

**DEPARTMENT OF COMMERCE****National Institutes of Standards and Technology****15 CFR Part 17****[Docket No.: 160311228–6788–02]****RIN 0693–AB62****Technology Innovation—Personnel Exchanges****AGENCY:** National Institute of Standards and Technology (NIST), United States Department of Commerce.**ACTION:** Final rule.

**SUMMARY:** This final rule clarifies the appropriate use of Cooperative Research and Development Agreement (CRADA) authority by a Federal laboratory for personnel exchanges where the Federal laboratory has an existing relationship with the potential partner through another legal mechanism, as well as in the context of joint research projects or the development of existing laboratory technology, and through use of the General Services Administration's Presidential Innovation Fellows program for Federal laboratory Entrepreneur-In-Residence programs. Another objective of this rulemaking is to remove outdated regulations addressing the licensing of inventions owned by the Department of Commerce.

**DATES:** *Effective Date:* This rule is effective November 23, 2016.

**FOR FURTHER INFORMATION CONTACT:** Courtney Silverthorn, via email: [courtney.silverthorn@nist.gov](mailto:courtney.silverthorn@nist.gov), or by telephone: 301–975–4189.

**SUPPLEMENTARY INFORMATION:**

The Stevenson-Wydler Technology Innovation Act of 1980, Public Law 96–480, as amended (codified at title 15 of the United States Code (U.S.C.), Section 3701 *et seq.*) (the Stevenson-Wydler Act), sets forth a national policy to promote cooperation among academia, Federal laboratories, labor, and industry in order to facilitate the transfer of innovative federal technologies to United States and world markets. In furtherance of that policy, the Administration's *Lab to Market* initiative seeks to “significantly accelerate and improve technology transfer by streamlining administrative processes, facilitating partnerships with industry, evaluating impact, and opening federal research and development (R&D) assets as a platform for innovation and economic growth.” (*Lab to Market: Cross Agency Priority Goal Quarterly Progress Update, Fiscal Year 2015 Quarter 4*). One proven method to ensure that federal

innovations are made available to industry and the public is to encourage frequent interactions among Federal laboratories, academic institutions, and industry, including small businesses.

The final rule clarifies the appropriate use of CRADA authority under 15 U.S.C. 3710a for personnel exchanges where a Federal laboratory has an existing relationship with the potential partner through another legal mechanism, such as a grant or cooperative agreement. The final rule also promotes the use of existing authorities to implement personnel exchange programs at Federal Laboratories: (1) By utilizing the existing CRADA authority to transfer personnel to and from a Federal laboratory for joint research projects or the development of existing laboratory technology; and (2) by utilizing the General Services Administration (GSA)'s Presidential Innovation Fellows program to offer Federal laboratories additional options for implementing Entrepreneur-In-Residence programs.

The final rule also provides for the deletion of all existing provisions in part 17 of title 15 of the Code of Federal Regulations (CFR), “Licensing of Government-Owned Inventions in the Custody of the Department of Commerce,” which are outdated. Outdated subpart A implemented for the Department of Commerce licensing rules found at 41 CFR part 101–4, which were themselves removed at 50 FR 28402, July 12, 1985. Outdated subpart B was reserved. Outdated subpart C set forth appeal procedures addressed to the outdated licensing rules of subpart A. All subparts are obsolete, and the rules governing the licensing of government-owned inventions are today found in 37 CFR part 404. The heading of part 17 will be revised to read “Personnel Exchanges Between Federal Laboratories and Non-Federal Entities,” and five new sections are added.

Section 17.1, Scope, sets forth the scope of revised part 17, which is to implement 15 U.S.C. 3712 and clarifies the appropriate use of personnel exchanges in relation to Federal laboratory CRADAs under the authority of 15 U.S.C. 3710a(a)(1), including CRADAs involving as parties recipients of Federal funding under grants (including cooperative agreements) and contracts, which could include National Network for Manufacturing Innovation awardees.

Section 17.2, Definitions, provides definitions for certain terms used in this part.

Section 17.3, Exchange of Federal Laboratory Personnel with Recipients of Federal Funding, provides in paragraph (a) that the existence of a funding

agreement (as defined in 35 U.S.C. 201(b)) between a Federal laboratory and a contractor shall not preclude a CRADA with that contractor, where the Federal laboratory director makes a determination that the technical subject matter of the funding agreement is sufficiently distinct from that of the CRADA. Paragraph (a) also provides that a contractor which is a collaborating party shall in no event transfer funds to a Federal laboratory under a CRADA using funds awarded to the contractor by that laboratory.

Paragraph (b) of § 17.3 provides that a Federal laboratory may exchange personnel with a contractor under a CRADA where the determination required under paragraph (a) cannot be made, provided that the CRADA includes at least one collaborating party in addition to the Federal laboratory and that contractor. In that circumstance, the Federal laboratory shall not provide services, property, or other resources to that contractor under the CRADA, and if any individual terms of that contractor's funding agreement conflict with the terms of the multi-party CRADA, then the funding agreement terms will control as applied to that contractor and the Federal laboratory only.

Paragraph (c) of § 17.3 sets forth a number of factors which may be taken into account in making the “sufficiently distinct” determination required under paragraph (a), including whether the conduct of specified research or development efforts under the CRADA would require the contractor to perform tasks identical to those required under the funding agreement; whether existing intellectual property to be provided by the Federal laboratory or the contractor under the CRADA is the same as that provided under, or referenced in, the funding agreement; whether the contractor's employees performing the specified research or development efforts under the CRADA are the same employees performing the tasks required under the funding agreement; and whether services, property or other resources contemplated by the Federal Laboratory to be provided to the contractor for the specified research or development efforts under the CRADA would materially benefit the contractor in the performance of tasks required under the funding agreement.

Section 17.4, Personnel Exchanges from a Federal Laboratory, provides in paragraph (a)(1) that a Federal laboratory may exchange its personnel with a collaborating party under a CRADA where no invention currently exists. Under paragraph (a)(2), a Federal laboratory may exchange personnel with

a non-Federal collaborating party for the purposes of developing or commercializing an invention in which the Federal government has an ownership interest, including an invention made by an employee or former employee while in the employment or service of the Federal government, and such personnel exchanged may include such employee who is an inventor. Paragraph (a)(2) also provides that funding may be provided by the non-federal collaborating party to the Federal laboratory for the participation of the Federal employee in developing or commercializing an invention, including costs for salary and other expenses, such as benefits and travel. Consistent with guidance in the Office of Legal Counsel's Memorandum for Gary Davis, Acting Director, Office of Government Ethics, September 7, 2000, "Application of 18 U.S.C. 209 to Employee-Inventors Who Receive Outside Royalty Payments,"<sup>1</sup> paragraph (a)(2) also sets forth that royalties from inventions received through a license agreement negotiated with the Federal laboratory and paid by the laboratory to an inventor who is a Federal employee are considered Federal compensation. Paragraph (a)(3) provides that where an employee leaves Federal service in order to receive salary or other compensation from a non-Federal organization, a Federal laboratory may use reinstatement authority in accordance with 5 CFR 315.401, or other applicable authorities, to rehire the former Federal employee at the conclusion of the exchange.

In exchanging personnel with a collaborating party under a CRADA, as in any other exercise of the CRADA authority, a Federal Laboratory should take into account the provisions of 15 U.S.C. 3710a(c)(3) regarding standards of conduct for its employees for resolving potential conflicts of interest.

Section 17.5, Personnel Exchanges to a Federal laboratory, provides that a Federal laboratory may provide funds for non-federal personnel exchanged in order to bring into a Federal laboratory outside personnel with expertise in scientific commercialization through the Presidential Innovation Fellows program, and that a laboratory will engage with the General Services Administration (GSA) to transfer funding for exchanged personnel and to select and place Entrepreneurs-In-Residence at the laboratory for the purposes of evaluating the laboratory's

technologies, and providing technical consulting to facilitate readying a technology for commercialization by an outside entity.

#### Response to Comments

During the proposed rule comment period, NIST received one written comment that noted that the changes likely posed no additional burden to universities, but requested additional time to provide comments due to the academic schedule of university staff.

*Discussion:* NIST appreciates the interest of the academic community in the rule. It is anticipated that these clarifications will strengthen the ability of Federal laboratories and partners through other agreements to work together with a third party, often a university, to support economic development and commercialization in the United States. NIST conducted extensive outreach to multiple groups that support universities to note the availability of the proposed rulemaking, and provided a link to the proposed rulemaking to the National Academies of Science Government-University-Industry Research Roundtable, which was distributed to their mailing list. We believe, as noted within the comment, that these changes are clarifications and that the lack of substantive comments from academia, as well as industry, is indicative of a lack of specific concerns rather than a lack of time and therefore do not believe an extended comment period is warranted.

#### Changes From the Proposed Rule

The final rule contains no substantive changes from the proposed rule.

#### Classification

NIST has determined that the final rule is consistent with the Stevenson-Wydler Act of 1980 and its amendments and other applicable law.

#### Executive Order 12866

This final rule was determined to be not significant for purposes of Executive Order 12866.

#### Executive Order 13132

This final rule does not contain policies with Federalism implications as defined in Executive Order 13132.

#### Regulatory Flexibility Act

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the

certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

#### Paperwork Reduction Act

This final rule contains no new collection of information subject to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

#### National Environmental Policy Act

This rule will not significantly affect the quality of the human environment. Therefore, an environmental assessment or Environmental Impact Statement is not required to be prepared under the National Environmental Policy Act of 1969.

#### List of Subjects in 15 CFR Part 17

Federal employees, Inventions and patents, Laboratories, Research and development, Science and technology, Technology transfer.

#### Kent Rochford,

*Associate Director for Laboratory Programs, National Institute of Standards and Technology.*

For the reasons stated in the preamble, the National Institute of Standards and Technology revises 15 CFR part 17 as follows:

### PART 17—PERSONNEL EXCHANGES BETWEEN FEDERAL LABORATORIES AND NON-FEDERAL ENTITIES

#### Sec.

##### 17.1 Scope.

##### 17.2 Definitions.

##### 17.3 Exchange of Federal laboratory personnel with recipients of Federal funding.

##### 17.4 Personnel exchanges from a Federal laboratory.

##### 17.5 Personnel exchanges to a Federal laboratory.

**Authority:** 15 U.S.C. 3712.

#### § 17.1 Scope.

(a) The Stevenson-Wydler Technology Innovation Act of 1980, Public Law 96-480, as amended (codified at title 15 of the United States Code (U.S.C.), section 3701 *et seq.*) (the Stevenson-Wydler Act), sets forth a national policy to renew, expand, and strengthen cooperation among academia, Federal laboratories, labor, and industry, in forms including personnel exchanges (15 U.S.C. 3701(3)). One proven method to ensure that Federal innovations are passed to industry and the public is to encourage frequent interactions among Federal laboratories, academic institutions, and industry, including both large and small businesses. In

<sup>1</sup> [https://www.oge.gov/web/oge.nsf/Legal%20Interpretation/604EE82C4CA3404A85257EF200502488/\\$FILE/op-olc-v024-p0170\\_0.pdf?open](https://www.oge.gov/web/oge.nsf/Legal%20Interpretation/604EE82C4CA3404A85257EF200502488/$FILE/op-olc-v024-p0170_0.pdf?open).

accordance with applicable ethics regulations and Agency policies, exchanges of personnel between Federal laboratories and outside collaborators should be encouraged (15 U.S.C. 3702(5)). Models that include Federal funding, as well as those that are executed without Federal funding, are encouraged.

(b) This part implements 15 U.S.C. 3712 and provides clarification regarding the appropriate use of personnel exchanges in relation to Federal laboratory Cooperative Research and Development Agreements (CRADAs) under the authority of 15 U.S.C. 3710a.

(c) This part is applicable to exchanges of personnel between Federal laboratories and parties to a CRADA under 15 U.S.C. 3710a(a)(1).

#### **§ 17.2 Definitions.**

(a) The term *funding agreement* shall have the meaning according to it under 35 U.S.C. 201(b).

(b) The term *contractor* shall have the meaning according to it under 35 U.S.C. 201(c).

(c) The term *Federal laboratory* shall have the meaning according to it under 15 U.S.C. 3703(4).

#### **§ 17.3 Exchange of Federal laboratory personnel with recipients of Federal funding.**

(a) In accordance with 15 U.S.C. 3710a(b)(3)(A) and 3710a(d)(1), a Federal laboratory may provide personnel, services, property, and other resources to a collaborating party, with or without reimbursement (but not funds to non-Federal parties) for the conduct of specified research or development efforts under a CRADA which are consistent with the missions of the Federal laboratory. The existence of a funding agreement between a Federal laboratory and a contractor shall not preclude the Federal laboratory from using its authority under 15 U.S.C. 3710a to enter into a CRADA with the contractor as a collaborating party for the conduct of specified research or development efforts, where the director of the Federal laboratory determines that the technical subject matter of the funding agreement is sufficiently distinct from that of the CRADA. In no event shall a contractor which is a collaborating party transfer funds to a Federal laboratory under a CRADA using funds awarded to the contractor by that laboratory.

(b) (1) A Federal laboratory may enter into a CRADA with a contractor as a collaborating party for the purpose of exchange of personnel for the conduct of specified research or development

efforts where the determination required under paragraph (a) of this section could not be made, provided that:

(i) The CRADA includes at least one collaborating party in addition to the Federal laboratory and that contractor; and

(ii) The Federal laboratory shall not provide services, property or other resources to that contractor under the CRADA.

(2) Where a Federal laboratory enters into a CRADA with a contractor under this paragraph (b), the terms of that contractor's funding agreement shall normally supersede the terms of the CRADA, to the extent that any individual terms conflict, as applied to that contractor and the Federal laboratory only.

(c) In making the determination required under paragraph (a) of this section, the director of a Federal laboratory may consider factors including the following:

(1) Whether the conduct of specified research or development efforts under the CRADA would require the contractor to perform tasks identical to those required under the funding agreement;

(2) Whether existing intellectual property to be provided by the Federal laboratory or the contractor under the CRADA is the same as that provided under, or referenced in, the funding agreement;

(3) Whether the contractor's employees performing the specified research or development efforts under the CRADA are the same employees performing the tasks required under the funding agreement; and

(4) Whether services, property or other resources contemplated by the Federal laboratory to be provided to the contractor for the specified research or development efforts under the CRADA would materially benefit the contractor in the performance of tasks required under the funding agreement.

#### **§ 17.4 Personnel exchanges from a Federal laboratory.**

(a) For personnel exchanges in which a Federal laboratory maintains funding for Federal personnel provided to a collaborating party—

(1) in accordance with 15 U.S.C. 3710a(b)(3)(A), a Federal laboratory may exchange personnel with a collaborating party for the purposes of specified scientific or technical research towards a mutual goal consistent with the mission of the Agency, where no invention currently exists, or

(2) in accordance with 15 U.S.C. 3710a(b)(3)(C), a Federal laboratory may exchange personnel with a non-Federal

collaborating party for the purposes of developing or commercializing an invention in which the Federal government has an ownership interest, including an invention made by an employee or former employee while in the employment or service of the Federal government, and such personnel exchanged may include such employee who is an inventor.

(i) Funding may be provided under a CRADA by the non-Federal collaborating party to the Federal laboratory for the participation of the Federal employee in developing or commercializing an invention, including costs for salary and other expenses, such as benefits and travel.

(ii) Royalties from inventions received through a license agreement negotiated with the Federal laboratory and paid by the Federal laboratory to an inventor who is a Federal employee are considered Federal compensation.

(3) Where an employee leaves Federal service in order to receive salary or other compensation from a non-Federal organization, a Federal laboratory may use reinstatement authority in accordance with 5 CFR 315.401, or other applicable authorities, to rehire the former Federal employee at the conclusion of the exchange.

#### **§ 17.5 Personnel exchanges to a Federal laboratory.**

For exchanges in which a Federal laboratory provides funds for the non-federal personnel—

(a) Outside personnel with expertise in scientific commercialization may be brought in to a Federal laboratory through the Presidential Innovation Fellows program or related programs (see 5 CFR 213.3102(r)) for Entrepreneur-In-Residence programs or similar, related programs run by the General Services Administration (GSA) or other Federal Agencies.

(b) A laboratory may engage with the GSA or other relevant Agency to transfer funding for exchanged personnel, and may work with such agency to select and place Entrepreneurs-In-Residence at the laboratory for the purposes of evaluating the laboratory's technologies, and providing technical consulting to facilitate readying a technology for commercialization by an outside entity.

**Phillip Singerman,**

*Associate Director for Innovations and Industry Services.*

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