

Draft Interagency March-In Framework

- The University and Small Business Patent Procedures Act of 1980, or more commonly known as the “Bayh-Dole Act”, was passed by Congress on December 12, 1980 (35 U.S.C. §§ 200-212)
 - Applies to any contract, grant, or cooperative agreement from any federal agency for the performance of experimental, developmental, or research work
 - Provides recipients of federal research funding the right to retain ownership of the inventions conceived or first actually reduced to practice under their federal funding agreements
 - Intended to promote utilization of inventions arising from federally supported R&D and encourage progression of inventions from the laboratories into the marketplace
- The Bayh-Dole Statute gives the Secretary of Commerce the authority to issue the Bayh-Dole Act’s implementing regulations
 - Implementing regulations are found at 37 CFR Part 401
- This authority was delegated by the Secretary to the National Institute of Standards and Technology (NIST)

March-In Rights

Among the rights and obligations detailed in the Bayh-Dole Act are “march-in rights”

March-in rights allow a federal funding agency to require the Bayh-Dole contractor to issue a license and if they refuse, the agency can issue a license themselves (35 U.S.C. § 204)

The statute only allows the exercise of march-in rights in 4 circumstances:

1. action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
2. action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
3. action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
4. action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

Requests for Clarity and the NPRM

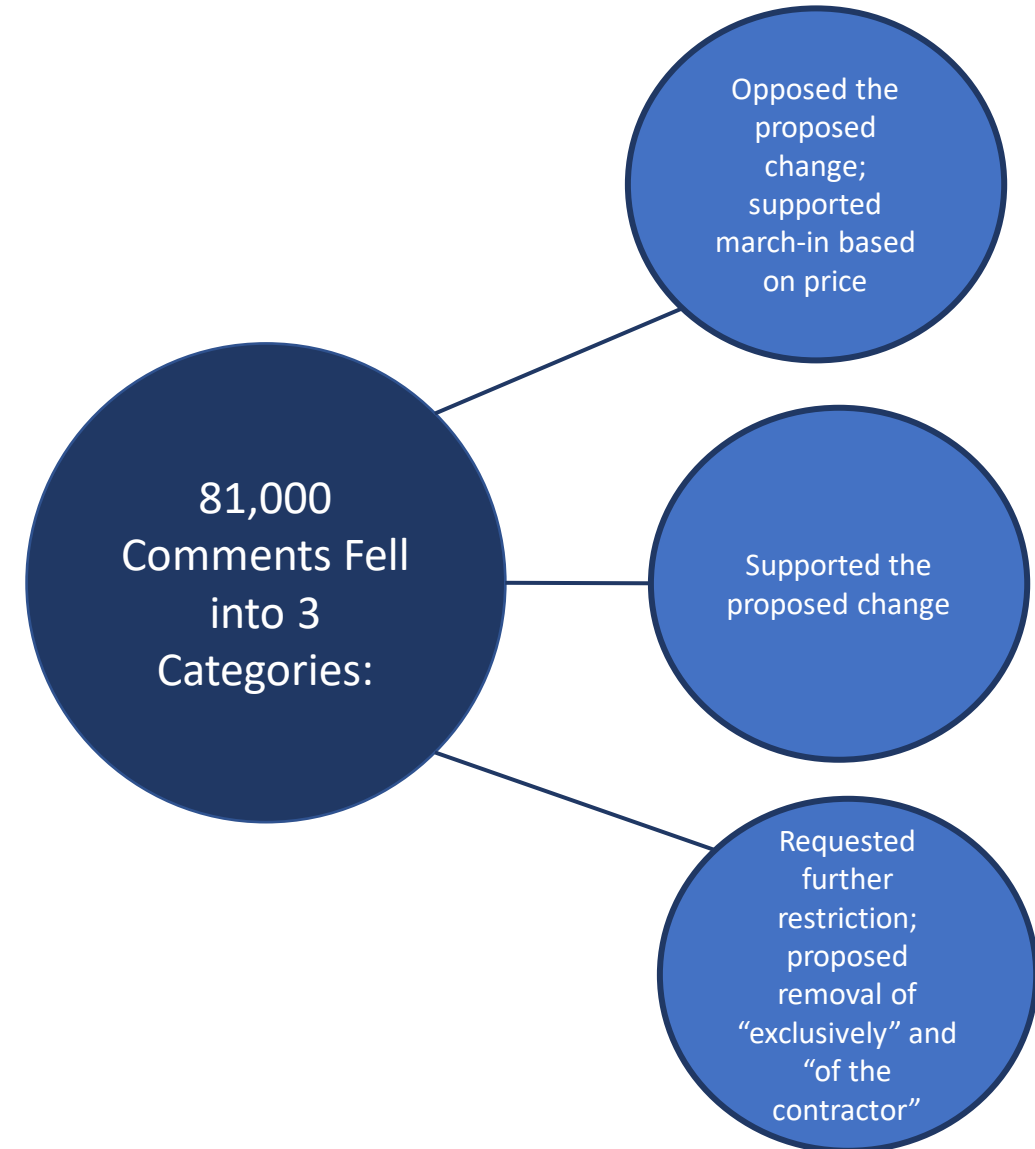


- To date, no agency has exercised march-in rights. However, NIST has repeatedly been asked to provide additional clarity regarding whether price can be considered a factor that an agency may consider when deciding whether to march-in.
- On January 4, 2021, NIST published a Notice of Proposed Rulemaking that sought to streamline, update, and clarify several provisions of the Bayh-Dole regulations.
- Among the proposed changes, the NPRM sought to include the following provision:

“March-in rights shall not be exercised exclusively based on the business decisions of the contractor regarding the pricing of commercial goods and services arising from the practical application of the invention.”

NPRM to Final Rule

- NIST received over 81,000 comments on the NPRM -- with the majority on this particular provision.
- On July 9, 2021, President Biden signed Executive Order 14036, which directed the Secretary of Commerce, acting through the Director of NIST to “consider not finalizing any provisions on march-in rights and product pricing in the proposed rule.”
- On March 24, 2023, NIST issued a Final Rule based on that NPRM, but did not finalize the provision related to march-in rights and product pricing.
- In the Federal Register Notice accompanying the Final Rule, NIST committed to “engage with stakeholders and agencies with the goal of developing a comprehensive framework for agencies considering the use of march-in provisions.”



Whole-of-Government Approach

- Along with the Final Rule publication, DOC and HHS jointly announced a plan to take a more comprehensive, whole-of-government approach to review and provide clarity on March-in Authority.



The screenshot shows the official website of the U.S. Department of Health and Human Services (HHS). The header includes the HHS logo, the department name, and the tagline "Enhancing the health and well-being of all Americans". A search bar is located in the top right corner. Below the header is a navigation bar with links to "About HHS", "Programs & Services", "Grants & Contracts", and "Laws & Regulations". The main content area displays a breadcrumb trail: "Home > About > News > HHS and DOC Announce Plan to Review March-In Authority". On the left side, there is a sidebar with links to "News", "Blog", "HHS Live", "Podcasts", and "Media Guidelines for HHS Employees". The main text area features a "FOR IMMEDIATE RELEASE" notice dated "March 21, 2023". To the right of this notice is contact information for the HHS Press Office, including the phone number "202-690-6343" and the email address "media@hhs.gov". The headline of the press release is "HHS and DOC Announce Plan to Review March-In Authority". The body text states that HHS and the Department of Commerce (DOC) have announced efforts to pursue a whole-of-government approach to review the march-in authority as laid out in the Bayh-Dole Act, which promotes commercialization of research results, maximizes the potential for federally-funded technologies to become products, and serves the broader interest of the American public. The Interagency Working Group for Bayh-Dole will develop a framework for implementation of the march-in provision that clearly articulates guiding criteria and processes for making determinations where different factors, including price, may be a consideration in agencies' assessments.

U.S. Department of
Health and Human Services
Enhancing the health and well-being of all Americans

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Home > About > News > HHS and DOC Announce Plan to Review March-In Authority

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T+ Print Facebook Twitter Email

FOR IMMEDIATE RELEASE
March 21, 2023

Contact: HHS Press Office
202-690-6343
media@hhs.gov

HHS and DOC Announce Plan to Review March-In Authority

Today, the U.S. Department of Health and Human Services (HHS) and the Department of Commerce (DOC) announced efforts to pursue a whole-of-government approach to review its march-in authority as laid out in the Bayh-Dole Act, which promotes commercialization of research results, maximizes the potential for federally-funded technologies to become products, and serves the broader interest of the American public. The Interagency Working Group for Bayh-Dole will develop a framework for implementation of the march-in provision that clearly articulates guiding criteria and processes for making determinations where different factors, including price, may be a consideration in agencies' assessments.

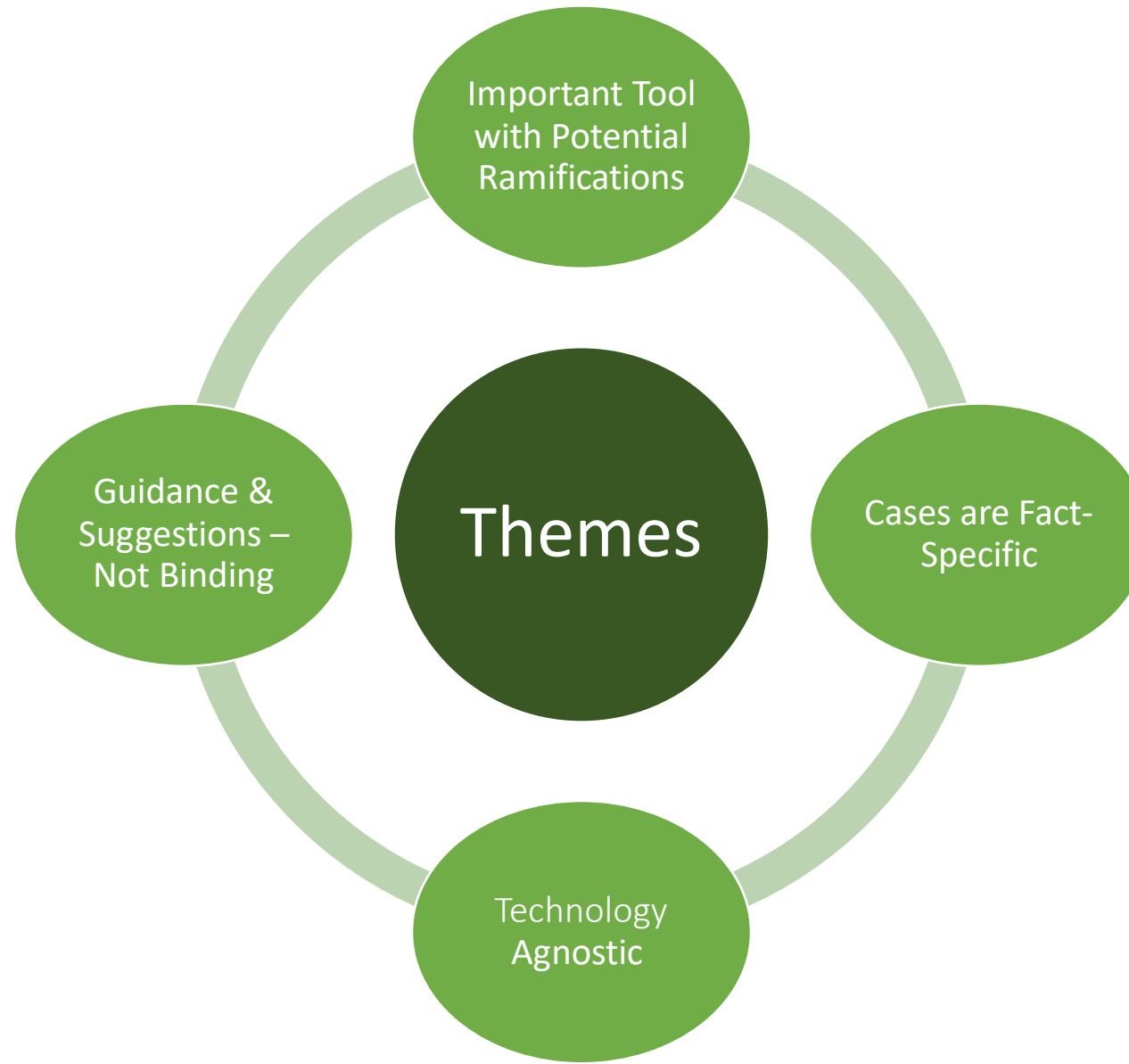
Interagency Process

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- NIST tasked the Interagency Working Group for Bayh-Dole (IAWGBD) with drafting an interagency framework that agencies could use when analyzing whether to exercise march-in rights
 - The IAWGBD was formed in 2015 to discuss policy issues surrounding Bayh-Dole to find consensus and create consistency in the application of the Bayh-Dole regulations
 - IAWGBD consists of nearly 120 members with representation from DOC, DHHS, DOE, DOD, NSF, DHS, DOT, DOJ, USDA, USAID, NASA, and the VA
 - The IAWGBD convened a subcommittee of volunteers to work on the framework. The subcommittee drafted and edited the framework as well as scenarios to demonstrate how an agency might apply the framework
 - Representation on the subcommittee included NIST, NIH, DOE, NSF, CDC, Army/MRDC, DOD R&D, DHS, DOT, USAID, Air Force, NOAA, and NASA
 - This draft framework was presented to the full IAWGBD and agencies were given the opportunity to provide feedback through several rounds of review until the IAWGBD came to consensus on a draft for RFI publication
 - NIST sent the framework to OMB for formal interagency review before publishing in the Federal Register

Goals & Themes of the Framework



Goals & Themes of the Framework



Structure of the Framework



- The draft framework asks the agencies to answer three questions in analyzing whether to exercise march-in rights:
 - 1. Does Bayh-Dole Apply?**
 - The invention(s) must be conceived or first actually reduced to practice in the performance of work under a federal funding agreement
 - 2. Is a Statutory Criterion Met?**
 - Provides facts that an agency may gather, questions they may ask, and factors they may consider in determining whether one of the criterion required to march-in under the Bayh-Dole statute has been met.
 - Broken down into 4 subsections – one for each statutory criterion
 - 3. Would March-In Support the Policy & Objective of Bayh-Dole, Considering the Specific Case and Broader Context?**
- The Framework concludes with **8 different example scenarios** illustrating how an agency might use the framework when considering whether to exercise march-in rights.

Does Bayh-Dole Apply?

- **Does Bayh-Dole Apply?**

- Was the invention reported to the funding agency as a subject invention under Bayh-Dole?
 - If an invention is reported to the agency as a subject invention, it will be assumed that it is a subject invention. If a contractor contends an invention is not a subject invention, then they would be given the opportunity to provide evidence to raise this as a “genuine dispute over a material fact” under 37 CFR 401.6(3-5).
- If it was not reported to the funding agency as a subject invention, further analysis will be needed by the agency. Agencies may consider
 - Reviewing patent applications and patents
 - Reviewing publications
 - Review funding agreements
 - Consulting with subject matter experts
 - Etc.

- **Ownership and Licensing**

- What parties are listed as owners of invention(s) and patent(s)?
- What current licenses exist that cover the invention(s)/patent(s)?
 - Exclusive or nonexclusive
 - Fields of Use

Statutory Criterion 1

Action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use

- **For inventions not licensed or commercialized:**
 - Focuses on what steps the contractor has taken to further develop the invention and/or seek licensees and whether there are concerns that the contractor is shelving the subject invention(s) without justification and not committing to discernable steps on re-engaging in its licensing.
- **For inventions licensed:**
 - Focuses on what steps the contractor and/or licensee is taking to progress the invention to manufacturing and/or commercialization and whether there are concerns that the contractor or licensee is shelving the subject invention(s) without justification and not committing to discernable steps to commercialize
- **For inventions commercialized:**
 - Focuses on whether the invention is being made available to the public on reasonable terms
 - Pricing is addressed in this criterion -- specifically:
 - At what price and on what terms has the product utilizing the subject invention been sold or offered for sale in the U.S.?
 - Has the contractor or licensee made the product available only to a narrow set of consumers or customers because of high pricing or other extenuating factors? Has the contractor or licensee provided any justification for the product's price or background on any extenuating factors which might be unreasonably limiting availability of the subject invention to consumers or customers?

Statutory Criterion 2

Action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contract or, assignee, or their licensees

- **Questions include:**
 - What the health or safety need is
 - How this product addresses the need
 - What is needed to address the need
 - Possible alternatives
- Pricing is addressed in this criterion -- specifically:
 - Is the contractor or the licensee exploiting a health or safety need in order to set a product price that is extreme and unjustified given the totality of circumstances?
 - For example, has the contractor or licensee implemented a sudden, steep price increase in response to a disaster that is putting people's health at risk?

Statutory Criterion 3

Action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees

- **Questions include:**
 - What the regulatory requirement is and whether or not the regulation expressly requires the product's use (or use in combination with another product)
 - How the invention addresses the requirement
 - What other technologies address the need
 - Whether this invention is available to those who need it to fulfil the requirement and if the contractor is imposing barriers or restricting access to the invention
 - How much time is required under the regulation to meet the requirement
- An example might be if the National Highway Traffic Safety Administration (NHTSA) issued a regulation requiring cars have a certain functionality and the subject invention in question achieved that functionality, but not enough volume was being manufactured to fulfill the public's need

Statutory Criterion 4

Action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204

- **Questions include:**
 - Whether the Preference for United States Industry under the regulations is triggered
 - Is there an exclusive license to use or sell in the United States?
 - Whether the contractor and/or licensee are compliant with the Preference for United States Industry required in the statute
 - Do exclusive licenses to use or sell in the United States include a requirement that products be manufactured substantially in the United States?
 - Are licensees compliant with that obligation?
 - Whether there has been a waiver request submitted
 - If yes, the outcome of that waiver request, if submitted
 - If no, whether the agency has demanded a waiver request

Policy & Objective of Bayh-Dole, Considering the Specific Case and Broader Context



Questions seek to determine:

- Whether march-in would achieve the desired results, for example:
 - Is there a willing and able licensee or is it likely that one could be found?
 - What additional IP rights would be needed in order to make the product in question?
- Whether there are other alternatives that would address the issue, for example:
 - What are the alternative technologies available and how effective are those alternatives?
 - Is there another government action (e.g., anti-trust activity, fraud, bankruptcy, other federal or state governmental authorities, etc.) that would better address the problem?
- The broader implications of use of march-in, for example:
 - Would exercise of march-in rights here promote competition without unduly encumbering future R&D?
 - Would exercise of march-in impact utilization of subject inventions more broadly?

Request for Information



- NIST published an RFI in the Federal Register on **Friday, December 8th** asking for feedback on the *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*
- The comment period will be open for 60-days from publication, closing at **5:00 PM Eastern time on February 6, 2024**
- NIST will then review all relevant comments received and present them to the IAWGBD for consideration to incorporate into a final document

Request for Information



- We welcome all comments, but we also ask certain specific questions in the RFI:
 1. After reading through the framework and example scenarios, if needed, how could the guidance about when an agency might want to exercise march-in and the factors that an agency might consider be made clearer?
 2. The framework contains many terms which have specific meanings under Bayh-Dole or in technology development and commercialization. Are the definitions provided at the beginning of the framework easy to understand? Do they aid in your ability to interpret the framework?
 3. How could the framework be improved to be easier to follow and comprehend?
 4. Does this framework sufficiently address concerns about public utilization of products developed from subject inventions, taking into account the fact that encouraging development and commercialization is a central objective of the Bayh-Dole Act?
 5. The framework is not meant to apply to just one type of technology or product or to subject inventions at a specific stage of development. Does the framework ask questions and capture scenarios applicable across all technology sectors and different stages of development? How could any gaps in technology sectors or stages of development be better addressed?

How to Submit Comments

- You can submit comments directly from the Federal Register Notice by clicking the button that says “Submit a Formal Comment”



The screenshot displays the Federal Register website interface. At the top, there is a navigation bar with links for Home, Sections, Browse, Search, Reader Aids, and My FR, along with a search box labeled 'Search Documents'. Below this is the header section featuring the National Archives logo, the text 'FEDERAL REGISTER The Daily Journal of the United States Government', and the National Archives and Records Administration seal. A blue banner with the text 'Notice' is visible. The main content area shows a notice titled 'Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights'. Below the title, it states 'A Notice by the Commerce Department and the National Institute of Standards and Technology on 12/08/2023'. At the bottom of the notice, there is a comment period indicator: 'This document has a comment period that ends in 55 days. (02/06/2024)'. To the right of this indicator is a green button labeled 'SUBMIT A FORMAL COMMENT', which is circled in red. Below the button, it says '9 comments received. View posted comments'.

How to Submit Comments

- Complete the comment form and click the “Submit Comment” button at the bottom

Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights

A Notice by the Commerce Department and the National Institute of Standards and Technology on 12/08/2023

You are submitting an official comment to Regulations.gov.
Comments are due 02/08/2024 at 11:59 pm EST.

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How to Submit Comments

- You can also go to www.regulations.gov and enter NIST-2023-0008 in the search field.

The screenshot shows the Regulations.gov website interface. At the top, the logo "Regulations.gov" and the tagline "Your Voice in Federal Decision Making" are visible. A search bar contains the text "NIST-2023-0008" and a green "Search" button. Below the search bar, there are three tabs: "Dockets", "Documents", and "Comments". The "Comments" tab is currently selected. On the left side, under "REFINE DOCUMENTS RESULTS", there is a checkbox for "Only show documents open for comment (1)". Below this, under "Document Type", there are four options: "Supporting & Related Material (75)", "Other (15)", "Proposed Rule (2)", and "Notice (1)". Under "Posted", there is a link for "Last 7 Days (1)". The main content area shows the search results for the document "Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights". The document is dated December 1, 2023, and is posted by the Agency: National Institute of Standards and Technology. The "Comment" button is highlighted with a red circle. The "Comments Due Feb 6, 2024" date is also visible.

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☐ Supporting & Related Material (75)
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☐ Proposed Rule (2)
☐ Notice (1)

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NOTICE

Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights

Dated: December 1, 2023.... Go to www.regulations.gov and enter **NIST-2023-0008** in the search field. 2.... In the Final Rule published in the Federal Register (88 FR 17730) 3 on March 24, 2023, NIST did not... Alicia Chambers, NIST Executive Secretariat.... This MCP was approved on June 20, 2023 and became effective on August 4, 2023 and is currently in... Dated: December 1, 2023.... Go to www.regulations.gov and enter **NIST-2023-0008** in the search field. 2.... In the Final Rule published in the Federal Register (88 FR 17730) 3 on March 24, 2023, NIST did not... Alicia Chambers, NIST Executive Secretariat.... This MCP was approved on June 20, 2023 and became effective on August 4, 2023 and is currently in

Agency: National Institute of Standards and Technology | Posted Dec 8, 2023 | ID NIST-2023-0008-0001

Comments Due Feb 6, 2024

Comment

How to Submit Comments

- Complete the comment form and click the “Submit Comment” button at the bottom

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Questions

- If you have further questions, you can feel free to reach out to Mojdeh Bahar at mojdeh.bahar@nist.gov
- Please continue to check our website at <https://www.nist.gov/tpo/policy-coordination/bayh-dole-act> available from the NIST TPO website for updates



Thank You!