37.49 be revised to reflect that a licensee is restricted in detection and assessment by available technology and resources.

Response: The NRC does not believe the change is necessary. The requirements do not specify a technology, and the licensee can change the method used to meet the requirements whenever it wants, as long as the plan is updated and training conducted on the revised plan.

Comment C86: One commenter expressed concern that the vocabulary was not consistent with part 73 and that it was unclear exactly what the rule required from a security standpoint in §§ 37.41(b) and 37.49.

Response: The commenter is correct that the terminology between 10 CFR parts 73 and 37 may not be consistent. Part 37 does not have any requirement for a design basis accident and pertains to less risky materials. Part 37 applies to a different type of material and licensee in most cases. The terminology used in 10 CFR part 37 is geared for a materials licensee and not a reactor or fuel cycle facility. Guidance for implementing 10 CFR part 37 is contained in the implementation guidance.

Comment C87: One commenter stated that the proposed regulations, as applied to Gamma Knife radiosurgery units, do not give sufficient weight to engineered controls. The commenter felt that the greatest risk was during source exchange, which only occurs every 5 to 7 years, and not from someone obtaining access to the equipment overnight or on a

weekend. The commenter further stated the opinion that there is almost no danger during the ordinary operation of the equipment to treat patients.

Response: The NRC acknowledges that accessibility of a category 2 source(s) depends on the design of the device containing the source(s) and the means used to gain access to and possibly remove the source(s). However it is anticipated that an adversary will use whatever means is available to gain access to and possibly remove a source. The category 2 designation has no basis in regard to the time it would take to remove a source from the device in which it is contained. The security program is designed to deny an adversary the opportunity to gain access to a category 2 source. It is reasonable to expect that overnight and weekend periods would provide an opportunity to an adversary.

Comment C88: One commenter stated that the requirement limiting unescorted access to approved individuals would appear to preclude the treatment of patients with a Gamma Knife radiosurgery unit since the patient is required to be unescorted in the treatment room due to the high radiation levels, and the treatment room would normally be considered to be the security zone. The commenter noted that closed circuit television is used to monitor the patient rather than line-of-sight observation, and that this could be used in place of human escort for those individuals needing entry to the treatment room.

Response: A patient undergoing treatment is considered to be an escorted individual. Closed circuit television used to monitor the patient meets the requirements of §§ 37.45 and 37.47.

Comment C89: One commenter stated that for a Gamma Knife radiosurgery unit, individuals subject to background investigations should be defined as those who have the key or pass code for the treatment room door and the ability to turn off the security system and not the personnel who may need access to a patient on treatment day. The commenter stated that individuals with the keys or pass code are the ones that can enter a room and have access to

the unit for a long enough time, such as outside of normal treatment days, to remove any or all of the radioactive sources.

Response: Gamma Knife radiosurgery is typically performed by a team of individuals. The licensee has the option of escorting those team members not authorized for unescorted access. For example, the licensee may decide to grant unescorted access to authorized medical physicists and have them provide escorted access for physicians, nurses, technologists, etc.

Comment C90: One commenter noted that it is important that Gamma Knife units secured behind electronically locked doors have a backup door alarm which operates during a fire alarm. The commenter noted that hospitals are increasingly adopting electronic locks for securing rooms and that the fire code requires electronic locks to be disabled during a fire alarm. The commenter noted that frequently the door alarm and motion detector are tied into the same system.

Response: The licensee must meet the requirements of the rule. Any additional alarms or other systems beyond those used to meet the requirements are at the discretion of the licensee.

Comment C91: One commenter noted that since a Gamma Knife treatment room has a single entrance that could be controlled by an assailant, one or more panic alarm buttons, unobtrusively placed, should be installed so that the staff could summon security without being noticed. The commenter also suggested requiring use of a portal radiation monitor tied into security at the exit.

Response: The use of duress/panic alarms could be used to enhance the licensee's response plans and a radiation monitor can be used to detect a situation where a source has been removed from a device. The licensee can determine which methods it will use to comply

with the rule. Any additional alarms or other systems beyond those used to meet the requirements are at the discretion of the licensee.

Comment C92: One commenter stated that additional security measures addressing radioactive materials are not necessary in the refining or petrochemicals industry due to the location, lack of accessibility, source holder design, and currently applicable security requirements. The commenter noted that the sources are continually monitored by process control systems and there would be an immediate response, due to process safety concerns, if they were to go off-line. The commenter noted that most sources are contained within source holders bolted individually to a process column or equipment and the source holders are typically very large, heavy, cumbersome metal containers. The commenter noted that to remove the source holders requires tools, cranes, hoist or scaffold support because of their weight and position on the process equipment. The commenter also noted that the sources are not aggregated but are located within the various operating unit locations scattered over several acres.

Response: Part 37 only applies if the material is aggregated such that the total equals or exceeds the category 2 threshold. As with the orders, the licensee can take measures such that the provisions do not apply. For example, if a source holder is welded to the column and has a cage around it, the NRC has determined that this is sufficient and the sources would not need to be considered in aggregating the material. Additional information has been added to the implementation guidance to clarify what types of barriers would be sufficient.

Comment C93: One commenter noted that the type and configuration of irradiators would render the probability of their use in an act of terrorism as extremely unlikely. The commenter noted that they are stationary, weigh in excess of 1000 pounds, and are secured within segregated and separately locked facilities on a secure campus requiring separate

authorized keycard access to both the buildings themselves and the irradiator rooms 365 days per year. The commenter recommended that the NRC exempt irradiators from 10 CFR part 37.

Response: The NRC disagrees that irradiators should be exempt from the requirements of 10 CFR part 37. The requirements are designed to control access both to the radioactive material and to the irradiator by controlling access to the security zone. The NRC has engaged the expertise of national laboratories that have shown that these devices may be vulnerable to theft, sabotage, or diversion under certain scenarios. For this reason, and the possibility that the necessary trained individual could be a malevolent insider, the NRC has determined that certain additional security measures are necessary in the current threat environment. Part 37 uses a layered, defense-in-depth approach to enhance the security of radioactive material in category 1 and category 2 quantities. No single measure can provide the required security for this material. Therefore, a licensee must implement all applicable 10 CFR part 37 requirements.

D. Transportation Security

Comment D1: In the proposed rule, the NRC specifically invited public comment on several aspects of license and address verification. Commenters were requested to provide information on: 1) whether there should be a requirement for verification of the license for transfers of category 2 quantities of radioactive material or whether it would be acceptable to wait for the system being developed before requiring license verification for transfers of category 2 quantities of radioactive material; 2) how the address verification might work for shipments to temporary job sites and the ability of both licensees and the Agreement States to comply with such a requirement; 3) the frequency of the license verification, and 4) how the transferring licensee would know if a license has been modified since the last check and that the licensee is still authorized to receive the material. Seventeen commenters provided responses to the specific questions on this subject.

Of those that provided responses to the questions on license verification, most commenters indicated that the current system for license verification for category 2 quantities of radioactive material is acceptable until the license verification is developed and ready for implementation. A few commenters indicated that phone verification for category 2 would be acceptable before the new system is available; others indicated that the NRC should wait for the new system. One commenter suggested that verification not be required for shipments that result in a change of jurisdiction but not a change of licensee. Most commenters did not support a requirement for address verification for temporary jobsites, noting that in most cases the regulatory authority will not know the address for a temporary site and that in some cases there is no address. One State indicated that it did not allow shipments to temporary jobsites. On the issue of frequency of license verification (every transfer, annual, etc.), the response was mixed; some noted that annual verification was adequate, some noted that every transfer should be verified, some noted that every transfer would be ok once the new system is available, some suggested semiannual, and some felt that use of the National Source Tracking System was sufficient. One commenter noted that amendments and enforcement actions typically take a long time so the likelihood of a license being modified after a copy is obtained by the transferor is very small. The commenter indicated that there was no compelling reason to take extra measures to verify that the license has not been modified since that last check. Most commenters noted the current practice was acceptable until the new license verification system is up and running. One commenter suggested obtaining a written statement from the receiving licensee RSO attesting to the current amendment number.

In addition to those that responded to the specific questions, 18 commenters provided comments on this topic. One commenter noted that it was unclear why additional work over and beyond the current requirements in § 30.41 is needed. Some commenters objected to the need to verify a licensee's validity prior to shipment as it creates a large burden on the licensee and

the regulatory agency. At least one commenter felt that the current method of obtaining a copy of the receiving licensee's license via either fax or e-mail was adequate to verify the validity of a licensee. Commenters felt that, for companies with which they do frequent business, verification was not necessary and that having a copy of the license on file or verification within the last year was adequate. Some commenters noted that verifying for every shipment would take time and personnel and increase the cost of doing business. One commenter indicated that they felt that it would take half a day to process 30 orders using the system which is 4 times the current time. Other commenters felt that that an annual check would not be acceptable and the verification should occur close to the shipping date. One commenter stated that a company should not be required to verify a same company license in another State prior to transfer between the same company but at different locations. Two commenters requested clarification on the need to report shipments within the same company but within different jurisdictions, such as temporary jobsites in another State.

One commenter suggested that the verification requirement be revised to allow for verification of the delivery address through the receiving licensee's RSO or another individual specifically identified on the license. The commenter pointed out that some licenses may list the primary address but not individual buildings and that the delivery (or dock) address may be different than the official building address that is listed on the license. Commenters were opposed to including a requirement to validate the address for transfers of category 2 quantities of radioactive material.

Commenters noted that it can be difficult to reach the regulator and once reached that it may take the individual some time to look up the license and verify the information. Commenters indicated that this could result in delays and/or stopped shipments. As an alternative, one commenter suggested that the regulatory agency could send a copy of an amended license to ensure up to date and valid copies are on file.

One commenter recommended removing reference to the License Verification System as it does not exist yet and another commenter noted that the system would unlikely be operational when the final rule is published. Several commenters expressed some concern over how well the license verification system will work; some asked for clarification on possible access to the system. One commenter recommended that the verification provision should not be implemented until the system is fully operational and demonstrated to be effective.

One commenter asked if the verification of license provisions applied to exports. One commenter asked if these requirements would replace the National Source Tracking System requirements.

One commenter noted that there is no need to document that a check has been done as it can be covered under a procedure that the licensee has in place for license checks and that adding additional documentation just adds time and effort without value. One commenter questioned what documentation was required for the transfer verification.

Response: One of the recommendations from the Independent Review Panel was that licenses be confirmed for all transfers of radioactive material in risk-significant quantities. The NRC agrees with the recommendation and believes that verification of the license before transfer is an important component that enhances the security of the material by validating the licensee's legitimacy. Use of the License Verification System is a key component to allow 100 percent validation of licenses before transfer of category 1 or category 2 quantities of radioactive material. While some commenters felt that a fax or e-mail was adequate to verify the validity of a license, the NRC disagrees. An individual can alter or tamper with a license to change the possession limits or location of use, or even the person that received the license. Currently, many licensees obtain copies of the license and keep the copy on file. The problem with this method is that the license could be amended or terminated and the licensee would not know that the license was no longer valid. The License Verification System is being developed

to prevent these scenarios from occurring. Licensees are required to use either the License Verification System or contact the regulatory agency (NRC or Agreement State) to verify that a license is valid before shipping category 1 or category 2 quantities of radioactive material to a domestic company. For category 1 shipments, the licensee must also verify that the shipping address is valid. Transfers within the same company in a different State do not need to be verified as the company knows what it is authorized to possess. The rule language has been clarified to make this clear. Verification is not required for imports and exports; the requirements of part 110 apply. The NRC agrees that the License Verification System (LVS) needs to be fully functional before this provision of the regulations is implemented. Although the NRC expects a timely startup of the LVS, this provision of 10 CFR part 37 permits a separate compliance date that can be changed if this startup is delayed.

The NRC does understand that it can be difficult to reach regulator personnel and that there may be times when the system is down. Therefore, the NRC has added a new provision that provides an alternative so that licensees can still ship. If the licensee cannot reach the regulator and the system is nonfunctional, the licensee will be able to use certification from the receiving licensee that the licensee is authorized to receive the requested radioactive material. The licensee must follow-up by the end of the next business day to confirm the license was valid.

The NRC has also changed the documentation requirement. The final rule only requires documentation if the licensee conducts the verification by contacting the license issuing authority (NRC or Agreement State). The documentation can simply be a note to file or a copy of an e-mail response from the NRC or Agreement State. The license verification system will keep the record of any verification conducted using the system, therefore, the licensee is not required to keep separate documentation. Documentation is important from an inspection and enforcement aspect.

Comment D2: One commenter noted that the verification requirement appears to duplicate the transfer requirements under § 30.41. The commenter noted that licensees should be exempted from § 30.41 if they have category 1 or category 2 quantities and follow 10 CFR part 37. The commenter noted that this is an example of an area where industry and the NRC could constructively work together through public meetings to find the most efficient and effective solution to address NRC's concern. One commenter noted that the proposed regulations should be consistent with existing NRC regulations related to radioactive materials, should not duplicate any existing requirements, and should not rely on the general statements of "notwithstanding the requirements of any other regulations in this chapter."

Response: The verification requirements in § 37.71 are in place of the requirements in § 30.41(d). The language has been revised to make this clear. In addition, the NRC has added a provision to address emergency situations where the License Verification System is down and the licensee cannot reach the licensing authority.

Comment D3: One commenter objected to the preplanning and coordination requirements in § 37.75 stating that it would be impossible to implement for category 2 sources for facilities that make numerous shipments a day. The commenter noted that it would require a dedicated individual to constantly communicate with customers and carriers throughout the day for the 40-60 shipments and receipts that occur during the day. The commenter noted that currently the customer is told of the shipment date and method of shipment and that the preplanning system takes advantage of the already understood arrival times if using FedEx or similar. The commenter noted that the shipper can review the FedEx confirmed deliveries each day (one central location) which verifies receipt by the customer. The commenter noted that this has been working very effectively, so there is no reason to change to a much more burdensome method.

Response: It is not clear why the commenter believes that it will need to constantly communicate with customers and carriers throughout the day. The basic requirements are similar to the orders, with the exception of establishing a no-later-than arrival time. The licensee could easily establish the no-later-than arrival time as the close of the business day on the expected arrival date. If the licensee is already telling the customer the shipping information, the addition of one additional piece of information does not present a large burden and does not require the shipping licensee to conduct its business in a different manner than it currently does. The NRC has revised the language to clarify the coordination activities and has removed the requirement that specified methods of sharing information to provide licensees more flexibility. Information has been added to the implementation guidance.

Comment D4: One commenter stated that in § 37.75(a)(2) alternate requirements should be added for those States who will not be providing law enforcement escorts for the licensee to identify the intended LLEA contacts it will use to summon an armed response should there be an actual or attempted theft or diversion of the shipment.

Response: The NRC disagrees with the comment. Part 37 does not require the use of escorts for shipments of category 1 or category 2 quantities of radioactive material; therefore, an alternate requirement is not necessary.

Comment D5: Two commenters noted that in § 37.75(a)(2)(i) the term “minimal delay” is ambiguous and subject to interpretation. The commenter recommended that the term be clarified or deleted.

Response: The NRC agrees with the comment and has removed the requirement. While the purpose of the preplanning and coordination with the State is to ensure minimal delays, the language is not necessary in the rule itself.

Comment D6: Several commenters recommended removing the provisions for preplanning and coordination activities with the Governors of each State that the category 1

shipment will pass through. The commenters noted that the advanced notification provided to the State by the licensee provides sufficient time for the State to contact the licensee if a revision to the route or additional State imposed controls, such as escorts, are to be implemented. The commenters noted that Appendix A of the regulatory analysis indicates that there had been zero event notifications in the past 10 years regarding missing or lost material, suspicious activities, theft, or diversion of category 1 materials and questioned how additional coordination efforts that are not currently required by the orders can be justified. The commenters noted that the licensee would be unable to comply with the requirement to arrange for positional information sharing when required by the State because, as written, States would be authorized to dictate which position tracking provider a carrier must utilize, or the State could request that the carrier authorize the State to log into the carrier's tracking system. This would result in additional costs as there are licensing and data communication fees associated with tracking systems. One commenter asked if the NRC has determined whether carriers are willing to share their positional information real time. One commenter noted that this requirement could provide a mechanism for a State to block the transport of category 1 material through the State if the requesting state official cannot log onto the tracking system. Another commenter expressed concern over possible denial of a shipment through a State due to tracking system incompatibility. The commenter noted that denial of shipment could result in noncompliance with Federal interstate transportation laws. The commenter noted that the licensee and carrier are capable of determining safe havens along the route and that past experience has shown that requesting a State to identify safe havens has been fruitless. One commenter strongly agreed with the preplanning and coordination requirements as both necessary and desirable. The commenter urged the NRC to encourage States to coordinate with the LLEAs and affected Tribes, including route and schedule information in the shipment verification system, as it can help States monitor shipments and the no-later-than arrival times.

One commenter noted that the coordination with the States is typically conducted by e-mail and that there is no discussion unless the State initiates one in response to the licensee's notification. One commenter stated that there shouldn't be any additional requirements for category 1 quantities that might serve to dilute attention paid to highway route control quantities (HRCQ). One commenter suggested including the Agreement State program on the list for notification and preplanning coordination for category 1 shipments. The commenter noted that the Governor's designee is not always the Agreement State program director. One commenter noted that the need to coordinate with all States for transport will be very burdensome unless there is a tool to assist with implementation.

Response: The NRC has determined that the requirement for preplanning and coordination with each State for category 1 shipments is necessary, but has removed several of the proposed elements.

The NRC believes that it is necessary to coordinate with the State to determine whether the State plans to provide escorts. If the licensee doesn't find out about the need for an escort until after the advance notification is provided to the State, the licensee would likely need to adjust the schedule and reissue the advance notifications. Knowing upfront about the need for escorts is likely to reduce the overall burden on the licensee and allow the licensee to better plan the route for any shipment. The licensee is responsible for identifying safe havens along the route. The licensee would provide that information to the State. If the licensee has difficulty identifying safe havens, it may want to discuss this with the NRC, State police, or other State contact. (See *also* response to Comment A11.)

The NRC agrees that the other elements of preplanning and coordination are not necessary. It was not the intent that the State be given direct access to the position monitoring system, only that the state be provided information about the shipment's location upon request. This provision is not included in the final rule. The NRC has only retained what it believes are

the minimum requirements for the preplanning and coordination. The rule does not specify the method for conducting the preplanning and coordination. The licensee can conduct the preplanning and coordination by e-mail.

The NRC will maintain the list of State contacts as it does for 10 CFR part 73 shipments. The list will be available on the NRC's Web site at <http://nrc-stp.ornl.gov/special/designee.pdf>. The list will also be published in the *Federal Register* on an annual basis, typically in early July.

Comment D7: Some commenters objected to the requirement to establish a no-later-than arrival time. One commenter pointed out that the shipping licensee has no control over when a common carrier delivers the material, noting that typically they know the day but not an exact hour. The commenter felt that the requirement would result in many unnecessary reports or an exaggeration of the time in order to avoid making reports and noted that licensees are responsible enough not to need a regulation that will burden them and ultimately be subverted. Another commenter felt that the rule would be extremely costly and time consuming to implement and impractical. The commenter stated that the NRC should place the requirement on the carrier and not the licensee, as the licensee has no control. Another commenter suggested waiting until the end of the day, which was previously agreed to, and send a report (NRC 748) into NSTS and hope that it gets put into the system, maybe receiving confirmation that the reports were received. Two commenters recommended allowing licensees to use the NSTS as method to fulfill the notification requirement in § 37.75(b) and (c). One commenter supported the concept and suggested timeframes. One commenter noted that a loss of material is an immediate notification and that the rule as proposed places the licensee in a burdensome position of devoting additional time, effort, and concern over movement of material that is not completely in their control. The commenter did agree that notification between the shipper and consignee is important but felt no need for further restrictions or regulations in this area. Another commenter noted that the shipper currently sends an e-mail

notification that has a receiving document attached to the message noting when the shipment was received. The commenters believe that licensees already effectively track the movement of sources without the need to impose additional regulation. One commenter noted that category 1 shipments are often held up in States for inspection. Commenters noted that common carrier delivery guarantees are not accurate to within 4 hours. Commenters noted that the 2- and 4-hour timeframes would result in numerous modifications to the time or ultra conservative estimates. Several commenters suggested 24 hours as the timeframe. One commenter noted that licensees routinely monitor the status of shipments and notify the carrier and regulatory agency when the shipment does not arrive within a reasonable timeframe. The commenter stated that the regulations should specify what is required and not how to achieve it. One commenter noted that the time of a shipment will not be known for material that is transported by common carrier as shippers like FedEx simply verify that a shipment will arrive by a certain date, and often the only notice that a shipment will be late is that it doesn't arrive by the end of the business day. One commenter requested clarification that the no-later-than arrival time applies only to domestic transfers, either within the definition or in the guidance. One commenter noted that § 37.75(b) requires licensees to e-mail or fax arrival times for shipments of category 2 material and that licensees must be made aware that the e-mail must be encrypted and faxes be made to an awaiting, known entity as was noted in Regulatory Issue Summary 2005-31.

Response: The NRC continues to believe that the establishment of a no-later-than arrival time is beneficial. The NRC notes that the orders currently require the licensee to coordinate the expected arrival time of the shipment and to initiate an investigation if the shipment has not arrived by the expected arrival time. The provision for the no-later-than arrival time actually provides the licensee with more flexibility. The no-later-than arrival time allows for traffic delays due to weather and other circumstances before an investigation is initiated. The

no-later-than arrival time for category 1 shipments has been removed as the licensee is required to maintain continuous communication capability. The no-later-than arrival time provision only applies to domestic shipments. There is no requirement that e-mail be encrypted and faxes be made to an awaiting, known entity.

Comment D8: One commenter stated that § 37.75(c) is a redundant requirement as licensees are already required to input data into the NSTS when shipping or receiving radioactive material. The commenter noted that licensees are already required to initiate an investigation if a shipment does not arrive and that there is no reason to require a licensee to notify the shipper when the shipment occurs as it is scheduled. The commenter noted that this would require a tremendous amount of resources and is unnecessary as a licensee is already required to notify the shipper if the shipment does not arrive. One commenter requested clarification on whether § 37.75(c) applied to notify international shippers of receipt within 4 hours. One commenter noted that the transferee licensee should notify the NRC (and the License Verification System) and the host State when a shipment arrives. The commenter indicated that the notification should reasonably occur within 2 hours after arrival instead of the 4 hours proposed in the rule. Another commenter objected to the need to confirm a shipment with the shipper and noted that it was redundant to current requirements for the NSTS. A commenter noted that if a notification must be made when a shipment does not arrive that it doesn't make sense to also require that a notification be made when and if it does arrive and therefore it just adds burden without benefit. One commenter recommended that the licensee should notify the NRC (and the License Verification System) as well as the States affected when a shipment is revised or cancelled. The commenter noted that the change should be reported by the carrier company after communication/coordination with the driver. One commenter objected to the requirement for the receiving licensee to notify the shipping licensee within 4 hours of a package arrival and recommended that the requirement be removed from the rule.

The commenter indicated that this would result in an undue cost and would require licensees to have personnel on evenings, weekends, and holidays to receive/send the information. One commenter asked why using NSTS wasn't sufficient.

Response: The requirement in § 37.75(c) to notify that a shipment has been received and the requirement to report to NSTS are not redundant. The reporting to NSTS is a report to a system and does not notify the shipping licensee that a source has been received. The shipping licensee would need to access the system to see if the status of the source has changed in order to determine if a shipment has been received. The reporting to NSTS is by the close of the next business day which means information on the receipt of the shipment might not be available for several days and this would be too long for a shipment to go missing without starting an investigation. Additionally, not all shipments are reported to NSTS. When shipments don't arrive on time, the shipping licensee needs to start an investigation to determine if the material is missing or just delayed in shipment. The requirement to confirm shipment is not new as it is a current requirement from the orders. The notification provisions do not apply to international shipments.

Comment D9: One commenter noted an inconsistency in the timeframes for the receiving licensee to notify the shipping licensee no later than 4 hours after the package arrives but that the shipping licensee is to begin an investigation within 2 hours of a category 1 shipment not arriving by the no-later-than arrival time.

Response: The NRC has removed the no-later-than arrival requirements for shipments of category 1 quantities of radioactive material because they are not needed with the communication and monitoring requirements associated with these shipments. The provision for no-later-than arrival time remains for category 2 shipments. The arrival time and the no-later-than arrival time are not the same times. The arrival time is the time the shipment actually arrives at the facility. The no-later-than arrival time is the time established that when a

shipment has not arrived and an investigation will be started to determine the whereabouts of the shipment.

Comment D10: Two commenters pointed out an editorial error in § 37.75(d), noting that the reference to § 37.75(a)(1) should be § 37.75(b).

Response: The NRC agrees with the comment and has made the correction.

Comment D11: One commenter noted that it may not be possible to provide the information for an advance notification before the shipment. The commenter stated that the information is not available to most licensees because carriers are not willing and may not be able to provide the detailed information to licensees. The commenter noted that for an import, a licensee may not have this information until the shipment is in progress, or even when it is received. The commenter noted that if it is assumed that this requirement is only applicable from the point of customs clearance, then it may be practicable. The commenter indicated that the regulation should specifically state that it is applicable to the portion of the movement of shipments after customs clearance. One commenter asked if NRC has coordinated with DOT to determine if the advance notification is practicable. One commenter noted that the activity levels are not available with much degree of accuracy as the activity is often not measured until the shipment arrives. One commenter noted that the shipper may not know when a shipment will commence, cross State lines, and arrive. The commenter also noted that the shipper may not know of schedule changes ahead of time.

Response: The NRC understands that all of the information may not be available at the time of the initial advance notification. Section 37.77(b) specifically states that the licensee must provide the required information if available at the time of the notification. In addition, § 37.77(c) provides for revised notifications for information that was not available at the time of the initial notification and for instances where information changes. The commenter is correct that the provisions only apply to the domestic portion of the transport for both imports and

exports. The requirements would begin at the point of customs clearance for imports and end at the border for exports. Section 37.73(d) and (e) notes that the provisions only apply to the domestic portion of the shipment. Both sections have been revised to address exports.

Although the NRC coordinates with DOT on a number of safety and security matters of mutual interest, licensees have implemented advance notification requirements for many years, and the practicability of these notifications is no longer in serious question.

Comment D12: Two commenters recommended that the advanced notifications to the Governor be made through the NRC's Operations Center. The commenters noted that the licensee could simply provide the advanced notification to the NRC's Operations Center with a list of States affected and the NRC's Operations Center would then transmit the advanced notification to the affected States. The commenters noted that this would reduce the record retention and notification burden on the licensee and would ensure consistency in how the States receive notifications.

Response: The NRC disagrees with the comment. It is the licensee's responsibility to notify the affected States. The need for the NRC's Operations Center to notify affected States could interfere with its primary responsibility to be available for response to events. Additionally, for those shipments that are made by an Agreement State licensee, the NRC would not be notified as the notification would go to the Agreement State. The Agreement State will need to provide the information to the NRC so that the NRC can share the information with its Federal partners.

Comment D13: Two commenters recommended including an e-mail address and fax number for the NRC point of contact receiving the notification in § 37.77(a)(1). The commenters noted that the e-mail address and fax numbers should be readily available as most notifications are made by e-mail or fax.

Response: The NRC agrees with the comment and has included the secure fax number and e-mail address to submit the notifications to the NRC.

Comment D14: Two commenters recommended removing the option in § 37.77(a)(2) to mail in notifications or require that notifications not submitted by fax or e-mail be sent via certified mail or delivery service. The commenters noted that 7 days prior to the shipment date may not be sufficient time to allow a notification transmitted through the regular mail to reach the intended recipient.

Response: The NRC disagrees with the comment. The 7 days prior notice requirement is consistent with the similar provision for advance notifications for spent fuel shipments. Transmittal of the SGI-M information must meet the requirements of § 73.23. The licensee always has the option of sending the notification earlier than required. The NRC has revised § 37.77(a) to clarify the procedures for submitting the notifications.

Comment D15: Two commenters recommended increasing the notification requirement in § 37.77(a)(3) from 4 days to 7 days. The commenters noted that the additional time would provide States enough time to review and evaluate the details regarding the shipment and would preclude the need to conduct the required preplanning and coordination. The commenters noted that this advance notification process has been in place and proven effective for the past 6 years. One commenter recommended that “other means” in § 37.77(a)(3) be defined or clarified. The commenter assumed it meant by e-mail or fax.

Response: The NRC disagrees with the comment. The NRC believes that 4 days provide sufficient time for the States to review and evaluate, particularly since the licensee is required to conduct preplanning and coordination with the States in addition to the advance notifications. The timeframe is also consistent with the similar provision for advance notifications for spent fuel shipments. No State that commented on the rule indicated that

additional time was necessary. Other means could include fax or e-mail, or delivery by messenger. Additional information has been added to the implementation guidance.

Comment D16: Two commenters indicated that it was unclear what information the point of contact, requested in § 37.77(b)(7) for the advance notifications, should be able to provide. The commenter noted that “current shipping information” could imply that the point of contact should be a person accompanying the shipment, or did it mean someone who has information regarding the details of the notification.

Response: The point of contact would be someone that has information regarding the details of the notification. It is not intended to be a person accompanying the shipment. Additional information has been added to the implementation guidance.

Comment D17: One commenter noted that the NRC should provide for advance notification to Tribes for shipments that cross their reservation. The commenter noted that this rule should be consistent with the rule that the NRC promulgates for Tribal notifications.

Response: The NRC may consider providing advance notification of these materials to Tribes in the future but does not currently plan to include the provision.

Comment D18: Three commenters suggested changing the phrase “movement control center” to “communication control center” in § 37.79 to maintain consistency with the orders.

Response: The NRC disagrees with the comment. Although the orders called the centers communication control centers, these centers are typically called movement control centers. The terms refer to the same function. The NRC is retaining the term movement control center to be consistent with the term in 10 CFR part 73 as the centers serve the same function.

Comment D19: One commenter noted that in the definition of “movement control center” various functions are combined and that there is no value in requiring that they all be accomplished by one entity as the functions may be accomplished by separate departments or personnel.

Response: The movement control center definition does not require that all of the functions be carried out by the same department or personnel. It does require an operations center or base from which all of the functions are handled. The primary purpose of the movement control center is to have staff available that can immediately respond to an emergency and coordinate the required response.

Comment D20: One commenter requested clarification in § 37.79(c)(1)(ii) on the use of authentication and duress codes. The commenter noted that it wasn't clear if there were two codes or if there needed to be a strategy for the "use" and "authentication" of duress codes.

Response: The NRC has revised the rule language to clarify that there are two types of codes.

Comment D21: One commenter noted that redundant communications systems are required but it was not clear if redundant position location or tracking systems are necessary.

Response: The rule does not contain a requirement for a redundant position location or tracking system.

Comment D22: One commenter noted that although a licensee can make arrangements to ensure that personnel are trained and can audit the carrier for compliance, it cannot ensure that personnel are trained as required. One commenter objected to the requirement for licensees providing training to entities beyond its control such as railroad personnel. The commenter noted that the carriers already have training and certification requirements under DOT. Two commenters recommended allowing the licensee to provide current copies of normal and contingency procedures in lieu of training as required by § 37.79(c)(2). The commenter noted that it is not feasible to provide "appropriate training" to a group of individuals that the licensee has no control over.

Response: The NRC agrees with the comment. The NRC agrees that it is acceptable to provide copies of the normal and contingency procedures in lieu of a formal training program. If

this mechanism is used, the licensee should have a signoff sheet associated with the procedure that the individual would sign indicating that he or she has read and understands the procedure. The NRC also agrees that the licensee would be unable to dictate that railroad personnel undergo training and follow the licensee's procedures. Railroads have their own processes and procedures in place and would be required to follow them. The NRC has removed the requirement for railroad shipments.

Comment D23: One commenter stated that the regulation must make it clear that the requirements in § 37.79 are only applicable from the point of customs clearance.

Response: Section 37.73(d) and (e) makes it clear that the provisions only apply during the domestic portion of the shipment. For imports, the provisions begin at the point of customs clearance.

Comment D24: One commenter noted that § 37.79 requires licensees to use companies who use package tracking systems (for category 2) and that it should be clarified that the package itself should be accounted for and not simply the paperwork.

Response: The NRC believes that the regulations are clear that it is the package that is being tracked and not the paperwork. No change to the regulations is needed.

Comment D25: One commenter objected to the requirement to start an investigation if a package does not arrive within 2 to 4 hours of its designated arrival time. The commenter noted that weather, traffic, etc. could affect delivery times and that starting an investigation because a package did not arrive on time due to poor weather, etc is a waste of time and resources with no foreseeable gains for security. The commenter noted that the timeframe should allow some time for investigation and suggested an 8- and 24-hour timeframes.

Response: The NRC agrees in part with the comment. The NRC has clarified the text in § 37.79(d) to remove reference to lost or unaccounted for material. The requirement to establish a no-later-than-arrival time for shipment of category 1 quantities has been removed as

the licensee is required to maintain constant communication capability. The NRC has increased the timeframe for the no-later-than arrival time for category 2 shipments to 6 hours.

Comment D26: One commenter stated that when shipping radioactive material meeting the requirements of HRCQ and RAMQC the requirements should include having two forms of communications available at all times for reporting incidents and requesting assistance.

Response: The NRC agrees and included a requirement for redundant communication capability for category 1 shipments (RAMQC) in the proposed rule. The final rule in § 37.79(a)(1)(ii) requires licensees to “Ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication.” Redundant communications are required to mitigate an interruption, caused by either natural events, such as storms, or deliberate actions, such as signal jamming, that may cause communications to be lost on the primary communication device. One or more additional communication devices must be available to operate independently of the primary device, thereby minimizing the possibility that whatever disabled the primary device will impact the redundant devices. For category 2 shipments, the NRC is not requiring a redundant means of communication.

The requirements for HRCQ shipments, other than the category 1 material, are beyond the scope of this rulemaking.

Comment D27: One commenter felt that the rule should be revised to require the licensee to provide some level of armed security during transport of HRCQ.

Response: The NRC disagrees and feels that the physical protection measures in place are adequate without requiring the use of armed security personnel. The licensees that ship category 1 quantities of radioactive material by road would be required to have sufficient protective measures which include: a movement control center that maintains periodic position

information from a location remote from the activity of the transport vehicle or trailer and monitors shipments 24 hours a day, 7 days a week; redundant communications that would allow the transport to contact an escort vehicle; and the ability to communicate an emergency immediately to appropriate law enforcement agencies that would provide an armed response. Since the appropriate States are to be notified in advance of the shipment, the State may decide to have armed escorts accompany the shipment within the State's borders.

The requirements for HRCQ shipments, other than the category 1 material, are beyond the scope of this rulemaking.

Comment D28: One commenter suggested adding an exemption to § 37.79 for shipments transported as Exclusive Use, in accordance with 49 CFR 173.441. The commenter noted that package tracking systems are necessary when a carrier handles multiple consignments on single vehicles and when packages traverse through delivery hubs. The commenter noted that an exclusive use shipment removes the risk of lost or misdirected packages and would provide the same level of control as a package tracking system. The commenter noted that adding the exemption would give the licensee the ability to transport their own category 1 materials.

Response: The NRC disagrees with the comment and does not believe that an exemption is appropriate for shipments transported as Exclusive Use. The shipment should still have the same security measures applied even if the shipment is in a dedicated truck. While it might remove the risk of a misdirected package, it does not remove the possibility that the material could be stolen during transport. The licensee is allowed to transport its own category 1 or category 2 material under the rule.

Comment D29: One commenter was disappointed that the proposed rule did not contain the requirement for GPS tracking for trucks carrying category 2 quantities of radioactive material that was requested in PRM-71-13 or, alternatively, for the rule to give Agreement States the

flexibility to be more stringent than NRC. The commenter was disappointed that the NRC did not request comments on the issues raised in the petition nor provided any further discussion or explanation for not including the two recommendations in the proposed rule. The commenter noted that NMED data shows that since the letter was sent, another truck carrying radiography sources was stolen, and the commenter further noted that it only takes one to become the terrorist event. The commenter noted that GPS tracking is very inexpensive and an easy way to help with rapid recovery should preventative measures fail and that GPS tracking for category 2 sources should be required.

Response: The NRC reevaluated the need for requiring GPS tracking for trucks carrying category 2 quantities of material. The NRC continues to disagree with the comment. Tracking a truck can be misleading as either the source or the device containing the source can be removed and the GPS would provide no benefit. There is no easy method of placing the GPS tracking mechanism on either the source or device. While GPS could help with locating the truck, the source/device may not still be on the truck. For devices in or on a vehicle, the licensee is supposed to maintain control and have constant surveillance of the material or use a method to disable the vehicle. The NRC believes that these measures are adequate. As for the compatibility of the provisions, the provisions need to remain compatibility B because there are significant transboundary implications.

Comment D30: One commenter noted that the shipping requirements are somewhat demanding with the authorized shippers having added responsibilities. The commenter assumed that the Commission will communicate with the shipping agencies accordingly. The commenter noted that the addition of GPS capabilities combined with vehicle/trailer alarms with remote features will be an added expense. Another commenter asked how to find the approved carriers.

Response: The NRC is not sure what the commenter meant by authorized shipper, but assumes that it refers to the licensee that is shipping the material. The NRC is also uncertain what the commenter meant by shipping agencies, but assumes that the term refers to common carriers. Common carriers do not have any responsibilities under part 37 as the NRC does not regulate the carrier. It is each licensee's responsibility to make sure that its shipments are compliant with the regulations. The NRC believes that the requirements in subpart D are necessary for the safe transport of category 1 and category 2 quantities of radioactive material. The regulations do not require the licensee to use GPS or vehicle/trailer alarms during shipment of the material. Alarms may be necessary, however, if the material is stored in the vehicle or trailer while the vehicle is unoccupied. The NRC does not approve the carriers.

Comment D31: One commenter stated that § 73.35 is not clear on what to include/exclude from the calculation for "net weight." The commenter indicated that if the "net weight" is intended to include only the weight of the nuclear or radioactive material contained in the irradiated fuel, then this should be clearly stated. The commenter noted that calculation by "exclusion" may lead to wide variation in interpretation.

Response: The rule addresses the irradiated reactor fuel weighing 100 g (0.22 lb) or less in net weight of irradiated fuel, exclusive of cladding or other structural or packaging material, and that has a total external radiation dose rate in excess of 1 Gray (100 rad) per hour at a distance of 1 m (3.3 ft) from any accessible surface without intervening shielding.

Comment D32: One commenter proposed an exemption for the aggregation of packages that individually each contain less than a category 2 quantity of material and were in a package with an external volume exceeding 1 cubic foot and with a mass exceeding 100 pounds. The commenter noted that these parameters would present a practical, individual barrier to theft. The commenter also suggested, as an alternative, the addition of a specific activity threshold to the category 2 table, and materials not exceeding the specified

concentration values (sum of fractions could be applied to packages containing multiple radionuclides of interest) would be exempted from the requirements.

Response: The NRC disagrees that the parameters described would present a practical barrier to theft. The requirements do not allow an individual licensee to aggregate less-than-category-2-quantity packages of material to exceed category 2 limits for an individual shipment unless the shipment complies with 10 CFR part 37 requirements. If two or more packages, each containing less than a category 2 quantity, in aggregate reach or exceed a category 2 quantity in a shipment from one NRC licensee, the licensee would be required to meet applicable subpart D requirements before shipping.

The NRC did consider specific activity and grants an exemption as stated in § 37.11(c), which states that licensees that possess radioactive waste that contains category 1 or category 2 quantities of radioactive material are exempt from the requirements of subpart B, C, and D of 10 CFR part 37, unless the radioactive waste contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs).

Comment D33: One commenter noted that category 1 rail shipments should be by dedicated trains.

Response: The NRC disagrees with the comment. There is no security or health and safety basis for requiring dedicated trains for rail shipments of category 1 quantities of radioactive material.

Comment D34: The proposed rule contained a provision that would require the licensee to have an NRC-approved monitoring plan to ensure that no unauthorized access to the shipment takes place while the shipment is in a railroad classification yard. The NRC specifically sought comment on the feasibility of this requirement. Commenters were requested to provide information on: 1) whether surveillance of the shipment could be accomplished while in the classification yard; 2) whether the classification yard would allow an individual to

accompany a shipment while the shipment is held in the classification yard; and 3) what precautions might be necessary from a personal safety standpoint. Five commenters provided responses to the specific questions on this subject.

Of the commenters that addressed the questions on the monitoring plans for use in railroad classification yards, only one commenter gave an answer other than unknown. The commenter noted that, due to insurance and liability concerns, it was highly unlikely that the classification yard would allow an individual to accompany a shipment. The commenter noted that DOT regulations were sufficient for personal safety from a radiological perspective.

In addition to those that addressed the specific questions, two commenters provided comment in this area. One commenter indicated that additional monitoring while the shipment is in a railroad classification yard is an impractical and unenforceable requirement. The commenter noted that the systems that are currently in place are sufficient. One commenter stated that remote monitoring of the package and not the railcar is necessary in a classification yard.

Response: The NRC has decided not to include the provision for an NRC-approved monitoring plan for the time that a shipment is located in a railroad classification yard. The NRC agrees that DOT regulations are sufficient.

Comment D35: One commenter asked if the requirement for continuous and active monitoring by licensees applies only to shipments carried by the licensee. The commenter noted that real-time information is not available to the licensee when a carrier is used.

Response: The continuous and active monitoring of category 1 shipments, whether by the licensee or by a carrier, is the responsibility of the licensee. It is also the licensee's responsibility to ensure that its carrier has the capabilities for continuous and active monitoring. Any time a shipment is enroute, the licensee must be knowledgeable of its whereabouts, which can be verified by a phone call to the movement control center or other means of

communication. This provides licensees with flexibility to design continuous and active monitoring systems that meet their unique circumstances. A licensee may use a carrier or third-party communications center in lieu of establishing one itself.

Comment D36: One commenter asked if FedEx's tracking system is considered to be proven and reliable as they are the primary carrier of radioactive material.

Response: The NRC does not prescribe a particular system for tracking shipments. The NRC regulations describe the performance characteristics for a method used for category 2 shipments and does not endorse any particular company. The regulations require licensees to use carriers that have an established package tracking system which is a documented, proven, and reliable system routinely used to transport objects of value. This gives licensees the flexibility to use tracking systems that work within their organization. The package tracking system must allow the shipper or transporter to identify when and where the package was last located and when it should arrive at the next point of control. The NRC does not object to the use of Federal Express, as long as they continue to meet these requirements.

Comment D37: One commenter asked how the security provision must be implemented when using a freight forwarder.

Response: Transportation security requirements will still apply to shipments using a freight forwarder. The NRC expects licensees to ensure that their shipments are received by the recipient in a timely manner and that any suspicious, attempted, or actual acts against a shipment would be quickly detected, assessed, and immediately reported to law enforcement authorities.

Comment D38: One commenter questioned who would be responsible for complying with the security requirements when a carrier aggregates the material during transport or storage incidental to transport. The commenter noted that it would be logical for the responsibility to be with the carrier.

Response: Licensees are not responsible for packages that are aggregated by the carrier as long as the individual licensee does not exceed category 2 thresholds. The licensees are not responsible if the carrier picks up radioactive material from multiple locations that, in the aggregate, meet or exceed the category 2 threshold, since the licensees have no knowledge of what the total quantity of material might be in the shipment. The NRC does not regulate the carrier.

Comment D39: One commenter suggested using a table to denote applicability for the different types of shipments in § 37.73 as the paragraph format was confusing.

Response: The NRC has added a table to denote applicability for different types of shipments to the implementation guidance.

Comment D40: One commenter indicated that synchronization of the NRC and DOT requirements should be addressed. The commenter noted that the rulemaking does not discuss the connection between the NRC and DOT requirements on security and physical protection. The commenter noted that the rulemaking appears to regulate carriers even if only for security purposes. The commenter felt that this situation could violate the separation of responsibilities that the two organizations have and will, at a minimum, create confusion among carriers. One commenter felt that the rule should more closely align with the DOT requirements for HRCQ shipments for routes used. One commenter asked if there has been coordination between DOT and NRC regarding security during transport, particularly in light of HM232F.

Response: The NRC shares responsibility for the safe and secure transport of radioactive material with DOT and DHS. The NRC has a Memorandum of Understanding (MOU) with DOT for safety and is currently in the process of developing an MOU with DOE, DHS, and DOT on transportation security to ensure that the agencies work together. The Commission believes that it is necessary and appropriate to require licensees to implement the proposed requirements, believes that the issuance of security requirements for the transport of

the material is not a significant regulatory impediment, and believes that licensees and carriers can successfully implement the requirements of both Title 49 and Title 10.

Comment D41: One commenter noted that the NRC's intent for shipments of category 2 quantities of radioactive material is not clear for licensees that are consignee, shipper, and consignor, as is the case for the movement of most industrial radiography sources used in the field. The commenter noted that this common situation should be addressed for clarity either by inclusion or exclusion in the rule.

Response: The situation where a licensee is transporting its own material is covered by § 37.79(a)(2).

Comment D42: One commenter stated that the requirements placed on licensees to coordinate with and to notify the LLEA for transport of category 1 and category 2 quantities cannot be achieved by the licensee alone, and thus seem unreasonable.

Response: The NRC disagrees with the comment. The rule does not contain any provisions to coordinate with the LLEA for transport of material. Licensees are required to notify the LLEA if a shipment of category 1 materials is lost or missing. The NRC continues to believe that this is an appropriate notification and sees nothing unreasonable in the requirement.

Comment D43: One commenter (a State) noted that a number of shippers are routing around States that charge fees for transportation of HRCQ shipments of radioactive material and that this results in longer transportation times and greater risk for shipment incidents because of the additional transit time and miles traveled. The commenter noted that because shipments of radioactive material are being routed around the fee States, they are now traveling through areas where there is little training and coordination of response to radioactive material incidents increasing the risk and vulnerability. The commenter suggested that language be added to require the shortest, most direct, approved route for all HRCQ shipments and to prohibit avoidance of States with transportation fees. The commenter further suggested that

licensees and shippers of HRCQ materials be required to meet and preplan shipment routes with States on an annual basis to ensure the States are ready to respond to incidents as needed.

Response: Routing of HRCQ material lies within the jurisdiction of DOT's regulations and is beyond the scope of this rulemaking. For category 1 shipments, the licensee is required to preplan and coordinate with the States along the shipment route.

Comment D44: One commenter questioned why spent fuel was not addressed in the rule.

Response: The rule does address transportation security of small quantities (less than 100 grams) of irradiated fuel. Transportation security of spent fuel is being addressed in a separate rulemaking. The proposed rule was published for public comment on October 13, 2010; 75 FR 62695. Most of the licensees impacted by 10 CFR part 37 do not possess spent fuel and large quantities of special nuclear material. Security of special nuclear material and spent fuel security is addressed in 10 CFR part 73 and in orders that were issued to specific licensees possessing the material. Security for independent spent fuel storage installations will be addressed in a future rulemaking.

Comment D45: One commenter noted that the link for Agreement State contacts did not appear to work.

Response: The NRC has tested the link for Agreement State contacts provided in the response to Q4 and it does take you to the webpage on the Agreement States. From that location, you can access the State transportation contacts. Part 37 contacts will not be added until just before the rule is implemented.

Comment D46: One commenter stated that it is imperative that the requirements for the transshipment of radioactive material be identical to those for domestic shipments, and urged the NRC to work with other Federal agencies to harmonize the regulations so that licensees and

their regulators at the Federal and State level follow consistent rules for all shipments. The commenter suggested general licensing of carriers as one way to resolve this issue. One commenter asked why transuranic shipments were not addressed in 10 CFR part 37 and whether these shipments fell under other security program requirements. Another commenter asked what security requirements covered transshipments and noted that it does not make sense to impose additional security on licensees, if transshipments are not covered. Another commenter recommended consistent regulations for transshipments, air shipments, and water shipments regardless of the Federal authority and that the standards for transshipments must be consistent with domestic shipments. The commenter urged the NRC to provide leadership in promoting consistency, perhaps via interagency agreement. The commenter also recommended that the license verification system (licensees and shipments by and among licensees) incorporate all RAMQC shipments, regardless of the Federal authority under which they are made and that the relevant information in the License Verification System be appropriately shared with the State and local authorities involved in enforcement.

Response: The NRC does not have any authority over transshipments and does not regulate common carriers. However, the NRC has provided copies of transportation security orders to companies that transship category 1 quantities of radioactive materials. These companies have agreed to voluntarily implement the security requirements for transshipments. DHS has the overall lead for harmonizing transshipment security, and the NRC has and will continue to work with other Federal agencies on the security requirements for transshipments. The License Verification System will be available to Agreement State personnel.

Comment D47: One commenter recommended that NRC work with the States and law enforcement groups to determine effective ways to support transport of category 1 and category 2 quantities of radioactive material.

Response: The NRC did coordinate with the States. The Agreement States were involved in both the development of the orders and development of 10 CFR part 37. Law enforcement is not involved in the routine transport of category 1 and category 2 quantities of radioactive material. If a shipment is lost or stolen, law enforcement would be contacted to assist.

E. Miscellaneous

Comment E1: One commenter wanted a clear, concise statement that the requirements in 10 CFR part 37 supersede the Increased Control Orders. The commenter suggested adding a second paragraph to § 37.1.

Response: The NRC disagrees with the comment. A provision in the rule is not necessary to note that the rule supersedes the orders. The orders will be formally rescinded (withdrawn) on the effective date of the final rule in each jurisdiction (Agreement State or NRC).

Comment E2: One commenter noted that the rule does not contain any punitive provisions regarding situations where employees or outside persons compromise safety and/or security. The commenter noted that there are no provisions that can be cited in the event that a licensee or an unlicensed person attempts to or gains unauthorized access, breaches security systems, or otherwise compromises the security of radioactive material.

Response: The NRC does not agree with the commenter's statement. The proposed rule does contain punitive provisions for situations where employees or outside persons compromise safety and/or security. Specifically, § 37.109 provides for criminal penalties. Section 37.109 of subpart G states that section 223 of the AEA provides criminal sanctions for violations of any regulation issued under 161b., 161i., or 161o., of the AEA. As stated in § 37.109, all relevant portions of this final rule have been issued pursuant to one or more of sections 161b., 161i., or 161o. of the AEA. Further, there are other applicable statutory

provisions that provide punitive sanctions for trespass and sabotage of nuclear facilities or fuel that could be imposed on employees or outside persons who compromise safety and/or security.

Comment E3: One commenter noted that the proposed rule fails to provide descriptions in most sections to outline how the regulations are applicable to a master materials licensee or a Federal agency. The commenter felt that this lack of descriptions follows the pattern of the previously issued increased controls and will likely result in confusion during NRC compliance inspections at master materials licensee facilities.

Response: A master material licensee and a Federal agency are still a licensee and are treated the same as any other licensee. While a master material licensee can issue permits within its organization for the use of material, the permittees must still meet the requirements of the license and the regulations. The NRC is not aware of any implementation or inspection issues that have resulted from a licensee being a master material licensee or a Federal agency.

Comment E4: Some States expressed concern that the proposed rule would result in a potential increase in workload for the Agreement State programs and that many States, particularly smaller States, may have trouble accommodating the additional workload. Some of the Agreement States also noted that the radiation control programs within the States do not have the necessary expertise to handle what are essentially “law enforcement” activities, nor will they likely be able to hire additional staff to undertake these responsibilities. They also noted that many of the proposed changes would impose duties that are beyond traditional radiation control agency functions, and it is likely that they would need to seek amendments to enabling legislation to undertake the activities. One commenter stated that since the regulatory activities formerly carried out under the NRC’s Common Defense and Security authority are being shifted to the Agreement States because the rule is being issued under the NRC’s Health and Safety authority, the NRC should provide the funds necessary to pay the direct costs incurred by the

Agreement State governments in implementing the regulation. One commenter (a State) indicated that NRC must determine if funding will be provided to the States to increase staffing levels to implement the rule or if other health and safety programs should be cut.

Response: The NRC acknowledges that the rule will result in a potential increase in workload for the Agreement State programs. However, this is not unique to 10 CFR part 37. Any time the NRC issues a rule that is a matter of compatibility for the Agreement States, there will be an increased workload for the States. The State must expend some effort to adopt the regulations and to include the provisions in its inspection programs. These costs are addressed in the regulatory analysis. The Agreement States will now need to conduct the security inspections for those facilities in their State that were issued orders under common defense and security and budget for those inspections instead of being reimbursed by the NRC for conducting the inspections. The NRC disagrees that the rule contains provisions that are essentially “law enforcement” activities. The NRC assumes that the commenters are referring to the regulatory agency approval of the reviewing official. The NRC does not believe that this is a law enforcement function, but in any case, regulatory agency approval of the reviewing official has been removed and is not in the final rule. As for the NRC paying the direct costs of increased staffing levels, the NRC is not authorized to pay the salary costs for Agreement State staff. The NRC can and will continue to pay for the necessary training for Agreement State staff.

Comment E5: One commenter agreed with the proposed provisions to remove the concept of sensitive information as used in the orders and address information security in relevant sections of the proposed rule. One commenter noted that placing all of the security requirements in one chapter significantly enhanced their clarity. One commenter supported the NRC decision to forgo conventional significant figure conventions and list the actual curie activity equivalents to three figures as many licensees use curies in their activities instead of

Becquerels. One commenter supported the general objective of the rulemaking. Two commenters supported the approach to terminate the orders coincident with the effective date of the rule in each jurisdiction to avoid potential confusion and noncompliance. One commenter expressed general support for the overall rulemaking and suggested enhancements in the transportation security area. Several commenters supported placing the security requirements in a rule instead of in orders as it allows for public input and shows the American population steps that are being taken to ensure their security.

Response: No response necessary. Suggested enhancements were considered as separate comments.

Comment E6: One commenter suggested that the NRC develop programs and information packets to all involved (regulatory personnel, shipping agencies, law enforcement agencies, Governors) so that everyone can be on the same page.

Response: The NRC does have information on its Web site. Information on radioactive material security can be found at <http://www.nrc.gov/security/byproduct.html> and information on radioactive material transportation at <http://www.nrc.gov/materials/transportation.html>. These sites provide links to a variety of source documents and specific NRC security enhancement activities, including those on a webpage on current NRC radioactive material security orders and requirements (<http://www.nrc.gov/security/byproduct/orders.html>) and a webpage on material transportation regulations, guidance, and communications (<http://www.nrc.gov/materials/transportation/regs-guides-comm.html>). The NRC also routinely participates in interagency efforts, such as the Task Force on Radiation Source Protection and Security, where subjects of common interest are discussed.

Comment E7: One commenter (a State agency that possesses radioactive material subject to the rule) stated that the State would not provide the additional funding necessary to implement the requirements in 10 CFR part 37.

Response: Licensees are responsible for implementing and complying with relevant regulations. A licensee may always request an exemption from specific aspects of the requirements for its regulator to consider.

Comment E8: One commenter stated that the phrase 'Background Check' was used inconsistently and seemed to mean different things in different places. The commenter recommended reviewing the rule text for consistent use of all terminology.

Response: The term "background check" is only used in the rule in the context of the Bureau of Alcohol, Tobacco, Firearms, and Explosives background checks. The term is used consistently in the rule. The NRC tries to be consistent within the document, and any inconsistencies identified have been corrected.

Comment E9: Three commenters addressed plain language in the rule. One commenter suggested using "you" instead of "licensee," pointed out some long sentences, and noted some use of passive instead of active voice. One commenter suggested rewriting the rule to address these concerns. Another commenter noted that a single standard, clearly spelled out in living room language, would better meet the need of all licensees. One commenter noted that the rule did not meet the goal or the intent of the President's directive.

Response: The NRC has considered the editorial changes and made changes as appropriate.

Comment E10: One commenter noted that 10 CFR part 37 does nothing to improve the security of radioactive materials that could be introduced into the United States from foreign origins.

Response: The NRC's regulations only apply once the radioactive material is in the U.S. The NRC does not have authority over material in foreign countries.

Comment E11: One commenter noted that while the rule will help protect the United States from terrorists, we should be thinking of the environmental consequences.

Response: The NRC prepared an environmental assessment to support the rulemaking.

Comment E12: One commenter suggested that the concept of what category 1 and category 2 quantities are should be introduced earlier in the summary and background sections to ensure that the distinction between radioactive materials and category 1 and 2 quantities of radioactive material is clear and that each term is used appropriately.

Response: The NRC disagrees with the comment. The summary notes that the rule establishes security requirements for category 1 and category 2 quantities of radioactive material and that the category 1 and category 2 thresholds are based on the IAEA Code of Conduct. The NRC believes that the Statements of Consideration adequately describe the material and are clear on what radioactive material is covered by the rule.

Comment E13: One commenter noted that since few changes were made by NRC as a result of Agreement States comments on the predecisional draft of the proposed regulations, the NRC should make available to the Director of the Office of Management and Budget (OMB) any written communications submitted to the agency by State officials, including State comments on the pre-decisional draft of 10 CFR part 37.

Response: The NRC made a number of changes in response to Agreement State comments on the predecisional draft of the proposed rule. The NRC did not make changes to the major issues on the reviewing official, background investigation, and temporary jobsites, but specifically invited comment on these issues in the proposed rule. Major differences with the States were identified to the Commission as is common practice. The NRC does not provide any comments to OMB, other than comments on the information collection associated with the rule.

Comment E14: One commenter stated that the title of the rule should also include a reference to the protection of information (SGI-M and SUNSI). The commenter also stated that references to the protection of information need to be made more consistent throughout the rule

as most sections and subsections only require implementation if individuals have access to category 1 and category 2 quantities of radioactive material. The commenter stated that those having access to safeguarded or sensitive information also need to be included in the majority of the sections in the rule, and the NRC should consider the inclusion of 10 CFR part 73 among the list of provisions of parts affecting licensees in § 37.1.

Response: The NRC disagrees with the comment. Part 73 contains the physical protection requirements for special nuclear material as well as requirements for protection of SGI. Reference to the SGI provisions in 10 CFR part 73 were added to parts 30, 35, etc., as part of the SGI rule that was published in the *Federal Register* on October 24, 2008; 73 FR 63546. References to 10 CFR part 73 are included at appropriate locations in 10 CFR part 37. Section 37.1 contains the purpose of 10 CFR part 37 and does not include a reference to any affected provisions of other NRC rules.

Comment E15: One commenter stated that the rule (and orders) moves the emphasis for security away from engineered controls toward administrative controls and that this goes against decades of NRC safety policy and generally-accepted safety philosophy.

Response: The NRC disagrees with the comment. Part 37 contains a mix of engineered controls and administrative controls.

Comment E16: One Agreement State expressed disappointment in what was viewed to be the overly prescriptive content of the proposed rule and the resurgence of issues that were previously discussed and agreed upon as resolved in the orders. One Agreement State indicated that the operational and practical understanding of the orders, together with the knowledge of the effectiveness of the orders that the collective Agreement States have gained during this time, should be taken into consideration by the NRC. Other Agreement States noted disappointment and concern that many concepts that were discussed at length during the development of the orders and rejected by the orders working groups/steering committees now

appear in this proposed rule. They further noted that they disagree with the new provisions and do not believe that the added benefit warrants the significant resource burden that would be incurred. One Agreement State felt that the rule contained too many prescriptive items and was not adequately performance based. One commenter noted that the knowledge and understanding that the Agreement States have obtained during implementation of the orders should be helpful to the NRC in improving the rulemaking.

Response: The rulemaking process is a more deliberative process than what is used to develop an order. The 10 CFR part 37 working group also had additional information to consider that included information from lessons learned, implementation issues, inspection issues, recommendations from other reviews, as well as the comments on the preliminary rule language. In some cases the 10 CFR part 37 working group and steering committee came to a different resolution than that for the orders. Agreement State experience was utilized. There were Agreement State representatives on the 10 CFR part 37 working group and on the steering committee that brought their experience to the discussions. In some areas where agreement could not be reached, the NRC sought public comment on the issue to better inform the final decision.

Comment E17: One commenter suggested that the NRC reconsider its decision to use the same software developers for the verification system as were used for the National Source Tracking System based on the multiple continuing problems with the system.

Response: The comment is beyond the scope of the rulemaking.

Comment E18: Two commenters suggested that NRC conduct one or more additional public workshops prior to submitting the draft final rule and implementation guidance to the Commission for approval. The commenters noted that the NRC could explain at the meeting how it addressed and resolved the more significant or controversial topics addressed by the public comments. The commenters noted that the September 2008 workshop that NRC

conducted on the Security and Continued Use of Cesium-137 Chloride sources could serve as an excellent model for such workshops. One commenter suggested holding public meetings to discuss the regulatory analysis document and receive insights and perspectives on its content.

Response: The NRC does not plan to hold any public meetings or workshops on the 10 CFR part 37 final rule. The public was provided opportunity to provide input on the rule and regulatory analysis during the public comment period. The NRC considered the comments received and made changes to the rule and supporting documents as appropriate.

Comment E19: Two commenters stated that continued stakeholder input and involvement in the security area are essential and requested that the NRC allow substantive opportunities to engage industry over the next 4 years on the myriad of issues that the Congressionally mandated Radiation Source Protection and Security Task Force is addressing as all stakeholders continue to work collectively toward mutual safety and security objectives.

Response: Continued stakeholder involvement in the security area is beyond the scope of this rulemaking.

Comment E20: Two commenters noted that the NRC does not routinely share the technical basis for rulemakings with stakeholders and recommended that this become routine practice. The commenters noted that providing the technical basis may have proven helpful for this rule.

Response: Stakeholder involvement in regulatory basis development is beyond the scope of this rulemaking. The decision to solicit stakeholder input during the development of the regulatory (technical) basis for a potential rule is decided on a case-by-case basis. The NRC does obtain stakeholder input more routinely than it did a few years ago. The NRC did obtain stakeholder input during the development of the technical basis for the transportation security portion of this rulemaking.

Comment E21: One commenter stated that the NRC should conduct inspections to ensure that licensees are following the requirements and that the focus on compliance verified by inspection should receive greater emphasis instead of imposing additional administrative burdens based on authorized use. Another commenter noted that the NRC must ensure compliance through periodic inspections as is currently done. Several commenters recommended that the NRC perform compliance audit based reviews similar to what was done after the orders were implemented. The commenter noted that the reviews were done with a level of discretion and without citation as long as the licensee made significant efforts to address the orders. One commenter requested that the inspection frequency be modified to more closely coincide with the risk.

Response: The NRC will conduct inspections to ensure that licensees are complying with 10 CFR part 37 requirements. The inspections will be conducted as part of the normal inspection program. The comment on inspection frequency is beyond the scope of the rulemaking as the inspection frequency is not set by the rule.

Comment E22: One commenter noted that a new licensee must have the physical protection measures in place prior to a license being issued and that this would be part of any precicensing inspection. The commenter noted that the agency should ensure implementation before issuing a license.

Response: The NRC agrees that licensees should have the majority of the provisions in place before the license is issued; some measures could not be implemented until material is actually at the facility. The NRC conducts precicensing inspections before granting a license to anyone that would be authorized to possess category 1 or category 2 quantities of radioactive material.

Comment E23: One commenter noted that certain materials licensees would remain subject to the SGI requirements. The commenter recommended that conforming changes to

10 CFR part 73 be included as part of the regulation development under 10 CFR part 37, to ensure efficiency, clarity, and help ensure compliance. The commenter noted that SECY-09-0181 was silent on the timing of the future rulemaking to revise 10 CFR part 73 to remove the SGI handling requirements for licensees subject to 10 CFR part 37.

Response: The changes to 10 CFR part 73 to revise the SGI requirements are beyond the scope of this rulemaking. The timing of any potential changes to 10 CFR part 73 is unknown at this time.

Comment E24: One commenter noted that the rule could result in institutions choosing to store materials, including waste, in separate locations. The commenter noted that this could cause logistical problems to keep track of the material and could inadvertently increase the risk to the security of these materials.

Response: A licensee may choose to store radioactive materials, in any form, in separate locations to avoid being subject to the proposed security requirements. Such action would not conflict with the intent of the proposed rule, which is to limit access to an aggregated category 2 quantity of radioactive material listed in Table 1. Aggregated, for purposes of this rule, means accessible by breach of a single physical barrier.

Comment E25: One commenter made several comments related to a change in the annual occupational radiation dose to a lower range and how it would impact the licensee.

Response: These comments are beyond the scope of the rulemaking as the proposed rule did not include any changes to the annual occupational radiation dose. These comments appeared to be filed under the wrong docket and were provided to the NRC working group that is looking at possible changes to 10 CFR part 20.

IV. Discussion of Final Amendments by Section.

Section 20.2201(c) Reports of theft or loss of licensed material.

This section is revised to include a reference to the reporting requirements in 10 CFR part 37 so that a licensee is not required to file duplicate reports for the same event.

Section 30.6 Communications.

This section is revised to include a reference to the new 10 CFR part 37.

Section 30.13 Carriers.

This section is revised to include 10 CFR part 37 in the list of regulations that exempt common carriers.

Section 30.33 General requirements for issuance of specific licenses.

Paragraph (a)(4) is revised to include a reference to the new 10 CFR part 37.

Section 32.1 Purpose and scope.

10 CFR part 37 is added to the list of 10 CFR parts that apply to applications and licenses subject to this part.

Section 33.1 Purpose and scope.

10 CFR part 37 is added to the list of 10 CFR parts that apply to applications and licenses subject to this part.

Section 34.1 Purpose and scope.

10 CFR part 37 is added to the list of 10 CFR parts that apply to applications and licensees subject to this part.

Section 35.1 Purpose and scope.

10 CFR part 37 is added to the list of 10 CFR parts that apply to applications and licenses subject to this part.

Section 36.1 Purpose and scope.

10 CFR part 37 is added to the list of 10 CFR parts that apply to applications and licenses subject to this part.

Section 37.1 Purpose.

This section establishes the purpose for the new 10 CFR part 37.

Section 37.3 Scope.

This section establishes the scope of the proposed new 10 CFR part 37. These regulations apply to any person licensed by the NRC, who possesses, uses, or transports an aggregated category 1 or category 2 quantity of radioactive material. Paragraph (a) establishes the applicability for subpart B and C. Paragraph (b) establishes the applicability for subpart D.

Section 37.5 Definitions.

Definitions of the following terms that are included in this part are identical to the definition of the term in other parts of this chapter: Act, Agreement State, Becquerel, Byproduct

material, Carrier, Commission, Curie, Government agency, License, Lost or missing material, Person, State, and United States. In addition, definitions for the following terms are included in this Part: Approved individuals, Access control, Aggregated, Background investigation, Category 1 quantity of radioactive material, Category 2 quantity of radioactive material, Diversion, Escorted access, Fingerprint Orders, License issuing authority, Local law enforcement agency, Mobile device, Movement control center, No-later-than arrival time, Reviewing official, Sabotage, Security zone, Telemetric position monitoring system, Trustworthiness and reliability, and Unescorted access.

Section 37.7 Communications.

This section specifies where all communications and reports concerning 10 CFR part 37 are to be sent.

Section 37.9 Interpretations.

This section establishes that no interpretations of the meaning of the regulations in 10 CFR part 37 by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized as binding upon the Commission, unless specifically authorized by the Commission in writing.

Section 37.11 Specific exemptions.

This section establishes that the Commission may grant exemptions from the requirements of the regulations in 10 CFR part 37 that it determines are authorized by law and that will not endanger life or property or the common defense and security, and are otherwise in the public interest. Paragraph (b) exempts an NRC licensee's activities from 10 CFR part 37 to the extent that the activities are covered under the physical protection requirements of 10 CFR

part 73. Paragraph (c) provides security measures for certain radioactive waste that contains category 1 or category 2 quantities of radioactive waste.

Section 37.13 Information collection requirements: OMB approval.

Paragraph (a) specifies that the NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Paragraph (b) lists those sections in 10 CFR part 37 that have approved information collection requirements.

Section 37.21 Personnel access authorization requirements for category 1 or category 2 quantities of radioactive material.

Paragraph (a) of this section establishes which licensees need to comply with the requirements of subpart B of 10 CFR part 37.

Paragraph (b) establishes the general performance objective to ensure that the individuals subject to the access authorization program are trustworthy and reliable.

Paragraph (c)(1) establishes the individuals that are subject to the access authorization program. Paragraph (c)(2) allows licensees to not subject those individuals listed in § 37.29(a) to the investigation elements of the access authorization program. Paragraph (c)(3) requires that licensees only approve those individuals whose job duties permit unescorted access to category 1 or category 2 quantities of radioactive material.

Section 37.23 Access authorization program requirements.

This section establishes the general requirements for the access authorization program, such as the use of reviewing officials, informed consent, personal history disclosure,

determination basis, procedures, the right to correct and complete information, and record retention.

Section 37.25 Background investigations.

This section establishes the elements of the background investigation that are necessary before granting an individual unescorted access to category 1 or category 2 quantities of radioactive material. The scope of the initial investigation is the past 7 years. This section also addresses reinvestigation and grandfathering of individuals.

Section 37.27 Requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material.

Paragraph (a) establishes the general requirements for criminal history records checks of individuals to be granted unescorted access to category 1 or category 2 quantities of radioactive material.

Paragraph (b) prohibits a licensee from basing a final determination to deny an individual unescorted access authorization solely on the basis of certain information received from the FBI.

Paragraph (c) establishes the procedure for submitting fingerprint records to the NRC.

Section 37.29 Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials.

This section provides relief from the fingerprinting and criminal history records check requirements and the background investigation requirements of this subpart for certain

categories of individuals.

Section 37.31 Protection of information.

This section outlines the requirements for the protection and release to authorized personnel of personal information collected by a licensee during a background investigation.

Section 37.33 Access authorization program review.

This section outlines the requirements for an annual access authorization program review to confirm compliance with the requirements of subpart B of 10 CFR part 37 and for comprehensive corrective actions to be taken in response to any nonconformance identified by the review.

Section 37.41 Security program.

Paragraph (a) establishes the applicability of the security program. Paragraph (a)(1) requires licensees that possess an aggregated quantity of category 1 or category 2 quantities of radioactive material to establish, implement, and maintain a security program. Paragraph (a)(2) requires those licensees that are newly subject to subpart C, upon application for modification of its license or an applicant submitting a new application, to implement the requirements before taking possession of an aggregated category 1 or category 2 quantity of radioactive material. Paragraph (a)(3) requires any licensee that has not previously implemented either the orders or subpart C to notify the NRC at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

Paragraph (b) establishes the general performance objective of the security program.

Paragraph (c) establishes the program features that must be addressed in the security program.

Section 37.43 General security program requirements.

Paragraph (a)(1) requires licensees to develop a written security plan that addresses how the licensee will implement the security program requirements. Paragraph (a)(2) requires the security plan to be reviewed and approved by the individual with overall responsibility for the security program. Paragraph (a)(3) allows a licensee to revise its security plan to ensure effective implementation of the plan. Paragraph (a)(4) requires the licensee to retain a copy of the current security plan until the license is terminated and any security plan revisions for 3 years.

Paragraph (b)(1) requires licensees to develop and maintain written procedures for implementation of the security plan. Paragraph (b)(2) requires the procedures to be approved by the individual with overall responsibility for the security program. Paragraph (b)(3) requires the licensee to retain a copy of the procedures for 3 years after the procedure is no longer needed or upon termination of the license and any revisions for 3 years.

Paragraph (c) requires licensees to conduct training and annual refresher training on the security plan. Licensees are required to maintain training records for 3 years from the date of the training.

Paragraph (d) requires licensees to protect the security plan, implementing procedures, and the list of individuals that have been approved for unescorted access from unauthorized disclosure. Licensees are required to develop, maintain and implement written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan and implementing procedures. Only individuals with a need-to-know and that have been determined to be trustworthy and reliable should have access to the protected information. The information protection procedures are retained for 3 years after the document is no longer needed.

Section 37.45 LLEA coordination.

Paragraph (a) requires that a licensee attempt to coordinate with an LLEA and specifies the types of information to be shared with the LLEA.

Paragraph (b) requires the licensee to notify the NRC if the LLEA isn't willing to participate in coordination activities or does not respond to the coordination request.

Paragraph (c) requires the licensee to maintain records of its coordination activities with any LLEA.

Section 37.47 Security zones.

Paragraph (a) requires licensees to establish security zones for the use of category 1 or category 2 quantities of radioactive material.

Paragraph (b) requires the establishment of temporary security zones, as necessary, to meet transitory or intermittent business activities.

Paragraph (c) requires that security zones use physical barriers or direct control of the security zone to allow unescorted access only to approved individuals.

Paragraph (d) requires licensees to provide an approved individual to maintain constant surveillance of sources in temporary security zones or in a security zone in which a physical barrier or intrusion detection system has been disabled to allow maintenance, source receipt, preparation for shipment, source installation, or removal or exchange of category 1 quantities of radioactive material.

Paragraph (e) requires individuals not approved for unescorted access to be escorted by an approved individual when in a security zone.

Section 37.49 Monitoring, detection, and assessment.

Paragraph (a) requires the licensee to establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into the security zones.

Paragraph (b) requires the licensee to assess without delay each actual or attempted unauthorized entry into the security zone.

Paragraph (c)(1) requires the licensee to maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems.

Paragraph (c)(2) requires the licensee to provide alternative capabilities for personnel communication and data transmission and processing.

Paragraph (d) requires the licensee to respond without delay to any actual or attempted unauthorized access to the security zone.

Section 37.51 Maintenance and testing.

This section requires licensees to implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition, are capable of performing their intended function when needed, and are inspected and tested for operability and performance. The testing and maintenance are to be conducted at the frequency recommended by the manufacturer or annually if there is no manufacturer's recommended frequency. Licensees are required to maintain the maintenance and testing records for 3 years.

Section 37.53 Requirements for mobile devices.

This section requires licensees that possess mobile devices containing category 1 or

category 2 quantities of radioactive materials to have two independent physical controls to secure the radioactive material from unauthorized removal and to use a method to disable the vehicle or trailer when the device is on a vehicle or trailer, unless the site prohibits the use of a disabling mechanism due to health and safety concerns.

Section 37.55 Security program review.

This section requires licensees to conduct an annual review of the security program. The licensee is required to document the results of the review and any findings and keep the records for 3 years.

Section 37.57 Reporting of events.

Paragraph (a) requires licensees to immediately notify the LLEA of any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and to then notify the NRC.

Paragraph (b) requires licensees to assess any suspicious activity related to the theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and to notify the LLEA as appropriate and then notify the NRC.

Paragraph (c) requires licensees to submit a written report to the NRC within 30 days of any report of actual or attempted theft, sabotage, or diversion of radioactive material.

Section 37.71 Additional requirements for transfer of category 1 and category 2 quantities of radioactive material.

Paragraphs (a) and (b) establish new requirements for licensees transferring category 1 and category 2 quantities of radioactive material. The licensee is required to verify the validity of the license by using the license verification system or contacting the license issuing authority.

Paragraph (c) provides an emergency method for when the licensee can't reach the license issuing authority and the license verification system is nonfunctional.

Paragraph (d) requires documentation to be maintained for 3 years.

Section 37.73 Applicability of physical protection of category 1 and category 2 quantities of radioactive material during transit.

This section establishes which requirements apply to licensees shipping category 1 or category 2 quantities of radioactive material and what requirements apply during the domestic portion of a shipment that is imported from another country or exported to another country. This section also allows the receiving licensee to arrange for the in-transit physical protection of a shipment instead of the shipping licensee as long as the agreement is in writing.

Section 37.75 Preplanning and coordination of shipment of category 1 or category 2 quantities of radioactive material.

This section establishes the preplanning and coordination necessary for a shipment of category 1 or category 2 quantities of radioactive material.

Section 37.77 Advance notification of shipment of category 1 quantities of radioactive material.

This section establishes the requirements for advance notification to the NRC and the governor of a State, or the governor's designee, of the shipment of category 1 quantities of radioactive material that will pass through or across the State.

Section 37.79 Requirements for physical protection of category 1 and category 2 quantities of radioactive material during shipment.

This section establishes the physical protection requirements for shipments of category 1 and category 2 quantities of radioactive material. Paragraph (a)(1) establishes the requirements for shipping a category 1 quantity of radioactive material by road. Paragraph (a)(2) establishes the requirements for a licensee that transports category 2 quantities of radioactive material by road. Paragraph (a)(3) establishes the requirements for a licensee that uses a carrier for shipping category 2 quantities of radioactive material.

Paragraph (b)(1) establishes the requirements for shipping category 1 quantities of radioactive material by rail. Paragraph (b)(2) establishes the security requirements for shipping category 2 quantities of radioactive material by rail.

Paragraph (c) requires the shipping licensee to immediately conduct an investigation of any shipment of category 2 quantities of radioactive material that is lost or unaccounted for after the designated no-later-than arrival time. It also requires the licensee to conduct an investigation once it is determined that a category 1 shipment is lost or missing.

Section 37.81 Reporting of events.

This section establishes requirements for the shipping licensee to make notifications upon the discovery that a shipment is lost or missing and upon discovery of any actual or attempted theft or diversion of a shipment, or suspicious activities related to the theft or diversion of a shipment of either a category 1 or category 2 quantity of radioactive material. This section also establishes requirements for notification upon recovery of a lost or missing shipment. Written follow-up reports are required for notifications of actual theft or attempted theft or diversion of a shipment.

Section 37.101 Form of records.

This section establishes the requirements for the storage and protection of records required by this part.

Section 37.103 Record retention.

This section establishes the Commission's termination of the license as the end point of the retention period for any record where a specific retention period is not specified.

Section 37.105 Inspections.

Paragraph (a) requires licensees to allow the Commission the opportunity to inspect the materials and facilities subject to 10 CFR part 37.

Paragraph (b) requires the licensee to make available for inspection any records subject to 10 CFR part 37.

Section 37.107 Violations.

Paragraph (a) of this section establishes that the Commission may obtain an injunction or other court order to prevent a violation of the AEA, Title II of the Energy Reorganization Act of 1974, as amended; or a regulation or order issued under those Acts.

Paragraph (b) of this section establishes the violations for which the Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the AEA.

Section 37.109 Criminal penalties.

This section establishes the sections in 10 CFR part 37 that are issued under one or more of Sections 161b, 161i, or 161o and are therefore subject to criminal sanctions for willful

violation of, attempted violation of, or conspiracy to violate the regulation.

Appendix A to 10 CFR Part 37 – Category 1 and Category 2 Radioactive Materials.

Table 1 of this appendix establishes the radionuclides and associated thresholds for category 1 and category 2 quantities of radioactive material. The appendix also provides the methodology for calculating the sum of fractions for evaluating combinations of multiple radionuclides.

Section 39.1 Purpose and scope.

10 CFR part 37 is added to the list of 10 CFR parts that apply to applications and licenses subject to this part.

Section 51.22 Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review.

Paragraph (c)(3) is revised to include 10 CFR part 37.

Section 71.97 Advance notification of shipment of irradiated reactor fuel and nuclear waste.

Paragraph (b) is revised to delete the reference to shipments of irradiated reactor fuel in quantities less than those subject to the advance notification requirements of 10 CFR 73.37(f). Section 73.35 provides that such irradiated reactor fuel shipments be subject to the same requirements that apply to shipments of category 1 radioactive material, including the advance notification requirements.

Section 73.35 Requirements for physical protection of irradiated reactor fuel (100 grams or less) in transit.

A new section is added to 10 CFR part 73 to address the physical protection

requirements for shipments of irradiated reactor fuel weighing 100 g (0.22 lb) or less in net weight of irradiated fuel, exclusive of cladding or other structural or packaging material, which has a total external radiation dose rate in excess of 1 Gray (100 rad) per hour at a distance of 1 m (3.3 ft) from any accessible surface without intervening shielding. The material is subject to the same transportation security requirements as category 1 quantities of radioactive material.

V. Criminal Penalties.

For the purpose of Section 223 of the AEA, the Commission is amending 10 CFR parts 20, 30, 32, 33, 34, 35, 36, 39, 51, 71, and 73 and adding new 10 CFR part 37 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

VI. Agreement State Compatibility.

Under the “Policy Statement on Adequacy and Compatibility of Agreement State Programs” approved by the Commission on June 30, 1997, and published in the *Federal Register* (62 FR 46517; September 3, 1997), this final rule is a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States and the NRC requirements. The NRC analyzed the final rule in accordance with the procedure established within part III, “Categorization Process for NRC Program Elements,” of Handbook 5.9 to Management Directive 5.9, “Adequacy and Compatibility of Agreement State Programs” (a copy of which may be viewed at <http://www.nrc.gov/reading-rm/doc-collections/management-directives/>).

The NRC program elements (including regulations) are placed into four compatibility categories (see the Compatibility Table in this section). In addition, the NRC program elements can also be identified as having particular health and safety significance or as being reserved solely to the NRC. Compatibility Category A elements are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B elements are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C elements are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D elements are those program elements that do not meet any of the criteria of Category A, B, or C, above, and, thus, do not need to be adopted by Agreement States for purposes of compatibility.

Health and Safety (H&S) elements are program elements that are not required for compatibility, but are identified as having a particular health and safety role (*i.e.*, adequacy) in the regulation of agreement material within the State. Although not required for compatibility, the State should adopt program elements in this H&S Category based on those of the NRC that embody the essential objectives of the NRC program elements because of particular health and safety considerations. Compatibility Category NRC elements are those program elements that

address areas of regulation that cannot be relinquished to Agreement States under the AEA or provisions of 10 CFR. These program elements are not adopted by Agreement States. The following table lists the parts and sections that have been created or revised and their corresponding categorization under the “Policy Statement on Adequacy and Compatibility of Agreement State Programs.” A bracket around a category means that the section may have been adopted elsewhere, and it is not necessary to adopt it again.

The Agreement States have 3 years from the publication of the final rule in the *Federal Register* to adopt compatible regulations.

Compatibility Table for Final Rule

Section	Change	Subject	Compatibility	
			Existing	New
Part 20				
20.2201(c)	Amend	Reports of theft or loss of licensed material	D	D
Part 30				
30.6	Amend	Communications	D	D
30.13	Amend	Carriers	B	B
30.33(a)(4)	Amend	General requirements for issuance of specific licenses	D	D
Part 32				
32.1(b)	Amend	Purpose and scope	D	D
Part 33				
33.1	Amend	Purpose and scope	D	D
Part 34				
34.1	Amend	Purpose and scope	D	D
Part 35				
35.1	Amend	Purpose and scope	D	D
Part 36				
36.1	Amend	Purpose and scope	D	D
Part 37				
37.1	New	Purpose	-	D
37.3	New	Scope	-	D
37.5	New	Definition Access control	-	C
37.5	New	Definition Act	-	D
37.5	New	Definition Aggregated	-	C
37.5	New	Definition Agreement State	-	[B]
37.5	New	Definition Approved individual	-	B

37.5	New	Definition Background Investigation	-	C
37.5	New	Definition Becquerel	-	[A]
37.5	New	Definition Byproduct Material	-	[H&S]
37.5	New	Definition Carrier	-	[B]
37.5	New	Definition Category 1 quantities of radioactive material	-	B
37.5	New	Definition Category 2 quantities of radioactive material	-	B
37.5	New	Definition Commission	-	D
37.5	New	Definition Curie	-	[A]
37.5	New	Definition Diversion	-	C
37.5	New	Definition Escorted access	-	B
37.5	New	Definition Fingerprint Orders		C
37.5	New	Definition Government agency	-	D
37.5	New	Definition License	-	D
37.5	New	Definition License issuing agency	-	D
37.5	New	Definition Local law enforcement agency	-	C
37.5	New	Definition Lost or missing material	-	[B]
37.5	New	Definition Mobile device	-	B
37.5	New	Definition Movement control center	-	B
37.5	New	Definition No-later-than arrival time	-	B
37.5	New	Definition Person	-	[C]
37.5	New	Definition Reviewing official	-	C
37.5	New	Definition Sabotage	-	C
37.5	New	Safe haven	-	B
37.5	New	Definition Security zone		C
37.5	New	Definition State	-	D
37.5	New	Definition Telemetric position monitoring system		B
37.5	New	Definition Trustworthiness and reliability	-	B
37.5	New	Definition Unescorted access	-	B
37.5	New	Definition United States	-	D
37.7	New	Communications	-	D
37.9	New	Interpretations	-	D
37.11(a)	New	Specific exemptions	-	D
37.11(b)	New	Specific exemptions	-	D
37.11(c)	New	Specific exemptions		B
37.13	New	Information collection requirements: OMB approval	-	D
37.21(a)	New	General		C
37.21(b)	New	General performance objective	-	B
37.21(c)	New	Applicability	-	B
37.23(a)	New	Granting unescorted access authorization	-	B

37.23(b)(1), (2), (4), (5)	New	Reviewing officials	-	B
37.23(b)(3)	New	Reviewing officials	-	C
37.23(c)	New	Informed consent	-	B
37.23(d)	New	Personal history disclosure	-	B
37.23(e)	New	Determination basis	-	B
37.23(f)	New	Procedures	-	C
37.23(g)	New	Right to correct and complete information	-	B
37.23(h)	New	Records	-	C
37.25(a)	New	Initial investigation	-	B
37.25(b)	New	Grandfathering		C
37.25(c)	New	Reinvestigations	-	B
37.27(a)	New	General performance objective and requirements	-	B
37.27(b)	New	Prohibitions	-	B
37.27(c)	New	Procedures for processing fingerprint checks	-	B
37.29(a), (b)	New	Relief from fingerprinting, identification, and criminal history records checks and other elements of a background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials	-	B
37.31(a)-(d)	New	Protection of information	-	B
37.31(e)	New	Protection of information		C
37.33(a), (b), (c)	New	Access authorization program review	-	C
37.41(a)	New	Applicability	-	B
37.41(b)	New	General performance objective	-	B
37.41(c)	New	Program features	-	C
37.43(a)	New	Security plan	-	B
37.43(b)	New	Implementing procedures	-	C
37.43(c)(1) – (c)(3)	New	Training	-	B
37.43(c)(4)	New	Training		C
37.43(d)(1) – (d)(8)	New	Protection of Information	-	C
37.43(d)(9)	New	Protection of Information		NRC
37.45(a), (b), (d)	New	LLEA coordination	-	B
37.45(c)	New	LLEA coordination (records)	-	C
37.47(a)-(e)	New	Security zones	-	B
37.49(a)	New	Monitoring and detection	-	B
37.49(b)	New	Assessment	-	B

37.49(c)	New	Personnel communications and data transmission	-	B
37.49(d)	New	Response	-	B
37.51	New	Maintenance and testing	-	C
37.53	New	Requirements for mobile devices	-	B
37.55(a), (b), (c)	New	Security program review	-	C
37.57(a)	New	Reporting of events	-	C
37.57(b)	New	Reporting of events	-	C
37.71	New	Additional requirements for transfer of category 1 and category 2 quantities of radioactive material	-	B
37.71(a), (b) (c)	New	Additional requirements for transfer of category 1 and category 2 quantities of radioactive material	-	B
37.71(d)	New	Additional requirements for transfer of category 1 and category 2 quantities of radioactive material	-	C
37.73(a), (b), (d), (e)	New	Applicability of physical protection of category 1 and category 2 quantities of radioactive material during transit	-	D
37.73(c)	New	Applicability of physical protection of category 1 and category 2 quantities of radioactive material during transit	-	B
37.75(a) – (d)	New	Preplanning and coordination of shipment of category 1 or category 2 quantities of radioactive material	-	B
37.75(e)	New	Preplanning and coordination of shipment of category 1 or category 2 quantities of radioactive material	-	C
37.77	New	Advance notification for shipments of category 1 quantities of radioactive material	-	B
37.77(a)	New	Procedures for submitting advance notification	-	B
37.77(b)	New	Information to be furnished in advance notification of shipment	-	B
37.77(c)	New	Revision notice	-	B
37.77(d)	New	Cancellation notice	-	B
37.77(e)	New	Records	-	C
37.77(f)	New	Protection of information	-	NRC
37.79(a)	New	Shipments by road	-	B
37.79(b)	New	Shipments by rail	-	B
37.79(c)	New	Investigations	-	B
37.81(a)	New	Reporting of events	-	B
37.81(b)	New	Reporting of events	-	B

37.81(c)	New	Reporting of events	-	B
37.81(d)	New	Reporting of events	-	B
37.81(e)	New	Reporting of events	-	B
37.81(f)	New	Reporting of events	-	B
37.81(g)	New	Reporting of events	-	C
37.81(h)	New	Reporting of events		C
37.101	New	Form of records	-	C
37.103	New	Record retention		C
37.105	New	Inspections	-	D
37.107	New	Violations	-	D
37.109	New	Criminal penalties	-	D
Appendix A	New	Category 1 and 2 thresholds	-	B
Part 39				
39.1	Amend	Purpose and scope	D	D
Part 51				
51.22(c)(3)	Amend	Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review	NRC	NRC
Part 71				
71.97(b)	Amend	Advance notification of shipment of irradiated reactor fuel and nuclear waste	B	B
Part 73				
73.35	New	Requirements for physical protection of irradiated reactor fuel (100 grams or less) in transit	-	NRC

VII. Plain Writing.

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, “Plain Language in Government Writing,” published June 10, 1998 (63 FR 31883).

VIII. Voluntary Consensus Standards.

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113), requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is establishing security requirements for the use of category 1 and category 2 quantities of radioactive materials. The NRC is not aware of any voluntary consensus standards that address the subject matter of this final rule. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

IX. Finding of No Significant Environmental Impact: Availability.

Under the National Environmental Policy Act of 1969, as amended, and the NRC regulations in subpart A of 10 CFR part 51, the NRC has determined that this final rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement is not required for this rulemaking. The NRC has prepared an environmental assessment and, on the basis of this environmental assessment, has made a finding of no significant impact.

The implementation of the final rule's security requirements would not result in significant changes to the licensee's facilities, nor would such implementation result in any significant increase in effluents released to the environment. Similarly, the implementation of the final rule's security requirements would not affect occupational exposure requirements. No major construction or other earth-disturbing activities on the part of affected licensees are anticipated in connection with licensees' implementation of the final rule's requirements. The Commission has determined that the implementation of this final rule is procedural and administrative in nature.

The determination of this environmental assessment is that there will be no significant impact to the public from this action.

This conclusion was published in the environmental assessment that was posted to the NRC's rulemaking Web site: <http://www.regulations.gov> after publication of the proposed rule. No comments were received on the content of the environmental assessment.

X. Paperwork Reduction Act Statement.

This final rule contains new information collection requirements in 10 CFR part 37 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget (OMB), approval number 3150-0214. The changes to 10 CFR parts 20, 30, 32, 33, 34, 35, 36, 39, 51, 71, and 73 do not contain new or amended information collection requirements. Existing requirements were approved by the OMB, approval numbers 3150-0014, 3150-0017, 3150-0001, 3150-0015, 3150-0007, 3150-0010, 3150-0158, 3150-0130, 3150-0021, 3150-0008, and 3150-0002.

The burden to the public for the information collections in 10 CFR part 37 is estimated to average 1.7 hours per response. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS.RESOURCE@NRC.GOV; and to the Desk Officer, Chad Whiteman, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0214), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XI. Regulatory Analysis.

The Commission has prepared a regulatory analysis on this final regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission.

The analysis is available for inspection in the NRC's Public Document Room, 11555 Rockville Pike, Rockville, Maryland 20852. The analysis may also be viewed and downloaded electronically via the Federal erulemaking portal at <http://www.regulations.gov> by searching for Docket ID NRC-2008-0120.

XII. Regulatory Flexibility Certification.

The NRC has prepared a regulatory analysis of the impact of this final rule on small entities. The final rule will affect about 300 NRC licensees and an additional 1,100 Agreement State licensees. Affected licensees include laboratories, reactors, universities, colleges, medical clinics, hospitals, irradiators, manufacturers and distributors, well loggers, and radiographers, some of which may qualify as small business entities as defined by 10 CFR 2.810. Based on the regulatory analysis conducted for this action, the costs of the rule for affected licensees are estimated to be between \$358 million and \$488 million (7-percent and 3-percent discount rate over 20 years, respectively) total. The average licensee will have a

one-time cost of approximately \$23,375 and an annual cost of approximately \$21,736 to fully implement the final rule. The NRC believes that the selected alternative reflected in the final rule is the least burdensome, most flexible alternative that accomplishes the NRC's regulatory objective. The Regulatory Flexibility Analysis is included as an Appendix to this final rule.

XIII. Backfit Analysis.

The NRC has determined that the backfit rule, which is found in the regulations at 10 CFR 50.109, 70.76, 72.62, 76.76, and in 10 CFR part 52, does not apply to this final rule because this amendment would not involve any provisions that would impose backfits as defined in 10 CFR chapter I. Therefore, a backfit analysis is not required.

XIV. Congressional Review Act.

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 33

Byproduct material, Criminal penalties, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 34

Criminal penalties, Packaging and containers, Radiation protection, Radiography, Reporting and recordkeeping requirements, Scientific equipment, Security measures.

10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 36

Byproduct material, Criminal penalties, Nuclear materials, Reporting and recordkeeping requirements, Scientific equipment, Security measures.

10 CFR Part 37

Byproduct material, Criminal penalties, Export, Hazardous materials transportation, Import, Licensed material, Nuclear materials, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 39

Byproduct material, Criminal penalties, Nuclear material, Oil and gas exploration - well logging, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Source material, Special nuclear material.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statement, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 71

Criminal penalties, Hazardous materials transportation, Nuclear materials, Packaging and containers, Reporting and recordkeeping requirements.

10 CFR Part 73

Criminal penalties, Export, Hazardous materials transportation, Import, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Security measures.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR parts 20, 30, 32, 33, 34, 35, 36, 37, 39, 51, 71, and 73.

PART 20 – STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for part 20 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 223, 234 1701 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2273, 2282, 2297f), Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005 sec. 651(e), Pub. L. No. 109-58, 119 Stat. 549 (2005) (42 U.S.C. 2014, 2021, 2021b, 2111).

2. In § 20.2201, paragraph (c) is revised to read as follows:

§ 20.2201 Reports of theft or loss of licensed material.

* * * * *

(c) A duplicate report is not required under paragraph (b) of this section if the licensee is also required to submit a report pursuant to §§ 30.55(c), 37.57, 37.81, 40.64(c), 50.72, 50.73, 70.52, 73.27(b), 73.67(e)(3)(vii), 73.67(g)(3)(iii), 73.71, or 150.19(c) of this chapter.

* * * * *

PART 30 - RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

3. The authority citation for part 30 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 81, 82, 161, 181, 182, 183, 186, 223, 234 (42 U.S.C. 2111, 2112, 2201, 2231, 2232, 2233, 2236, 2273, 2282); Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 549 (2005).

Section 30.7 also issued under Energy Reorganization Act sec. 211, Pub. L. 95-601, sec. 10, as amended by Pub. L. 102-486, sec. 2902 (42 U.S.C. 5851). Section 30.34(b) also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234). Section 30.61 also issued under Atomic Energy Act sec. 187 (42 U.S.C. 2237).

4. In § 30.6, the introductory text of paragraph (a) is revised to read as follows:

§ 30.6 Communications.

(a) Unless otherwise specified or covered under the regional licensing program as provided in paragraph (b) of this section, any communication or report concerning the regulations in parts 30 through 37 and 39 of this chapter and any application filed under these regulations may be submitted to the Commission as follows:

* * * * *

5. Section 30.13 is revised to read as follows:

§ 30.13 Carriers.

Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from the regulations in this part and parts 31 through 37 and 39 of this chapter and the requirements for a license set forth in section 81 of the Act to the extent that they transport or store byproduct material in the regular course of carriage for another or storage incident thereto.

6. In § 30.33, paragraph (a)(4) is revised to read as follows:

§ 30.33 General requirements for issuance of specific licenses.

(a)* * *

(4) The applicant satisfies any special requirements contained in parts 32 through 37 and 39 of this chapter; and

* * * * *

PART 32 - SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

7. The authority citation for part 32 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 81, 161, 181, 182, 183, 223, 234 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282); Energy Reorganization Act sec. 201 (42 U.S.C.5841); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, sec. 651(e), Pub. L. No. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

8. In § 32.1, paragraph (b) is revised to read as follows:

§ 32.1 Purpose and scope.

* * * * *

(b) The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of part 30 of this chapter apply to applications, licenses and certificates of registration subject to this part, and the provisions of part 37 of this chapter apply to applications and licenses subject to this part.

* * * * *

PART 33 - SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL

9. The authority citation for part 33 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 81, 161, 181, 182, 183, 223, 234 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282); Energy Reorganization Act sec. 201 (42 U.S.C. 5841); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005 sec. 651(e), Pub. L. No. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

10. Section 33.1 is revised to read as follows:

§ 33.1 Purpose and scope.

This part prescribes requirements for the issuance of specific licenses of broad scope for byproduct material (“broad licenses”) and certain regulations governing holders of such licenses. The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of parts 30 and 37 of this chapter apply to applications and licenses subject to this part.

PART 34 - LICENSES FOR INDUSTRIAL RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

11. The authority citation for part 34 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 81, 161, 181, 182, 183, 223, 234 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282); Energy Reorganization Act sec. 201 (42 U.S.C. 5841); Government Paperwork Elimination Act sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note). Atomic Energy Act of 2005 sec. 651(e), Pub. L. No. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111). Section 34.45 also issued under Energy Reorganization Act sec. 206 (42 U.S.C. 5846).

12. Section 34.1 is revised to read as follows:

§ 34.1 Purpose and scope.

This part prescribes requirements for the issuance of licenses for the use of sealed sources containing byproduct material and radiation safety requirements for persons using these sealed sources in industrial radiography. The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the requirements and provisions of parts 19, 20, 21, 30, 37, 71, 150, 170, and 171 of this chapter apply to applications and licenses subject to this part. This rule does not apply to medical uses of byproduct material.

PART 35 – MEDICAL USE OF BYPRODUCT MATERIAL

13. The authority citation for part 35 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 81, 161, 181, 182, 183, 223, 234 (42 U.S.C.

2111, 2201, 2231, 2232, 2233, 2273, 2282); Energy Reorganization Act sec. 201, 206 (42 U.S.C. 5841, 5842, 5846); sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, sec. 651(e), Pub. L. No. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

14. Section 35.1 is revised to read as follows:

§ 35.1 Purpose and scope.

This part contains the requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of parts 19, 20, 21, 30, 37, 71, 170, and 171 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.

PART 36 – LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

15. The authority citation for part 36 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 81, 82, 161, 181, 182, 183, 186, 223, 234 (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2273, 2282); Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Atomic Energy Act of 2005 sec. 651(e), Pub. L. No. 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

16. In § 36.1, paragraph (a) is revised to read as follows:

§ 36.1 Purpose and scope.

(a) This part contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This part also contains radiation safety requirements for operating irradiators. The requirements of this part are in addition to other requirements of this chapter. In particular, the provisions of parts 19, 20, 21, 30, 37, 71, 170, and 171 of this chapter apply to applications and licenses subject to this part. Nothing in this part relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

* * * * *

17. Part 37 is added to read as follows:

PART 37 – PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

Subpart A - General Provisions

Sec.

37.1 Purpose.

37.3 Scope.

37.5 Definitions.

37.7 Communications.

37.9 Interpretations.

37.11 Specific exemptions.

37.13 Information collection requirements: OMB approval.

Subpart B – Background Investigations and Access Control Program

- 37.21 Personnel access authorization requirements for category 1 or category 2 quantities of radioactive material.
- 37.23 Access authorization program requirements.
- 37.25 Background investigations.
- 37.27 Requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material.
- 37.29 Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials.
- 37.31 Protection of information.
- 37.33 Access authorization program review.

Subpart C – Physical Protection Requirements During Use

- 37.41 Security program.
- 37.43 General security program requirements.
- 37.45 LLEA coordination.
- 37.47 Security zones.
- 37.49 Monitoring, detection, and assessment.
- 37.51 Maintenance and testing.
- 37.53 Requirements for mobile devices.
- 37.55 Security program review.
- 37.57 Reporting of events.

Subpart D – Physical Protection in Transit

- 37.71 Additional requirements for transfer of category 1 and category 2 quantities of radioactive material.
- 37.73 Applicability of physical protection of category 1 and category 2 quantities of radioactive material during transit.
- 37.75 Preplanning and coordination of shipment of category 1 or category 2 quantities of radioactive material.
- 37.77 Advance notification of shipment of category 1 quantities of radioactive material.
- 37.79 Requirements for physical protection of category 1 and category 2 quantities of radioactive material during shipment.
- 37.81 Reporting of events.

Subpart E – (Reserved)

Subpart F – Records

- 37.101 Form of records.
- 37.103 Record retention.

Subpart G – Enforcement

37.105 Inspections.
37.107 Violations.
37.109 Criminal penalties.

Appendix A to Part 37—Category 1 and Category 2 Radioactive Materials

AUTHORITY: Atomic Energy Act secs. 53, 81, 103, 104, 147, 148, 149, 161, 182, 183, 223, 234 (42 U.S.C. 2073, 2111, 2133, 2134, 2167, 2168, 2169, 2201a., 2232, 2233, 2273, 2282).

Subpart A – General Provisions

§ 37.1 Purpose.

This part has been established to provide the requirements for the physical protection program for any licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material listed in Appendix A to this part. These requirements provide reasonable assurance of the security of category 1 or category 2 quantities of radioactive material by protecting these materials from theft or diversion. Specific requirements for access to material, use of material, transfer of material, and transport of material are included. No provision of this part authorizes possession of licensed material.

§ 37.3 Scope.

(a) Subparts B and C of this part apply to any person who, under the regulations in this chapter, possesses or uses at any site, an aggregated category 1 or category 2 quantity of radioactive material.

(b) Subpart D of this part applies to any person who, under the regulations of this chapter:

(1) Transports or delivers to a carrier for transport in a single shipment, a category 1 or category 2 quantity of radioactive material; or

(2) Imports or exports a category 1 or category 2 quantity of radioactive material; the provisions only apply to the domestic portion of the transport.

§ 37.5 Definitions.

As used in this part:

Access control means a system for allowing only approved individuals to have unescorted access to the security zone and for ensuring that all other individuals are subject to escorted access.

Act means the Atomic Energy Act of 1954 (68 Stat. 919), including any amendments thereto.

Aggregated means accessible by the breach of a single physical barrier that would allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a category 2 quantity of radioactive material.

Agreement State means any state with which the Atomic Energy Commission or the U.S. Nuclear Regulatory Commission has entered into an effective agreement under subsection 274b. of the Act. *Non-agreement State* means any other State.

Approved individual means an individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with subpart B of this part and who has completed the training required by § 37.43(c).

Background investigation means the investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

Becquerel (Bq) means one disintegration per second.

Byproduct material means—

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute “byproduct material” within this definition;

(3)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(4) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

Carrier means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

Category 1 quantity of radioactive material means a quantity of radioactive material meeting or exceeding the category 1 threshold in Table 1 of Appendix A to this part. This is determined by calculating the ratio of the total activity of each radionuclide to the category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

Category 2 quantity of radioactive material means a quantity of radioactive material meeting or exceeding the category 2 threshold but less than the category 1 threshold in Table 1 of Appendix A to this part. This is determined by calculating the ratio of the total activity of each radionuclide to the category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 2 quantity. Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

Commission means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

Curie means that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second.

Diversion means the unauthorized movement of radioactive material subject to this part to a location different from the material's authorized destination inside or outside of the site at which the material is used or stored.

Escorted access means accompaniment while in a security zone by an approved individual who maintains continuous direct visual surveillance at all times over an individual who is not approved for unescorted access.

Fingerprint orders means the orders issued by the U.S. Nuclear Regulatory Commission or the legally binding requirements issued by Agreement States that require fingerprints and criminal history records checks for individuals with unescorted access to category 1 and category 2 quantities of radioactive material or safeguards information-modified handling.

Government agency means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

License, except where otherwise specified, means a license for byproduct material issued pursuant to the regulations in parts 30 through 36 and 39 of this chapter;

License issuing authority means the licensing agency that issued the license, *i.e.* the U.S. Nuclear Regulatory Commission or the appropriate agency of an Agreement State;

Local law enforcement agency (LLEA) means a public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed category 1 or category 2 quantity of radioactive material is used, stored, or transported.

Lost or missing licensed material means licensed material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

Mobile device means a piece of equipment containing licensed radioactive material that is either mounted on wheels or casters, or otherwise equipped for moving without a need for

disassembly or dismounting; or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.

Movement control center means an operations center that is remote from transport activity and that maintains position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies and can request and coordinate appropriate aid.

No-later-than arrival time means the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than-arrival time may not be more than 6 hours after the estimated arrival time for shipments of category 2 quantities of radioactive material.

Person means—

(1) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the DOE (except that the Department shall be considered a person within the meaning of the regulations in 10 CFR chapter I to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission under section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), the Nuclear Waste Policy Act of 1982 (96 Stat. 2201), and section 3(b)(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (99 Stat. 1842), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and

(2) Any legal successor, representative, agent, or agency of the foregoing.

Reviewing official means the individual who shall make the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to

have, unescorted access to the category 1 or category 2 quantities of radioactive materials that are possessed by the licensee.

Sabotage means deliberate damage, with malevolent intent, to a category 1 or category 2 quantity of radioactive material, a device that contains a category 1 or category 2 quantity of radioactive material, or the components of the security system.

Safe haven means a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law enforcement authorities.

Security zone means any temporary or permanent area determined and established by the licensee for the physical protection of category 1 or category 2 quantities of radioactive material.

State means a State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Telemetric position monitoring system means a data transfer system that captures information by instrumentation and/or measuring devices about the location and status of a transport vehicle or package between the departure and destination locations.

Trustworthiness and reliability are characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to category 1 or category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

Unescorted access means solitary access to an aggregated category 1 or category 2 quantity of radioactive material or the devices that contain the material.

United States, when used in a geographical sense, includes Puerto Rico and all territories and possessions of the United States.

§ 37.7 Communications.

Except where otherwise specified or covered under the regional licensing program as provided in § 30.6(b) of this chapter, all communications and reports concerning the regulations in this part may be sent as follows:

(a) By mail addressed to: ATTN: Document Control Desk; Director, Office of Nuclear Reactor Regulation; Director, Office of New Reactors; Director, Office of Nuclear Material Safety and Safeguards; Director, Office of Federal and State Materials and Environmental Management Programs; or Director, Division of Security Policy, Office of Nuclear Security and Incident Response, as appropriate, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001;

(b) By hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland 20852;

(c) Where practicable, by electronic submission, for example, Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>; by e-mail to MSHD.Resource@nrc.gov; or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information.

§ 37.9 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretations of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized as binding upon the Commission.

§ 37.11 Specific exemptions.

(a) The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security, and are otherwise in the public interest.

(b) Any licensee's NRC-licensed activities are exempt from the requirements of subparts B and C of this part to the extent that its activities are included in a security plan required by part 73 of this chapter.

(c) A licensee that possesses radioactive waste that contains category 1 or category 2 quantities of radioactive material is exempt from the requirements of subparts B, C, and D of this part. Except that any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements of this part. The licensee shall implement the following requirements to secure the radioactive waste:

(1) Use continuous physical barriers that allow access to the radioactive waste only through established access control points;

(2) Use a locked door or gate with monitored alarm at the access control point;

(3) Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and

(4) Immediately notify the LLEA and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains category 1 or category 2 quantities of radioactive material.

§ 37.13 Information collection requirements: OMB approval.

(a) The U.S. Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB has approved the information collection requirements contained in this part under control number 3150-0214.

(b) The approved information collection requirements contained in this part appear in §§ 37.11, 37.21, 37.23, 37.25, 37.27, 37.29, 37.31, 37.33, 37.41, 37.43, 37.45, 37.49, 37.51, 37.55, 37.57, 37.71, 37.75, 37.77, 37.79, and 37.81.

Subpart B – Background Investigations and Access Authorization Program

§ 37.21 Personnel access authorization requirements for category 1 or category 2 quantities of radioactive material.

(a) *General.* (1) Each licensee that possesses an aggregated quantity of radioactive material at or above the category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements of this subpart.

(2) An applicant for a new license and each licensee that would become newly subject to the requirements of this subpart upon application for modification of its license shall implement

the requirements of this subpart, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

(3) Any licensee that has not previously implemented the Security Orders or been subject to the provisions of this subpart B shall implement the provisions of this subpart B before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

(b) *General performance objective.* The licensee's access authorization program must ensure that the individuals specified in paragraph (c)(1) of this section are trustworthy and reliable.

(c) *Applicability.* (1) Licensees shall subject the following individuals to an access authorization program:

(i) Any individual whose assigned duties require unescorted access to category 1 or category 2 quantities of radioactive material or to any device that contains the radioactive material; and

(ii) Reviewing officials.

(2) Licensees need not subject the categories of individuals listed in § 37.29(a)(1) through (13) to the investigation elements of the access authorization program.

(3) Licensees shall approve for unescorted access to category 1 or category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to category 1 or category 2 quantities of radioactive material.

(4) Licensees may include individuals needing access to safeguards information-modified handling under part 73 of this chapter in the access authorization program under this subpart B.

§ 37.23 Access authorization program requirements.

(a) *Granting unescorted access authorization.* (1) Licensees shall implement the requirements of this subpart for granting initial or reinstated unescorted access authorization.

(2) Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by § 37.43(c) before being allowed unescorted access to category 1 or category 2 quantities of radioactive material.

(b) *Reviewing officials.* (1) Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 quantities of radioactive materials possessed by the licensee.

(2) Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. The fingerprints of the named reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a State to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every 10 years in accordance with § 37.25(b).

(3) Reviewing officials must be permitted to have unescorted access to category 1 or category 2 quantities of radioactive materials or access to safeguards information or safeguards information-modified handling, if the licensee possesses safeguards information or safeguards information-modified handling.

(4) Reviewing officials cannot approve other individuals to act as reviewing officials.

(5) A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

(i) The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

(ii) The individual is subject to a category listed in § 37.29(a).

(c) *Informed consent.* (1) Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals that meet the requirements of § 37.25(b). A signed consent must be obtained prior to any reinvestigation.

(2) The subject individual may withdraw his or her consent at any time. Licensees shall inform the individual that:

(i) If an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the individual withdrew his or her consent; and

(ii) The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

(d) *Personal history disclosure.* Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by this subpart is sufficient cause for denial or termination of unescorted access.

(e) *Determination basis.* (1) The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all of the information collected to meet the requirements of this subpart.

(2) The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all of the information collected to meet the requirements of this subpart and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.

(3) The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

(4) The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access authorization.

(5) Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee shall remove the person from the approved list as soon as possible, but no later than 7 working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

(f) *Procedures.* Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures must include provisions for the notification of individuals who are denied unescorted access. The procedures must include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures must contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

(g) *Right to correct and complete information.* (1) Prior to any final adverse determination, licensees shall provide each individual subject to this subpart with the right to complete, correct, and explain information obtained as a result of the licensee's background

investigation. Confirmation of receipt by the individual of this notification must be maintained by the licensee for a period of 1 year from the date of the notification.

(2) If, after reviewing his or her criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures include direct application by the individual challenging the record to the law enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in 28 CFR 16.30 through 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the data, and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. Licensees must provide at least 10 days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his or her review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

(h) *Records.* (1) The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

(2) The licensee shall retain a copy of the current access authorization program procedures as a record for 3 years after the procedure is no longer needed. If any portion of the

procedure is superseded, the licensee shall retain the superseded material for 3 years after the record is superseded.

(3) The licensee shall retain the list of persons approved for unescorted access authorization for 3 years after the list is superseded or replaced.

§ 37.25 Background investigations.

(a) *Initial investigation.* Before allowing an individual unescorted access to category 1 or category 2 quantities of radioactive material or to the devices that contain the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation must encompass at least the 7 years preceding the date of the background investigation or since the individual's eighteenth birthday, whichever is shorter. The background investigation must include at a minimum:

(1) Fingerprinting and an FBI identification and criminal history records check in accordance with § 37.27;

(2) Verification of true identity. Licensees shall verify the true identity of the individual who is applying for unescorted access authorization to ensure that the applicant is who he or she claims to be. A licensee shall review official identification documents (*e.g.*, driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information. Licensees shall document the type, expiration, and identification number of the identification document, or maintain a photocopy of identifying documents on file in accordance with § 37.31. Licensees shall certify in writing that the identification was properly reviewed, and shall maintain the certification and all related documents for review upon inspection;

(3) Employment history verification. Licensees shall complete an employment history verification, including military history. Licensees shall verify the individual's employment with each previous employer for the most recent 7 years before the date of application;

(4) Verification of education. Licensees shall verify that the individual participated in the education process during the claimed period;

(5) Character and reputation determination. Licensees shall complete reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under this subpart must be limited to whether the individual has been and continues to be trustworthy and reliable;

(6) The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the individual (*e.g.*, seek references not supplied by the individual); and

(7) If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at least after 10 business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation; and attempt to obtain the information from an alternate source.

(b) *Grandfathering.* (1) Individuals who have been determined to be trustworthy and reliable for unescorted access to category 1 or category 2 quantities of radioactive material under the Fingerprint Orders may continue to have unescorted access to category 1 and

category 2 quantities of radioactive material without further investigation. These individuals shall be subject to the reinvestigation requirement.

(2) Individuals who have been determined to be trustworthy and reliable under the provisions of part 73 of this chapter or the security orders for access to safeguards information, safeguards information-modified handling, or risk-significant material may have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. The licensee shall document that the individual was determined to be trustworthy and reliable under the provisions of part 73 of this chapter or a security order. Security order, in this context, refers to any order that was issued by the NRC that required fingerprints and an FBI criminal history records check for access to safeguards information, safeguards information-modified handling, or risk significant material such as special nuclear material or large quantities of uranium hexafluoride. These individuals shall be subject to the reinvestigation requirement.

(c) *Reinvestigations.* Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to category 1 or category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with § 37.27. The reinvestigations must be completed within 10 years of the date on which these elements were last completed.

§ 37.27 Requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material.

(a) *General performance objective and requirements.* (1) Except for those individuals listed in § 37.29 and those individuals grandfathered under § 37.25(b), each licensee subject to the provisions of this subpart shall fingerprint each individual who is to be permitted unescorted access to category 1 or category 2 quantities of radioactive material. Licensees shall transmit all collected fingerprints to the Commission for transmission to the FBI. The licensee shall use

the information received from the FBI as part of the required background investigation to determine whether to grant or deny further unescorted access to category 1 or category 2 quantities of radioactive materials for that individual.

(2) The licensee shall notify each affected individual that his or her fingerprints will be used to secure a review of his or her criminal history record, and shall inform him or her of the procedures for revising the record or adding explanations to the record.

(3) Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to category 1 or category 2 quantities of radioactive materials if:

(i) The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his or her unescorted access authorization; and

(ii) The previous access was terminated under favorable conditions.

(4) Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to category 1 or category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee, based upon a background investigation conducted under this subpart, the Fingerprint Orders, or part 73 of this chapter. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of § 37.31(c).

(5) Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to category 1 or category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

(b) *Prohibitions.* (1) Licensees may not base a final determination to deny an individual unescorted access authorization to category 1 or category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

(i) An arrest more than 1 year old for which there is no information of the disposition of the case; or

(ii) An arrest that resulted in dismissal of the charge or an acquittal.

(2) Licensees may not use information received from a criminal history records check obtained under this subpart in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

(c) *Procedures for processing of fingerprint checks.* (1) For the purpose of complying with this subpart, licensees shall use an appropriate method listed in § 37.7 to submit to the U.S. Nuclear Regulatory Commission, Director, Division of Facilities and Security, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop TWB-05 B32M, Rockville, Maryland 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 1-630- 829-9565, or by e-mail to FORMS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at <http://www.nrc.gov/site-help/e-submittals.html>.

(2) Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to

“U.S. NRC.” (For guidance on making electronic payments, contact the Security Branch, Division of Facilities and Security at 301-492-3531.) Combined payment for multiple applications is acceptable. The Commission publishes the amount of the fingerprint check application fee on the NRC’s public Web site. (To find the current fee amount, go to the Electronic Submittals page at <http://www.nrc.gov/site-help/e-submittals.html> and see the link for the Criminal History Program under Electronic Submission Systems.)

(3) The Commission will forward to the submitting licensee all data received from the FBI as a result of the licensee’s application(s) for criminal history records checks.

§ 37.29 Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials.

(a) Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, and other elements of the background investigation are not required for the following individuals prior to granting unescorted access to category 1 or category 2 quantities of radioactive materials:

(1) An employee of the Commission or of the Executive Branch of the U.S. Government who has undergone fingerprinting for a prior U.S. Government criminal history records check;

(2) A Member of Congress;

(3) An employee of a member of Congress or Congressional committee who has undergone fingerprinting for a prior U.S. Government criminal history records check;

(4) The Governor of a State or his or her designated State employee representative;

(5) Federal, State, or local law enforcement personnel;

(6) State Radiation Control Program Directors and State Homeland Security Advisors or their designated State employee representatives;

(7) Agreement State employees conducting security inspections on behalf of the NRC under an agreement executed under section 274.i. of the Atomic Energy Act;

(8) Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;

(9) Emergency response personnel who are responding to an emergency;

(10) Commercial vehicle drivers for road shipments of category 2 quantities of radioactive material;

(11) Package handlers at transportation facilities such as freight terminals and railroad yards;

(12) Any individual who has an active Federal security clearance, provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that granted the Federal security clearance or reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material; and

(13) Any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to category 1 or category 2 quantities of radioactive material. Written verification from the service provider must be provided to the licensee. The licensee shall retain the documentation for a period of 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

(b) Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the

last 5 years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material. These programs include, but are not limited to:

- (1) National Agency Check;
- (2) Transportation Worker Identification Credentials (TWIC) under 49 CFR part 1572;
- (3) Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR part 555;
- (4) Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR part 73;
- (5) Hazardous Material security threat assessment for hazardous material endorsement to commercial drivers license under 49 CFR part 1572; and
- (6) Customs and Border Protection's Free and Secure Trade (FAST) Program.

§ 37.31 Protection of information.

(a) Each licensee who obtains background information on an individual under this subpart shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

(b) The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his or her representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.

(c) The personal information obtained on an individual from a background investigation may be provided to another licensee:

(1) Upon the individual's written request to the licensee holding the data to disseminate the information contained in his or her file; and

(2) The recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.

(d) The licensee shall make background investigation records obtained under this subpart available for examination by an authorized representative of the NRC to determine compliance with the regulations and laws.

(e) The licensee shall retain all fingerprint and criminal history records (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, on an individual for 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

§ 37.33 Access authorization program review.

(a) Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements of this subpart and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. Each licensee shall periodically (at least annually) review the access program content and implementation.

(b) The results of the reviews, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the access authorization program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

(c) Review records must be maintained for 3 years.

Subpart C – Physical Protection Requirements During Use

§ 37.41 Security program.

(a) *Applicability.* (1) Each licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of this subpart.

(2) An applicant for a new license and each licensee that would become newly subject to the requirements of this subpart upon application for modification of its license shall implement the requirements of this subpart, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

(3) Any licensee that has not previously implemented the Security Orders or been subject to the provisions of subpart C shall provide written notification to the NRC regional office specified in § 30.6 of this chapter at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

(b) *General performance objective.* Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive material.

(c) *Program features.* Each licensee's security program must include the program features, as appropriate, described in §§ 37.43, 37.45, 37.47, 37.49, 37.51, 37.53, and 37.55.

§ 37.43 General security program requirements.

(a) *Security plan.* (1) Each licensee identified in § 37.41(a) shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this subpart. The security plan must, at a minimum:

(i) Describe the measures and strategies used to implement the requirements of this subpart; and

(ii) Identify the security resources, equipment, and technology used to satisfy the requirements of this subpart.

(2) The security plan must be reviewed and approved by the individual with overall responsibility for the security program.

(3) A licensee shall revise its security plan as necessary to ensure the effective implementation of Commission requirements. The licensee shall ensure that:

(i) The revision has been reviewed and approved by the individual with overall responsibility for the security program; and

(ii) The affected individuals are instructed on the revised plan before the changes are implemented.

(4) The licensee shall retain a copy of the current security plan as a record for 3 years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for 3 years after the record is superseded.

(b) *Implementing procedures.* (1) The licensee shall develop and maintain written procedures that document how the requirements of this subpart and the security plan will be met.

(2) The implementing procedures and revisions to these procedures must be approved in writing by the individual with overall responsibility for the security program.

(3) The licensee shall retain a copy of the current procedure as a record for 3 years after the procedure is no longer needed. Superseded portions of the procedure must be retained for 3 years after the record is superseded.

(c) *Training.* (1) Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training must include instruction in:

(i) The licensee's security program and procedures to secure category 1 or category 2 quantities of radioactive material, and in the purposes and functions of the security measures employed;

(ii) The responsibility to report promptly to the licensee any condition that causes or may cause a violation of Commission requirements;

(iii) The responsibility of the licensee to report promptly to the local law enforcement agency and licensee any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material; and

(iv) The appropriate response to security alarms.

(2) In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of category 1 or category 2 quantities of radioactive material. The extent of the training must be commensurate with the individual's potential involvement in the security of category 1 or category 2 quantities of radioactive material.

(3) Refresher training must be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training must include:

(i) Review of the training requirements of paragraph (c) of this section and any changes made to the security program since the last training;

(ii) Reports on any relevant security issues, problems, and lessons learned;

(iii) Relevant results of NRC inspections; and

(iv) Relevant results of the licensee's program review and testing and maintenance.

(4) The licensee shall maintain records of the initial and refresher training for 3 years from the date of the training. The training records must include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

(d) *Protection of information.* (1) Except as provided in paragraph (d)(9) of this section, licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

(2) Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan and implementing procedures.

(3) Before granting an individual access to the security plan or implementing procedures, licensees shall:

(i) Evaluate an individual's need to know the security plan or implementing procedures; and

(ii) If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in § 37.25(a)(2) through (a)(7).

(4) Licensees need not subject the following individuals to the background investigation elements for protection of information:

(i) The categories of individuals listed in § 37.29(a)(1) through (13); or

(ii) Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in § 37.25(a)(2) through (a)(7), has been provided by the security service provider.

(5) The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan or implementing procedures.

(6) Licensees shall maintain a list of persons currently approved for access to the security plan or implementing procedures. When a licensee determines that a person no longer needs access to the security plan or implementing procedures or no longer meets the access

authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than 7 working days, and take prompt measures to ensure that the individual is unable to obtain the security plan or implementing procedures.

(7) When not in use, the licensee shall store its security plan and implementing procedures in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

(8) The licensee shall retain as a record for 3 years after the document is no longer needed:

- (i) A copy of the information protection procedures; and
- (ii) The list of individuals approved for access to the security plan or implementing procedures.

(9) Licensees that possess safeguards information or safeguards information-modified handling are subject to the requirements of § 73.21 of this chapter, and shall protect any safeguards information or safeguards information-modified handling in accordance with the requirements of that section.

§ 37.45 LLEA coordination.

(a) A licensee subject to this subpart shall coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA must include:

- (1) A description of the facilities and the category 1 and category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with this subpart; and

(2) A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of material.

(b) The licensee shall notify the appropriate NRC regional office listed in § 30.6(a)(2) of this chapter within 3 business days if:

(1) The LLEA has not responded to the request for coordination within 60 days of the coordination request; or

(2) The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

(c) The licensee shall document its efforts to coordinate with the LLEA. The documentation must be kept for 3 years.

(d) The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

§ 37.47 Security zones.

(a) Licensees shall ensure that all aggregated category 1 and category 2 quantities of radioactive material are used or stored within licensee-established security zones. Security zones may be permanent or temporary.

(b) Temporary security zones must be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.

(c) Security zones must, at a minimum, allow unescorted access only to approved individuals through:

(1) Isolation of category 1 and category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established

access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the category 1 or category 2 quantities of radioactive material within a security zone; or

(2) Direct control of the security zone by approved individuals at all times; or

(3) A combination of continuous physical barriers and direct control.

(d) For category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

(e) Individuals not approved for unescorted access to category 1 or category 2 quantities of radioactive material must be escorted by an approved individual when in a security zone.

§ 37.49 Monitoring, detection, and assessment.

(a) *Monitoring and detection.* (1) Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees shall provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

(2) Monitoring and detection must be performed by:

(i) A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility; or

(ii) Electronic devices for intrusion detection alarms that will alert nearby facility personnel; or

(iii) A monitored video surveillance system; or

(iv) Direct visual surveillance by approved individuals located within the security zone; or

(v) Direct visual surveillance by a licensee designated individual located outside the security zone.

(3) A licensee subject to this subpart shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide:

(i) For category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability must be provided by:

- (A) Electronic sensors linked to an alarm; or
- (B) Continuous monitored video surveillance; or
- (C) Direct visual surveillance.

(ii) For category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

(b) *Assessment.* Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

(c) *Personnel communications and data transmission.* For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessment systems, licensees shall:

(1) Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and

(2) Provide an alternative communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of

communication or data transmission and processing. Alternative communications and data transmission systems may not be subject to the same failure modes as the primary systems.

(d) *Response.* Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.

§ 37.51 Maintenance and testing.

(a) Each licensee subject to this subpart shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of this part must be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no suggested manufacturer's suggested frequency, the testing must be performed at least annually, not to exceed 12 months.

(b) The licensee shall maintain records on the maintenance and testing activities for 3 years.

§ 37.53 Requirements for mobile devices.

Each licensee that possesses mobile devices containing category 1 or category 2 quantities of radioactive material must:

(a) Have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and

(b) For devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, the licensee shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

§ 37.55 Security program review.

(a) Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of this subpart and that comprehensive actions are taken to correct any noncompliance that is identified. The review must include the radioactive material security program content and implementation. Each licensee shall periodically (at least annually) review the security program content and implementation.

(b) The results of the review, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the security program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

(c) The licensee shall maintain the review documentation for 3 years.

§ 37.57 Reporting of events.

(a) The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the NRC's Operations Center (301-816-5100). In no case shall the

notification to the NRC be later than 4 hours after the discovery of any attempted or actual theft, sabotage, or diversion.

(b) The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than 4 hours after notifying the LLEA, the licensee shall notify the NRC's Operations Center (301-816-5100).

(c) The initial telephonic notification required by paragraph (a) of this section must be followed within a period of 30 days by a written report submitted to the NRC by an appropriate method listed in § 37.7. The report must include sufficient information for NRC analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

Subpart D – Physical Protection in Transit

§ 37.71 Additional requirements for transfer of category 1 and category 2 quantities of radioactive material.

A licensee transferring a category 1 or category 2 quantity of radioactive material to a licensee of the Commission or an Agreement State shall meet the license verification provisions listed below instead of those listed in § 30.41(d) of this chapter:

(a) Any licensee transferring category 1 quantities of radioactive material to a licensee of the Commission or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license issuing authority, the

transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

(b) Any licensee transferring category 2 quantities of radioactive material to a licensee of the Commission or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

(c) In an emergency where the licensee cannot reach the license issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. The certification must include the license number, current revision number, issuing agency, expiration date, and for a category 1 shipment the authorized address. The licensee shall keep a copy of the certification. The certification must be confirmed by use of the NRC's license verification system or by contacting the license issuing authority by the end of the next business day.

(d) The transferor shall keep a copy of the verification documentation as a record for 3 years.

§ 37.73 Applicability of physical protection of category 1 and category 2 quantities of radioactive material during transit.

(a) For shipments of category 1 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in §§ 37.75(a) and (e); 37.77; 37.79(a)(1), (b)(1), and (c); and 37.81(a), (c), (e), (g) and (h).

(b) For shipments of category 2 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in §§ 37.75(b) through (e); 37.79(a)(2), (a)(3), (b)(2), and (c); and 37.81(b), (d), (f), (g), and (h). For those shipments of category 2 quantities of radioactive material that meet the criteria of § 71.97(b) of this chapter, the shipping licensee shall also comply with the advance notification provisions of § 71.97 of this chapter.

(c) The shipping licensee shall be responsible for meeting the requirements of this subpart unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under this subpart.

(d) Each licensee that imports or exports category 1 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in §§ 37.75(a)(2) and (e); 37.77; 37.79(a)(1), (b)(1), and (c); and 37.81(a), (c), (e), (g), and (h) for the domestic portion of the shipment.

(e) Each licensee that imports or exports category 2 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in §§ 37.79(a)(2), (a)(3), and (b)(2); and 37.81(b), (d), (f), (g), and (h) for the domestic portion of the shipment.

§ 37.75 Preplanning and coordination of shipment of category 1 or category 2 quantities of radioactive material.

(a) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:

(1) Preplan and coordinate shipment arrival and departure times with the receiving licensee;

(2) Preplan and coordinate shipment information with the governor or the governor's designee of any State through which the shipment will pass to:

(i) Discuss the State's intention to provide law enforcement escorts; and

(ii) Identify safe havens; and

(3) Document the preplanning and coordination activities.

(b) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

(c) Each licensee who receives a shipment of a category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

(d) Each licensee, who transports or plans to transport a shipment of a category 2 quantity of radioactive material, and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to paragraph (b) of this section, shall promptly notify the receiving licensee of the new no-later-than arrival time.

(e) The licensee shall retain a copy of the documentation for preplanning and coordination and any revision thereof, as a record for 3 years.

§ 37.77 Advance notification of shipment of category 1 quantities of radioactive material.

As specified in paragraphs (a) and (b) of this section, each licensee shall provide advance notification to the NRC and the governor of a State, or the governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the State, before the transport, or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

(a) Procedures for submitting advance notification. (1) The notification must be made to the NRC and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governors' designees, is available on the NRC's Web site at <http://nrc-stp.ornl.gov/special/designee.pdf>. A list of the contact information is also available upon request from the Director, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Notifications to the NRC must be to the NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The notification to the NRC may be made by e-mail to RAMQC_SHIPMENTS@nrc.gov or by fax to 301-816-5151.

(2) A notification delivered by mail must be postmarked at least 7 days before transport of the shipment commences at the shipping facility.

(3) A notification delivered by any means other than mail must reach NRC at least 4 days before the transport of the shipment commences and must reach the office of the governor or the governor's designee at least 4 days before transport of a shipment within or through the State.

(b) Information to be furnished in advance notification of shipment. Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;

(2) The license numbers of the shipper and receiver;

(3) A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(4) The point of origin of the shipment and the estimated time and date that shipment will commence;

(5) The estimated time and date that the shipment is expected to enter each State along the route;

(6) The estimated time and date of arrival of the shipment at the destination; and

(7) A point of contact, with a telephone number, for current shipment information.

(c) *Revision notice.* (1) The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the State or the governor's designee and to the NRC's Director of Nuclear Security, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(2) A licensee shall promptly notify the governor of the State or the governor's designee of any changes to the information provided in accordance with paragraphs (b) and (c)(1) of this section. The licensee shall also immediately notify the NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 of any such changes.

(d) *Cancellation notice.* Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified and to the NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

(e) *Records.* The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for 3 years.

(f) *Protection of information.* State officials, State employees, and other individuals, whether or not licensees of the Commission or an Agreement State, who receive schedule information of the kind specified in § 37.77(b) shall protect that information against unauthorized disclosure as specified in § 73.21 of this chapter.

§ 37.79 Requirements for physical protection of category 1 and category 2 quantities of radioactive material during shipment.

(a) *Shipments by road.* (1) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(i) Ensure that movement control centers are established that maintain position information from a remote location. These control centers must monitor shipments 24 hours a day, 7 days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies.

(ii) Ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication.

(iii) Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center must provide positive confirmation of the location, status, and control over the shipment. The movement control center must be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

(iv) Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver.

(v) Develop written normal and contingency procedures to address:

(A) Notifications to the communication center and law enforcement agencies;

(B) Communication protocols. Communication protocols must include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;

(C) Loss of communications; and

(D) Responses to an actual or attempted theft or diversion of a shipment.

(vi) Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

(2) Each licensee that transports category 2 quantities of radioactive material shall maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

(3) Each licensee who delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(i) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

(ii) Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(iii) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

(b) *Shipments by rail.* (1) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(i) Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

(ii) Ensure that periodic reports to the communications center are made at preset intervals.

(2) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(i) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

(ii) Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(iii) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

(c) *Investigations.* Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall immediately conduct an investigation upon the discovery that a category 1 shipment is lost or missing. Each licensee who makes arrangements for the shipment of category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

§ 37.81 Reporting of events.

(a) The shipping licensee shall notify the appropriate LLEA and the NRC's Operations Center (301-816-5100) within 1 hour of its determination that a shipment of category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law enforcement agency in the area of the shipment's last confirmed location. During the investigation required by § 37.79(c), the shipping licensee will provide agreed upon updates to the NRC's Operations Center on the status of the investigation.

(b) The shipping licensee shall notify the NRC's Operations Center (301-816-5100) within 4 hours of its determination that a shipment of category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secured, the licensee shall immediately notify the NRC's Operations Center.

(c) The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the NRC's Operations Center (301-816-5100) upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of category 1 radioactive material.

(d) The shipping licensee shall notify the NRC's Operations Center (301-816-5100) as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a category 2 quantity of radioactive material.

(e) The shipping licensee shall notify the NRC's Operations Center (301-816-5100) and the LLEA as soon as possible upon recovery of any lost or missing category 1 quantities of radioactive material.

(f) The shipping licensee shall notify the NRC's Operations Center (301-816-5100) as soon as possible upon recovery of any lost or missing category 2 quantities of radioactive material.

(g) The initial telephonic notification required by paragraphs (a) through (d) of this section must be followed within a period of 30 days by a written report submitted to the NRC by an appropriate method listed in § 37.7. A written report is not required for notifications on suspicious activities required by paragraphs (c) and (d) of this section. In addition, the licensee shall provide one copy of the written report addressed to the Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The report must set forth the following information:

- (1) A description of the licensed material involved, including kind, quantity, and chemical and physical form;
- (2) A description of the circumstances under which the loss or theft occurred;
- (3) A statement of disposition, or probable disposition, of the licensed material involved;
- (4) Actions that have been taken, or will be taken, to recover the material; and
- (5) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

(h) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

Subpart E – [Reserved]

Subpart F – Records

§ 37.101 Form of records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§ 37.103 Record retention.

Licensees shall maintain the records that are required by the regulations in this part for the period specified by the appropriate regulation. If a retention period is not otherwise specified, these records must be retained until the Commission terminates the facility's license. All records related to this part may be destroyed upon Commission termination of the facility license.

Subpart G – Enforcement

§ 37.105 Inspections.

(a) Each licensee shall afford to the Commission at all reasonable times opportunity to inspect category 1 or category 2 quantities of radioactive material and the premises and facilities wherein the nuclear material is used, produced, or stored.

(b) Each licensee shall make available to the Commission for inspection, upon reasonable notice, records kept by the licensee pertaining to its receipt, possession, use, acquisition, import, export, or transfer of category 1 or category 2 quantities of radioactive material.

§ 37.107 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of --

- (1) The Atomic Energy Act of 1954, as amended;
- (2) Title II of the Energy Reorganization Act of 1974, as amended; or
- (3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of --

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended:

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

§ 37.109 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation

issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in this part 37 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in this part 37 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 37.1, 37.3, 37.5, 37.7, 37.9, 37.11, 37.13, 37.107, and 37.109.

Appendix A to Part 37—Category 1 and Category 2 Radioactive Materials

Table 1 – Category 1 and Category 2 Threshold

The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Americium-241	60	1,620	0.6	16.2
Americium-241/Be	60	1,620	0.6	16.2
Californium-252	20	540	0.2	5.40
Cobalt-60	30	810	0.3	8.10
Curium-244	50	1,350	0.5	13.5
Cesium-137	100	2,700	1	27.0
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,160	0.8	21.6
Plutonium-238	60	1,620	0.6	16.2
Plutonium-239/Be	60	1,620	0.6	16.2
Promethium-147	40,000	1,080,000	400	10,800
Radium-226	40	1,080	0.4	10.8
Selenium-75	200	5,400	2	54.0
Strontium-90	1,000	27,000	10	270
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81.0

Note: Calculations Concerning Multiple Sources or Multiple Radionuclides

The "sum of fractions" methodology for evaluating combinations of multiple sources or multiple radionuclides is to be used in determining whether a location meets or exceeds the threshold and is thus subject to the requirements of this part.

I. If multiple sources of the same radionuclide and/or multiple radionuclides are aggregated at a location, the sum of the ratios of the total activity of each of the radionuclides must be determined to verify whether the activity at the location is less than the category 1 or category 2 thresholds of Table 1, as appropriate. If the calculated sum of the ratios, using the equation below, is greater than or equal to 1.0, then the applicable requirements of this part apply.

II. First determine the total activity for each radionuclide from Table 1. This is done by adding the activity of each individual source, material in any device, and any loose or bulk material that contains the radionuclide. Then use the equation below to calculate the sum of the ratios by inserting the total activity of the applicable radionuclides from Table 1 in the numerator of the equation and the corresponding threshold activity from Table 1 in the denominator of the equation. Calculations must be performed in metric values (i.e., TBq) and the numerator and denominator values must be in the same units.

R_1 = total activity for radionuclide 1

R_2 = total activity for radionuclide 2

R_N = total activity for radionuclide n

AR_1 = activity threshold for radionuclide 1

AR_2 = activity threshold for radionuclide 2

AR_N = activity threshold for radionuclide n

$$\sum_1^n \left[\frac{R_1}{AR_1} + \frac{R_2}{AR_2} + \frac{R_n}{AR_n} \right] \geq 1.0$$

PART 39 - LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

18. The authority citation for part 39 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 53, 57, 62, 63, 65, 69, 81, 82, 161, 181, 182, 183, 186, 223, 234 (42 U.S.C. 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2112, 2201, 2231, 2232, 2233, 2236, 2273, 2282); Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note).

19. In § 39.1, paragraph (a) is revised to read as follows:

§ 39.1 Purpose and scope.

(a) This part prescribes requirements for the issuance of a license authorizing the use of licensed materials including sealed sources, radioactive tracers, radioactive markers, and uranium sinker bars in well logging in a single well. This part also prescribes radiation safety requirements for persons using licensed materials in these operations. The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of parts 19, 20, 21, 30, 37, 40, 70, 71, and 150 of this chapter apply to applicants and licensees subject to this part.

* * * * *

PART 51 – ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

20. The authority citation for part 51 continues to read as follows:

AUTHORITY: Atomic Energy Act sec. 161, 1701 (42 U.S.C. 2201, 2297f); Energy Reorganization Act secs. 201, 202, 211 (42 U.S.C. 5841, 5842, 5851); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note). Subpart A also issued under National Environmental Policy Act secs. 102, 104, 105 (42 U.S.C. 4332, 4334, 4335); Pub. L. 95 604, Title II, 92 Stat. 3033 3041; Atomic Energy Act sec. 193 (42 U.S.C. 2243). Sections 51.20, 51.30, 51.60, 51.80. and 51.97 also issued under Nuclear Waste Policy Act secs. 135, 141, 148 (42 U.S.C. 10155, 10161, 10168). Section 51.22 also issued under Atomic Energy Act sec. 274

(42 U.S.C. 2021) and under Nuclear Waste Policy Act sec. 121 (42 U.S.C. 10141). Sections 51.43, 51.67, and 51.109 also issued under Nuclear Waste Policy Act sec. 114(f) (42 U.S.C. 10134(f)).

21. In § 51.22, the introductory text of paragraph (c)(3) is revised to read as follows:

§ 51.22 Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review.

* * * * *

(c)* * *

(3) Amendments to parts 20, 30, 31, 32, 33, 34, 35, 37, 39, 40, 50, 51, 52, 54, 60, 61, 63, 70, 71, 72, 73, 74, 81, and 100 of this chapter which relate to—

* * * * *

PART 71--PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

22. The authority citation for part 71 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 53, 57, 62, 63, 81, 161, 182, 183, 223, 234, 1701 (42 U.S.C. 2073, 2077, 2092, 2093, 2111, 2201, 2232, 2233, 2273, 2282, 2297f); Energy Reorganization Act secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear

Waste Policy Act sec. 180 (42 U.S.C. 10175); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 594 (2005).
Section 71.97 also issued under sec. 301, Pub. L. 96 295, 94 Stat. 789 790.

23. In § 71.97, the introductory text of paragraph (b) is revised to read as follows:

§ 71.97 Advance notification of shipment of irradiated reactor fuel and nuclear waste.

* * * * *

(b) Advance notification is also required under this section for the shipment of licensed material, other than irradiated fuel, meeting the following three conditions:

* * * * *

PART 73—PHYSICAL PROTECTION OF PLANTS AND MATERIALS

24. The authority citation for part 73 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 53, 147, 161, 223, 234, 1701 (42 U.S.C. 2073, 2167, 2169, 2201, 2273, 2282, 2297(f), 2210(e)); Energy Reorganization Act sec. 201, 204 (42 U.S.C. 5841, 5844); Government Paperwork Elimination Act sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109-58, 119 Stat. 594 (2005).
Section 73.1 also issued under Nuclear Waste Policy Act secs. 135, 141 (42 U.S.C. 10155, 10161). Section 73.37(f) also issued under sec. 301, Pub. L. 96-295, 94 Stat. 789 (42 U.S.C. 5841 note).

25. A new § 73.35 is added to read as follows:

§ 73.35 Requirements for physical protection of irradiated reactor fuel (100 grams or less) in transit.

Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a quantity of irradiated reactor fuel weighing 100 grams (0.22 pounds) or less in net weight of irradiated fuel, exclusive of cladding or other structural or packaging material, which has a total external radiation dose rate in excess of 1 Gray (100 rad) per hour at a distance of 1 meter (3.3 feet) from any accessible surface without intervening shielding, shall follow the physical protection requirements for category 1 quantities of radioactive material in subpart D of part 37 of this chapter.

Dated at Rockville, Maryland, this 8th day of March, 2013.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

Note: This Appendix Will Not Appear in the *Code of Federal Regulations*.

**APPENDIX A TO THIS FINAL RULE -- REGULATORY FLEXIBILITY ANALYSIS FOR THE
AMENDMENTS TO 10 CFR PARTS 20, 30, 32, 33, 34, 35, 36, 37, 39, 51, 71, AND 73
(PHYSICAL PROTECTION OF BYPRODUCT MATERIAL)**

I. Background.

The Regulatory Flexibility Act (RFA), as amended 5 U.S.C. 601 *et seq.*, requires that agencies consider the impact of their rulemakings on small entities and, consistent with applicable statutes, consider alternatives to minimize these impacts on the businesses, organizations, and government jurisdictions to which they apply.

The U.S. Nuclear Regulatory Commission (NRC) has established standards for determining which NRC licensees qualify as small entities (10 CFR 2.810). These size standards were based on the Small Business Administration's most common receipts-based size standards and include a size standard for business concerns that are manufacturing entities.

Description of the reasons that action by the agency is being considered.

The NRC has long participated in efforts to address radioactive source protection and security. The terrorist attacks of September 11, 2001, heightened concerns about the use of risk-significant radioactive materials in a malevolent act. Such an attack is of particular concern because of the widespread use of radioactive materials in the United States by industrial, medical, and academic institutions. The theft or diversion of risk-significant radioactive materials could lead to their unauthorized use in a radiological dispersal device or a radiological exposure device.

Commission regulations provide requirements for the safe use, transport, and control of licensed material. A licensee's loss of control of risk-significant radioactive material, whether it is inadvertent or through a deliberate act, could result in significant adverse impacts that could reasonably constitute a threat to the public health and safety or the common defense and security of the United States. After the attacks of September 11, 2001, the Commission determined that certain licensed material should be subject to enhanced security provisions and safeguarded during transport, and that individuals with unescorted access to risk-significant radioactive material should be subject to background investigations. For additional information see the Discussion portion of the Statements of Consideration (SOC).

Succinct statement of the objectives of, and legal basis for, the final rule.

The objective of this rule is to establish generically applicable security requirements for the protection of category 1 and category 2 quantities of radioactive materials possessed by certain NRC and Agreement State licensees. These security requirements are similar to the requirements imposed on these licensees through the NRC's applicable previously-issued security orders. The NRC has determined that it is preferable to regulate through rulemaking rather than order because notice and comment rulemaking is an open and transparent process that facilitates public participation. In developing the final rule, the NRC considered, among other things, the various orders, lessons-learned during implementation, the recommendations from the Independent Review Panel and the Materials Working Group, and stakeholder comments. The rule also considered a petition for rulemaking submitted by the State of Washington. For additional information see the Discussion portion of the SOC. The authority citation sections of the final rule contain the statutory authority for the rule.

Description of and, where feasible, an estimate of the number of small entities to which the final rule will apply.

The final rule would affect about 300 NRC licensees and about 1,100 Agreement State licensees. This includes a wide range of licensees, including pool-type irradiator licensees; manufacturer and distributor licensees; medical facilities with gamma knife devices; self-shielded irradiator licensees (including blood irradiators); teletherapy unit licensees; radiographers; well loggers; broad scope users; radioisotope thermoelectric generator licensees; and licensees that ship or prepare for shipment category 1 or category 2 quantities of radioactive material. Some of these licensees would be considered small entities. In fiscal year 2008, about 26 percent of materials licensees qualified as small entities. Using the same percentage, approximately 364 of the licensees that will be affected by the rule would be considered small entities.

Description of the projected reporting, recordkeeping, and other compliance requirements of the final rule, including an estimate of the classes of small entities that will be subject to the requirements, and the type of professional skills necessary for preparation of reports and records.

Licensees will be required to: (1) develop procedures for implementation of the security provisions; (2) develop a security plan that describes how security is being implemented; (3) conduct training on the procedures and security plan; (4) conduct background investigations for those individuals permitted access to category 1 or category 2 quantities of radioactive material; (5) coordinate with local law enforcement agencies (LLEAs) so the LLEAs would be better prepared to respond in an emergency; (6) conduct preplanning and coordination activities before shipping radioactive material; and (7) implement security measures for the protection of the radioactive material. Licensees will be required to promptly report any attempted or actual

theft or diversion of the radioactive material. Licensees will be required to keep copies of the security plan, procedures, background investigation records, training records, and documentation that certain activities have occurred. For additional information on the requirements, see the SOC or the final rule text. No special skills are necessary for the preparation of reports or records.

On average, a licensee would have a one-time cost of approximately \$23,375 and an annual cost of approximately \$21,736 to fully implement the final rule. Much of this cost would result from the requirements to have procedures, conduct training, and to develop a security plan. Although not required by the various orders, many licensees may have developed procedures and conducted training that may require only minor revisions; if so, the actual cost may be lower. Additional large costs are the annual program review and the maintenance and testing of the security-related equipment. The program review is important for licensees to review the effectiveness of the program and to ensure that requirements are being implemented. Maintenance and testing is essential to ensure that the equipment is operational and available when needed. More information on the cost of the rule is contained in the Regulatory Analysis.

Identification, to the extent practicable, of all relevant Federal rules that may duplicate, overlap, or conflict with the final rule.

Several U.S. Government programs involve fingerprinting and an FBI identification and criminal history records check. These include the National Agency Check; Transportation Worker Identification Credentials in accordance with 49 CFR 1572; Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances in accordance with 27 CFR 555; Health and Human Services security risk assessments for possession and use of select agents and toxins in accordance with 42 CFR 73; Hazardous Material security threat assessment for

hazardous material endorsement to commercial drivers license in accordance with 49 CFR 1572; and Customs and Border Protection's Free and Secure Trade Program. Any individual that has favorably undergone the background investigation required by these programs would be relieved from the fingerprinting and FBI criminal history records check element of the final rule as long as the licensee has appropriate documentation. Any individual who has an active Federal security clearance would also be relieved assuming appropriate documentation is provided.

The Department of Transportation requires security plans for the transport of highway route control quantities of radioactive material in accordance with 49 CFR 172.800. This provision covers only a small portion of the category 1 and category 2 quantities of radioactive material covered by the rule.

The NRC is not aware of any other relevant Federal rules that may duplicate, overlap, or conflict with the final rule.

Description of any significant alternatives to the final rule that accomplish the stated objectives of applicable statutes and that minimize any significant economic impact of the final rule on small entities, including alternatives considered, such as: (1) establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) clarification, consolidation, or simplification of compliance and reporting requirements under the rule for small entities; (3) use of performance rather than design standards; and (4) any exemption from coverage of the rule, or any part thereof, for such small entities.

As noted earlier, some of the licensees that would be impacted by the final rule are small businesses. The rule would impose the minimum requirements that the NRC believes are necessary to adequately protect the public health and safety and the common defense and

security. Therefore, the NRC could not generically grant relief to small entities to allow them to implement less effective measures. The final rule provides some flexibility in the particular measures that a licensee can choose to employ. Licensees affected by the rule have already implemented the bulk of the rule's requirements in response to various orders.

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