

APPENDIX 5 MODIFICATION AND WAIVER GUIDANCE

Guidance on U.S. Manufacturing Modifications and Waivers

A primary objective of the Department of Energy's (DOE) multi-billion-dollar research, development and demonstration investments is to cultivate new research and development ecosystems, manufacturing capabilities, and supply chains for and by U.S. industry and labor. To further this objective, using DOE statutory and regulatory authorities, DOE typically requires DOE awards to have commitments to manufacture technology resulting from the award in the U.S. Per the S&E and other Determinations of Exceptional Circumstances (DEC) as well as the DOE patent waivers for non-Bayh-Dole entities, the award may include the U.S. Competitiveness Provision,¹ i.e., U.S. manufacturing (USM) requirement, that requires all products resulting from inventions made under the award to be substantially manufactured in the U.S.

The expectation is that most recipients will be able to comply with the U.S. Competitiveness Provision in the awards. However, DOE recognizes the need to be flexible to promote commercialization of the DOE funded technology, such as to accommodate situations like the lack of domestic manufacturing capacity and other business considerations in the global supply chain. In such cases, the recipient may request a modification to or waiver of the USM requirement. DOE is committed to a transparent, reasonable and timely waiver/modification process.

DOE will consider any request to modify or waive certain aspects of the U.S. Competitiveness Provision in an award from the recipient or from any entity receiving rights in an invention made under the award, such as assignees, exclusive licensees, and non-exclusive licensees.

Due to the importance of U.S. manufacturing to the mission of DOE, DOE is unlikely to approve a complete waiver of the U.S. Competitiveness Provision in an award. The rationale for the U.S. Competitiveness Provision policy is clearly set forth in the S&E DEC: U.S. job creation, securing a domestic supply chain for critical technologies, and increasing national security with domestic production. U.S. manufacturing is an essential component of the return on investment to the taxpayer for funding new technologies. However, the realities of modern manufacturing can lead to a need to modify or waive the U.S. Competitiveness Provision. Any deviations from the DEC policy should be specific, fact-based, and tailored.

- **Specific:** requestors need to present DOE programs with a clearly defined commercial feasibility problem that the U.S. Competitiveness Provision causes – the business justification for the modification/waiver.
- **Fact-based:** requestors must provide concrete evidence that the U.S. Competitiveness Provision is causing the identified problem and that a deviation from the U.S. Competitiveness Provision will address the problem.
- **Tailored:** using the facts, DOE and the requestor will tailor a solution to fit the specifically defined problem.

DOE's policy is to consider modification and waivers that still provide benefits to the U.S. economy and competitiveness while allowing an awardee or other partner to successfully

¹ This guidance may be applied to other U.S. manufacturing commitments, such as U.S. Preference, commitments under other DEC's, and patent waivers.

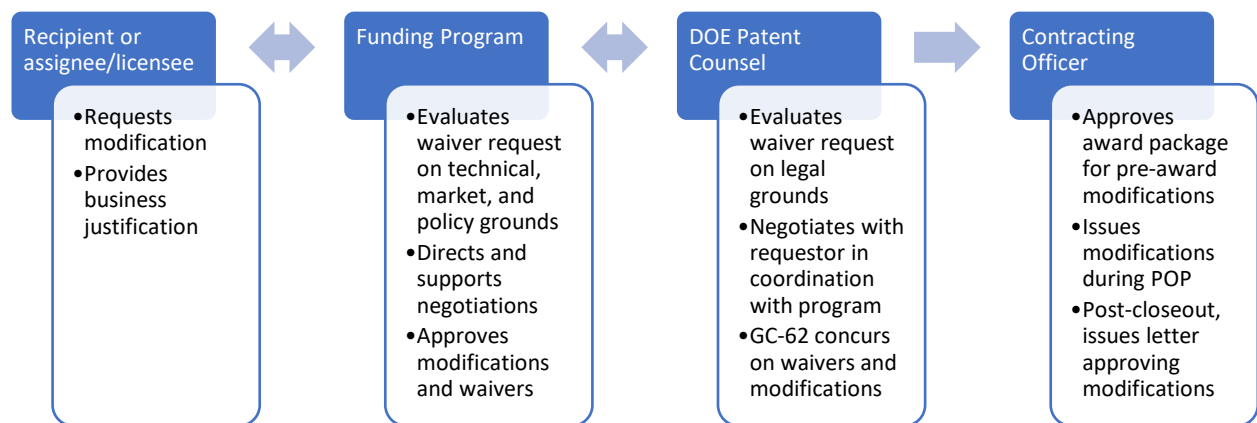
commercialize the technology. For example, an entity may propose modifying the language of the U.S. Competitiveness Provision to change the scope of the requirements or to provide more specifics on the application of the requirements for a particular technology. As another example, an entity may request that the U.S. Competitiveness Provision be waived in lieu of a net benefits statement or U.S. manufacturing plan. The statement or plan would contain specific and enforceable commitments that would be beneficial to the U.S. economy and competitiveness. Examples of such commitments could include manufacturing specific products in the U.S., making a specific investment in a new or existing U.S. manufacturing facility, keeping certain activities based in the U.S. or supporting a certain number of jobs in the U.S. related to the technology

Processing of USM Waiver Requests

The DOE funding program, in coordination with the Office of General Counsel Technology Transfer and Intellectual Property (GC-62) or DOE field patent counsel, will consider any requests for a modification or waiver of the U.S. Competitiveness Provision in a DOE award although granting any modification or waiver is within DOE's sole discretion. Any modification or waiver must be approved by the DOE funding program and concurred with by GC-62 or its delegee.

The recipient/requestor, the funding program, and DOE patent counsel shall exercise reasonable due diligence to resolve the USM waiver or modification request. It is recognized that the need for leadership or stakeholder briefings, complex business issues, the scope and nature of the request, and other extenuating circumstances may prolong the process.

This chart shows the general order in which entities are brought into the modification/waiver process. While the chart implies a linear process, in practice the process will likely be iterative, with the different offices and entities working together to achieve a workable solution for both DOE and the entity making the request.



Requestor: The requestor initiates the process by requesting a waiver or modification in writing to the DOE funding program. Any entity with rights in an invention covered by a U.S. manufacturing commitment may initiate a waiver or modification request. The request may be

submitted during award negotiations, during the performance of the award or post award. Even though it is not limited to the recipient, the recipient of the award is most likely the entity to submit a request, especially during the performance of the award. All requests and communications containing confidential business or financial information should be marked with the appropriate FOIA exemption and will be protected from disclosure to the maximum extent allowable by law. When a requestor proposes either a modification or a waiver, it is recommended that the requestor use Attachment A, *Request for Waiver of U.S. Manufacturing Requirement for Subject Inventions*. The questions in Attachment A are designed to elicit the business justification(s) that programs will need to evaluate the modification/waiver request. By using Attachment A, the requestor is more likely to provide the necessary information to the DOE funding program to allow a complete review to determine the merits of the request. If Attachment A is not used, the requestor should ensure that the written request provides sufficient information and detail to demonstrate the commercial feasibility with and without the modification or waiver and the benefits to the U.S. economy and competitiveness with the modification or waiver.

The request for a waiver or modification should be focused on specific situations and is typically accompanied by a commitment by the requestor to benefit the U.S. economy. If the request itself does not include the commitment to benefit the U.S. economy, benefits will be negotiated during the process.

Note: In the future, recipients may be able to submit requests digitally through iEdison, a government wide online database used by government recipients for intellectual property reporting. The iEdison-supplied form will closely resemble Attachment A. The iEdison option would not be available for any modification or waiver requests prior to the reporting of a subject invention and will likely be limited to recipients only. DOE will follow the current process to consider waivers for non-recipients if the iEdison form cannot accommodate non-recipients.

Funding Program: Each DOE funding program should determine a process for receiving and evaluating modification/waiver requests. For example, all programs should designate a POC for receiving modification/waiver requests. The POC may be the program manager, technology-to-market personnel, administrative personnel, or other program personnel. Program may also work with the relevant CO to designate the CO receive the requests.

Each program should establish a process for reviewing and approving or rejecting requests. At a minimum, the program should be prepared to review the information in the requests against the waiver criteria factors listed below, work with the requestor to obtain additional information when necessary, negotiate changes to the waiver or modifications with the requestor to maximize the benefits to the U.S. economy and competitiveness while allowing the requestor to successfully commercialize the technology, approving the waiver or modifications based on DOE guidance and policy considerations and documenting the approval or rejection. The approval of any waiver or modification should be made by senior leadership within the program. The funding program should also coordinate with the cognizant DOE patent counsel for support throughout the process and to obtain concurrence from GC-62.

Policy Factors for Program Consideration

Program is expected to evaluate various policy factors to determine if a deviation from the USM requirement is warranted. This is a non-exhaustive list of relevant policy factors to consider when evaluating a request for a modification or waiver of the USM requirement.

- The extent to which the request supports the objectives of DOE's mission.
- The commercial feasibility of manufacturing the subject invention in the U.S., including the feasibility of developing all or part of the related supply chain(s) in the U.S.
- Any reasonable efforts to substantially manufacture the subject invention in the U.S., including licensing U.S. firms for manufacturing.
- Legally enforceable commitments proposed by the recipient to provide alternative benefits to the U.S. economy and industrial competitiveness, preferably related to the commercial use of the subject invention, e.g., direct or indirect investment in U.S.-based plant and equipment, creation of high-quality U.S.-based jobs, and further domestic development of the subject invention technology.
- The geographic, technological, commercial, and temporal scope of the requested waiver compared to any proposed contractual or other benefits.
 - How much of the subject invention would be manufactured outside of the U.S. and where, including components and subcomponents?
 - Special consideration should be given to requests to manufacture in DOE-designated countries of risk.
 - Can the modification or waiver be time limited, to allow for the development of domestic capacity or to give domestic manufacturers a head start?
- Agreement by the requestor to provide at least a non-exclusive license with commercially reasonable terms to any recipient agreeing to the U.S. Competitiveness Provision.
- Effect on the availability of the technology within the U.S.
- Nature of the technology
 - Special consideration should be given before permitting foreign manufacture of technologies that impact supply chains identified in *America's Supply Chains*, E.O. 14017, such as semiconductor manufacturing and advanced packaging, high-capacity batteries, including electric-vehicle batteries, and critical minerals and other identified strategic materials, including rare earth elements.
- Special circumstances
 - OSS: Open Source Software (OSS) licenses with an included non-exclusive patent license may require using the same OSS license for subsequent inventions. This may prohibit adding a U.S. Competitiveness Provision to the subsequent inventions. This situation is expected to be rare.
 - Software inventions. A modification may be made clarifying the DOE approach to software inventions, since software itself is not manufactured as that term is traditionally understood.
- Any other factors that may be relevant.

DOE Patent Counsel: Patent counsel will work with the funding program to evaluate the legal considerations for the modification request. Patent counsel will also work with program to tailor a solution to the identified problem created by the U.S. Competitiveness Provision, draft

appropriate award language that reflects that solution, and negotiate the modification with the recipient, including a confirmatory license incorporating the recipient's commitments.

GC-62: Until further notice, the Assistant General Counsel for Technology Transfer and Intellectual Property (GC-62) must concur with any modifications, even if another DOE patent counsel is leading negotiations with the recipient. At a future date, GC-62 may delegate the concurrence authority to the cognizant DOE patent counsel.

Contracting Officer: Once program leadership has approved and GC-62 has concurred in a modification to the patent clause of an award, a Contracting Officer (CO) will execute a modification to the award.

- If the modification is approved during pre-award, the CO will implement the approved patent clause, drafted by the DOE patent counsel that will incorporate the waiver or modification, as an Attachment to the award as part of existing award processes.
- If the modification request is approved during the period of performance, the CO should use best efforts to execute a modification to the award within 30 days upon receiving program approval/requisition.
- If the modification is post-closeout, the CO should use best efforts to issue a letter, co-signed by the funding program leadership and GC-62, setting forth the permitted deviation from the USM requirement to the award within 30 days upon receiving program approval/requisition.

Attachment A:
Request for Waiver of U.S. Manufacturing Requirement
for Subject Inventions

Date:

U.S. Agency Managing Request: DOE - [[FUNDING PROGRAM]]

APPLICANT/RECIPIENT INFORMATION

Contact First and Last Name: [Click here to enter text.](#)

E-Mail Address: [Click here to enter text.](#)

Phone Number: [Click here to enter text.](#)

Grantee/Contractor Organization/Company Full Legal Name: [Click here to enter text.](#)

Grantee/Contractor Organization/Company Address: [Click here to enter text.](#)

[Click here to enter text.](#)

Subject Invention Report Number(s): [Click here to enter text.](#)

Grant/Contract Number: [Click here to enter text.](#)

Subject Invention Title(s): [Click here to enter text.](#)

DOE MAY REQUEST ADDITIONAL DETAILS TO RENDER A DECISION, BUT REQUESTOR IS NOT ASSURED OF HAVING AN OPPORTUNITY TO SUPPLEMENT ITS ANSWERS PRIOR TO A DECISION.

DESCRIPTION OF THE TECHNOLOGY AND MARKET

Describe the technology, including the products/processes covered by the subject invention(s), and the size and geographic distribution of the market.

The Technology:

Hurdles to be overcome to make the technology practical and investigate whether it will be useful and economical in a commercial environment:

The Market: The market size and geographic distribution potential is...

APPLICANT'S BUSINESS MODEL

Discuss Applicant's business model, including plans for manufacturing or otherwise commercializing the subject invention(s).

REASONABLE BUT UNSUCCESSFUL EFFORTS TO MANUFACTURE IN THE U.S.

Discuss previous efforts by the Applicant to manufacture the subject invention(s) in the U.S.

REASONABLE BUT UNSUCCESSFUL EFFORTS TO LICENSE

Discuss previous efforts to license the subject invention(s) to companies for U.S. manufacture.

NOT COMMERCIALY FEASIBLE TO U.S. MANUFACTURE - FACTORS

Discuss the factors that make domestic manufacture of the subject invention(s) not commercially feasible, including the relative costs of U.S. and foreign manufacturing, the Applicant's or Applicant's licensee's manufacturing capabilities within the U.S., overall manufacturing capabilities within the U.S. for the technology, and the efforts made by the Applicant or licensee to locate, develop, or contract for such manufacturing capabilities, and any other circumstances that make foreign manufacture necessary.

POTENTIAL MANUFACTURING PARTNERS, LOCATIONS

Discuss likely companies for manufacturing the subject invention(s) (if not the Applicant or Applicant's subsidiary), the location of such manufacture, whether by the Applicant, Applicant's subsidiary, or a third party (city and country), the mechanism by which a non-Applicant company or subsidiary will acquire the rights to manufacture (e.g., license, exclusive license, assignment), the scope of rights given (e.g., U.S. versus worldwide use and

sales) , and how the know-how to manufacture is being transferred (e.g., Applicant's employee or other in-house knowledge being provided on a permanent or temporary basis to the manufacturer). Provide specific information regarding the Applicant's ongoing oversight of the manufacturing and distribution of the resultant products, if any.

U.S. vs. NON-U.S. MANUFACTURING CONTENT

Identify the part or percentage of products arising from the subject invention(s) that would be manufactured outside the U.S. If listing the part, please provide a listing of all the parts in the subject invention(s) and indicate where each part is or is expected to be manufactured.

POTENTIAL BENEFIT TO THE U.S. ECONOMY OF NON-U.S. MANUFACTURE

NOTE: ANY OR ALL OF THESE BENEFITS MAY BECOME REQUIRED COMMITMENTS BY THE APPLICANT IN EXCHANGE FOR ANY GRANTED WAIVER. Discuss value or benefit to the United States of manufacturing the subject invention(s) outside of the U.S. or licensing the technology even if it will not be manufactured in the United States, including i) the direct or indirect investment in U.S. plants or equipment, such as for supply chain, 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.

RECOGNITION OF THE U.S. TAXPAYER SUPPORT

Discuss how the Applicant will appropriately recognize U.S. taxpayer support of the development of the subject invention in the absence of U.S. manufacture.

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