

Under 5 U.S.C. 552a(k)(6), the head of an agency may promulgate rules to exempt a system of records from certain provisions of 5 U.S.C. 552a if the system is material used solely to determine individual qualifications for appointment or promotion in the Federal service. DO .306 TIGTA—Recruiting and Placement Records contains material used to determine an individual’s qualification for appointment or promotion in the Federal service. The provisions of the Privacy Act from which this system of records is exempt pursuant to 5 U.S.C. 552a(k)(6) are as follows: 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I), and (f).

The proposed rule requested that public comments be sent to the Office of Chief Counsel, Treasury Inspector General for Tax Administration, 1125 15th Street, NW., Suite 700A, Washington, DC 20005, no later than October 22, 2003.

TIGTA did not receive comments on the proposed rule. Accordingly, the Department of the Treasury is hereby giving notice that the following systems of records are exempt from certain provisions of the Privacy Act: DO .303—TIGTA General Correspondence; DO .306—TIGTA Recruiting and Placement; DO .307—TIGTA Employee Relations Matters, Appeals, Grievances, and Complaint Files; DO .308—TIGTA Data Extracts; DO .309—TIGTA Chief Counsel Case Files; and, DO .310—TIGTA Chief Counsel Disclosure Section Records.

As required by Executive Order 12866, it has been determined that this proposed rule is not a significant regulatory action, and therefore, does not require a regulatory impact analysis.

The regulation will not have a substantial direct effect on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

Pursuant to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601–612, it is hereby certified that these regulations will not significantly affect a substantial number of small entities. The final rule imposes no duties or obligations on small entities.

In accordance with the provisions of the Paperwork Reduction Act of 1995, the Department of the Treasury has determined that this final rule would not impose new record keeping, application, reporting, or other types of information collection requirements.

List of Subjects in 31 CFR Part 1

Privacy.

■ Part 1 Subpart C of Title 31 of the Code of Federal Regulations is amended as follows:

PART 1—[AMENDED]

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

Authority: 5 U.S.C. 301, 31 U.S.C. 321, subpart A also issued under 5 U.S.C. 552, as amended. Subpart C also issued under 5 U.S.C. 552a.

■ 2. Section 1.36 is amended as follows:

■ a. Paragraph (c)(1)(i) is amended by adding “DO .303—TIGTA General Correspondence; DO .307—TIGTA Employee Relations Matters, Appeals, Grievances, and Complaint Files; DO .308—TIGTA Data Extracts; DO .309—TIGTA Chief Counsel Case Files; DO .310—TIGTA Chief Counsel Disclosure Section Records” to the table in numerical order.

■ b. Paragraph (g)(1)(i) is amended by adding “DO .303—TIGTA General Correspondence; DO .307—TIGTA Employee Relations Matters, Appeals, Grievances, and Complaint Files; DO .308—TIGTA Data Extracts; DO .309—TIGTA Chief Counsel Case Files; DO .310—TIGTA Chief Counsel Disclosure Section Records” to the table in numerical order.

■ c. Paragraph (m)(1)(i) is amended by adding “DO .306—TIGTA Recruiting and Placement” to the table in numerical order.

■ d. Paragraph (o)(1) is amended by adding “DO .306—TIGTA Recruiting and Placement” to the table in numerical order. The additions to Sec. 1.36 read as follows:

§ 1.36 Systems exempt in whole or in part from provisions of 5 U.S.C. 522a and this part.

* * * * *
 (c) * * *
 (1) * * *
 (i) * * *

Number	System name
DO .303	TIGTA General Correspondence.
DO .307	TIGTA Employee Relations Matters, Appeals, Grievances, and Complaint Files.
DO .308	TIGTA Data Extracts.
DO .309	TIGTA Chief Counsel Case Files.
DO .310	TIGTA Chief Counsel Disclosure Section Records.

* * * * *
 (g) * * *
 (1) * * *

(i) * * *

Number	System name
DO .303	TIGTA General Correspondence.
DO .307	TIGTA Employee Relations Matters, Appeals, Grievances, and Complaint Files.
DO .308	TIGTA Data Extracts.
DO .309	TIGTA Chief Counsel Case Files.
DO .310	TIGTA Chief Counsel Disclosure Section Records.

* * * * *
 (m) * * *
 (1) * * *
 (i) * * *

Number	System name
DO .306	TIGTA Recruiting and Placement.

* * * * *
 (O) * * *
 (1) * * *

Number	System name
DO .306	TIGTA Recruiting and Placement.

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Dated: March 25, 2004.

Mary Beth Shaw,

Acting Deputy Assistant Secretary for Headquarters Operations.

[FR Doc. 04–7413 Filed 4–1–04; 8:45 am]

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DEPARTMENT OF COMMERCE

37 CFR Part 401

[Docket No. 950615153–3312–03]

RIN 0692–AA14

Assistant Secretary for Technology Policy; Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts, and Cooperative Agreements; Special Agreements To Provide Services for a Government Laboratory Under a Cooperative Research and Development Agreement (CRADA) With a Collaborating Party

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

ACTION: Final rule.

SUMMARY: The Under Secretary for Technology, United States Department of Commerce, is today issuing a final rule amending regulations to authorize Federal agencies to use an alternate patent rights clause in certain agreements with nonprofit organizations and small business firms to provide services at Government-owned and Government-operated and Government-owned and contractor-operated laboratories in connection with a CRADA between the laboratory and a collaborating party. A proposed rule, with a request for public comment, was published in the **Federal Register** on September 11, 2000 (65 FR 54826). This final rule responds to comments received in response to this **Federal Register** notice. The changes in this final rule include clarifications and editorial corrections.

DATES: This rule is effective on May 3, 2004.

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

SUPPLEMENTARY INFORMATION: Under the authority of 35 U.S.C. 206 and the delegation by the Secretary of Commerce in section 3(g) of DOO 10-18, the Assistant Secretary of Commerce for Technology Policy may issue revisions to 37 CFR part 401.

Background

Under the Bayh-Dole Act (Pub. L. 96-517), nonprofit and small business contractors and grantees have the option to retain rights in their inventions in order to facilitate the commercialization of the results of federally funded research. However, this option may be limited if an "exceptional circumstances" determination is made by the funding agency under 37 CFR 401.3(a)(2). The criteria for such a determination are exacting and the contractor or grantee may appeal such a determination within the agency. There is a need to limit the rights of certain contractors and grantees in their inventions when they are performing research for the Government under a cooperative research and development agreement (CRADA) with a collaborating party as authorized by the Federal Technology Transfer Act (Pub. L. 99-502) (FTTA). If these rights are not limited, the collaborating party would not receive the rights to which it would normally be entitled under a CRADA, which includes the option for an exclusive license to any CRADA invention made by a Government employee. Contractors are now being used at certain federally-owned laboratories of various agencies such as

the Department of Defense and the Environmental Protection Agency. The contracts are not usually entered into for securing research expertise of a particular company or individual but rather to provide general support to the operation of the laboratories.

Presently, some agencies using contractors for CRADAs have notified their collaborating parties that they will endeavor to acquire the necessary rights from their contractors but cannot promise that those rights will be obtained. Other agencies preclude their contractors from working on CRADAs or permit them to own their inventions whether or not made under a CRADA. When the Department of Defense proposed several years ago a special clause for their contractors limiting rights in their inventions, DOC was concerned that the exception was too broad and that the clause should encourage negotiation.

Since the laboratory's obligations under the FTTA do not technically apply to the inventions of its contractors or grantees, DOC does not consider that there is an actual conflict between the Bayh-Dole Act and the FTTA. Nevertheless, we do believe that the situation presents a conflict between the general policies of the Bayh-Dole Act and the specific directives of the FTTA. We think that allowing a contractor or grantee to work under a CRADA in such circumstances might be a negative factor or disincentive to the participation by private parties in a CRADA because they would not be assured of receiving rights in all CRADA inventions as mandated by the FTTA.

DOC published a proposed rule in the **Federal Register** on September 11, 2000 (65 FR 54826), seeking public comment on a proposal to add an alternate new subparagraph to paragraph (b) of the basic patent rights clause (37 CFR 401.14). The comment period closed October 11, 2000. The new subparagraph encourages the contractor or grantee to negotiate with the collaborating party but, in the absence of an agreement, provides certain minimum rights for the collaborating party in inventions made by the contractor or grantee. The provision of those minimum rights in the agreement constitutes an "exceptional circumstances" determination by the agency pursuant to 37 CFR 401.3(a)(2) and would be appealable under § 401.4. The rights would be of the same scope and terms the collaborating party would receive in an invention made by a Government laboratory employee under the CRADA, which is typically an option for an exclusive license. Although negotiation should occur prior

to the contractor or grantee starting work under the CRADA, it could be postponed with the permission of the Government until an invention is made by the contractor or grantee under the CRADA. The procedures for using the alternate clause are provided in new § 401.3(a)(5). The alternate clause is optional and laboratories may allow contractors or grantees to own their inventions made under a CRADA.

Summary of Public Comments Received by DOC in Response to the September 11, 2000 Proposed Rule and DOC's Response to Those Comments

DOC received four responses to the request for comments. Two responses were from Federal government agencies. One response was from a not-for-profit association of research universities and another from a private individual. An analysis of the comments follows.

Comment: One comment supported the proposed language which clarifies that, in the absence of a separate agreement with a contractor, the contractor is obligated to grant the collaborating party an option for a license in the contractor's CRADA inventions in the same scope and terms set forth in the CRADA for inventions made by the Government. However, the comment concluded that a Federal agency's use of the alternate rights clause may be limited if a determination of "exceptional circumstances" is made by the funding agency under 37 CFR 401.3(a)(2).

Response: DOC agrees with the comment with the exception of the conclusion which appears to be based on a misunderstanding of 37 CFR 401.3(a)(2). The regulation does not require a determination of "exceptional circumstances" to limit the use of the alternate rights clause. To the contrary, the determination authorizes the use of an alternate clause.

Comment: One comment suggested the phrase "the Government may require the Contractor to try to negotiate an agreement with the CRADA collaborating party or parties, over the rights to any subject invention the Contractor makes, solely or jointly" in the proposed 37 CFR 401.14(b)(2) could better be expressed by re-wording "to try to" and "over the rights."

Response: DOC agrees with the comment and has revised the phrase to read: "the Government may require the Contractor to negotiate an agreement with the CRADA collaborating party or parties regarding the allocation of rights to any subject invention the Contractor made, solely or jointly." In addition to the revisions suggested by the comment, the word "makes" was changed to

“made,” which is defined in the Bayh-Dole Act and the FTTA and the phrase “in the course of its work” was dropped because it does not appear in these laws.

Comment: One comment noted that the proposed rule was too narrowly drawn in that it applied only to CRADAs at Government-owned Government-operated (GOGO) laboratories. The comment suggested that the proposed rule should be broadened to include CRADAs at Government-owned contractor-operated (GOCO) laboratories.

Response: DOC agrees with the comment. Accordingly, changes were made to 37 CFR 401.14(c) of the proposed rule so that the rule now applies to both GOCOs and GOGOs.

Comment: One comment questioned whether the proposed regulatory change was sufficient to achieve the desired result, without additional amendments to the Bayh-Dole Act, because the need to grant the CRADA collaborator rights to inventions made by a laboratory contractor under a CRADA does not constitute “exceptional circumstances” as required by 35 U.S.C. 202(a)(ii). This comment also suggested that “support contractor” be defined and that in order to ensure exclusivity, support contractors should be denied all rights to CRADA inventions, including non-exclusive rights, particularly in a non-CRADA environment.

Response: DOC believes that the requirement of the Federal Technology Transfer Act (Pub. L. 99-502) that Federal laboratories “shall ensure through such agreement, that the collaborating party has the option to choose an exclusive license for a pre-negotiated field of use for any such invention” (15 U.S.C. 3710a(b)(1)) is sufficient justification to merit an “exceptional circumstances” determination for contractors or grantees working on CRADAs. Such a determination is consistent with the policies and objectives of the Bayh-Dole Act. At this time, DOC does not see a need to restrict the contractor from having any rights in its inventions. However, we dropped the word “support” from the term “support contractor” because it is subject to interpretation and have made it clear that the rule also applies to grantees working under CRADAs. Since the scope of this rule change is limited to CRADAs, there is no issue of rights in inventions not made under a CRADA.

Additional Information

Classification

Administrative Procedure Act:
Although the notice and comment

requirements of the Administrative Procedure Act (APA) are not applicable to this rule of agency policy pursuant to 5 U.S.C. 553(a)(2), all public comments received on this policy have been considered.

Executive Order 12866

This final rule has been determined to be not significant for purposes of E.O. 12866 (58 FR 51735, October 4, 1993).

Executive Order 13132

This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under E.O. 13132.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Assistant General Counsel for Legislation and Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy, Small Business Administration that this rule would not have a significant economic impact on a substantial number of small entities. No comments were received regarding this certification. As a result, no final regulatory flexibility analysis is required and none has been prepared.

Paperwork Reduction Act

This rule will impose no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

List of Subjects in 37 CFR Part 401

Inventions, Nonprofit organizations, Patents, Small business firms.

■ For the reasons set forth in the preamble, 37 CFR part 401 is amended as follows:

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

■ 1. The authority citation for 37 CFR part 401 continues to read as follows:

Authority: 35 U.S.C. 206 and the delegation of authority by the Secretary of Commerce to the Assistant Secretary of Commerce for Technology Policy at sec. 3(g) of DDO 10-18.

■ 2. Section 401.3 is amended by adding a new paragraph (a)(5) to read as follows:

§ 401.3 Use of the standard clauses at § 401.14.

(a) * * *

(5) If any part of the contract may require the contractor to perform work

on behalf of the Government at a Government laboratory under a Cooperative Research and Development Agreement (CRADA) pursuant to the statutory authority of 15 U.S.C. 3710a, the contracting officer may include alternate paragraph (b) in the basic patent rights clause in § 401.14. Because the use of the alternate is based on a determination of exceptional circumstances under § 401.3(a)(2), the contracting officer shall ensure that the appeal procedures of § 401.4 are satisfied whenever the alternate is used.

* * * * *

■ 3. A new paragraph (c) is added to § 401.14 to read as follows:

§ 401.14 Standard patent rights clauses.

* * * * *

(c) As prescribed in § 401.3, replace (b) of the basic clause with the following paragraphs (1) and (2):

(b) Allocation of principal rights. (1) The Contractor may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause, including (2) below, and 35 U.S.C. 203. With respect to any subject invention in which the Contractor retains title, the Federal Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

(2) If the Contractor performs services at a Government owned and operated laboratory or at a Government owned and contractor operated laboratory directed by the Government to fulfill the Government's obligations under a Cooperative Research and Development Agreement (CRADA) authorized by 15 U.S.C. 3710a, the Government may require the Contractor to negotiate an agreement with the CRADA collaborating party or parties regarding the allocation of rights to any subject invention the Contractor makes, solely or jointly, under the CRADA. The agreement shall be negotiated prior to the Contractor undertaking the CRADA work or, with the permission of the Government, upon the identification of a subject invention. In the absence of such an agreement, the Contractor agrees to grant the collaborating party or parties an option for a license in its inventions of the same scope and terms set forth in the CRADA for inventions made by the Government.

Phillip J. Bond,

Under Secretary of Commerce for Technology.
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