



## **DEPARTMENT OF COMMERCE**

### **National Institutes of Standards and Technology**

#### **37 CFR Parts 401 and 404**

**[Docket No.: 160311229-8347-02]**

**RIN 0693-AB63**

#### **Rights to Federally Funded Inventions and Licensing of Government Owned Inventions**

**AGENCY:** National Institute of Standards and Technology (NIST), United States Department of Commerce.

**ACTION:** Final rule.

**SUMMARY:** This final rule reduces regulatory burdens by clarifying electronic reporting, updating certain sections to conform with changes in the patent laws, and streamlining the licensing application process for some Federal laboratory collaborators, makes technical corrections, clarifies the role of provisional patent application filing, explains a unique situation that may be appropriate for a Determination of Exceptional Circumstances, clarifies the role of funding agencies in the Bayh-Dole process, and addresses subject inventions as to which a Federal laboratory employee is a co-inventor.

**DATES:** This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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**SUPPLEMENTARY INFORMATION:** These rule revisions are promulgated under the University and Small Business Patent Procedures Act of 1980, Public Law 96-517 (as amended), codified at title 35 of the United States Code (U.S.C.) 200 *et seq.*, commonly known as the “Bayh-Dole Act” or simply “Bayh-Dole,” which governs rights in inventions made with Federal assistance. The Bayh-Dole Act obligates nonprofit organizations and small business firms (“contractors”), and large businesses, as directed by Executive Order 12591 and to the extent permitted by law, to disclose each “subject invention” (that is, each invention conceived or first actually reduced to practice in the performance of work under a funding agreement, 35 U.S.C. 201(e)) within a reasonable time after the invention becomes known to the contractor, 35 U.S.C. 202(c)(1), and permits contractors to elect, within a reasonable time after disclosure, to retain title to a subject invention, 35 U.S.C. 202(a). Under certain defined “exceptional” circumstances, Bayh-Dole permits the Government to restrict or eliminate the contractor’s right to elect to retain title, 35 U.S.C. 202(a), 202(b).

The Secretary of Commerce has delegated to the Director of NIST the authority to promulgate implementing regulations. Regulations implementing 35 U.S.C. 202 through 204 are codified at 37 CFR part 401, “Rights to Inventions Made by Nonprofit Organizations and Small Business Firms under Government Grants, Contracts, and Co-operative Agreements,” and apply to all Federal agencies, 37

CFR 401.1(b). These regulations govern all “subject inventions,” as defined in 37 CFR 401.2(d), even if the Federal government is not the sole source of funding for either the conception or the reduction to practice, 37 CFR 401.1(a). Regulations implementing 35 U.S.C. 208, specifying the terms and conditions upon which federally owned inventions, other than inventions owned by the Tennessee Valley Authority, may be licensed on a nonexclusive, partially exclusive, or exclusive basis, are codified at 37 CFR part 404, “Licensing of Government Owned Inventions.”

Bayh-Dole and its implementing regulations require Federal funding agencies to employ certain “standard clauses” in funding agreements awarded to contractors, except under certain specified conditions, 37 CFR 401.3. Through these standard clauses, set forth at 37 CFR 401.14(a), contractors are obligated to take certain actions to properly manage subject inventions. These actions include, but are not limited to, disclosing each subject invention to the Federal agency within two months after the contractor’s inventor discloses it in writing to contractor personnel responsible for patent matters, paragraph (c)(1) of the clause; electing in writing whether or not to retain title to any subject invention by notifying the Federal agency within two years of disclosure to the Federal agency, paragraph (c)(2) of the clause; filing an initial patent application on a subject invention as to which the contractor elects to retain title within one year after election, paragraph (c)(3) of the clause; executing and promptly delivering to the Federal agency all instruments necessary to establish or confirm the rights the Government has throughout the world in those subject inventions to which the contractor elects to retain title, paragraph (f)(1) of the clause; requiring, by written agreement, the contractor’s employees to disclose promptly in writing each subject invention made under contract, paragraph (f)(2) of the clause; notifying the Federal agency of any decision not to continue the prosecution of a patent application, paragraph (f)(3) of the clause; and including in the specification of any U.S. patent applications and any patent issuing thereon covering a subject invention, a statement that the invention was made with

Government support under the grant or contract awarded by the Federal agency, and that the Government has certain rights in the invention, paragraph (f)(4) of the clause.

In addition, a contractor is obligated to include the requirements of the standard clauses in any subcontracts under the contractor's award, paragraph (g) of the clause; to submit periodic reports as requested on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the contractor or its licensees or assignees, paragraph (h) of the clause; and to agree that neither the contractor nor any assignee will grant to any person the exclusive right to use or sell any subject inventions in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States, paragraph (i) of the clause, subject to waiver.

Bayh-Dole and its implementing regulations also specify certain conditions applicable to licenses granted by Federal agencies in any federally owned invention. The implementing regulations include 37 CFR 404.5, which sets forth restrictions and conditions applicable to all Federal agency licenses, 37 CFR 404.6, which addresses requirements pertaining to nonexclusive licenses, and 37 CFR 404.7, which addresses requirements pertaining to exclusive and partially exclusive licenses.

This rulemaking reduces regulatory burdens on large and small businesses, universities, non-profit organizations, and other recipients of federal funding in several ways. The rule provides greater clarity to large businesses by codifying the applicability of Bayh-Dole as directed in Executive Order 12591 which has been in effect since 1987, and provides greater clarity to all federal funding recipients by updating regulatory provisions to align with provisions of the Leahy-Smith America Invents Act in terms of definitions, required time frames, and use of royalty funds, which will reduce compliance

burdens on recipients of federal funding. The rule also clarifies electronic reporting processes, simplifying the burden of the statutorily required reporting process. Finally, the rule provides for automatic extensions of the requirement to file non-provisional patent applications, and removes the requirement for a business, university, or other collaborator to submit a separate license application for a federal invention being used under a cooperative research and development agreement.

Pursuant to authority delegated to it by the Secretary of Commerce, NIST is revising parts 401 and 404 of title 37 of the Code of Federal Regulations (CFR) which address rights to inventions made under Government grants, contracts, and co-operative agreements, and licensing of government owned inventions. The rule shall apply to all new funding agreements as defined in 37 CFR 401.2(a) that are executed after the effective date of the rule. The rule shall not apply to a funding agreement in effect on or before the effective date of the rule, provided that if such existing funding agreement is thereafter amended, the funding agency may, in its discretion, make the amended funding agreement subject to the rule prospectively.

### **Response to Comments**

NIST received 17 comment submissions during the public comment period for the notice of proposed rulemaking published November 7, 2016, 81 FR 78090. NIST thanks the public for its careful review and submissions. The comments received and NIST's responses are summarized below.

1. One comment requested clarification about the revised definition of *statutory period* in §§ 401.2(o) and 401.14(a)(7). NIST has revised the definition to clarify that the statutory period refers to the one-year period in 35 U.S.C. 102(b)(1) as amended by the Leahy-Smith America Invents Act.

2. Several comments suggested a revision to § 401.3(a)(1) permitting foreign collaborators to receive standard Bayh-Dole rights. NIST declines to revise this provision of the regulations. NIST notes that the language of § 401.3(a)(1) closely tracks that of 35 U.S.C. 202(a)(i). Both the statute and the regulation accord a funding agency discretion in crafting the terms and conditions of a funding agreement “when the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government.”
3. Several comments noted the removal of the appeals process in § 401.3(a)(5). This was not NIST’s intent. Accordingly, NIST has added reference to § 401.3(a)(5) in § 401.3(b), requiring an agency exercising that exception to use the standard clause at § 401.14 with only such modifications as are necessary to address the exceptional circumstances or concerns which led to the use of the exception. In addition, the first sentence of § 401.4(a) of the final rule makes clear that each of the exceptions at § 401.3(a)(1) through (6) of the final rule is subject to a contractor right to an administrative review.
4. Several comments objected to the addition of the exception, recited in § 401.3(a)(6), which authorizes a funding agency to use alternative provisions if the contract provides for services and the contractor is not a nonprofit organization and does not promote the commercialization and public availability of subject inventions. This exception is intended to address the scenario in which a services contractor, whose business model by design does not promote the commercialization or public availability of subject inventions, can, by simply neglecting to waive title for as long as two years, delay (at best) efforts to achieve commercialization or public availability. In reciting the § 401.3(a)(6) exception, the final rule also provides that it is subject to an administrative review right.

5. Several comments objected to provisions in § 401.5 allowing Federal agencies to request additional invention reporting. NIST notes that the alternative reporting set forth in § 401.5(f)(1) through (3) is neither new language nor obligatory upon funding agencies. The suggestion of several commenters, that this is new language, is incorrect.
6. Several comments objected to the proposed revisions to §§ 401.7 and 401.14(k) (by reference to § 401.7), regarding the small business preference requirement of 35 U.S.C. 202(c)(7)(D). The proposed revision to § 401.7(b) provides that small business firms that believe a nonprofit organization is not according appropriate preference to small business firms may report their concerns in the first instance to the funding agency, rather than to the Secretary of Commerce as previously provided. It is believed that this change will in many instances facilitate resolution of concerns, given the funding agency's familiarity with the subject matter and purpose of its award. Where a small business firm is dissatisfied with the funding agency response, or receives none within 90 days, the proposed revision provides that it may thereafter report its concerns, together with any response from the funding agency, to the Secretary of Commerce. NIST declines to remove these proposed changes.
7. One comment suggested revisions to §§ 401.7 and 401.14(k) to address licensing to what were characterized by the commenter as "non-practicing entities." NIST declines to make the suggested revisions, and notes that under § 401.14(k)(4), a nonprofit contractor must give a licensing preference to a small business firm with a marketing plan for the invention which is as likely to bring the invention to practical application as the plans of other firms, however those other firms might be characterized. At the same time, § 401.14(k)(4) does not prescribe the type of license (exclusive, non-exclusive, or partially exclusive) to be granted, the result of which is that a nonprofit contractor is accorded the flexibility, through its licensing policies, procedures

and practices, to promote the practical application and public availability of subject inventions, while according to small business firms the preference required under 35 U.S.C. 202(7)(D).

8. Comments generally supported revisions to § 401.10 on the management of subject inventions when there is a Federal employee who is a co-inventor of the subject invention, and NIST appreciates the suggestions for additional clarification. NIST has required consultation with the contractor in § 401.10(a)(2), but declines the suggestion that it should restrict the scope of the required consultation. In addition, NIST has clarified that paragraphs (ii) through (vi) of § 401.10(a)(3) all apply only after a contractor has elected not to retain title, and has added a paragraph (c) to clarify that the regulation will not supersede inter-institutional agreements for the management of jointly-owned subject inventions. As appropriate, NIST has also revised § 401.10(a)(3) to recite “title” rather than “rights” for consistency and clarity.
9. Several comments pertained to priority of patent applications and prosecution or abandonment of an initial patent application filed by the Government per § 401.10(a)(2). Priority of applications is an individual determination made by the U.S. Patent and Trademark Office and is outside the scope of this rulemaking. With regard to prosecution or abandonment of an initial patent application filed by the Government on a jointly-owned subject invention, NIST notes that it is within the discretion of the funding agency to determine, in consultation with the contractor as required by this paragraph, the appropriate course of action for a particular subject invention, which could include abandoning an initial patent application or transferring the prosecution of an initial patent application to the contractor under an inter-institutional or other appropriate agreement. In all cases, NIST observes that actions taken by a funding agency should not operate to preclude a contractor from electing title to a subject invention.
10. One comment requested clarification as to whether the “team exception” of post-AIA 35 U.S.C. 102(b)(2)(C) may be invoked for filings on joint subject inventions. That provision of the patent

statute provides that subject matter disclosed 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under 35 U.S.C. 102(a)(2), where that subject matter and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person. The present rulemaking is not intended to affect the prosecution strategy of a sole or joint applicant for patent. At the same time, NIST notes that prior art determinations, including the applicability of the “team exception,” are made by the U.S. Patent and Trademark Office, and so are outside the scope of this rulemaking.

11. One comment noted that § 401.14 does not contain a definition of the term *contractor*. NIST has made this addition in § 401.14(a)(8) to recite the revised definition found in § 401.2(b).
12. A number of comments objected to the proposed revision to § 401.14(c)(2), providing that a Federal agency may shorten the two-year period for election of title by a contractor if “necessary to protect the Government’s interests.” NIST has removed this revision from the final rulemaking.
13. A number of comments objected to the proposed revision to § 401.14(d)(1), which would remove the 60-day time limit within which a Federal agency must make written request to a contractor to convey title, after learning of the failure of the contractor to disclose an invention or elect title within the specified times. While NIST appreciates the concerns of commenters, the proposed revision will be maintained in the final rule. A contractor’s failure to timely disclose or elect title to a subject invention, both as required by its funding agreement, can work to deny the Federal government any rights in the funded invention, through no fault of the funding agency.
14. A number of comments urged clarification of proposed revisions relating to the increased use by contractors of provisional applications under the Leahy-Smith America Invents Act and the Government’s ability to request conveyance of rights in abandoned provisional applications.

NIST acknowledges the increased use of provisional applications, and that a contractor may reasonably decide, as a matter of prosecution strategy, not to convert a provisional application under appropriate circumstances, without abandoning the subject invention itself or foreclosing the contractor's ability to file one or more additional applications directed to that invention. NIST has revised § 401.14(d)(3) to make clear that this section applies to abandoned non-provisional applications, and has made an analogous revision to § 401.14(f)(3). NIST expects that a contractor making a strategic decision such as described above will communicate its decision, and its intent not to abandon the subject invention itself, to the funding agency.

15. A number of comments objected to the proposed revision in § 401.14(f)(3) to extend the required notification period for decisions not to continue patent prosecution from 30 days before the expiration of the response period to 120 days. NIST aims to balance the needs of contractors to have sufficient time to respond to actions, and the needs of Federal agencies to receive information in sufficient time to evaluate whether to request conveyance and assume prosecution of an application. NIST appreciates comments reflecting appreciation of these competing needs. NIST has shortened the notification period from the proposed 120 days to 60 days in the final rule.
16. One comment requested clarification of references to Patent Trial and Appeals Board proceedings in § 401.14(f)(3). NIST has revised this paragraph to clarify that the list of decisions requiring the contractor to notify the Federal agency pertain to a subject invention.
17. Several comments requested revisions to the Government support clause in § 401.14(f)(4) to allow flexibility in the statement required by the contractor rather than the precise language recited. NIST declines to do so, and notes that, apart from the requirement to identify the contract and the funding agency, the language of the statement required by the rule tracks almost

*verbatim* that of 35 U.S.C. 202(c)(6). NIST will not invite departure from these two clear, concise sentences, which notify readers of the Federal government’s rights in a subject invention.

18. Several comments suggested revision to § 401.14(i) to permit automatic waivers from the requirement for substantial U.S. manufacture. NIST declines to make such a change, noting that § 401.14(i) tracks very closely the language of 35 U.S.C. 204, which itself makes clear that waivers from the requirement may be granted by the funding agency “in individual cases,” upon a showing.
19. Several comments were directed towards electronic filing and the Interagency Edison (iEdison) system, and noted the proposed changes in §§ 401.16 and 401.17. While NIST strongly supports the use of iEdison by funding agencies, it cannot mandate or compel agency use. Accordingly, revisions to § 401.16, which provides that written notices may be electronically delivered to the agency or the contractor through an electronic database, do not mandate the use of iEdison or any other system. NIST also notes comments directed to compliance and training, and is pleased to note that it is collaborating with the National Institutes of Health to develop a series of iEdison training modules expected to be available to agencies and contractors after publication of this final rule.
20. A number of comments noted specific challenges and error messages relating to the iEdison reporting system. NIST is pleased to note that it is working with the National Institutes of Health to evaluate the iEdison messaging system and identify opportunities for updates and improvements. Contractors and agencies are encouraged to contact the National Institutes of Health to report specific errors in the system so these can be flagged for evaluation.
21. One comment concerned the publication process for patent applications, which NIST notes is unrelated to this rulemaking.

22. Several comments were submitted regarding the management and licensing of federally owned inventions with regard to transparency and availability to the public. NIST notes that 35 U.S.C. 209 and 37 CFR 404.7 direct agencies in the criteria to be applied and the public notification processes to be followed in exercising the authority to grant exclusive and partially exclusive licenses to federally owned inventions, and provide for administrative appeals from agency licensing decisions, which appeals are also subject to review by the United States Court of Federal Claims.
23. One comment stated that the notice of proposed rulemaking was not as widely publicized as other regulation changes, and suggested that more time should be provided “if few comments are received.” NIST published its notice of proposed rulemaking in the Federal Register, in which it announced a public meeting/webinar, which took place during the 30-day period set in the Federal Register notice of proposed rulemaking for public comment. In addition to the Federal Register, NIST utilized multiple communications media to publicize the notice of proposed rulemaking, the public meeting, and the request for comments. NIST was pleased to receive 17 comments through Regulations.gov, which NIST has taken into account in this final rule.

### **Changes from the Proposed Rule**

1. Revise the scope in § 401.1(e) to include the alternate provisions in § 401.3(a)(5) and (6) in the list of deviations that do not require the Secretary’s approval.
2. Revise the proposed definition of the term *initial patent application* in § 401.2(n) to include Patent Cooperative Treaty applications and applications for Plant Variety Protection certificates, when applicable.

3. Revise the proposed definition of the term *statutory period* in § 401.2(o) and in § 401.14(a)(7) to clarify that it refers to the one-year period in 35 U.S.C. 102(b) as amended by the Leahy-Smith America Invents Act.
4. Revise § 401.3(b) to include the exception at § 401.3(a)(5) in the list of exceptions where an agency must use only the modifications necessary to address the exceptional circumstances.
5. Correct formatting error to retain § 401.3(e) through (g).
6. Re-insert the small business certification requirement in § 401.3(h).
7. Revise § 401.4(a) to include the exceptions at § 401.3(a)(5) and (6) in the list of exceptions as to which a contractor has the right to an administrative review.
8. Revise § 401.5 to make technical clarifications.
9. Revise the proposed addition at § 401.10(a)(2) to require a Federal agency to consult with a contractor before submitting an initial patent application.
10. Revise the proposed additions at § 401.10(a)(3)(iv) and (vi) to clarify that they apply after a contractor has waived title to the subject invention.
11. Add a paragraph at § 401.10(c) to allow other inter-institutional agreements for the management of jointly-owned subject inventions to supersede § 401.10.
12. Revise § 401.10 to align regulatory language with statute language.
13. Revise § 401.13(c)(2) to remove the time limit under which agencies shall not disclose patent applications, and state that the prohibition on agency release does not apply to documents published by the U.S. Patent and Trademark Office.
14. Add a paragraph at § 401.14(a)(8) to define the term *contractor* as defined in § 401.2(b).
15. Remove the proposed revision at § 401.14(c)(2) which would allow an agency to shorten the two-year period for election of title if necessary to protect the Government's interest.

16. Revise § 401.14(c)(3) to require a contractor to file a non-provisional application 10 months after filing a provisional application.
17. Revise the proposed addition at § 401.14(c)(4) to clarify that the Federal agency employing a co-inventor may file an initial patent application, provided that the contractor retains the ability to elect title, in accordance with the revisions at § 401.10.
18. Revise § 401.14(c)(5) to state that a request to extend the 10-month deadline for filing a non-provisional application after first filing a provisional application will be automatically granted for one year unless an agency notifies the contractor within 60 days of the request.
19. Revise § 401.14(d)(3) to state that the section only applies to non-provisional applications and update the conditions under which a contractor will convey title to the Federal agency to be consistent with the Leahy-Smith America Invents Act provisions.
20. Revise the proposed revision at § 401.14(f)(3) to change the notification period to 60 days prior to the expiration of the statutory deadline and clarify that only decisions pertaining to the subject invention made under contract require the contractor to provide notification to the Federal agency.
21. Correct formatting error to retain § 401.14(f)(4) and (g)(1).
22. Revise the proposed revisions at § 401.14(k)(4) to reference § 401.7.
23. Revise § 404.7(a)(1)(i) and (b)(1)(i) to allow prospective exclusive, co-exclusive, or partially exclusive licenses to be advertised in places other than the Federal Register.

### **Classification**

NIST has determined that the final rule is consistent with the Bayh-Dole Act of 1980 and other applicable law.

### **Executive Order 12866**

This rulemaking is a significant regulatory action under sections 3(f)(3) and 3(f)(4) of Executive Order 12866, as it raises novel policy issues. This rulemaking, however, is not an “economically significant” regulatory action under section 3(f)(1) of the Executive order, as it does not have an effect on the economy of \$100 million or more in any one year, and it does not have a material adverse effect on the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

### **Executive Order 13771**

This final rule is considered to be an EO 13771 deregulatory action. Details on the cost savings can be found in the rule’s Estimated Cost Savings section.

### **Executive Order 13132**

This rule does not contain policies with Federalism implications as defined in Executive Order 13132.

### **Regulatory Flexibility Act**

The Regulatory Flexibility Act (RFA) requires the preparation and availability for public comment of “an initial regulatory flexibility analysis” which will “describe the impact of the rule on small entities.” (5 U.S.C. 603(a)). Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this rule would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination was published in the proposed rule and is not repeated here. No comments were received regarding the certification and NIST has not received any new information that would affect its determination. As a result, a final regulatory flexibility analysis was not required and none was prepared.

### **Estimated Cost Savings**

Cost savings are anticipated from this rule by streamlining the licensing process for licensees that are already partnering with a Federal agency under a Cooperative Research and Development Agreement (CRADA). Federal agency collaborators include members from industry, academia, state and local governments, and individuals from the public. Costs to enter into a license with a Federal agency include the labor time on the part of the non-government collaborator to negotiate and execute the license with the Federal agency. NIST subject matter experts utilized annual technology transfer data reported by several Federal agencies to determine that the average Federal license takes approximately 5 months to execute<sup>1</sup>. Assuming 5 hours of effort per month, approximately 25 hours of effort is invested by the non-Federal collaborator in executing a license with a Federal agency. Based on NIST database information, NIST subject matter experts estimate approximately one in five invention licenses is associated with a CRADA research plan, and Federal agencies report approximately 446 new invention licenses each year.<sup>2</sup>

For the purposes of estimating opportunity costs, NIST subject matter experts deemed it reasonable to use the average of a lawyer's mean hourly wage (\$67.25) and a legal support worker's hourly wage (\$31.81), as informed by the Bureau of Labor and Statistics<sup>3</sup>, to approximate an hourly wage for the average Federal license negotiator. That rate is \$49.52/hour.

Eliminating the need to negotiate a separate license document from CRADA collaborators is estimated to save Federal agency collaborators approximately \$110,430 annually, as reflected in the chart below.

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<sup>1</sup> DOC average time over last five years to execute a license is 5 months: <https://www.nist.gov/sites/default/files/documents/2017/09/08/fy2016-doc-tech-trans-report-final-9-5-17.pdf>; DOE average time to execute a license is 98 business days; 22 business days per month averages 4.5 months: <https://www.nist.gov/sites/default/files/documents/2017/04/19/technologytransferreporttocongressfy14.pdf>; USDA average time over last five years to execute a license is 4.6 months: <https://www.usda.gov/sites/default/files/documents/usda-fy16-tech-transfer-report.pdf>.

<sup>2</sup> Average over the last five years:

[https://www.nist.gov/sites/default/files/documents/2016/10/26/fy2014\\_federal\\_tech\\_transfer\\_report.pdf](https://www.nist.gov/sites/default/files/documents/2016/10/26/fy2014_federal_tech_transfer_report.pdf)

<sup>3</sup> Bureau of Labor and Statistics May 2016 wage data: [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm)

<b>New invention licenses/year</b>	<b>% of licenses associated with a CRADA</b>	<b># of licenses associated with a CRADA</b>	<b>Negotiation time/license</b>	<b>Hourly wage of non-Federal negotiator</b>	<b>Projected cost savings to the public</b>
446	20%	92	25 hours	\$49.52	-\$110,430

### **National Environmental Policy Act**

This rule will not significantly affect the quality of the human environment. Therefore, an environmental assessment or Environmental Impact Statement is not required to be prepared under the National Environmental Policy Act of 1969.

### **List of Subjects in 37 CFR Parts 401 and 404**

Inventions and patents, Laboratories, Research and development, Science and technology, Technology transfer.

For the reasons stated in the preamble, the National Institute of Standards and Technology amends 37 CFR parts 401 and 404 as follows:

### **PART 401 - RIGHTS TO INVENTIONS MADE BY NONPROFIT ORGANIZATIONS AND SMALL BUSINESS FIRMS UNDER GOVERNMENT GRANTS, CONTRACTS, AND COOPERATIVE AGREEMENTS**

1. The authority citation for 37 CFR part 401 continues to read as follows:

**Authority:** 35 U.S.C. 206; DOO 30-2A.

2. Section 401.1 is amended as follows:
  - a. Revise the second sentence of paragraph (b); and
  - b. Revise the fourth and fifth sentences of paragraph (e).

The revisions read as follows:

**§ 401.1 Scope.**

\* \* \* \* \*

(b) \* \* \* It applies to all funding agreements with business firms regardless of size (consistent with section 1, paragraph (b)(4) of Executive Order 12591, as amended by Executive Order 12618) and to nonprofit organizations, except for a funding agreement made primarily for educational purposes. \* \* \*

\* \* \* \* \*

(e) \* \* \* Modifications or tailoring of clauses as authorized by § 401.5 or § 401.3, when alternate provisions are used under § 401.3(a)(1) through (6), are not considered deviations requiring the Secretary's approval. Three copies of proposed and final agency regulations supplementing this part shall be submitted to the Secretary at the office set out in § 401.17 for approval for consistency with this part before they are submitted to the Office of Management and Budget (OMB) for review under Executive Order 12866 or, if no submission is required to be made to OMB, before their submission to the Federal Register for publication.

\* \* \* \* \*

3. Section 401.2 is amended as follows:
  - a. Revise paragraphs (b) and (n); and
  - b. Add paragraph (o).

The revisions and additions read as follows:

**§ 401.2 Definitions.**

\* \* \* \* \*

(b) The term *contractor* means any person, small business firm or nonprofit organization, or, as set forth in section 1, paragraph (b)(4) of Executive Order 12591, as amended, any business firm regardless of size, which is a party to a funding agreement.

\* \* \* \* \*

(n) The term *initial patent application* means, as to a given subject invention, the first provisional or non-provisional U.S. national application for patent as defined in 37 CFR 1.9(a)(2) and (3), respectively, the first international application filed under the Patent Cooperation Treaty as defined in 37 CFR 1.9(b) which designates the United States, or the first application for a Plant Variety Protection certificate, as applicable.

(o) The term *statutory period* means the one-year period before the effective filing date of a claimed invention during which exceptions to prior art exist per 35 U.S.C. 102(b) as amended by the Leahy-Smith America Invents Act, Public Law 112-29.

4. Section 401.3 is amended as follows:

- a. Revise the first sentence of paragraph (a) introductory text;
- b. In paragraph (a)(4), remove the period at the end of the paragraph and add in its place “; or”;
- c. Revise paragraph (a)(5);
- d. Add paragraph (a)(6);
- e. In paragraph (b), revise the first sentence, remove “§ 401.14(b)” and add in its place “paragraph (c) of this section”, remove “§ 401.3(a)(2)” and add in its place “paragraph (a)(2) of this section”, remove “§ 401.14(a)” and add in its place “§ 401.14”, and remove “this paragraph” and add in its place “this paragraph (b)”;

- f. Revise paragraph (c);
- g. Revise the first sentence of paragraph (d);
- h. Revise paragraph (h); and
- i. Add paragraph (i).

The revisions and additions read as follows:

**§ 401.3 Use of the standard clauses at § 401.14.**

(a) Each funding agreement awarded to a contractor (except those subject to 35 U.S.C. 212) shall contain the clause found in § 401.14 with such modifications and tailoring as authorized or required elsewhere in this part. \*\*\*

\* \* \* \* \*

(5) If any part of the contract may require the contractor to perform work on behalf of the Government at a Government laboratory under a Cooperative Research and Development Agreement (CRADA) pursuant to the statutory authority of 15 U.S.C. 3710a; or

(6) If the contract provides for services and the contractor is not a nonprofit organization and does not promote the commercialization and public availability of subject inventions pursuant to 35 U.S.C. 200.

(b) When an agency exercises the exceptions at paragraph (a)(2), (3), (5), or (6) of this section, it shall use the standard clause at § 401.14 with only such modifications as are necessary to address the exceptional circumstances or concerns which led to the use of the exception. \*\*\*

(c) When the Department of Energy (DOE) determines to use alternative provisions under paragraph (a)(4) of this section, the standard clause at §401.14 shall be used with the following modifications, or substitute thereto with such modification and tailoring as authorized or required elsewhere in this part:

(1) The title of the clause shall be changed to read as follows: Patent Rights to Nonprofit DOE Facility Operators.

(2) Add an “(A)” after “(1)” in paragraph (c)(1) of the clause in § 401.14 and add paragraphs (B) and (C) to paragraph (c)(1) of the clause in § 401.14 as follows:

<p>(B) If the subject invention occurred under activities funded by the naval nuclear propulsion or weapons related programs of DOE, then the provisions of this paragraph (c)(1)(B) will apply in lieu of paragraphs (c)(2) and (3) of this clause. In such cases the contractor agrees to assign the government the entire right, title, and interest thereto throughout the world in and to the subject invention except to the extent that rights are retained by the contractor through a greater rights determination or under paragraph (e) of this clause. The contractor, or an employee-inventor, with authorization of the contractor, may submit a request for greater rights at the time the invention is disclosed or within a reasonable time thereafter. DOE will process such a request in accordance with procedures at 37 CFR 401.15. Each determination of greater rights will be subject to paragraphs (h) through (k) of this clause and such additional conditions, if any, deemed to be appropriate by the Department of Energy.</p> <p>(C) At the time an invention is disclosed in accordance with paragraph (c)(1)(A) of this clause, or within 90 days thereafter, the contractor will submit a written statement as to whether or not the invention occurred under a naval nuclear propulsion or weapons-related program of the Department of Energy. If this statement is not filed within this time, paragraph (c)(1)(B) of this clause will apply in lieu of paragraphs (c)(2) and (3) of this clause. The contractor statement will be deemed conclusive unless, within 60 days thereafter, the Contracting Officer disagrees in writing, in which case the determination of the Contracting Officer will be deemed conclusive unless the contractor files a claim under the Contract Disputes Act within 60 days after the Contracting Officer's determination. Pending resolution of the matter, the invention will be subject to paragraph (c)(1)(B) of this clause.</p>
--

(3) Paragraph (k)(3) of the clause in § 401.14 will be modified as prescribed at §401.5(g).

(d) When a funding agreement involves a series of separate task orders, an agency may apply the exceptions at paragraph (a)(2) or (3) of this section to individual task orders, and it may structure the contract so that modified patent rights provisions will apply to the task order even though either the standard clause at § 401.14 or the modified clause as described in paragraph (c) of this section is applicable to the remainder of the work. \*\*\*

\* \* \* \* \*

(h) A prospective contractor may be required by an agency to certify that it is either a small business firm or a nonprofit organization. If the agency has reason to question the status of the

prospective contractor, it may require the prospective contractor to furnish evidence to establish its status.

- (i) When an agency exercises the exception at paragraph (a)(5) of this section, replace paragraph (b) of the basic clause in § 401.14 with the following paragraphs (b)(1) and (2):

(b) *Allocation of principal rights.* (1) The Contractor may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause, including paragraph (b)(2) of this clause, and 35 U.S.C. 203. With respect to any subject invention in which the Contractor retains title, the Federal Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

(2) If the Contractor performs services at a Government owned and operated laboratory or at a Government owned and contractor operated laboratory directed by the Government to fulfill the Government's obligations under a Cooperative Research and Development Agreement (CRADA) authorized by 15 U.S.C. 3710a, the Government may require the Contractor to negotiate an agreement with the CRADA collaborating party or parties regarding the allocation of rights to any subject invention the Contractor makes, solely or jointly, under the CRADA. The agreement shall be negotiated prior to the Contractor undertaking the CRADA work or, with the permission of the Government, upon the identification of a subject invention. In the absence of such an agreement, the Contractor agrees to grant the collaborating party or parties an option for a license in its inventions of the same scope and terms set forth in the CRADA for inventions made by the Government.

- 5. In § 401.4, revise the first sentence of paragraph (a) to read as follows:

**§ 401.4 Contractor appeals of exceptions.**

- (a) In accordance with 35 U.S.C. 202(b)(4) a contractor has the right to an administrative review of a determination to use one of the exceptions at § 401.3(a)(1) through (6) if the contractor believes that a determination is either contrary to the policies and objectives of this chapter or constitutes an abuse of discretion by the agency. \*\*\*

\* \* \* \* \*

- 6. Revise § 401.5 to read as follows:

**§ 401.5 Modification and tailoring of clauses.**

(a) Agencies should complete the blank in paragraph (g)(2) of the clauses at § 401.14 in accordance with their own or applicable government-wide regulations such as the Federal Acquisition Regulation. In funding agreements, agencies wishing to apply the same clause to all subcontractors as is applied to the contractor may delete paragraph (g)(2) of the clause in § 401.14 and delete the words “to be performed by a small business firm or domestic nonprofit organization” from paragraph (g)(1). Also, if the funding agreement is a grant or cooperative agreement, paragraph (g)(3) of the clause may be deleted. When either paragraph (g)(2) of the clause in § 401.14 or paragraphs (g)(2) and (3) of the clause in § 401.14 are deleted, the remaining paragraph or paragraphs should be renumbered appropriately.

(b) Agencies should complete paragraph (l), “Communications”, at the end of the clauses at § 401.14 by designating a central point of contact for communications on matters relating to the clause. Additional instructions on communications may also be included in paragraph (l) of the clause in § 401.14.

(c) Agencies may replace the italicized words and phrases in the clause at § 401.14 with those appropriate to the particular funding agreement. For example, “contractor” could be replaced by “grantee.” Depending on its use, “agency” or “Federal agency” can be replaced either by the identification of the agency or by the specification of the particular office or official within the agency.

(d)(1) When the agency head or duly authorized designee determines at the time of contracting that it would be in the national interest to acquire the right to sublicense foreign governments, their nationals, or international organizations in accordance with any existing treaty or international agreement, a sentence may be added at the end of paragraph (b) of the clause at §401.14 as follows:

This license will include the right of the government to sublicense foreign governments, their nationals, and international organizations, in accordance with the following treaties or international agreements: _____.
--

(2) The blank in the added text in paragraph (d)(1) of this section should be completed with the names of applicable existing treaties or international agreements, including agreements of cooperation, and military agreements relating to weapons development and production. The added language is not intended to encompass treaties or other agreements that are in effect on the date of the award but which are not listed. Alternatively, agencies may use substantially similar language relating the government's rights to specific treaties or other agreements identified elsewhere in the funding agreement. The language may also be modified to make clear that the rights granted to the foreign government, and its nationals or an international organization may be for additional rights beyond a license or sublicense if so required by the applicable treaty or other international agreement. For example, in some cases exclusive licenses or even the assignment of title to the foreign country involved might be required. Agencies may also modify the added language to provide for the direct licensing by the contractor of the foreign government or international organization.

(e) If the funding agreement involves performance over an extended period of time, such as the typical funding agreement for the operation of a government-owned facility, the following language may also be added:

The <i>agency</i> reserves the right to unilaterally amend this <i>funding agreement</i> to identify specific treaties or international agreements entered into or to be entered into by the government after the effective date of this <i>funding agreement</i> and effectuate those license or other rights which are necessary for the government to meet its obligations to foreign governments, and international organizations under such treaties or international agreements with respect to subject inventions made after the date of the amendment.
--

(f) Agencies may add additional paragraphs to paragraph (f) of the clauses at § 401.14 to require the contractor to do one or more of the following:

(1) Provide a report prior to the close-out of a funding agreement listing all subject inventions or stating that there were none.

(2) Provide, upon request, the filing date, patent application number and title; a copy of the patent application; and patent number and issue date for any subject invention in any country in which the contractor has applied for a patent.

(3) Provide periodic (but no more frequently than annual) listings of all subject inventions which were disclosed to the agency during the period covered by the report.

(g) If the contract is with a nonprofit organization and is for the operation of a government-owned, contractor-operated facility, the following will be substituted for the text of paragraph (k)(3) of the clause at § 401.14:

After payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, the balance of any royalties or income earned and retained by the contractor during any fiscal year on subject inventions under this or any successor contract containing the same requirement, up to any amount equal to five percent of the budget of the facility for that fiscal year, shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility. If the balance exceeds five percent, 15 percent of the excess above five percent shall be paid by the contractor to the Treasury of the United States and the remaining 85 percent shall be used by the contractor only for the same purposes as described in the preceding sentence. To the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by contractor employees on location at the facility.

(h) If the contract is for the operation of a government-owned facility, agencies may add paragraph (f)(5) to the clause at § 401.14 with the following text:

The contractor shall establish and maintain active and effective procedures to ensure that subject inventions are promptly identified and timely disclosed and shall submit a description of the procedures to the *contracting officer* so that the *contracting officer* may evaluate and determine their effectiveness.

7. In § 401.7, revise paragraph (b) to read as follows:

**§ 401.7 Small business preference.**

\* \* \* \* \*

(b) Small business firms that believe a nonprofit organization is not meeting its obligations under the clause may report their concerns to the funding agency identified at § 401.14(1),

and following receipt of the funding agency's initial response to their concerns or, if no initial funding agency response is received within 90 days from the date their concerns were reported to the funding agency, may thereafter report their concerns, together with any response from the funding agency, to the Secretary. To the extent deemed appropriate, the Secretary, in consultation with the funding agency, will undertake informal investigation of the concern, and, if appropriate, enter into discussions or negotiations with the nonprofit organization to the end of improving its efforts in meeting its obligations under the clause. However, in no event will the Secretary intervene in ongoing negotiations or contractor decisions concerning the licensing of a specific subject invention. All investigations, discussions, and negotiations of the Secretary described in this paragraph (b) will be in coordination with other interested agencies, including the funding agency and the Small Business Administration. In the case of a contract for the operation of a government-owned, contractor operated research or production facility, the Secretary will coordinate with the agency responsible for the facility prior to any discussions or negotiations with the contractor.

**§ 401.9 [Amended]**

8. In § 401.9, remove “§ 401.14(a)” and add in its place “§ 401.14”.

9. Revise § 401.10 to read as follows:

**§ 401.10 Government assignment to contractor of rights in invention of government employee.**

(a) In any case when a Federal employee is a co-inventor of any invention made under a funding agreement with a contractor:

- (1) If the Federal agency employing such co-inventor transfers or reassigns to the contractor the right it has acquired in the subject invention from its employee as authorized by 35 U.S.C. 202(e), the assignment will be made subject to the patent rights clause of the contractor's funding agreement.
- (2) The Federal agency employing such co-inventor, in consultation with the contractor, may submit an initial patent application, provided that the contractor retains the right to elect to retain title pursuant to 35 U.S.C. 202(a).
- (3) When a Federal employee is a co-inventor of a subject invention developed with contractor-employed co-inventors under a funding agreement from another agency:
  - (i) The funding agency will notify the agency employing a Federal co-inventor of any report of invention and whether the contractor elects to retain title.
  - (ii) If the contractor does not elect to retain title to the subject invention, the funding agency must promptly provide notice to the agency employing a Federal co-inventor, and to the extent practicable, at least 60 days before any statutory bar date.
  - (iii) Upon notification by the funding agency of a subject invention in which the contractor has not elected to retain title, the agency employing a Federal co-inventor must determine if there is a government interest in patenting the invention and will notify the funding agency of its determination.
  - (iv) If the agency employing a Federal co-inventor determines there is a government interest in patenting the subject invention in which the contractor has not elected to retain title, the funding agency must provide administrative assistance (but is not required to provide financial assistance) to the agency

employing a Federal co-inventor in acquiring rights from the contractor in order to file an initial patent application.

(v) The agency employing a Federal co-inventor has priority for patenting over funding agencies that do not have a Federal co-inventor when the contractor has not elected to retain title.

(vi) When the contractor has not elected to retain title, the funding agency and the agency employing a Federal co-inventor shall consult in order to ensure that the intent of the programmatic objectives conducted under the funding agreement is represented in any patenting decisions. The agency employing a Federal co-inventor may transfer patent management responsibilities to the funding agency.

(4) Federal agencies employing such co-inventors may enter into an agreement with a contractor when an agency determines it is a suitable and necessary step to protect and administer rights on behalf of the Federal Government, pursuant to 35 U.S.C. 202(e).

(5) Federal agencies employing such co-inventors will retain all ownership rights to which they are otherwise entitled if the contractor elects to retain title to the subject invention.

(b) Agencies may add additional conditions as long as they are consistent with 35 U.S.C. 201-206.

(c) Nothing in this section shall supersede any existing inter-institutional agreements between a contractor and a Federal agency for the management of jointly-owned subject inventions.

10. Section 401.13 is amended as follows:

- a. Revise the second sentence of paragraph (c)(1);
- b. Revise paragraph (c)(2); and
- c. Revise the second sentence of paragraph (c)(3).

The revisions read as follows:

**§ 401.13 Administration of patent rights clauses.**

\* \* \* \* \*

(c) \*\*\*

(1) \*\*\* With respect to subject inventions of contractors that are small business firms or nonprofit organizations, a reasonable time shall be the time during which an initial patent application may be filed under paragraph (c) of the standard clause found at § 401.14 or such other clause may be used in the funding agreement. \*\*\*

(2) In accordance with 35 U.S.C. 205, agencies shall not disclose or release, pursuant to requests under the Freedom of Information Act or otherwise, copies of any document which the agency obtained under the clause in §401.14 which is part of an application for patent with the U.S. Patent and Trademark Office or any foreign patent office filed by the contractor (or its assignees, licensees, or employees) on a subject invention to which the contractor has elected to retain title. This prohibition does not extend to disclosure to other government agencies or contractors of government agencies under an obligation to maintain such information in confidence. This prohibition does not apply to documents published by the U.S. Patent and Trademark Office or any foreign patent office.

(3) \*\*\* In recognition of the fact that such publication, if it included descriptions of a subject invention could create bars to obtaining patent protection, it is the policy of the executive branch that agencies will not include in such publication programs copies of disclosures of inventions submitted by small business firms or nonprofit organizations, pursuant to paragraph (c) of the standard clause

found at § 401.14, except under the same circumstances under which agencies are authorized to release such information pursuant to FOIA requests under paragraph (c)(1) of this section agencies may publish such disclosures.

\* \* \* \* \*

11. Amend § 401.14 as follows:

- a. Redesignate paragraph (a) introductory text as undesignated introductory text and republish the introductory text;
- b. Remove the heading “Patent Rights (Small Business Firms and Nonprofit Organizations)” and add in its place the heading “Standard Patent Rights”;
- c. In “Standard Patent Rights”:
  - i. Add paragraphs (a)(7) and (8);
  - ii. Revise paragraphs (c)(2) and (3);
  - iii. Redesignate paragraph (c)(4) as paragraph (c)(5);
  - iv. Add a new paragraph (c)(4);
  - v. Revise newly redesignated paragraph (c)(5);
  - vi. Revise paragraphs (d)(1) through (3), (f)(2) and (3), (g)(1) first sentence, and (k)(4); and
  - vii. Revise the undesignated text after the heading of paragraph (l); and
- d. Remove paragraphs (b) and (c) at the end of the section.

The additions and revisions read as follows:

**§401.14 Standard patent rights clauses.**

The following is the standard patent rights clause to be used as specified in § 401.3(a):

\* \* \* \* \*

(a) \* \* \*

(7) The term *statutory period* means the one-year period before the effective filing date of a claimed invention during which exceptions to prior art exist per 35 U.S.C. 102(b) as amended by the Leahy-Smith America Invents Act, Public Law 112-29.

(8) The term *contractor* means any person, small business firm or nonprofit organization, or, as set forth in section 1, paragraph (b)(4) of Executive Order 12591, as amended, any business firm regardless of size, which is a party to a funding agreement.

\* \* \* \* \*

(c) \* \* \*

(2) The *contractor* will elect in writing whether or not to retain title to any such invention by notifying the *Federal agency* within two years of disclosure to the *Federal agency*. However, in any case where a patent, a printed publication, public use, sale, or other availability to the public has initiated the one year statutory period wherein valid patent protection can still be obtained in the United States, the period for election of title may be shortened by the *agency* to a date that is no more than 60 days prior to the end of the statutory period.

(3) The *contractor* will file its initial patent application on a subject invention to which it elects to retain title within one year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use. If the *contractor* files a provisional application as its initial patent application, it shall file a non-provisional application within 10 months of the filing of the provisional application. The *contractor* will file patent applications in additional countries or international patent offices within either ten months of the first filed patent application or six months from the date permission is granted by the Commissioner of Patents to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) For any subject invention with *Federal agency* and *contractor* co-inventors, where the *Federal agency* employing such co-inventor determines that it would be in the interest of the government, pursuant to 35 U.S.C. 207(a)(3), to file an initial patent application on the subject invention, the *Federal agency* employing such co-inventor, at its discretion and in consultation with the *contractor*, may file such application at its own expense, provided that the *contractor* retains the ability to elect title pursuant to 35 U.S.C. 202(a).

(5) Requests for extension of the time for disclosure, election, and filing under paragraphs (1), (2), and (3) of this clause may, at the discretion of the *Federal agency*, be granted. When a *contractor* has requested an extension for filing a non-provisional application after filing a provisional application, a one-year extension will be granted unless the *Federal agency* notifies the *contractor* within 60 days of receiving the request.

(d) \* \* \*

(1) If the *contractor* fails to disclose or elect title to the subject invention within the times specified in paragraph (c) of this clause, or elects not to retain title.

(2) In those countries in which the *contractor* fails to file patent applications within the times specified in paragraph (c) of this clause; provided, however, that if the *contractor* has filed a patent application in a country after the times specified in paragraph (c) of this clause, but prior to its receipt of the written request of the *Federal agency*, the *contractor* shall continue to retain title in that country.

(3) In any country in which the *contractor* decides not to continue the prosecution of any non-provisional patent application for, to pay a maintenance, annuity or renewal fee on, or to defend in a reexamination or opposition proceeding on, a patent on a subject invention.

\* \* \* \* \*

(f) \* \* \*

(2) The *contractor* agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the *contractor* each subject invention made under contract in order that the *contractor* can comply with the disclosure provisions of paragraph (c) of this clause, to assign to the *contractor* the entire right, title and interest in and to each subject invention made under contract, and to execute all papers necessary to file patent applications on subject inventions and to establish the government's rights in the subject inventions. This disclosure format should require, as a minimum, the information required by paragraph (c)(1) of this clause. The *contractor* shall instruct such employees through employee agreements or other suitable educational programs on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) For each subject invention, the *contractor* will, no less than 60 days prior to the expiration of the statutory deadline, notify the *Federal agency* of any decision: not to continue the prosecution of a non-provisional patent application; not to pay a maintenance, annuity or renewal fee; not to defend in a reexamination or opposition proceeding on a patent, in any country; to request, be a party to, or take action in a trial proceeding before the Patent Trial and Appeals Board of the U.S. Patent and Trademark Office, including but not limited to post-grant review, review of a business method patent, *inter partes* review, and derivation proceeding; or to request, be a party to, or take action in a non-trial submission of art or information at the U.S. Patent and Trademark Office, including but not limited to a pre-issuance submission, a post-issuance submission, and supplemental examination.

\* \* \* \* \*

(g) \* \* \*

(1) The *contractor* will include this clause, suitably modified to identify the parties, in all subcontracts, regardless of tier, for experimental, developmental or research work to be performed by a subcontractor. \* \* \*

\* \* \* \* \*

(k) \* \* \*

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business firms and that it will give a preference to a small business firm when licensing a subject invention if the *contractor* determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms; provided, that the *contractor* is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the contractor. However, the *contractor* agrees that the *Federal agency* may review the *contractor's* licensing program and decisions regarding small business applicants, and the *contractor* will negotiate changes to its licensing policies, procedures, or practices with the *Federal agency* when the *Federal agency's* review discloses that the *contractor* could take reasonable steps to implement more effectively the requirements of this paragraph (k)(4). In accordance with 37 CFR 401.7, the *Federal agency* or the *contractor* may request that the Secretary review the *contractor's* licensing program and decisions regarding small business applicants.

(l) \* \* \*

[Complete according to instructions at § 401.5(b)]

**§ 401.15 [Amended]**

12. In § 401.15:

- a. In paragraph (b), remove “§ 401.14(a)” and add in its place “§ 401.14”; and
- b. In paragraph (d), remove “§ 401.14(a)” and add in its place “§ 401.14” and remove “of this part”.

13. In § 401.16:

- a. In paragraphs (a) and (b), remove “§ 401.14(a) may” and add in its place “§ 401.14 shall”;
- b. In paragraph (c), remove “(f)(1)” and add in its place “paragraph (f)(1)”, remove “(f)(2) and (f)(3)” and add in its place “paragraphs (f)(2) and (3)”, and remove “may” and add in its place “shall”; and
- c. Add paragraph (d).

The addition reads as follows:

**§ 401.16 Electronic filing.**

\* \* \* \* \*

(d) Other written notices required in the clause in §401.14 may be electronically delivered to the agency or the contractor through an electronic database used for reporting subject inventions, patents, and utilization reports to the funding agency.

14. Revise § 401.17 to read as follows:

**§ 401.17 Submissions and inquiries.**

All submissions or inquiries should be directed to the Chief Counsel for NIST, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 1052, Gaithersburg, Maryland 20899-1052; telephone: (301) 975-2803; email: nistcounsel@nist.gov. Information

about and procedures for electronic filing under this part are available at the Interagency Edison web site and service center, <http://www.iedison.gov>, telephone (301) 435-1986.

**PART 404—LICENSING OF GOVERNMENT OWNED INVENTIONS**

15. The authority citation for 37 CFR part 404 continues to read as follows:

**Authority:** 35 U.S.C. 207-209, DOO 30-2A.

16. Amend § 404.7 by revising paragraphs (a)(1)(i) and (b)(1)(i) to read as follows:

**§ 404.7 Exclusive, co-exclusive and partially exclusive licenses.**

(a)(1) \* \* \*

(i) Notice of a prospective license, identifying the invention and the prospective licensee, has been published in the FEDERAL REGISTER or other appropriate manner, providing opportunity for filing written objections within at least a 15-day period;

\* \* \* \* \*

(b)(1) \* \* \*

(i) Notice of a prospective license, identifying the invention and the prospective licensee, has been published in the FEDERAL REGISTER or other appropriate manner, providing opportunity for filing written objections within at least a 15-day period and following consideration of such objections received during the period;

\* \* \* \* \*

17. Revise § 404.8 to read as follows:

**§ 404.8 Application for a license.**

(a) An application for a license should be addressed to the Federal agency having custody of the invention and shall normally include:

- (1) Identification of the invention for which the license is desired including the patent application serial number or patent number, title, and date, if known;
- (2) Identification of the type of license for which the application is submitted;
- (3) Name and address of the person, company, or organization applying for the license and the citizenship or place of incorporation of the applicant;
- (4) Name, address, and telephone number of the representative of the applicant to whom correspondence should be sent;
- (5) Nature and type of applicant's business, identifying products or services which the applicant has successfully commercialized, and approximate number of applicant's employees;
- (6) Source of information concerning the availability of a license on the invention;
- (7) A statement indicating whether the applicant is a small business firm as defined in § 404.3(c);
- (8) A detailed description of applicant's plan for development or marketing of the invention, or both, which should include:
  - (i) A statement of the time, nature and amount of anticipated investment of capital and other resources which applicant believes will be required to bring the invention to practical application;
  - (ii) A statement as to applicant's capability and intention to fulfill the plan, including information regarding manufacturing, marketing, financial, and technical resources;
  - (iii) A statement of the fields of use for which applicant intends to practice the invention; and

(iv) A statement of the geographic areas in which applicant intends to manufacture any products embodying the invention and geographic areas where applicant intends to use or sell the invention, or both;

(9) Identification of licenses previously granted to applicant under federally owned inventions;

(10) A statement containing applicant's best knowledge of the extent to which the invention is being practiced by private industry or Government, or both, or is otherwise available commercially; and

(11) Any other information which applicant believes will support a determination to grant the license to applicant.

(b) An executed CRADA which provides for the use for research and development purposes by the CRADA collaborator under that CRADA of a Federally-owned invention in the Federal laboratory's custody (pursuant to 35 U.S.C. 209 and 15 U.S.C. 3710a(b)(1)), and which addresses the information in paragraph (a) of this section, may be treated by the Federal laboratory as an application for a license.

Kevin A. Kimball,  
Chief of Staff.

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