INTERAGENCY DOMESTIC MANUFACTURING WAIVER REQUEST FORM

NOTE: Agencies may follow up with supplementary questions, requests for clarification, or requirements for additional information. Attach additional pages where needed to provide additional information.

CONTROLLED UNCLASSIFIED INFORMATION NOTICE: This document may contain Controlled Unclassified Information, trade secrets, commercial, or financial information obtained from a non-governmental source. Such information may be protected by law or regulation from unauthorized disclosure.

OMB REPORTING BURDEN: OMB Control Number: ####-#### Expiration Date: __/__/____
A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with an information collection subject to the requirements of the Paperwork Reduction Act of 1995 unless the information collection has a currently valid OMB Control Number. The approved OMB Control Number for this information collection is ####-####. Without this approval, we could not conduct this survey/information collection. Public reporting for this information collection is estimated to be approximately: 13 hours, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to National Institute of Standards and Technology, Technology Partnership Office at: 100 Bureau Drive, Gaithersburg, MD 20899, Attn: iEdison Administrator, iedison@nist.gov.

PRIVACY ACT STATEMENT: Pursuant to 5 U.S.C. § 552a(e)(3), this Privacy Act Statement serves to inform you of why the U.S. Department of Commerce (the Department), National Institute of Standards and Technology (NIST) is requesting the information on this form.

Authority: The National Institute of Standards and Technology Act, as amended, 15 U.S.C. 271 et seq. (which includes Title 15 U.S.C. 272) and The Bayh-Dole Act (35 USC 18) and its implementing regulations (37 CFR 401).

Purpose: The iEdison System collection of information 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 data for calculation of return on investment (ROI) from federal funding and identifies successful research programs. This information also allows the government the opportunity to timely protect inventions which the Contractor declines title or discontinues patent protection.

The information solicited on this form may be made available as a "routine use" pursuant to 5 U.S.C. § 552a(a)(7) and (b)(3). The information may be made available to other federal agencies to assist the Department in connection with NIST's management of the purposes stated above; or for other authorized routine uses.
A complete list of the routine uses can be found in the system of records notice associated with this form, "COMMERCE/DEPT-23: Information Collected Electronically in Connection with Department of Commerce Activities, Events, and Programs. This system of records notice can be found on the Department's website at https://www.osec.doc.gov/opog/privacyact/privacyact_sorns.html

CONSEQUENCES OF FAILURE TO PROVIDE INFORMATION: Providing this information is voluntary. However, failure to provide the requested information may result in an inability for NIST to process, review, and/or act on such requests. In limited circumstances, NIST may authorize the submission of the requested information via paper forms pursuant to the requirements in 15 CFR 748.1(d).

CONTACT INFORMATION

1.	**Contractor/Petitioner Organization**	Click or tap here to enter text.
2.	**Contractor/Petitioner Organization Address**	Click or tap here to enter text.
3.	**Contractor/Petitioner Point of Contact**	Click or tap here to enter text.
	a. Name	
	b. Email Address	Click or tap here to enter text.
	c. Phone Number	Click or tap here to enter text.
4.	**Primary Contact** *(if different from above)* **or Additional Point of Contact** *(optional)*[1] **a. Name**	Click or tap here to enter text.
	b. Email Address	Click or tap here to enter text.
	c. Phone Number	Click or tap here to enter text.
	d. Name of the Party the Additional Contact Represents	Click or tap here to enter text.

SUBJECT INVENTION DETAILS

Repeat this section for each subject invention involved. Attach additional pages as needed.

5	**Invention Report Number(s)**	Click or tap here to enter text.
6.	**Primary Funding Agency**	Click or tap here to enter text.
7.	**Other Funding Agency(ies)**	Click or tap here to enter text.
8.	**Agreement Number(s)**	Click or tap here to enter text.
9.	**Invention Title(s)**	Click or tap here to enter text.
10.	**Invention Docket Number(s)**	Click or tap here to enter text.
11.	**Patent Docket Number(s)**	Click or tap here to enter text.
12.	**Patent Applications and Patent Numbers included in request**	Click or tap here to enter text.

LICENSE & LICENSEE INFORMATION (if applicable)

Licensee information provided may be of existing licensee(s) or prospective licensee(s)

13.	**Name of Licensee or Proposed Licensee**	Click or tap here to enter text.
14.	**Names of any Sub-Licensees**	Click or tap here to enter text.
15.	**Business Address of Licensee** (optional)	Click or tap here to enter text.

[1] Additional Point of Contacts may be a secondary person at the Contractor Organization, an attorney, the Licensee, or other representative. Adding an Alternative Point of Contact allows the agency to also correspond with this individual regarding this request.

16.	**Exclusive or Non-Exclusive License**	Click or tap here to enter text.
17.	**Fields of use to which the license is or could be restricted**	Click or tap here to enter text.
18.	**What is the scope of rights given (e.g., U.S. versus worldwide use and sales)?**	Click or tap here to enter text.

TECHNOLOGY AND PRODUCT

19. **Describe the technology, including products to be manufactured or specific processes implementing the subject invention.**

20. **Describe the current stage of development of the subject invention and any development milestone plans necessary for manufacturing and commercialization.**

MANUFACTURING INFORMATION

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.**

22. **Discuss the factors that make domestic manufacture not commercially feasible, including:**

    a. 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:

    b. The relative costs of U.S. and foreign manufacturing:

c. Manufacturing capabilities within the U.S.:

d. 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.:

e. Approximately how much additional time, funding, and/or other factors that would be necessary in order to make U.S. manufacturing commercially feasible:

f. Any other circumstances that make foreign manufacture necessary:

23. **Identify any companies, including contract 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.?**

24. **Has the Hollings Manufacturing Extension Partnership (MEP) or similar organizations been consulted to identify domestic manufacturers for the product?**

☐ **YES** ☐ **NO**

If so, provide any information or documentation provided by MEP or similar organization regarding the availability of a U.S. manufacturer.

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).**

26. **Where would the proposed manufacturing facility be located (city and country)?**

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.**

28. **Is the proposed manufacturing facility new or an existing facility?**

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 unionization of workplaces, health and safety standards, labor and wage laws, and environmental impacts).**

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)?**

31. **How will the know-how to manufacture be transferred (e.g., Licensee's employee or other knowledge being provided)?**

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.**

PREVIOUS MARKETING EFFORTS

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.**

MARKET AND IMPACT INFORMATION

34. **Describe the market size and geographic distribution potential of the technology.**

35. **Discuss the significance of the technology, including the availability of alternative products, the size of intended patient 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.**

36. **Identify any value or benefit to the United States of 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.**

OTHER CONSIDERATIONS

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.**

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.**

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.*** *(Optional)*