



DEPARTMENT OF COMMERCE

National Institutes of Standards and Technology

37 CFR Parts 401 and 404

[Docket No.: 160311229-6229-01]

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: Notice of proposed rulemaking.

SUMMARY: The National Institute of Standards and Technology (NIST) requests comments on proposed revisions to regulations. The proposed revisions make technical corrections, update certain sections to conform with changes in the patent laws, clarify the role of provisional patent application filing, create a new Determination of Exceptional Circumstances, increase the role of Funding Agencies in the Bayh-Dole process, address subject inventions as to which a Federal laboratory employee is a co-inventor, and streamline the licensing application process for some Federal laboratory collaborators.

NIST will hold a public meeting and simultaneous webinar regarding the proposed changes on November 21, 2016.

DATES:

For Comments:

Comments must be received no later than December 9, 2016.

For Public Meeting/Webinar:

A meeting and simultaneous webinar will be held on November 21, 2016, from 1 p.m. until 3 p.m. Eastern Time. Requests to participate in-person must be received via the meeting website no later than November 14, 2016.

ADDRESSES: Submit your comments, identified by docket identification (ID) number: 160311229-6229-01, through the *Federal e-Rulemaking Portal*: <http://www.regulations.gov> (search using the docket number). Follow the online instructions for submitting comments. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

For Public Meeting/Webinar:

A November 21, 2016 public meeting will be held in Lecture Room A on the NIST Campus in Gaithersburg, MD. Details about attending the meeting in-person or for accessing the webinar are available via the Technology Partnerships Office web site at <http://www.nist.gov/tpo/bayh-dole>.

FOR FURTHER INFORMATION CONTACT: Courtney Silverthorn, via e-mail: courtney.silverthorn@nist.gov or by telephone at 301-975-4189.

SUPPLEMENTARY INFORMATION:

A meeting and simultaneous webinar will be held on November 21, 2016, from 1 p.m. until 3 p.m. Eastern Time in Building 101, Lecture Room A on the NIST Campus in Gaithersburg, MD. Details about attending the meeting in-person or for accessing the webinar are available via the Technology Partnerships Office web site at <http://www.nist.gov/tpo/bayh-dole>. Requests to participate in-person must be received via the meeting website no later than November 14, 2016; forty seats are available on a first-come, first-served basis. For participants attending in person, please note that Federal agencies, including NIST, can only accept a state-issued driver's license or identification card for access to Federal facilities if such license or identification card is issued by a state that is compliant with the REAL ID Act of 2005 (Pub. L. 109-13), or by a state that has an extension for REAL ID compliance. NIST currently accepts other forms of Federal-issued identification in lieu of a state-issued driver's license. To request accommodation of a disability, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**, no later than November 10, 2016, to give NIST as much time as possible to process your request.

I. General Information

Does this action apply to me?

This action may be of interest to you if you are an educational institution, company, or nonprofit organization, especially one that has or would like to receive Federal funding for scientific research and development.

II. Background

These proposed 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,” 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, 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), and under such circumstances, rights vest in the Government.

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, 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 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, 37 CFR 401.14(a)(c)(1); electing in writing whether or not to retain title to any subject invention by notifying the Federal agency within two years of disclosure, 37 CFR 401.14(a)(c)(2); filing an initial patent application on a subject invention as to which the contractor elects to retain title within one year after election, 37 CFR 401.14(a)(c)(3); 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, 37 CFR 401.14(a)(f)(1); requiring, by written agreement, the contractor's employees to disclose promptly in writing each subject invention made under contract, 37 CFR 401.14(a)(f)(2); notifying the Federal agency of any decision not to continue the prosecution of a patent application, 37 CFR 401.14(a)(f)(3); 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, 37 CFR 401.14(a)(f)(4).

In addition, a contractor is obligated to include the requirements of the standard clauses in any subcontracts under the contractor's award, 37 CFR 401.14(a)(g); 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, 37 CFR 401.14(a)(h); 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, 37 CFR 401.14(a)(i), 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.

Pursuant to authority delegated to it by the Secretary of Commerce, NIST is providing notice to the public of proposed rulemaking to revise 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. NIST is seeking public comments on the proposed amendments. Brief explanations of the proposed changes are included below; the full text of 37 CFR part 401 is available at <https://www.gpo.gov/fdsys/pkg/CFR-2010-title37-vol1/pdf/CFR-2010-title37-vol1-part401.pdf> and the full text of 37 CFR part 404 is available at <https://www.gpo.gov/fdsys/granule/CFR-2004-title37-vol1/CFR-2004-title37-vol1-part404>. This section is followed by a request for comments (Section III).

The proposed revisions to 37 CFR part 401 will:

1. Clarify in § 401.1(b) that Federal agencies, under section 1., subparagraph (b)(4) of Executive Order 12591, as amended, may apply the presumption of the right to retain title to contractors which are large business firms as well as to those which are small business firms and nonprofit organizations;
2. Correct § 401.1(e) to refer to § 401.17, identifying the office to which copies of proposed and final agency regulations should be directed for approval by the Secretary of Commerce;
3. Clarify in § 401.2(b) that the term *contractor* includes any business firm regardless of size, under section 1., subparagraph (b)(4) of Executive Order 12591, as amended, which is a party to a funding agreement;

4. Clarify that the term *initial patent application* means the first provisional or nonprovisional U.S. national application for a patent as defined in 37 CFR 1.9(a)(2) and (3), respectively, or the first international application as defined in 37 CFR 1.9(b) which designates the United States, in accordance with accepted practice;
5. Clarify that the term *statutory period* refers to the one-year period in 35 U.S.C. 102(b).
6. Clarify that the use of the standard clause at § 401.14 is applicable to nonprofits and to all businesses regardless of size, consistent with section 1., subparagraph (b)(4) of Executive Order 12591, as amended.
7. Create additional conditions under § 401.3(a) for the use of alternate provisions other than § 401.14(a) through a formatting revision;
8. Create additional conditions under § 401.3(a) for the use of alternate provisions other than § 401.14(a) when work is completed under a Cooperative Research and Development Agreement (CRADA) and removes outdated language related to Department of Energy naval nuclear propulsion and weapons related programs;
9. Create additional conditions under § 401.3(a) for the use of alternate provisions other than § 401.14(a) when the contractor is not a non-profit organization and is not in the business of commercializing subject inventions that would arise under a funding agreement, consistent with the commercialization intent of 35 U.S.C. 200;
10. Remove language from § 401.3(h) related to size protests that, per subparagraph (b)(4) of Executive Order 12591, as amended, no longer applies to a distinction between large and small businesses, and clarify language related to furnishing evidence of non-profit status;
11. Update the provision for distribution of royalty payments in § 401.5(g)(3) to be consistent with 35 U.S.C. 202(c)(7)(E)(i) as amended by the America Invents Act, Public Law 112-29;
12. Revise § 401.7(b) to include participation of the funding Agency in the review of an organization's nonprofit status;

13. Revise § 401.10 to clarify the management of subject inventions when there is a Federal employee who is a co-inventor of the subject invention, including clarifying that an agency may file an initial patent application provided that it does not negate a contractor's ability to elect rights, that a funding agency will provide administrative assistance to an agency who employs a Federal co-inventor in the management of co-invented subject inventions when a contractor has waived rights, that funding agencies and Federal agencies employing co-inventors shall consult on the management of co-invented subject inventions that Federal agencies may enter into agreements with contractors for the management of co-invented subject inventions, and that Federal agencies employing co-inventors retain their ownership rights when a contractor elects title to a co-invented subject invention;
14. Redesignate § 401.14(a)(c)(4) as 401.14(a)(c)(5);
15. Revise § 401.14 (a)(c)(2) to clarify that a Federal agency may shorten the two year period of election of title by a contractor if necessary to protect the Government's interests
16. Clarify in § 401.14(c) that a Federal agency may file an initial patent application at its own expense on a jointly-owned subject invention, if necessary to protect the Government's interest in the subject invention;
17. Remove the 60-day agency time limitation after learning that a contractor has failed to disclose an invention or elect rights, in § 401.14(a)(d)(1), in order to improve due diligence and enhance the ability of agencies to work with contractors;
18. Clarify the requirement in § 401.14(a)(f)(2) for a contractor to require its employees to assign rights in subject inventions to the contractor and in order for the contractor to file patent applications on subject inventions developed under the contract;
19. Revise § 401.14(a)(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, in

order to allow the Federal agency adequate time to determine whether to assume responsibility for patent prosecution of the subject invention;

20. Revise § 401.14(a)(k)(4) to provide for the funding agency's participation in the small business preference review process for the licensing of subject inventions by nonprofit contractors, and providing that the funding agency or the contractor may request review by the Secretary of Commerce as well;
21. Revise § 401.16 to make electronic filing the default format for reporting and elections unless otherwise directed by an agency; and
22. Add contact information for Interagency Edison, which is used by many Federal agencies, to § 401.17.

The proposed revisions to 37 CFR part 404 will:

23. Redesignate the existing text in § 404.8 as paragraph (a) and create a new paragraph (b) to provide that a CRADA partner is not required to submit a separate license application to an agency in order to access, under the CRADA, background technology owned by the Government.

This proposed rulemaking does not address contractor appeals of exceptions (§ 401.4), exercise of march-in rights (§ 401.6), small business preference (§ 401.7), subject invention utilization reporting (§ 401.8), contractor employee inventor rights retention (§ 401.9), appeals (§ 401.11), background patent rights licensing (§ 401.12), patent rights clauses administration (§ 401.13), or deferred determinations (§ 401.15) of part 401, and addresses only the license application provision (§ 404.8) of part 404.

III. Request for Comments

NIST is requesting comments about parts 401 and 404 of the Bayh-Dole regulations. We have included some questions that you might consider as you develop your comments:

1. Are there any changes to these regulations, consistent with current law, that you or your organization think would accelerate the transfer of federally funded research and technology to entrepreneurs, or otherwise strengthen the Nation's innovation system?
2. Are there provisions within 37 CFR part 401 or 404 that are inconsistent with, or otherwise affected by, changes in the patent laws under the Leahy-Smith America Invents Act, Public Law 112-29, or that Act's implementing regulations?
3. Are there ways that the Federal Government can better share information on federally funded inventions in order to increase technology transfer and licensing opportunities?
4. Are there ways to incentivize reporting compliance and compliance with the requirement to include a government support clause in patents?
5. Do recipients of Federal funding, and their licensees, encounter issues in the reporting process?
Are there changes that could streamline the requirements and reduce barriers to reporting?

When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Please organize your comments by referencing the specific question you are responding to or the relevant section number in the proposed regulatory text.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. Provide specific examples to illustrate your concerns and suggest alternatives.
- vi. Explain your views as clearly as possible.
- vii. Comments that contain profanity, vulgarity, threats, or other inappropriate language will not be considered.
- viii. Make sure to submit your comments by the comment period deadline identified.

IV. References

1. Federal Laboratory Consortium for Technology Transfer. (n.d.) *Technology Transfer Mechanisms*. Retrieved from <http://www.federallabs.org/education/t2-mechanisms/>.
2. National Institute of Standards and Technology, *Federal Laboratory Technology Transfer, Fiscal Year 2010 Summary Report to the President and the Congress*, August 2012, <http://www.nist.gov/tpo/publications/index.cfm>. See [appendix table 4-40](#).
3. Federal Laboratory Consortium for Technology Transfer. (2011). *Technology Transfer Desk Reference*. Retrieved from: http://globals.federallabs.org/pdf/T2_Desk_Reference.pdf.
4. Kalil, T. and Wong, J. (2015). *Lab to Market: Cross Agency Priority Goal Quarterly Progress Update, Fiscal Year 2015 Quarter 4*. Retrieved from: <https://www.performance.gov/node/3395/view?view=public#progress-update>.

V. Statutory and Executive Order Reviews

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 13132

This proposed 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 proposed 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 proposed 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 (SBA) that this rulemaking, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination is as follows:

A description of this proposed rule, why it is being considered, and the objectives of this proposed rule are contained in the preamble and in the **SUMMARY** section of the preamble. The statutory basis for this proposed rule is provided by 35 U.S.C. 200-212. The Bayh-Dole Act and its implementing regulations apply to all small business firms and nonprofit organizations that have entered into a Federal funding agreement, as defined in 35 U.S.C. 201, and express a policy to “encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; [and] to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery.” 35 U.S.C. 200. For small business firms and nonprofit organizations that deal with the Government in areas of technology development, the Bayh-Dole implementing regulations make it easier to participate in federally-supported programs by guaranteeing the protection of the intellectual property they create. This proposed rule, if implemented, would predominantly make technical changes and clarifications and is not anticipated to have any quantifiable economic impact with respect to small entities. Several proposed changes would bring the regulations into conformity with the America Invents Act, Public Law 112-29, and Executive Order 12591, which gave Federal agencies discretion to expand applicability of certain provisions to firms regardless of their size. Proposed changes to the definition of “initial patent application” clarify that it would include a provisional application, making it

less costly and burdensome for small entities to comply with the regulations' requirements. Proposed changes to 37 CFR 401.3 provide Federal agencies with some additional flexibility in choosing when to include the "standard clauses" described earlier in funding agreements awarded to contractors, which could benefit small businesses and nonprofits. The additional flexibility provided by these changes could provide some benefit to small entities. While proposed changes to 37 CFR 401.14 would allow Federal agencies to shorten certain time limitations applicable to election of title by a contractor (including small entities), these proposed changes are only intended to provide more efficient resolution of issues and not anticipated to have any negative substantive result.

The information provided above supports a determination that this proposed rule would not have a significant economic impact on a substantial number of small entities. Because this rulemaking, if implemented, is not expected to have a significant economic impact on any small entities, an initial regulatory flexibility analysis is not required and none has been prepared.

Paperwork Reduction Act

This proposed rule contains no new collection of information subject to the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

National Environmental Policy Act

This proposed 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 proposes to amend 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. In paragraph (e), remove “401.16” and add in its place “401.17”.

The revision reads as follows:

§ 401.1 Scope.

* * * * *

(b) * * * It applies to all funding agreements with business firms regardless of size (consistent with section 1., subparagraph (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. * * *

* * * * *

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., subparagraph (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 the first provisional or non-provisional U.S. national application for patent as defined in 37 CFR 1.9(a)(2) and (3), respectively, or the first international application as defined in 37 CFR 1.9(b) which designates the United States.

(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).

4. Section 401.3 is amended as follows:

- a. Revise the first sentence of paragraph (a);
- 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” and remove “§ 401.14(a)” and add in its place “§ 401.14”
- f. Revise the paragraph (c);
- g. Revise paragraph (h); and
- h. 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(a) 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 § 401.3(a)(2), (3), or (6), 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 § 401.3(a)(4), 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 subparagraphs (B) and (C) to paragraph (c)(1) of the clause in § 401.14 as follows:

(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.

(C) At the time an invention is disclosed in accordance with (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). 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.

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

* * * * *

(h) A prospective contractor may be required by an agency to certify that it is a nonprofit organization. If the agency has reason to question the nonprofit status of the prospective contractor, it may require the prospective contractor to furnish evidence to establish its status as a nonprofit organization.

(i) When an agency exercises the exception at § 401.3(a)(5), replace (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. 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 grants and cooperative agreements (and in contracts, if not inconsistent with the Federal Acquisition Regulation) 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) 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 clauses at § 401.14 with those appropriate to the particular funding agreement. For example, “contracts” could be replaced by “grant,” “contractor” by “grantee,” and “contracting officer” by “grants officer.” Depending on its use, “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 with a small business firm or nonprofit organization that it would be in the national interest to acquire the right to sublicense foreign governments or international organizations pursuant to 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, pursuant to 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, agreements of cooperation, memoranda of understanding, or similar arrangements, including military agreements relating to weapons development and production. The added language is not intended to apply to 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 international agreement. For example, in some exclusive licenses or even the assignment of title in 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 agency reserves the right to unilaterally amend this funding agreement to identify specific treaties or international agreements entered into or to be entered into by the government after the effective date of this funding agreement and effectuate those license or other rights which are necessary for the government to meet its obligations to foreign governments, their nationals 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 subparagraphs 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.

6. 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(l), 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 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.

7. 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 the right it has acquired in the subject invention from its employee to the contractor 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 may submit an initial patent application, provided that the contractor retains the ability to elect rights 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 or waives rights.
 - (ii) If the contractor waives rights 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 waived rights, 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, 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 invention.
 - (v) The agency employing a Federal co-inventor has priority for patenting over funding agencies that do not have a Federal co-inventor when a contractor has waived rights.

(vi) 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 title to the subject invention.

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

8. Amend § 401.14 as follows:

- a. Remove the paragraph (a) designation from the first sentence of the section and republish the sentence;
- b. Add paragraph (a)(7);
- c. Revise paragraph (c)(2);
- d. Redesignate the existing paragraph (c)(4) as paragraph (c)(5);
- e. Add a new paragraph (c)(4); and
- f. Revise paragraphs (d)(1), (f)(2) and (3), (g)(1), and (k)(4);
- g. Revise the text after the paragraph heading of paragraph (l);
- h. Remove the second paragraphs (b) and (c) from the end of the section which appear after paragraph (l).

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):

Standard Patent Rights

(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).

* * * * *

(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, the period for election of title may be shortened by the Federal agency where the agency determines that a shorter period is necessary in order to protect the government's interest, and 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.

* * * * *

(4) Where the Federal agency determines that it would be in the interest of the government, pursuant to 35 U.S.C. 207(a)(3), for the Federal agency to file an initial patent application on any subject invention with Federal agency and contractor inventors, the Federal agency, at its discretion and in consultation with the contractor, may file such application at its own expense.”

* * * * *

(d) * * *

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

* * * * *

(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) The contractor will, no less than 120 days prior to the expiration of any applicable response period or other filing deadline required by the relevant patent office, notify the Federal agency of any decision: not to continue the prosecution of a 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). 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)]

9. In § 401.16:

a. Remove the word “may” from paragraphs (a), (b), and (c), and add in its place the word “shall”; and

b. Add paragraph (d).

The addition reads as follows:

§ 401.16 Electronic filing.

* * * * *

(d) Other written notices required in this clause 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.

11. 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

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

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

13. 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.

Kent Rochford

Associate Director for Laboratory Programs

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