

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

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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 sin-

gle 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

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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.