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'' 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 any funding agreement with a nonprofit organization or small business firm as defined by 35 U.S.C. 201, except for an agreement made primarily for educational purposes under 35 U.S.C. 212.

This part also applies to any funding agreement with business firms regardless of size in accordance with section 1, paragraph (b)(4) of Executive Order 12591, as amended by Executive Order 12618, unless directed otherwise pursuant to NASA or DOE vesting statutes.

(c) This regulation supersedes OMB Circular A–124 and shall take precedence over any regulations or other guidance dealing with ownership of inventions made by businesses and nonprofit organizations which are inconsistent with it. 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.

(d) 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).

[88 FR 17735, Mar. 24, 2023]

§ 401.2 Definitions.

In addition to the definitions in 35 U.S.C. 201, 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 system.

(l) The term *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'' may be the following:

(1) A United States provisional application as defined in 37 CFR 1.9(a)(2) and filed under 35 U.S.C. 111(b); or

(2) A United States nonprovisional application as defined in 37 CFR 1.9(a)(3) and filed under 35 U.S.C. 111(a); or

(3) A patent application filed in a foreign country or an international patent office; or

(4) An application for a Plant Variety Protection certificate.

(n) The term *initial patent application* means, as to a given subject invention:

(1) The first United States provisional application as defined in 37 CFR 1.9(a)(2) and filed under 35 U.S.C. 111(b); or

(2) The first United States nonprovisional application as defined in 37 CFR 1.9(a)(3) and filed under 35 U.S.C. 111(a); or

(3) The first patent application filed under the Patent Cooperation Treaty as defined in 37 CFR 1.9(b); or

(4) The first application for a Plant Variety Protection certificate.

(o) The term *statutory period* means the one-year period before the effective filing date of a claimed invention in a patent application 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; 88 FR 17735, Mar. 24, 2023]

§ 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(f).

(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 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) 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.

(h) 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; 88 FR 17736, Mar. 24, 2023]

§ 401.4 Contractor appeals of exceptions.

(a) In accordance with 35 U.S.C. 202(b)(3) 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 Court of Federal Claims, 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; 88 FR 17736, Mar. 24, 2023]

§ 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. If the funding agreement is a grant or cooperative agreement, paragraph (g)(3) of the clause may be deleted.

(b) Agencies should complete paragraph (l) of the clause in § 401.14, ''Communication,'' by designating a

central point of contact for communications on matters relating to the clause. Agencies may also include additional information on communications 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) 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.

(g) 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, as amended at 88 FR 17736, Mar. 24, 2023]

§ 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:

(1) 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 (including electronic means) of the information and request an informal consultation and information relevant to the matter with the contractor to understand the nature of the issue and may also consider possible alternatives other than exercising march-in rights. In the absence of response from the contractor to the agency request for informal consultation within 30 days, the agency may, at its discretion, proceed with the procedures below. If informal consultation occurs within 30 days, or later if the agency has not initiated the procedures below, then the agency shall, within 120 days after informal consultation, either notify the contractor of the initiation of the procedures below with a summary of the efforts taken, or notify the contractor, in writing, that it will not pursue march-in rights on the basis of the available information.

(2) 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.

(3) 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.

(4) 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) or otherwise required by law.

(5) 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.

(6) 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.

(7) 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.

(b) 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.

(c) 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(b).

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

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

[88 FR 17736, Mar. 24, 2023]

§§ 401.7–401.8 [Reserved]

§ 401.9 Contractor and contractor employee inventor requests for rights in inventions.

(a) Agencies shall allow a contractor to request greater rights in an invention, including a request to return title to an invention to the contractor, when the funding agreement contains alternate provisions in accordance with § 401.3(a)(2):

(1) The agency shall consider if the circumstances which originally led the agency to invoke an exception under § 401.3(a) are currently valid and applicable to the actual subject invention.

(i) The agency shall provide the contractor the opportunity to submit information on its plans and intentions to bring the subject invention to practical application pursuant to 35 U.S.C. 200.

(ii) The agency shall assess whether government ownership of the invention will better promote the policies and objectives of 35 U.S.C. 200 than the plans and intentions submitted by the contractor.

(iii) The agency shall consider whether to allow the standard clause at § 401.14 to apply with additional conditions imposed upon the contractor's use of the invention for specific uses or applications, or with expanded government license rights in such uses or applications.

(2) The agency shall reply to the contractor with its determination within 90 days after receiving a request and any supporting information from the contractor. If a bar to patenting is sooner than 90 days from receipt of a request, the agency may either file a patent application on the subject invention or authorize the contractor to

file a patent application at its own risk and expense.

(3) The Department of Energy is authorized to process deferred determinations either in accordance with its waiver regulations or this section.

(b) Pursuant to 35 U.S.C. 202(d), a contractor is required to obtain approval from a funding Agency before assigning rights to a subject invention made under a funding agreement to an employee/inventor. When an employee/inventor retains rights to a subject invention made under a funding agreement, either the Agency or the contractor must ensure compliance by the employee/inventor with at least those conditions that would apply under paragraphs (b), (d), (f)(4), (h), (i), and (j) of the clause at § 401.14.

[88 FR 17737, Mar. 24, 2023]

§ 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) 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)(5) of the standard clause at § 401.14.

(2) A request for a conveyance of title under paragraph (d)(1) of the standard clause at § 401.14.

(3) A refusal to grant a waiver under paragraph (i) of the standard clause at § 401.14.

(4) A refusal to approve an assignment under paragraph (k)(1) of the standard clause at § 401.14.

(b) Each agency shall establish and publish procedures under which any of the agency actions listed in paragraph (a) 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.

(c) Appeals procedures established under paragraph (b) of this section shall include administrative due process procedures and standards for fact-finding at least comparable to those set forth in § 401.6(a)(4) through (6) 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 at § 401.14, including any dispute as to whether or not an invention is a subject invention.

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

[88 FR 17737, Mar. 24, 2023]

§ 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 Confidentiality of contractor submissions.

Pursuant to 35 U.S.C. 202(c)(5) and 205, the following procedures shall govern confidentiality of documents submitted under paragraph (c) of the standard clause found at § 401.14:

(a) Agencies shall not disclose to third parties pursuant to requests under the Freedom of Information Act (FOIA) any information disclosing a subject invention during the time which an initial patent application may be filed under paragraph (c) of the standard clause found at § 401.14 or such other clause in the funding agreement. This prohibition does not apply to information that has previously been

published by the inventor, contractor, or otherwise.

(b) Agencies shall not disclose or release, pursuant to requests under the Freedom of Information Act or otherwise, copies of any document 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.

(c) When implementing policies that encourage public dissemination of the results of work supported by the agency through government publications or other publications of technical reports, agencies shall not include copies of documents submitted by contractors pursuant to § 401.14(c) when a contractor 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, or such publication could create a statutory bar to obtaining patent protection.

[88 FR 17737, Mar. 24, 2023]

§ 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) *Statutory period* means the one-year period before the effective filing date of a claimed invention in a patent application 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) *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*. If required by the *Federal agency*, the *contractor* will 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, and will provide a report prior to the closeout of a funding agreement listing all subject inventions or stating that there were none.

(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)(i) 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.

(ii) If the *contractor* files a provisional application as its initial patent application, it shall file a nonprovisional application within 10 months of the filing of the provisional application. So long as there is a pending patent application for the subject invention and the statutory period wherein valid patent protection can be obtained in the United States has not expired, additional provisional applications may be filed within the initial 10 months or any extension period granted under paragraph (c)(5) of this clause. If an extension(s) is granted under paragraph (c)(5) of this clause, the *contractor* shall file a nonprovisional patent application prior to the expiration of the extension(s) or notify the agency of any decision not to file a nonprovisional application prior to the expiration of the extension(s), or if earlier, 60 days prior to the end of any statutory period wherein valid patent protection can be obtained in the United States.

(iii) 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.

(iv) If required by the *Federal agency*, the *contractor* will provide 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.

(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.

(6) 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.

(d) Conditions When the Government May Obtain Title

(1) A *Federal agency* may require the *contractor* to convey title to the *Federal agency* of any subject invention—

(i) 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.

(ii) 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.

(iii) In any country in which the *contractor* decides not to continue the prosecution of any nonprovisional 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.

(2) A *Federal agency*, at its discretion, may waive the requirement for the *contractor* to convey title to any 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 successor 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) incidental 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, when appropriate, it will give a preference to a small business firm when licensing a subject invention;

(5) 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 more effectively implement the requirements of paragraph (k)(4) of this clause; and

(6) The *Federal agency* may take into consideration concerns presented by small businesses in making such determinations in paragraph (k)(5) of this clause.

(l) Communication

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

(m) Electronic Filing

(1) Unless otherwise requested or directed by the *Federal agency*—

(i) The written disclosure required in (c)(1) of this clause shall be electronically filed;

(ii) The written election required in (c)(2) of this clause shall be electronically filed; and

(iii) If required by the agency to be submitted, the close-out report in paragraph (c)(1) of this clause and the patent information and periodic reporting identified in paragraph (c)(3) of this clause shall be electronically filed.

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

[52 FR 8554, Mar. 18, 1987, as amended at 69 FR 17301, Apr. 2, 2004; 83 FR 15961, Apr. 13, 2018; 88 FR 17738, Mar. 24, 2023]

§ 401.15 [Reserved]

§ 401.16 Federal agency reporting requirements.

Federal agencies will report annually to the Secretary on data pertaining to reported subject inventions under a funding agreement, including—

(a) Number of subject inventions reported to the Federal agency;

(b) Patent applications filed on subject inventions;

(c) Issued patents on subject inventions;

(d) Number of requests and number of requests granted for extension of the time for disclosures, election, and filing per 37 CFR 401.14(c)(5);

(e) Number of subject inventions conveyed to the Government in accordance with 37 CFR 401.14(d);

(f) Number of waivers requested and waivers granted per 37 CFR 401.14(i);

(g) Number of requests for assignment of invention rights; and

(h) Summary of utilization information provided by contractors. Such information will be received by the Secretary no later than the last day of October of each year.

[88 FR 17739, Mar. 24, 2023]

§ 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*.

[83 FR 15963, Apr. 13, 2018, as amended at 88 FR 17739, Mar. 24, 2023]

§ 401.18 Severability.

The provisions of this part are separate and severable from one another. If any provision is stayed or determined to be invalid, the remaining provisions shall remain in effect.

[88 FR 17739, Mar. 24, 2023]

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.

(a) 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:

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

(2) 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;

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

(4) 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).

(b) Royalties collected pursuant to this part, and used in accordance with 15 U.S.C. 3710c(a)(1)(B), are not intended as an alternative to appropriated funding or as an alternative funding mechanism.

[88 FR 17739, Mar. 24, 2023]

§ 404.2 Policy and objective.

It is the policy and objective of this subpart to promote the results of federally funded research and development through the patenting and licensing process. In negotiating licenses, the Government may consider payments under a licensing agreement as a means for encouraging the licensee to develop an invention in order to advance practical application and promote commercialization by the licensee.

[88 FR 17739, Mar. 24, 2023]

§ 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