

SUPPORTING STATEMENT
U.S. Department of Commerce
National Institute of Standards and Technology
iEdison
OMB Control No. 0693-0090

SUPPORTING STATEMENT PART A

Abstract

The Bayh-Dole Act (35 USC 18) and its implementing regulations (37 CFR 401) allow for recipients of federal research funding (Contractors) to retain ownership of inventions developed under federal funding agreements. In exchange, the government retains certain rights to the invention, including a world-wide right to use by or on behalf of the U.S. government. Several agencies utilize the iEdison system as a means for collecting required reporting from the Contractors. The law also requires the Contractor to obtain permission for certain actions and fulfill reporting requirements including:

- a. Initial reporting of invention;
- b. Decision to retain title to invention;
- c. Filing of patent protection;
- d. Evidence of government support clause within patents;
- e. Submission of a license confirming the government's rights;
- f. Notice if the Contractor is going to discontinue the pursuit or continuance of patent protection;
- g. Information related to the development and utilization of invention;
- h. Permission to assign to a third party or inventor; and
- i. Permission to request waiver of domestic manufacturing requirements at agency's discretion under certain circumstances.

This information is used for a variety of reasons. It allows the government to identify technologies to which the government has rights to use without additional payment or licensing. This acts as a time and cost-saving mechanism to avoid unnecessary negotiating and payment. It also provides some data for calculation of return on investment (ROI) from federal funding, identifies resulting products that are on the market, and allows agencies to confirm compliance with certain requirements such as progress toward practical application, preference or United States industry, and efforts to attract small business firms for licensing. The information can also be used to identify successful research programs. Lastly, it allows the government the opportunity to timely protect inventions which the Contractor declines title or discontinues patent protection.

This amendment/renewal makes some revisions to existing questions and adds additional selections in field answers.

Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Bayh-Dole Act (35 USC § 200-212) and its implementing regulations (37 CFR 401) require Contractors to report information related to inventions and patents to the federal agency which awarded the relevant funding. The Act allows agencies to ask Contractors for periodic reports on the utilization of a subject invention or on efforts at obtaining such utilization. The purpose of this legislation included promoting utilization of inventions resulting from federal R&D funding, encourage collaboration between non-profit and for-profit entities, increase commercialization and public availability of inventions made in the United States, and to ensure that the Government obtains sufficient rights in federally funded inventions to meet the needs of the Government and protect the public. To facilitate these and other objectives as well as to track both compliance with and effectiveness of this legislation, collection of data is required.

The collection of this information allows the federal government to:

1. Ensure compliance with Bayh-Dole Act reporting and timing requirements to ensure that federally funded inventions are protected in a timely manner in accordance with patent laws, that federally funded inventions are being commercially developed, and ensure that preference is giving to US industry and small businesses.
2. Aid in determining return on investment (ROI) of taxpayer dollars used on extramural federal research programs.
3. Identify technologies to which the government has rights to avoid unnecessary licensing and fees.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

The information will be collected from recipients of federal funding with resulting inventions, including universities, research institutions, hospitals, non-profit organizations, for-profit businesses, etc. Information will also be collected from individual inventors who, with federal agency approval in accordance with the Bayh-Dole Act and associated regulations, had patent rights assigned back to them by the organization that received federal funding. Although there may be rare occasions where information may need to be collected via email, by phone, or by paper mail, the information will be primarily collected via the iEdison website to allow for an easily centralized location for reporting information to all of the agencies who have registered with iEdison. The information will be provided to all federal agencies who have registered iEdison accounts. Agencies registered with iEdison will have full read access to records to which they are associated as a funding agency or have been given view access (the primary funding agency will have edit access) and limited access to those records awarded only to other federal agencies.

The table shown in question 15 of this supporting statement details the information/data fields being requested as well as the statute or regulation(s) authorizing the collection of this information and the needs or uses for collection of this piece of information. The information will be collected in one of three major record categories within iEdison: Invention, Patent, or Utilization Records. Some of the data collected are questions already being asked by the current iEdison system, though some questions and field selections have been amended and some questions have been added to provide additional data to the funding agencies on the impact of their research programs and to comply with EOs 14104 and 13985. It should be noted that because the iEdison system is used by multiple agencies, the needs/uses listed represent the needs/uses for all agency iEdison users. If only certain agencies use or requested a particular piece of information, that is indicated within the chart.

In general, we only anticipate that limited data derived from the information entered into the system will be made public. Some information provided may be required to be reported by funding agencies to the Department of Commerce and/or the Made in America Director pursuant to 37 CFR 401.16 and Executive Order 14104 respectively.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Information will be primarily entered electronically via NIST's iEdison website. NIST has also implemented a number of technological features to minimize the burden on users. NIST has made an Application Programming Interface (API) available for users to connect the system to their own internal intellectual property database as well as a bulk upload functionality to allow users to submit large amounts of reports at one time. By integration of the domestic manufacturing waiver form directly in iEdison, it provides a way for Contractors to fill in the form directly in iEdison instead of submitting an attachment. This capability also tracks when requests were submitted and confirm when an agency is reviewing the request (the agencies can change the status from "Submitted" to "Pending"). Additionally, this allows for one report to be submitted instead of multiple reports to different agencies in the event that more than one funding agency funded an invention. These features reduce burden on the Contractors. Additionally, pursuant to EO 14104, steps are being made to transition all funding agencies to iEdison to further eliminate duplicative reporting where a Contractor might have to report in iEdison and then again to an agency that does not participate in iEdison.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

Pursuant to the regulations and federal funding agreements, each agency that provides federal funding contributing to the conception or first actual reduction to practice of an invention must have inventions, associated patents, and other information reported to them. Utilizing iEdison, if multiple funding agreements supported one invention, each agency and funding agreement are entered into the single Invention Report and Utilization Reports are completed under that

Invention Report. Therefore, the users only have to report this information in iEdison once to report it to every funding agency that contributed to the invention instead of having to report it to each funding agency individually. Additionally, pursuant to EO 14104, steps are being made to transition all funding agencies to iEdison to further eliminate duplicative reporting where a Contractor might have to report in iEdison and then again to an agency that does not participate in iEdison. Currently, more than 35 federal agencies are either enrolled in the current iEdison system or intend to participate in the redesigned iEdison system.

To avoid duplication with the iEdison system itself, the system recognizes if a contractor tries to enter an invention record with the same title as a previously submitted record and notifies that contractor that this could be a duplicate record, and they should confirm that this record was not previously entered. Additionally, each patent serial number can only be entered into the system once (across all contractors). If a contractor tries to enter a patent serial number that has already been entered, they are given an error and told that the serial number already exists in the system.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

Small businesses and entities normally do not have the same volume of information to enter into the database as larger institutions, such as universities. However, NIST has implemented time-saving features by building in certain capabilities. For example, users are allowed to enter most items through API or bulk upload functionality. NIST has programmed portions of the database to auto-populate basic information. For example, utilization reports allow a “copy over” feature from previous utilization report data to a new utilization report.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

If this information is not collected by Federal funding agencies in a timely manner, then agencies would be unable to confirm Contractors’ compliance with requirements under the Bayh-Dole Act (35 USC § 200-212). Additional information not specifically required under the Bayh-Dole Act and its implementing regulations at 37 CFR 401, is allowed as additional information which can be collected under 37 CFR 401.5(f), which permits requiring certain additional information to be entered into grants or contracts terms and conditions, and 401.14(h), which allows agencies to require information related to utilization of inventions up to annually and required under EO 14104. In addition to an inability to track compliance, the consequences of not receiving this information in a timely manner include:

- a. Loss of intellectual property rights of interest to the government;
- b. Inability to use this data to aid in calculating ROI from federally funded research programs;
- c. Unnecessary government spending as a result of government licensing and paying for rights to inventions in which they already have a government use license.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner: requiring respondents to report information to the agency more often than quarterly; requiring respondents to prepare a written response to a collection of

information in fewer than 30 days after receipt of it; requiring respondents to submit more than an original and two copies of any document; requiring respondents to retain records, other than health, medical, government contract; grant-in-aid, or tax records, for more than three years; in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study; requiring the use of a statistical data classification that has not been reviewed and approved by OMB; that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

a. Respondents required to report information to the agency more often than quarterly: In accordance with the regulation, it is necessary for respondents to notify the federal funding agency of inventions, including their inventors on an ongoing basis. As such, respondents with multiple funding agreements will likely be required to report information more than quarterly in order to adhere to the regulations and to ensure that patent applications are filed before they are legally barred from doing so. For domestic manufacturing waiver requests, respondents would only need to submit these waiver forms in instances where they are required to manufacture substantially in the United States and they wish to seek permission to waive that requirement. Once a waiver is granted, it is often valid for a number of years. Therefore, the only time a respondent would need to submit this form more often than quarterly would be if they had a completely different invention/product for which they were also seeking a waiver within a short time frame of one another, however, it is unlikely that the information submitted would be the same as in this form if it were for a different invention/product.

b. Respondents required to submit proprietary information: Because the Bayh-Dole Act and its regulations require the disclosure of inventions that are most often pre-patent application and/or patents that are pre-publication, the information contained therein is inevitably proprietary. However, the iEdison system is built to only provide this information to the federal government and is held in confidence. Pursuant to U.S. law, this information cannot be made public until a reasonable amount of time has passed in which to file a patent. Furthermore, the agencies are not required to produce copies of documents included in patent applications. In accordance with these laws, the Bayh-Dole regulations specifically exempt these documents from FOIA requests for reasonable time periods and only allow disclosure of this information under certain circumstances. Finally, the Bayh-Dole Act specifically states that any information on utilization shall be treated as “commercial and financial information obtain from a person and privileged and confidential and not subject to disclosure under section 552 of title 5.” As such, proprietary information obtained is kept confidential. For domestic manufacturing waiver requests, there may be circumstances under which business confidential information may be needed in order to support an argument that domestic manufacturing is not commercially feasible.

The remaining scenarios described do not apply.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments

on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

A 60-day Federal Register Notice soliciting public comment was published on Tuesday, June 2, 2026 (Vol. 91, pg. 32951-32952). Comments were received and are addressed below.

A 30-day Federal Register Notice soliciting public comment was published on Thursday, September 17, 2026 (Vol. 91, pg. 58850-58851).

We appreciate all of the comments received and will take them into consideration for future planning of the iEdison system. We have grouped the comments received into categories, with examples of each comment as well as NIST's response below the category.

CATEGORY ONE: Respondents Comment regarding the Methodology for Calculation of Time Collection Burden (Invention Report 1.25 hours, Patent Report .75 hours, Utilization Report 25 minutes).

The accuracy of the projected burden of this information is the utmost importance to NIST. NIST follows guidelines from both the Department of Commerce Chief Data Officer and the Office of Information and Regulatory Affairs (OIRA) within OMB. Calculations of burden estimations within the Paperwork Reduction Act (44 USC §3501 et seq.) are accomplished through a programmatic analysis of the (1) total amount of respondents (2) the frequency in which respondents provide responses and (3) the average time to produce a response. Although the estimation of burden also considers the time needed for respondents to read instructions, gather data, and complete the information collection, estimations generally do not include hours for customary and usual business practices.

In the instance of iEdison, the estimate of burden is complex due to the varying degree of effort that exists across the expanse of respondents using the system. These variances may be due to the level of knowledge of the reporting organization about Bayh-Dole compliance, complexity of the resulting invention, and accessibility to the relevant data. The time burden was calculated based on estimated time to enter data into the relevant and required fields into iEdison and verifying information that would not normally be collected in a contractor's regular course of business. The majority of the data collected in iEdison is information that would have been previously generated through business processes associated with organizational intellectual property policies and, therefore, not new information being produced specifically for the iEdison system. Examples of this are activities such as invention disclosure reporting (for invention reports), patent filing documents, information sent by their counsel for patent reports, and commercialization information on royalty or milestone reports (provided by their licensee or by the organization itself).

The respondents stated that the time burden should reflect correcting notification errors and updating the report(s) throughout the life of the technology. The methodology used was for initial report creation, not correcting errors or making updates if/when details of the invention change overtime.

Furthermore, while some agencies may ask supplemental, funding agency-specific questions as part of utilization reporting, agencies are not limited to specific questions and have discretion under 37 CFR 401.14(h) to request “such other data and information as the agency may reasonably specify.” NIST took this into consideration when calculating the estimated response time. It should be noted that the time burden reflects the average time used to enter data into iEdison, reflecting that some reports may take longer than others. For example, if utilization reports are not licensed or commercialized, the entry takes significantly less time than if they are commercialized.

Because iEdison is an interagency system, NIST continues to reduce the burden on awardees by adding new agencies onto iEdison. As more agencies onboard into the system, it allows for a more streamlined process. For example, if an invention is co-funded by multiple agencies on iEdison, the awardees create one invention and list all the applicable funding.

CATEGORY TWO: Respondents Comments regarding Duplicative Reporting or Agencies Requiring Information outside iEdison.

Although this topic pertains to the Bayh-Dole process, the topic is outside the scope of the collection of information of the iEdison system. If agencies are using iEdison as their primary method of invention reporting and collecting/requesting information beyond the iEdison system, respondents should contact those agency’s respective PRA offices. NIST does not have oversight what agency users do with their iEdison data, so respondents should contact their funding agency and ask them for further clarification on the additional requests outside of iEdison. If agencies require more information about previously accepted work, please reach out to your funding agency and request further clarification. This PRA renewal extends to the iEdison system, not efforts conducted by agencies outside the normal operation of the iEdison system.

CATEGORY THREE: Inconsistency in Bayh-Dole Application and Review of Information. Although this topic pertains to Bayh-Dole or other agreement compliance, these topics are outside of the scope of the data collection of information in the iEdison system for purposes of this PRA renewal. For example, a respondent stated that the system allows awardees to submit their invention under Other Transaction Agreements (OTAs) to their respective funding agency. NIST states in organization trainings that OTA timelines may not follow the Bayh-Dole timeline, so the notifications may not align with their funding agreement’s terms and conditions. Although the iEdison notification system does not cover agency-specific OTA requirements, it is outside the scope of this data collection.

NIST conducts regular training and has resources available on our website for both agency and organization users including a user guide, field definitions, video tutorials, and a new document

library which includes checklists for invention disclosures, government support clauses, and confirmatory licenses. Finally, NIST offers bi-monthly live trainings for both Contractors and agency users. These resources are meant to help users learn how to use the system, reduce burden, and encourage consistency. As stated previously, NIST cannot control agency use of their iEdison data. Similarly, while NIST provides guidance on how to review iEdison submissions, NIST cannot dictate other agency's policies. If the respondents believe their funding agency requires more information than is required by the regulations, please contact the funding agency directly. Finally, the iEdison system is updated every 6-8 weeks (notices posted on our website) to fix bugs, make enhancements in functionality, and to make sure the system functions with applicable laws and regulations. If the respondents identify instances where the system is not programmed in alignment with the regulations, they are encouraged to submit a Help Desk ticket to notify the system's development team.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

There are no plans to provide payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If the collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

Information in this system may be governed by the provisions of 5 U.S.C. 522a (known as the Privacy Act of 1974). Each agency may decide whether their own agency data will be maintained as a System of Record as outlined under 5 U.S.C. 522a.

NIST disclosures of this information are subject to all the published routine uses as identified in the Privacy Act System of Records Notices:

COMMERCE/DEPT-23: Information Collected Electronically in Connection with Department of Commerce Activities, Events, and Programs System of records notices can be found here:

<https://www.commerce.gov/opog/privacy/SORN>

In accordance with the privacy provisions of the E-Government Act of 2002, a Privacy Impact Assessment (PIA) is required for NIST system 401-01, where this data resides. The collection and maintenance of information is outlined in the PIA for 401-01 and is approved by the Department of Commerce's Senior Agency Official for Privacy (SAOP) and is publicly viewable here: <https://www.commerce.gov/node/4668>

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be

given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

No questions of a sensitive nature will be asked.

12. Provide estimates of the hour burden of the collection of information.

Providing burden estimates for the iEdison System is complicated as not all record types (discussed in the answer to question 2 above) fields (discussed in the answer to question 3 above) will be applicable to each case. Furthermore, the frequency of entering information by users varies drastically based on the volume of their federal funding and how often that funding results in inventions.

The overall increase in burden from the original PRA package submitted to OMB in 2023 occurred for three reasons:

1. At the time, NIST did not have access to accurate legacy data regarding number of respondents from the years that the iEdison System resided with NIH. Now that this system has been under NIST custody for 3 years, we are able to better quantify these numbers.
2. Since the original PRA submission to OMB in 2023, approximately 15 additional federal agencies have onboarded onto the iEdison System for use, each adding to the overall respondent numbers.
3. The formerly separate Domestic Manufacturing Waiver Form is integrated into the iEdison system.

Annual Burden

Record Type	Number of respondents	Time to complete	Burden Hours
Invention Records	6,193	75 minutes (5 times /year)	38,706 hours
Patent Records	6,193	45 minutes (5 times / year)	23,224 hours
Utilization Records	6,193	25 minutes (30 times / year)	77,413 hours
Domestic Manufacturing Wavier Request	22	13 Hours (only a select few will be required to complete)	286 hours

13. Provide an estimate for the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected on the burden worksheet).

There are no capital/start-up or ongoing operation/maintenance costs associated with this information collection.

14. Provide estimates of annualized costs to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies may also aggregate cost estimates from Items 12, 13, and 14 in a single table.

There is not anticipated to be a significant change to the overall cost to the government from the original supporting statement due to the changes in utilization questions. The chart below details the estimated cost provided in the supporting statement for the system's original approval.

Type	Annual Budget
OISM Personnel (2 programmers, one data manager)	\$68,000
Contractor Support	\$505,000
TPO Personnel (1 manager, 1 data manager)	\$400,000
Software and Hosting Fees (iEdison.gov domain cost, login.gov service fee, AWS service fee, Salesforce service fee)	\$120,000
TOTAL	\$1,705,000

15. Explain the reasons for any program changes or adjustments reported on the burden worksheet.

The table below details additions and changes in the information/data fields being requested as well as the statute or regulation(s) authorizing the collection of this information and the needs or uses for collection of this piece of information. The information will be collected in one of three major record categories within iEdison: Invention, Patent, or Utilization Records. Any additional data fields and/or changes to data fields have been made to comply with updated regulations, to provide clarity, or at the justified request of federal agencies or Contractors who provide the information into the iEdison database. It should be noted that because the iEdison system is used by multiple agencies, the needs/uses listed represent the needs/uses for all agency iEdison users. If only certain agencies use or requested a particular piece of information, that is indicated within the chart.

Item No.	Record Type where Requirement is Located	Requirement	Statute	Regulation	Needs/Uses
1	Invention Report	Award Type			- To be used by the agency to determine whether the funding agreement was awarded to the Contractor

					directly or subawarded by another organization. - If subaward is selected, Contractor would fill out the details in the subaward section - This is an existing field in iEdison. This will be a required field in iEdison.
2	Invention Report	Agreement Type			- Used by the agency to determine the type of funding agreement (for example, a contract, a grant, a cooperative agreement, other transaction authority (OTA), etc.). This may determine certain internal federal processes for reporting. - This is an existing field in iEdison. We are adding Other Transaction Authority (OTA) as a field selection.
3	Utilization Report	For each licensee listed in Question 4 (exclusive licensee) and Question 5 (non-exclusive licensee), was equity retained in the designated reporting period as part of the license? (Y/N)	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to aid in calculation of ROI (including impact) from federal research dollars. - Provides a key indicator of commercial success of an invention; an objective way to measure the benefit to the US economy of DOE's investment in supporting the R&D of a particular energy technology, and helps verify that subject inventions are being utilized in a manner consistent with DOE's US manufacturing requirements. - Specifically requested by DOE for use for DOE-funded inventions
4	Patent Report	Patent Type			- To be used by Contractors to indicate the type of patent

					which determines if certain regulatory requirements have been fulfilled or if other regulatory requirements are triggered. - Used by Contractors to quickly assist in identifying (in graphic view) if all patent records have been recorded. - Used by agencies to confirm if regulatory requirements have been met or triggered. - Used by agencies to determine if a new/additional confirmatory license is needed (in cases of CIP patent applications). - Used by both Contractors and agencies to run reports on total numbers of different patent types during specified time periods. - This is an existing field in iEdison. We are adding Design and Plant as additional field selections.
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The information detailed below will be collected from recipients of federal funding with resulting inventions, including universities, research institutions, hospitals, non-profit organizations, for-profit businesses, etc., who wish to seek a waiver of domestic manufacturing requirements. These organizations may need to collect some of this information from companies and manufacturers who are seeking to license and/or manufacture the invention(s)/product(s). federal funding. This information will generally be submitted electronically as request form through the iEdison reporting system for an easily centralized location for reporting information to all of the agencies who have registered with iEdison. If an agency is not a registered user of iEdison, the individual agency will be responsible for the collection of the information outside of the iEdison system as well as the retention and security of the data.

Pursuant to Executive Order 14104, NIST was directed to consult with the Interagency Working Group for Bayh-Dole to create a set of common questions to be used by all agencies as an application to apply for waivers of the domestic manufacturing requirement under the Bayh-Dole Act. The product of this effort was the development of a Common Form named The Domestic Manufacturing Waiver Form) which was approved under the Paperwork Reduction Act (OMB

Control #0693-0103). In an effort to streamline the process and consolidate locations of information collections, this submission plans on integrating the Domestic Manufacturing Waiver Form into the iEdison System. Upon approval, NIST will discontinue the separate information collection, OMB Control 0693-0103.

Item No.	Question	Needs/Uses
1	Contractor/Petitioner Organization	Used by agencies to identify the party(ies) who are requesting the waiver
2	Contractor/Petitioner Organization Address	Used by agencies to identify the party(ies) who are requesting the waiver
3	Contractor/Petitioner Point of Contact including Name, Email Address, and Phone Number	Used by agencies to know who to contact with additional questions or follow-ups to the waiver request
4	Primary Contact (if different from above) or Additional Point of Contact including Name, Email Address, Phone Number, and the Name of the Party the Additional Contact Represents	Allows contractor to designate another point of contact and give agencies authorization to speak with those parties about the waiver form
5	Invention Report Number(s)	Used by agencies to identify invention and associated Bayh-Dole/iEdison that are associated with the request
6	Primary Funding Agency	Used by agencies to identify the agency designated to take the lead in receiving Bayh-Dole/iEdison related reporting
7	Other Funding Agency(ies)	Used by agencies to identify any other agency that supported the conception or first actual reduction to practice of the invention
8	Agreement Number(s)	Used by agencies to identify funding agreements and programs that supported the conception or first actual reduction to practice of the invention
9	Invention Title(s)	Used by agencies to identify inventions associated

		with the waiver request
10	Invention Docket Number(s)	Used by agencies to identify inventions and invention records associated with the request as some inventions have similar titles but docket numbers are often unique.
11	Patent Docket Number(s)	Used by agencies to identify patents and patent records associated with the request
12	Patent Applications and Patent Numbers included in request	Used by agencies to confirm any and all patents associated with the waiver request
13	Name of Licensee or Proposed Licensee	Used by agencies to identify to whom the invention is being licensed to give rise to the waiver request
14	Names of any Sub-Licensees	Used by agencies to identify to whom the invention is may have been sub-licensed to in order to identify all parties involved
15	Business Address of Licensee	Used by agencies to identify to whom the invention is being licensed to give rise to the waiver request and where they are located which may have economic impact in regards to jobs, etc.
16	Exclusive or Non-Exclusive License	- Used by agencies to identify the breadth of rights afforded in the license agreement - Required under EO 14104
17	Fields of use to which the license is or could be restricted	Used by agencies to identify the breadth of rights afforded in the license agreement
18	What is the scope of rights given (e.g., U.S. versus worldwide use and sales)?	Used by agencies to identify the breadth of rights afforded in the license agreement

19	Describe the technology, including products to be manufactured or specific processes implementing the subject invention.	Used by agencies to understand the invention and what resulting products will be
20	Describe the current stage of development of the subject invention and any development milestone plans necessary for manufacturing and commercialization.	Used by agencies to understand where inventions are in the development process and how soon they may be brought to market
21	What are the manufacturing plans for the subject invention? Describe any hurdles (manufacturing or otherwise) to be overcome to make the technology practical as well as the projected manufacturing start date.	Used by agencies to understand the process for manufacturing the invention and potential issues and/or difficulties that may arise
22	Discuss the factors that make domestic manufacture not commercially feasible, including: - Implications of substantially manufacturing in the U.S. on commercial adoption risks, including those related to the value proposition for the technology to meet the market demand, market acceptance and risks posed by existing players in the global competitive landscape, resource maturity and the domestic and global inputs needed to produce the technology, and societal, non-economic risks that may hinder deployment - The relative costs of U.S. and foreign manufacturing - Manufacturing capabilities within the U.S. - The efforts made to locate, develop, or contract for such manufacturing capabilities, including any previous efforts to manufacture the subject invention(s) in the U.S. - Approximately how much additional time, funding, and/or other factors that would be necessary in order to make U.S. manufacturing commercially feasible - Any other circumstances that make foreign manufacture necessary	Used by agencies to understand the scope and nature of the domestic and foreign manufacturing capabilities related to this specific invention(s) and product(s)
23	Identify any companies, including contract	Used by agencies to understand the

	companies, that would be manufacturing the subject invention(s) (if other than the Contractor/Petitioner, Licensee, or a subsidiary of either one). Do any of those companies, including contract companies, have manufacturing locations within the U.S.?	entities are may manufacture the product(s) and their U.S. presence (if any)
24	Has the Hollings Manufacturing Extension Partnership (MEP) or similar organizations been consulted to identify domestic manufacturers for the product?	Used by agencies to understand the degree to which contractors attempted to find domestic manufacturers
25	Is there any product embodying the subject invention or produced through the use of the subject invention manufactured in the U.S., or alternatively, is there any U.S. content used in manufacturing the product(s)? Please describe the scale of U.S. manufacturing (i.e., quantities of U.S. product(s) or content).	Used by agencies to understand whether any products or any part of a product will be manufactured in the United States to understand the scope of benefit to United States' manufacturing and economy.
26	Where would the proposed manufacturing facility be located (city and country)?	Used by agencies to understand where the Contractor and/or licensee propose manufacturing to take place
27	If the location(s) of current or proposed manufacturing facility(ies) is/are not in an allied or partner country (e.g., Canada, Mexico, South Korea, Japan, the UK, EU countries, those with a free trade agreement as identified by the U.S. Trade Representative (USTR) in official USTR publications or public announcements such as on Free Trade Agreements United States Trade Representative (ustr.gov)), has there been any effort to locate manufacturing facilities in such jurisdictions? If yes, please provide details of such efforts.	Used by agencies to understand the nature of the location of the proposed manufacturing and whether the country is one with which the United States has an allyship or partnership
28	Is the proposed manufacturing facility new or an existing facility?	Used by agencies to understand whether an existing manufacturing facility is proposed or one where investment went into the creation of a new facility that might have also been created in the United States
29	For any step in the manufacturing process that would occur outside of the United States, describe the conditions under which the subject invention will be manufactured abroad (including	- Used by agencies to understand the nature of the proposed manufacturing location.

	unionization of workplaces, health and safety standards, labor and wage laws, and environmental impacts).	- Required under EO 14104
30	What is the mechanism(s) by which the company manufacturing the product will acquire the necessary rights to the subject invention to manufacture the products (e.g., license, exclusive license, assignment)?	- Used by agencies to understand the nature of the agreement, particularly if it is not a license
31	How will the know-how to manufacture be transferred (e.g., Licensee's employee or other knowledge being provided)?	- Used by agencies to understand whether and how additional information is being transferred in relation to the invention
32	How will the Contractor/Petitioner monitor and oversee compliance with the terms of a waiver, if approved, including the manufacturing and distribution of the products? Please specify the legal mechanism(s) used by the Contractor/Petitioner and/or Licensee to enforce (e.g., license, exclusive license, assignment) in your response.	- Used by agencies to understand how a waiver, if granted would be monitored to ensure compliance and ensure that the Contractor/Petitioner has a plan in regards to monitoring and compliance
33	Describe all reasonable but unsuccessful efforts made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States. This may include past marketing strategies and efforts for the technology, including the number of companies contacted, the methods used for marketing and contacting companies, the types of licenses and terms offered to potential licensees, comparison of terms offered to potential foreign licensee and those offered to U.S. companies, and the responses of companies to marketing efforts.	- Used by agencies to determine whether and to what degree reasonable but unsuccessful efforts were taken to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States
34	Describe the market size and geographic distribution potential of the technology.	- Used by agencies to determine potential impact of the technology and resulting product(s) and its need in the marketplace
35	Discuss the significance of the technology, including the availability of alternative products, the size of intended patient or other customer populations (if applicable), whether requiring U.S. manufacture will delay entry of the product into the U.S. market, and the effect any such delay may have on U.S. public health.	- Used by agencies to determine potential impact of the technology and resulting product(s) and its need in the marketplace
36	Identify any value or benefit to the United States of	- Used by agencies to ascertain benefits to

	the technology even if it would not be manufactured in the United States, including I) the direct or indirect investment in U.S. plants or equipment, such as for marketing or packaging; ii) the creation of new or higher quality U.S.-based jobs, iii) the enhancement of the domestic skills base, iv) the further domestic development of the technology, v) a positive impact on the U.S. trade balance considering product and service exports as well as foreign licensing royalties and receipts, or vi) cross-licensing, sublicensing, and reassignment provisions in the license which seek to maximize benefits to the U.S.	the United States other than those that might be received if the product(s) were manufactured substantially in the United States, benefits that might not be received if a waiver were not granted.
37	To the extent known to the Contractor/Petitioner at the time of the submission of this request, are any potential economic or national security impacts related to the subject invention or manufacturing the subject invention abroad? If so, identify those impacts and explain any mitigating factors.	- Used by agencies to understand the economic and national security implications of the invention and the potential granting of a waiver
38	Please propose revised U.S. manufacturing requirements. Contractors/Petitioners are encouraged to maintain the applicable U.S. manufacturing requirements with only such modifications as are necessary to address the circumstances or concerns which led to this waiver request. Contractors/Petitioners are also encouraged to include contractual obligations to promote approval by the funding agencies.	- Allows the Contractor to propose manufacturing requirements to the agency for consideration as these terms are usually negotiated through the waiver process
39	Please add any additional information or considerations you would like to include with this request. You may also add any relevant attachments for support.	- Allows the Contractor the opportunity to provide any additional information they think might be helpful to the agency in weighing whether or not the criteria are met or otherwise whether or not to grant a waiver

Overall, the information collected is either required by the Bayh-Dole Act and its regulations or they help advance, track compliance and/or measure impact related to the Act's purpose and objectives. Agreement to provide the information is essentially a requirement to receive the benefit of federal research dollars. The information is used by federal agencies in the following ways:

- a. To tie inventions and patents and resulting products to their associated federal funding programs;

- b. To track compliance with the Bayh-Dole Act and its implementing regulations, specifically as it relates to taking steps to achieve practical application and compliance with domestic manufacturing requirements;
- c. To track ROI from federal research funding in a number of ways, including revenue, licenses, products, domestic manufacturing, jobs, etc.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

There are no current plans for detailed statistical analyses.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

The expiration date will be clearly displayed with the OMB Control Number on the Warning Notice page on iEdison.

18. Explain each exception to the topics of the certification statement identified in “Certification or Paperwork Reduction Act Submissions.”

There will be no exceptions to the certification statement and NIST certifies compliance with 5 CFR 1320.9 and the related provisions of 5 CFR 1320.8(b)(3).