



May 2024

DEPARTMENT OF ENERGY

Actions Needed to Assess U.S. Manufacturing Policy and Protect Technology from Foreign Acquisition

GAO Highlights

Highlights of [GAO-24-106504](#), a report to congressional requesters

Why GAO Did This Study

To increase the benefits of DOE's research and development (R&D) investments, the Bayh-Dole Act lets national labs and universities patent DOE-funded inventions and license them to companies. In recent years, some companies have manufactured important products developed with such funding overseas. In 2021, DOE expanded requirements for U.S. manufacturing of DOE-funded technologies to cover a broader range of circumstances. Previously, by law, they applied only to licensees with exclusive rights to sell and use the covered product in the U.S.

This report examines (1) DOE's 2021 policy, its process for waiving domestic manufacturing requirements, and lab and university views on these issues; (2) DOE's efforts to oversee lab and university licensees' compliance with U.S. manufacturing requirements; and (3) procedures for managing risks of foreign acquisition of DOE-funded technologies. GAO analyzed relevant laws and policies, analyzed patent license templates, and surveyed officials at all 17 DOE national labs and 19 universities, selected to represent different regions and varying numbers of DOE licenses. The universities were selected out of 184 academic institutions that filed patent applications for DOE-funded research from fiscal years 2012 through 2022.

What GAO Recommends

GAO is making six recommendations, including that DOE evaluate its U.S. manufacturing policy, review university licensing practices, and provide guidance about managing the risk of licensee foreign ownership. DOE concurred with the recommendations.

View [GAO-24-106504](#). For more information, contact Candice N. Wright at (202) 512-6888 or wrightc@gao.gov.

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What GAO Found

In 2021, the Department of Energy (DOE) changed its policy on the licensing of technologies developed with DOE research funding to expand the scope of the U.S. manufacturing requirements for DOE-funded inventions. However, GAO found DOE does not have a strategy or approach to assess the effects of this policy. In particular, DOE does not have metrics to measure whether this policy is likely to increase U.S. manufacturing of DOE-funded inventions or the willingness of companies to develop these inventions. National lab contractors, universities, and stakeholders raised concerns that the 2021 policy could make DOE-funded inventions less attractive to prospective licensees because of the new requirements. As a result, national labs and universities may be less likely to patent these inventions, although stakeholders noted that it is still too soon to tell.

Battery Testing at Pacific Northwest National Laboratory



Source: Pacific Northwest National Laboratory. | GAO-24-106504

DOE oversees efforts by the contractors that run its national labs to ensure that their licensees comply with U.S. manufacturing requirements. However, DOE does not similarly oversee the universities it funds. DOE recently reviewed how labs manage technology licensing, but it has not similarly reviewed universities, even though they license patents to a similar extent. Without such a review, DOE will not know whether university licensees are generally complying with the terms of their licenses, including U.S. manufacturing requirements.

All 17 DOE labs and 19 selected universities GAO reviewed take steps to manage risks posed by foreign companies acquiring DOE-funded technology via licensing. However, their approaches are inconsistent and, in some cases, not thorough. For example, GAO found that some national labs and universities use less rigorous approaches and do not always monitor whether foreign acquisition of the companies took place after licensing. This inconsistency results, in part, from DOE's lack of guidance or requirements about foreign acquisition risks. Without consistent risk management practices, DOE cannot ensure that inventions it funds are sufficiently protected from the risk of foreign control. This is particularly important for critical and emerging technologies, such as renewable energy generation and storage.

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Abbreviations

BIS	Bureau of Industry and Security
DEC	Determination of Exceptional Circumstances
DOE	Department of Energy
NETL	National Energy Technology Laboratory
NIST	National Institute of Standards and Technology
NNSA	National Nuclear Security Administration
PNNL	Pacific Northwest National Laboratory
R&D	research and development
S&T	science and technology
USPTO	U.S. Patent and Trademark Office

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May 23, 2024

The Honorable John Barrasso, M.D.
Ranking Member
Committee on Energy and Natural Resources
United States Senate

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
House of Representatives

The Department of Energy (DOE) is one of the largest federal research funding agencies and annually funds billions of dollars in research on basic science, energy technologies, and nuclear security and waste cleanup.¹ With this funding, DOE's 17 national laboratories and other entities, such as universities, may create inventions and other intellectual property that have application beyond DOE's immediate, mission-related goals. These inventions can lead to the creation of new companies, jobs, and products. For example, researchers at DOE's Argonne National Laboratory developed a type of lithium-ion battery now found in the majority of electric and hybrid vehicles on the road. Similarly, a DOE-funded research consortium led by the University of Wisconsin, Madison resulted in a new technology that enables small power sources, such as solar panel arrays, to seamlessly supply energy to the electric grid. The process of moving knowledge, technologies, and expertise from researchers to private industry, or to other entities that can bring such innovations to market, is known as technology transfer.

Technology transfer often occurs through licensing: a DOE lab or a university patents an invention, and then grants a license for that

¹Preliminary data show that DOE obligated \$13.912 billion toward research and development in fiscal year 2022 (the most recent year for which data were available at the time of our review). National Science Foundation, National Center for Science and Engineering Statistics, *Federal Funds for Research and Development: Fiscal Years 2021-2022, NSF 24-309* (Alexandria, VA.: 2023). The National Science Foundation (NSF) refers to FY 2022 data as 'preliminary' in survey documentation because the data will be updated in the subsequent volume of the survey.

invention to a private company.² From fiscal years 2010 through 2022, DOE facilities and universities applied to patent more than 14,000 DOE-funded inventions.³ As of fiscal year 2022, the latest year for which statistics were available at the time of our review, labs and universities that developed DOE-funded inventions had more than 1,400 active licenses that they granted to companies or other recipients to use the technologies and further their development for commercial use. Such licensing can enhance U.S. economic benefits of federally funded research.

To enhance the benefits of federally funded research, technology transfer, and commercialization, Congress passed a law widely known as the Bayh-Dole Act. Enacted in 1980, it grants small businesses such as DOE national labs and nonprofits such as universities that develop federally funded technologies the right to patent and commercialize those technologies.⁴ The Bayh-Dole Act generally requires the domestic manufacture of products resulting from exclusive patent licenses for federally funded inventions if those products are to be used or sold in the United States, unless a waiver or modification to the requirement is granted by the funding agency.⁵

In recent years, some U.S. companies have manufactured products, including those developed with federal funding, in foreign countries—a practice that is often called offshoring. While it may lower costs or provide

²A U.S. patent gives its owner the right to exclude others from making, using, offering for sale, or selling an invention or importing it into the United States. A patent may be owned by someone other than the inventor(s), such as an employer. The United States Patent and Trademark Office (USPTO) grants patents for qualifying utility, plant, and design inventions. See, e.g., 35 U.S.C. §§ 101–103, 112, 115, 161, and 171.

³DOE facilities refer to Department of Energy (DOE) labs and National Nuclear Security Administration (NNSA) sites. NNSA is a semi-autonomous agency within DOE.

⁴Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified at 35 U.S.C. §§ 200-212). The Bayh-Dole Act applies to “any person, small business firm, or nonprofit organization” that receives federal experimental, developmental, or research funding through a contract, grant, or cooperative agreement, and the act was expanded to contractors of all size via Executive Order 12,591. 52 Fed. Reg. 13,414 (Apr. 10, 1987), as amended by Exec. Order No. 12,618, 52 Fed. Reg. 48,661 (Dec. 22, 1987). Large business management and operating contractors receive similar rights through applicable Class Patent Waivers issued under DOE’s patent waiver authority. See DEAR 970.5227-12.

⁵35 U.S.C. § 204. Throughout this report, when we refer to the entities subject to the Bayh-Dole Act, we will refer to lab contractors and universities because that is the scope of our review, recognizing that these are not the only entities subject to the Bayh-Dole Act.

other strategic advantages for companies, offshoring has reduced domestic manufacturing of DOE priorities, including semiconductors, components of solar panels, and energy storage systems. In one case, a breakthrough battery technology developed through research funded by DOE's Pacific Northwest National Laboratory (PNNL) was sublicensed⁶ to a Chinese company in 2017 and potentially manufactured in China.⁷ Foreign manufacturing and the acquisition of U.S. technology through licensing may disadvantage the United States in an era of increased global competition, in which U.S. jobs and industries are being lost to other countries. In response to concerns about offshoring DOE-funded technologies, DOE has adopted several policies outlined in documents called Determinations of Exceptional Circumstances⁸ (DEC), starting in 2013.⁹ DOE's most recent DEC, issued in June 2021 (the 2021 DEC), applies broader domestic manufacturing requirements to DOE-funded technologies than called for by the Bayh-Dole Act.¹⁰

You requested that we review DOE's technology transfer and commercialization efforts to protect U.S. intellectual property, including from foreign acquisition, and strengthen U.S. competitiveness. In this report, we examine: (1) lab contractor and university views on DOE's 2021 DEC domestic manufacturing policy, as well as its process for waiving domestic manufacturing requirements, and what actions has DOE taken to assess the effects of its policy; (2) the extent to which DOE oversees lab contractor and university activities for monitoring their licensees' compliance with U.S. manufacturing requirements; and (3) the

⁶A sublicense is a grant to a third party (the sublicensee) of certain rights by the entity that initially licensed the technology.

⁷See, for example, NPR, *The U.S. made a breakthrough battery discovery — then gave the technology to China* (August 3, 2022), accessed July 23, 2023, <https://www.npr.org/2022/08/03/1114964240/new-battery-technology-china-vanadium>.

⁸See <https://www.energy.gov/gc/determination-exceptional-circumstances-decs>.

⁹The Bayh-Dole Act allows agencies to restrict or eliminate the right of an entity covered by the act to retain title in exceptional circumstances where they determine that such restriction or elimination will better promote the policy and objectives of the act. 35 U.S.C. §§ 202(a)(ii) and 202(b)(1); 37 C.F.R. § 401.3(e). Thus, when DOE has determined that exceptional circumstances exist and an objective of the Bayh-Dole Act is not being met because of those circumstances, it issues a DEC. In the case of the 2021 DEC, DOE found that exceptional circumstances existed because of the amount of offshoring of manufacturing of DOE-funded inventions.

¹⁰Department of Energy, Department of Energy Determination of Exceptional Circumstances Under the Bayh-Dole Act to Further Promote Domestic Manufacture of DOE Science and Energy Technologies (Washington, D.C.: June 2021).

extent to which labs and universities manage the risk of foreign acquisition of licensed DOE-funded technologies.

To address our objectives, we obtained documentary and testimonial evidence from DOE, management and operating contractors at DOE national labs, and selected universities.¹¹ To achieve a diverse set of university perspectives, we selected institutions from different regions of the United States and with varying numbers of active DOE licenses. We spoke with contractors at DOE national labs and obtained and reviewed DOE manufacturing policies issued since 2013, including the 2021 DEC, and DOE waivers or modifications of those manufacturing requirements. We identified and evaluated relevant criteria, including DOE policies and internal controls, and applied the criteria to our research objectives, as appropriate. We evaluated exclusive patent license templates that DOE labs and universities use to draft licensing agreements. To show general trends in patent filings and licensing of DOE-supported technologies since 2012, we analyzed DOE lab and facility data published by the National Institute of Standards and Technology and university data from the interagency Edison (iEdison) system.¹² We determined that these data were sufficiently reliable to provide context on general trends through a review of data-related documentation and discussions with agency officials about their accuracy and completeness. We also interviewed DOE personnel from key offices, including patent counsel officials in the Office of the Assistant General Counsel for Technology Transfer and Intellectual Property and personnel from the Office of Technology Transitions. In addition, we conducted a survey and interviews with various stakeholders. Specifically, we conducted a survey of the directors

¹¹Management and operating contractors manage 16 of DOE's 17 national labs. The remaining lab, the National Energy Technology Laboratory, is operated by DOE rather than a management and operating contractor.

¹²DOE provided lab and facility data for fiscal years 2021-2022. iEdison is managed by the National Institute of Standards and Technology. It allows government grantees and contractors to report federally funded subject inventions, patents, and utilization data via the web to the government agency that issued the funding award.

of technology transfer offices at all 17 DOE national labs¹³ and 21 selected universities.¹⁴ We held interviews with 22 stakeholder groups, including nonprofit groups, a venture capital firm, academic institutions, former senior DOE technology transfer officials, and license holders of DOE-funded patents.¹⁵ For more information on our scope and methodology, see appendix I.

We conducted this performance audit from January 2023 to May 2024, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

This section outlines (1) the framework and process under which labs and universities grant licenses for the use of patents on DOE-funded technologies, (2) U.S. manufacturing requirements and DOE manufacturing policy, (3) the process for requesting waivers or

¹³Each of the 17 national labs is stewarded by a major DOE office: Office of Science (10); NNSA (3); Office of Nuclear Energy (1); Office of Energy Efficiency & Renewable Energy (1); Office of Fossil Energy (1); and Office of Environmental Management (1). National Energy Technology Laboratory (NETL) is not subject to the Bayh-Dole Act because it is operated by DOE rather than a management and operating contractor, but all national labs including NETL are subject to the Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311 (1980). In this report, we generally exclude NETL from our discussions of the Bayh-Dole Act and the 2021 DEC, but we have included NETL in our discussion of how DOE national labs and universities manage licensing activities, including monitoring licensee compliance with license agreements and managing the risk of foreign acquisition of DOE-funded technologies. Additionally, in this report, when we refer to labs, we are referring to the 17 DOE national labs.

¹⁴We received responses from 19 of the selected universities: Arizona State University, California Institute of Technology, Case Western Reserve University, Harvard University, Massachusetts Institute of Technology, Michigan State University, Missouri University of Science and Technology, State University of New York, University of California Berkeley, University of Colorado Boulder, University of Florida, University of Minnesota, University of Pittsburgh, University of Southern California, University of Texas at Austin, University of Washington, University of Wisconsin Madison, Vanderbilt University, and Yale University. The two universities that did not respond to our survey were generally similar to other selected universities that responded.

¹⁵Throughout the report, we use the indefinite quantifiers, “a few”, “some”, “several”, “many”, “majority”, and “most” to inform the reader of the approximate quantity of survey respondents or stakeholder interviewees that expressed a particular viewpoint. For the purposes of our review, a few refers to 2-3, several refers to 4-6, many refers to more than 6, a majority is considered more than 51 percent, most is considered 80-90 percent, and some refers to more than one but less than a majority.

modifications of U.S. manufacturing requirements, and (4) DOE's process for managing risks from the foreign acquisition of U.S. technology through licensing.

Patent Licensing Framework and Process

A major part of DOE's mission is to enhance the economic growth of the United States and expand the public impact of DOE research and development (R&D) through technology transfer. DOE seeks to facilitate the use of inventions resulting from the research it funds, with the aim of supporting the creation of new goods and services that benefit the public. Under the Bayh-Dole Act, entities such as lab contractors and universities may elect to retain ownership of their federally funded inventions if they perceive that they have commercial potential, and the act enables them to patent these inventions. The Bayh-Dole Act grants these entities broad statutory rights and flexibilities to elect title to and license the intellectual property they develop with federal funding.¹⁶ The Act applies to entities, such as labs and universities, that receive federal experimental, developmental, or research funding through a contract, grant, or cooperative agreement (collectively, "funding agreements") subject to certain conditions.¹⁷ DOE must balance the lab contractors' and universities' broad statutory rights to license federally funded intellectual property with its responsibility under the Bayh-Dole Act to promote the role of U.S. industry and labor in manufacturing those inventions.¹⁸ DOE's Office of the Assistant General Counsel for Technology Transfer and Intellectual Property, in conjunction with the Office of Technology Transitions, cognizant DOE Field Patent Counsel, the relevant DOE Site Offices and the DOE Program stewards for each lab, oversees the technology transfer process for DOE with respect to the Bayh-Dole Act, which process includes patent licensing by lab contractors and universities. In addition, all of DOE's national labs have technology transfer as part of their mission.¹⁹ DOE labs and universities also have technology transfer offices that help researchers patent inventions and

¹⁶The Government is not a party to license agreements pursuant to inventions it does not own. License agreements are between the entities covered by the Bayh-Dole Act, such as lab contractors and universities, and third-party licensees.

¹⁷35 U.S.C. §§ 202(a), 201(b)-(c). As noted above, Executive Order 12,591 extended the Bayh-Dole Act to contractors of all size. 52 Fed. Reg. 13,414 (Apr. 10, 1987), as amended by Exec. Order No. 12,618, 52 Fed. Reg. 48,661 (Dec. 22, 1987).

¹⁸35 U.S.C. §§ 200, 202(a)(ii).

¹⁹See 15 U.S.C. § 3710(a).

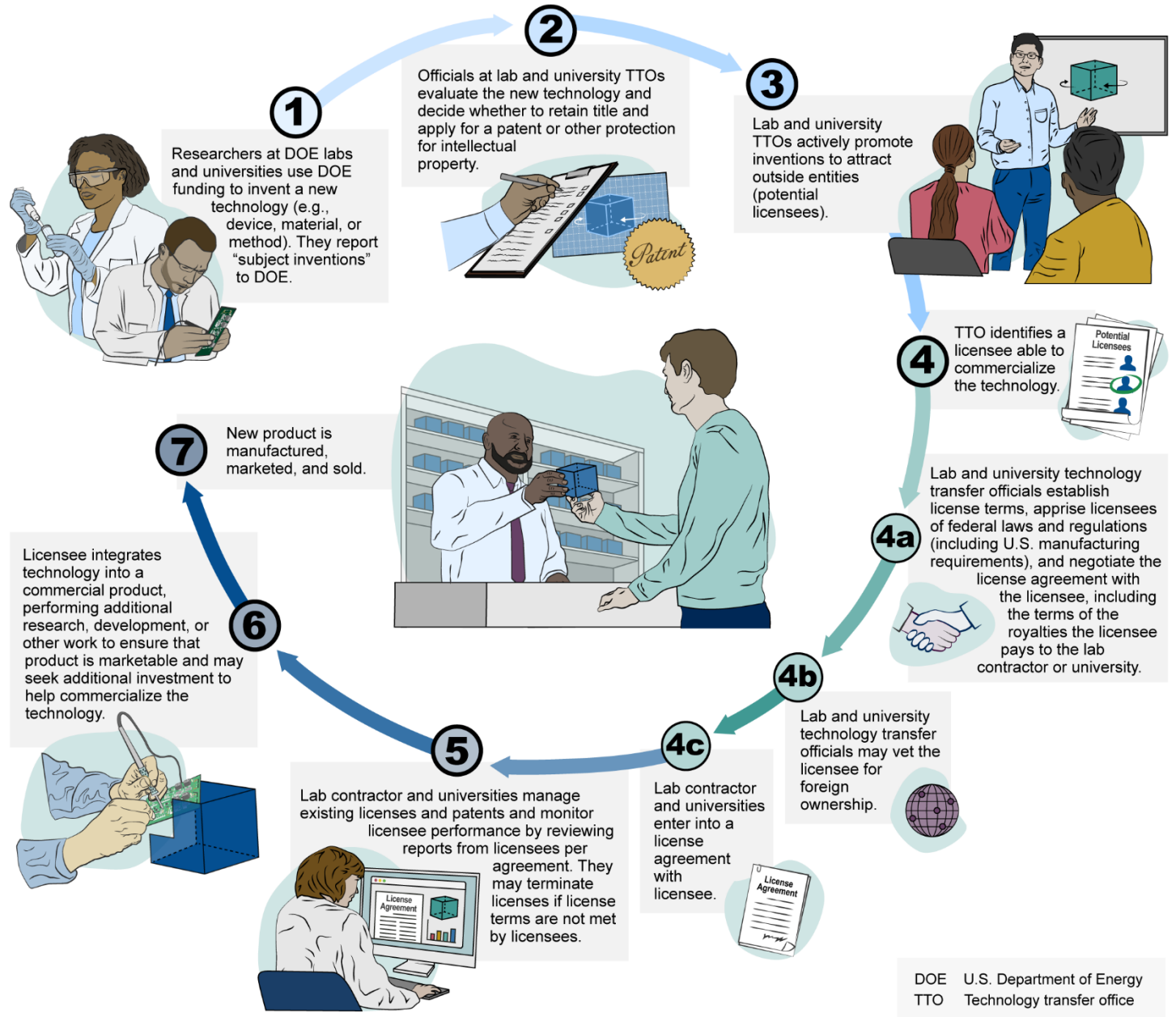
partner with private-sector companies to bring these technologies to market.

Upon informing the relevant federal agency (such as DOE) in writing that it has chosen to retain legal rights of ownership to an invention (known as electing title) and seeking and receiving patent protection, under the Bayh-Dole Act, the lab contractor or university retains most rights to the invention by law, with the exception of certain government rights.²⁰

Among the entity's rights as a patent holder is the right to grant a license to another party (the licensee, and the lab contractor or university is the licensor). The pathway of an invention from R&D to commercial product can end at any point, and products may not always be commercially successful. Steps along that pathway include lab contractors and universities disclosing their federally funded inventions, determining whether to retain ownership, and applying for patent protection (see fig. 1).

²⁰See 35 U.S.C. § 202 (setting forth government rights to restrict or eliminate an entity's right under the Bayh-Dole Act to retain title under certain circumstances, conditions on the entity's rights, and other limited government rights), § 203 (setting forth government march-in rights where an entity or its exclusive licensee has not taken certain actions), and § 204 (setting forth the U.S. Manufacturing Preference, discussed below).

Figure 1: Generalized Illustration of Technology Transfer and Commercialization Process at DOE National Laboratories and Universities



Source: GAO (analysis and illustrations). | GAO-24-106504

Note: The steps shown above differ at the National Energy Technology Laboratory because it is operated by DOE rather than a lab contractor.

When a potential licensee is identified, lab and university technology transfer offices craft and negotiate the terms of the patent license agreement, usually using their own template with a standard set of terms as the basis for negotiation. Labs and universities may include provisions in the agreement to help manage risk, such as requirements for the licensee to notify or seek approval from the lab or university for certain actions (e.g., issuing a sublicense or transferring the license to another entity). After a license agreement has been executed, the lab or university technology transfer offices monitor licensee compliance with the license agreement requirements. These requirements can include provisions to help monitor the risk of potential foreign acquisition of the licensed technology. For example, a license agreement may require licensees to report to the licensor any new ownership interests (also known as changes in control). Compliance with these requirements provides information on federally funded inventions that DOE can use to protect the government's interests in them.

As of February 2024, there were more than 1,200 DOE-funded, active license agreements in fiscal year 2022. This number included 863 active patent licenses across DOE's 22 national labs and facilities and 548 active patent licenses reported by universities to DOE through iEdison.²¹ Figures 3 and 4 in appendix II illustrate general trends at labs and U.S. universities from fiscal year 2012 through 2022.

U.S. Manufacturing Requirements and DOE Manufacturing Policy

The Bayh-Dole Act also identifies certain interests the government has in federally funded inventions including an interest in promoting their domestic manufacture. The Act specifies a preference for certain products derived from a federally funded invention to be "manufactured substantially in the United States." The Bayh-Dole Act and its implementing regulations do not define "manufactured substantially in the United States." The U.S. Manufacturing Preference provision applies when a federally funded entity covered by the Bayh-Dole Act, such as a lab contractor or university, grants an exclusive license to manufacture products for use or sale in the United States, unless a waiver or modification is granted.²² If such lab contractor or university that

²¹Active licenses in DOE and National Institute of Standards and Technology data are defined as either new or continuing license agreements legally in force during the reporting period. Counts of inventions licenses in iEdison data are based on similar criteria: license or option agreements that were or are active during the reporting period. DOE provided the lab total (863) and we used iEdison data to obtain the university total (548).

²²35 U.S.C. § 204.

developed the invention manufactures the product itself, it faces no limitations under the Bayh-Dole Act on where manufacturing can occur.

Since 2000, DOE has issued various policies aimed at enhancing domestic manufacturing requirements for inventions generated from research it funds.²³ In June 2021, DOE issued a DEC that broadened its ability to require the domestic manufacture of DOE-funded inventions beyond the U.S. Manufacturing Preference in the Bayh-Dole Act. The 2021 DEC provides that DOE may include a “U.S. Competitiveness Provision” in most future DOE Science and Energy program funding opportunity announcements, solicitations or funding agreements—contracts, grants, or cooperative agreements—that begin in fiscal year 2022 or later with DOE lab contractors and universities (among other entities). The 2021 DEC requires all inventions developed pursuant to such funding agreements to be “manufactured substantially in the United States”.²⁴ Under the 2021 DEC, DOE instituted a domestic manufacturing requirement that applies to inventions regardless of whether they are licensed or, if so, whether the license is exclusive or non-exclusive and includes all products derived from DOE-funded research—regardless of where the product will be used or sold.²⁵ In contrast, the U.S. Manufacturing Preference in the Bayh-Dole Act applies only to inventions that are exclusively licensed, and only to products derived from DOE-funded research used or sold in the United States (see table 3 in app. III).²⁶ The U.S. Competitiveness Provision applies to exclusive and non-exclusive licenses and when the funded entity does its own

²³In 2012, in the House of Representatives Committee on Appropriations report accompanying the Energy and Water Development Appropriations Bill, 2013, the Committee expressed its concern that DOE was not sufficiently keeping the value of DOE-funded research in the United States when DOE-funded intellectual property is commercialized by foreign manufacturers. Further, it directed DOE to report on “what authorities are available to control intellectual property, including the Bayh-Dole Act, that may help the retention of domestic manufacturing” including “specific recommendations for improving domestic intellectual property transfer and retention”. H.R. Rep. No. 112-462, pt. III, at 81-82 (2012).

²⁴Terms of the 2021 DEC became effective during fiscal year 2022 for DOE labs and applied to most DOE programs and agencies, some retroactively. The 2021 DEC was applied to the National Nuclear Security Administration in May 2022 and DOE programs under the cognizance of the Under Secretary for Infrastructure (S3) in March 2023.

²⁵An exclusive license grants the licensee the sole right to use, manufacture, and sell a patented invention. In contrast, a non-exclusive license grants the licensee the right to use the patented invention, but the patent owner remains free to grant any number of other licensees rights to make, use, or sell the technology.

²⁶35 U.S.C. § 204.

manufacturing, including in cases when the invention is to be used or sold outside the United States. Appendix III provides a timeline and summary of DOE policies since 2000 to strengthen domestic manufacturing for DOE-funded inventions.

DOE may require forfeiture of title to the invention if the lab contractor or university does not comply with the manufacturing requirements specified in a funding agreement. DOE patent counsel told us that it issued the 2021 DEC to close loopholes in the Bayh-Dole Act.²⁷ In its guidance documents, DOE notes that entities have maneuvered around the existing U.S. Manufacturing Preference language to manufacture federally funded technologies overseas.

To support U.S. competitiveness and the domestic manufacturing of federally funded inventions, in July 2023, the President signed Executive Order No. 14104 on *Federal Research and Development in Support of Domestic Manufacturing and United States Jobs*.²⁸ It tasks DOE, as well as the Departments of Defense, Agriculture, Commerce, Health and Human Services, Transportation, and Homeland Security, the National Science Foundation and the National Aeronautics and Space Administration, with, among other things, considering how their R&D funding agreements support domestic manufacturing objectives and whether “exceptional circumstances” warrant the adoption of enhanced U.S. manufacturing requirements for critical or emerging technologies.²⁹ Implementation of Executive Order 14104 is being led by the “Invent it Here. Make it Here” interagency policy committee, which is co-chaired by the National Security Council and the National Economic Council, according to DOE officials. They added that the interagency committee is examining whether enhanced domestic manufacturing requirements, similar to those outlined by DOE in its 2021 DEC, should be expanded across the federal government, among other issues.

²⁷Regarding the “loopholes,” DOE described three scenarios where federally-funded inventions may be legally manufactured overseas, without a waiver or modification, under the U.S. Manufacturing Preference in Bayh-Dole: (1) a technology transfer office seeks to issue non-exclusive licenses for an invention because it does not believe it can meet the more stringent requirements for exclusive licenses; (2) a company licenses only the international use and sales of an invention; and (3) a company manufactures, itself, patented technology it developed with federal support.

²⁸Exec. Order No. 14,104, 88 Fed. Reg. 51,203 (July 28, 2023).

²⁹Exec. Order No. 14,104, §§ 3(a), 5(a), 88 Fed. Reg. 51,203, 51,203–51,204, 51,205–51,206 (July 28, 2023).

Waiver or Modification Requests Under Bayh-Dole Act and 2021 DEC

The Bayh-Dole Act allows federal agencies to waive the U.S. Manufacturing Preference if: (1) “reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States” or (2) “under the circumstances domestic manufacture is not commercially feasible.”³⁰ The 2021 DEC’s U.S. Competitiveness Provision allows for a waiver or modification only where the entity such as a lab contractor or university seeking to grant a license or otherwise manufacture its invention can show to the satisfaction of DOE that manufacturing substantially in the United States is not commercially feasible. Absent a waiver or modification, failure to comply with the requirement to substantially manufacture in the U.S. could result in DOE requiring the lab contractor or university to forfeit title to the subject invention.

DOE waiver and modification guidance states that the department anticipates it will rarely approve requests to completely waive U.S. manufacturing requirements.³¹ Instead, DOE patent counsel and program offices negotiate with licensees or the relevant lab contractor or university on a case-by-case basis to request concessions to achieve enforceable alternative net benefits to the United States, such as domestic jobs or investment.³²

³⁰35 U.S.C. § 204.

³¹DOE guidance references the availability of both ‘waivers’ and ‘modifications’ of DOE manufacturing requirements. Here we sometimes use ‘waiver’ as a shorthand for waivers and modifications.

³²Agency documents note that “DOE is committed to a transparent, reasonable and timely waiver/modification process.”

Alternative Benefits Achieved through the Modification of U.S. Manufacturing Requirements

The Department of Energy (DOE) expects entities licensing a patent from a DOE lab or university to comply with its U.S. Competitiveness Provision that requires domestic manufacturing of DOE-funded inventions. However, DOE will consider requests to modify or waive aspects of the provision if the entity can: (1) demonstrate that it is not commercially feasible to meet the U.S. manufacturing requirement and (2) make other commitments that would benefit the U.S. economy and U.S. competitiveness, such as:

- Investment in U.S. plants or equipment
- Creation of high-quality U.S. jobs
- Further domestic development of the technology
- A positive effect on U.S. trade balance

Case Study

In 2020, DOE approved a request to waive certain manufacturing requirements for a photonics technology (science of light waves) developed with DOE funding. The company initially sought to manufacture the technology in China. After negotiations with DOE, it agreed not to manufacture in China or other DOE-designated countries of risk, and instead manufacture in its U.S. facilities for 6 years, after which it has the option to manufacture elsewhere. It also agreed to discuss any future relocations with DOE.



Robots in a solar panel factory

Note: While this case study involves a waiver granted under the Bayh-Dole Act prior to the 2021 Determination of Exceptional Circumstances (DEC), it is an example of the type of alternative benefit negotiation DOE continues to engage in pursuant to the 2021 DEC.

Source: GAO analysis of DOE documents; IM Imagery/stock.adobe.com (image). | GAO-24-106504

The process for requesting waivers or modifications of the U.S. Competitiveness Provision in licenses for DOE-funded inventions has several steps. The process usually begins when a licensee determines that its commercial success depends on foreign manufacture and that a full or partial waiver is necessary. The completed waiver or modification request is submitted directly to the relevant DOE funding program or uploaded to the iEdison system. DOE and the licensee seek to negotiate mutually agreeable alternative benefits in return for the waiver or modification, and if successful, DOE approves the request. For an illustrative depiction of the process for requesting a domestic waiver or modification, see appendix IV.

Managing Risk from the Foreign Acquisition of Licensed U.S. Technology

There are several pathways through which a foreign entity can acquire a license to a DOE-funded technology. While all licensees are subject to the domestic manufacturing requirements of the U.S. Competitiveness Provision, these foreign acquisition pathways are not prohibited by law or existing DOE regulations.³³

- The technology can be **licensed** directly to a foreign entity.
- The technology can be **sublicensed** by the licensee to a foreign entity.
- The licensee can undergo a **change in control** that involves a foreign entity.³⁴
- The license agreement for the technology can be **transferred** by the licensee to a foreign entity. This might occur in the case of an asset sale or merger.
- The licensee can become **bankrupt**. When the licensee's assets are sold in the bankruptcy process, the license agreement may be transferred to a foreign entity.
- The licensee can use the license agreement as **collateral** to secure a loan. If the licensee defaults on the loan, the license agreement could be transferred to a foreign entity creditor.

Labs and universities may consider two types of risk posed by the foreign acquisition of DOE-funded technology through patent licensing. The first is "technology risk," which is higher for critical and emerging technologies—advanced technologies that have great potential significance to U.S. national security interests—such as renewable energy generation and storage or high-performance computing.³⁵ While some critical and emerging technologies are protected with mechanisms

³³DOE is in the process of updating regulations to require additional approvals for some of these pathways, including licensing certain technologies to entities from a country of risk.

³⁴In this report, we use the term "change in control" to refer to a change in a company's ownership or management that results in a different group of equity holders or directors possessing the power, directly or indirectly, to direct or cause the direction of the management and policies of the company. Some patent license provisions we reviewed reference changes in control and some reference changes in ownership; we use the term "change in control" to refer to both. The 2021 DEC requires that licensees or the relevant licensors report changes in control to DOE within 6 months.

³⁵Office of Science and Technology Policy, National Science and Technology Council, *Critical and Emerging Technologies List Update* (February 2022). Patented technologies are publicly disclosed. The concern with such technologies is not national security, but whether the economic benefits will accrue to the United States.

like classification safeguards and export controls,³⁶ others are not presently protected through such mechanisms. The second type of foreign acquisition risk, “entity risk,” is associated with acquisition by a foreign entity.³⁷ While only 10 percent of DOE’s active lab license agreements involved foreign entities in fiscal year 2022, these entities can present threats, according to DOE documents. Understanding entity risk—particularly “countries of risk” to the United States—is an important step to reduce the likelihood of losing the economic gains associated with DOE-funded technology to adversaries.³⁸

Prior to executing a license agreement, labs and universities may consider technology risk by evaluating the technology that is going to be licensed. Additionally, they may vet prospective licensees for foreign ownership, control, or influence using a variety of approaches. For example, labs may require licensees to complete a pre-licensing questionnaire, which may contain information about the management team, company ownership, and major investors. The lab or university may vet the prospective licensee using open-source tools, such as:

- **Restricted party screening tools**, which help identify entities that are listed on federal restricted party lists.

³⁶Government agencies with responsibility for export controls include the Department of Commerce’s Bureau of Industry and Security, which regulates the export of some less sensitive military items and items that have both commercial and military applications (e.g., electronics, computers, navigation and avionics, and space and propulsion equipment) through the Export Administration Regulations. Other government agencies with responsibility for export controls include the Department of State’s Directorate of Defense Trade Controls and the Nuclear Regulatory Commission Office of International Programs.

³⁷DOE Policy 485.1A defines “foreign entities” as including “(1) any foreign government or foreign government agency or instrumentality thereof; (2) any international organization; (3) any form of business enterprise or legal entity organized, chartered or incorporated under the laws of any country other than the United States or its territories; (4) any form of business enterprise organized or incorporated under the laws of the United States or a State or other jurisdiction within the United States which is owned, controlled or influenced by a foreign government, agency, firm, corporation, or a person who is not a citizen or national of the United States; and (5) any person who is not a citizen or national of the United States.”

³⁸As of November 2022, there were no active exclusive licenses between DOE labs and entities from a DOE country of risk, according to DOE’s *180-Day Review Report: Licensing of Intellectual Property by Department of Energy and National Nuclear Security Administration Laboratories* (March 2023). Countries of risk are those that may present a risk to DOE-funded research. DOE’s countries of risk list were limited to China, Iran, North Korea, and Russia, as of March 2024, and can change over time, according to DOE documents.

- **Commercial databases**, which provide details about a company, such as ownership, investors, and financials.
- **Other publicly available information** found via web searches.

Some lab and university technology transfer offices may work with other offices at their institutions to vet licensees, including export control offices and general counsel's offices. Additionally, DOE labs (but not universities) have access to DOE's field counterintelligence offices. These offices can conduct counterintelligence reviews, in which officials vet potential licensees for foreign ownership, control, or influence using multiple sources of information, some of which are unavailable to technology transfer offices, according to DOE counterintelligence officials.

Lab Contractors and Universities Had Concerns about DOE Manufacturing Policy, and DOE Is Not Assessing Implementation

Lab contractors and universities we surveyed, as well as other stakeholders we spoke to, raised concerns that DOE's 2021 DEC could reduce interest in commercializing DOE-funded inventions. Yet, DOE has not developed a strategy or approach for how to assess the effects of the 2021 DEC. Further, DOE has not fully communicated and demonstrated the expected timelines for its process for approving waiver or modification requests, nor has it provided sufficient concrete examples of how to demonstrate alternative benefits to the U.S. economy.

Lab Contractors and Universities Raised Concerns That DOE's Policy Could Reduce Interest in Commercialization

DOE lab contractors and university representatives we surveyed, as well as other stakeholders, expressed a range of concerns about the potential for the 2021 DEC to reduce commercialization of DOE technologies and decrease patent filings, which, in turn, may reduce the economic benefits of DOE R&D funding. Specifically, they offered the following perspectives:

- **Reduced company and investor interest.** Several survey respondents and other stakeholders said they anticipated the 2021 DEC would have a "chilling effect" on commercialization that would ultimately lead to less investment and fewer companies licensing DOE-funded technologies.³⁹ In particular, survey respondents noted that prospective licensees and investors are likely to be more cautious because they face the risk of losing money if the eventual product

³⁹Throughout the report, we use the indefinite quantifiers, "a few", "some", "several", "many", "majority", and "most" to inform the reader of the approximate quantity of survey respondents or stakeholder interviewees that expressed a particular viewpoint. For the purposes of our review, a few refers to 2-3, several refers to 4-6, many refers to more than 6, a majority is considered more than 51 percent, most is considered 80-90 percent, and some refers to more than one but less than a majority.

cannot be manufactured domestically and their companies cannot get a timely waiver or modification of DOE's U.S. manufacturing requirement.⁴⁰ One DOE lab contractor reported that a foreign company with a U.S. manufacturing presence withdrew from licensing negotiations after learning about the terms of the 2021 DEC and despite being told they could seek a domestic manufacturing waiver or modification.

One DOE official acknowledged it is a "worst case scenario" when DOE-funded technologies are never commercially developed. However, other officials said they do not anticipate the 2021 DEC having a negative effect on commercialization. The majority of lab contractors (nine of 16)⁴¹ and universities (11 of 19) reported in response to our survey that it was "too soon to tell" whether the 2021 DEC will affect their decisions to patent or elect title to DOE-funded inventions.⁴² As of August 2023, only half of the lab contractors (eight of 16) and about one-quarter of the selected universities (five of 19) had issued patent licenses subject to the 2021 DEC.

- **Reduced university interest.** Under the terms of the 2021 DEC, if a licensee does not comply with the U.S. manufacturing requirement, DOE could take back ownership of and rights to the invention from the funded entity. Because of this risk, several universities reported in their survey responses that they were likely to reduce patenting of DOE-funded technologies. Such actions could impede DOE's goal of supporting domestic manufacturing. For example, it could leave more DOE-funded inventions without U.S. patent protection, making it legal for foreign companies to manufacture them abroad and sell them in the United States.

DOE patent counsel officials told us that DOE would not enforce its rights under the 2021 DEC in a "draconian" manner and would give patent holders advanced notice to comment on violations of U.S. manufacturing requirements before DOE determines whether to take

⁴⁰The 2021 DEC provides that the owner of an invention may lose its rights to the invention if it or its licensee is in breach of the domestic manufacturing requirements. This consequence is known as forfeiture of title.

⁴¹The 17 labs include the 16 contractor-operated labs plus NETL. NETL is government operated, and thus its management and operations are not subject to the Bayh-Dole Act. We nevertheless included it in our survey in order to present a full picture.

⁴²Lab contractors and universities must file a U.S. patent application for the invention within 1 year of electing title. See 35 U.S.C. § 202(c); 37 C.F.R. § 401.14(C).

an enforcement action.⁴³ However, several lab contractor and university survey respondents were unaware of this assurance. Several survey respondents and other stakeholders pointed out that DOE has not specified whether licensees will have a chance to correct violations or, if so, how long they will have to do so. Others noted that the new U.S. manufacturing reporting obligations are a significant compliance risk and administrative burden for university technology transfer offices with limited resources that must fulfill several other federal reporting requirements. DOE officials noted that there may be tension between the incentives of labs and universities to maximize technology transfer and DOE's goals of achieving U.S. manufacturing objectives.

Lab contractor and university survey respondents told us that instead of imposing restrictions like those in the 2021 DEC, DOE could better achieve its goal of enhancing domestic manufacturing by offering incentives to patent holders and potential licensees. For example, lab contractor and university survey respondents (and other stakeholders) suggested enhancing grants for domestic manufacturing or soliciting private sector investment to support domestic manufacturers.⁴⁴ They further suggested that, by providing additional funding to patent holders to seek patent protection in other countries, DOE could limit the ability of foreign companies to manufacture such inventions overseas and thus potentially create more opportunity for U.S. manufacturing.⁴⁵ DOE officials agreed with the need for incentives to bolster the U.S. manufacturing base. As we have previously reported, there are a number of tools that

⁴³DOE guidance states that it is committed to resolving funding recipient business concerns through an accessible and transparent waiver and modification process working closely with recipients to avoid any need to pursue formal remedies under an award. *Implementation of the DOE Determination of Exceptional Circumstances under the Bayh-Dole Act to Further Promote Domestic Manufacture of DOE Science and Energy Technologies – Class Deviation*, FAL 2022-06, (September 27, 2022).

⁴⁴Incentives have been offered to companies to domestically manufacture key technologies through the Bipartisan Infrastructure Law (BIL) and the Inflation Reduction Act (IRA).

⁴⁵U.S. patents do not provide intellectual property protection in foreign countries, leaving U.S. patent holders vulnerable to infringement outside of the United States. Foreign patents provide benefits but are expensive to acquire. According to one lab contractor, benefits include: (1) enhanced competitiveness of domestic licensees internationally, and (2) potentially stronger basis to prevent unauthorized use of DOE-funded technologies in foreign countries.

the federal government can use to influence the U.S. manufacturing sector.⁴⁶

DOE Has Not Established a Strategy or Approach for Monitoring and Assessing Implementation of Its 2021 Manufacturing Policy

DOE implemented its 2021 DEC with the objectives of reducing offshoring and enhancing domestic manufacturing of DOE-funded inventions.⁴⁷ DOE patent counsel officials stated that the 2021 DEC will do so by closing loopholes in the U.S. Manufacturing Preference under the Bayh-Dole Act. In its implementation guidance for the 2021 DEC, DOE noted that it plans to require funding programs to collect data on performance and impact metrics such as U.S. jobs created, U.S. R&D investments, commitments to the U.S. economy, and supply chain impacts. Those officials told us DOE plans to use these data to track progress towards the 2021 DEC's objectives.⁴⁸ Further, DOE patent counsel officials told us in December 2023 that, to evaluate implementation of the 2021 DEC, they have begun to collect data to monitor researcher interest in DOE funding (applicants for DOE grants) and the health of the technology transfer process (funded entities claiming ownership of new inventions reported through iEdison). DOE officials said they will use these and other data to develop metrics for the effectiveness of the 2021 DEC.

However, DOE has not yet established a strategy or approach for how it will use these data to assess whether its policy is achieving its objectives. In particular, it has not specified a measure of progress toward its objective of increasing domestic manufacturing by reducing offshoring of DOE-funded technologies. Nor has it established activities to monitor and assess any effects of the policy on the broad DOE objectives of promoting technology transfer and commercialization. For example, it has not determined how often it will collect data on researcher interest in DOE funding. According to DOE documents, promoting technology transfer is key to achieving its mission of enhancing economic growth of the United States and expanding the public impact of DOE research and development. As we detailed above, lab contractors, universities, and

⁴⁶See GAO, *U.S. Manufacturing: Federal Programs Reported Providing Support and Addressing Trends*, [GAO-17-240](#) (Washington, D.C.: Mar. 28, 2017).

⁴⁷Department of Energy, *Department of Energy Determination of Exceptional Circumstances Under the Bayh-Dole Act to Further Promote Domestic Manufacture of DOE Science and Energy Technologies* (2021).

⁴⁸Department of Energy, *Implementation of the DOE Determination of Exceptional Circumstances under the Bayh-Dole Act to Further Promote Domestic Manufacture of DOE Science and Energy Technologies – Class Deviation*, FAL 2022-06, (September 27, 2022).

stakeholders stated that the policy could reduce patenting and commercialization of DOE-funded inventions.

According to *Standards for Internal Control in the Federal Government*, agencies should establish and implement monitoring activities and evaluate the results.⁴⁹ Further, they should define objectives in measurable terms so that performance toward achieving those objectives can be assessed. However, DOE has not specified measurable objectives that will help it determine the effectiveness of its policy. Assessing technology transfer performance has proven challenging to DOE for a number of years. We reported in 2002, 2009, and 2015 that DOE faces challenges in measuring technology transfer performance, including monitoring domestic manufacture of the inventions it funded.⁵⁰ In 2021, we reported that some DOE measures of trends in technology transfer activities do not align with DOE's strategic goals and objectives.⁵¹

DOE officials told us that one reason they have not developed a strategy or approach to formally evaluate the effects of the 2021 DEC is that their practice has been to rely on the collection of anecdotal evidence.⁵² The officials stated that systematically evaluating the impact of manufacturing policy is challenging. For example, it can take 5 years or more from the time a research project begins to the time any resulting inventions are

⁴⁹GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: Sept. 2014).

⁵⁰See GAO, *Intellectual Property: Federal Agency Efforts in Transferring and Reporting New Technology*, [GAO-03-47](#) (Washington, D.C.: Oct. 31, 2002), GAO, *Federal Research: DOE Is Addressing Invention Disclosure and Other Challenges but Needs a Plan to Guide Data Management Improvements*, [GAO-15-212](#) (Washington, D.C.: Jan. 30, 2015) and GAO, *Technology Transfer: Clearer Priorities and Greater Use of Innovative Approaches Could Increase the Effectiveness of Technology Transfer at Department of Energy Laboratories*, [GAO-09-548](#) (Washington, D.C.: June 16, 2009).

⁵¹See GAO, *Department of Energy: Improved Performance Planning Could Strengthen Technology Transfer*, [GAO-21-202](#) (Washington, D.C.: Feb. 1, 2021).

⁵²DOE patent counsel stated that the 2021 DEC was motivated by specific and general information related to lessons learned over time. For example, one motivating factor was the broad trend in the photovoltaic industry, which has been significantly offshored.

commercialized, according to DOE officials.⁵³ They stated that this time lag makes it difficult to identify appropriate metrics and to attribute the change in a performance measure to a specific policy change. Our prior work has shown that the link between federal research efforts and desired outcomes is often difficult to establish and may not be apparent for years.⁵⁴ In addition to the challenges identified, DOE was waiting, in part, for the issuance of Executive Order 14104 and expected new Government-wide requirements including modifications to the invention utilization reporting system (the data informing the assessments) to execute a specific assessment strategy, according to DOE officials.

Nonetheless, without a plan to assess performance, along with measurable objectives that align with agency goals and objectives, DOE will lack an objective way to determine if the 2021 DEC is working and, if not, to make changes as appropriate. Conversely, by relying on anecdotal evidence, DOE is at risk of pursuing a policy that could be ineffective or counterproductive.

Lab Contractors and Universities Had Concerns About the Timeliness and Transparency of the Process for Requesting a Waiver or Modification to U.S. Manufacturing Requirements

DOE guidance states that the agency is committed to a transparent, reasonable, and timely process for waiving or modifying the U.S. manufacturing requirements in the 2021 DEC.⁵⁵ However, many lab contractor and university officials we surveyed, as well as other stakeholders, said that DOE's waiver and modification process created uncertainty and risk for potential licensees. They said the process is not timely, nor is it clear on how licensees should demonstrate alternate means of creating jobs or other benefits to the United States in lieu of U.S. manufacturing.

The following details lab contractors', selected universities' and other stakeholders' concerns about the waiver and modification process and

⁵³The time lag is due in part to the milestones built into the invention reporting and patent licensing process. Lab contractors and universities must notify DOE within 2 months from the date the inventor discloses the invention to their institution and then generally must notify DOE whether they have elected to retain or waive title to the invention within 2 years of the date of disclosure. Following disclosure, they evaluate whether to apply for patent protection. Should they choose to file a U.S. patent application, they must do so within 1 year of election of title.

⁵⁴See GAO, *Executive Guide: Effectively Implementing the Government Performance and Results Act*, GAO/GGD-96-118, (Washington, D.C.: June 1996).

⁵⁵Department of Energy, *Implementation of the DOE Determination of Exceptional Circumstances under the Bayh-Dole Act to Further Promote Domestic Manufacture of DOE Science and Energy Technologies – Class Deviation*, FAL 2022-06, Appendix 5 (September 27, 2022).

describes practices that they suggested could improve DOE's waiver and modification process and reduce uncertainty:

Lack of transparency on demonstrating alternate benefits to the U.S. economy. As discussed above, potential licensees may request that the U.S. manufacturing requirement be waived or modified and substituted with a plan with specific and enforceable commitments that would be beneficial to the U.S. economy. Examples of such commitments could include making a specific investment in a new or existing U.S. manufacturing facility or supporting a certain number of jobs in the United States related to the technology. However, several lab contractors and universities told us that it was unclear how potential licensees would demonstrate alternative benefits that would qualify for a waiver or modification. While DOE guidance and officials highlighted several situations likely to require waivers (or modifications), such as lack of domestic manufacturing capacity or processes that depend on locally available materials, they provided only one example of specific DOE-approved alternative benefits that would create jobs or other benefits to the U.S. economy. Officials from some lab contractors and universities we surveyed noted that it was unclear what rationale was used to make decisions or what factors DOE was prioritizing in its review of waiver or modification requests. Lab contractors, universities and other stakeholders proposed that DOE disseminate specific anonymized examples (or hypothetical scenarios) of approved waiver or modification requests. They also said it would be useful if DOE were to provide examples of the types of alternative benefits licensees have successfully offered in lieu of manufacturing their products domestically. In one example provided to us by DOE, a licensee agreed to manufacture one component of a product overseas as long as the final product assembly was done in the United States. One university noted that DOE could develop and share examples like this, which would increase transparency and reduce uncertainty.

Potential for long waiver review timelines. Officials from some lab contractors and universities we surveyed reported lengthy and inconsistent DOE review timelines for waiver or modification requests submitted since 2013. For example, officials from four DOE lab contractors reported that DOE decisions required an average of five or fewer months to complete. In contrast, officials from two DOE lab contractors and two universities reported that decisions required an average of more than 6 months to complete. One university reported that they withdrew a waiver request made in 2015 after more than 6 years of prolonged negotiations with DOE. Officials from one lab contractor we

surveyed stated that companies may not be interested in seeking waivers due to uncertainty about the length of the process and the potential to be denied.

Recognizing that the length of time for the waiver or modification process can vary, DOE patent counsel officials told us they help guide waiver applicants through the process and provide updates on the status of waiver requests, as necessary.⁵⁶ Officials also noted that DOE has not externally communicated time frames for how long waivers should take. A few survey respondents also suggested that an expedited waiver review process (e.g., 30 days or less) would help facilitate the commercialization of DOE-funded technologies.

Overall, survey respondents and stakeholders we interviewed emphasized that a clear, timely, and consistent waiver review process is vital because market conditions are dynamic, and funding opportunities for licensees may be short-lived. In this environment, a protracted waiver process that lacks transparency may cause companies to pursue non-DOE-funded technologies rather than assuming additional risk and uncertainty from seeking a waiver or modification.

DOE officials told us they expect to receive more requests to modify or waive requirements in the future as lab contractor and university technology transfer offices seek to license patents subject to the 2021 DEC.⁵⁷ Officials acknowledged that stakeholders, such as lab contractors and universities, have raised concerns with the waiver process. But they said these concerns were largely mitigated by the design of DOE's waiver and modification process, which is intended to be flexible, transparent, and efficient. According to DOE's implementation guidance for the 2021 DEC, its process for modifying or waiving requirements uses a tailored approach that is responsive to each applicant's needs. DOE officials said

⁵⁶The close relationship that DOE has with its labs may better facilitate communication about the waiver request process and enable more rapid decisions. For example, one lab contractor said DOE effectively communicated concerns about waiver or modification requests through established communication pathways with its DOE field office and intellectual property counsel. In contrast, one university in our survey that has applied for DOE waivers reported a need for timely and specific feedback from DOE about the requests.

⁵⁷We estimated that, from fiscal year 2012 through fiscal year 2022, non-exclusive agreements made up an average of 23 percent of the total licenses or options held by universities. Using FY 2021 as an example, we estimated that full implementation of the new policy would have required the 110 non-exclusive licenses or options (out of a total of 548) to also be substantially manufactured in the United States.

they have made fairly detailed guidance available to make the process transparent to applicants for waivers or modifications and communicated this information through various outreach efforts, such as holding meetings with stakeholder groups to address concerns that had been raised.⁵⁸ DOE officials said that they are interested in streamlining the waiver and modification process to make it more efficient and have considered whether some categories of waiver requests could potentially be expedited. However, they acknowledged that there may be a need to update aspects of their existing guidance, which is from 2021, and enhance communication with lab contractors, universities, and other stakeholders about the process.⁵⁹ DOE officials told us that one reason they have not communicated more about the process is that they assumed the process was working as intended. Specifically, they assumed that the low number of waiver and modification requests prior to the 2021 DEC was because U.S. manufacturing requirements were less stringent. They did not believe that negative experiences and perceptions of the waiver process limited applicant willingness to seek waivers.

Because DOE has not fully communicated and demonstrated the expected timelines of its waiver and modification process or provided sufficient concrete examples of how to demonstrate alternative benefits to the U.S. economy, lab contractors and universities we surveyed stated that they lack sufficient information to reduce their uncertainty about DOE's waiver process. DOE's implementation guidance for its 2021 DEC states that the agency is committed to a transparent, reasonable, and timely process for waiving or modifying the U.S. manufacturing requirements.⁶⁰ Furthermore, GAO's internal control standards call for management to externally communicate the quality information necessary

⁵⁸Table 1 in app. I lists the DOE guidance documents DOE made available to labs and universities between September 2021 and September 2022.

⁵⁹DOE officials told us that internal efforts are underway to update waiver and modification guidance in alignment with Executive Order 14104. They added that the Interagency Working Group on Bayh-Dole, which is led by the National Institute of Standards and Technology, is coordinating across federal agencies and with other interagency groups, such as the National Science and Technology Council's Lab to-Market Subcommittee, to develop additional guidance on the waiver and modification guidance to implement Executive Order 14104.

⁶⁰Department of Energy, *Implementation of the DOE Determination of Exceptional Circumstances under the Bayh-Dole Act to Further Promote Domestic Manufacture of DOE Science and Energy Technologies – Class Deviation*, FAL 2022-06, Appendix 5 (September 27, 2022).

to achieve its objectives.⁶¹ In this case, doing so would help to meet DOE's goal of a transparent waiver process.

Without more fully communicating with lab contractors, universities, and other stakeholders, in particular to (1) clarify how to demonstrate alternative benefits to the U.S. economy and (2) set forth expected timelines for the waiver or modification process, it will be difficult for DOE to achieve transparency and address stakeholder concerns. Doing so may help reduce uncertainty in the process and better promote licensing and commercialization of DOE-funded technology to the benefit of the U.S. economy.

DOE Oversight and Guidance on U.S. Manufacturing Requirements Have Focused on Lab Contractors, Not Universities

We found that DOE oversees efforts by its lab contractors to ensure that licensees comply with U.S. manufacturing requirements; however, DOE does not similarly oversee universities and has not provided them with sufficient guidance to monitor licensee compliance. In addition, we found that, while DOE has increased its attention in recent years on how lab contractors handle licensing, it has not performed a similar review of university licensing activities.

DOE Oversees Lab Contractor Efforts but Has Not Provided Sufficient Guidance to Universities

DOE Labs

Lab contractors are responsible for the day-to-day management of their licenses. According to DOE patent counsel officials, lab contractors are in the best position to manage their licensees' compliance with the license obligations because each license agreement has different requirements.

Lab contractors monitor licensee activities by requiring those licensees to periodically report certain information. This information includes commercial sales, the status of products developed using an invention, and any changes in control (e.g., changes in management or ownership). Lab contractors then review these reports and identify missing items,

⁶¹[GAO-14-704G](#).

inconsistencies, and other issues. Should anything raise concerns, they generally engage with their licensees to resolve the issues by requesting additional information or follow-up meetings. If the concerns are not sufficiently resolved, they may terminate the license.

DOE program and site officials do not monitor individual lab licenses, but they oversee lab contractors' management of licenses by collecting license-related information through several channels. Specifically, DOE collects and reviews information submitted by lab contractors through its Annual Technology Transitions Data Call and through the federal invention database iEdison and may engage with the contractors to resolve any issues or questions. DOE can also collect information through license compliance reviews, a process in which DOE reviews selected patent licenses to determine adherence to terms and conditions. A little more than half of the DOE labs we surveyed reported that DOE conducts license compliance reviews at their labs (10 of 17). In addition, DOE may initiate a review or enforcement action under certain circumstances, according to DOE patent counsel officials. Specifically, DOE officials can initiate an enforcement action if they discover that a licensee has (1) failed to timely report or elect to use its invention or (2) violated its U.S. manufacturing commitments to the detriment of U.S. economic and national security. Past enforcement actions have resulted in four settlements where lab contractors, universities, or their licensees have agreed to more than \$100 million in legally binding U.S. manufacturing commitments, according to DOE documents.

Lab license agreements generally require licensees to report on commercialization, but not always on compliance with the 2021 DEC's U.S. Competitiveness Provision.⁶² We obtained and analyzed exclusive license agreement templates from 13 labs and found that seven of the 13 templates required reporting on compliance with the U.S.

⁶²As a caveat, the license agreement templates provided for our review may be general templates used by lab contractors and universities that receive funding from many agencies and may therefore not reflect all DOE-specific standard provisions. Thus, the lack of a given provision in a license agreement template we reviewed does not necessarily mean the actual negotiated license agreement lacks that provision.

Competitiveness Provision.⁶³ DOE lab contractors are updating their license templates as part of the recommendations from DOE's 180-Day Review of DOE Lab Licensing, issued in March 2023.⁶⁴

Universities

As with lab contractors, universities are responsible for the day-to-day management of their licensees. According to DOE officials, it is the responsibility of the funding recipient and intellectual property owner (in this case, the universities) to comply with the terms and conditions of the award. DOE does not conduct oversight of university monitoring activities, though it has the right to do so, and it is not prohibited from issuing guidance.⁶⁵ But some universities we surveyed noted that they did not obtain guidance on monitoring compliance with license agreements from DOE. In the absence of such guidance, they have developed their own procedures and practices.

As with lab contractor licensors, the 2021 DEC requires that universities ensure that their licensees comply with U.S. manufacturing requirements. However, almost none of the university license agreement templates we reviewed require licensees to report on this compliance. Of the 13 templates we reviewed, we found that one required such reporting as of September 2023.⁶⁶ This situation may leave universities without this form of contractual leverage to obtain the information they need to ensure that they themselves are complying with the 2021 DEC.

Unlike lab contractors, which all reported obtaining guidance on monitoring compliance with license agreements from DOE, seven of the 19 selected universities reported that they did not obtain guidance from

⁶³We collected the templates from labs between July and September 2023 and they were therefore current at the time. Beginning October 1, 2023, the National Institute of Standards and Technology updated iEdison to collect annual utilization reports on all federally funded inventions, including information on whether the invention is subject to U.S. manufacturing requirements beyond Bayh-Dole's U.S. Manufacturing Preference, whether the commercialized product is manufactured substantially in the United States, and the country of manufacture. This may lead to DOE labs and universities updating the reporting requirements in their license agreement templates to collect this information from licensees.

⁶⁴Department of Energy, *180-Day Review Report: Licensing of Intellectual Property by Department of Energy and National Nuclear Security Administration Laboratories* (March 2023). In 2023, DOE examined licensing practices across all 17 DOE national labs.

⁶⁵See 37 C.F.R. §§ 401.14(K)(5) and 401.1(c).

⁶⁶We collected the templates from universities between June and September 2023 and they were therefore current at the time.

direct communication from DOE. Most universities (17 of 19) reported obtaining guidance from other sources, including university offices and stakeholder organizations, such as AUTM.⁶⁷

Monitoring compliance with certain license requirements can be difficult, according to university officials. The majority of universities we surveyed (10 of 19) expressed uncertainty as to what terms and conditions should be included in license agreements for DOE-funded inventions. Also, most university survey respondents (13 of 19) noted that certain terms—such as “manufactured substantially in the United States”—are not clear and should be better explained in DOE guidance. While the term “manufactured substantially in the United States” has been part of the Bayh-Dole Act since 1980, the act does not define the term, Congress has not amended the act to define this phrase,⁶⁸ and ambiguity remains. Further, over half of universities (10 of 19) we surveyed reported that this sort of ambiguous terminology will reduce their ability to enforce the terms of their license agreements. Most university survey respondents (14 of 19) suggested that it would be helpful for DOE to provide guidance that explicitly identifies what particular terms and conditions need to be included in license agreements for DOE-funded patents, including clarifying when terms should be applied retroactively (e.g., when grants are modified post-funding, in the case of an award renewal or extension). Others noted that additional guidance from DOE, such as Frequently Asked Questions resources, would be particularly helpful at the funding award stage. In addition to universities, labs may also benefit from additional guidance on where the threshold for “manufactured substantially in the United States” lies, according to feedback provided by DOE’s National Lab Technology Transfer Group, which collected information from the labs and provided feedback to DOE following issuance of the 2021 DEC. DOE officials, including patent counsel, told us they have not provided guidance (to universities or lab contractors) defining U.S. manufacturing because what constitutes “manufactured substantially in the United States” varies based on the product or industry. Even though the term is undefined in the Bayh-Dole Act, DOE could provide information to labs and universities to clarify how DOE interprets the term when making waiver and modification decisions, which would

⁶⁷AUTM is a nonprofit organization that supports academic research, technology transfer, and intellectual property protection.

⁶⁸35 U.S.C. § 204.

remove ambiguity for stakeholders about DOE's decision-making process.

Written guidance on such definitions is important because, according to *Standards for Internal Control in the Federal Government*, information must be communicated in a suitable form and in a timely manner to those who need it to carry out their responsibilities.⁶⁹ Further, these standards call for some level of agency documentation (in this case, guidance) so that the components of internal controls can be designed, implemented, and operated effectively. Without additional DOE guidance, universities may develop their own procedures for monitoring compliance with license agreements, which may not be rigorous. That situation would increase the risk that universities' efforts to monitor licensees will be incomplete or inconsistent. Further, DOE may lack assurance that universities' licensees are complying with the U.S. manufacturing requirements in their license agreements.

DOE Has Reviewed Licensing Practices at Labs but Not Universities

DOE increased its attention in recent years on how lab contractors handle licensing, including how they have managed licensees' compliance with the U.S. Manufacturing Preference in the Bayh-Dole Act and the U.S. Competitiveness Provision in the 2021 DEC. In particular, DOE has conducted two reviews of lab licensing practices, at the direction of the Secretary of Energy:

⁶⁹[GAO-14-704G](#).

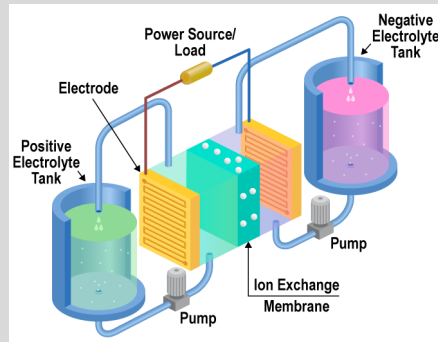
PNNL's Licensing of Vanadium Redox Flow Battery Technology

In 2010, the Pacific Northwest National Laboratory (PNNL) made a breakthrough discovery involving an advanced battery technology with funding from the Department of Energy (DOE) and applied for a patent that was granted in 2014. That technology was later transferred via licensing agreements to a Chinese company and later potentially manufactured in China.

First developed in the 1970s, redox flow batteries are a type of rechargeable battery that stores chemical energy in liquids pumped through the battery. They have potential for wide use in stationary energy storage.

PNNL's research improved upon the existing designs by developing a new-generation electrolyte solution for vanadium flow batteries to make existing battery systems cheaper and more durable.

In 2012, PNNL granted a license to a small U.S.-based startup company. The startup executed a sublicense to a Chinese company in 2017. The U.S. company struggled technically and financially. It pledged the PNNL license as collateral for a loan and eventually had its assets sold to a Dutch company. PNNL terminated the license in 2022.



Schematic illustration of a redox flow battery

Source: GAO analysis of DOE and PNNL documents; sivector/stock.adobe.com (image). | GAO-24-106504

- **30-Day Review of PNNL Battery Licensing (September 2022) (the 30-Day Report):** This review focused on the licensing of vanadium redox flow battery technology by the contractor operating PNNL, which was technology developed with DOE R&D funding (see text box). While PNNL began updating its technology transfer procedures and developing best practices in collaboration with other DOE labs in February 2022, the review was prompted by multiple news reports that a breakthrough discovery involving the battery technology had been transferred to China. It found that PNNL's contractor, its licensees, and its sublicensees complied with applicable U.S. manufacturing laws and regulations, and that PNNL's contractor went above the statutory minimum by placing a substantial U.S. manufacturing requirement into the license. However, the review also found there was a lack of internal controls and timely communication with DOE. For example, PNNL did not effectively track and monitor licensing activities and did not have a provision prohibiting use of the license as collateral. Including such a provision would have better positioned PNNL to terminate the license or withhold approval of the transfer of the licensee's assets, including the non-exclusive patent license, to a foreign company. To address these deficiencies, PNNL's contractor has begun to implement a number of initiatives designed to improve its technology transfer procedures.
- **180-Day Review of DOE Lab Licensing (March 2023) (the 180-Day Report):** This review examined licensing practices at all 17 DOE national labs. It found that monitoring and management of intellectual property licenses varied across labs, and that lab contractors generally had not actively monitored or required specific licensee reporting on compliance with U.S. manufacturing obligations. DOE recommended that the DOE lab contractors perform a compliance review of all lab licenses and improve risk management practices. The report presented eight recommendations. Three were for immediate action and five were policy recommendations, such as improved lab contractor coordination and communication with DOE to ensure more robust license management and monitoring processes, among others. DOE noted that the findings from the 180-Day Report were generally consistent with the findings of the 30-Day Report and formed three working groups that were tasked with addressing recommendations

from the 180-Day Report.⁷⁰ DOE anticipates completing its implementation strategy for the corrective actions by mid-2024.

Although the fiscal year 2022 total number of university patent licenses is a significant proportion of the total number of DOE's active patent licenses (548 out of 1,411), DOE has not performed a similar review of university licensing activities.⁷¹ DOE officials reported that some of the deficiencies identified in recent lab reviews, such as insufficient internal controls, may also be present at universities, although they did not identify any specific concerns. DOE is not planning to conduct a review of university licensing practices, but it is something that they would be willing to consider, according to DOE patent counsel officials. However, they have not established a plan or time frames for doing so. Officials said they are currently focused on addressing the lab licensing issues identified in the 180-Day Report. Further, they said it has been more difficult for them to examine university licensing practices compared to labs because it can be challenging to obtain licensing data from universities. One reason is that for some universities, DOE-funded inventions are only a small share of their licensing portfolios (in contrast to DOE labs, which primarily focus on DOE-funded inventions). According to DOE officials, another reason it is challenging for DOE to examine university licensing practices is because there are significantly more universities with licenses resulting from DOE-funded inventions than labs (97 versus 17).

Standards for Internal Control in the Federal Government call for management to assess the risks faced entity-wide, and at the activity level, from external and internal sources and decide what actions to take to mitigate such risks.⁷² Further, they call for ensuring that ongoing oversight—such as management reviews—occurs during normal operations and that management obtains relevant data from reliable internal and external sources in a timely manner based on the identified information requirements. The lack of such internal controls in the case of university licensing practices makes it more difficult for DOE to ensure

⁷⁰Working group 1 is focused on intellectual property license agreement safeguards and research technology and economic security issues for intellectual property licenses. Working group 2 is focused on licensee lifecycle monitoring. Working group 3 is focused on improved coordination and communication with DOE/NNSA.

⁷¹These totals for fiscal year 2022 were current as of February 2024.

⁷²[GAO-14-704G](#).

effective monitoring of the U.S. Competitiveness Provision and other aspects of license agreements.

A DOE review of university licensing practices would help ensure that universities are enforcing the provisions of their license agreements. In the absence of a plan with clear time frames for reviewing university licensing practices, DOE will continue to lack an understanding of the extent of the risks that universities' licensees are not complying with license terms, including the U.S. Competitiveness Provision in DOE's 2021 DEC.

Lab and University Management of Risks from Foreign Acquisition of Licensed Technology Is Inconsistent

The management of DOE's 17 labs, along with that of all 19 of the universities we reviewed, take steps to manage risks posed by the foreign acquisition of DOE-funded technology through patent licensing. However, we found that they use inconsistent approaches to managing risk, in part due to insufficient DOE guidance, potentially leaving federally funded intellectual property unduly exposed to risks associated with foreign control. In addition, we found that DOE labs do not consistently use counterintelligence reviews, a potentially effective tool for identifying foreign ownership.

Labs and Universities Take Some Steps to Manage Risks, but Their Approaches Are Inconsistent or Insufficient

We found that management at all 17 DOE labs and all 19 universities we reviewed take steps to manage risks posed by the foreign acquisition of DOE-funded technology through patent licensing. But we also found inconsistencies in these steps during all three phases of patent licensing: (1) pre-licensing, (2) license drafting and execution, and (3) post-licensing. These inconsistencies are partly due to a lack of comprehensive DOE guidance.

Pre-licensing risk assessment activities

Labs and universities can manage risk by assessing the licensed technology and potential licensees before executing a license agreement. We found two main inconsistencies during this phase. The first is that only some labs and universities assess risks specific to the technology itself, known as technology risk. While some labs and universities GAO surveyed consider technology risk, which may occur at the time that an invention disclosure is received, others do not. For example, six of the 17 labs reported assessing technology risk by using DOE's internal Science and Technology (S&T) Risk Matrix—which calls for increased scrutiny on six critical and emerging technologies and on DOE's four countries of

risk.⁷³ As noted above, according to DOE, its countries of risk were China, Iran, North Korea, and Russia. However, DOE does not require the use of this matrix to assess licensing risk, and in fact it was intended for assessing risk from other forms of contact between DOE labs and foreign entities, such as unclassified access to the lab by a foreign national. DOE officials told us that they are considering whether it would be appropriate to apply the risk matrix to licensing.

The second inconsistency is that labs and universities assess prospective licensees differently. While all DOE labs and all selected universities reported reviewing the ownership of companies seeking to license DOE-funded technology, we found that there is no consistent process or set of criteria for doing so. Moreover, some approaches are less rigorous than others. For example, one lab contractor vets the prospective licensee and any domestic entity with more than 20 percent ownership of the licensee, and any foreign entity with more than 5 percent ownership. In contrast, another lab contractor does not assess foreign entities that have less than 50 percent ownership of the prospective licensee.

In addition, labs and universities use varying tools to vet prospective licensees. The majority (nine of 17) of labs reported using commercial databases containing financial information to conduct due diligence and compliance activities, compared to only two universities that use this technique. A similar share of labs (six of 17) and universities (seven of 19) reported using restricted party screening tools.⁷⁴ Using such tools represents a more rigorous approach to risk management.

Some labs and universities acknowledged limitations in their risk assessment approaches. One lab contractor reported that it does not currently have access to tools to investigate second- or third-level ownership of licensees, while one university noted that it only performs a comprehensive due diligence review of prospective licensees if they are startups.⁷⁵ Additionally, it can be challenging to uncover actual ownership

⁷³The S&T Risk Matrix is a tool intended to identify and protect critical and emerging DOE science and technology research areas.

⁷⁴Restricted party screening tools help identify entities that are listed on federal restricted party lists, which are lists of entities (organizations, or individuals) for which the U.S. government maintains restrictions on certain exports, reexports, or transfers of items. Labs and universities may purchase subscriptions to these tools.

⁷⁵Second- and third-level ownership relates to the difficulty in determining who the ultimate beneficial owner of a licensee or sublicensee is, if the licensee or sublicensee is owned by another company, which is owned by another company, etc.

structures, especially if they are complex, involve offshore companies, or involve obfuscation, according to a senior DOE official.

License drafting and execution

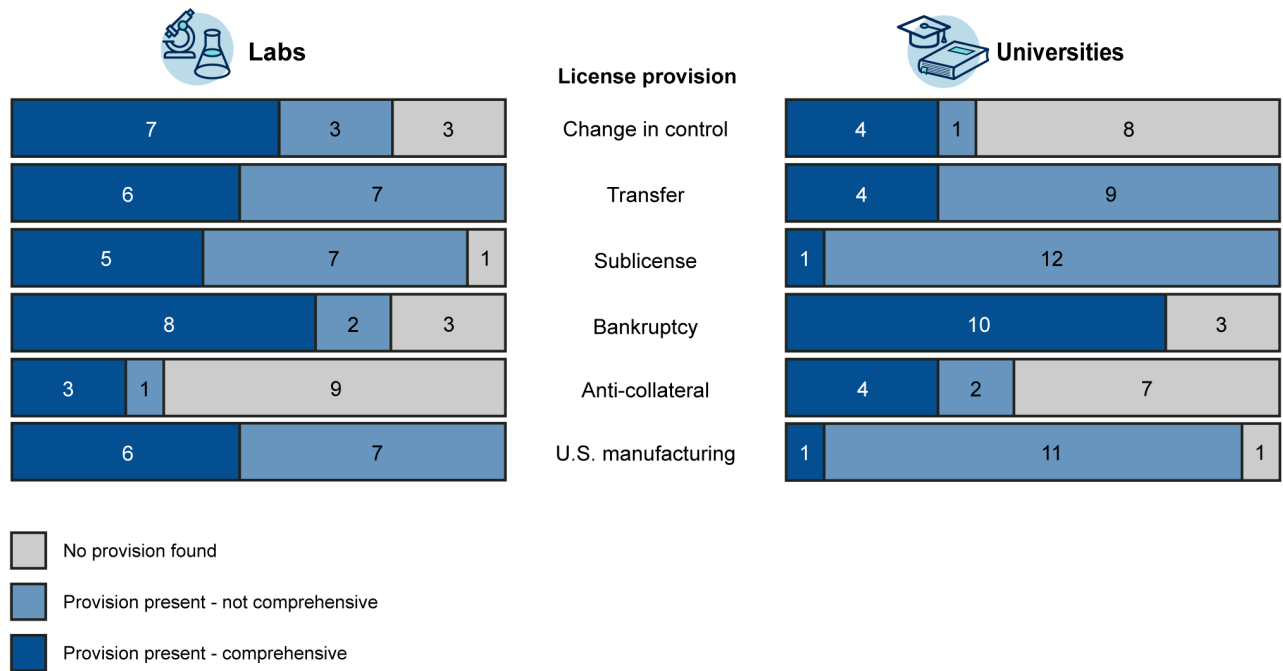
Labs and universities can manage risk by including certain provisions in the agreements they execute with licensees, which give them the ability to monitor and control their licensees' subsequent activities. These include restrictions on actions by the licensee related to (1) change in control; (2) transfer of the license; (3) sublicensing; (4) bankruptcy; (5) the use of the license as collateral; and (6) manufacturing location. We obtained and analyzed exclusive license agreement templates from 13 labs and 13 selected universities.⁷⁶ These labs and universities maintain their own templates that include a set of license agreement provisions, which a lab or university may use as a basis for negotiation with potential licensees. For a description of what we considered comprehensive license template provisions, see appendix I, table 2.

We found that the comprehensiveness of these provisions varied across DOE labs and universities, as shown in figure 2. Less comprehensive (or absent) provisions may leave gaps in labs' and universities' ability to monitor evolving conditions that may increase risk. For example, fewer than half of lab and university templates contained provisions prohibiting or allowing the licensor to terminate the license for the use of the licensed technology as collateral to secure a loan, which occurred with the PNNL battery licensing event, as previously described.⁷⁷

⁷⁶Our analysis focused on exclusive license templates; however, some labs and universities were not included in our analysis for various reasons. Four of the 17 labs and six of the 19 universities did not provide templates to GAO for review. The labs stated that they do not have their own exclusive templates; some use a sample agreement for non-exclusive licenses, which was created by DOE's Technology Transfer Working Group. Six universities declined to share their templates.

⁷⁷Any deviations in these provisions that come about in the negotiation process tend to be accommodations requested by a licensee. Therefore, if a template is missing a given provision that would more comprehensively protect the licensor's oversight of its intellectual property, it is unlikely that it would be included in the negotiated license agreement derived from the template. See *Technology Transfer with a University or National Laboratory*, Heather J. Meeker, Tech Law Partners, LLP, July 13, 2023.

Figure 2: Comprehensiveness of 13 DOE Laboratory and 13 University Exclusive License Templates Reviewed



Source: GAO (analysis and icons). | GAO-24-106504

Note: Four of the 17 labs and six of the 19 universities did not provide templates to GAO for review. The labs stated that they do not have their own exclusive templates and instead use a sample agreement for non-exclusive licenses, which was created by DOE's Technology Transfer Working Group. Six universities declined to share their templates. For each of the license template provisions shown above, we reviewed whether the provision was comprehensive, present but not comprehensive, or not present. We use "comprehensive" to mean that the clause is strongly drafted to protect the lab or university from the risks associated with the applicable activity, for example, a change in control. We use "present – not comprehensive" to mean that the clause is drafted in an incomplete way that provides some protection but still leaves the lab or university somewhat exposed to such risks. A template where "no [such] provision [is] found" provides no protection from such risks.

Some lab and university license agreement templates include provisions that impose limits on interactions involving foreign entities, which may reduce the risk of DOE-funded technology being acquired by entities from countries of risk. We found that six of 13 lab license templates and one of 13 university license templates included such provisions. For example, one lab precludes licensees from granting sublicenses to entities on DOE's countries of risk list.

Additionally, not all lab contractor and university license templates that we reviewed contained the 2021 DEC's U.S. manufacturing requirement or

its requirement that licensees report changes in control within 6 months. DOE officials told us that DOE lab contractors are updating their license templates as part of the recommendations from the 180-Day Report that was issued in March 2023. It remains to be seen whether universities will incorporate the 2021 DEC's U.S. manufacturing requirement or change in control notice requirement into their license templates or simply add its provisions to license agreements as needed.

Post-licensing risk monitoring activities

Labs and universities can manage risk by monitoring licensees after a license agreement is executed. Actively monitoring licensee ownership is an important part of managing risk, given that pre-licensing risk assessments may be point-in-time, and licensee ownership can change after the license is executed. According to DOE, post-licensing risk monitoring practices tend to be ad hoc or reliant on licensee self-reporting. We similarly found that as of August 2023, only three of 17 DOE labs and only one of the 19 selected universities review company ownership outside of self-reported licensee information after a license agreement is executed.

Lack of specific DOE guidance

Despite these inconsistencies, we found that DOE has few requirements for and does not provide specific guidance to labs or universities on how they might most effectively manage foreign acquisition risks. We found limitations across three main sources of DOE requirements and guidance:

- **2021 DEC.** As of January 2024, the 2021 DEC is the only DOE requirement related to risk assessment and monitoring of potential or existing licensees.⁷⁸ One requirement of the 2021 DEC's U.S. Competitiveness Provision is that lab contractors and universities must ensure that any future potential sublicensee, transferee, or new owner following a change in control also agrees to be bound by the U.S. Competitiveness Provision. While DOE has released several guidance documents related to the 2021 DEC, none of them include guidance on how to manage risk of foreign acquisition of DOE-funded technology in the pre-licensing or post-licensing stage. DOE has not provided guidance to labs and universities on how or when they should document or ensure that new owners or sublicensees have agreed to the provision, according to a senior lab official. We also found that the department has several research security policies that

⁷⁸In [GAO-15-212](#), we found that DOE has a limited ability to influence changes in control of financial assistance award recipients. While the 2021 DEC does not give DOE influence over changes in control since it requires notification, not approval, it does give DOE insight into these changes.

govern interactions between DOE labs and foreign entities, but that none provide guidance on patent licensing.⁷⁹

- **S&T Risk Matrix.** DOE's internal S&T Risk Matrix raises the level of scrutiny on an interaction between DOE labs and foreign entities if it involves one of six critical and emerging technologies and any of DOE's four countries of risk. However, the risk matrix is only intended to guide lab contractors (but not universities) in identifying and protecting higher-risk pre-publication research. While some lab contractors use it to inform licensing decisions, according to DOE officials, it is not intended for that purpose. Further, we found that DOE does not have comparable guidance for the licensing process, including whether certain critical and emerging technologies should receive additional protections when being licensed.⁸⁰
- **Technology Transfer Working Group resources.** DOE's Technology Transfer Working Group has developed some risk management resources, including a sample license agreement.⁸¹ However, we found the sample license agreement is missing some

⁷⁹These research security policies include DOE Order 142.3B (Unclassified Foreign National Access Program), DOE Order 481.1E (Strategic Partnership Projects), DOE Order 483.1B (DOE Cooperative Research and Development Agreements), DOE Policy 485.1A (Foreign Engagements with DOE National Laboratories), and DOE Order 550.1 (Official Travel). Additionally, DOE lab contractors have been required to abide by a U.S. Industrial Competitiveness clause in their licensing and assignments of intellectual property since 2001. While this clause is a domestic manufacturing preference, it also requires that lab contractors seek DOE contracting officer approval if the license or assignment will likely not meet one of the following two conditions: (1) any resulting design and development will be performed domestically and resulting products will be substantially manufactured in the United States, or (2) the prospective licensee has a domestic business unit with significant U.S. economic and technical benefits and if licensing to a foreign entity, that foreign government provides reciprocity with the United States in licenses and Cooperative Research and Development Agreements and policies protecting U.S. intellectual property. DEAR 970.5227-3(f).

⁸⁰The use of the risk matrix is integrated into existing DOE research security policies that govern interactions between DOE labs and foreign entities. These research security policies are: (1) DOE Order 142.3B (Unclassified Foreign National Access Program), (2) DOE Order 481.1E (Strategic Partnership Projects), (3) DOE Order 483.1B (DOE Cooperative Research and Development Agreements), (4) DOE Policy 485.1A (Foreign Engagements with DOE National Laboratories), and (5) DOE Order 550.1 (Official Travel).

⁸¹The Technology Transfer Working Group was established as part of the Energy Policy Act of 2005 and coordinates technology transfer activities occurring at DOE labs and single-purpose research facilities, facilitates the exchange of information about technology transfer practices, and develops and disseminates information about DOE technology transfer opportunities and procedures. The group consists of technology transfer professionals from across DOE labs and research facilities.

key license provisions, such as the 2021 DEC's requirement for lab contractors and universities to notify DOE of changes in control.

Labs and universities we surveyed also called for additional guidance from DOE in several areas. First, they requested definitions of "ownership" and "controlling interest" (potentially including a percentage threshold) for the purpose of the 2021 DEC's change in control notification requirement. Nine of 16 lab contractors and four of 19 universities stated that the 2021 DEC's use of the term "change in ownership amounting to a controlling interest" was unclear; six lab contractors and three universities requested additional clarification. Further, lab contractors identified the need for additional information, and DOE officials acknowledged that clarification in some of these areas would be useful:⁸²

- Definitions of "foreign ownership," "foreign company," or "foreign control."
- Guidance on what tools can be used to understand whether foreign ownership or control exists.
- Foreign licensing guidelines to ensure that foreign partners are appropriate or that license agreements align with DOE technology transfer mission objectives.

Effective oversight of lab and university licensing activities is required to accomplish DOE's mission. However, DOE's guidance lacks the level of specificity needed by labs and universities to clarify key licensing terminology, such as "foreign control", and contributes to inconsistent or limited efforts to manage risk from licensing, according to a senior lab official. These inconsistencies create risks for DOE and puts the department at odds with its own Policy 410.3 on program management, which states that risk management is among the guiding principles of program management.⁸³ The policy states that risk management includes proactively identifying and managing risks, establishing well-defined risk management processes and procedures, and implementing "a consistent and disciplined approach to responding to risks." DOE is responsible for

⁸²We did not directly ask whether the labs or universities wanted guidance in these areas. Instead, some labs requested guidance in their responses to the open-ended questions in our survey or in other documents provided during our review.

⁸³DOE issued DOE Policy (P) 410.3 on program management in September 2021 to establish departmental expectations for program management.

carrying out this policy in all its programs, including R&D programs where labs and universities play a vital role.

Additionally, to comply with the 2021 DEC, a lab contractor or university must have comprehensive provisions in its license agreements related to change in control, transfer, sublicense, bankruptcy, anti-collateral, and U.S. manufacturing. We found these to be inconsistent in licensing templates, as noted above. Further, according to *Standards for Internal Control in the Federal Government*, federal agency management should respond to risks by clearly documenting the actions it will take in the form of policies.⁸⁴ In the case of R&D funding to labs and universities, a key policy for managing the risk of foreign acquisition is the guidance DOE issues to those labs and universities.

In the absence of more detailed guidance, lab contractors and universities are likely to continue with inconsistent approaches. Guidance on managing risks, key terminology about defining foreign ownership or control, and the inclusion of certain license provisions, such as reporting changes in control and prohibiting using the license as collateral can ensure labs and universities more consistently and fully address the risks of foreign acquisition or influence. According to DOE, leaving risks unaddressed creates the potential for licensing to an entity with “unwanted or unknown foreign connections.”⁸⁵ DOE is particularly concerned about preventing licensing to entities with connections to countries of risk. Without consistent, effective pre-licensing risk assessment and post-licensing monitoring practices, DOE cannot ensure that it is sufficiently managing such risks, which is particularly important for critical and emerging technologies.

DOE Labs Inconsistently Use Counterintelligence Reviews

We found that DOE labs are inconsistently using counterintelligence reviews in patent licensing. These reviews involve having DOE counterintelligence experts vet prospective licensees using tools that may not be available to DOE lab staff, according to a DOE counterintelligence official. The reviews may also involve screening existing licensees when they undergo changes in control, according to a lab official. As of August 2023, 11 of 17 labs reported using counterintelligence reviews for some

⁸⁴GAO-14-704G.

⁸⁵Department of Energy, *180-Day Review Report: Licensing of Intellectual Property by Department of Energy and National Nuclear Security Administration Laboratories* (March 2023).

or all prospective licensees.⁸⁶ The extent of the use of these reviews varies for those 11 labs. Two have established a process in which their field counterintelligence office reviews all prospective licensees before license agreements are finalized. The remaining labs use counterintelligence reviews in certain situations, such as when the prospective licensee is a foreign entity. According to field counterintelligence officials we interviewed, it is important for licensees with potential foreign connections (particularly when they involve a country of risk) to undergo a counterintelligence review.

The inconsistency in lab approaches to seek counterintelligence reviews is due in part to DOE not having established a policy or provided guidance about when DOE labs should use them. The integration of counterintelligence reviews into the licensing process is still nascent, according to a field counterintelligence official. Another official acknowledged that there is no DOE order requiring labs to obtain counterintelligence reviews of potential or existing licensees, and that labs have developed varying approaches to these reviews. Additionally, officials from all field counterintelligence offices we interviewed told us that their capacity to review lab licensees is limited by the availability of resources. Further, counterintelligence offices are challenged by growing counterintelligence mission requirements, according to one lab.

The inconsistent use of counterintelligence reviews among labs creates risks for DOE in its oversight of technology licensing by lab contractors. As previously noted, risk management is among the guiding principles of DOE program management, according to DOE's Policy 410.3. The policy states that risk management includes proactively identifying and managing risks, establishing well-defined risk management processes and procedures, and implementing "a consistent and disciplined approach to responding to risks." Additionally, *Standards for Internal Control in the Federal Government* state that management should design control activities to achieve objectives and respond to risks, and that it should implement these control activities through policies (such as guidance).⁸⁷

In the absence of a recommended procedure for when to seek counterintelligence reviews or a DOE order requiring counterintelligence

⁸⁶Of the 10 labs with the most licenses in their intellectual property license portfolios as of November 2022, nine reported using counterintelligence reviews for some or all prospective licensees.

⁸⁷[GAO-14-704G](#).

office reviews of license agreements, DOE cannot ensure that these reviews are conducted in a manner that responds to the most significant licensing risks and makes the most effective use of limited counterintelligence resources.

Conclusions

DOE funds its national labs and many universities to develop technologies; however, it has faced challenges with foreign manufacturing and acquisition of such inventions through the technology transfer and patent licensing process. DOE implemented its 2021 DEC to tighten restrictions on the foreign manufacture of DOE-funded inventions for new licenses, among other goals. However, DOE has not specified measurable objectives or established an approach to evaluate the policy and determine, after it has time to take effect, whether it actually reduces offshoring and promotes domestic manufacturing. Nor has DOE fully informed prospective licensors and licensees on key details of the process for waiving U.S. manufacturing requirements, which could hinder them from identifying alternate means of creating domestic jobs. Without effectively evaluating the impact of its manufacturing policy, DOE will be implementing it without fully understanding how well it is achieving DOE's objectives. Furthermore, without ensuring a timely and transparent waiver and modification process, DOE may be unknowingly hindering commercialization of DOE-funded technology, thereby damaging U.S. economic competitiveness rather than promoting it.

DOE has not reviewed university patent licensing practices as part of its efforts to manage risk from foreign acquisition of DOE-funded technology. Nor has it provided universities with guidance on monitoring compliance with license agreements. Among other things, it has not clarified what terms and conditions should be included in license agreements for DOE-funded inventions or explained key terms, such as how it interprets "manufactured substantially in the United States." In the absence of such guidance, universities may leave gaps in their license agreements and develop their own procedures for monitoring compliance with license agreements. Therefore, DOE has less assurance that universities are enforcing license agreement requirements satisfactorily, including domestic manufacturing requirements. If DOE does not address these issues, it may leave DOE-funded intellectual property exposed to undesirable foreign control.

Finally, lab and university management of foreign acquisition risk is inconsistent or insufficient, in part due to a lack of comprehensive DOE guidance on how to effectively manage such risks. In the absence of such guidance, lab contractors and universities are likely to continue with their

inconsistent approaches for vetting entities, which may lead to licensing to entities with undue foreign influence. Similarly, foreign acquisition risk may be elevated in the continued absence of clear DOE procedures for when labs should use counterintelligence reviews. Without taking steps to ensure consistent and effective risk management practices by labs and universities, DOE cannot ensure that current and potential licensees are free from undue foreign influence, which is particularly important for critical and emerging technologies.

Recommendations for Executive Action

To improve DOE's oversight of intellectual property licensing practices, U.S. manufacturing policies, and risk management strategies, we recommend that the Secretary of Energy ensure that the Office of the Assistant General Counsel for Technology Transfer and Intellectual Property take the following six actions:

- Develop and implement, in coordination with DOE's Office of Technology Transitions and other relevant offices, a strategy or approach for monitoring and assessing the effects of the U.S. Competitiveness Provision pursuant to its 2021 DEC and identify whether it is achieving progress towards planned performance. (Recommendation 1)
- Provide additional guidance to waiver or modification applicants to help improve transparency on how to demonstrate alternative benefits to the U.S. economy, such as clear examples for approval, as well as communicate expectations for waiver review timelines. (Recommendation 2)
- Provide clarifying information to universities for monitoring compliance with U.S. manufacturing commitments, including guidance on how it interprets "manufactured substantially in the United States." (Recommendation 3)
- Conduct a review of university licensing procedures to ensure that appropriate licensing monitoring and enforcement practices are in place. (Recommendation 4)
- Provide guidance to labs and universities on license provisions and other risk management practices and procedures for monitoring licensee foreign ownership, with consideration of critical and emerging technologies, to encourage consistency across all DOE-funded inventions. (Recommendation 5)
- Develop and implement procedures or a DOE order for labs detailing when counterintelligence reviews of potential and existing licensees are indicated. (Recommendation 6)

Agency Comments

We provided a draft of this report to DOE, as well as the Bureau of Industry and Security (BIS), the National Institute for Standards and Technology (NIST), and the U.S. Patent and Trademark Office (USPTO) for review and comment. In its written comments DOE concurred with our recommendations and described ongoing and planned actions to address them. DOE's comments are reproduced in Appendix V. DOE, BIS, NIST and USPTO also provided technical comments which we incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the appropriate congressional committees, the Secretary of Commerce, Secretary of Energy, and other interested parties. In addition, this report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-6888 or WrightC@gao.gov. Contact points for our Office of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix VI.



Candice N. Wright
Director, Science, Technology
Assessment, and Analytics

Appendix I: Objectives, Scope, and Methodology

The objectives of this review were to examine three questions: (1) what are lab contractor and university views on the Department of Energy's (DOE) 2021 Determination of Exceptional Circumstances (the 2021 DEC) and domestic manufacturing policy, as well as its process for waiving domestic manufacturing requirements, and what actions has DOE taken to assess the effects of its policy; (2) to what extent does DOE oversee lab contractor and university activities for monitoring their licensees' compliance with U.S. manufacturing requirements; and (3) to what extent do labs and universities manage the risk of foreign acquisition of licensed DOE-funded technologies.

To address our first objective, we reviewed the Bayh-Dole Act, and obtained and analyzed relevant domestic manufacturing policies. These include the DEC's that DOE issued under the Bayh-Dole Act, such as the DEC issued since 2013 and the most recent DEC issued in 2021, as well as information about DOE-issued waivers or modifications of those manufacturing requirements and other related documentation.¹ We determined that the control activities component of internal control—the actions management establishes through policies and procedures to achieve objectives and respond to risks—was significant to our first objective.² We compared DOE's policy documents and information from our interviews to our internal control standards.

To determine stakeholders' views on the effects of DOE's domestic manufacturing policies, we conducted a survey and interviews with various stakeholders. Specifically, we distributed a survey to the directors

¹Department of Energy, Determination of Exceptional Circumstances under the Bayh-Dole Act for Energy Efficiency, Renewable Energy, and Advanced Energy Technologies (2013) and Department of Energy, Department of Energy Determination of Exceptional Circumstances Under the Bayh-Dole Act to Further Promote Domestic Manufacture of DOE Science and Energy Technologies (2021).

²GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: Sept. 2014).

of technology transfer offices at all 17 DOE national labs³ and 21 selected universities.⁴ To achieve a diverse set of perspectives, we selected different regions of the United States and institutions with varying numbers of active DOE licenses. We assessed universities' recent levels of patent licensing activity by determining the total number of patent licenses issued for each university from fiscal years 2012 through 2022⁵ using a dataset containing annual invention utilization records for DOE-supported inventions, reported to DOE through iEdison, the federal invention reporting and patent tracking system managed by the National Institute of Standards and Technology.⁶ We excluded fiscal year 2023 because data for that year were incomplete. We also excluded academic institutions with fewer than four reported DOE-funded licenses over this 10-year period because they had limited or no recent experiences commercializing DOE-funded technologies. Our non-generalizable selection of universities cannot be used to make inferences about all universities that have DOE-funded licenses in their portfolio.⁷ To carry out

³We distributed a survey to all 17 national labs: 10 Office of Science labs (Ames Laboratory, Argonne National Laboratory, Brookhaven National Laboratory, Fermi National Accelerator Laboratory, Lawrence Berkeley National Laboratory, Oak Ridge National Laboratory, Pacific Northwest National Laboratory, Princeton Plasma Physics Laboratory, SLAC National Accelerator Laboratory, Thomas Jefferson National Accelerator Facility), three National Nuclear Security Administration labs (Lawrence Livermore National Laboratory, Los Alamos National Laboratory, Sandia National Laboratory), one Office of Environmental Management lab (Savannah River National Laboratory), one Office of Nuclear Energy lab (Idaho National Laboratory), one Office of Energy Efficiency & Renewable Energy lab (National Renewable Energy Laboratory) and one Office of Fossil Energy lab (National Energy Technology Laboratory).

⁴We received responses from 19 of the selected universities: Arizona State University, California Institute of Technology, Case Western Reserve University, Harvard University, Massachusetts Institute of Technology, Michigan State University, Missouri University of Science and Technology, State University of New York, University of California Berkeley, University of Colorado Boulder, University of Florida, University of Minnesota, University of Pittsburgh, University of Southern California, University of Texas at Austin, University of Washington, University of Wisconsin Madison, Vanderbilt University, and Yale University. The two universities that did not respond to our survey were generally similar to other selected universities that responded.

⁵The universities were selected out of 184 academic institutions that filed patent applications for DOE-funded research from fiscal years 2012 through 2022.

⁶The funding agency may request annual utilization reports under 35 U.S.C. § 202(c)(5). Utilization reporting includes the status of the subject invention's development, date of first commercial sale or use, gross royalties received by the lab contractor, university, or other licensing entity, and other information the agency may reasonably request. 37 C.F.R. § 401.14(H).

⁷While not generalizable, the selected universities accounted for approximately 55% of the 4,764 DOE-funded patent licenses issued by all universities, from fiscal years 2012-2022.

our survey, we developed a set of questions with the assistance of a GAO survey specialist.

Our survey questionnaire included both closed- and open-ended questions that covered a range of topics, including patent licensing policies and practices, compliance and monitoring, DOE's 2021 DEC, the process for submitting a domestic manufacturing waiver or modification request (including time frames), and assessing risk when licensing critical and emerging technologies. To obtain feedback on our survey questions, we conducted survey pre-tests with two labs and two universities. We incorporated lab and university pre-test feedback into our survey questions and distributed a revised survey with updated questions for them to respond to and return. We made final revisions based on feedback as they completed the survey and then distributed the survey to the remaining 15 DOE laboratories and 19 selected universities. We received completed questionnaires for all 17 DOE labs between July and August 2023 and 19 selected universities between August and September 2023. We contacted officials to clarify survey responses, as necessary. The completed questionnaires were processed into a final analysis file.

In addition to our lab and university surveys, to obtain viewpoints from a wide range of stakeholders that represent different disciplines, we conducted interviews with 22 stakeholder groups.⁸ We identified these groups using a snowball sampling technique in which we identified contacts through referrals from prior interviews. The 22 stakeholder groups included: seven nonprofit organizations, one venture capital firm, seven academic institutions, two former senior DOE technology transfer officials, and three organizations that assist federal labs and universities in licensing DOE-funded patents or that have an interest in DOE technology transfer and licensing practices, as well as two license holders of DOE-funded patents working to commercialize DOE-funded technologies. In addition, we conducted 22 separate meetings with DOE officials and interviewed personnel from relevant DOE offices, including the Office of the Assistant General Counsel for Technology Transfer and Intellectual Property, Office of Technology Transitions, Office of

⁸Throughout the report, we use the indefinite quantifiers, "a few", "some", "several", "many", "majority", and "most" to inform the reader of the approximate quantity of survey respondents or stakeholder interviewees that expressed a particular viewpoint. For the purposes of our review, a few refers to 2-3, several refers to 4-6, many refers to more than 6, a majority is considered more than 51 percent, most is considered 80-90 percent, and some refers to more than one but less than a majority.

Intelligence and Counterintelligence, and Advanced Research Projects
Agency-Energy.

To corroborate testimonial information obtained from our survey effort about the effect of DOE's policies, we asked survey respondents to provide data on their DOE-funded patent portfolios and past waiver or modification requests and reviewed these data. To show general trends in patent filings and licensing of DOE-supported technologies, we analyzed DOE lab and facility data published by the National Institute of Standards and Technology and university data reported to DOE through the iEdison system.⁹ iEdison is used by numerous agencies, including DOE, as the centralized repository for mandated invention reporting by entities such as lab contractors and universities.¹⁰ For our analysis of DOE iEdison data for fiscal years 2012-2022, which related only to universities, we used a combination of filtering and manual review of the data elements containing the organization name to extract records submitted only by universities or similar institutions of higher education. Using this process, we produced the two datasets used in our analysis: the first contained records from 184 universities that sought one or more patent protections for DOE-funded inventions between fiscal years 2012-2022. The second contained records from 165 universities that reported one or more active licenses for DOE-funded inventions for the same period. We assessed the reliability of these data (1) by reviewing existing information about the data and the system that produced them, (2) through discussions with agency officials knowledgeable about the data and its accuracy and completeness, and (3) by performing electronic testing of required data elements. DOE officials stated that a limitation with iEdison is that the data is self-reported, and some stakeholders noted it can be an administrative burden to meet iEdison reporting requirements. However, iEdison is well known by technology transfer offices, and DOE officials said that invention reporting issues tend to be unintentional. We determined that these data were sufficiently reliable to provide context on

⁹DOE is required to provide data to the Office of Management and Budget (with a copy to, among others, the Secretary of Commerce) for the annual federal laboratory technology transfer report (15 U.S.C. § 3710(f)). DOE provided data to GAO for fiscal years 2021-2022 as those reports were not published as of February 2024.

¹⁰See 37 C.F.R. § 401.14(H). 27 U.S. federal funding agencies use iEdison and 3-4 others are in the final stages of joining (reviewing or signing memorandums of understanding), as of December 2023, according to National Institute of Standards and Technology officials. All 17 DOE labs report data in iEdison. However, one lab (Sandia) recently transitioned to using the system; Sandia is reporting all new invention disclosure information but has a large backlog to address and has not fully updated historical information in iEdison, as of October 2023.

general trends through a review of data related documentation and discussions with agency officials about its accuracy and completeness.

To address our second objective, we reviewed the Bayh-Dole Act, applicable regulations, as well as relevant procedures, guidance, and other documents to determine how DOE oversees lab and university activities for monitoring their licensees' compliance with U.S. manufacturing requirements. We determined that the information and communication component of internal control—the quality information and effective communication management uses to achieve its objectives—was significant to our second objective, along with the related principle that management should define objectives clearly to enable the identification of risks and define risk tolerances.¹¹ We compared DOE's lab oversight documents and information from our interviews and documentation we collected to our internal control standards. For example, we reviewed DOE guidance documents, including several Frequently Asked Questions resources that DOE made available to labs and universities between September 2021 and September 2022, as shown in table 1.

¹¹[GAO-14-704G](#).

Appendix I: Objectives, Scope, and Methodology

Table 1: DOE Guidance Provided to Stakeholders Related to U.S. Manufacturing Requirements

Title	Document date	Website
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	September 2021	https://www.energy.gov/sites/default/files/2021-09/FAQs_09292021.pdf (Accessed March 13, 2024)
Request for Waiver of U.S. Manufacturing Requirement for Subject Inventions	September 2021	https://www.energy.gov/gc/articles/request-modification-us-manufacturing-requirement (Accessed March 15, 2024)
Financial Assistance Letter: Implementation of the DOE Determination of Exceptional Circumstances under the Bayh-Dole Act to Further Promote Domestic Manufacture of DOE Science and Energy Technologies – Class Deviation	November 2021	https://www.energy.gov/sites/default/files/2021-11/2022-01%20Financial%20Assistance%20Letter%20%28FAL%29%20-DEC%20Implementation.pdf (Accessed April 20, 2023)
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 (Version 3.9.2022)	March 2022	https://www.energy.gov/sites/default/files/2022-03/FAQs_03092022.pdf (Accessed September 28, 2023)
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 (Version 6.6.2022)	June 2022	https://www.energy.gov/sites/default/files/2022-06/FAQs_06062022.pdf (Accessed November 8, 2023)
Appendix 5: Modification and Waiver Guidance	September 2022	https://www.energy.gov/sites/default/files/2021-11/Appendix%20%20-%20Modification%20and%20Waiver%20Guidance.pdf (Accessed April 9, 2023)

Source: GAO analysis of DOE documents and other information. | GAO-24-106504

Through our survey effort, we obtained documentation from labs and universities, including monitoring guidance, to understand how they monitor their licensees’ compliance with U.S. manufacturing requirements. In addition, we reviewed DOE’s recent reviews of lab

licensing practices.¹² We also reviewed an analysis completed by the Congressional Research Service on federal technology licensing policies and agency actions to further the domestic manufacturing of federally funded innovations and communicated with the report authors regarding their conclusions.¹³ Also, we interviewed patent counsel officials in DOE's Office of the Assistant General Counsel for Technology Transfer and Intellectual Property to gather information on their efforts overseeing lab and university activities for monitoring their licensees' compliance with U.S. manufacturing requirements.

To address our third objective, we analyzed DOE policies and related documentation about managing the risk of the foreign acquisition of DOE-funded technology, including DOE's internal Science and Technology (S&T) Risk Matrix and the Technology Transfer Working Group guidance. We compared DOE's risk management documents and information from our interviews to DOE criteria for risk management, which is among the guiding principles of program management, according to DOE Policy 410.3 on program management.¹⁴

In addition, we obtained and analyzed exclusive license agreement templates from 13 of the 17 labs and 13 of the 19 selected universities.¹⁵ Specifically, we evaluated relevant provisions in patent license templates from DOE labs and universities to identify whether certain elements were present and assess the comprehensiveness of these provisions. Table 2

¹²Department of Energy, *30-Day Review Report: Licensing of Pacific Northwest National Laboratory Vanadium Redox Flow Battery Technology* (September 2022) and Department of Energy, *180-Day Review Report: Licensing of Intellectual Property by Department of Energy and National Nuclear Security Administration Laboratories* (March 2023).

¹³Congressional Research Service, *U.S. Technology Made In China: The Role of Federal Technology Licensing Policies* (September 20, 2022).

¹⁴DOE issued DOE Policy (P) 410.3 on program management in September 2021 to establish departmental expectations for program management.

¹⁵Four of the 17 labs and six of the 19 universities did not provide templates to GAO for review. We chose to focus on analyzing one license type: exclusive license agreement templates versus non-exclusive license agreement templates for a few reasons. First, while we requested both exclusive and non-exclusive license agreement templates from labs and selected universities, we received more exclusive agreements than non-exclusive for labs (13 versus 9) and more exclusive license agreement templates than non-exclusives for universities (13 versus 8). Second, some provisions we were interested in analyzing, such as U.S. manufacturing requirements before the 2021 DEC, were only included in exclusive license agreement templates. Third, some provisions, such as those related to transfer or bankruptcy were substantively similar in exclusive and non-exclusive license agreements.

describes the license template provisions that we reviewed for DOE labs and selected universities and what qualified a provision as “comprehensive” for purposes of our analysis. DOE conducted a similar review of lab license agreement templates as part of its 180-Day Report that was issued in March 2023. The department reviewed license templates collected from DOE labs between October 2022 and January 2023, while we reviewed license templates collected from DOE labs and universities between June and September 2023. Some labs updated their templates between the two reviews. Additionally, there are some minor differences in how we categorized the strength of the provisions compared to DOE’s review.

Table 2: DOE License Template Provisions

Provision	Description	What we considered comprehensive
Change in control	Governs licensee changes in control, which may involve sale of company shares, sale of company physical and intellectual property assets, or a merger, acquisition, consolidation, or reorganization.	Requires the licensee to obtain consent from the licensor before undergoing a change in control, or both (a) requires the licensee to notify the licensor (or DOE) about the change in control within 6 months of the change, and (b) ensures that after the change in control the licensee will continue to be bound by the provisions of the license.
Transfer	Governs whether and when a licensee can transfer the license agreement to another entity, which might occur in the case of an asset sale or merger.	Requires the licensee to obtain consent from the licensor before transferring the license. ^a
Sublicense	Governs whether and how licensees may grant rights to the licensed intellectual property to third parties.	Requires the licensee to obtain consent from the licensor before sublicensing the license or expressly prohibits sublicensing. ^a
Bankruptcy	Governs what happens when a licensee undergoes voluntary or involuntary bankruptcy, including whether the licensor can terminate the license agreement. ^b	Permits the licensor to terminate the license agreement in the event of bankruptcy.
Anti-collateral	Governs whether a license agreement can be used as collateral to secure a loan.	Either (1) prohibits the use of the license as collateral or (2) allows for termination if the license is used as collateral.
U.S. manufacturing	Outlines any requirements that licensed products be manufactured in the United States.	Requires the licensed product to be substantially manufactured in the United States for sales or use worldwide.

Source: GAO analysis of DOE documents and information reported by lab and university officials. | GAO-24-106504

^aWe considered provisions that stated consent would not be “unreasonably withheld,” or in which consent was only required in certain situations, to be weaker and therefore categorized them as “present – not comprehensive.”

^bLicense agreements are typically treated as executory contracts in bankruptcy. If the licensee is the debtor, bankruptcy law generally prevents a licensor from terminating the license immediately upon the licensee’s commencement of a bankruptcy proceeding. However, depending on factors including

Appendix I: Objectives, Scope, and Methodology

the license agreement's assignment provision, intellectual property law may still protect the licensor by precluding the licensee from assigning its interest to a third party, even in the bankruptcy context.

We also interviewed DOE Office of Intelligence and Counterintelligence personnel from the DOE headquarters office and three counterintelligence field offices to understand how labs use counterintelligence reviews to vet prospective licensees for a foreign nexus.

We conducted this performance audit from January 2023 to May 2024, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Trends in DOE Technology Transfer

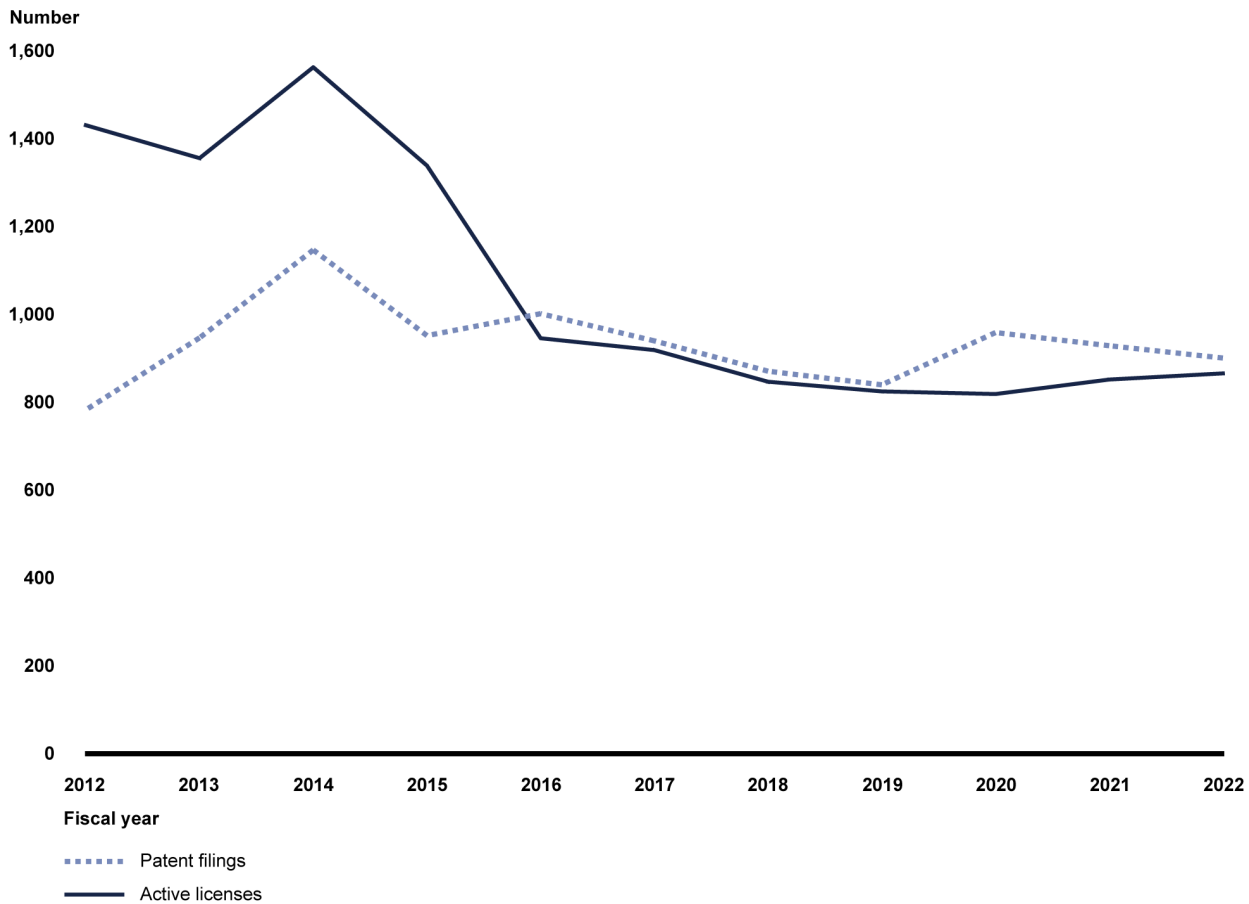
DOE uses patent filings (both U.S. and foreign) and active license agreements¹ as indicators of the “health” of DOE technology transfer transactions and activities, according to DOE officials and documents.² Figures 3 and 4 illustrate trends in patent filings and active licenses at DOE labs and U.S. universities from fiscal years 2012-2022.

¹Active license agreements are defined as license agreements or options that were active during the reporting period (fiscal year). Options are short-term agreements (e.g., 6 months) that companies use to assess the suitability of an invention for their needs. Options can be converted to longer-term license agreements.

²DOE is required to provide data to the Office of Management and Budget (with a copy to, among others, the Secretary of Commerce) for the annual federal laboratory technology transfer report (15 U.S.C. § 3710(f)). DOE provided GAO with lab and facility data for fiscal years 2021-2022 as published data were not yet available in February 2024. DOE requires universities and others to use iEdison for mandated invention reporting (see 37 C.F.R. § 401.14(H)).

Appendix II: Trends in DOE Technology Transfer

Figure 3: Patent Filings and Active Licenses at Department of Energy Laboratories, Fiscal Years 2012-2022

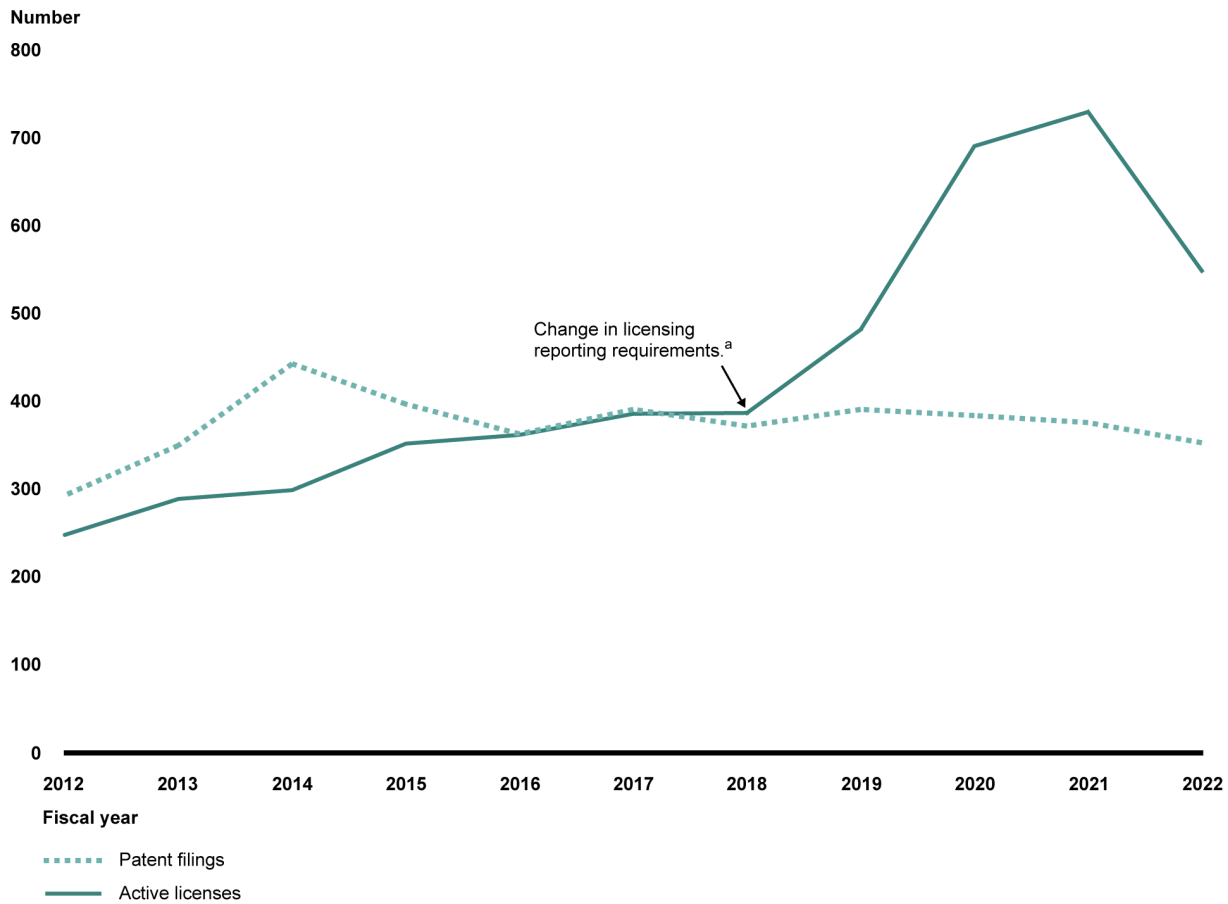


Source: Department of Energy and National Institutes of Standards and Technology data. | GAO-24-106504

Note: Data current as of February 2024. Fiscal year 2022 is the most recent year for which complete data were available. Laboratories include the 17 Department of Energy (DOE) labs and five National Nuclear Security Administration sites. Patent filings include domestic and foreign applications. Active licenses do not include sub-licenses. According to DOE officials, the drop in active licenses beginning around 2014 was caused in part by: (1) the expiration of a patent which accounted for more than 300 licenses and (2) enhanced normalization of license counts to account for labs which had reported licenses with multiple fields of use as separate licenses. Caution should be taken in any comparison of numbers between the DOE labs and universities and in comparisons over time because annual university reporting periods were not standardized to the federal fiscal year until October 2023, among other reasons.

Appendix II: Trends in DOE Technology Transfer

Figure 4: Patent Filings and Active Licenses at Universities for Department-of-Energy-Funded Research, Fiscal Years 2012-2022



Source: GAO analysis of Department of Energy iEdison data. | GAO-24-106504

Note: iEdison data is current as of February 2024 and may be subject to change. Universities include colleges, medical schools, and institutes of technology. Patent filings include domestic and foreign applications. Active licenses may include sub-licenses. We were not able to independently verify these data. Caution should be taken in any comparison of numbers between DOE and university figures because annual university reporting periods were not standardized to the federal fiscal year until October 2023, among other reasons.

^aPrior to 2019, reporting of active licenses was voluntary and, according to Department of Energy (DOE) officials, data may be incomplete.

Appendix III: Summary of the Department of Energy’s (DOE) U.S. Manufacturing Provisions

As part of GAO’s review of Department of Energy (DOE) technology transfer and intellectual property protection, we examined U.S. manufacturing commitments DOE has imposed, including the Bayh-Dole Act’s U.S. Manufacturing Preference (see table 3). We present a timeline of selected events illustrating the progressive strengthening of DOE’s domestic manufacturing requirements included in R&D funding awards with entities subject to the Bayh-Dole Act, such as lab contractors and universities (see fig. 5).

Table 3: Summary of Bayh-Dole Act’s U.S. Manufacturing Preference

Overview	In December 1980, Congress enacted the Bayh-Dole Act, which governs licensing of federally funded technologies by small business firms and nonprofit organizations to third parties. ^a Executive Order 12,591 expanded applicability of the Bayh-Dole Act to contractors of all sizes. ^b
Agencies	Applicable across federal agencies and categories of technology.
Types of licenses affected	Exclusive licenses (does not apply if licenses granted are only non-exclusive or if no license is granted).
Location of sale/use of subject invention	Inventions to be used or sold in the United States (does not apply if inventions are to be used or sold only outside the United States).
U.S. Manufacturing Preference	“[N]o small business or nonprofit organization which receives title to any subject invention...shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States...” (emphasis added).
Determinations of Exceptional Circumstances	The Bayh-Dole Act provides that a federal agency may restrict or eliminate the right of a small business firm or nonprofit organization to retain title to a subject invention in exceptional circumstances where the agency determines that such restriction or elimination of such right will better promote the policy and objectives of the act.
Enforcement	The Bayh-Dole Act includes a march-in rights provision, which enables the applicable federal agency to grant a non-exclusive license to a new applicant if, among other reasons, the original licensee is in breach of its agreement to manufacture substantially in the United States.

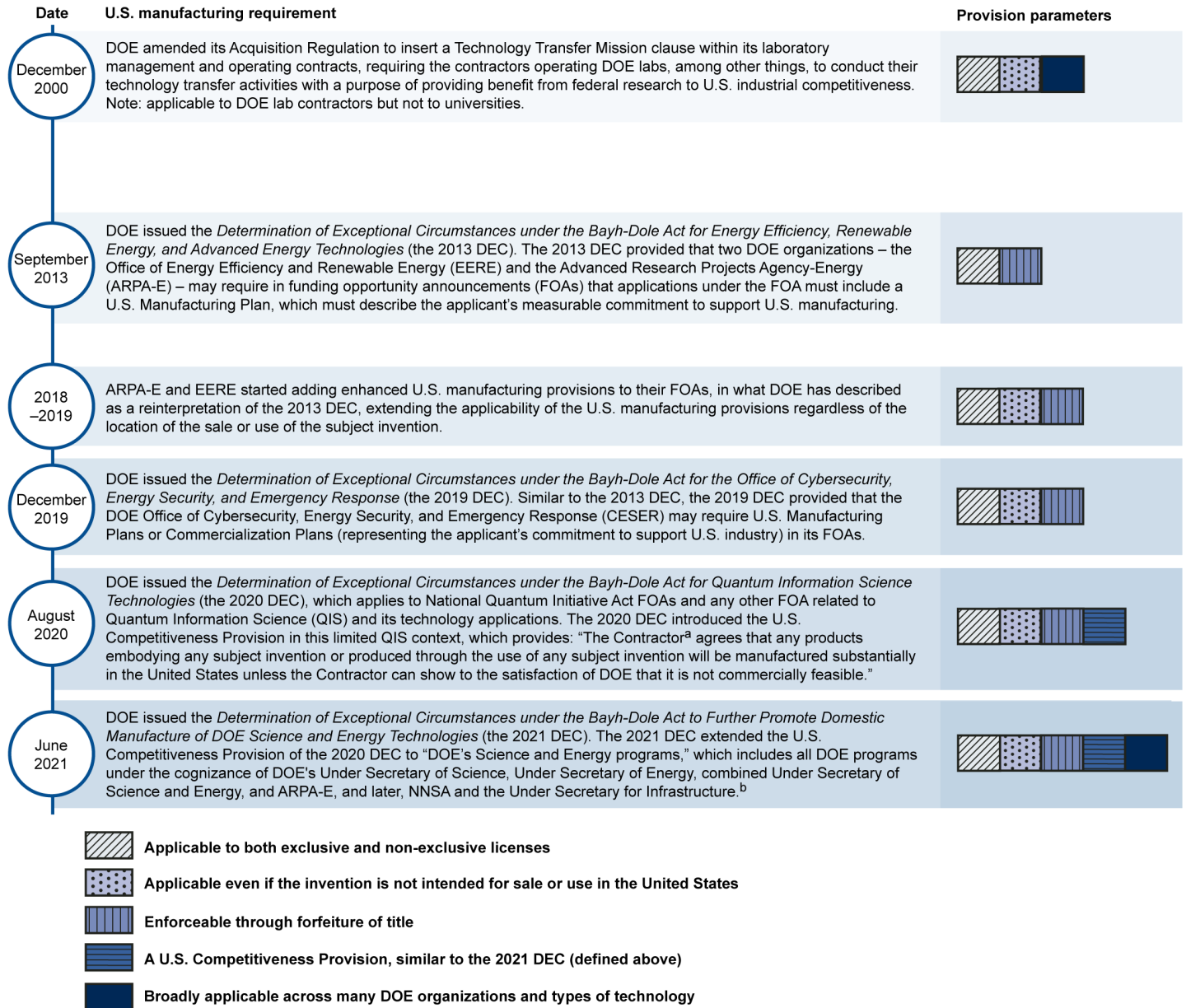
Source: GAO analysis of the Bayh-Dole Act. | GAO-24-106504

^aBayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified at 35 U.S.C. §§ 200-212).

^b52 Fed. Reg. 13,414 (Apr. 10, 1987), as amended by Exec. Order No. 12,618, 52 Fed. Reg. 48,661 (Dec. 22, 1987).

Appendix III: Summary of the Department of Energy's (DOE) U.S. Manufacturing Provisions

Figure 5: Timeline of Selected Events Regarding U.S. Manufacturing Provisions in DOE Organizations' R&D Funding Awards to Entities Covered by the Bayh-Dole Act



Source: GAO analysis of DOE documents. | GAO-24-106504

^aWhile "Contractor" is not defined in the Department of Energy's (DOE) 2021 Determination of Exceptional Circumstances (DEC), the Bayh-Dole Act uses the term to refer to any person, small business firm, or nonprofit organization party to a funding agreement. For our purposes, we also include large business contractors in this definition, as they are subject to similar rights and obligations via Executive Order 12,591 and applicable Class Patent Waivers. 52 Fed. Reg. 13,414

**Appendix III: Summary of the Department of
Energy's (DOE) U.S. Manufacturing Provisions**

(Apr. 10, 1987), as amended by Exec. Order No. 12,618, 52 Fed. Reg. 48,661 (Dec. 22, 1987); DEAR 970.5227-12.

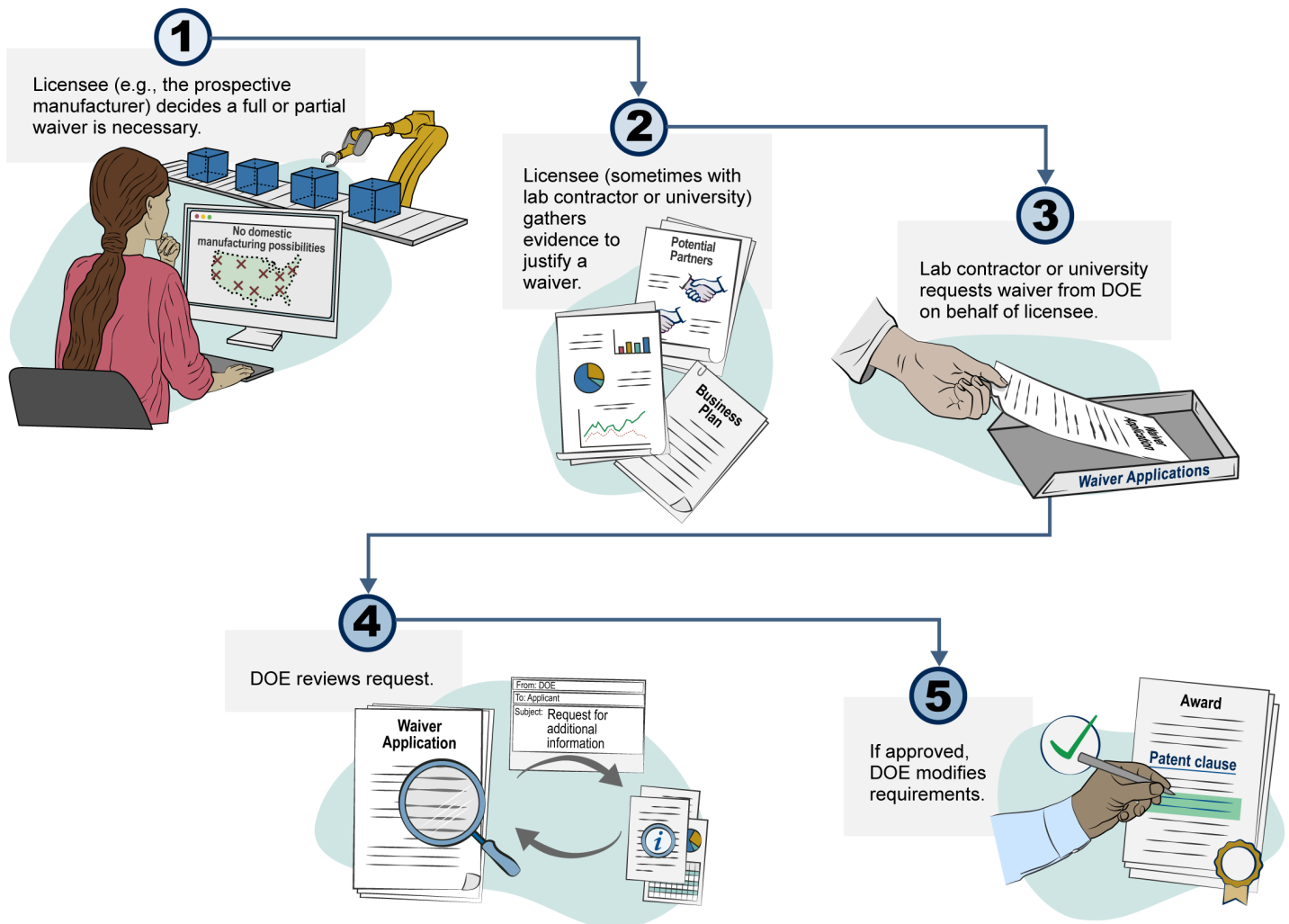
^bThe full U.S. Competitiveness Provision in the 2021 DEC is similar but not identical to the U.S. Competitiveness provision in the 2020 DEC. The 2021 DEC was extended to the National Nuclear Security Administration in May 2022, and to programs under the cognizance of the Under Secretary for Infrastructure (S3) in March 2023 (effective for fiscal year 2022).

Appendix IV: Process for Requesting a Domestic Manufacturing Waiver

The process for requesting waivers or modifications of the U.S. Competitiveness Provision in licenses for Department of Energy (DOE)-funded inventions has several steps, as shown in figure 6.

Figure 6: Process for Requesting a Department of Energy (DOE) Domestic Manufacturing Waiver

The process for requesting waivers of the U.S. Competitiveness Provision in licenses for DOE-funded inventions has several steps, which generally include:



Source: GAO (analysis and illustrations). | GAO-24-106504

Appendix V: Comments from the Department of Energy



Department of Energy
Washington, DC 20585

May 3, 2024

Candice N. Wright
Director
Science, Technology Assessment, and Analytics (STAA)
U.S. Government Accountability Office
441 G Street, N.W.
Washington, DC 20548

Dear Director Wright:

The Department of Energy (DOE or Department) appreciates the opportunity to comment on the Government Accountability Office's (GAO) draft report titled, "Department of Energy: Actions Needed to Assess U.S. Manufacturing Policy and Protect Technology from Foreign Acquisition" (GAO-24-106504). DOE provides the following comments below.

The Department is fully committed to ensuring that innovation funded in America stays in America. In fact, DOE took administrative action in 2021 to go beyond minimum statutory obligations to require that new breakthrough science and energy technologies funded by the Department are manufactured here in America whenever commercially feasible. This policy applies to all entities receiving taxpayer R&D funding and all entities obtaining legal rights to taxpayer-funded inventions. Last July, DOE's policy served as the framework for Executive Order 14104, which formalized the Administration's "Invent it Here, Make it Here" policy to ensure that the President's historic R&D investments in America benefit American workers, communities, and supply chain resilience. As part of DOE's ongoing implementation of its enhanced U.S. manufacturing policy and E.O. 14104, the Department has engaged with stakeholders, issued guidance and FAQs, and plans to publish a U.S. manufacturing handbook to provide further details on the modification process and alternative commitments to the U.S. economy to support a modification request.¹

DOE has also enhanced its review and oversight of U.S. manufacturing of technologies developed and owned by our National Laboratories through patent licensing. As discussed in the report, in 2022, the Secretary directed a 30-day and 180-day comprehensive review of patent licensing across the DOE/NNSA complex. The 180-day review produced eight recommendations currently being implemented to improve U.S. manufacturing and national and economic security safeguards in licenses and laboratory licensing due diligence and monitoring programs. As part of the implementation effort, the Technology Transfer Working Group (TTWG), comprised of DOE/NNSA laboratory technology transfer experts, is working with the DOE Office of Technology Transitions (OTT) to publish a revised licensing guide and sample license for potential licensees that

¹ [Financial Assistance Letter No. FAL 2022-06 | Department of Energy: U.S. Manufacturing | Department of Energy.](#)

**Appendix V: Comments from the Department
of Energy**

2

addresses issues identified in DOE's reviews such as U.S. competitiveness, change in control, and anti-collateral provisions. An internal licensing playbook for DOE/NNSA laboratories will also be developed. DOE also plans to release a U.S. manufacturing handbook for all DOE partners and to update the Technology Transfer Mission (TTM) Clause (48 CFR 970.5227-3) in national laboratory contracts, as necessary, to establish standards for laboratory license provisions and due diligence and monitoring programs. These safeguards will balance the statutory ownership rights of contractors while protecting our national security and economic interests and preserving the technology transfer ecosystem needed to drive commercialization in the United States.

DOE's specific responses to GAO's recommendations are enclosed. GAO should direct any questions to Brian Lally, Assistant General Counsel for Technology Transfer and Intellectual Property, by phone at (202) 230-7592 or via email at brian.lally@hq.doe.gov.

Sincerely,

**Samuel T.
Walsh**

Digitally signed by
Samuel T. Walsh
Date: 2024.05.03
18:52:19 -0400

Samuel Walsh
General Counsel

Enclosure

Enclosure

Management Response
GAO Draft Report: “Department of Energy: Actions Needed to Assess U.S. Manufacturing Policy and Protect Technology from Foreign Acquisition” (GAO-24-106504)

Recommendation #1: Develop a strategy or approach for monitoring and assessing the effects of the U.S. Competitiveness Provision pursuant to its 2021 DEC and identify whether it is achieving progress towards planned performance.

DOE Response: Concur

DOE policy guidance issued in September 2022 established a process to develop an assessment strategy for the 2021 Determination of Exceptional Circumstances (DEC) once fully implemented. DOE policy states that “[a]fter full implementation of the S&E DEC in later fiscal years, the Under Secretary plans to require programs to report on various S&E DEC performance and impact metrics such as U.S. jobs created, U.S. R&D investments, commitments to the U.S. economy, supply chain impacts, etc.”² As a result, the DOE Office of General Counsel is working with a crosscutting U.S. Manufacturing Policy Working Group established by the Under Secretary for Science and Innovation in 2022 and comprised of representatives from across DOE/NNSA to develop an assessment strategy for the 2021 DEC. DOE funding programs will report on the effectiveness of the 2021 DEC on a periodic basis, e.g., bi-annually, beginning in FY2025.

Estimated Completion Date: September 30, 2024

Recommendation #2: Provide waiver applicants additional guidance to help improve transparency on how to demonstrate alternative benefits to the U.S. economy, such as clear examples for approval, as well as communicate expectations for waiver review timelines.

DOE Response: Concur

Please note that current DOE guidance provides a detailed description of the types of alternative commitments to the U.S. economy to support a U.S. manufacturing modification request including “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,” “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,” and “[a]greement by the requestor to provide at least a non-exclusive license with commercially reasonable terms to any recipient agreeing to the

² [Financial Assistance Letter No. FAL 2022-06 | Department of Energy.](#)

Appendix V: Comments from the Department of Energy

U.S. Competitiveness Provision.”³ The modification process is an iterative process and often requires additional time to identify commercially reasonable commitments to the U.S. economy for a specific technology, entity, and sector. The median time to a DOE decision on a U.S. manufacturing modification request, including any negotiations, based on 16 requests from laboratories (included in data provided to GAO) was approximately two months.

In addition to providing DOE guidance and a modification request form, DOE is working with NIST and other agencies including through the Interagency Working Group on Bayh-Dole to implement the requirements in E.O. 14104 to improve the modification process, including a common application form and policy factors for modification decisions. DOE intends to use the common application form and related guidance once published.

Finally, DOE plans to publish a U.S. manufacturing modification handbook for all DOE partners, including additional guidance on the modification process, timeline, and examples of alternative commitments to the U.S. economy agreed to by DOE, consistent with E.O. 14104 and the forthcoming interagency guidance.

Estimated Completion Date: September 30, 2024

Recommendation #3: Provide clarifying information to universities for monitoring compliance with U.S. manufacturing commitments, including guidance on how it interprets “manufactured substantially in the United States.”

DOE Response: Concur

DOE plans to release a U.S. manufacturing handbook for all DOE partners, including universities, which will address licensee U.S. manufacturing compliance.

DOE consults with NIST regarding guidance for “manufactured substantially in the United States” as this language is based on 35 U.S.C. 204 and 37 CFR 401.14(i), part of the regulations implementing the Bayh-Dole Act administered by NIST. DOE will continue to ensure that any guidance on “manufactured substantially in the United States” is consistent with interagency efforts. DOE has found that the flexibility of the statutory standard allows DOE and its laboratories and partners to negotiate customized, technology-specific modifications and alternative commitments to the U.S. economy.

Estimated Completion Date: September 30, 2024

Recommendation #4: Conduct a review of university licensing procedures to ensure that appropriate licensing monitoring and enforcement practices are in place.

DOE Response: Concur

³ *Id.* at App. 5.

Appendix V: Comments from the Department of Energy

DOE will review applicable authorities and processes for grantee oversight and develop a targeted strategy for reviewing university patent licensing practices.

DOE notes that all Bayh-Dole entities, including universities, have broad statutory rights to elect to retain title to, license, and commercialize inventions funded by the Government.

Estimated Completion Date: September 30, 2024

Recommendation #5: Provide guidance to labs and universities on license provisions and other risk management practices and procedures for monitoring licensee foreign ownership, with consideration of critical and emerging technologies, to encourage consistency across all DOE-funded inventions.

DOE Response: Concur

The TTWG, working with the Office of Technology Transitions, is in the process of updating the public facing licensing guide and sample license intended to introduce the laboratory licensing process to potential licensees and, in part, address the recommendations of the 180-day review on laboratory patent licensing. DOE also plans to coordinate development of a more detailed internal licensing playbook for laboratory licensing due diligence and monitoring programs and license agreement provisions. In addition, DOE plans to update the Technology Transfer Mission (TTM) Clause (48 CFR 970.5227-3) in laboratory prime contracts to establish requirements for such safeguards and programs while balancing the broad statutory rights of contractors under the Bayh-Dole Act.

To the extent applicable, DOE will incorporate the above guidance for laboratory contractors into the U.S. manufacturing handbook as guidance for all DOE partners, including universities.

Estimated Completion Date: September 30, 2024

Recommendation #6: Develop and implement procedures or a DOE order for labs detailing when counterintelligence reviews of potential and existing licensees are indicated.

DOE Response: Concur

DOE plans to require, as part of the updated TTM Clause, counterintelligence reviews as part of laboratory due diligence programs for patent licensing.

Estimated Completion Date: September 30, 2024

Appendix VI: GAO Contact and Staff Acknowledgements

GAO Contact

Candice N. Wright, (202) 512-6888 or wrightc@gao.gov

Staff Acknowledgments

In addition to the individual named above, Rob Marek (Assistant Director), Eric Bachhuber (Analyst in Charge), Caroline Gross, Nathan Hamm, Caroline Johnson, Ben Shouse, and Amber Sinclair made key contributions to this report. Also contributing to this report were Ryan Han, Erin McAuliffe, Gabe Nelson, and Claire Saint-Rossy.

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