

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.¹ This is a broader recognition of the vital role of the DOE in America's security and prosperity as represented by its 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.

While Bayh-Dole has been one of the most impactful pieces of legislation over the past century, and the transition of technologies from federally funded research and development has been an important engine for economic growth, too often the transition of these technologies has resulted in manufacture being offshored. At DOE, for example, despite having funded many of the solar and energy storage breakthroughs over the past forty years, the U.S. only accounts for approximately 1% of worldwide photovoltaic shipments and only 8% of global EV lithium-ion cell production.^{2,3} While the reasons for these results are complex and multi-dimensional, DOE has determined that exceptional circumstances are present, driven, in part, by the statutory U.S. Preference clause in 35 U.S.C. § 204 - an inadequate tool for addressing the practice of "Invent it Here. Make it There".

The U.S. Preference provision contains textual limitations in that its domestic manufacturing requirements only apply to inventions that are *exclusively licensed to a third party*, and even then, *only apply to use and sale in the U.S.* Case examples provided in these updated FAQs illustrate how these statutory limitations allow valuable U.S. taxpayer funded technologies to be easily offshored to the detriment of U.S. manufacturing, American labor and industry, and domestic supply chain security.

Thus, under these exceptional circumstances, DOE has repeatedly been faced with the decision of whether to continue to rely on a manufacturing requirement in 35 U.S.C. § 204, one that has been difficult to enforce and has allowed DOE-funded technologies to be offshored, or whether to implement an enhanced U.S. manufacturing requirement that would better serve the U.S. economic objectives envisioned by Bayh-Dole. The inadequate safeguards of the U.S. Preference provision, combined with a hypercompetitive new normal, made it clear that DOE had to stand with American workers and protect the rights of American taxpayers. Thus, beginning in 2013, DOE instituted a series of narrowly tailored DEC's to enhance U.S. manufacturing requirements in certain DOE funding awards.⁴

¹ 35 U.S.C. § 200.

² NREL Solar Industry Update, David Feldman et al., citing 2004-2020: Paula Mints. "Photovoltaic Manufacturer Capacity, Shipments, Price & Revenues 2020/2021." SPV Market Research. Report SPV-Supply9. April 2021

³ DOE National Blueprint for Lithium Batteries (June 2021) citing Lithium-Ion Battery Megafactory Assessment", Benchmark Mineral Intelligence, March 2021. Available for purchase. <https://www.benchmarkminerals.com/megafactories>

⁴ DOE's enhanced U.S. manufacturing requirements act as an initial floor (that can be modified or waived when appropriate) that allows balance based on demonstrated business realities.

The reality is that the nation currently sits at a unique technological, economic, and geopolitical crossroads in which the erosion of the U.S. manufacturing base and an urgent need to secure U.S. supply chains for a wide-range of critical and emerging technologies are exacerbated by aggressive near-peer state actors. These state actors have strategically positioned themselves to dominate the manufacturing of, and the associated supply chains for, next generation technologies for their own military and economic benefit, all to the detriment of American workers and U.S. national and economic security. Accordingly, we find ourselves not only in an exceptional circumstance but one that is vitally urgent. Therefore, ensuring taxpayer-funded technologies support the U.S. economy and secure domestic and allied supply chains is critical to our national interests in ways not envisioned forty years ago when Bayh-Dole was enacted.

DOE recognizes the importance of working with academia and industry in achieving these goals and for flexibility in implementing the Science and Energy DEC while also 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.

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.^{5,6} It is a permissive document in that its provisions may or may not 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. However, even for FOAs that apply the DEC, awardees may request waivers or modifications to the domestic manufacturing requirement to address their unique circumstances. It is important to note that the S&E DEC only applies to DOE S&E “funding agreements” as defined by 35 U.S.C 201(b).

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

⁵ 35 U.S.C. § 204.

⁶ 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.

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.

Will the S&E DEC be applied to new licenses to subject inventions that pre-date the S&E DEC?

The S&E DEC (issued on June 7, 2021) is prospective, and its requirements attach to subject inventions developed under funding agreements funded with FY22 or later appropriations.⁷ The U.S. manufacturing requirements that have attached to the subject invention are required in any licenses, regardless of when that license is negotiated and signed. Therefore, if the subject invention pre-dates the S&E DEC, then the S&E DEC U.S. manufacturing requirements are not required in licenses to that subject invention.

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 taxpayer-funded agreement beyond the Bayh-Dole Act requirement of U.S. Preference. The Science and Energy DEC does not alter DOE acquisitions⁸ 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.

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.⁹ U.S. manufacturing requirements are among those where flexibility is available. DOE has elected to narrowly tailor the changes 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 are the concerns with the U.S. Preference Clause in 35 U.S.C. § 204 ?

The U.S. Preference provision codified in 35 U.S.C. § 204 contains textual limitations that enable recipients to easily maneuver around its domestic manufacturing requirements. The U.S. Preference provision is narrow in that it 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 U.S.* Actual case examples illustrate how these statutory limitations can allow valuable U.S. taxpayer funded technologies to be easily offshored to the detriment of U.S. manufacturing, American labor, and domestic supply chain security.

⁷ For FY21 and earlier appropriated funds, the Under Secretary for Science and Energy has directed that use of the S&E DEC is permitted for such funding opportunity announcements and financial assistance actions issued on or after June 7, 2021, for select funding programs with appropriate notice to applicants and recipients. Further the Under Secretary for Science and Energy has permitted the use of the S&E DEC for the rare Office of Fossil Energy funding opportunity announcements issued prior to June 7, 2021, that referenced a forthcoming DEC for U.S. manufacturing, including contract modifications for issued awards. For Lab management and operating contracts, the S&E DEC applies to subject inventions developed using FY22 funds once the required contract modification is in place. See [FAL 2022-01](#) at page 2, footnote 2.

⁸ 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.

⁹ 35 U.S.C. § 202(a)(ii).

Example 1 – restricted to exclusivity: If a university decides to non-exclusively license its new cutting-edge battery technology developed with federal funding, the statutory U.S. Preference clause has no legal effect, since the clause only places obligations on exclusive licensees. These non-exclusive licensees are thus completely free to manufacture that U.S. taxpayer funded technology anywhere in the world even when the technology can be manufactured in the U.S.

Example 2 – restricted to (exclusive) licensees: If a business develops a next generation semiconductor technology with federal taxpayer funding, and the business is manufacturing the technology itself, it can offshore its manufacturing without any restriction whatsoever, since the U.S. Preference provision only applies to exclusive licensees, not the awardees of the funding themselves.

Example 3 – restricted to U.S. sales and use: When a university spin-out based on technology funded by DOE decides to first commercialize, manufacture, and market its new technology for sale abroad, Bayh-Dole is legally ineffective because it applies only to U.S. use and sales. Therefore, the company is free to offshore its taxpayer funded technology for sales and use outside the United States.

Unfortunately, the examples above are not merely hypotheticals, but are based on actual factual scenarios DOE has witnessed multiple times over the past several decades.

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.¹⁰ 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.”

How has DOE responded to feedback from its stakeholders?

DOE sincerely appreciates feedback from its stakeholder communities on this important issue including the feedback received during a number of stakeholder engagement sessions held in the summer and fall of 2021, which included a widely attended webcast on July 23, 2021, organized with the help of the Bayh-Dole Coalition. In September 2021, DOE published a number of materials on its website further explaining the DEC while also providing a variety of clarifications in an earlier published set of these FAQs issued as a direct result of the stakeholder engagement sessions.^{11,12} Despite these efforts to address stakeholder concerns and clarify DOE's policies, it became apparent that the change of control language in our U.S. Competitiveness provision, and lingering confusion regarding whether that provision requires DOE to review or approve licenses, would benefit from additional clarity. This important stakeholder feedback led DOE to clarify and/or change portions of its U.S. Manufacturing policies including: (1) substantively modifying the change of control provision in its U.S. Competitiveness Clause and (2) making it clear that DOE will not approve licenses, as further described below.

¹⁰ 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](#)

¹¹ <https://www.energy.gov/gc/us-manufacturing>

¹² <https://www.energy.gov/gc/articles/frequently-asked-questions-faqs>

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 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 as noted above in detail. Therefore, the Science and Energy DEC was necessary to address some of these statutory limitations to make U.S. manufacturing provisions more robust and enforceable.

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 does not 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 whether the DEC applies, although 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. manufacturing 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 directly or as a cc: when submitting a request to a contact provided by the funding program. See [Request for Modification of U.S. Manufacturing Requirement | Department of Energy](#) at <https://www.energy.gov/gc/articles/request-modification-us-manufacturing-requirement>.

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.

It is important to note that enhanced U.S. manufacturing provisions in DOE awards act as an initial floor for domestic manufacturing and, when appropriate, the Department may grant a modification or waiver of these requirements. DOE is committed to streamlining the waiver and modification request process, issuing guidance in November 2021 to assist financial assistance awardees. Requests to waive U.S. manufacturing commitments are heavily fact-dependent and are rarely granted in full because DOE prefers to tailor modifications to meet the needs demonstrated by the requesting entity instead of waiving domestic manufacturing in its entirety. Also, whenever possible, DOE seeks to obtain alternate, legally binding commitments to the U.S. economy if U.S. manufacturing commitments are modified.

For example, in a project to develop next generation photonics, the Department's enhanced domestic manufacturing requirements (and associated waiver review process) were essential in keeping this critical technology here in the U.S. While the awardee originally requested a full waiver of U.S. manufacturing that would have allowed the manufacture of key components in the PRC, DOE was not willing to grant such a broad waiver due to the critical nature of the technology, the proposed advancement, and the risk of misappropriation of this technology. Instead, DOE negotiated with the company, which agreed to manufacture the technology exclusively in the U.S. for several years, agreed not to manufacture in certain countries of risk, and agreed to return to the cognizant DOE program if it needed to move any manufacturing of the technology outside the U.S. in the future. It is important to note that under a typical federal award (containing only the statutory U.S. Preference clause), the company could have offshored this key technology without any safeguards.

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. See [Request for Modification of U.S. Manufacturing Requirement | Department of Energy](https://www.energy.gov/gc/articles/request-modification-us-manufacturing-requirement) at <https://www.energy.gov/gc/articles/request-modification-us-manufacturing-requirement>.

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. See [Request for Modification of U.S. Manufacturing Requirement | Department of Energy](https://www.energy.gov/gc/articles/request-modification-us-manufacturing-requirement) at <https://www.energy.gov/gc/articles/request-modification-us-manufacturing-requirement>.

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 if it is determined that 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, full waiver requests are 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. Additional guidance issued by DOE on the waiver/modification process can be found on the DOE website as Appendix 5 to Financial Assistance Letter No. FAL 2022-01 at <https://www.energy.gov/management/financial-assistance-letter-no-fal-2022-01>.

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. In fact, as DOE noted in its FAQs posted in September 2021, the Department has been considering potential modifications to the change of control language to provide additional clarity and address stakeholder concerns. As a result of stakeholder feedback, and as part of our effort to incorporate the DEC into the terms and conditions of our awards, DOE reevaluated this language and decided to substantially modify the change of control language in the U.S. Competitiveness clause required by the DEC. Specifically, DOE removed the original change of control language (that required DOE approval of certain change of control transactions) and substituted a diligence and notice requirement.¹³ More specifically, the new default language reads as follows: "In the event that the Recipient or other such entity receiving rights in the Subject Invention undergoes a change in ownership amounting to a controlling interest, the Recipient or other such entity receiving rights shall ensure continual compliance with the requirements of this paragraph (m) and shall inform DOE, in writing, of the change in ownership

¹³ The DEC's language allows DOE to make administrative change to the U.S. Competitiveness Provision to clarify funding agreement requirements and reduce requirements of the provision as appropriate.

within 6 months of the change.”¹⁴ DOE believes this modified language properly balances the need to protect taxpayer rights while maintaining the core rights of small business firms and nonprofit organizations to retain ownership of, and flexibility and certainty to commercialize, their federally funded technologies.

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?

In our original FAQs published in September of 2021, DOE stated that: “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.” Despite this clarification it appears some stakeholders continue to assert that: “If a licensor wants to issue an exclusive license, the DOE must provide its approval prior to the transfer of rights”.¹⁵ Let us be clear, DOE **will not** require awardees to get DOE approval of their exclusive or non-exclusive licenses.¹⁶ This additional clarification combined with DOE’s decision to substantially reduce the aforementioned “change of control” language to a diligence and notice requirement, is intended to remove all doubt about this issue. A read through of the modified U.S. Competitiveness requirement in Appendix A of the DEC (provided below) makes clear that the clause has one purpose and one purpose only: to create a robust and enforceable U.S. manufacturing provision to better ensure DOE funded innovation is substantially manufactured here in America unless it is commercially infeasible.¹⁷

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

The statute provides for availability of an agency appeal, and DOE has an interim process for appealing agency actions under 37 C.F.R. Part 401, which includes decisions related to the S&E DEC. The interim process for appeals may be found here: [Appeals Procedures for Agency Action Under a 37 C.F.R. Part 401 | Department of Energy](#). The waiver/modification request process is set forth in Appendix 5 of the Financial Assistance Letter No. 2022-1 found here: [Financial Assistance Letter No. FAL 2022-01 | Department of Energy](#). DOE recommends using this sample waiver/modification request form. See [Request for Modification of U.S. Manufacturing Requirement | Department of Energy](#) at <https://www.energy.gov/gc/articles/request-modification-us-manufacturing-requirement>.

¹⁴ A copy of the revised U.S. Competitiveness Clause that will be used in DOE Science and Energy funding agreements with Bayh-Dole entities, including financial assistance awards and M&O contracts is attached as Appendix A. This revised clause has already been inserted into our updated financial assistance terms and conditions and DOE is actively working to modify terms for our M&O contracts.

¹⁵ AUTM DOE DEC Survey Results dated February 9, 2022.

¹⁶ DOE will not require approval of licenses and the only time DOE expects the possibility of reviewing a license to arise, is as part of a formal compliance review (historically significantly less than 0.5% of DOE awards) to ensure requirements are being properly flowed down and abided by.

¹⁷ A copy of the revised U.S. Competitiveness Clause that will be used in DOE Science and Energy funding agreements with Bayh-Dole entities, including financial assistance awards and M&O contracts is attached as Appendix A. This revised clause has already been inserted into our updated financial assistance terms and conditions and DOE is actively working to modify terms for our M&O contracts.

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 security¹⁸. 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.¹⁹

The importance of having DOE Science and Energy Technologies manufactured by U.S. industry and labor has never been greater. DOE invests billions of taxpayer 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, in which the Committee on Appropriations 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.²⁰

“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 . . .*”²¹ (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.

Does the S&E DEC apply to CRADAs, Strategic Partnership Projects, or Agreements for Commercializing Technology?

Generally no, the DEC only applies to “funding agreements” as defined by 35 U.S.C. 201(b). That being said, if an entity/sponsor/participant is funding a CRADA, SPP or ACT, using funds from a “funding agreement”, and if the DEC applies to the funding agreement, then the U.S. Manufacturing provisions from such funding agreement should be flowed into the CRADA, SPP, or ACT.

¹⁸ 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.

¹⁹ 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>

²⁰ H. Rept. 112-462 - ENERGY AND WATER DEVELOPMENT APPROPRIATIONS BILL, 2013 at page 81.

²¹ *Id.*

Does the S&E DEC affect rights to funding agreements made by a Federal agency primarily for educational purposes and covered by 35 U.S.C. 212

No.

Does the S&E DEC require M&O Contractors to seek DOE approval to elect title to inventions pursuant to 48 CFR 970.5227-10?

No. DOE intends for the provisions of the S&E DEC to be implemented with as few additional administrative burdens on the contractor as possible. The S&E DEC is narrowly tailored and, except for the addition of the U.S. Competitiveness clause (and the associated enforcement mechanism), the patent rights granted to Bayh-Dole entities under the S&E DEC remain the same.

The language of the Bayh-Dole patent clause addresses this question directly and should be read to preclude requiring DOE approval to elect title to subject inventions to which the S&E DEC U.S. Competitiveness Clause attaches. In the Bayh-Dole patent clause, 970.5227-10, one of the key parts of the provision is subsection 970.5227-10(b)(3) which states “**Except to the extent that rights are retained by the Contractor in a determination of exceptional circumstance...**” (emphasis added) Since the S&E DEC maintains the contractor’s right to elect title as established in the statute, the exception applies. The remainder of that section of the patent clause that does require DOE approval to elect title to “exceptional circumstance subject inventions” refers to determinations of exceptional circumstances that alter the title-election rights of the contractor and, therefore, does not apply to the S&E DEC for Bayh-Dole entities.

Further, the following language in the S&E DEC underscores DOE’s intentions: “Over the past 8 years, DOE has determined that requiring enhanced U.S. manufacturing for select programs and technologies more effectively achieves the objectives of Bayh-Dole and DOE’s mission, **while ensuring that small business firms and nonprofit organizations retain the right to elect title to their subject inventions.**” S&E DEC at 6-7. “The U.S. Competitiveness Provision described herein calls for increased domestic manufacturing to promote commercialization of DOE Science and Energy Technologies by U.S. industry and labor, and provides stronger support for U.S. national security and economic interests while also maintaining the important core rights of small business firms and nonprofit organizations to **retain ownership and commercialize their federally-funded inventions.**” S&E DEC at 1 (emphasis added)

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.
- If applying to a Funding Opportunity Announcement, please contact the email address identified for the specific Funding Opportunity Announcement in question.

Appendix A: Updated U.S. Competitiveness Provision

(m) U.S. Competitiveness

The Recipient agrees that any products embodying any subject invention or produced through the use of any subject invention will be manufactured substantially in the United States unless the Recipient can show to the satisfaction of DOE that it is not commercially feasible. In the event DOE agrees to foreign manufacture, there will be a requirement that the Government's support of the technology be recognized in some appropriate manner, e.g., alternative binding commitments to provide an overall net benefit to the U.S. economy. The Recipient agrees that it will not license, assign or otherwise transfer any subject invention to any entity, at any tier, unless that entity agrees to these same requirements. In the event that the Recipient or other such entity receiving rights in the Subject Invention undergoes a change in ownership amounting to a controlling interest, the Recipient or other such entity receiving rights shall ensure continual compliance with the requirements of this paragraph (m) and shall inform DOE, in writing, of the change in ownership within 6 months of the change. The Recipient and any successor assignee will convey to DOE, upon written request from DOE, title to any subject invention, upon a breach of this paragraph (m). The Recipient will include this paragraph (m) in all subawards/contracts, regardless of tier, for experimental, developmental or research work.