

# Frequently Asked Questions (FAQs) for Applicants and Awardees of DOE Financial Assistance and R&D Contracts regarding the Department's Determination of Exceptional Circumstances (DEC) for DOE Science and Energy Technologies issued in June of 2021

## Background: American Innovation. Made Here.

*Science and Energy Determination of Exceptional Circumstances (June 2021) - Harnessing Federally Funded Research and Innovation for Science and Energy Technologies to Revitalize Domestic Manufacturing, Secure U.S. Supply Chains, and Create Good-Quality American Jobs*

An important goal of the Bayh-Dole Act is to promote the commercialization of federally-funded technologies by U.S. industry and labor while ensuring that the Government obtains sufficient rights in federally-funded subject inventions to meet the needs of the Government.<sup>1</sup> This is a broader recognition of the vital role in America's security and prosperity represented by DOE's multi-billion-dollar R&D investment to cultivate new research and development ecosystems, manufacturing capabilities and industries, supply chains, and good-quality jobs within the U.S.

Unfortunately, this goal has often not been realized as we have seen the manufacturing of countless federally-funded technologies (ranging from solar technologies to semi-conductors to energy storage) increasingly offshored to locations other than the United States over the past several decades since passage of Bayh-Dole. The resulting confluence of circumstances, including erosion of the U.S. manufacturing base, its associated manufacturing jobs, and the urgent need to secure U.S. supply chains for a wide range of technologies, has created an exceptional circumstance requiring urgent action. The urgency is further exacerbated by the fact that several areas of science and technology are undergoing disruptions that could rapidly shift the balance of global power in the 21st Century. Since many (if not all) of these disruptive areas are funded by DOE, and since it is often impossible to accurately predict the next disruption, the Department has determined that issuing a DEC for DOE's Science and Energy Technologies will better ensure current and future technologies are best positioned to be commercialized by U.S. industry and labor and better ensure the national security of the United States.

The U.S. Preference clause of Bayh-Dole provides for a limited domestic manufacturing requirement on granting certain exclusive licenses. Its reach is only to substantial manufacturing for *domestic use and sale* and only by *exclusive licensees*. The U.S. Preference clause has been rendered largely ineffective due to these textual limitations that allow recipients to easily maneuver around it. The new Science and Energy Determination of Exceptional Circumstances (DEC) extends the domestic manufacturing requirement to other uses and sales beyond the domestic market, and for all manufacturers of the technology, not only for exclusive licensees, in order to better achieve the stated goals of Bayh-Dole.

DOE recognizes the importance of working with industry in achieving these goals, and for flexibility in implementing the Science and Energy DEC, taking into account existing limitations in domestic manufacturing capacity for certain technologies. The Science and Energy DEC allows for waivers and modifications to the domestic manufacturing requirement when doing so will facilitate or promote commercialization.

For additional clarification on the DOE Science and Energy DEC and its implementation, please refer to the Frequently Asked Questions, below.

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<sup>1</sup> 35 U.S.C. § 200.

## **Does the Science and Energy DEC apply to all DOE funding?**

The Science and Energy DEC provides DOE the flexibility to increase U.S. manufacturing requirements for DOE Science and Energy Technologies beyond the minimum U.S. Preference standard set forth in Bayh-Dole.<sup>2,3</sup> It is a permissive document in that its provisions may be included in a funding opportunity announcement (FOA) or solicitation and the resulting financial assistance agreements or contracts, though the expectation is that the DEC will apply to **most** funding opportunities. Even for FOAs that apply the DEC, awardees may request waivers or modifications to the domestic manufacturing requirement to address their unique circumstances.

## **Does the Science and Energy DEC change what constitutes “manufactured substantially in the United States”?**

No. DOE made a deliberate decision not to change the “manufactured substantially in the United States” standard established by Bayh-Dole over 41 years ago, as DOE finds that “manufactured substantially in the United States” preserves needed flexibilities while promoting U.S. manufacturing. While the DEC addresses some textual limitations within the statutory provision, DOE did not alter the manufacturing standard itself.

## **Will the DEC be applied retroactively to financial assistance agreements (grants and cooperative agreements) and contracts in force before the DEC was issued? If so, will patents already licensed be subjected to review?**

The Science and Energy DEC will be generally applied to agreements prospectively (i.e., to grants, cooperative agreements, and contracts issued after the release of the DEC although there may be some limited exceptions for a subset of awards like our Management and Operating Contracts for our National Labs and DOE Facilities. However, even in those limited cases, the DEC provisions will only apply prospectively (i.e., to subject inventions conceived or first actually reduced to practice **after** the agreement is modified to include the DEC). For example, the Science and Energy DEC should not affect patents that were licensed prior to issuance of the DEC.

## **What does the DEC accomplish?**

The Science and Energy DEC allows DOE to extend the requirement for substantial domestic manufacture of DOE Science and Energy Technologies developed under a funding agreement beyond the Bayh-Dole Act requirement of U.S. Preference. The Science and Energy DEC does not alter DOE acquisitions<sup>4</sup> or partnering engagements with industry. Since one of the stated goals of Bayh-Dole is to “promote the commercialization and public availability of inventions made in the United States by United States industry and labor” DOE has determined that enhanced domestic manufacturing requirements will better promote the goals of Act, better ensure domestic impact of DOE-funded technologies, and better protect critical supply chains.

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<sup>2</sup> 35 U.S.C. § 204.

<sup>3</sup> Although programs will have flexibility to apply or not apply the DEC to various FOAs, agreements etc., the default will be for the DEC to apply.

<sup>4</sup> Federal acquisitions are subject to the provisions of The Buy American Act, 41 U.S.C. § 8301 *et seq.* The Science and Energy DEC does not and cannot alter the provisions of this statute.

## How can DOE extend the U.S. manufacturing requirement of Bayh-Dole?

The Bayh-Dole Act provides flexibility for agencies to modify certain requirements in funding agreements that better promote the policy and objectives of the Act when the agency makes a determination that exceptional circumstances exist.<sup>5</sup> U.S. manufacturing requirements are among those where flexibility is available. DOE has elected to tailor the changes narrowly to address U.S. manufacturing while balancing and maintaining the core rights of small business firms and nonprofit organizations to retain ownership and commercialize their federally-funded inventions.

## What is different when the Science and Energy DEC applies?

While use of the Science and Energy DEC for some DOE programs will be new, some existing program/technology-specific DEC's requiring this enhanced U.S. manufacture have been already successfully implemented by DOE.<sup>6</sup> The standard U.S. Preference clause of Bayh-Dole provides for a limited domestic manufacturing restriction on granting certain exclusive licenses. Its reach is only to substantial manufacturing for *domestic use and sale* and only by *exclusive licensees*. The Science and Energy DEC allows DOE to extend this requirement to other uses and sales beyond the domestic market, and to do so for all manufacturers of the technology, not only for exclusive licensees, in order to better achieve the stated goals of Bayh-Dole to “promote the commercialization and public availability of inventions made in the United States by United States industry and labor.”

## **The Bayh-Dole Act [through the U.S. Preference Provision in 35 U.S.C. § 204] requires patent owners to receive a case-by-case waiver from a funding agency if they are unable to find a licensee to manufacture resulting technologies substantially in the United States. The agency can deny the request without appeal. Why isn't this statutory authority sufficient to encourage domestic manufacturing whenever possible?**

As noted above, Bayh-Dole's goals to promote the commercialization of federally-funded technologies by U.S. industry and labor have often not been realized for DOE Science and Energy Technologies, as we have seen the manufacturing for countless DOE technologies and industries (ranging from solar technologies to energy storage) increasingly offshored to locations other than the United States in the decades since passage of Bayh-Dole. While the reasons for this result are complex and multi-dimensional, the limitations within the statutory U.S. Preference clause have not been an adequate tool in meeting Bayh-Dole's goal of promoting domestic manufacture of DOE funded energy technologies. Therefore, the Science and Energy DEC was necessary to address some of these statutory limitations and make U.S. manufacturing provisions more robust and enforceable.

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<sup>5</sup> 35 U.S.C. § 202(a)(ii).

<sup>6</sup> The Office of Energy Efficiency and Renewable Energy (EERE), Advanced Research Projects Agency – Energy (ARPA-E), The Office of Cybersecurity, Energy Security, and Emergency Response (CESER), and The Office of Science's Quantum Information Sciences (QIS) program have existing DEC's that permit these programs to elevate the U.S. manufacturing standard to U.S. Competitiveness. A list of the current DOE DEC's is available here: [Determination of Exceptional Circumstances \(DECs\) | Department of Energy](#)

While Bayh-Dole has been one of the most impactful pieces of legislation for economic growth over the past century, the U.S. Preference provision contains textual limitations that allow recipients to easily maneuver around it since the provision only requires substantial manufacture in the U.S. if an invention is exclusively licensed to a third party, and even then, it only applies to use and sale in the United States. A few examples may be helpful to emphasize this point:

- DOE's experience has been that owners of DOE-funded subject inventions may design their licensing strategy to focus more on non-exclusive licensing to avoid the U.S. Preference requirement.
- Given DOE's experience in seeing the offshoring of nationally important technologies and the low number of waiver requests that DOE receives to accommodate U.S. manufacturing requirements, DOE has concluded that a low waiver request rate reflects the limited scope and ineffectiveness of the provision in promoting the Act's goals.

## **Does the Science and Energy DEC impact the ability of non-profit or small business entities to elect title to a DOE-funded invention?**

The DEC is narrowly tailored and doesn't substantively affect the ability of nonprofit and small business firms to elect title to their inventions as long as inventions are timely reported to DOE via the interagency iEdison system at <https://era.nih.gov/iedison>, and entities abide by their election and the enhanced U.S. manufacturing requirements. Except for the addition of an enhanced domestic manufacturing provision, the patent rights granted to nonprofit and small business recipients under Bayh-Dole remain the same.

## **When does the Science and Energy DEC apply?**

The Science and Energy DEC will apply primarily to funding opportunities published beginning with FY2022 on October 1, 2021. These funding opportunities will specifically identify applicability of the DEC, though the expectation is that the DEC will apply to most funding opportunities. It may also apply to certain FY2021 funding opportunities that included notice of the U.S. manufacture requirement.

## **What if the non-profit or small business finds it impossible to strictly comply with the enhanced domestic manufacturing provision?**

DOE recognizes the need for flexibility when relying on the Science and Energy DEC, and expects to modify the U.S. Competitiveness Provision in certain situations. The Science and Energy DEC allows for DOE to grant waiver or modification requests. At this time, [petitions for a waiver or modification](#) of U.S. manufacturing requirements should be sent to [GC-62@hq.doe.gov](mailto:GC-62@hq.doe.gov) directly or as a cc: when submitting a request to a contact provided by the funding program to a contact provided by the funding program. DOE will accept and consider all applications for a waiver or modification of the requirements under the U.S. Competitiveness Provision, though it is incumbent upon the requestor to provide a business justification in support of the request. The Science and Energy DEC authorizes modification of the U.S. Competitiveness Provision to tailor requirements when doing so will facilitate or promote commercialization. For example, DOE may authorize certain technologies or products be manufactured outside the U.S. in certain quantities, fields of use, or for certain time periods. Additionally, administrative changes may be made to the U.S. Competitiveness Provision, for example to clarify funding agreement requirements, provide contact information, or to tailor requirements of the provision as appropriate.

## What conditions are eligible for requesting a waiver/modification?

DOE offices will be encouraged to provide program-specific information for the waiver process including contact information for local field patent counsel and program approval information. Any waiver or modification of the U.S. Competitiveness Provision must consider the factors described below as well as substantial U.S. economic benefits. DOE recommends using this [sample waiver/modification](#) request form.

### *Factors Considered for Waivers/Modifications*

- (1) the extent to which the request supports the objectives of DOE's mission;
- (2) 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.;
- (3) any reasonable efforts to substantially manufacture the subject invention in the U.S., including licensing U.S. firms for manufacturing;
- (4) legally enforceable commitments proposed as part of the waiver or modification request 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;
- (5) the geographic, technological, commercial, and temporal scope of the requested waiver compared to any proposed contractual or other benefits;
- (6) agreement to provide at least a non-exclusive license with commercially reasonable terms to any entity agreeing to the U.S. Competitiveness Provision; and
- (7) any other such factors that may be relevant.

## What is the process for obtaining a waiver/modification?

Any entity impacted by the U.S. Competitiveness Provision obligations may request a modification or waiver. Once DOE receives a request and determines a modification is warranted, DOE will work with the requesting entity to modify the U.S. Competitiveness Provision to meet the needs of the requesting entity while ensuring a sufficient benefit to the U.S. economy and competitiveness. Instead of modifying the U.S. Competitiveness Provision, DOE and the requesting entity may agree to alternate legally binding commitments to the U.S. economy in lieu of the U.S. Competitiveness Provision. An entity may request a waiver of U.S. manufacturing commitments and DOE will consider it. However, any waiver request is unlikely to support DOE's mission or provide a sufficient net benefit to the U.S. economy so it is anticipated that complete waivers of U.S. manufacturing commitments will rarely be approved. DOE plans to issue additional guidance on the waiver/modification process in early FY2022.

## **Does DOE intend to review every exclusive and non-exclusive license, even if the patent owner secured a commitment that the resulting product will be substantially manufactured in the United States?**

DOE has no intention to routinely review and/or approve exclusive and/or non-exclusive licenses contemplated or executed by Bayh-Dole entities. DOE understands and respects that small business, academic, and non-profit entities need flexibility to negotiate and execute licensing arrangements without significant encumbrances or federal micromanagement so that federally funded technology can be effectively transferred to the marketplace. In keeping with established practice, DOE only intends to review licenses that are (1) part of a compliance review (historically significantly less than 1% of DOE awards), (2) as part of a request for a modification or waiver of the U.S. manufacturing provision, or (3) as part of an approval that may be necessary as a result from a change of control. To the extent that DOE receives properly marked business sensitive information, it protects that marked information to the maximum extent allowed by law.

## **Can individual applications of the Science and Energy DEC be appealed?**

The statute provides for availability of an agency appeal. DOE is developing streamlined processes for handling both the waiver/modification requests and an appeal process.

### **Why now?**

Securing domestic supply chains and revitalizing U.S. Manufacturing for critical and emerging technologies is essential to U.S. economic, environmental, and national security<sup>7</sup>. It is vital to America's security and prosperity that DOE's multi-billion-dollar R&D investments cultivate new research and development ecosystems, manufacturing capabilities and industries, supply chains and good-quality jobs within the U.S. Since 2001, the year China joined the World Trade Organization, the United States has lost nearly one-third of its manufacturing jobs, and the number of workers employed in manufacturing has declined to 12 million.<sup>8</sup>

The importance of having DOE Science and Energy Technologies manufactured by U.S. industry and labor has never been greater. DOE invests billions of dollars a year in science-based solutions to ensure continued U.S. science and technology leadership. DOE efforts include a broad range of science, energy, environmental and nuclear science and technology solutions to advance DOE's mission for the nation. The importance was underscored in the House Report accompanying the 2013 Energy and Water Appropriations Bill, the Committee on Appropriations which identified the specific need for DOE to take a leadership role in improving U.S. manufacturing and domestic intellectual property retention. It requested that DOE examine what authorities are available to maintain intellectual property, specifically including Bayh-Dole.<sup>9</sup>

“The Department’s research and development efforts yield several thousand patents and licenses each year, and taxpayers expect their support to result in commercialized technologies that benefit both American consumers and American industry. This

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<sup>7</sup> See, EO 14017 on America's Supply Chains and EO 13953 on Addressing the Threat to the Domestic Supply Chain from Reliance on Critical Minerals.

<sup>8</sup> As reported by the U.S. Bureau of Labor Statistics, the number of U.S. manufacturing jobs peaked in 1979 at 19.6 million; in June 2019, manufacturing employment was 12.8 million, a decline of 35 percent. See, <https://www.bls.gov/opub/btn/volume-9/forty-years-of-falling-manufacturing-employment.htm>

<sup>9</sup> H. Rept. 112-462 - ENERGY AND WATER DEVELOPMENT APPROPRIATIONS BILL, 2013 at page 81.

expectation is not met when intellectual property that was developed with public funding is commercialized only by foreign manufacturers. *The Committee believes that intellectual property policies offer substantial opportunities to encourage domestic manufacturing without obstructing commercial efficiency, eroding the value of intellectual property, or under-mining free trade . . .*<sup>10</sup> (emphasis added)

While strong U.S. manufacturing standards are not always a zero-cost requirement for DOE awardees, they better ensure the technologies that are funded by DOE are substantially manufactured in America by U.S. industry and labor.

**It appears that DOE plans to review any merger or acquisition of the patent owner or licensee before such actions can go forward. Is that accurate? If so, it may seriously jeopardize the opportunities, if any, for investment in developing these technologies as it is standard and accepted practice of the past four decades for licensees and industry partners to require the freedom to seek acquisition and investment opportunities without need for consent of the licensor or funding agency.**

DOE understands and respects that small business, academic, and non-profit entities and their downstream licensees need certainty when bringing DOE funded technologies to the market and we respect the concerns raised by the change of control provisions. Even though similar change of control provisions have been successfully implemented by the DOE in its patent waiver process (spanning several decades), DOE is providing additional information on this provision to: (1) enable the reservation or modification of the clause when such a reservation or modification would not negatively affect U.S. economic or national security interests, including supply chain security and resiliency, (2) best ensure timely and transparent reviews and approvals by DOE program elements, and (3) provide additional clarity.

*The DEC's Change of Control Provision states:* "Should the Contractor or other such entity receiving rights in the invention(s): (1) undergo a change in ownership amounting to a controlling interest, or (2) sell, assign, or otherwise transfer title or exclusive rights in the invention(s), then the assignment, license, or other transfer of rights in the subject invention(s) is/are suspended until approved in writing by DOE."

*Review and Approval Process:*

When contemplating review and approval requests for a change of control transaction, DOE primarily considers whether an approval of a transaction would run counter to the national or economic security interests of the United States. When making such a determination, DOE considers factors such as the nature of the technology (e.g., is it a critical or emerging technology) and the entity taking control (e.g., is it an entity from or controlled by a sensitive country). DOE will use best efforts to review and approve/disapprove any such requests within 30 days of receiving the request and DOE's approval should not be unreasonably withheld.

*Preapprovals:*

Applicants for, and recipients of, DOE Science and Energy funding agreements may submit to DOE pre-approval requests for any potential/pending transactions that might trigger a change of control approval by the Department. DOE will use best efforts to review and approve/disapprove any such request within 30 days of receiving the request, and DOE's approval should not be unreasonably withheld.

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<sup>10</sup> *Id.*

*Reservation of the Change of Control Provision:*

DOE Program Offices with the concurrence of the Assistant General Counsel for Technology Transfer and Intellectual Property may remove or modify the above-identified change of control provision in individual transactions or for a class of agreements/transactions when:

- When the applicable technology to be developed (or having been already developed) is not a critical and emerging technology.
- When reservation of the change of control provision is determined not to be counter to U.S. national and economic security interests.

Additional Notes:

- Reservation of, or a limitation of, the change of control provision can occur prior to, during, or after an award or contract.
- DOE is considering potential modifications to the change of control provision, such as to limit DOE reviews/approvals to those transactions that include critical and emerging technologies and involve a transfer to a sensitive country or country of risk. Any such modifications may be made by DOE at its discretion.
- DOE intends to continue to engage with the stakeholder community on this provision to better inform future decisions and/or updated guidance.
- The Assistant General Counsel for Technology Transfer and Intellectual Property may issue additional guidance on this issue as appropriate.

## **Who can I contact with questions?**

- [GC-62@hq.doe.gov](mailto:GC-62@hq.doe.gov)
- Please contact the email address above for questions regarding the DOE Science and Energy Determination of Exceptional Circumstances. DOE may add responses to this FAQ to any questions that are received. DOE may re-phrase questions or consolidate similar questions for administrative purposes.
- If applying to a Funding Opportunity Announcement, please contact the email address identified for the specific Funding Opportunity Announcement in question.