

Notice of Proposed Rulemaking: Regulatory Updates to 37 CFR 401 and 404

- Background
- Proposed Regulatory Changes – 37 CFR 401
- Proposed Regulatory Changes – 37 CFR 404
- How to Submit Comments
- Public Statements (23 requests received by NIST)

Today's webinar is being recorded and will be made available in approximately one week at <https://www.nist.gov/tpo/bayh-dole>

NPRM a Goal Under Lab-to-Market



- L2M an ongoing interagency effort since 2014
- Currently led by National Science and Technology Council's Lab-to-Market subcommittee (26 agencies/sub-agencies)
- Subcommittee workplan includes strategic objective to “Reduce regulatory impediments and administrative barriers in Federal technology transfer policies and practices”
- Deliverables include regulatory and legislative proposals, SBIR improvements, and improved intramural/extramural invention reporting
- NPRM presented today a result of nearly two years of effort, including extensive L2M interagency discussions beginning in October 2019

NIST's Technology Transfer Leadership



NIST has a unique role in promoting and reporting on the overall strength of federal technology transfer efforts

Policy coordination and promulgation of technology transfer regulation

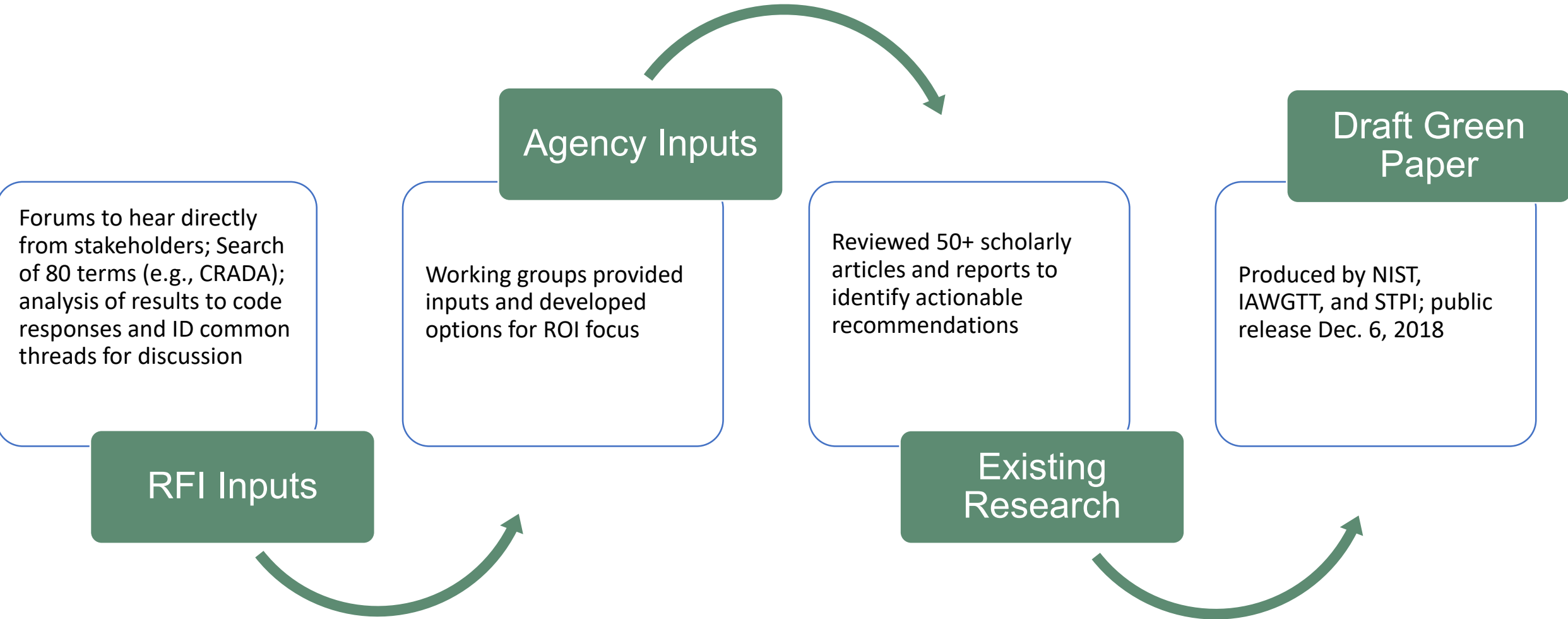
Lead for Interagency Workgroup for Technology Transfer (11 agencies) and Interagency Workgroup for Bayh-Dole

Annual reports for the President, the Congress, and OMB on technology transfer across federal agencies

Co-Chair Lab-to-Market NSTC Subcommittee and led Cross Agency Priority Goal Efforts x2

Host Agency for the Federal Laboratory Consortium for Technology Transfer

Return on Investment Initiative



ROI Green Paper

NIST

RETURN ON
INVESTMENT
INITIATIVE

TO ADVANCE
THE PRESIDENT'S
MANAGEMENT
AGENDA

FINAL GREEN PAPER
APRIL 2019

UNLEASHING
AMERICAN
INNOVATION

NIST Special Publication 1234

NIST
National Institute of
Standards and Technology
U.S. Department of Commerce

- ✓ Green Paper published April 24, 2019 as NIST Special Publication 1234
- ✓ Based on extensive stakeholder inputs via open, inclusive process—and closely coordinated with interagency working groups
- ✓ 15 key findings to inform actions that will help remove unwarranted impediments to innovation at the public private sector interface, and streamline and accelerate transfer of technology from Lab-to-Market
- ✓ Used to develop milestones for cross-agency implementation

Sources of Information: <https://www.nist.gov/unleashing-american-innovation/roi-sources-information>

Final Green Paper: <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf>

Changes Color-Coded Throughout Presentation

- Changes intended to streamline and/or remove outdated material are presented in **BLACK**
- Technical corrections are presented in **BLUE**
- Minor revisions and clarifications are presented in **PURPLE**
- Substantial changes are presented in **GREEN**

*Please contact courtney.silverthorn@nist.gov if you would like to receive a colorblind-friendly version of this presentation.

Proposed Regulatory Changes – 37 CFR 401

- Streamlines section by removing unnecessary or outdated language from:
 - Paragraph (a) – language does not provide any regulatory instructions
 - Paragraphs (c), (d), and (f) – describe applicability of regulations at the time the regulation was first implemented, outdated and no longer needed
 - Paragraph (e) – eliminates “three copies” submission requirement for agencies
- Adds additional clarification to applicability of Bayh-Dole to large businesses in Paragraph (b) when agency vesting statutes supersede EO 12591

- Updates definitions of *electronically filed* and *electronic submission*
- Expands definitions of *patent application* and *initial patent application* to include PCT applications designating the United States and Plant Variety Protection certificates
- Revises definition of *statutory period* to clarify that it refers to “...the one-year period before the effective filing date of a claimed invention in a patent application...”

§ 401.3 - Use of the standard clauses

- Makes technical corrections to:
 - A reference to § 401.5 in Paragraph (c)(3)
 - A reference to “Secretary” in Paragraph (f)
- Removes an outdated agency submission previously required under OMB Circular A-124 in Paragraph (g)

§ 401.4 - Contractor appeals of exceptions

- Makes technical corrections to:
 - A reference to 35 U.S.C. 202 in Paragraph (a)
 - The title of the “United States Court of Federal Claims” in paragraph (b)

§ 401.5 - Modification and tailoring of clauses

- Makes a technical correction to references to § 401.14 in Paragraphs (a) and (g)
- Revises the language in Paragraph (b) to eliminate ambiguity of “instructions” to the agency versus “instructions” to the contractor
- Moves additional reporting at the discretion of the agency in Paragraph (f) to § 401.14(c)(1) and (c)(3)

§ 401.6 - Exercise of march-in rights

- Restructures existing Paragraphs (b)-(h) as subparagraphs under “procedures [that] shall govern the exercise of march-in rights”
- Provides agencies with increased time to review information submitted by a contractor (60 days --> 120 days)
- Clarifies that agencies may disclose information obtained during a march-in proceeding when authorized by the contractor (assignee or licensee) “or otherwise required by law”
- Provides additional guidance to agencies that, consistent with the Policy and Objective of Bayh-Dole in 35 U.S.C. 200, the price of goods and services arising from the practical application of the invention shall not be the sole basis for the exercise of march-in rights
- Corrects a reference to 35 U.S.C. 202 in current Paragraph (j)

§ 401.7 - Removed and Reserved

- As part of the overall streamlining effort in this proposed rule, the provisions of § 401.7 “Small business preference” have been substantially re-incorporated into § 401.14 paragraph (k)

§ 401.8 - Removed and Reserved

- As part of the overall streamlining effort in this proposed rule, § 401.8 “Reporting on utilization of subject inventions” was identified as redundant and unnecessary – reporting procedures are already identified in § 401.14 and agencies are required by law to comply with the Paperwork Reduction Act

§ 401.9 - Contractor and contractor employee inventor requests for rights in inventions

- Section has been renamed from “Retention of rights by contractor employee inventor”
- Consolidates provisions from § 401.15 regarding the process by which a contractor subject to a determination of exceptional circumstances may request greater rights to an invention in Paragraph (a) and provisions from § 401.9 regarding the flow-down of applicable requirements in § 401.14 when an invention is waived to a contractor employee inventor

- Removes outdated references to superseded OMB Circulars in Paragraphs (a) and (b)(5)
- Makes technical corrections to:
 - The reference to the “standard clause” in Paragraphs (b)(1)-(4) and Paragraph (d)
 - References to § 401.6
 - Internal references to this section

§ 401.13 - Confidentiality of contractor submissions

- Section has been renamed from “Administration of patent rights clauses”
- Provision in Paragraph (a) regarding designating a lead agency for an invention funded by two or more agencies has been moved to § 401.14(c)
- Removes outdated references to superseded OMB Circulars in Paragraph (b)
- Paragraph (c) rewritten for clarity while retaining confidentiality provisions pursuant to 35 U.S.C. 202 and 205 of:
 - Information disclosing an invention while an initial patent application may still be filed
 - Patent applications filed by the contractor which have not been disclosed by the USPTO or a foreign patent office
 - Copies of documents that contain disclosures of a subject invention where publication would create a statutory bar to patenting

§ 401.14 - Standard patent rights clauses (1/3)

- Definition of *subject invention* included in error – had previously intended to incorporate a provision of § 401.1(a)(2)
- Replicates revised definition of *statutory period* from § 401.2
- Incorporates additional reporting at the discretion of the agency from § 401.5(f) to:
 - Paragraph (c)(1) – annual listings of subject inventions (§ 401.5(f)(3)) and close out report (§ 401.5(f)(1))
 - Paragraph (c)(3) – patent application and issued patent information (§ 401.5(f)(2))
- Provides additional clarifications in Paragraph (c)(3) on the filing of serial provisional applications on the same subject invention – must be approved by agency, and subsequent provisional application(s) must contain information not previously disclosed in a prior application

§ 401.14 - Standard patent rights clauses (2/3)

- Provision from § 401.13(a) regarding designating a lead agency for an invention funded by two or more agencies added as Paragraph (c)(6)
- Paragraph (d) restructured – current conditions unchanged in (d)(1)
- New provision added in Paragraph (d)(2) to permit an agency, at their discretion, to explicitly waive the requirement for a contractor to convey title to a subject invention (e.g., if corrective actions have been taken to an agency's satisfaction)
- Clarification added to Paragraph (f)(3) that the contractor's requirement to notify an agency of decisions regarding patent prosecution must be 60 days prior to a statutory bar or 60 days prior to the end of an extended time period granted by the agency

- Small business considerations from § 401.7 incorporated into § 401.14(k):
 - Contractors must make efforts to attract small business licensees and give preference to small businesses in licensing (§ 401.7(a))
 - Agencies may review contractors' licensing programs and negotiate improvements to the contractors' policies, procedures and practices to more effectively implement small business preference, and
 - Small business may present concerns to the agency in order to facilitate review of a contractor's licensing program (§ 401.7(b))
- Electronic filing provisions from § 401.16 moved to § 401.14(m)

§ 401.15 - Removed and Reserved

- As part of the overall streamlining effort in this proposed rule, the provisions of § 401.15 “Deferred determinations” have been substantially re-incorporated into § 401.9 Paragraph (a)

§ 401.16 - Federal agency reporting requirements

- Section has been renamed from “Electronic filing”
- As part of the overall streamlining effort in this proposed rule, the provisions of § 401.16 “Electronic filing” have been substantially re-incorporated into § 401.14 paragraph (m)
- New requirement for agencies to report annually on Bayh-Dole metrics:
 - Number of subject inventions reported to agency
 - Number of patent applications filed on reported subject inventions
 - Number of issued patents on reported subject inventions
 - Number of time extensions requested and granted by agency
 - Number of subject inventions conveyed to government
 - Number of US manufacturing waivers requested and granted
 - Number of requests for assignments

- Makes a technical correction to contact information provided in the regulation; future contact information will be updated on the iEdison website

Proposed Regulatory Changes – 37 CFR 404

§ 404.1 - Scope of part

- Section restructured – current provisions regarding applicability unchanged in Paragraph (a)
- New Paragraph (b) provides clarification that licensing revenues are not alternatives to appropriated funds or alternate funding mechanisms

§ 404.2 - Policy and objective

- Policy and objective re-written to clarify the purpose of royalties collected by the government*:
 - For promoting the practical application of a subject invention
 - A method to ensure commercialization by the licensee

* In the 2018 Government Accountability Office Report “Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions” the GAO recommended: “The Secretary of Commerce should instruct NIST to clarify the link between establishing patent license financial terms and the goal of promoting commercial use, through appropriate means, such as the upcoming rule-making process and updating relevant guidance. (Recommendation 2)”

§ 404.4 - Removed and Reserved

- As part of the overall streamlining effort in this proposed rule, § 404.4 “Authority to grant licenses” was identified as redundant and unnecessary – agencies are already authorized to grant licenses in 35 U.S.C. 207, and language addressing immunity from antitrust laws and patent misuse charges is repeated in § 404.5

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

- Makes a technical correction to Paragraph (b)(8)(iv) by citing to statute (35 U.S.C. 209(b))

§ 404.7 - Exclusive, co-exclusive, and partially exclusive licenses (1/2)

- Paragraph (a) regarding “domestic licenses” and Paragraph (b) regarding “foreign licenses” largely duplicative, and the domestic vs foreign distinction is undefined and subject to confusing interpretations – Paragraphs (a)(1) and (b)(1) revised into a single paragraph detailing processes and considerations for granting all exclusive, co-exclusive, or partially exclusive licenses aligned with statutory requirements in 35 U.S.C. 209:
 - Public notice of intent to grant license and agency review of objections
 - Determination that the licensee has adequate plans and ability to bring the invention to practical application/public utilization, the exclusive license is necessary, and the scope of exclusivity is appropriate
 - Granting the license does not lessen competition or violate anti-trust laws
 - Small business preferences have been considered
 - In the case of an invention covered by a foreign patent application or patent, US interests in foreign commerce will be enhanced

§ 404.7 - Exclusive, co-exclusive, and partially exclusive licenses (2/2)

- Paragraph (a)(2) regarding additional provisions for “domestic licenses” and Paragraph (b)(2) regarding additional provisions for “foreign licenses” largely duplicative – have been revised into a single paragraph detailing additional terms and conditions applicable to all exclusive licenses:
 - Subject to government use rights
 - Agency rights to require sub-licenses when necessary to fulfill health or safety needs
 - Subject to any licenses in force at the time
 - May grant licensee to take necessary actions to protect the IP on behalf of the government

§ 404.10 - Modification and termination of licenses

- Requires licensees (not the agency) to inform their sublicensees of a notice of intention to modify or terminate a license

§ 404.11 - Appeals

- Provides additional clarification that, consistent with the Policy and Objective of Bayh-Dole in 35 U.S.C. 200, appeals other than by the licensee should be related to “being denied the opportunity to promote the commercialization of the invention”
- Requires agencies to establish procedures for considering appeals

§ 404.14 - Confidentiality of information

- Makes technical corrections to the citations:
 - Revises initial reference to 35 U.S.C. 209 to identify correct Paragraph
 - § 404.8(h) → § 404.8(a)(8)
 - § 404.5(b)(6) → 35 U.S.C. 209 (d)(2)

How to submit comments

- Public statements given today will become part of the record
- Written comments are strongly encouraged through the Federal e-Rulemaking Portal (<http://www.regulations.gov>) under Docket ID Number **201207-0327**
 - Specific proposed changes presented in the Notice of Proposed Rulemaking
 - Suggestions for regulatory changes that would further accelerate the transfer of federally funded research and technology to entrepreneurs
 - Suggestions for regulatory language that could help clarify the existing statutory scope of the Government Use License
 - Regulatory provisions that may be inconsistent with the America Invents Act

Comments must be received no later than April 5, 2021

Public Statements

** 3 minutes per person*

** 23 requests received*

** Called in order request was received*

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