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except for a funding agreement made primarily for educational purposes. Certain sections also provide guidance for the administration of funding agreements which predate the effective date of this part. In accordance with 35 U.S.C. 212, no scholarship, fellowship, training grant, or other funding agreement made by a Federal agency primarily to an awardee for educational purposes will contain any provision giving the Federal agency any rights to inventions made by the awardee.

- (c) The march-in and appeals procedures in §§ 401.6 and 401.11 shall apply to any march-in or appeal proceeding under a funding agreement subject to Chapter 18 of Title 35, U.S.C., initiated after the effective date of this part even if the funding agreement was executed prior to that date.
- (d) At the request of the contractor, a funding agreement for the operation of a government-owned facility which is in effect on the effective date of this part shall be promptly amended to include the provisions required by §§ 401.3(a) unless the agency determines that one of the exceptions at 35 U.S.C. 202(a)(i) through (iv) § 401.3(a)(8) through (iv) of this part) is applicable and will be applied. If the exception at §401.3(a)(iv) is determined to be applicable, the funding agreement will be promptly amended to include the provisions required by §401.3(c).
- (e) This regulation supersedes OMB Circular A-124 and shall take precedence over any regulations dealing with ownership of inventions made by small businesses and nonprofit organizations which are inconsistent with it. This regulation will be followed by all agencies pending amendment of agency regulations to conform to this part and amended Chapter 18 of Title 35. Only deviations requested by a contractor and not inconsistent with Chapter 18 of Title 35, United States Code, may be made without approval of the Secretary. Modifications or tailoring of clauses as authorized by §401.5 or §401.3, when alternate provisions are used under $\S401.3(a)(1)$ through (6), are not considered deviations requiring the Secretary's approval. Three copies of proposed and final agency regulations supplementing this part shall be submitted to the Secretary at the office

set out in §401.17 for approval for consistency with this part before they are submitted to the Office of Management and Budget (OMB) for review under Executive Order 12866 or, if no submission is required to be made to OMB, before their submission to the FEDERAL REGISTER for publication.

- (f) In the event an agency has outstanding prime funding agreements that do not contain patent flow-down provisions consistent with this part or earlier Office of Federal Procurement Policy regulations (OMB Circular A-124 or OMB Bulletin 81-22), the agency shall take appropriate action to ensure that small business firms or nonprofit organizations that are subcontractors under any such agreements and that received their subcontracts after July 1, 1981, receive rights in their subject inventions that are consistent with Chapter 18 and this part.
- (g) This part is not intended to apply to arrangements under which nonprofit organizations, small business firms, or others are allowed to use governmentowned 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" defined at 35 U.S.C. 201(b) and §401.2(a) of this part.

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

§ 401.2 Definitions.

As used in this part—

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

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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 non-profit 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.
- (1) 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