adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation because this rule is not expected to result in any significant adverse environmental impact as described in the National Environmental Policy Act of 1969 (NEPA).

A draft ''Environmental Analysis Check List'' and a draft ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES.** Comments on this section will be considered before we make the final decision on whether the rule should be categorically excluded from further environmental review.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.835 to read as follows:

§ 165.835 Security Zone; Port of Mobile, Mobile Ship Channel, Mobile, AL.

(a) *Definition.* As used in this section—

Cruise Ship means a passenger vessel over 100 gross tons, carrying more than 12 passengers for hire, making a voyage lasting more than 24 hours any part of which is on the high seas, and for which passengers are embarked or disembarked in the United States or its territories. This definition covers passenger vessels that must comply with 33 CFR parts 120 and 128.

(b) *Location.* The following areas are security zones: all waters of the Port of Mobile and Mobile Ship Channel?

(1) Within 100 yards of a cruise ship that is transiting shoreward of the Mobile Sea Buoy (located in approximate position 28°07′50″ N, 88°04′12″ W; NAD 83), and

(2) Within 25 yards of a cruise ship that is moored shoreward of the Mobile Sea Buoy.

(c) *Periods of enforcement.* This rule will only be enforced when a cruise ship is transiting the Mobile Ship Channel shoreward of the Mobile Sea Buoy, while transiting in the Port of Mobile, or while moored in the Port of Mobile. The Captain of the Port Mobile or a designated representative would inform the public through broadcast notice to mariners of the enforcement periods for the security zone.

(d) *Regulations.* (1) Under § 165.33, entry into a security zone is prohibited unless authorized by the Captain of the Port Mobile or a designated representative.

(2) While a cruise ship is transiting on the Mobile Ship Channel shoreward of the Mobile Sea Buoy, and while transiting in the Port of Mobile, all persons and vessels are prohibited from entering within 100 yards of a cruise ship.

(3) While a cruise ship is moored in the Port of Mobile, all persons and vessels are prohibited from entering within 25 yards of a cruise ship.

(4) Persons or vessels that desire to enter into the security zone for the purpose of passing or overtaking a cruise ship that is in transit on the Mobile Ship Channel or in the Port of Mobile must contact the on-scene Coast Guard representative, request permission to conduct such action, and receive authorization from the on-scene Coast Guard representative prior to initiating such action. The on-scene Coast Guard representative may be contacted on VHF–FM channel 16.

(5) All persons and vessels authorized to enter into this security zone must obey any direction or order of the Captain of the Port or designated representative. The Captain of the Port Mobile may be contacted by telephone at (251) 441–5976. The on-scene Coast Guard representative may be contacted on VHF–FM channel 16.

(6) All persons and vessels must comply with the instructions of the Captain of the Port Mobile and designated on-scene U.S. Coast Guard patrol personnel. On-scene Coast Guard patrol personnel include commissioned, warrant, and petty officers of the U.S. Coast Guard.

Dated: December 6, 2004.

Steven D. Hardy,

Captain, U.S. Coast Guard, Captain of the Port Mobile.

[FR Doc. 05–379 Filed 1–6–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF COMMERCE

37 CFR Part 404

[Docket No. 040305084–4084–01]

RIN 0692–AA19

Assistant Secretary for Technology Policy; Licensing of Government Owned Inventions

AGENCY: Assistant Secretary for Technology Policy, Department of Commerce (DOC).

ACTION: Notice of proposed rule making; request for comments.

SUMMARY: This proposed rule incorporates several changes made by the Technology Transfer Commercialization Act of 2000 with respect to the granting of licenses by Federal agencies on Federally owned inventions. It also streamlines the licensing procedures to focus primarily on statutory requirements.

DATES: Comments must be received no later than February 7, 2005.

ADDRESSES: Comments on the proposed revisions must be submitted to: Mr. John Raubitschek, Office of the Chief Counsel for Technology, Room 4835, HCHB, Department of Commerce, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Mr. John Raubitschek, Patent Counsel, at telephone: (202) 482–8010.

SUPPLEMENTARY INFORMATION: *Summary of the Proposed Amendments:*

1. DOC proposes to revise the index of sections to remove § 404.9 which would become reserved and to modify the title of § 404.7 to add ''co-exclusive.''

2. DOC proposes to revise § 404.1 to change the effective date of the regulation and remove the reference to the first licensing regulation in 1981. Other proposed changes include the adding of additional examples of licenses which would not be subject to the regulation, including exchange of rights in settlements of patent disputes, licenses and assignments of certain joint inventions as authorized by 35 U.S.C. 202(e) or of inventions under cooperative research and development agreements (CRADAs) as authorized by

15 U.S.C. 3710a or by a treaty, or licenses where the agency has acquired rights under 35 U.S.C. 207(a)(3) to facilitate the licensing of a federally owned invention, sometimes referred to as ''bundling inventions.''

3. DOC proposes to revise § 404.3(a) to remove the limitation that the invention must be described in a patent or application to be licensable in view of the change to 35 U.S.C. 207 made by Public Law 106–404. The only requirement would be that the invention is or may be patentable or protectable subject matter although it may be covered by a patent or patent application. Since ''invention'' is defined in 35 U.S.C. 201(d), this is included in subparagraph (a) with the additional reference to foreign patent law. Under this authority, agencies may now license computer software and biological materials as inventions without filing a patent application because they are patentable subject matter. In addition, the phrase ''in whole or in part'' is added to make it clear that an agency can license its undivided interest in a joint invention.

4. DOC proposes to revise § 404.4 to require each agency to notify the public of its inventions which are available for licensing. Such notification was encouraged by the House Committee on Science in H.R. Report 106–129, Part I, 106th Cong., 1st sess. Previously, notice was required only if the agency was going to exclusively license the invention. *See* § 404.7(a)(1). However, the form of notification is left to the discretion of the agency, which is strongly encouraged to use the internet or other electronic means to notify the public. Also, DOC proposes to move the substance of §§ 404.5(b)(2), (7) and (11) to this section.

5. DOC proposes to add a sentence in § 404.5(a)(1) to permit an abbreviated development plan for a non-exclusive research license because 35 U.S.C. 209(a) requires that all applicants for a license submit a plan even though the applicant may have no present intent to commercialize the invention. Such a license would be appropriate for a party working with an agency under a CRADA on the agency's pre-existing invention(s), which may now be included in the CRADA under Public Law 106–404 if a patent application was filed prior to the CRADA.

6. DOC proposes to add a sentence to § 404.5(a)(2) to provide guidance for an agency to waive or modify the domestic manufacturing requirement. This proposal is based substantially on 35 U.S.C. 204, which applies to inventions made by nonprofit organizations and small business firms with federal funds.

7. As mentioned in paragraph no. 4, DOC proposes to move §§ 404.5(b)(2), (7) and (11) to § 404.4, which is more directed to policy. This will result in a renumbering of § 404.5. A new § 404.5(b)(2) is being added to permit any licensee to enforce a licensed patent. As noted in *Nutrition 21* v. *U.S.,* 930 F.2d 867, 871, 18 USPQ2d (BNA) 1351, 1354, n.7 (Fed. Cir. 1991), the authority for enforcement in 35 U.S.C. 207(b)(1) is not limited to exclusive licensees. Editorial changes are proposed to § 404.5(b)(4) as well as adding a requirement that copies of sublicenses and modifications be promptly provided to the agencies. § § 404.5(b)(5) and (b)(6) are being slightly modified to adopt the language from Public Law 106–404.

8. DOC proposes to modify § 404.5(b)(9), now renumbered as 404.5(b)(8), to include the language of Public Law 106–404, which specifically mentions terminating for a breach of the domestic manufacturing requirement in § 404.5(a)(2) and the new requirement in § 404.5(b)(8)(v) that a license be terminated if a court determines that it violates the antitrust laws.

9. DOC proposes to remove the exclusion in § 404.6(a) for publishing the availability of an invention for licensing, which is subsequently licensed non-exclusively. This is not necessary in view of the proposed change described in paragraph no. 4 that the public will be notified of all inventions which are available for licensing. In addition, the suggestion in § 404.6(b) that after expiration of a specific time period, the field of use be limited to where the licensee has commercialized the invention is being deleted because it implies that non-exclusive licenses should contain such a clause. In fact, few agencies use such a clause because most nonexclusive licenses are for the full term of the patent. However, an agency may still use such a clause if it so chooses.

10. DOC proposes to add co-exclusive licenses to § 404.7 to specifically recognize that an agency may grant an exclusive license to more than one company to better achieve commercialization or to resolve disputes with competing license applications.

11. DOC proposes to remove the requirement in § 404.7(a)(1) to publish in the **Federal Register** a notice of availability of an invention for licensing prior to granting an exclusive license on that invention. However, agencies will be required to make the public aware of their inventions through use of the Internet or other electronic means in accordance with the revised § 404.4.

12. DOC proposes to delete § 404.7(a)(1)(ii)(B) because the new law does not contain a preference for nonexclusive licenses. § 404.7(a)(1)(ii)(C) would be renumbered as (B) and contain the slightly different language from the new law for the justification for an exclusive license. Similarly, the justification in § 404.7(a)(1)(ii)(A) is being slightly revised in view of the language in the new law. The antitrust consideration in §§ 404.7(a)(1)(iii) and (b)(1)(iii) is being revised in view of the new law although a positive determination by the agency is not required. Similarly, the small business preference in § 404.7(a)(1)(iv) is being revised slightly because of the new law.

13. DOC proposes to change the semicolon to a colon at the end of § 407(a)(2) and delete §§ 404.7(a)(2)(iv) and (b)(2)(iii) in view of the new § 404.5(b)(2), which permits all licensees to have the right to enforce licensed patents.

14. DOC proposes to delete § 404.9 since review by the Attorney General of an exclusive license notice is not required by statute. It is noted that the license may be terminated if there is a violation of the antitrust law. *See* proposed 404.5(b)(8)(v).

15. DOC proposes to delete the second reference to a sublicensee in § 404.10 because there is no need to give a sublicensee the right to be involved in the modification or termination of a license to which it is not a party. However, many agencies allow a sublicensee to become a direct licensee if the license is terminated.

16. DOC proposes to modify the appeal rights in § 404.11 to remove a dispute over the interpretation of a license from being appealable except as it may relate to the termination of a license, which is appealable. DOC also proposes adding a right for a hearing when a license has been modified or terminated if there is a dispute over any relevant fact. Alternate Dispute Resolution is now being authorized instead of an appeal, if the parties agree.

17. DOC proposes to corrects the misspelling of ''owned'' in § 404.12.

18. DOC proposes to make the FOIA exemption in § 404.14 mandatory in accordance with the new law.

Classification

Executive Order 12866

This rule has been determined not to be significant for purposes of E.O. 12866.

Executive Order 13132

This rule does not contain policies with Federalism implications as that term is defined in E.O. 13132.

Administrative Procedure Act

This rule involves rules of agency practice and procedure under 5 U.S.C. 553(b)(A) and prior notice and an opportunity for public comment are, therefore, not required by the Administrative Procedure Act, or any other statute or regulation, for this rule.

Regulatory Flexibility Act

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule pursuant to 5 U.S.C. 553(b)(A), or by any other law, this rule is not subject to the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Paperwork Reduction Act

The proposed rule does not impose any new collection of information requirements under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*). However, OMB approval for the application for a license in 404.8 and the utilization reports in 404.5(a)(6) (number 0692–0006) expired on June 30, 2003, we are resubmitting the package to OMB. The time to complete the license application is estimated to be 2 hours and the utilization report 1 hour. These estimated response times include the time for completing and reviewing the collections of information.

Comments are invited on (a) whether the collections of information are necessary for the functions of the agencies; (b) the accuracy of the estimates on the time to complete and review the collected information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden on respondents to collect the information.

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 404

Inventions, Patents, Licenses.

Dated: January 4, 2005.

Benjamin H. Wu,

Assistant Secretary of Commerce for Technology Policy.

For the reasons set forth in the preamble, 37 CFR Part 404 is proposed to be amended as follows:

PART 404—LICENSING OF GOVERNMENT OWNED INVENTIONS

1. The authority citation for Part 404 is revised to read as follows:

Authority: 35 U.S.C. 207–209.

2. Section 404.1 is revised to read as follows:

§ 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. This part does not affect licenses which:

(a) Were in effect prior to [INSERT FINAL RULE EFFECTIVE DATE];

(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, including interferences; or

(d) Are otherwise authorized by law or treaty, including 35 U.S.C. 202(e), 35 U.S.C. 207(a)(3) and 15 U.S.C. 3710a, which also may authorize the assignment of inventions. Although licenses on inventions made under a cooperative research and development agreement (CRADA) are not subject to this regulation, agencies are encouraged to apply the same policies and use similar terms when appropriate. Similarly, this should be done for licenses granted under inventions where the agency has acquired rights pursuant to 35 U.S.C. 207(a)(3).

3. In § 404.3, paragraph (a) is revised to read as follows:

§ 404.3 Definitions.

(a) *Federally owned invention* means an invention, whether or not covered by a patent or patent application, or discovery which is or may be patentable or otherwise protectable under title 35, the Plant Variety Protection Act (7 U.S.C. 2321 *et seq.*) or foreign patent law, owned in whole or in part by the United States Government.

* * * * *

4. Section 404.4 is revised to read as follows:

§ 404.4 Authority to grant licenses.

Federally owned inventions shall be made available for licensing as deemed appropriate in the public interest and each agency shall notify the public of these inventions. The agencies having custody of these inventions may grant nonexclusive, co-exclusive, partially exclusive, or exclusive licenses thereto under this part. Licenses may be royalty-free or for royalties or other consideration. They may be for all or less than all fields of use or in specified geographic areas and may include a release for past infringement. Any license shall not confer on any person immunity from the antitrust laws or from a charge of patent misuse, and the exercise of such 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.

5. In Section 404.5, paragraph (a), paragraph (b)(2) and paragraphs (b)(4) through (b)(9) are revised to read as follows:

§ 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 satisfactory plan for development or marketing of the invention, or both, and with information about the applicant's capability to fulfill the plan. The plan for a non-exclusive research license may be limited to describing the research phase of development.

(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 license who agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States. However, this condition may be waived or modified if reasonable but unsuccessful efforts have been made to grant licenses to potential licensees that would be likely to manufacture substantially in the United States or if domestic manufacture is not commercially feasible.

(b) * * *

(1) * * *

(2) Any patent license may grant the licensee the right of enforcement of the licensed patent without joining the Federal agency as a party as determined appropriate in the public interest.

(3) * * *

(4) The license may provide the licensee 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 with any modifications thereto, shall be promptly 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 reasonable time as specified in the license, and 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 but only to the extent necessary to enable the agency to determine compliance with the terms of the license.

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

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

(i) The licensee is not executing its commitment to achieve practical application of the invention, including commitments contained in any plan submitted in support of 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) Termination 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;

(iv) The licensee commits a substantial breach of a covenant or provision contained in the license agreement, including the requirement in § 404.5(a)(2); or

(v) The licensee has been found by a court of competent jurisdiction to have violated the Federal antitrust laws in connection with its performance under the license agreement.

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

* * * * *

6. Section 404.6 is revised to read as follows:

§ 404.6 Nonexclusive licenses.

Nonexclusive licenses may be granted under federally owned inventions without a public notice of a prospective license.

7. Section 404.7 is revised to read as follows:

§ 404.7 Exclusive, co-exclusive and partially exclusive licenses.

(a)(1) Exclusive, co-exclusive or partially exclusive domestic licenses may be granted on federally owned inventions, 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 filing 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 public will be served by the granting of the license, in view of the applicant's intentions, plans and ability to bring the invention to the point of practical application or otherwise promote the invention's utilization by the public.

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

(C) The proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public;

(iii) The Federal agency has not determined that the grant of such a license will tend substantially to lessen competition or create or maintain a violation of the Federal 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 capability of the firms and as having equal or greater likelihood as those from other applicants to bring the invention to practical application within a reasonable time.

(2) In addition to the provisions of § 404.5, the following terms and conditions apply to domestic exclusive, co-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 or 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, co-exclusive or partially exclusive license.

(b)(1) Exclusive, co-exclusive or partially exclusive foreign licenses may be granted on a federally owned invention provided that;

(i) Notice of the prospective license, identifying the invention and prospective licensee, has been published in the **Federal Register**, providing opportunity for filing written objections within at least a 15-day period and following consideration of such 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 a license will tend substantially to lessen competition or create or maintain a violation of the Federal antitrust laws.

(2) In addition to the provisions of § 404.5, the following terms and conditions apply to foreign exclusive, co-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, co-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, co-exclusive or partially exclusive licenses.

§ 404.9 [Removed and reserved]

8. Section 404.9 is removed and reserved:

9. Section 404.10 is revised to read as follows:

§ 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 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.

10. Section 404.11 is revised to read as follows:

§ 404.11 Appeals.

(a) 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, modification, or termination of a license:

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

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

(3) 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.

(b) An appeal by a licensee under paragraph (a)(2) of this section may include a hearing, upon the request of the licensee, to address a dispute over any relevant fact. The parties may agree to Alternate Dispute Resolution in lieu of an appeal.

11. Section 404.12 is revised to read as follows:

§ 404.12 Protection and administration of inventions.

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

12. Section 404.14 is revised to read as follows:

§ 404.14 Confidentiality of information.

Title 35, United States Code, section 209, requires that any plan submitted pursuant to § 404.8(h) and any report required by § 404.5(b)(6) shall be treated as commercial or 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.

[FR Doc. 05–338 Filed 1–6–05; 8:45 am]

BILLING CODE 3510–18–P