

Frequently Asked Questions: 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. This is a broader recognition of the vital role in America's security and prosperity that is the Department of Energy's (DOE) multi-billion-dollar research & development (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 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 new Science and Energy Determination of Exceptional Circumstances (DEC) allows this requirement to be extended 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."

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.

[Why has DOE issued a Determination of Exceptional Circumstances for Science and Energy Technologies¹?](#)

¹ For the purpose of this determination, DOE Science and Energy Technologies include any Subject Invention as defined by Bayh-Dole, conceived or first actually reduced in the performance of work under a DOE funding agreement issued by one or more DOE programs under the cognizance of DOE's Under Secretary of Science, Under Secretary of Energy, combined Under Secretary of Science and Energy, or the Advanced Research Project Agency-Energy.

One of Bayh-Dole's primary goals is to promote the commercialization of federally-funded technologies by U.S. industry and labor² Unfortunately, this goal has often not been realized as we have seen the manufacturing for 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 going through 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 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.

[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. 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.

[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 acquisitions³ or laboratory 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.

[How can DOE extend the U.S. manufacture 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. U.S. manufacture requirements are among those where flexibility is available. DOE has elected to tailor

² 35 U.S.C. §200.

³ 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.

the changes narrowly to address U.S. manufacture 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 successfully implemented by DOE.⁴ The 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.”

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

No. The DEC is narrowly tailored, allowing nonprofit and small business firms to elect title to their inventions that are timely reported to DOE via the interagency iEdison system at <https://era.nih.gov/iedison>. Except for the addition of an enhanced domestic manufacturing provision, the patent rights granted to non-profit and small business recipients under Bayh-Dole remain the same.

What is the added benefit of the new Science and Energy DEC?

By having consistent terms for all funding agreements where exceptional circumstances are present (including DOE funding agreements with entities other than nonprofit organizations and small business firms) the administrative burden may be significantly reduced for all parties. DOE and its partners, including nonprofit organizations and small business firms, are already familiar with the enhanced manufacturing requirement of the U.S. Competitiveness Provision that has been successfully implemented for years by some DOE programs. DOE has also required substantial U.S. manufacturing similar to the U.S. Competitiveness Provision for decades in funding agreements with large businesses, implemented through DOE's patent waiver authorities. This provision has protected domestic manufacturing by ensuring that investment in domestic manufacturing and industry is a primary consideration. Although the substantial U.S. manufacturing

⁴ 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](#)

requirement is typically accepted by large businesses, waivers and modifications are granted as appropriate.

When does the Science and Energy DEC apply?

The Science and Energy DEC will apply primarily to funding opportunities published beginning with fiscal year (FY) 2022 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 include 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 of U.S. manufacturing requests should be sent to the Office of General Counsel (GC) at GC-62@hq.doe.gov. DOE will consider all applications for a waiver or modification of the requirements under the U.S. Competitiveness Provision, although granting any modification or waiver is within DOE's sole discretion. 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. For more on this process, see "Guidance on U.S. Manufacturing Modifications and Waivers."

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 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;
- (5) the geographic, technological, commercial, and temporal scope of the requested waiver compared to any proposed contractual or other benefits;
- (6) agreement by the Contractor to provide at least a non-exclusive license with commercially reasonable terms to any Contractor 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?](#)

DOE works with a Bayh-Dole entity to tailor modifications to meet the needs of the requesting entity instead of waiving domestic manufacturing in its entirety. Whenever possible, DOE seeks to obtain alternate, legally binding commitments to the U.S. economy if U.S. manufacturing commitments are modified. Requests to *waive* U.S. manufacturing commitments are heavily fact dependent and are rarely granted in full. It is the responsibility of the entity desiring the waiver or modification to initiate the DOE waiver/modification process when it is needed. For further information, see “Guidance on U.S. Manufacturing Modifications and Waivers.” DOE is committed to a transparent, reasonable and timely waiver/modification process.

[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 security⁵. 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

⁵ 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.

nearly one-third of its manufacturing jobs, and the number of workers employed in manufacturing has declined to 12 million.⁶

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.⁷

“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 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 . . .*”⁸ (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.

[Who can I contact with questions?](#)

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.

Please contact the email address identified for the specific Funding Opportunity Announcement in question.

⁶ As reported “the number of U.S. manufacturing jobs peaked in 1979 at 19.5 million; in March 2017, manufacturing employment was 12.4 million, a decline of more than 36 percent.”

⁷ *Id.*

⁸ H. Rept. 112-462 - ENERGY AND WATER DEVELOPMENT APPROPRIATIONS BILL, 2013 at page 81.