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led the agency to invoke an exception under §401.3(a) are not applicable to the actual subject invention or are no longer valid because of subsequent events, the agency should allow the contractor to retain title to the invention on the same conditions as would have applied if the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 Electronic filing.

Unless otherwise requested or directed by the agency,

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

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

(c) The close-out report in (f)(1) and the information identified in (f)(2) and (f)(3) of §401.5 may be electronically filed.

[60 FR 41812, Aug. 14, 1995]

§401.17 Submissions and inquiries.

All submissions or inquiries should be directed to Director, Technology Competitiveness Staff, Office of Technology Policy, Technology Administration, telephone number 202–482–2100, Room H4418, U.S. Department of Commerce, Washington, DC 20230.

[60 FR 41812, Aug. 14, 1995]

PART 404—LICENSING OF GOVERNMENT OWNED INVENTIONS

Sec.

AUTHORITY: 35 U.S.C. 208 and the delegation of authority by the Secretary of Commerce

to the Assistant Secretary of Commerce for Technology Policy at sec. 3(d)(3) of DOO 10–18.

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

§ 404.1 Scope of part.

This part prescribes the terms, conditions, and procedures upon which a federally owned invention, other than an invention in the custody of the Tennessee Valley Authority, may be licensed. It supersedes the regulations at 41 CFR Subpart 101–4.1. This part does not affect licenses which (a) were in effect prior to July 1, 1981; (b) may exist at the time of the Government's acquisition of title to the invention, including those resulting from the allocation of rights to inventions made under Government research and development contracts; (c) are the result of an authorized exchange of rights in the settlement of patent disputes; or (d) are otherwise authorized by law or treaty.

§ 404.2 Policy and objective.

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

§ 404.3 Definitions.

(a) *Federally owned invention* means an invention, plant, or design which is covered by a patent, or patent application in the United States, or a patent, patent application, plant variety protection, or other form of protection, in a foreign country, title to which has been assigned to or otherwise vested in the United States Government.

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

(c) *Small business firm* means a small business concern as defined in section 2 of Pub. L. 85–536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration.

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

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

§ 404.4 Authority to grant licenses.

Federally owned inventions shall be made available for licensing as deemed appropriate in the public interest. Federal agencies having custody of federally owned inventions may grant nonexclusive, partially exclusive, or exclusive licenses thereto under this part.

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

(a)(1) A license may be granted only if the applicant has supplied the Federal agency with a satifactory plan for development or marketing of the invention, or both, and with information about the applicant's capability to fulfill the plan.

(2) A license granting rights to use or sell under a federally owned invention in the United States shall normally be granted only to a licensee who agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

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

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

(2) The license may be granted for all or less than all fields of use of the invention or in specified geographical areas, or both.

(3) The license may extend to subsidiaries of the licensee or other parties if provided for in the license but shall be nonassignable without approval of the Federal agency, except to the successor

of that part of the licensee's business to which the invention pertains.

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

(5) The license shall require the licensee to carry out the plan for development or marketing of the invention, or both, to bring the invention to practical application within a period specified in the license, and to continue to make the benefits of the invention reasonably accessible to the public.

(6) The license shall require the licensee to report periodically on the utilization or efforts at obtaining utilization that are being made by the licensee, with particular reference to the plan submitted.

(7) Licenses may be royalty-free or for royalties or other consideration.

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

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

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

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

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

(iv) The licensee commits a substantial breach of a covenant or agreement contained in the license.

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

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

§ 404.6 Nonexclusive licenses.

(a) Nonexclusive licenses may be granted under federally owned inventions without publication of availability or notice of a prospective license.

(b) In addition to the provisions of §404.5, the nonexclusive license may also provide that, after termination of a period specified in the license agreement, the Federal agency may restrict the license to the fields of use or geographic areas, or both, in which the licensee has brought the invention to practical application and continues to make the benefits of the invention reasonably accessible to the public. However, such restriction shall be made only in order to grant an exclusive or partially exclusive license in accordance with this subpart.

§ 404.7 Exclusive and partially exclusive licenses.

(a)(1) Exclusive or partially exclusive domestic licenses may be granted on federally owned inventions three months after notice of the invention's availability has been announced in the FEDERAL REGISTER, or without such notice where the Federal agency determines that expeditious granting of such a license will best serve the interest of the Federal Government and the public; and in either situation, only if;

(i) Notice of a prospective license, identifying the invention and the prospective licensee, has been published in the FEDERAL REGISTER, providing opportunity for written objections within at least a 15-day period;

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

(A) The interests of the Federal Government and the public will best be served by the proposed license, in view of the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public;

(B) The desired practical application has not been achieved, or is not likely expeditiously to be achieved, under any nonexclusive license which has been granted, or which may be granted, on the invention;

(C) Exclusive or partially exclusive licensing is a reasonable and necessary incentive to call forth the investment of risk capital and expenditures to bring the invention to practical application or otherwise promote the invention's utilization by the public; and

(D) The proposed terms and scope of exclusivity are not greater than reasonably necessary to provide the incentive for bringing the invention to practical application or otherwise promote the invention's utilization by the public;

(iii) The Federal agency has not determined that the grant of such license will tend substantially to lessen competition or result in undue concentration in any section of the country in any line of commerce to which the technology to be licensed relates, or to create or maintain other situations inconsistent with the antitrust laws; and

(iv) The Federal agency has given first preference to any small business firms submitting plans that are determined by the agency to be within the capabilities of the firms and as equally likely, if executed, to bring the invention to practical application as any plans submitted by applicants that are not small business firms.

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

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

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

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

(iv) The license may grant the licensee the right of enforcement of the licensed patent pursuant to the provisions of Chapter 29 of Title 35, United States Code, or other statutes, as determined appropriate in the public interest.

(b)(1) Exclusive or partially exclusive licenses may be granted on a federally owned invention covered by a foreign patent, patent application, or other form of protection, provided that;

(i) Notice of a prospective license, identifying the invention and the prospective licensee, has been published in the FEDERAL REGISTER, providing opportunity for written objections within at least a 15-day period and following consideration of such written objections received during the period.

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

(iii) The Federal agency has not determined that the grant of such license will tend substantially to lessen competition or result in undue concentration in any section of the United States in any line of commerce to which the technology to be licensed relates, or to create or maintain other situations inconsistent with antitrust laws.

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

(i) The license shall be subject to the irrevocable, royalty-free right of the Government of the United States to practice and have practiced the invention on behalf of the United States and on behalf of any foreign government or

international organization pursuant to any existing or future treaty or agreement with the United States.

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

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

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

[50 FR 9802, Mar. 12, 1985, as amended at 66 FR 34546, June 29, 2001]

§ 404.8 Application for a license.

An application for a license should be addressed to the Federal agency having custody of the invention and shall normally include:

(a) Identification of the invention for which the license is desired including the patent application serial number or patent number, title, and date, if known;

(b) Identification of the type of license for which the application is submitted;

(c) Name and address of the person, company, or organization applying for the license and the citizenship or place of incorporation of the applicant;

(d) Name, address, and telephone number of the representative of the applicant to whom correspondence should be sent;

(e) Nature and type of applicant's business, identifying products or services which the applicant has successfully commercialized, and approximate number of applicant's employees;

(f) Source of information concerning the availability of a license on the invention;

(g) A statement indicating whether the applicant is a small business firm as defined in § 404.3(c)

(h) A detailed description of applicant's plan for development or marketing of the invention, or both, which should include:

(1) A statement of the time, nature and amount of anticipated investment of capital and other resources which applicant believes will be required to bring the invention to practical application;

(2) A statement as to applicant's capability and intention to fulfill the plan, including information regarding manufacuturing, marketing, financial, and technical resources;

(3) A statement of the fields of use for which applicant intends to practice the invention; and

(4) A statement of the geographic areas in which applicant intends to manufacture any products embodying the invention and geographic areas where applicant intends to use or sell the invention, or both;

(i) Identification of licenses previously granted to applicant under federally owned inventions;

(j) A statement containing applicant's best knowledge of the extent to which the invention is being practiced by private industry or Government, or both, or is otherwise available commercially; and

(k) Any other information which applicant believes will support a determination to grant the license to applicant.

§ 404.9 Notice to Attorney General.

A copy of the notice provided for in § 404.7 (a)(1)(i) and (b)(1)(i) will be sent to the Attorney General.

§ 404.10 Modification and termination of licenses.

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

§ 404.11 Appeals.

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

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

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

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

§ 404.12 Protection and administration of inventions.

A Federal agency may take any suitable and necessary steps to protect and administer rights to federally owner inventions, either directly or through contract.

§ 404.13 Transfer of custody.

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

§ 404.14 Confidentiality of information.

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