Guidance for Preparing Annual Agency Technology Transfer Reports Under the Technology Transfer Commercialization Act

> Prepared by The Technology Partnerships Office National Institute of Standards and Technology U.S. Department of Commerce

> > in conjunction with

The Interagency Working Group on Technology Transfer

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## 1 INTRODUCTION: STATUTE SUMMARY

Under the Technology Transfer Commercialization Act of 2000 (P.L. 106-404), each Federal agency that operates or directs one or more Federal laboratories, or that conducts activities under sections 207 and 209 of title 35, United States Code, must submit to the Office of Management and Budget (OMB), as part of its annual budget submission, an annual performance report addressing the technology transfer activities of its Federal laboratories.<sup>1</sup>

According to OMB Circular A-11,<sup>2</sup> this report is to be provided by January 31 to the agency's OMB program examiner and a copy submitted to the National Institute of Standards and Technology (NIST). Statistics and other relevant data from each agency's technology transfer report will be consolidated and summarized in the Secretary of Commerce's Annual Summary Report to the President, the Congress, and U.S. Trade Representative on the status of Federal laboratory technology transfer.<sup>3</sup>

The two main categories of information that are requested include 1) a description of the current technology transfer programs and plans of the agency's Federal laboratories, and 2) statistics and other relevant data that describe the Federal laboratories' intramural activities and achievements in technology transfer over the most recently closed fiscal year and the 4 years prior. Reports should also include selected abstracts of intramural economic impact studies that have been completed during the fiscal year (if any). Data related to extramural activities is not included in this report.

The following tables have been designed to facilitate the reporting of the requested statistics. Agencies may transfer copies of these tables to a text file for use in preparing their annual report. Expansions or format modifications of the tables may be done to meet an agency's specific needs. Agencies may exclude any table or metric if the corresponding mechanism(s) are not used by the agency over the time periods covered.<sup>4</sup> Since "technology transfer" at an agency may be broader than the activities this report is required by statute to include, agencies may also report additional voluntary metrics that more fully capture their technology transfer activities in section 6, "Other Performance Measures Deemed Important by the Agency". Appendix A of this guidance lists a number of metrics that are currently reported by at least one agency and is intended to be informative for agencies as they determine what additional metrics they may like to report.

Once an agency's annual technology transfer report has been cleared by the agency's management, one copy is to be sent to the agency's OMB examiner along with a copy of the agency's proposed annual budget, and another copy is to be sent to NIST c/o: Technology Partnerships Office, <u>t2report@nist.gov</u>.

<sup>&</sup>lt;sup>1</sup> 15 U.S. Code § 3710 (f)(1)

<sup>&</sup>lt;sup>2</sup> OMB Circular A-11, Section 25, Table 1

<sup>&</sup>lt;sup>3</sup> 15 US. Code § 3710 (g)(2)

<sup>&</sup>lt;sup>4</sup> At the time of this revision, legislative changes are being proposed which include changing the metrics required with the statute; however, unless and until there are any statutory changes, these metrics continue to be required. Specific metrics identified for possible removal are highlighted in red within this guidance document. If the statute is revised, this guidance document will be updated to reflect any changes.

## 2 INVENTION DISCLOSURES AND PATENTS

The number of invention disclosures, non-provisional patent applications filed, and patents issued are the most often cited metrics of active management of intellectual assets and technical know-how.

Definitions can be found in Section 9 of the guidance document.

	Table 1: Invention Disclosures and Patenting							
		FY-4	FY-3	FY-2	FY-1	FY		
1	Invention Disclosures Received							
2	Total Patent Applications Filed							
3	U.S.							
4	Foreign							
5	Total PCT Applications Filed							
6	Total Patents Issued							
7	U.S.							
8	Foreign							

#### Table 1: Invention Disclosures and Patenting<sup>5</sup>

#### **3** LICENSES

Successful development and commercialization of agency technologies benefit the nation's economy by contributing to competitiveness and economic growth. Without the ability to grant licenses to develop and commercialize government-owned technologies and inventions, many innovations would languish within laboratories and would not be further developed into products or services. Licensing is the primary mechanism used to transfer research use rights and/or commercialization rights of government-owned technologies and inventions.

The licensing of government-owned patents is one of the tools used to promote the utilization and commercialization of inventions that arise from agency-supported R&D. The government may grant licenses to the private sector for use of federally funded inventions. These licenses are referred to as "transfer mechanisms" and are counted in this report. Licenses granted to the government from the private sector are not counted because they do not involve the transfer of federally developed technologies.

Under 15 USC 3710(f)(2)(B)(iii) agencies should report the number of active licenses that produce income for the agency and separate these licenses according to type (i.e., exclusive, partially exclusive, or nonexclusive). This report also distinguishes between invention licenses (e.g., patentable subject inventions) and other licenses (e.g., copyright, trademark, etc.). Agencies should revise the table as necessary to provide a comprehensive report of their individual licensing activities.

<sup>&</sup>lt;sup>5</sup> Enter "0" to report there are no incidences of a mechanism that is being used by the agency. Enter "n.a." to report data are not available at time of report. Add rows and interpretive notes as needed.

In addition, 15 USC 3710(f)(2)(B)(iii) also requires agencies to report the average, minimum, and maximum amount of time that elapsed from the date on which each license was requested by the licensee in writing to the date on which each license was executed. Reporting requirements under 15 USC 3710(f)(2)(B)(vi) include the number of licenses terminated for cause.

Definitions can be found in Section 9 of this guidance document.

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	20								
22 Licenses Terminated for Cause	21	Maximum (months)							
	22	Licenses Terminated for Cause							

Table 2: Licenses

#### 4 INCOME FROM LICENSING

Under 15 USC 3710(f)(2)(B)(iv), agencies must report the disposition of total earned royalty income including the breakdown of total earned royalty income for the top 1 percent, 5 percent, and 20 percent of the licenses, and the range of royalty income. However, the statute is clear that these distributional statistics may be suspended if such information would inappropriately reveal the amount of income associated with an individual license or licensee. In this case include the table below and enter "n.r." in the appropriate cells.

Reporting requirements under 15 USC 3710(f)(2)(B)(v) include the disposition of the income in clause (iv).

Definitions can be found in Section 9 of this guidance document.

Table 3: Income from Licensing							
		FY-4	FY-3	FY-2	FY-1	FY	
23	Invention License Income						
24	Other License Income						
25	Total Earned Royalty Income (ERI)						
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26	ERI from Top 1% of Licenses						
27	ERI from Top 5% of Licenses						
28	ERI from Top 20% of Licenses						
29	Minimum ERI						
30	Maximum ERI						
31	Median ERI						
	Disposition of ERI						
32	Percentage Distributed to Inventors						
33	Percentage Distributed to Lab/Agency						

#### **Table 3: Income from Licensing**

### 5 COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS AND OTHER COLLABORATIVE AGREEMENTS

Cooperative Research and Development Agreements (CRADAs) are authorized by 15 USC 3710a. They provide Federal laboratories with a flexible vehicle to cooperate with other Federal and non-federal parties, including facilitating the transfer of technologies from Federal laboratories to the non-federal sector and providing access to other R&D assets at Federal labs. The primary purpose is to allow government-owned, government-operated and government-owned, contractor-operated laboratories to enter into collaborative R&D agreements for technology transfer with all types of organizations.

CRADAs allow Federal laboratories to enter into agreements with other Federal agencies; nonfederal parties (i.e., units of state or local government; industry organization; private and public foundation; universities and other nonprofit organizations; and/or other persons, including individuals who are licensees of government-owned inventions) to conduct specified research and development-related activities that are consistent with the laboratory's mission. The

Government, through its laboratories, may provide personnel, services, facilities, equipment, intellectual property, or other resources with or without reimbursement (but not funds to nonfederal parties) and the non-federal parties may provide funds, personnel, services, facilities, equipment, intellectual property, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the laboratory. The CRADA may not include a procurement contract, grant, or cooperative agreement as those terms are used in sections 6303, 6304, and 6305 of Title 31.

Other Collaborative Agreements may include Material Transfer and Facility Use Agreements and other agreement types that do not cite the CRADA statute or include a research plan or statement of work. Definitions can be found in Section 9 of this guidance document.

		FY-4	FY-3	FY-2	<b>FY-1</b>	FY
34	Total Active CRADAs					
35	New CRADAs					
36	New CRADAs					
	Involving Small					
	Businesses					
37	Other Collaborative Agreements <sup>7</sup>					

 Table 4: Collaborative Agreements<sup>6</sup>

## 6 OTHER PERFORMANCE MEASURES DEEMED IMPORTANT BY THE AGENCY

Metrics reported under this heading will depend on what other measures agencies elect to provide. Agencies may consider presenting this information in a separate table (as shown below) or add this information at appropriate points in one or more of the tables presented above. Appendix A provides a list of additional performance measures that are reported by one or more agencies.

NIST obtains publications metrics from the Scopus (Elsevier) databases that are reported on a fractional-count and whole-count basis. Since this database is not all inclusive of publications that agency researchers utilize, agencies should include their own publications metrics to provide a more accurate count.

<sup>&</sup>lt;sup>6</sup> Enter "0" to report there are no incidences of a mechanism that is being used by the agency. Enter "n.a." to report data are not available at time of report. Add rows and interpretive notes as needed.

<sup>&</sup>lt;sup>7</sup> In a footnote, please describe the types of relationships and provide a citation for the authority to execute those agreements.

	FY-4	FY-3	FY-2	FY-1	FY
(Add agency-specific metrics)					
"any other parameters or discussion that the agency deems relevant or unique to its practice of technology transfer"					

#### Table 6: Other Intramural Performance Measures Deemed Important by the Agency

# 7 SUCCESS STORIES DEMONSTRATING DOWNSTREAM OUTCOMES FROM TECHNOLOGY TRANSFER ACTIVITIES

In this section each agency is asked to provide anecdotal evidence in the form of success stories that demonstrate the broad range of positive impacts and downstream outcomes achieved by their technology transfer activities. This should include three to five stories (approximately one page each) on different technology transfer developments that took place during the fiscal year and have notable impacts, for example life-saving treatments, increased security or awareness about dangers and hazards, new business start-ups, products, etc. Supporting pictures are encouraged provided they include citations for their legal use.

# **8 ECONOMIC IMPACT STUDIES**

Agencies that produce impact studies should include a summary of those studies in their reports. Note that since this report deals with Federal technology transfer activities, impact studies should primarily involve intramural research rather than extramural research performed solely by nonfederal researchers.

# **9 DEFINITIONS**

**Cooperative Research and Development Agreement (CRADA):** An agreement that is executed under the authority of 15 USC 3710a and that includes a Research Plan or Statement of Work.<sup>8</sup>

**Disposition of Income:** As required by Federal technology transfer legislation, specific incentives are in place to encourage government employees to participate in the technology transfer process. Typically, government employees who invent are entitled to a share of license revenues received by the Federal agency from licensing their inventions. According to 15 USC 3710c<sup>9</sup>, a federal agency must pay the first \$2,000 per year in license income and a minimum of 15% of the yearly income thereafter from all inventions to the inventors. Each agency is permitted to enact its own sharing scheme; however, the maximum that a single inventor can

<sup>&</sup>lt;sup>8</sup> This definition of CRADA differentiates agency R&D activities from other CRADA uses and includes agreements that both do and do not include IP licensing rights.

<sup>&</sup>lt;sup>9</sup> https://www.govinfo.gov/content/pkg/USCODE-2011-title15/pdf/USCODE-2011-title15-chap63-sec3710c.pdf

receive per year is \$150,000.<sup>10</sup> Any residual funds are usually distributed to the activity where the intellectual property was developed.

Exclusive License: Grants the licensee the sole right to use, make, or sell an invention.

**Extramural:** Activities conducted outside a Federal laboratory with Federal funds through a contract, grant, or cooperative agreement.

**Federal Technology Transfer:** Technology transfer activities for intramural research that are conducted by federal laboratories as defined in 15 USC 3703.

**Foreign Patent Application:** Foreign patent applications filed during the fiscal year that result in their own unique patent number, including national stage applications. This does not include Patent Cooperation Treaty (PCT) applications; only includes applications that would result in their own unique patent number. Includes joint applications where the other party is filing the application, since the agency would have patent ownership.

**Income-Bearing Invention License:** An invention license for which the agency may receive payment during the term of the license; it has the ability to have earned income. It excludes royalty-free agreements, such as research licenses.

**Income-Bearing Other License:** A license that is not an invention license (see definition below) for which the agency may receive payment during the term of the license; it has the ability to have earned income.

**Intramural:** Activities conducted within government-owned laboratories, funded through the reporting agency or another Federal agency. Work is carried out by agency or lab personnel.

**Invention:** Any art or process, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the patent laws of the United States.<sup>11</sup>

**Invention Disclosures:** Federal employees are required to report inventions in a reasonable time though the agency's Invention Disclosure Form. The number of Invention Disclosures refers to the number of invention disclosure forms submitted to an agency's management during the fiscal year.

**Invention License:** An invention license includes patents, biological materials, plant varieties, or tangible materials. It can be income bearing or non-income bearing.

**Invention License Income:** Income to the lab resulting from income-bearing invention licenses (see definition above). It includes any one-time or reoccurring income. It includes, but is not

<sup>&</sup>lt;sup>10</sup> Per the National Defense Authorization Act for Fiscal Year 2018 (P.L. 114-328), under a 5-year pilot program, DoD inventors currently employed by DOD may receive up to \$500,000 per year.

<sup>&</sup>lt;sup>11</sup> As defined in 37 CFR 501.3(d)

limited to: earned royalties, license issue fees, minimum annual royalties, paid-up licenses, past and future patent costs, and milestone payments.

**Issued Foreign Patents:** Foreign patents received in any non-U.S. country during the fiscal year. Does not include Patent Cooperation Treaty applications or any other provisional-type application.

**Issued U.S. Patents:** Patents "issued in the name of the United States of America, under the seal of the Patent and Trademark Office, and shall be signed by the Director or have his signature placed thereon and shall be recorded in the Patent and Trademark Office."<sup>12</sup>

**License:** A written contract between the owner/licensor of a patent, copyright, trademark, knowhow, service mark, or other intellectual property, and a licensee to use, manufacture, or sell copies of the original. Commercialization of a technology is a major purpose for licensing agreements. These contracts typically (1) limit the licensee's scope or field, (2) make the license exclusive or nonexclusive, (3) demands royalties or other compensation if further licensing occurs by the licensee.<sup>13</sup> The government may grant non-exclusive, partially exclusive, or exclusive licenses.

**Licenses Terminated for Cause:** All licenses include the right of the Federal agency, laboratory director, or designee to either partially or fully terminate a license agreement. Termination may occur if the laboratory director determines that the licensee is not executing the plan submitted with the license application and is unable to achieve practical applications<sup>14</sup> of the invention within a reasonable time. Other reasons for termination include: public use requirements that might be stipulated in any subsequent Federal legislation promulgated after the agreement; the licensee made a false statement or omitted a material fact in the license: or the licensee has been found to have violated Federal Antitrust laws in connection with performance under the license.

**Maximum Earned Royalty Income:** The maximum amount of royalty income earned from a license during the fiscal year.

**Median Earned Royalty Income:** The amount of royalty income earned from a license whose income is halfway between the minimum and maximum royalty income earned during the fiscal year.

**Minimum Earned Royalty Income:** The minimum (non-zero) amount of royalty income earned from a license during the fiscal year.

**Non-Exclusive Licenses:** A license in which the same rights to use, make, and sell products/services based on the intellectual property are granted to more than one licensee within the same scope or field, consecutively or simultaneously. This includes co-exclusive licenses.

<sup>12</sup> 35 USC 153

<sup>13</sup> https://thelawdictionary.org/licensing-agreement/

<sup>&</sup>lt;sup>14</sup> 37 CFR 404.3(d)

**Other Collaborative R&D Relationship:** Any agreement that is not executed under the authority of 15 USC 3710a, or cites 15 USC 3710a but does not include a Research Plan or Statement of Work. These may include, but are not limited to, material transfer agreements, trust fund cooperative agreements, material transfer research agreements, facility use agreements, technical assistance agreements, and Space Act agreements.

**Other License:** Includes licenses which are excluded in Invention Licenses, such as copyright, trademark, or commercial evaluation licenses, that may or may not be income-bearing. Open-source licenses are not included.

**Other License Income:** Income resulting from income-bearing licenses that are not classified under invention licenses. It includes any one-time or reoccurring income. It includes, but is not limited to, earned royalties, license issue fees, minimum annual royalties, paid-up licenses, past and future patent costs, and milestone payments.

**Partially Exclusive License:** A license that restricts the licensee to a specific field of use, geography, or term. Multiple partially exclusive licenses may be granted for one invention or patent. Note that in this report, each partially exclusive license counts as one license.

**Patent:** A legal document which provides protection to the ideas of any individual. Usually issued by the Patent Office of a country, the patent is granted to any firm or individual.<sup>15</sup> For more information refer to 35 USC 101, 35 USC 102, and 35 USC 103. This includes patents in which the Government-owned, Government-operated or Government-owned, Contractor-operated lab has ownership interest where the patent is jointly owned with another party regardless of which party leads the filing or licensing.

**Patent Cooperation Treaty (PCT):** The Patent Cooperation Treaty (PCT) is an international treaty with more than 150 Contracting States. The PCT makes it possible to seek patent protection for an invention simultaneously in a large number of countries by filing a single "international" patent application instead of filing several separate national or regional patent applications.<sup>16</sup>

**PCT Applications Filed:** Any application filed under the authority of the Patent Cooperation Treaty. PCT applications are not included in the metric "Total Patent Applications Filed" because they do not result in patents.

**Provisional Patent Application:** A provisional application for patent (provisional application) is a U.S. national application filed in the USPTO under 35 USC 111(b). It is not required to have a formal patent claim or an oath or declaration. It establishes an early filing date but does not mature into an issued patent unless the applicant files a regular non-provisional patent application within one year.<sup>17</sup>

<sup>&</sup>lt;sup>15</sup> <u>https://thelawdictionary.org/patent-2/</u>

<sup>&</sup>lt;sup>16</sup> https://www.uspto.gov/patents-getting-started/international-protection/patent-cooperation-treaty

<sup>&</sup>lt;sup>17</sup>https://www.uspto.gov/patents-getting-started/patent-basics/types-patent-applications/provisional-application-patent

**Small Business Concern:** A small business firm that meets the standards maintained by the U.S. Small Business Administration in its implementation of 13 CFR 121.5.

**U.S. Patent Application:** Non-provisional U.S. patent application filed at the United States Patent and Trademark Office. This includes: non-provisional U.S. applications in which the agency or lab has an ownership interest; non-provisional applications where the invention is owned jointly with another party, regardless of which party is filing the application; and applications such as continuations, continuations in part and divisional applications. This number does not include provisional applications or PCT applications.

#### TECHNOLOGY TRANSFER "À LA CARTE METRICS MENU"

The "à la carte Metrics Menu" was developed by Strategy Team 5 of the National Science and Technology Council (NSTC) Lab to Market Subcommittee and comprises a set of metrics that were collected by various agencies in excess of those that they are legally required to report under 15 USC 3710 (f)(2)(B).<sup>18</sup> The Strategy Team recognizes that each agency approaches technology transfer activities differently and in order to capture all that is reported across the agencies, ST5 has compiled a list of **optional** metrics in order to inform all agencies of additional possible metrics that they may want to consider. This list is intended to serve as a list of possibilities, rather than a strict prescription.

The metrics on this list were collected in March 2019 from Strategy Team member agencies-Centers for Disease and Control and Prevention (CDC), Departments of Agriculture, Commerce, Defense, Energy, Interior, Homeland Security, Transportation, Environmental Protection Agency (EPA), Food & Drug Administration (FDA), National Aeronautics and Space Administration (NASA), and National Institutes of Health (NIH).

The list is analogous to an "à la carte" menu where you may wish to choose none, a few, or all of the metrics as you see fit. The metrics are categorized under 5 categories: Research and Academic Dissemination; Scientific & Technology Transfer Training; Collaborations and Research Outputs; Economic Development Impacts; and Miscellaneous.

- 1. Research and Academic Dissemination
  - Number of publications by scientific or technology transfer staff
  - Number of citations to those publications
- 2. Scientific & Technology Transfer Training
  - Number of fellows, interns, or international staff trained, specifically regarding:
    - Amount and quality of management training at the project initiation and operations stage
    - Amount and quality of management and research staff training on invention disclosure, e.g., criteria for identifying, reporting, and protecting inventions and IP
    - Amount and quality of management training on the choice of transfer mechanism, e.g., criteria for selecting patents, publications, and for patenting itself

<sup>&</sup>lt;sup>18</sup> The NSTC Lab to Market Subcommittee was established in FY2018-Q2 to support the President's Management Agenda (PMA). The Subcommittee's goal is to improve the transfer of federally funded research and development (R&D) to the private sector. The Subcommittee was divided into 5 "Strategy Teams," made up of Federal technology transfer experts, each aimed at developing milestones to accomplish one of 5 strategies outlined in the PMA.

- Amount and quality of training of technology transfer staff on transfer and marketing activities
- Amount and quality of training research and technology transfer staff on acquiring and communicating feedback
- Number of talks, conference attendances, speeches, webinars (i.e., other forms of outreach) on Federal technology transfer
- Establishment of Personnel Exchange Programs
- Development of future scientists/number of scientists trained at the Federal Labs
- 3. Collaborations and Research Activities
  - Number of reimbursable agreements (with universities and non-profits)
  - Number of projects initiated under agency-specific agreements, (e.g., Strategic Partnering Projects)
  - Number of new alliances, (e.g., Partnership Intermediary Agreements (PIA), Memorandum of Understanding (MOU))
  - Number and nature of alliances with local or state economic development organizations
  - Amount of non-federal partner funds and in-kind contributions from agreements or projects
  - Use of unique facilities by businesses (e.g., user facilities, laboratory enhanceduse lease or out-lease transactions to private sector)
  - Number of Federal sites involved in trials (clinical, field)
  - Number of and extent to which Biological Materials are transferred
  - Development of reference materials, standards
  - Development of new methods o Number of plant releases
  - Interagency collaborations, (e.g., joint solicitations, joint funding for research equipment or infrastructure, joint research)
  - Number of software licenses executed
  - Number of software products available for licensing
  - Number of copyright licenses executed
  - Number of demonstrations & Field days
  - Number of newsletters, briefs, or non-academic publications
  - Number of data sets open to the public
  - Number of SBIR-TT contracts and grants
- 4. Miscellaneous
  - Methods of leveraging Federal technologies
  - Number and types of evaluation processes implemented
  - Number of impact studies performed
  - o New methods and mechanisms to transfer technologies
  - $\circ~$  Challenges in licensing government-owned patents pursuant to recommendations in GAO-18-327^{19}

<sup>&</sup>lt;sup>19</sup> <u>https://www.gao.gov/products/gao-18-327</u>