



Department of Energy

Washington, DC 20585

January 3, 2008

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Michael Kluse
Interim Laboratory Director
Battelle Memorial Institute
Pacific Northwest National Laboratory
902 Battelle Boulevard
Richland, Washington 99352

EA-2007-07

Dear Mr. Kluse:

This letter refers to the Department of Energy (DOE) investigation into the facts and circumstances associated with the following events and issue at the Pacific Northwest National Laboratory (PNNL):

1. The December 15, 2006, airborne release of plutonium at the Radiochemical Processing Laboratory (RPL);
2. The June 16, 2007, spread of contamination from a leaking sealed source; and
3. The failure to address identified deficiencies in the assessment program, and ensure that a fully effective independent assessment function is in place at PNNL.

The results of our onsite investigation were provided in an Investigation Summary Report (ISR) dated October 24, 2007. An enforcement conference was held on November 15, 2007, with you and members of your staff to discuss these findings. A summary of the conference is enclosed.

Based on our evaluation of the evidence in this matter, including information provided by you and your staff during the enforcement conference, DOE has concluded that violations of 10 C.F.R. Part 830, *Nuclear Safety Management*, and 10 C.F.R. Part 835, *Occupational Radiation Protection*, have occurred. Accordingly, DOE is issuing the enclosed Preliminary Notice of Violation (PNOV) with eight violations categorized as Severity Level II and a civil penalty



of \$288,750. Because the violations occurred under a contract that was entered into in August 2003, prior to the enactment of the Energy Policy Act of 2005, the penalty is waived in this case

DOE views these violations as significant. Both radiological events resulted in uptakes and exposures to personnel. The leaking sealed source event resulted in the spread of contamination off site and exposure to members of the public. DOE is also concerned about the scope of the underlying work control deficiencies, and the quality improvement breakdowns common to the two events and the deficiencies in the assessment program. In each case, prior events or external identification had presented an opportunity to correct specific deficiencies at an early stage. However, corrective actions were ineffective at resolving the deficiencies.

Your own investigation into these events demonstrated the site-wide nature of these weaknesses. Unfortunately, implementation deficiencies precluded the potential early self-identification of these weaknesses through your own management and independent assessment programs.

In calculating the penalty, no mitigation was provided for timely self-identification of the violations, since the events were self-disclosing and the assessment issue was initially identified by DOE. DOE recognizes your investigations into the subject issues were formal, detailed, and appropriately scoped. Your corrective actions were generally broad and addressed the issues on multiple levels (i.e., activity, project, and institutional). Consequently, full mitigation for corrective actions was applied for those violations related to the sealed source event and the independent assessment deficiencies. Due to issues noted in the ISR (lack of detail of corrective action plan, insufficient linkage between causes and actions), partial corrective action mitigation was applied to those violations related to the RPL airborne release event. We acknowledge that your subsequent revisions to the corrective action plan and development of a crosswalk between the plan and the causal analysis resulted in significant improvements. However, these improvements were prompted in part by our observations. As a result, partial (versus full) corrective action mitigation was also applied to the three quality improvement violations in the PNOV.

During the enforcement conference, we were encouraged by your strong commitment to correcting the underlying behavioral issues at PNNL, and your desire to appropriately refocus your organization on the safety component of Battelle's "simultaneous excellence" model. Appropriate and consistent safety focus led by senior management will be essential during the challenging months ahead.

Pursuant to 10 C.F.R. Part 820.24, *Preliminary Notice of Violation*, you are required to respond within 30 days of the date of this letter and to follow the instructions specified in the enclosed PNOV when preparing your response. After

reviewing your response to the PNOV, including any proposed additional corrective actions entered into the Noncompliance Tracking System, DOE will determine whether further enforcement action is necessary to ensure compliance with DOE nuclear safety requirements. DOE will continue to monitor the completion of corrective actions until these matters are resolved.

Sincerely,

A handwritten signature in black ink, appearing to read "A. Guevara", written in a cursive style.

Arnold E. Guevara
Director
Office of Enforcement
Office of Health, Safety and Security

Enclosures

cc: Sandra English, Battelle
Richard Azzaro, DNFSB

Preliminary Notice of Violation

Battelle Memorial Institute
Pacific Northwest National Laboratory (PNNL)

EA-2007-07

As a result of a Department of Energy (DOE) investigation into two radiological events and a programmatic performance deficiency at the PNNL, multiple violations of DOE nuclear safety requirements were identified. The radiological events included: (1) the December 2006 airborne plutonium release at the Radiochemical Processing Laboratory (RPL); and (2) the June 2007 spread of contamination from a leaking sealed source. The programmatic performance deficiency involved the implementation of the Battelle Memorial Institute (Battelle) independent assessment program.

The subsequently identified violations involved the adequacy and implementation of work control and radiological procedures, sealed source control, the effectiveness of corrective actions in preventing recurrence (quality improvement), and the effectiveness of independent and management assessment programs. The associated violations have been grouped and categorized as eight Severity Level II violations. A civil penalty of \$288,750 is proposed. However, because the violations occurred under a contract that was entered into in August 2003, prior to the enactment of the Energy Policy Act of 2005, the penalty is waived in this case.

In accordance with 10 C.F.R. Part 820, Appendix A, *General Statement of Enforcement Policy*, the violations are listed below. Citations specifically referencing the quality assurance criteria of 10 C.F.R. Part 830.122 also represent a violation of Part 830.121(a), which requires compliance with those quality assurance criteria.

VIOLATIONS

I. Radiochemical Processing Laboratory December 2006 Airborne Plutonium Release Event

A. Procedural Adequacy

Title 10 C.F.R. Part 830.122(e)(1) states that DOE contractors are to “Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.”

Contrary to the above, approved work control procedures and documented radiological authorizations were inadequate and failed to effectively control and limit hazards associated with the RPL room 414 research activity conducted during December 2006 and leading to the RPL airborne release event. Specific examples include the following:

1. The primary procedure used during the conduct of the RPL room 414 research activity was not adequate to effectively control the hazards associated with the activity. Project-specific procedures and/or technical work documents were not developed to control the setup and operation of the equipment used for research conducted in RPL room 414 on December 13-15, 2006. Instead, the work was conducted utilizing, and governed by, a routine operating procedure (RPL-OP-001, rev. 4, *Routine Research Operations*) intended to control routine bench scale chemical research operations.

Subsequent to the event, RPL management indicated that the research activities and glovebox modifications leading to the December 2006 release should have been determined to be non-routine during the initial Battelle evaluation and thus would not fall within the scope of RPL-OP-001. The inappropriate use of RPL-OP-001 as the controlling work document precluded the development of a project-specific work control procedure, which would have required specific review and approval. RPL management indicated that such review would likely have resulted in additional controls on the equipment setup, such as the inclusion of a high efficiency particulate air (HEPA) filter in the vacuum line.

2. Procedurally required radiological reviews of the proposed work activity were not adequate to effectively control the research activity in RPL room 414. This shortcoming resulted from the incomplete or inaccurate communication of information related to the scope of the work activity, and led to a lack of controls in the radiological work permit (RWP). Specific examples include the following:
 - i. Procedure RCP-3.1.01, *Radiological Work, Planning*, dated February 2003, requires the individual planning radiological work to complete a *Radiological Risk Assessment/RWP Request Form* (RRA/RRF) and to forward it to the radiological control specialist. This form identifies the specific radiological hazards that the planner expects might be encountered during the scope of work.

The RRA/RRF submitted for the glovebox work activity did not correctly identify the hazards of the planned work, and therefore failed to adequately communicate the hazards to the Radiological Control organization. For example, the RRA/RRF form indicated that the work would not involve breaching contaminated or potentially contaminated systems; however, the vacuum system connection to the facility ventilation manifold did constitute a breach of a ventilation system, which is a potentially contaminated system. Also, the form indicated that the experiment would use millicurie quantities of radionuclides, rather than the curie amounts that were used.

- ii. Procedure RCP-3.1.03, rev. 5, *Radiological Work Planning and Evaluation*, requires the radiological control specialist to review the submitted RRA/RRF form and to identify appropriate radiological control hold points and radiological control technician (RCT) actions for the planned work. Discussion with the radiological control specialist and evaluation of the documented review of the project (letter dated December 5, 2006, titled “*Rad Engineering review for the RWP 325-06-077 New*”) indicated that the planned equipment configuration was not clearly communicated to and/or understood by the radiological control specialist, even after discussions between the specialist and the researcher. Specifically, the radiological control specialist’s documented review stated that the vacuum exhaust system would be exhausted back into the glovebox, rather than being routed through a room manifold into the facility ventilation. The documented review also stated that the “System will be tested prior to use.” However, no formal requirement or control for testing the system was established in the developed RWP, and such testing was not performed prior to the use of the glovebox vacuum assembly.

Collectively, these deficiencies constitute a Severity Level II violation.
Proposed Civil Penalty – \$41,250 (waived)

B. Procedural Implementation

Title 10 C.F.R. Part 830.122(e)(1) states that DOE contractors are to “Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.”

Title 10 C.F.R. Part 835.104 requires that “Written procedures shall be developed and implemented as necessary to ensure compliance with this part, commensurate with the radiological hazards created by the activity”

Contrary to the above, controlling procedures were not effectively implemented in association with the December 2006 RPL airborne release event. Specific examples include the following:

1. The scope and limiting conditions of the applicable RWP were exceeded during the research work activity. RWP 325-06-077, rev. 0, *Install Vacuum System in Glovebox to Test Radioisotope Battery Devices Using Various Isotopes*, was the primary RWP used by the Battelle researcher, and others, to set up the equipment and collect data during the research activity. The following specific violations of the RWP scope and limiting conditions were noted:
 - i. On December 13, 2006, the Battelle researcher connected the flexible tubing exhaust line from the vacuum pumps to the facility ventilation manifold located in room 414. The facility ventilation was considered to be a potentially contaminated system, and this connection therefore constituted a breach of a potentially contaminated system.

Such a connection was outside the stated scope of work allowed on RWP 325-06-077, and no controls were provided in the RWP for performing such a breach.

- ii. RWP 325-06-077 includes open quantity limits that restrict the quantity of isotopes that can be used or handled on the RWP. The RWP specifies an open quantity limit of 5 millicuries (0.005 curies) for Pu-238. On December 15, 2006, a two curie Pu-238 source was introduced into the room 414 glovebox as part of the research activity, thereby exceeding the open quantity limit by nearly three orders of magnitude.
2. Several procedural noncompliances were identified in association with the escorting of Trace Photonics, Inc., (TPI) visitors into RPL room 414 by PNNL personnel during the period from December 13 through 15, 2006. Specific examples include the following:
 - i. During the subject period, the PNNL staff member responsible for providing escort for the TPI visitors was signed in on RWP 325-06-077. This RWP did not identify the escorting of visitors as an authorized activity within the scope of the RWP.
 - ii. Procedure RCP-3.3.01, dated May 2005, *Radiological Access Control*, section 5, requires escorts exiting a radiation area to record measured dose on the visitor's *Visitor Supplemental Dosimeter Tracking Form*. Upon exit from the radiation area on December 14, 2006, the visitor's radiation doses (zero) were not recorded on the forms.
 - iii. During the period December 13-15, 2006, the visiting TPI scientists were signed in on the appropriate RWP for tours (PNL-06-Tour). That RWP required a briefing from the Radiological Control organization before any tours. However, prior to signing in on the RWP, the TPI visitors were briefed by the Battelle researcher hosting the visitors, rather than by a representative of the Radiological Control organization.

Collectively, these deficiencies constitute a Severity Level II violation.
Proposed Civil Penalty – \$41,250 (waived)

C. Quality Improvement

Title 10 C.F.R. Part 830.122(c) requires DOE contractors to: “(1) Establish and implement processes to detect and prevent quality problems. (2) Identify, control, and correct items, services, and processes that do not meet established requirements. (3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem.”

Contrary to the above, Battelle failed to take effective corrective actions in response to a 2005 precursor event to the subject RPL airborne release event. During the investigation of the December 2006 airborne release in RPL room 414, Office of Enforcement personnel learned of an October 3, 2005, event in which a viewing window on a vacuum chamber, contained in an RPL glovebox, splintered during an experiment. The splintered glass

punctured a glovebox glove, but fortuitously no personnel contamination resulted from the event. The Battelle investigation of the 2005 event identified numerous quality problems in the planning and execution of this work, several of which were similar to the December 2006 airborne release event. Specifically, the October 2005 event involved the same researcher as the December 2006 airborne release event, and occurred in the glovebox immediately adjacent to the glovebox involved in the December 2006 event. The October 2005 event also involved the inappropriate use of procedure RPL-OP-001 to cover a work activity that should not have been considered to be routine bench work.

Battelle completed several corrective actions in response to the October 2005 event, including an action to retrain the researchers on the appropriate use of RPL-OP-001. The Office of Enforcement concluded, based on the similarity between the events, that corrective actions were not effective in preventing recurrence.

This deficiency constitutes a Severity Level II violation.
Proposed Civil Penalty – \$41,250 (waived)

II. Leaking Sealed Source Event

A. Sealed Source Control

Title 10 C.F.R. Part 835.1201 requires that “Sealed radioactive sources shall be used, handled, and stored in a manner commensurate with the hazards associated with operations involving the sources.”

Contrary to the above, Battelle did not establish adequate controls to ensure that a 3.9 millicurie Pu-238 sealed source was used and handled in a manner commensurate with its associated hazards. This Pu-238 sealed source was used during experimental activities in building 326 between March and June 2007. Despite the unusual characteristics of the source and the recognized fragility of its design, no special post-fabrication testing or extended surveying was performed to evaluate source integrity over time. The controls employed by Battelle to address source hazards (labeling and tagging of the source storage box) were limited and temporary in nature, and proved to be ineffective. Although radiological engineering personnel were aware of the fragility of the source, this concern was not effectively communicated to all involved source custodians and users. None of the readily available controls, such as designation as a Type M source (see Section II.C, Quality Improvement) requiring additional surveys, were employed. As a consequence of the lack of controls and the unrestricted use and handling of the source, several personnel were contaminated and/or received unplanned uptakes of radioactive material.

This deficiency constitutes a Severity Level II violation
Proposed Civil Penalty – \$27,500 (waived)

B. Procedural Implementation

Title 10 C.F.R. Part 830.122(e)(1) states that DOE contractors are to “Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.”

Title 10 C.F.R. Part 835.104 requires that “Written procedures shall be developed and implemented as necessary to ensure compliance with this part, commensurate with the radiological hazards created by the activity”

Contrary to the above, controlling procedures were not effectively implemented in association with the transfer and experimental use of the Pu-238 sealed source subsequently involved in the leaking sealed source event. Specific examples include the following:

1. Procedure RCP-3.1.01, *Radiological Work, Planning*, section 1, dated February 2003, requires that work planners, who are planning radiological work, complete and submit an RRA/RRF form to the radiological control organization. However, with respect to the subject event, no RRA/RRF form was completed and submitted for either the planned use of the Pu-238 radiological source in the Environmental Molecular Sciences Laboratory (EMSL) or the experimental activities involving the source conducted in building 326.
2. Procedure RCP-3.1.03, *Radiological Work Planning and Evaluation*, section 2.1[2], dated October 2006, requires the radiological work control specialist to initiate preparation of a *Nondispersible Radioactive Material Review Form (NRMRF)* if the use of nondispersible radioactive material is planned in the EMSL. The form is designed to determine whether, in fact, the material is nondispersible and suitable for use in the EMSL.

However, with respect to the subject event, no NRMRF was completed before the Pu-238 source was transferred to the EMSL. PNNL staff indicated during interviews that, although strictly required by procedure, the NRMRF was typically not completed for sealed sources, as they were viewed as being nondispersible by design. The Office of Enforcement’s review of the NRMRF screening criteria indicated that, given the source’s known fragility issues, it would have been unlikely to successfully pass this screen if one were performed. Specifically, question 3 on the NRMRF asks, “Does the source configuration maintain the materials as nondispersible if dropped?”

3. Procedure RCP-5.4.02, rev. 2, *RCT Response to a Personnel/Personal Effects Survey Alarm*, sections 2.1 through 2.3, identifies the steps to be followed when RCTs respond to alarms generated by a contamination monitor or hand-held survey instrument. In general, in response to a positive personnel contamination alarm, the RCT is to verify the presence of contamination by performing surveys; once verified, contact the RCT supervisor or building manager within 30 minutes; determine the source of the contamination; and initiate decontamination activities in accordance with a referenced

procedure. Procedure RCP-5.4.02 allows for bagging and 24-hour decay of items suspected of radon/thoron contamination; however, this reference is specific to contaminated personal effects and does not reference or relate to personnel.

The RCT response to the positive hand and foot monitor alarm at the exit to building 329 on June 14, 2007, did not follow the process outlined above. After verifying the contamination on the individual, but not identifying any contamination in the 329 work area, the RCT assumed natural radon/thoron contamination to be present and instructed the worker to re-survey after a decay period. The worker was allowed to return to his work area in 329. Neither the RCT supervisor nor the building manager was contacted at this point. During the resurvey attempt approximately 1.5 hours later, the monitor alarmed again. Damp towels proved unsuccessful in removing the hand contamination. At this point, the RCT contacted the RCT supervisor and had the worker don gloves to cover the contamination. Radon was still suspected, however, and the worker was allowed to travel to his office in building 326 for an additional decay period. During a later re-survey attempt, contamination was again identified. Additional surveys and interviews by the RCT and RCT supervisor eventually led to the identification of the leaking source in building 326.

4. Procedure RCP-4.3.03, *Controlling Sealed Radioactive Sources and Licensed Radioactive Material*, section 4, dated March 2005, requires the radiological engineer approving the transfer of a sealed source from one facility to another within the laboratory to “determine if the proposed use can be accomplished safely in the proposed location and without unnecessary exposure to the user and other individuals in the vicinity. Check the applicable Facility Use Agreements for the new location to determine if use is permitted. If the proposed use is acceptable, document approval in writing by email or equivalent.”

With respect to the subject event, the review performed by the building 326 radiological engineer did not adequately evaluate all proposed uses of the source and the associated risks to individuals in the vicinity. The building 326 radiological engineer acknowledged the receipt of the source by initialing a Material Transaction Report (MTR), which documented certain characteristics of the source and indicated that the source was being added to the inventory. However, this MTR was initialed and dated on December 19, 2006, 6 days after the source was transferred to the building. The initialed MTR did not clearly demonstrate that the objectives of the RCP-4.3.03 review were achieved; did not include notations regarding safe use of the source or list any restrictions; and did not specify if the Facility Use Agreements were being maintained. As noted in the Battelle investigation and causal analysis of the event, the radiological engineer was not contacted regarding the experimental uses of the source, which included thermal cycling of the source and the taping of the source to a crystal. Consequently, these planned uses of the source were never evaluated by the radiological engineer.

Collectively, these deficiencies constitute a Severity Level II violation.
Proposed Civil Penalty – \$27,500 (waived)

C. Quality Improvement

Title 10 C.F.R. Part 830.122(c) requires DOE contractors to: “(1) Establish and implement processes to detect and prevent quality problems. (2) Identify, control, and correct items, services, and processes that do not meet established requirements. (3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem.”

Contrary to the above, Battelle corrective actions, taken in response to precursor events involving fragile sealed sources, were inadequately implemented and failed to prevent recurrence. The Battelle investigation and causal analysis of the leaking sealed Pu-238 source event identified precursor failures of Mylar-covered (and consequently fragile) sealed sources (February and September 2003 and December 2004), and noted that corrective actions from these events were not effective in preventing the subject event. The December 2004 source failure led to the development of a Type M (for Mylar-covered) category for PNNL sources with additional procedural requirements for care in handling such sources; source storage in source holders when not in use; and performance of precautionary surveys after handling. However, the June 2007 Pu-238 leaking source event shows that the corrective actions were not sufficient to prevent recurrences of similar types of problems (e.g., leak of a fragile source) and ensure that the corrective action (i.e., the Type M categorization approach) was sufficient to address the full range of fragile sources at PNNL. Specific concerns include:

1. The Type M category was not broadly defined in revised PNNL procedures and only directly referenced Mylar-covered sources. Consequently, although the Pu-238 source was recognized as being fragile in construction, it was not designated a Type M source because it was not Mylar-covered.
2. Sources designated as fragile or Type M were not specifically labeled as such, nor was a specific notation made in the source inventory records.
3. Training on the Type M categorization and procedural controls was not adequately implemented. The relevant building 326 work practice, titled *Working With Sealed Radioactive Sources*, rev. 4, was revised to include controls specific to Type M sources. However, this revision was not assigned as required reading for active staff in the facility at the time of the revision.

Consequently, as identified in the Battelle investigation and causal analysis of the event, the sealed source custodian and users in building 326 were generally unaware of the revision involving the addition of Type M source provisions or special concerns with fragile sources. Additionally, when made aware of the provisions, the custodians and users indicated that they would not necessarily have applied those provisions to the subject Pu-238 source.

This deficiency constitutes a Severity Level II violation.
Proposed Civil Penalty – \$41,250 (waived)

III. Assessment Program

A. Management/Independent Assessment

Title 10 C.F.R. Part 830.122(i) requires contractors to “Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.”

Title 10 C.F.R. Part 830.122(j)(1) requires contractors to “Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.”

Contrary to the above, Battelle management and independent assessment processes were not effective in identifying and correcting significant problems, or in measuring the adequacy of work performance. Specific concerns are described below:

1. Battelle management assessment activities were not effective in identifying the programmatic and site-wide project management deficiencies discovered as a result of the RPL airborne release event. During the onsite investigation and subsequent enforcement conference, Battelle management attributed this failure of the management assessment program to an inappropriately narrow focus of the program. Although a large number of line management assessments are conducted at PNNL (approximately 5000 completed in the first three quarters of fiscal year 2007), most were “space-based” inspections, focusing on unsafe conditions in the workspace. Battelle indicated that only a small percentage of line management self-assessments focus on “activities” (such as ongoing research or work activities) to identify unsafe or inappropriate behavior or work practices. Battelle management also indicated that most of the issues identified through the conduct of the space-based inspections were minor in nature.
2. During the period from September 2005 to approximately February 2007, the majority of independent assessments scheduled as part of the Battelle independent assessment function were not conducted. Instead, the Battelle Independent Oversight group directed its resources towards conducting event-related causal analyses and responding to line management requests. Consequently, the Battelle independent assessment program was not effective in identifying the programmatic deficiencies disclosed by the RPL 414 airborne release event and the leaking sealed source event.

Collectively, these deficiencies represent a Severity Level II violation.
Proposed Civil Penalty – \$27,500 (waived)

B. Quality Improvement

Title 10 C.F.R. Part 830.122(c) requires DOE contractors to: “(1) Establish and implement processes to detect and prevent quality problems. (2) Identify, control, and correct items,

services, and processes that do not meet established requirements. (3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem.”

Contrary to the above, Battelle failed to implement timely, effective corrective actions to correct known independent assessment function deficiencies as described in section III.A above. These deficiencies were identified to Battelle senior management by the Office of Enforcement in November 2005, and again by Battelle Corporate in August 2006. Although Battelle undertook initial corrective actions in response to communication from the Office of Enforcement in 2005, these actions were not fully implemented and did not address the underlying issues (e.g., lack of perceived value in the independent assessment program by Battelle senior management). After more than one year, an improved set of corrective actions was initiated in early 2007.

This deficiency constitutes a Severity Level II violation.
Proposed Civil Penalty – \$41,250 (waived)

REPLY

Pursuant to the provisions of 10 C.F.R. Part 820.24, Battelle is hereby required, within 30 days after the date of filing this Preliminary Notice of Violation (PNOV), to submit a written reply by overnight carrier to the following address:

Director, Office of Enforcement
Attention: Office of the Docketing Clerk
270 Corporate Square Building
U.S. Department of Energy
19901 Germantown Road
Germantown, MD 20874-1290

Copies should also be sent to the Under Secretary for Science and the Manager of the DOE Pacific Northwest Site Office. This reply should be clearly marked as a “Reply to a Preliminary Notice of Violation” and should include the following for each violation: (1) any facts, explanations, and arguments which support a denial that a violation has occurred as alleged; and (2) full and complete answers to any questions set forth in the Notice. Copies of all relevant documents shall be submitted with the reply. The reply shall include a discussion of the relevant authorities which support the position asserted, including rulings, regulations, interpretations, and previous decisions issued by DOE. Corrective actions that have been or will be taken to avoid further violations should be delineated with target and completion dates in DOE's Noncompliance Tracking System. If Battelle admits the violations and waives any right to contest the Notice, this PNOV will constitute a Final Order upon the filing of the reply.

If Battelle should fail to reply within the time specified, the Director will request that a default order be issued against Battelle.

A handwritten signature in black ink, appearing to read "A. Guevara", written in a cursive style.

Arnold E. Guevara
Director
Office of Enforcement
Office of Health, Safety and Security

Washington, DC
this 3rd day of January 2008

ENFORCEMENT CONFERENCE SUMMARY

Battelle Memorial Institute Pacific Northwest National Laboratory Radiological Exposure Events and Independent Assessment Deficiencies

On November 15, 2007, the Department of Energy's (DOE) Office of Enforcement held an Enforcement Conference with management representatives from the Battelle Memorial Institute (Battelle) in Germantown, Maryland. The conference was held to discuss apparent violations identified in the Investigation Summary Report (ISR) provided to Battelle on October 24, 2007. Specific events included in the scope of the enforcement investigation included the December 2006 airborne release event at the Radiochemical Processing Laboratory (RPL), the June 2007 leaking sealed source event, and performance deficiencies associated with the Battelle independent assessment program.

The conference was opened by Ms. Martha Thompson, Deputy Director for the Office of Enforcement, who provided introductions and an overview of the conference's purpose and objectives.

Battelle presentations were opened by Mr. Michael Kluse, Interim Director for the Pacific Northwest National Laboratory (PNNL). Mr. Kluse provided a senior management perspective on the events and issues discussed in the ISR, their underlying causes, and the Battelle path forward. This included an acknowledgement of the significance of the deficiencies; the recognition that management presence in the workplace was inadequate; that work procedures and processes were complicated and ineffectively delivered; and that independent assessment functions were inadequate. Mr. Kluse discussed the Battelle corporate fundamental principles of "Simultaneous Excellence" and indicated that Battelle had lost focus on these principles during PNNL operations. Mr. Kluse discussed Battelle's corrective actions to the subject events and issues, and Battelle's emphasis on developing comprehensive improvements.

Mr. Kluse also noted that a few corrections had been identified in the Battelle review of the ISR. Mr. Kluse characterized these as minor and indicated they did not appear to change the substance of the report. These corrections will be included in the enforcement docket file.

Mr. Michael Schlender, Associate Laboratory Director for Operational Systems, provided a more detailed discussion on the underlying causes of the two events and the independent assessment deficiencies, and Battelle's corrective actions. His presentation emphasized the top to bottom nature of Battelle's corrective actions in response to the events, and identified actions directed at the institutional level, project level, and activity level for the various events. When questioned regarding the failure of Battelle's management assessment processes in identifying the

widespread project management deficiencies underlying the events, he attributed the failure to an over-emphasis on space-based (versus activity-based) assessments throughout much of PNNL.

Mr. Bryan Mohler, Director for Quality and Performance Management, indicated this emphasis is shifting based on direction from the Interim Laboratory Director.

Messrs. Michael Davis and Barry Merrill, Associate Laboratory Directors for Energy and Environment and National Security, respectively, provided line management perspectives on the scope and significance of the ongoing Battelle corrective actions in response to the subject events. Mr. Davis noted how two completed actions (revised laboratory roles and responsibilities and developed management expectations for research and development) had significantly clarified management's expectations and in so doing had made work easier for the researchers.

Mr. James Tarpinian, the Battelle Corporate Vice-President for Environment, Safety and Health, then discussed the corporate role in oversight and lessons-learned related to laboratory performance. He indicated that the corporate organization would be participating in upcoming effectiveness reviews of completed corrective actions.

Mr. Schlender then discussed several factors for Office of Enforcement consideration for potential mitigation. These included Battelle's critical and comprehensive causal analyses of the subject issues, the significant and rapid changes made to improve the Independent Assessment function once the issue was recognized by the new management team, the scope and comprehensive nature of corrective actions, and Battelle-PNNL's history of strong Price-Anderson Amendments Act Program performance and conservative reporting. Mr. Schlender acknowledged Battelle had some difficulty communicating corrective actions related to the RPL airborne release event, but felt that actions associated with the leaking sealed source event were communicated appropriately.

Mr. Kluse then concluded the presentation by emphasizing the scope and comprehensive nature of Battelle's corrective actions, and their commitment to undertake the behavioral changes necessary to enhance operational discipline.

Ms. Thompson concluded the conference by indicating that DOE would consider the information presented in its enforcement deliberations. The conference was then adjourned.

Enforcement Conference List of Attendees

Battelle Memorial Institute
Radiological Exposure Events and Independent Assessment Deficiencies

November 15, 2007

DOE – Office of Enforcement

Martha Thompson, Deputy Director, Office of Enforcement
Richard Day, Acting Director, Office of Price-Anderson Enforcement
Tony Weadock, Senior Enforcement Officer

DOE – Pacific Northwest Site Office

Roger Christensen, Operations Division Director
Carrie Swafford-Bennett, Quality Assurance Program Manager

DOE – Office of Science

Marc Jones, Associate Director, Safety, Security and Infrastructure
Barry Parks, Price-Anderson Amendments Act Enforcement Coordinator

Battelle Memorial Institute – Pacific Northwest National Laboratory

Mike Kluse, Interim Laboratory Director
Mike Schlender, Associate Laboratory Director for Operational Systems
Mike Davis, Associate Laboratory Director for Energy and Environment
Barry Merrill, Acting Associate Laboratory Director for National Security
Roby Enge, Director for Environment, Health, Safety, and Security
Bryan Mohler, Director for Quality and Performance Management
Steve Cooke, Assistant General Counsel
Sandra English, PAAA Coordinator

Battelle Memorial Institute

Jim Tarpinian, Vice President for Corporate ES&H