DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

NOV 24 1987

TO: Heads of PHS Agencies, Centers and Institutes
(Delegatees of October 14 Memorandum)

From: Assistant Secretary for Health

Under my authorities under Chapter 1-901-10 of the department Organization Manual, I am delegating to the delegatees indicated in my October 14, 1987 memorandum implementing the Federal Technology Transfer Act of 1986, the following agency responsibilities under P. L. 96-517 as amended and as implemented under the Department of Commerce regulations found at 37 CFR, Part 401 (Attached):

a) The authority as provided to the agency under 35 USC 202(c)(7), to grant approval of the assignment of a subject invention to organizations who do not have as one of its primary junctions the management of inventions.

b) The authority, as provided to the agency under 35 USC 202(c) (7) (B) prior to its amendment by P.L. 98-620, to on a case-by-case basis approve longer exclusive licenses than specified by 202(c) (7) (B) to organizations other than small business firms.

c) The authority as provided to the agency under 35 USC 204, to waive the requirement that when a small business firm or nonprofit organization grants an exclusive license the licensee must agree that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States.

d) The authority, as provided to the agency by 35 USC 205, to withhold from disclosure to the public information , 1) disclosing any invention in which the government may own an interest for a reasonable time in order for a patent application to be filed, and 2) copies of documents which are part of foreign or domestic patent applications.

e) The authorities provided to the agency under 35 USC 207 and 209 where delegated to you by my October 14, 1987 memorandum. (35 US 209 sets out the procedures and conditions that must be undertaken when exercising the licensing authority of 35 US 207).

All other agency responsibilities specified by P.L. 96-517, as amended, will be retained by ASH. As necessary, the delegatee shall discuss the exercise of these authorities with the Department of Commerce, who is responsible for implementation of P.L. 96-517, as amended, through their regulation as 37 CFR, Part 401, copies attached herewith.

Robert E. Windom, M.D.

federal register

Wednesday
March 18, 1987

Part II

Department of Commerce

Office of the Assistant Secretary for Productivity, Technology and Innovation

37 CFR Part 401

Rights to Inventions Made by Nonprofit Organizations and Small Business Firms; Final Rule

DEPARTMENT OF COMMERCE

Office of the Assistant Secretary for Productivity, Technology and Innovation

37 CFR Part 401

[Docket No. 41278-7006]

Rights to Inventions Made by Nonprofit Organizations and Small Business Firms

AGENCY: Assistant Secretary for Productivity, Technology and Innovation.

ACTION: Final rule.

SUMMARY: Public Law 98-620 amended Chapter 18 of Title 35, United States Code, dealing with patent rights in inventions made with Federal funding by nonprofit organizations and small business firms. It also reassigned responsibility for the promulgation of regulations implementing 35 U.S.C. 202 through 204 and the establishment of standard funding agreement provisions from the Office of Mangement and Budget (OMB) to the Secretary of Commerce. This rule makes final the interim final rule published in the Federal Register on July 14, 1986, and incorporates minor changes as a result of comments received on the interim final rule.

EFFECTIVE DATE: April 17, 1987.

FOR FURTHER INFORMATION CONTACT: Mr. Norman Latker, Director, Federal Technology Management Policy Division, Office of Productivity, Technology and Innovation, U.S. Department of Commerce, Room 4837, Washington, DC 20230. Phone: 202-377-0658.

SUPPLEMENTARY INFORMATION:

Background

Public Law 98-620 amended Chapter 18 of Title 35, United States Code, and assigned regulatory authority to the Secretary of Commerce. The Secretary has delegated his authority under 35 U.S.C. 206 to the Assistant Secretary for Productivity, Technology and Innovation. Section 206 of Title 35 U.S.C. requires that the regulations and the standard funding agreement be subject to public comment before their issuance. Accordingly, on April 4, 1985, the Assistant Secretary published a notice of proposed rulemaking in the Federal Register (50 FR 13524) for public comment. As noted at that time, the regulation closely follows OMB Circular A-124 which the regulation replaced. Differences between the proposed rule and the Circular were highlighted in Supplementary Information accompanying the notice of proposed rulemaking.

Additionally, to comply fully with section 206 of Title 35 U.S.C., the Department published in the Federal Register (51 FR 25508) on July 14, 1986, a final interim rule and requested comments by September 12, 1986.

Copies of all comments received were made available for public inspection in the Department's Central Reference Records Inspection Facility (CRRIF), Room 6628 in the Hoover Building.

Information about the availability of these records for inspection may be obtained from Mrs. Hedy Walters at (202) 377-3271.

Treatment of Substantative Comments on Interim Final Rule.

A number of comments from eight (8) different sources were received on the interim final rule in response to the July 14, 1986 notice.

The Department of Energy (DOE) submitted five comments on the interim final rule. All of the comments were found to have merit and have been incorporated in the final rule as follows:

DOE's first comment relates to a suggested clarification in the discussion portion of the interim final rule relating to § 401.3(a) (2). DOE's concern is that the discussion suggests that the right of the government to declare exceptional circumstance for national security reasons is limited to "some limited situations" and that application of this section is therefore limited to situations where the invention report is classified. DOE correctly points out that this is not consistent with the actual language of the regulation. We agree that the words "some limited situations" should not have been included in the discussion portion of the July 14, 1986 notice.

DOE's second comment states that the reference in the discussion portion of the interim final rule, in § 401.14(b) to nuclear weapons programs is inaccurate. We agree that the word nuclear should not have been included in the discussion of § 401.14(b).

DOE's third comment suggests that § 401.3(c) be revised to be consistent with § 401.14(b), which permits DOE to draft a substitute clause. We agree and have included the words, "or substitute thereto" after the reference to § 401.14(b) in § 401.3(c).

Another DOE comment suggests that § 401.13(c) (2) goes beyond the similar provision of OMB Circular A-124 by appearing to preclude confidential disclosure of patent applications or information which is part of a patent application obtained under the clause to other agencies or contractors of government agencies. We have clarified this by adding the following additional language to the end of § 401.13(c) (2):

> 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.

DOE also suggests that § 401.13(c)(3) is unnecessary in view of § 401.13(c)(1). However, DOE suggests that if it is retained, § 401.13(c)(3) should be limited to the same time period as § 401.13(c)(1). We agree but have made no change because the language of § 401.13 (c) (3) already refers back to and incorporates the § 401.13(c)(3) already refers back to and incorporates the § 401.13(b)(1) limitation.

DOE also states that in § 401.15, first sentence, third word from the last word, "of" should be "or". We agree and have made this change.

Finally, DOE suggests that § 401.15(b) should have the following five words added at the end: "Unless it has been licensed." We agree and have included these five words at the end of § 401.15(b).

Another person submitted six comments which have been treated as follows:

The first comment suggests that a statement be added to § 401.3(c) as follows: "the Department of Energy may only exercise the exception at § 401.3(a) (4) with regard to inventions at the facility that are made directly and primarily with funds provided by either the Department's naval nuclear propulsion or nuclear weapons related programs." This comment was not accepted since the statute does not use these terms. Further, all determinations made under section 401(a)(4) by DOE are subject to review by the Department of Commerce under § 401.14(f) and each determination will be examined to ensure compliance with the law.

The second comment points out that in order to make a determination under § 401.3(a) (4), an agency must find one of the conditions set out in § 401.3(a) (1), (2) or (3). We disagree with this interpretation as § 401.3(a) (4) is independent of § 401.3(a) (1), (2) and (3).

A third comment suggests that consideration should be given to adding language to § 401.5(g) requiring the contractor to return a significant or a major portion of income to the facility at which the invention was made. This issue was disposed of in the earlier interim final rule notice of July 14, 1986, on page 25509 under the discussion of § 401.5(f). The matter of royalty disposal is one that is best left to negotiations between the interested parties.

The fourth comment relates to the language in § 401.5(g) regarding the physical location of contractor employees responsible for licensing of facility inventions. The comment suggests that 401.5(g) expressly state that contractors be obligated to maintain personnel responsible for licensing at the facility. However, another person requested that the subsection not be interpreted strictly to *require* that such a person be physically located at the facility. Section 202(c)(7)(C) of Pub. L. 98-620 indicates that licensing be done at the facility, "to the extent it provides the most effective technology transfer . . .". We believe this language precludes arbitrarily requiring that licensing personnel be located at the facility.

A fifth comment recommended requiring DOE funding agreements to conform to the language prescribed by § 401.14(b)(2) when the exception at § 401.3(a)(4) is used. This was not accepted. Although we have, in fact, permitted DOE to use a substitute clause for that set out in § 401.14(b)(2), we will be reviewing all agency regulations including DOE's to ensure compliance with the law and regulations, including all substitute clauses contained in agency regulations.

The final comment of this second person is that we modify the statement in § 401.15(a) that "within 90 days after receiving . . ." to read: Within 90 days after receiving a request and supporting information or sooner if a statutory bar to patenting is imminent, the agency shall either make a determination or inform the contractor of why a determination has not yet been made and when one can reasonably be expected." This comment was not accepted. At this time, this is a matter best left to the parties to determine on a case-by-case basis.

A number of comments were also received regarding a typographical error in the "Background" section on page 25510 of the July 14, 1986 Federal Register notice. The word "not" was inadvertently left out of the last sentence of the first paragraph discussing § 401.7. The sentence should have read as follows: "this change has been made because small business preference is not intended to inhibit industrial support of university research."

Two comments were received that relate to the exceptions to be made for handling of inventions if they are under research at a government-owned, contractor-operated facility (GOCO):

The first comment relates to the requirement in § 401.5(g) that specifies that income be used for purposes "consistent with research and development mission and objectives of the facility." The commenter suggests it would be preferable that a university be able to direct the net royalty income to the most promising research needs, which may not necessarily be consistent with the objective of the GOCO facility. We cannot accept this suggestion since the language in the regulation is based on the statute—Pub. L. 98-620.

The second comment goes on to state that § 401.5(g) further specifies that if a licensing program is successful, then above a certain point, 75 percent is to be paid to the U.S. Treasury. The suggestion is that this reduces the incentive to be successful, and recommends the deletion of this requirement. Again, we cannot accept this suggestion since the regulatory language herein is based on the statute—Pub. L. 98-620.

A third comment references the special clause entitled, "patent rights to nonprofit DOE facility operations." The comment states that this clause removes a subject invention funded by the naval nuclear propulsion or weapons related programs of DOE from the normal presumption of rights to the contractor, and requires the petitioning process that was in effect before the enactment of Pub. L. 96-517. The concern is that if these programs are exempted, then there may be additional proposals to delete other programs from the full operations of Pub. L. 96-517. The comment then concludes by recommending that this special clause not be implemented. We cannot accept this recommendation since the statute, Pub. L. 98-620, gives DOE the discretionary authority to use this for its naval nuclear propulsion or weapons related programs.

Another comment received relates to § 401.14(c)(1), which calls for disclosure by a contractor to the contracting government agency of each "subject invention . . ." within two months of the time it is disclosed by the inventor in writing. The commenter complains that two months is "too harsh." We do not accept this comment for two reasons. (1) The statute, Pub. L. 98-620, uses the words "reasonable time" and we think two months is reasonable; and (2) § 401.14(c)(4) allows extensions of time at the discretion of the agency.

One person asked for greater guidance on whether contractor funding of individual scientists at different universities is an educational award within 35 U.S.C. 212 and, if so, what rights such awardees should have. We have not acted on this comment since we do not believe any contractor has the authority to use funding for the educational awards covered by 35 U.S.C. 212.

A comment was submitted that relates to the discussion in the July 14, 1986 notice of § 401.13(b). The concern is that the discussion may be misinterpreted to imply that agencies may not apply the provisions of Pub. L. 98-620 retroactively. This point is well taken. It was our intent in the July 14, 1986 discussion of § 401.13(b) to note only that the Department of Commerce has no authority under the law to require agencies to waive the cap on the term of an exclusive license in a patent clause that predates enactment of Pub. L. 98-620. There is no question that the agencies themselves have authority under the law to waive such cap and the regulations in fact urge them to do so absent a substantive reason to do otherwise.

Another person requested that the Department of Commerce set a time for issuance of draft supplementary regulations relating to foreign filing deadlines at § 401.14(c)(3). As we previously indicated in the interim final rule notice on July 14, 1986, we are considering this matter. Therefore, we see no reason at this time to set a deadline.

Finally, pursuant to requests by two persons, we have included in this final notice, uniform policy guidance in § 401.1(a) to these final regulations similar to that included in OMB Circular A-124. This has been done to ensure clarity and continuity between OMB Circular A-124 and these final regulations with regard to policy.

Rulemaking Requirements

As stated in the proposed notice and the interim final rule, this regulation is not a major rule as defined in Executive Order 12291, and it adds no paperwork burdens. In fact, it reduces certain paperwork requirements of the regulations it replaces. And, as discussed in connection with the proposed rule and the interim final rule, the General Counsel of the Department of Commerce has certified to the Small Business Administration that this rule will not have a substantial economic impact on a substantial number of small entities.

List of Subjects in 37 CFR Ch. IV

Inventions, Patents, Nonprofit organizations, Small Business firms.

Date: March 11, 1987.

D. Bruce Merrifield,

Assistant Secretary for Productivity, Technology and Innovation.

Accordingly, Part 401 of Chapter IV of Title 37, the Code of Federal Regulations is revised to read as follows:

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

Sec.

401.1 Scope.
401.2 Definitions.
401.3 Use of the Standard Clauses at § 401.14.
401.4 Contractor appeals of exceptions.
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401.7 Small business preference.
401.8 Reporting on utilization of subject inventions.
401.9 Retention of rights by contractor employee inventor.
401.10 Government assignment to contractor of rights in invention of government employee.
401.11 Appeals.
401.12 Licensing of background patent rights to third parties.
401.13 Administration of patent rights clauses.
401.14 Standard patent rights clauses.
401.15 Deferred determinations.
401.16 Submissions and inquiries.

Authority: 35 U.S.C. 206 and the delegation of authority by the Secretary of Commerce to the Assistant Secretary for Productivity, Technology and Innovation at Sec. 3(g) of DOO 10-1.

§ 401.1 Scope.

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

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

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

(b) This part inplements 35 U.S.C. 202 through 204 and is applicable to all Federal agencies. It applies to all funding agreements with small business firms and nonprofit organizations executed after the effective date of this part, 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 alternative provisions are used under § 401.3(a)(1) through (4), 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 § 401.16 for approval for consistency with this part before they are submitted to the Office of Management and Budget (OMB) for review under Executive Order 12291 or, if no submission is required to be made to OMB, before their submission to the Federal Register for publication.

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

inventions that are consistent with Chapter 18 and this part.

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

§ 401.2 Definitions.

As used in this part—

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

(b) The term "contractor" means any person, small business firm or nonprofit organization 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 Secretary of Commerce or his or her designee.

§ 401.3 Use of the Standard Clauses at § 401.14.

(a) Each funding agreement awarded to a small business firm or nonprofit organization (except those subject to 35 U.S.C. 212) shall contain the clause found in § 401.14(a) with such modifications and tailoring as authorized or required elsewhere in this part. 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.

(b) When an agency exercises the exceptions at § 401.3(a)(2) or (3), it shall use the standard clause at § 401.14(a) 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 § 401.14(b). 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 § 401.3(a)(2) 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(a) 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 programs are exempted from this paragraph.

(c) When the Department of Energy exercises the exception at § 401.3(a)(4), it shall use the clause prescribed at § 401.14(b) or substitute thereto with such modification and tailoring as authorized or required elsewhere in this part.

(d) When a funding agreement involves a series of separate task orders, an agency may apply the exceptions at § 401.3(a)(2) or (3) to individual task orders, and it may structure the contract so that modified patent rights provisions will apply to the task order even though the clauses at either § 401.14(a) or (b) are applicable to the remainder of the work. Agencies are authorized to negotiate such modified provisions with respect to task orders added to a funding agreement after its initial award.

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

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

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

(h) To qualify for the standard clause, 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 as a small business firm, it may file a protest in accordance with 13 CFR 121.9. If it questions nonprofit status, it may require the prospective contractor to furnish evidence to establish its status as a nonprofit organization.

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

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

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

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

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

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

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

§ 401.5 Modification and tailoring of clauses.

(a) Agencies should complete the blank in paragraph (g)(2) of the clauses at § 401.14 in accordance with their own or applicable government-wide regulations such as the Federal Acquisition Regulation. In grants and cooperative agreements (and in

contracts, if not inconsistent with the Federal Acquisition Regulation) agencies wishing to apply the same clause to all subcontractors as is applied to the contractor may delete paragraph (g)(2) of the clause and delete the words "to be performed by a small business firm or domestic nonprofit organization" from paragraph (g)(1). Also, if the funding agreement is a grant or cooperative agreement, paragraph (g)(3) may be deleted. When either paragraph (g)(2) or paragraphs (g) (2) and (3) are deleted, the remaining paragraph or paragraphs should be renumbered appropriately.

(b) Agencies should complete paragraph (l), "Communications", at the end of the clauses at § 401.14 by designating a central point of contact for communications on matters relating to the clause. Additional instructions on communications may also be included in paragraph (l).

(c) Agencies may replace the italicized words and phrases in the clauses at § 401.14 with those appropriate to the particular funding agreement. For example, "contracts" could be replaced by "grant," "contractor" by "grantee," and "contracting officer" by "grants officer." Depending on its use, "Federal agency" can be replaced either by the identification of the agency or by the specification of the particular office or official within the agency.

(d) When the agency head or duly authorized designee determines at the time of contracting with a small business firm or nonprofit organization that it would be in the national interest to acquire the right to sublicense foreign governments or international organizations pursuant to any existing treaty or international agreement, a sentence may be added at the end of paragraph (b) of the clause at § 401.14 as follows:

> This license will include the right of the government to sublicense foreign governments, their nationals, and international organizations, pursuant to the following treaties or international agreements:
>
> _____.

The blank above should be completed with the names of applicable existing treaties or international agreements, agreements of cooperation, memoranda of understanding, or similar arrangements, including military agreements relating to weapons development and production. The above language is not intended to apply to treaties or other agreements that are in effect on the date of the award but which are not listed. Alternatively, agencies may use substantially similar language relating the government's rights to specific treaties or other agreements identified elsewhere in the funding agreement. The language may also be modified to make clear that the rights granted to the foreign government, and its nationals or an international organization may be for additional rights beyond a license or sublicense if so required by the applicable treaty or international agreement. For example, in some exclusive licenses or even the assignment of title in the foreign country involved might be required. Agencies may also modify the language above to provide for the direct licensing by the contractor of the foreign government or international organization.

(e) If the funding agreement involves performance over an extended period of time, such as the typical funding agreement for the operation of a government-owned facility, the following language may also be added:

> The *agency* reserves the right to unilaterally amend this *funding agreement* to identify specific treaties or international agreements entered into or to be entered into by the government after the effective date of this *funding agreement* and effectuate those license or other rights which are necessary for the government to meet its obligations to foreign governments, their nationals and international organizations under such treaties or international agreements with respect to subject inventions made after the date of the amendment.

(f) Agencies may add additional subparagraphs to paragraph (f) of the clauses at § 401.14 to require the contractor to do one or more of the following:

(1) Provide a report prior to the close-out of a funding agreement listing all subject inventions or stating that there were none.

(2) Provide, upon request, the filing date, serial 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 patents.

(3) Provide periodic (but no more frequently than annual) listings of all subject inventions which were disclosed to the agency during the period covered by the report.

(g) If the contract is with a nonprofit organization and is for the operation of a government-owned, contractor-operated facility, the following will be substituted for paragraph (k)(3) of the clause at § 401.14(a):

> (3) 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, 75 percent of the excess above five percent shall be paid by the contractor to the Treasury of the United States and the remaining 25 percent shall be used by the *contractor* only for the same purposes as described above. To the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by *contractor* employees on location at the facility.

(h) If the contract is for the operation of a government-owned facility, agencies may add the following at the end of paragraph (f) of the clause at § 401.14(a):

> (5) 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.

§ 401.6 Exercise of march-in rights.

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

(b) Whenever an agency receives information that it believes might warrant the exercise of march-in rights, before initiating any march-in proceeding, it shall notify the contractor in writing of the information and request informal written or oral comments from the contractor as well as information relevant to the matter. In the absence of any comments from the contractor within 30 days, the agency may, at its discretion, proceed with the procedures below. If a comment is received within 30 days, or later if the agency has not initiated the procedures below, then the agency shall, within 60 days after it receives the comment, either initiate the procedures below or notify the contractor, in writing, that it will not pursue march-in rights on the basis of the available information.

(c) A march-in proceeding shall be initiated by the issuance of a written notice by the agency to the contractor and its assignee or exclusive licensee, as applicable and if known to the agency, stating that the agency is considering the exercise of march-in rights. The

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

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

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

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

(g) In cases in which fact-finding has been conducted, the head of the agency or designee shall base his or her determination on the facts found, together with any other information and written or oral arguments submitted by the contractor (assignee or exclusive licensee) and agency representatives, and any other information in the administrative record. The consistency of the exercise of march-in rights with the policy and objectives of 35 U.S.C. 200 shall also be considered. In cases referred for fact-finding, the head of the agency or designee may reject only those facts that have been found to be clearly erroneous, but must explicitly state the rejection and indicate the basis for the contrary finding. Written notice of the determination whether march-in rights will be exercised shall be made by the head of the agency or designee and sent to the contractor (assignee of exclusive licensee) by certified or registered mail within 90 days after the completion of fact-finding or 90 days after oral arguments, whichever is later, or the proceedings will be deemed to have been terminated and thereafter no march-in based on the facts and reasons upon which the proceeding was initiated may be exercised.

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

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

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

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

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

§ 401.7 Small Business Preference.

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

(b) Small business firms that believe a nonprofit organization is not meeting its obligations under the clause may report their concerns to the Secretary. To the extent deemed appropriate, the Secretary will undertake informal investigation of the concern, and, if appropriate, enter into discussions or negotiations with the nonprofit organization to the end of improving its efforts in meeting its obligations under the clause. However, in no event will the Secretary intervene in ongoing negotiations or contractor decisions concerning the licensing of a specific subject invention. All the above investigations, discussions, and negotiations of the Secretary will be in coordination with other interested agencies, including the Small Business Administration; and in the case of a contract for the operation of a government-owned, contractor operated research or production facility, the Secretary will coordinate with the agency responsible for the facility prior to any discussions or negotiations with the contractor.

401.8 Reporting on utilization of subject inventions.

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

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

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

§ 401.9 Retention of Rights by Contractor Employee Inventor.

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

§ 401.10 Government Assignment to Contractor of Rights in Invention of Government Employee.

In any case when a Federal employee is a co-inventor of any invention made under a funding agreement with a small business firm or nonprofit organization and the Federal agency employing such co-inventor transfers or reassigns the right it has acquired in the subject invention from its employee to the contractor as authorized by 35 U.S.C. 202(e), the assignment will be made subject to the same conditions as apply to the contractor under the patent rights clause of its funding agreement. Agencies may add additional conditions as long as they are consistent with 35 U.S.C. 201–206.

§ 401.11 Appeals.

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

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

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

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

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

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

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

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

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

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

§ 401.12 Licensing of Background Patent Rights to Third Parties.

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

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

§ 401.13 Administration of Patent Rights Clauses.

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

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

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

requirements should be followed for funding agreements covered by and predating this Part 401.

(1) To the extent authorized by 35 U.S.C. 205, agencies shall not disclose to third parties pursuant to requests under the Freedom of Information Act (FOIA) any information disclosing a subject invention for a reasonable time in order for a patent application to be filed. With respect to subject inventions of contractors that are small business firms or nonprofit organizations, a reasonable time shall be the time during which an initial patent application may be filed under paragraph (c) of the standard clause found at § 401.14(a) or such other clause may be used in the funding agreement. However, an agency may disclose such subject inventions under the FOIA, at its discretion, after a contractor has elected not to retain title or after the time in which the contractor is required to make an election if the contractor has not made an election within that time. Similarly, an agency may honor a FOIA request at its discretion if it finds that the same information has previously been published by the inventor, contractor, or otherwise. If the agency plans to file itself when the contractor has not elected title, it may, of course, continue to avail itself of the authority of 35 U.S.C. 205.

(2) In accordance with 35 U.S.C. 205, agencies shall not disclose or release for a period of 18 months from the filing date of the application to third parties pursuant to requests under the Freedom of Information Act or otherwise copies of any document which the agency obtained under this clause 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.

(3) A number of agencies have policies to encourage public dissemination of the results of work supported by the agency through publication in government or other publications of technical reports of contractors or others. In recognition of the fact that such publication, if it included descriptions of a subject invention could create bars to obtaining patent protection, it is the policy of the executive branch that agencies will not include in such publication programs copies of disclosures of inventions submitted by small business firms or nonprofit organizations, pursuant to paragraph (c) of the standard clause found at § 401.14(a), except that under the same circumstances under which agencies are authorized to release such information pursuant to FOIA requests under paragraph (e)(1) of this section, agencies may publish such disclosures.

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

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

§ 401.14 Standard patent rights clauses.

(a) The following is the standard patent rights clause to be used as specified in § 401.3(a).

Patent Rights (Small Business Firms and Nonprofit Organizations)

(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 (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

(b) *Allocation of Principal Rights*

The *Contractor* may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause and 35 U.S.C. 203. With respect to any subject invention in which the *Contractor* retains title, the Federal government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

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

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

(2) The *Contractor* will elect in writing whether or not to retain title to any such invention by notifying the *Federal agency* within two years of disclosure to the *Federal agency*. However, in any case where

publication, on sale or public use has initiated the one year statutory period wherein valid patent protection can still be obtained in the United States, the period for election of title may be shortened by the *agency* to a date that is no more than 60 days prior to the end of the statutory period.

(3) The *contractor* will file its initial patent application on a subject invention to which it elects to retain title within one year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use. The *contractor* will file patent applications in additional countries or international patent offices within either ten months of the corresponding initial patent application or six months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) Requests for extension of the time for disclosure, election, and filing under subparagraphs (1), (2), and (3) may, at the discretion of the *agency*, be granted.

(d) Conditions When the Government May Obtain Title

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

(1) If the *contractor* fails to disclose or elect title to the subject invention within the times specified in (c), above, or elects not to retain title; provided that the *agency* may only request title within 60 days after learning of the failure of the *contractor* to disclose or elect within the specified times.

(2) In those countries in which the *contractor* fails to file patent applications within the times specified in (c) above; provided, however, that if the *contractor* has filed a patent application in a country after the times specified in (c) above, but prior to its receipt of the written request of the *Federal agency*, the *contractor* shall continue to retain title in that country.

(3) In any country in which the *contractor* decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

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

(1) The *contractor* will retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, except if the *contractor* fails to disclose the invention within the times specified in (c), above. The *contractor's* license extends to its domestic subsidiary and affiliates, if any, within the corporate structure of which the *contractor* is a party and includes the right to grant sublicenses of the same scope to the extent the *contractor* was legally obligated to do so at the time the *contract* was awarded. The license is transferable only with the approval of the *Federal agency* except when transferred to the sucessor of that party of the *contractor's* business to which the invention pertains.

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

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

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

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

(2) The *contractor* agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the *contractor* each subject invention made under *contract* in order that the *contractor* can comply with the disclosure provisions of paragraph (c), above, 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 (c)(1), above. The *contractor* shall instruct such employees through employee agreements or other suitable educational programs on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The *contractor* will notify the *Federal agency* of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than thirty days before the expiration of the response period required by the relevant patent office.

(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 small business firm or domestic nonprofit organization. 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 commerical sale or use, gross royalties received by the contractor, and such other data and information as the *agency* may reasonably specify. The *contractor* also agrees to provide additional reports as may be requested by the *agency* in connection with any march-in proceeding undertaken by the *agency* in accordance with paragraph (j) of this clause. As required by 35 U.S.C. 202(c)(5), the *agency* agrees it will not disclose such information to persons outside the government without permission of the *contractor*.

(i) Preference for United States Industry

Notwithstanding any other provision of this clause, the *contractor* agrees that neither it nor any assignee will grant to any person the

exclusive right to use or sell any subject inventions in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the *Federal agency* upon a showing by the *contractor* or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(j) March-in Rights

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

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

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

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

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

(k) Special Provisions for *contracts* with Nonprofit organizations

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

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

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

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

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject invention that are small business firms and that it will give a preference to a small business firm when licensing a subject invention if the *contractor* determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms; provided, that the *contractor* is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the *contractor*. However, the *contractor* agrees that the Secretary 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 Secretary when the Secretary's review discloses that the *contractor* could take reasonable steps to implement more effectively the requirements of this paragraph (k)(4).

(l) Communication

(Complete According to Instructions at 401.5(b))

(b) When the Department of Energy (DOE) determines to use alternative provisions under § 401.3(a)(4), the standard clause at § 401.14(a), above, shall be used with the following modifications unless a substitute clause is drafted by DOE:

(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) and add subparagraphs (B) and (C) to paragraph (c)(1) 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 subparagraph (c)(1)(B) will apply in lieu of paragraphs (c)(2) and (3). 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), below. 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)–(k) of this clause and such additional conditions, if any, deemed to be appropriate by the *Department of Energy*.

(C) At the time an invention is disclosed in accordance with (c)(1)(A) above, 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, subparagraph (c)(1)(B) will apply in lieu of paragraphs (c)(2) and (3). The contractor statement will be deemed conclusive unless, within 60 days thereafter, the Contracting Officer disagrees in writing, in which case the determination of the Contracting Officer will be deemed conclusive unless the contractor files a claim under the Contract Disputes Act within 60 days after the Contracting Officer's determination. Pending resolution of the matter, the invention will be subject to subparagraph (c)(1)(B).

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

§ 401.15 Deferred determinations.

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

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

(c) If paragraph (b) is not applicable the agency shall make its determination

based on an assessment whether its own plans regarding the invention will better promote the policies and objectives of 35 U.S.C. 200 than will contractor ownership of the invention. Moreover, if the agency is concerned only about specific uses or applications of the invention, it shall consider leaving title in the contractor with additional conditions imposed upon the contractor's use of the invention for such applications or with expanded government license rights in such applications.

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

§ 401.16 Submissions and inquiries.

All submissions or inquiries should be directed to Federal Technology Management Policy Division, telephone number 202–377–0659, Room H4837, U.S. Department of Commerce, Washington, DC 20230.

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