usage reporting is received or where a correction would alter one or more of any Licensee's Quarterly Allocation shares by at least 10%.

(f) *Recoupment of minimum-fee.* Each Allocated Licensee's minimum fee will be offset against its Quarterly Allocation shares, if any, and additional payment will not be due from a Licensee unless and until its total Quarterly Allocation shares exceed its annual minimum fee payment. To the extent that an Allocated Licensee's minimum fee exceeds that Licensee's Quarterly Allocation shares for a given Assessment period, the excess amounts will be pooled and credited pro rata to all Allocated Licensees based on the Quarterly Allocation shares for the first quarter of the following year.

(g) *Reports to DLC.* The MLC shall report to the DLC no later than 75 days after the end of every quarter the Aggregate Sound Recordings Count for that quarter.

(h) *Startup Assessment allocation and payment.* The Startup Assessment shall be allocated and paid in the same manner and on the same dates as the 2021 Annual Assessment, including as to each of the applicable provisions above, and shall be separately itemized in invoices from the MLC to Licensees. Pursuant to § 390.3, a single annual minimum fee shall be assessed for the 2021 Annual Assessment, and no additional annual minimum fee shall be assessed for the Startup Assessment.

[86 FR 6570, Jan. 22, 2021]

PARTS 391–399 [RESERVED]

CHAPTER IV—NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY, DEPARTMENT OF COMMERCE

PART 400 [RESERVED]

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

Sec.

AUTHORITY: 35 U.S.C. 206; DOO 30–2A.

SOURCE: 52 FR 8554, Mar. 18, 1987, unless otherwise noted.

§401.1 Scope.

(a) Traditionally there have been no conditions imposed by the government on research performers while using private facilities which would preclude them from accepting research funding from other sources to expand, to aid in completing or to conduct separate investigations closely related to research activities sponsored by the government. Notwithstanding the right of research organizations to accept supplemental funding from other sources for the purpose of expediting or more comprehensively accomplishing the research objectives of the government sponsored project, it is clear that the ownership provisions of these regulations would remain applicable in any invention ''conceived or first actually reduced to practice in performance'' of the project. Separate accounting for the two funds used to support the project in this case is not a determining factor.

(1) To the extent that a non-government sponsor established a project which, although closely related, falls outside the planned and committed activities of a government-funded project and does not diminish or distract from the performance of such activities, inventions made in performance of the non-government sponsored project would not be subject to the conditions of these regulations. An example of such related but separate projects would be a government sponsored project having research objectives to expand scientific understanding in a field and a closely related industry sponsored project having as its objectives the application of such new knowledge to develop usable new technology. The time relationship in conducting the two projects and the use of new fundamental knowledge from one in the performance of the other are not important determinants since most inventions rest on a knowledge base built up by numerous independent research efforts extending over many years. Should such an invention be claimed by the performing organization to be the product of non-government sponsored research and be challenged by the sponsoring agency as being reportable to the government as a ''subject invention'', the challenge is appealable as described in §401.11(d).

(2) An invention which is made outside of the research activities of a government-funded project is not viewed as a ''subject invention'' since it cannot be shown to have been ''conceived or first actually reduced to practice'' in performance of the project. An obvious example of this is a situation where an instrument purchased with government funds is later used, without interference with or cost to the government-funded project, in making an invention all expenses of which involve only non-government funds.

(b) This part implements 35 U.S.C. 202 through 204 and is applicable to all Federal agencies. 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. Certain sections also provide guidance for the administration of funding agreements which predate the effective date of this part. In accordance with 35 U.S.C. 212, no scholarship, fellowship, training grant, or other funding agreement made by a Federal agency primarily to an awardee for educational purposes will contain any provision giving the Federal agency any rights to inventions made by the awardee.

(c) The *march-in* and appeals procedures in §§ 401.6 and 401.11 shall apply to any march-in or appeal proceeding under a funding agreement subject to Chapter 18 of Title 35, U.S.C., initiated after the effective date of this part even if the funding agreement was executed prior to that date.

(d) At the request of the contractor, a funding agreement for the operation of a government-owned facility which is in effect on the effective date of this part shall be promptly amended to include the provisions required by §§ 401.3(a) unless the agency determines that one of the exceptions at 35 U.S.C. 202(a)(i) through (iv) § 401.3(a)(8) through (iv) of this part) is applicable and will be applied. If the exception at § 401.3(a)(iv) is determined to be applicable, the funding agreement will be promptly amended to include the provisions required by § 401.3(c).

(e) This regulation supersedes OMB Circular A–124 and shall take precedence over any regulations dealing with ownership of inventions made by small businesses and nonprofit organizations which are inconsistent with it. This regulation will be followed by all agencies pending amendment of agency regulations to conform to this part and amended Chapter 18 of Title 35. Only deviations requested by a contractor and not inconsistent with Chapter 18 of Title 35, United States Code, may be made without approval of the Secretary. 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.

(f) In the event an agency has outstanding prime funding agreements that do not contain patent flow-down provisions consistent with this part or earlier Office of Federal Procurement Policy regulations (OMB Circular A–124 or OMB Bulletin 81–22), the agency shall take appropriate action to ensure that small business firms or nonprofit organizations that are subcontractors under any such agreements and that received their subcontracts after July 1, 1981, receive rights in their subject inventions that are consistent with Chapter 18 and this part.

(g) This part is not intended to apply to arrangements under which nonprofit organizations, small business firms, or others are allowed to use government-owned research facilities and normal technical assistance provided to users of those facilities, whether on a reimbursable or nonreimbursable basis. This part is also not intended to apply to arrangements under which sponsors reimburse the government or facility contractor for the contractor employee's time in performing work for the sponsor. Such arrangements are not considered ''funding agreements'' as defined at 35 U.S.C. 201(b) and § 401.2(a) of this part.

[52 FR 8554, Mar. 18, 1987, as amended at 83 FR 15958, Apr. 13, 2018]

§ 401.2 Definitions.

As used in this part—

(a) The term *funding agreement* means any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal government. This term also includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research

work under a funding agreement as defined in the first sentence of this paragraph.

(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.

(c) The term *invention* means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 *et seq.*).

(d) The term *subject invention* means any invention of a contractor conceived or first actually reduced to practice in the performance of work under a funding agreement; provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance.

(e) The term *practical application* means to manufacture in the case of a composition of product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.

(f) The term *made* when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(g) The term *small business firm* means a small business concern as defined at section 2 of Pub. L. 85–536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this part, the size standards for small business concerns involved in government procurement and subcontracting at 13 CFR 121.5 will be used.

(h) The term *nonprofit organization* means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

(i) The term *Chapter 18* means Chapter 18 of Title 35 of the United States Code.

(j) The term *Secretary* means the Director of the National Institute of Standards and Technology.

(k) The term *electronically filed* means any submission of information transmitted by an electronic or optical-electronic system.

(l) The term *electronic or optical-electronic system* means a software-based system approved by the agency for the transmission of information.

(m) The term *patent application* or ''application for patent'' includes a provisional or nonprovisional U.S. national application for patent as defined in 37 CFR 1.9 (a)(2) and (a)(3), respectively, or an application for patent in a foreign country or in an international patent office.

(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.

[52 FR 8554, Mar. 18, 1987, as amended at 60 FR 41812, Aug. 14, 1995; 78 FR 4766, Jan. 23, 2013; 83 FR 15958, Apr. 13, 2018]

§ 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. However, a funding agreement may contain alternative provisions—

(1) 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; or

(2) In exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of Chapter 18 of Title 35 of the United States Code; or

(3) When it is determined by a government authority which is authorized by statute or executive order to conduct foreign intelligence or counterintelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to protect the security to such activities; or

(4) When the funding agreement includes the operation of the government-owned, contractor-operated facility of the Department of Energy primarily dedicated to that Department's naval nuclear propulsion or weapons related programs and all funding agreement limitations under this subparagraph on the contractor's right to elect title to a subject invention are limited to inventions occurring under the above two programs; or

(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. For example, if the justification relates to a particular field of use or market, the clause might be modified along lines similar to those described in paragraph (c) of this section. In any event, the clause should provide the contractor with an opportunity to receive greater rights in accordance with the procedures at §401.15. When an agency justifies and exercises the exception at paragraph (a)(2) of this section and uses an alternative provision in the funding agreement on the basis of national security, the provision shall provide the contractor with the right to elect ownership to any invention made under such funding agreement as provided by the Standard Patent Rights Clause found at §401.14 if the invention is not classified by the agency within six months of the date it is reported to the agency, or within the same time period the Department of Energy does not, as authorized by regulation, law or Executive order or implementing regulations thereto, prohibit unauthorized dissemination of the invention. Contracts in support of DOE's naval nuclear propulsion program are exempted from this paragraph (b).

(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:

(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 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.

(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. Agencies are authorized to negotiate such modified provisions with respect to task orders added to a funding agreement after its initial award.

(e) Before utilizing any of the exceptions in § 401.3(a) of this section, the agency shall prepare a written determination, including a statement of facts supporting the determination, that the conditions identified in the exception exist. A separate statement of facts shall be prepared for each exceptional circumstances determination, except that in appropriate cases a single determination may apply to both a funding agreement and any subcontracts issued under it or to any funding agreement to which such an exception is applicable. In cases when § 401.3(a)(2) is used, the determination shall also include an analysis justifying the determination. This analysis should address with specificity how the alternate provisions will better achieve the objectives set forth in 35 U.S.C. 200. A copy of each determination, statement of facts, and, if applicable, analysis shall be promptly provided to the contractor or prospective contractor along with a notification to the contractor or prospective contractor of its rights to appeal the determination of the exception under 35 U.S.C. 202(b)(4) and § 401.4 of this part.

(f) Except for determinations under § 401.3(a)(3), the agency shall also provide copies of each determination, statement of fact, and analysis to the Secretary. These shall be sent within 30 days after the award of the funding agreement to which they pertain. Copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration if the funding agreement is with a small business firm. If the Secretary of Commerce believes that any individual determination or pattern of determinations is contrary to the policies and objectives of this chapter or otherwise not in conformance with this chapter, the Secretary shall so advise the head of the agency concerned and the Administrator of the Office of Federal Procurement Policy and recommend corrective actions.

(g) To assist the Comptroller General of the United States to accomplish his or her responsibilities under 35 U.S.C. 202, each Federal agency that enters into any funding agreements with nonprofit organizations or small business firms shall accumulate and, at the request of the Comptroller General, provide the Comptroller General or his or her duly authorized representative the total number of prime agreements entered into with small business firms or nonprofit organizations that contain the patent rights clause in this part or under OMB Circular A–124 for each fiscal year beginning with October 1, 1982.

(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.

[52 FR 8554, Mar. 18, 1987, as amended at 69 FR 17301, Apr. 2, 2004; 83 FR 15959, Apr. 13, 2018]

§ 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. Paragraph (b) of this section specifies the procedures to be followed by contractors and agencies in such cases. The assertion of such a claim by the contractor shall not be used as a basis for withholding or delaying the award of a funding agreement or for suspending performance under an award. Pending final resolution of the claim the contract may be issued with the patent rights provision proposed by the agency; however, should the final decision be in favor of the contractor, the funding agreement will be amended accordingly and the amendment made retroactive to the effective date of the funding agreement.

(b)(1) A contractor may appeal a determination by providing written notice to the agency within 30 working days from the time it receives a copy of the agency's determination, or within such longer time as an agency may specify in its regulations. The contractor's notice should specifically identify the basis for the appeal.

(2) The appeal shall be decided by the head of the agency or by his/her designee who is at a level above the person who made the determination. If the notice raises a genuine dispute over the material facts, the head of the agency or the designee shall undertake, or refer the matter for, fact-finding.

(3) Fact-finding shall be conducted in accordance with procedures established by the agency. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures should afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may rely upon. A transcribed record shall be made and shall be available at cost to the contractor upon request. The requirement for a transcribed record may be waived by mutual agreement of the contractor and the agency.

(4) The official conducting the fact-finding shall prepare or adopt written findings of fact and transmit them to the head of the agency or designee promptly after the conclusion of the fact-finding proceeding along with a recommended decision. A copy of the findings of fact and recommended decision shall be sent to the contractor by registered or certified mail.

(5) Fact-finding should be completed within 45 working days from the date the agency receives the contractor's written notice.

(6) When fact-finding has been conducted, the head of the agency or designee shall base his or her decision on the facts found, together with any argument submitted by the contractor, agency officials or any other information in the administrative record. In cases referred for fact-finding, the agency head or the designee may reject only those facts that have been found to be clearly erroneous, but must explicitly state the rejection and indicate the basis for the contrary finding. The agency head or the designee may hear oral arguments after fact-finding provided that the contractor or contractor's attorney or representative is present and given an opportunity to make arguments and rebuttal. The decision of the agency head or the designee shall be in writing and, if it is unfavorable to the contractor shall include an explanation of the basis of the decision. The decision of the agency or designee shall be made within 30 working days after fact-finding or, if there was no fact-finding, within 45 working days from the date the agency received the contractor's written notice. A contractor adversely affected by a determination under this section may, at any time within sixty days after the determination is issued, file a petition in the United States Claims Court, which shall have jurisdiction to determine the appeal on the record and to affirm, reverse, remand, or modify as appropriate, the determination of the Federal agency.

[52 FR 8554, Mar. 18, 1987, as amended at 83 FR 15960, Apr. 13, 2018]

§ 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 *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, 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.

[83 FR 15960, Apr. 13, 2018]

§ 401.6 Exercise of march-in rights.

(a) The following procedures shall govern the exercise of the march-in rights of the agencies set forth in 35 U.S.C. 203 and paragraph (j) of the clause at § 401.14.

(b) Whenever an agency receives information that it believes might warrant the exercise of march-in rights, before initiating any march-in proceeding, it shall notify the contractor in writing of the information and request informal written or oral comments from the contractor as well as information relevant to the matter. In the absence of any comments from the

contractor within 30 days, the agency may, at its discretion, proceed with the procedures below. If a comment is received within 30 days, or later if the agency has not initiated the procedures below, then the agency shall, within 60 days after it receives the comment, either initiate the procedures below or notify the contractor, in writing, that it will not pursue march-in rights on the basis of the available information.

(c) A march-in proceeding shall be initiated by the issuance of a written notice by the agency to the contractor and its assignee or exclusive licensee, as applicable and if known to the agency, stating that the agency is considering the exercise of march-in rights. The notice shall state the reasons for the proposed march-in in terms sufficient to put the contractor on notice of the facts upon which the action would be based and shall specify the field or fields of use in which the agency is considering requiring licensing. The notice shall advise the contractor (assignee or exclusive licensee) of its rights, as set forth in this section and in any supplemental agency regulations. The determination to exercise march-in rights shall be made by the head of the agency or his or her designee.

(d) Within 30 days after the receipt of the written notice of march-in, the contractor (assignee or exclusive licensee) may submit in person, in writing, or through a representative, information or argument in opposition to the proposed march-in, including any additional specific information which raises a genuine dispute over the material facts upon which the march-in is based. If the information presented raises a genuine dispute over the material facts, the head of the agency or designee shall undertake or refer the matter to another official for fact-finding.

(e) Fact-finding shall be conducted in accordance with the procedures established by the agency. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures should afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may present. A transcribed record shall be made and shall be available at cost to the contractor upon request. The requirement for a transcribed record may be waived by mutual agreement of the contractor and the agency. Any portion of the march-in proceeding, including a fact-finding hearing that involves testimony or evidence relating to the utilization or efforts at obtaining utilization that are being made by the contractor, its assignee, or licensees shall be closed to the public, including potential licensees. In accordance with 35 U.S.C. 202(c)(5), agencies shall not disclose any such information obtained during a march-in proceeding to persons outside the government except when such release is authorized by the contractor (assignee or licensee).

(f) The official conducting the fact-finding shall prepare or adopt written findings of fact and transmit them to the head of the agency or designee promptly after the conclusion of the fact-finding proceeding along with a recommended determination. A copy of the findings of fact shall be sent to the contractor (assignee or exclusive licensee) by registered or certified mail. The contractor (assignee or exclusive licensee) and agency representatives will be given 30 days to submit written arguments to the head of the agency or designee; and, upon request by the contractor oral arguments will be held before the agency head or designee that will make the final determination.

(g) In cases in which fact-finding has been conducted, the head of the agency or designee shall base his or her determination on the facts found, together with any other information and written or oral arguments submitted by the contractor (assignee or exclusive licensee) and agency representatives, and any other information in the administrative record. The consistency of the exercise of march-in rights with the policy and objectives of 35 U.S.C. 200 shall also be considered. In cases referred for fact-finding, the head of the agency or designee may reject only those facts that have been found to be clearly erroneous, but must explicitly state the rejection and indicate the basis for the contrary finding. Written notice of the determination whether march-in rights will be exercised shall

be made by the head of the agency or designee and sent to the contractor (assignee of exclusive licensee) by certified or registered mail within 90 days after the completion of fact-finding or 90 days after oral arguments, whichever is later, or the proceedings will be deemed to have been terminated and thereafter no march-in based on the facts and reasons upon which the proceeding was initiated may be exercised.

(h) An agency may, at any time, terminate a march-in proceeding if it is satisfied that it does not wish to exercise march-in rights.

(i) The procedures of this part shall also apply to the exercise of march-in rights against inventors receiving title to subject inventions under 35 U.S.C. 202(d) and, for that purpose, the term ''contractor'' as used in this section shall be deemed to include the inventor.

(j) An agency determination unfavorable to the contractor (assignee or exclusive licensee) shall be held in abeyance pending the exhaustion of appeals or petitions filed under 35 U.S.C. 203(2).

(k) For purposes of this section the term *exclusive licensee* includes a partially exclusive licensee.

(l) Agencies are authorized to issue supplemental procedures not inconsistent with this part for the conduct of march-in proceedings.

§ 401.7 Small business preference.

(a) Paragraph (k)(4) of the clauses at § 401.14 Implements the small business preference requirement of 35 U.S.C. 202(c)(7)(D). Contractors are expected to use efforts that are reasonable under the circumstances to attract small business licensees. They are also expected to give small business firms that meet the standard outlined in the clause a preference over other applicants for licenses. What constitutes reasonable efforts to attract small business licensees will vary with the circumstances and the nature, duration, and expense of efforts needed to bring the invention to the market. Paragraph (k)(4) is not intended, for example, to prevent nonprofit organizations from providing larger firms with a right of first refusal or other options in inventions that relate to research being supported under long-term or other arrangements with larger companies. Under such circumstances it would not be resonable to seek and to give a preference to small business licensees.

(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 (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.

[52 FR 8554, Mar. 18, 1987, as amended at 83 FR 15960, Apr. 13, 2018]

§ 401.8 Reporting on utilization of subject inventions.

(a) Paragraph (h) of the clauses at § 401.14 and its counterpart in the clause at Attachment A to OMB Circular A–124 provides that agencies have the right to receive periodic reports from the contractor on utilization of inventions. Agencies exercising this right should accept such information, to the extent feasible, in the format that the contractor normally prepares

it for its own internal purposes. The prescription of forms should be avoided. However, any forms or standard questionnaires that are adopted by an agency for this purpose must comply with the requirements of the Paperwork Reduction Act. Copies shall be sent to the Secretary.

(b) In accordance with 35 U.S.C. 202(c)(5) and the terms of the clauses at § 401.14, agencies shall not disclose such information to persons outside the government. Contractors will continue to provide confidential markings to help prevent inadvertent release outside the agency.

§ 401.9 Retention of rights by contractor employee inventor.

Agencies which allow an employee/inventor of the contractor to retain rights to a subject invention made under a funding agreement with a small business firm or nonprofit organization contractor, as authorized by 35 U.S.C. 202(d), will impose upon the inventor at least those conditions that would apply to a small business firm contractor under paragraphs (d)(1) and (3); (f)(4); (h); (i); and (j) of the clause at § 401.14.

[52 FR 8554, Mar. 18, 1987, as amended at 83 FR 15960, Apr. 13, 2018]

§ 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.

[83 FR 15961, Apr. 13, 2018]

§ 401.11 Appeals.

(a) As used in this section, the term *standard clause* means the clause at § 401.14 of this part and the clauses previously prescribed by either OMB Circular A–124 or OMB Bulletin 81–22.

(b) The agency official initially authorized to take any of the following actions shall provide the contractor with a written statement of the basis for his or her action at the time the action is taken, including any relevant facts that were relied upon in taking the action.

(1) A refusal to grant an extension under paragraph (c)(4) of the standard clauses.

(2) A request for a conveyance of title under paragraph (d) of the standard clauses.

(3) A refusal to grant a waiver under paragraph (i) of the standard clauses.

(4) A refusal to approve an assignment under paragraph (k)(1) of the standard clauses.

(5) A refusal to grant an extension of the exclusive license period under paragraph (k)(2) of the clauses prescribed by either OMB Circular A–124 or OMB Bulletin 81–22.

(c) Each agency shall establish and publish procedures under which any of the agency actions listed in paragraph (b) of this section may be appealed to the head of the agency or designee. Review at this level shall consider both the factual and legal basis for the actions and its consistency with the policy and objectives of 35 U.S.C. 200–206.

(d) Appeals procedures established under paragraph (c) of this section shall include administrative due process procedures and standards for fact-finding at least comparable to those set forth in § 401.6 (e) through (g) whenever there is a dispute as to the factual basis for an agency request for a conveyance of title under paragraph (d) of the standard clause, including any dispute as to whether or not an invention is a subject invention.

(e) To the extent that any of the actions described in paragraph (b) of this section are subject to appeal under the Contract Dispute Act, the procedures under the Act will satisfy the requirements of paragraphs (c) and (d) of this section.

§ 401.12 Licensing of background patent rights to third parties.

(a) A funding agreement with a small business firm or a domestic nonprofit organization will not contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject inventions unless such provision has been approved by the agency head and a written justification has been signed by the agency head. Any such provision will clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically identified work object, or both. The agency head may not delegate the authority to approve such provisions or to sign the justification required for such provisions.

(b) A Federal agency will not require the licensing of third parties under any such provision unless the agency head determines that the use of the invention by others is necessary for the practice of a subject invention or for the use of a work object of the funding agreement and that such action is necessary to achieve practical application of the subject invention or work object. Any such determination will be on the record after an opportunity for an agency hearing. The contractor shall be given prompt notification of the determination by certified or registered mail. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of such determination.

§ 401.13 Administration of patent rights clauses.

(a) In the event a subject invention is made under funding agreements of more than one agency, at the request of the contractor or on their own initiative the agencies shall designate one agency as responsible for administration of the rights of the government in the invention.

(b) Agencies shall promptly grant, unless there is a significant reason not to, a request by a nonprofit organization under paragraph (k)(2) of the clauses prescribed by either OMB Circular A–124 or OMB Bulletin 81–22 inasmuch as 35 U.S.C. 202(c)(7) has since been amended to eliminate the limitation on the duration of exclusive licenses. Similarly, unless there is a significant reason not to, agencies shall promptly approve an assignment by a nonprofit organization to an organization which has as one of its primary functions the management of inventions when a request for approval has been necessitated under paragraph (k)(1) of the clauses prescribed by either OMB Circular A–124 or OMB Bulletin 81–22 because the patent management organization is engaged in or holds a substantial interest in other organizations engaged in the manfacture or sale of products or the use of processes that might utilize the invention or be in competition with embodiments of the invention. As amended, 35 U.S.C. 202(c)(7) no longer contains this limitation. The policy of this subsection should also be followed in connection with similar approvals that may be required under Institutional Patent Agreements, other patent rights clauses, or waivers that predate Chapter 18 of Title 35, United States Code.

(c) The President's Patent Policy Memorandum of February 18, 1983, states that agencies should protect the confidentiality of invention disclosure, patent applications, and utilization reports required in performance or in consequence of awards to the extent permitted by 35 U.S.C. 205 or other applicable laws. The following requirements should be followed for funding agreements covered by and predating this part 401.

(1) To the extent authorized by 35 U.S.C. 205, agencies shall not disclose to third parties pursuant to requests under the Freedom of Information Act (FOIA) any information disclosing a subject invention for a reasonable time in order for a patent application to be filed. 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. However, an agency may disclose such subject inventions under the FOIA, at its discretion, after a contractor has elected not to retain title or after the time in which the contractor is required to make an election if the contractor has not made an election within that time. Similarly, an agency may honor a FOIA request at its discretion if it finds that the same information has previously been published by the inventor, contractor, or otherwise. If the agency plans to file itself when the contractor has not elected title, it may, of course, continue to avail itself of the authority of 35 U.S.C. 205.

(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) A number of agencies have policies to encourage public dissemination of the results of work supported by the agency through publication in government or other publications of technical

reports of contractors or others. 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.

(4) Nothing in this paragraph is intended to preclude agencies from including in the publication activities described in the first sentence of paragraph (c)(3), the publication of materials describing a subject invention to the extent such materials were provided as part of a technical report or other submission of the contractor which were submitted independently of the requirements of the patent rights provisions of the contract. However, if a small business firm or nonprofit organization notifies the agency that a particular report or other submission contains a disclosure of a subject invention to which it has elected title or may elect title, the agency shall use reasonable efforts to restrict its publication of the material for six months from date of its receipt of the report or submission or, if earlier, until the contractor has filed an initial patent application. Agencies, of course, retain the discretion to delay publication for additional periods of time.

(5) Nothing in this paragraph is intended to limit the authority of agencies provided in 35 U.S.C. 205 in circumstances not specifically described in this paragraph.

[52 FR 8554, Mar. 18, 1987, as amended at 60 FR 41812, Aug. 14, 1995; 83 FR 15961, Apr. 13, 2018]

§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) Definitions

(1) *Invention* means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321 *et seq.*).

(2) *Subject invention* means any invention of the *contractor* conceived or first actually reduced to practice in the performance of work under this *contract*, provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of *contract* performance.

(3) *Practical Application* means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.

(4) *Made* when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(5) *Small Business Firm* means a small business concern as defined at section 2 of Pub. L. 85–536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in government procurement and subcontracting at 13 CFR 121.3–8 and 13 CFR 121.3–12, respectively, will be used.

(6) *Nonprofit Organization* means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c) and exempt from taxation under section 501(a) of the Internal Revenue Code (25 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

(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.

(b) Allocation of Principal Rights

The *Contractor* may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions 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.

(c) Invention Disclosure, Election of Title and Filing of Patent Application by *Contractor*

(1) The *contractor* will disclose each subject invention to the *Federal Agency* within two months after the inventor discloses it in writing to *contractor* personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify the *contract* under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the *agency*, the *Contractor* will promptly notify the *agency* of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the *contractor*.

(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) Conditions When the Government May Obtain Title

The *contractor* will convey to the *Federal agency*, upon written request, title to any subject invention—

(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.

(e) Minimum Rights to *Contractor* and Protection of the *Contractor* Right to File

(1) The *contractor* will retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, except if the *contractor* fails to disclose the invention within

the times specified in (c), above. The *contractor's* license extends to its domestic subsidiary and affiliates, if any, within the corporate structure of which the *contractor* is a party and includes the right to grant sublicenses of the same scope to the extent the *contractor* was legally obligated to do so at the time the *contract* was awarded. The license is transferable only with the approval of the *Federal agency* except when transferred to the sucessor of that party of the *contractor's* business to which the invention pertains.

(2) The *contractor's* domestic license may be revoked or modified by the *funding Federal agency* to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted in accordance with applicable provisions at 37 CFR part 404 and *agency* licensing regulations (if any). This license will not be revoked in that field of use or the geographical areas in which the *contractor* has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of the *funding Federal agency* to the extent the *contractor*, its licensees, or the domestic subsidiaries or affiliates have failed to achieve practical application in that foreign country.

(3) Before revocation or modification of the license, the *funding Federal agency* will furnish the *contractor* a written notice of its intention to revoke or modify the license, and the *contractor* will be allowed thirty days (or such other time as may be authorized by the *funding Federal agency* for good cause shown by the *contractor*) after the notice to show cause why the license should not be revoked or modified. The *contractor* has the right to appeal, in accordance with applicable regulations in 37 CFR part 404 and *agency* regulations (if any) concerning the licensing of Government-owned inventions, any decision concerning the revocation or modification of the license.

(f) *Contractor* Action to Protect the Government's Interest

(1) The *contractor* agrees to execute or to have executed and promptly deliver to the *Federal agency* all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those subject inventions to which the *contractor* elects to retain title, and (ii) convey title to the *Federal agency* when requested under paragraph (d) above and to enable the government to obtain patent protection throughout the world in that subject invention.

(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.

(4) The *contractor* agrees to include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, ''This invention was made with government support under (identify the *contract*) awarded by (identify the Federal agency). The government has certain rights in the invention.''

(g) Subcontracts

(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.. The subcontractor will retain all rights provided for the *contractor* in this clause, and the *contractor* will not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(2) The *contractor* will include in all other subcontracts, regardless of tier, for experimental developmental or research work the

patent rights clause required by (*cite section of agency implementing regulations or FAR*).

(3) In the case of subcontracts, at any tier, when the prime award with the Federal agency was a contract (but not a grant or cooperative agreement), the *agency*, subcontractor, and the contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the Federal agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (j) of this clause.

(h) Reporting on Utilization of Subject Inventions

The *Contractor* agrees to submit on request periodic reports no more frequently than annually 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. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the contractor, and such other data and information as the *agency* may reasonably specify. The *contractor* also agrees to provide additional reports as may be requested by the *agency* in connection with any march-in proceeding undertaken by the *agency* in accordance with paragraph (j) of this clause. As required by 35 U.S.C. 202(c)(5), the *agency* agrees it will not disclose such information to persons outside the government without permission of the *contractor*.

(i) Preference for United States Industry

Notwithstanding any other provision of this clause, the *contractor* agrees that neither it 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. However, in individual cases, the requirement for such an agreement may be waived by the *Federal agency* upon a showing by the *contractor* or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(j) March-in Rights

The *contractor* agrees that with respect to any subject invention in which it has acquired title, the *Federal agency* has the right in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the *agency* to require the *contractor*, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the *contractor*, assignee, or exclusive licensee refuses such a request the *Federal agency* has the right to grant such a license itself if the *Federal agency* determines that:

(1) Such action is necessary because the *contractor* or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use.

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the *contractor*, assignee or their licensees;

(3) Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the *contractor*, assignee or licensees; or

(4) Such action is necessary because the agreement required by paragraph (i) of this clause has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.

(k) Special Provisions for *Contracts* with Nonprofit Organizations

If the *contractor* is a nonprofit organization, it agrees that:

(1) Rights to a subject invention in the United States may not be assigned without the approval of the *Federal agency*, except where such assignment is made to an organization which has as one of its primary functions the management of inventions, provided that such assignee will be subject to the same provisions as the *contractor;*

(2) The *contractor* will share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (when the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) The balance of any royalties or income earned by the *contractor* with respect to subject inventions, after payment of expenses (including payments to inventors) incidential to the administration of subject inventions, will be utilized for the support of scientific research or education; and

(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) Communication

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

[52 FR 8554, Mar. 18, 1987, as amended at 69 FR 17301, Apr. 2, 2004; 83 FR 15961, Apr. 13, 2018]

§ 401.15 Deferred determinations.

(a) This section applies to requests for greater rights in subject inventions made by contractors when deferred determination provisions were included in the funding agreement because one of the exceptions at § 401.3(a) was applied, except that the Department of Energy is authorized to process deferred determinations either in accordance with its waiver regulations or this section. A contractor requesting greater rights should include with its request information on its plans and intentions to bring the invention to practical application. Within 90 days after receiving a request and supporting information, or sooner if a statutory bar to patenting is imminent, the agency should seek to make a determination. In any event, if a bar to patenting is imminent, unless the agency plans to file on its own, it shall authorize the contractor to file a patent application pending a determination by the agency. Such a filing shall normally be at the contractor's own risk and expense. However, if the agency subsequently refuses to allow the contractor to retain title and elects to proceed with the patent application under government ownership, it shall reimburse the contractor for the cost of preparing and filing the patent application.

(b) If the circumstances of concerns which originally led the agency to invoke an exception under § 401.3(a) are not applicable to the actual subject invention or are no longer valid because of subsequent events, the agency should allow the contractor to retain title to the invention on the same conditions as would have applied if the standard clause at § 401.14 had been used originally, unless it has been licensed.

(c) If paragraph (b) is not applicable the agency shall make its determination based on an assessment whether its own plans regarding the invention will better promote the policies and objectives of 35 U.S.C. 200 than will contractor ownership of the invention. Moreover, if the agency is concerned only about specific uses or applications of the invention, it shall consider leaving title in the contractor with additional conditions imposed upon the contractor's use of the invention for such applications or with expanded government license rights in such applications.

(d) A determination not to allow the contractor to retain title to a subject invention or to restrict or condition its title with conditions differing from those in the clause at § 401.14, unless made by the head of the agency, shall be appealable by the contractor to an agency official at a level above the person who made the determination. This appeal shall be subject to the procedures applicable to appeals under § 401.11.

[52 FR 8554, Mar. 18, 1987, as amended at 83 FR 15963, Apr. 13, 2018]

§ 401.16 Electronic filing.

Unless otherwise requested or directed by the agency,

(a) The written report required in (c)(1) of the standard clause in § 401.14 shall be electronically filed;

(b) The written election required in (c)(2) of the standard clause in § 401.14 shall be electronically filed; and

(c) The close-out report in paragraph (f)(1) and the information identified in

paragraphs (f)(2) and (3) of § 401.5 shall be electronically filed.

(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.

[60 FR 41812, Aug. 14, 1995, as amended at 83 FR 15963, Apr. 13, 2018]

§ 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 website and service center, *http://www.iedison.gov*, telephone (301) 435–1986.

[83 FR 15963, Apr. 13, 2018]

PART 404—LICENSING OF GOVERNMENT-OWNED INVENTIONS

Sec.

AUTHORITY: 35 U.S.C. 207–209, DOO 30–2A.

SOURCE: 50 FR 9802, Mar. 12, 1985, unless otherwise noted.

§ 404.1 Scope of part.

This part prescribes the terms, conditions, and procedures upon which a federally owned invention, other than an invention in the custody of the Tennessee Valley Authority, may be licensed. This part does not affect licenses which:

(a) Were in effect prior to April 7, 2006;

(b) May exist at the time of the Government's acquisition of title to the invention, including those resulting from the allocation of rights to inventions made under Government research and development contracts;

(c) Are the result of an authorized exchange of rights in the settlement of patent disputes, including interferences; or

(d) Are otherwise authorized by law or treaty, including 35 U.S.C. 202(e), 35 U.S.C. 207(a)(3) and 15 U.S.C. 3710a, which also may authorize the assignment of inventions. Although licenses on inventions made under a cooperative research and development agreement (CRADA) are not subject to this regulation, agencies are encouraged to apply the same policies and use similar terms when appropriate. Similarly, this should be done for licenses granted under inventions where the agency has acquired rights pursuant to 35 U.S.C. 207(a)(3).

[71 FR 11512, Mar. 8, 2006]

§ 404.2 Policy and objective.

It is the policy and objective of this subpart to use the patent system to promote the utilization of inventions arising from federally supported research or development.

§ 404.3 Definitions.

(a) *Government owned invention* means an invention, whether or not covered by a patent or patent application, or discovery which is or may be patentable or otherwise protectable under Title 35, the Plant Variety Protection Act (7 U.S.C. 2321 *et seq.*) or foreign patent law, owned in whole or in part by the United States Government.

(b) *Federal agency* means an executive department, military department, Government corporation, or independent establishment, except the Tennessee Valley Authority, which has custody of a federally owned invention.

(c) *Small business firm* means a small business concern as defined in section 2

of Pub. L. 85–536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration.

(d) *Practical application* means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

(e) *United States* means the United States of America, its territories and possessions, the District of Columbia, and the Commonwealth of Puerto Rico.

[50 FR 9802, Mar. 12, 1985, as amended at 71 FR 11512, Mar. 8, 2006]

§ 404.4 Authority to grant licenses.

Federally owned inventions shall be made available for licensing as deemed appropriate in the public interest and each agency shall notify the public of these available inventions. The agencies having custody of these inventions may grant nonexclusive, co-exclusive, partially exclusive, or exclusive licenses thereto under this part. Licenses may be royalty-free or for royalties or other consideration. They may be for all or less than all fields of use or in specified geographic areas and may include a release for past infringement. Any license shall not confer on any person immunity from the antitrust laws or from a charge of patent misuse, and the exercise of such rights pursuant to this part shall not be immunized from the operation of state or federal law by reason of the source of the grant.

[71 FR 11512, Mar. 8, 2006]

§ 404.5 Restrictions and conditions on all licenses granted under this part.

(a)(1) A license may be granted only if the applicant has supplied the Federal agency with a satisfactory plan for development or marketing of the invention, or both, and with information about the applicant's capability to fulfill the plan. The plan for a non-exclusive research license may be limited to describing the research phase of development.

(2) A license granting rights to use or sell under a Government owned invention in the United States shall normally be granted only to a licensee who agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States. However, this condition may be waived or modified if reasonable but unsuccessful efforts have been made to grant licenses to potential licensees that would be likely to manufacture substantially in the United States or if domestic manufacture is not commercially feasible.

(b) Licenses shall contain such terms and conditions as the Federal agency determines are appropriate for the protection of the interests of the Federal Government and the public and are not in conflict with law or this part. The following terms and conditions apply to any license:

(1) The duration of the license shall be for a period specified in the license agreement, unless sooner terminated in accordance with this part.

(2) Any patent license may grant the licensee the right of enforcement of the licensed patent without joining the Federal agency as a party as determined appropriate in the public interest.

(3) The license may extend to subsidiaries of the licensee or other parties if provided for in the license but shall be nonassignable without approval of the Federal agency, except to the successor of that part of the licensee's business to which the invention pertains.

(4) The license may provide the licensee the right to grant sublicenses under the license, subject to the approval of the Federal agency. Each sublicense shall make reference to the license, including the rights retained by the Government, and a copy of such sublicense with any modifications thereto, shall be promptly furnished to the Federal agency.

(5) The license shall require the licensee to carry out the plan for development or marketing of the invention, or both, to bring the invention to practical application within a reasonable time as specified in the license, and

continue to make the benefits of the invention reasonably accessible to the public.

(6) The license shall require the licensee to report periodically on the utilization or efforts at obtaining utilization that are being made by the licensee, with particular reference to the plan submitted but only to the extent necessary to enable the agency to determine compliance with the terms of the license.

(7) Where an agreement is obtained pursuant to § 404.5(a)(2) that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States, the license shall recite such an agreement.

(8) The license shall provide for the right of the Federal agency to terminate the license, in whole or in part, if the agency determines that:

(i) The licensee is not executing its commitment to achieve practical application of the invention, including commitments contained in any plan submitted in support of its request for a license and the licensee cannot otherwise demonstrate to the satisfaction of the Federal agency that it has taken, or can be expected to take within a reasonable time, effective steps to achieve practical application of the invention;

(ii) Termination is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license and such requirements are not reasonably satisfied by the licensee;

(iii) The licensee has willfully made a false statement of or willfully omitted a material fact in the license application or in any report required by the license agreement;

(iv) The licensee commits a substantial breach of a covenant or provision contained in the license agreement, including the requirement in § 404.5(a)(2); or

(v) The licensee has been found by a court of competent jurisdiction to have violated the Federal antitrust laws in connection with its performance under the license agreement.

(9) The license may be modified or terminated, consistent with this part, upon mutual agreement of the Federal agency and the licensee.

(10) The license may be modified or terminated, consistent with this part, upon mutual agreement of the Federal agency and the licensee.

(11) Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to this part shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

[50 FR 9802, Mar. 12, 1985, as amended at 71 FR 11512, Mar. 8, 2006]

§ 404.6 Nonexclusive licenses.

Nonexclusive licenses may be granted under Government owned inventions without a public notice of a prospective license.

[71 FR 11513, Mar. 8, 2006]

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

(a)(1) Exclusive, co-exclusive or partially exclusive domestic licenses may be granted on Government owned inventions, only if;

(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;

(ii) After expiration of the period in § 404.7(a)(1)(i) and consideration of any written objections received during the period, the Federal agency has determined that;

(A) The public will be served by the granting of the license, in view of the applicant's intentions, plans and ability to bring the invention to the point of practical application or otherwise promote the invention's utilization by the public.

(B) Exclusive, co-exclusive or partially exclusive licensing is a reasonable and necessary incentive to call

forth the investment capital and expenditures needed to bring the invention to practical application or otherwise promote the invention's utilization by the public; and

(C) The proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public;

(iii) The Federal agency has not determined that the grant of such a license will tend substantially to lessen competition or create or maintain a violation of the Federal antitrust laws; and

(iv) The Federal agency has given first preference to any small business firms submitting plans that are determined by the agency to be within the capability of the firms and as having equal or greater likelihood as those from other applicants to bring the invention to practical application within a reasonable time.

(2) In addition to the provisions of §404.5, the following terms and conditions apply to domestic exclusive, co-exclusive and partially exclusive licenses:

(i) The license shall be subject to the irrevocable, royalty-free right of the Government of the United States to practice or have practiced the invention on behalf of the United States and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the United States.

(ii) The license shall reserve to the Federal agency the right to require the licensee to grant sublicenses to responsible applicants, on reasonable terms, when necessary to fulfill health or safety needs.

(iii) The license shall be subject to any licenses in force at the time of the grant of the exclusive, co-exclusive or partially exclusive license.

(b)(1) Exclusive, co-exclusive or partially exclusive foreign licenses may be granted on a Government owned invention provided that;

(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;

(ii) The agency has considered whether the interests of the Federal Government or United States industry in foreign commerce will be enhanced; and

(iii) The Federal agency has not determined that the grant of such a license will tend substantially to lessen competition or create or maintain a violation of the Federal antitrust laws.

(2) In addition to the provisions of §404.5, the following terms and conditions apply to foreign exclusive, co-exclusive and partially exclusive licenses:

(i) The license shall be subject to the irrevocable, royalty-free right of the Government of the United States to practice and have practiced the invention on behalf of the United States and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the United States.

(ii) The license shall be subject to any licenses in force at the time of the grant of the exclusive, co-exclusive or partially exclusive license.

(iii) The license may grant the licensee the right to take any suitable and necessary actions to protect the licensed property, on behalf of the Federal Government.

(c) Federal agencies shall maintain a record of determinations to grant exclusive, co-exclusive or partially exclusive licenses.

[71 FR 11513, Mar. 8, 2006, as amended at 83 FR 15963, Apr. 13, 2018]

§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.

[83 FR 15963, Apr. 13, 2018]

§ 404.9 [Reserved]

§ 404.10 Modification and termination of licenses.

Before modifying or terminating a license, other than by mutual agreement, the Federal agency shall furnish the licensee and any sublicensee of record a written notice of intention to modify or terminate the license, and the licensee shall be allowed 30 days after such notice to remedy any breach of the license or show cause why the license shall not be modified or terminated.

[71 FR 11514, Mar. 8, 2006]

§ 404.11 Appeals.

(a) In accordance with procedures prescribed by the Federal agency, the following parties may appeal to the agency head or designee any decision or determination concerning the grant, denial, modification, or termination of a license:

(1) A person whose application for a license has been denied;

(2) A licensee whose license has been modified or terminated, in whole or in part; or

(3) A person who timely filed a written objection in response to the notice required by § 404.7(a)(1)(i) or § 404.7(b)(1)(i) and who can demonstrate to the satisfaction of the Federal agency that such person may be damaged by the agency action.

(b) An appeal by a licensee under paragraph (a)(2) of this section may include a hearing, upon the request of the licensee, to address a dispute over any relevant fact. The parties may agree to Alternate Dispute Resolution in lieu of an appeal.

[71 FR 11514, Mar. 8, 2006]

§ 404.12 Protection and administration of inventions.

A Federal agency may take any suitable and necessary steps to protect and

administer rights to Government owned inventions, either directly or through contract.

[71 FR 11514, Mar. 8, 2006]

§ 404.13 Transfer of custody.

A Federal agency having custody of a federally owned invention may transfer custody and administration, in whole or in part, to another Federal agency, of the right, title, or interest in such invention.

§ 404.14 Confidentiality of information.

Title 35, United States Code, section 209, requires that any plan submitted pursuant to § 404.8(h) and any report required by § 404.5(b)(6) shall be treated as commercial or financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of Title 5 of the United States Code.

[71 FR 11514, Mar. 8, 2006]

PART 501—UNIFORM PATENT POLICY FOR RIGHTS IN INVENTIONS MADE BY GOVERNMENT EMPLOYEES

Sec.

AUTHORITY: Sec. 4, E.O. 10096, 3 CFR, 1949–1953 Comp., p. 292, as amended by E.O. 10930, 3 CFR, 1959–1963 Comp., p. 456 and by E.O. 10695, 3 CFR, 1954–1958 Comp., p. 355, DOO 30–2A.

SOURCE: 53 FR 39735, Oct. 11, 1988, unless otherwise noted.

EDITORIAL NOTE: At 78 FR 4766, Jan. 23, 2013, parts 500–599 were transferred from Title 37, Chapter V, to Title 37, Chapter IV. Chapter V was removed and reserved.

§ 501.1 Purpose.

The purpose of this part is to provide for the administration of a uniform patent policy for the Government with respect to the rights in inventions made by Government employees and to prescribe rules and regulations for implementing and effectuating such policy.

[61 FR 40999, Aug. 7, 1996]

§ 501.2 Scope.

This part applies to any invention made by a Government employee and to any action taken with respect thereto.

§ 501.3 Definitions.

(a) The term *Secretary*, as used in this part, means the Director of the National Institute of Standards and Technology.

(b) The term *Government agency*, as used in this part, means any Executive department or independent establishment of the Executive branch of the Government (including any independent regulatory commission or board, any corporation wholly owned by the United States, and the Smithsonian Institution), but does not include the Department of Energy for inventions made under the provisions of 42 U.S.C. 2182, the Tennessee Valley Authority, or the Postal Service.

(c) The term *Government employee*, as used in this part, means any officer or employee, civilian or military, of any Government agency, including any special Government employee as defined in 18 U.S.C. 202 or an individual working for a Federal agency pursuant to the Intergovernmental Personnel Act (IPA), 5 U.S.C. 1304 and 3371–3376, or a part-time consultant or part-time employee as defined in 29 U.S.C. 2101(a)(8) except as may otherwise be provided by agency regulation approved by the Secretary.

(d) The term *invention*, as used in this part, means any art or process, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the patent laws of the United States.

(e) The term *made* as used in this part in relation to any invention, means the conception or first actual reduction to practice of such invention as stated in *In re King*, 3 USPQ2d (BNA) 1747 (Comm'r Pat. 1987).

[61 FR 40999, Aug. 7, 1996, as amended at 78 FR 4766, Jan. 23, 2013]

§ 501.4 Determination of inventions and rights.

Each Government agency has the approval of the Secretary to determine whether the results of research, development, or other activity in the agency constitute an invention within the purview of Executive Order 10096, as amended by Executive Order 10930 and Executive Order 10695, and to determine the rights in and to the invention in accordance with the provisions of §§ 501.6 and 501.7.

[61 FR 40999, Aug. 7, 1996]

§ 501.5 Agency liaison officer.

Each Government agency shall designate a liaison officer to represent the agency before the Secretary; Provided, however, that the Departments of the Army, the Navy, and the Air Force may each designate a liaison officer.

§ 501.6 Criteria for the determination of rights in and to inventions.

(a) The following rules shall be applied in determining the respective rights of the Government and of the inventor in and to any invention that is subject to the provisions of this part:

(1) The Government shall obtain, except as herein otherwise provided, the entire right, title and interest in and to any invention made by any Government employee:

(i) During working hours, or

(ii) With a contribution by the Government of facilities, equipment, materials, funds or information, or of time or services of other Government employees on official duty, or

(iii) Which bears a direct relation to or is made in consequence of the official duties of the inventor.

(2) In any case where the contribution of the Government, as measured by any one or more of the criteria set forth in paragraph (a)(1) of this section, to the invention is insufficient equitably to justify a requirement of assignment to the Government of the entire right, title and interest in and to such invention, or in any case where the Government has insufficient interest in an invention to obtain the entire right, title and interest therein (although the Government could obtain same under paragraph (a)(1) of this section), the Government agency concerned shall leave title to such invention in the employee, subject however, to the reservation to the Government of a nonexclusive, irrevocable, royalty-free license in the invention with power to grant licenses for all governmental purposes. The terms of such reservation will appear, where practicable, in any patent, domestic or foreign, which may issue on such invention. Reference is made to section 15 of the Federal Technology Transfer Act of 1986 (15 U.S.C. 3710d) which requires a Government agency to allow the inventor to retain title to any covered invention when the agency does not intend to file a patent application or otherwise promote commercialization.

(3) In applying the provisions of paragraphs (a)(1) and (2) of this section to the facts and circumstances relating to the making of a particular invention, it shall be presumed that an invention made by an employee who is employed or assigned:

(i) To invent or improve or perfect any art or process, machine, design, manufacture, or composition of matter;

(ii) To conduct or perform research, development work, or both,

(iii) To supervise, direct, coordinate, or review Government financed or conducted research, development work, or both, or

(iv) To act in a liaison capacity among governmental or non-governmental agencies or individuals engaged in such research or development work,

falls within the provisions of paragraph (a)(1) of this section, and it shall be presumed that any invention made by any other employee falls within the provisions of paragraph (a)(2) of this section. Either presumption may be rebutted by a showing of the facts and circumstances in the case and shall not preclude a determination that these facts and circumstances justify leaving

the entire right, title and interest in and to the invention in the Government employee, subject to law.

(4) In any case wherein the Government neither:

(i) Obtains the entire right, title and interest in and to an invention pursuant to the provisions of paragraph (a)(1) of this section nor

(ii) Reserves a nonexclusive, irrevocable, royalty-free license in the invention, with power to grant licenses for all governmental purposes, pursuant to the provisions of paragraph (a)(2) of this section,

the Government shall leave the entire right, title and interest in and to the invention in the Government employee, subject to law.

[53 FR 39735, Oct. 11, 1988, as amended at 61 FR 40999, Aug. 7, 1996]

§ 501.7 Agency determination.

(a) If the agency determines that the Government is entitled to obtain title pursuant to § 501.6(a)(1) and the employee does not appeal, no further review is required.

(b) In the event that a Government agency determines, pursuant to paragraph (a)(2) or (a)(4) of § 501.6, that title to an invention will be left with the employee, the agency shall notify the employee of this determination. In cases pursuant to § 501.6(a)(2) where the Government's insufficient interest in the invention is evidenced by its decision not to file a patent application, the agency may impose on the employee any one or all of the following conditions or any other conditions that may be necessary in a particular case:

(1) That a patent application be filed in the United States and/or abroad, if the Government has determined that it has or may need to practice the invention;

(2) That the invention not be assigned to any foreign-owned or controlled corporation without the written permission of the agency; and

(3) That any assignment or license of rights to use or sell the invention in the United States shall contain a requirement that any products embodying the invention or produced through the use of the invention be substantially manufactured in the United States. The agency shall notify the employee of any conditions imposed.

(c) In the case of a determination under either paragraph (a) or (b) of this section, the agency shall promptly provide the employee with:

(1) A signed and dated statement of its determination and reasons therefor; and

(2) A copy of 37 CFR part 501.

[53 FR 39735, Oct. 11, 1988, as amended at 61 FR 40999, Aug. 7, 1996]

§ 501.8 Appeals by employees.

(a) Any Government employee who is aggrieved by a Government agency determination pursuant to §§ 501.6(a)(1) or (a)(2), may obtain a review of any agency determination by filing, within 30 days (or such longer period as the Secretary may, for good cause shown in writing, fix in any case) after receiving notice of such determination, two copies of an appeal with the Secretary. The Secretary then shall forward one copy of the appeal to the liaison officer of the Government agency.

(b) On receipt of a copy of an appeal filed pursuant to paragraph (a) of this section, the agency liaison officer shall, subject to considerations of national security, or public health, safety or welfare, promptly furnish both the Secretary and the inventor with a copy of a report containing the following information about the invention involved in the appeal:

(1) A copy of the agency's statement specified in § 501.7(c);

(2) A description of the invention in sufficient detail to identify the invention and show its relationship to the employee's duties and work assignments;

(3) The name of the employee and employment status, including a detailed statement of official duties and responsibilities at the time the invention was made; and

(4) A detailed statement of the points of dispute or controversy, together with copies of any statements or written arguments filed with the agency, and of any other relevant evidence that the agency considered in making its determination of Government interest.

(c) Within 25 days (or such longer period as the Secretary may, for good cause shown, fix in any case) after the

transmission of a copy of the agency report to the employee, the employee may file a reply with the Secretary and file one copy with the agency liaison officer.

(d) After the time for the inventor's reply to the Government agency's report has expired and if the inventor has so requested in his or her appeal, a date will be set for hearing of oral arguments before the Secretary, by the employee (or by an attorney whom he or she designates by written power of attorney filed before, or at the hearing) and a representative of the Government agency involved. Unless it shall be otherwise ordered before the hearing begins, oral arguments will be limited to thirty minutes for each side. The employee need not retain an attorney or request an oral hearing to secure full consideration of the facts and his or her arguments. The employee may expedite such consideration by notifying the Secretary when he or she does not intend to file a reply to the agency report.

(e) After a hearing on the appeal, if a hearing was requested, or after expiration of the period for the inventor's reply to the agency report if no hearing is set, the Secretary shall issue a decision on the matter within 120 days, which decision shall be final after a thirty day period for requesting reconsideration expires or on the date that a decision on a petition for reconsideration is finally disposed of. Any request for reconsideration or modification of the decision must be filed within 30 days from the date of the original decision (or within such an extension thereof as may be set by the Secretary before the original period expires). The decision of the Secretary shall be made after consideration of the statements of fact in the employee's appeal, the agency's report, and the employee's reply, but the Secretary at his or her discretion and with due respect to the rights and convenience of the inventor and the Government agency, may call for further statements on specific questions of fact or may request additional evidence in the form of affidavits or depositions on specific facts in dispute.

[53 FR 39735, Oct. 11, 1988, as amended at 61 FR 41000, Aug. 7, 1996]

§ 501.9 Patent protection.

(a) A Government agency, upon determining that an invention coming within the scope of §§ 501.6(a)(1) or (a)(2) has been made, shall promptly determine whether patent protection will be sought in the United States by or on behalf of the agency for such invention. A controversy over the respective rights of the Government and of the employee shall not unnecessarily delay the filing of a patent application by the agency to avoid the loss of patent rights. In cases coming within the scope of § 501.6(a)(2), the filing of a patent application shall be contingent upon the consent of the employee.

(b) Where there is an appealed dispute as to whether §§ 501.6 (a)(1) or (a)(2) applies in determining the respective rights of the Government and of an employee in and to any invention, the agency may determine whether patent protection will be sought in the United States pending the Secretary's decision on the dispute. If the agency decides that an application for patent should be filed, the agency will take such rights as are specified in § 501.6(a)(2), but this shall be without prejudice to acquiring the rights specified in paragraph (a)(1) of that section should the Secretary so decide.

(c) Where an agency has determined to leave title to an invention with an employee under § 501.6(a)(2), the agency will, upon the filing of an application for patent, take the rights specified in that paragraph without prejudice to the subsequent acquisition by the Government of the rights specified in paragraph (a)(1) of that section should the Secretary so decide.

(d) Where an agency has filed a patent application in the United States, the agency will, within 8 months from the filing date of the U.S. application, determine if any foreign patent applications should also be filed. If the agency chooses not to file an application in any foreign country, the employee may request rights in that country subject to the conditions stated in § 501.7(b) that may be imposed by the agency. Alternatively, the agency

may permit the employee to retain foreign rights by including in any assignment to the Government of an unclassified U.S. patent application on the invention an option for the Government to acquire title in any foreign country within 8 months from the filing date of the U.S. application.

[61 FR 41000, Aug. 7, 1996]

§ 501.10 Dissemination of this part and of implementing regulations.

Each Government agency shall disseminate to its employees the provisions of this part, and any appropriate implementing agency regulations and delegations. Copies of any such regulations shall be sent to the Secretary. If the Secretary identifies an inconsistency between this part and the agency regulations or delegations, the agency, upon being informed by the Secretary of the inconsistency, shall take prompt action to correct it.

§ 501.11 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, MD 20899–1052; telephone: (301) 975–2803; email: *nistcounsel@nist.gov*.

[78 FR 4766, Jan. 23, 2013]

PARTS 502–599 [RESERVED]

CHAPTER V [RESERVED]