

Subject: 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

References:

DOE Determination of Exceptional Circumstances under the Bayh-Dole Act to Further Promote Domestic Manufacture of DOE Science and Energy Technologies, signed on June 7, 2021, attached as Appendix 1 and <u>available here</u>

Bayh-Dole Act, 35 U.S.C. §§ 201, 202(a)(ii)

37 C.F.R. § 401.3

2 C.F.R. §§ 910.362, 910.366(b)

E.O. 14017, America's Supply Chains, dated February 24, 2021

When is this Financial Assistance Letter (FAL) Effective?

This FAL is effective upon issuance.

When does the FAL expire?

This FAL is in effect for FY 2022 and remains in effect for fiscal years after FY 2022 until superseded or canceled. This FAL also applies to certain financial assistance actions on or after June 7, 2021 funded with earlier appropriated funds.

Who is the intended audience for this FAL?

Department of Energy (DOE or Department) Contracting and Grants Officers in an organization under the cognizance of the Under Secretary for Science and Energy and in the Advanced Research Projects Agency-Energy. Any reference in this guidance to Contracting Officer should be understood to include Grants Officer.

Who are the Points of Contact?

For DOE questions, please contact the Contract and Financial Assistance Policy Division at <u>DOE_OAPMPolicy@hq.doe.gov</u> or the Office of the Assistant General Counsel for Technology Transfer and Intellectual Property (GC-62) at <u>GC-62@hq.doe.gov</u>.

What is the purpose of this FAL?

The purpose of this FAL is to provide information and guidance regarding DOE's implementation of the DOE Determination of Exceptional Circumstances under the Bayh-Dole Act to Further Promote Domestic Manufacture of DOE Science and Energy Technologies, signed on June 7, 2021 ("Science and Energy DEC" or "S&E DEC"), Appendix 1, in financial assistance for Bayh-Dole entities.

Please note that related AL 2021-XX provides information and guidance for the implementation of the S&E DEC in DOE contracts with Bayh-Dole entities, including Laboratory Management and Operating contracts.¹

What types of actions are affected by this FAL?

This FAL applies to funds appropriated to DOE Science and Energy Programs for funding opportunity announcements and funding agreements, including financial assistance actions, directed to R&D activities for fiscal year 2022 and after. This FAL will be updated as other program offices not currently subject to the S&E DEC notify the Secretary and the Assistant General Counsel for Technology Transfer and Intellectual Property of their approval of the S&E DEC (Appendix 1, page 15).

For funding opportunity announcements and financial assistance actions funded in whole or in part with fiscal year 2021 or earlier appropriated funds, please contact your cognizant DOE patent counsel or the Office of the Assistant General Counsel for Technology Transfer and Intellectual Property at <u>GC-62@hq.doe.gov</u> for further information.²

What is the background information?

In connection with the 100-day review of critical supply chains as directed under E.O. 14017, *America's Supply Chains*, on June 8, 2021, the <u>Department announced</u> new immediate policy actions to support U.S. job creation and bolster the domestic manufacturing supply chain for advanced battery materials and technologies. The policy actions included direction to strengthen

¹ The S&E DEC enables the new U.S. manufacturing policy, as described below, for Bayh-Dole entities only. The policy will be implemented for non-Bayh-Dole entities such as large businesses through DOE's patent waiver process under 10 C.F.R. Part 784 and 2 C.F.R. § 910.362. Although this FAL implements the S&E DEC for financial assistance, DOE programs may follow the guidance in this FAL, such as the waiver and modification guidance in Section I, to implement the S&E DEC in other funding agreements, as appropriate. ² The Under Secretary for Science and Energy has directed that use of the S&E DEC is permitted for such funding

² The Under Secretary for Science and Energy has directed that use of the S&E DEC is permitted for such funding opportunity announcements and financial assistance actions issued on or after June 7, 2021, for select funding programs with appropriate notice to applicants and recipients. Further the Under Secretary for Science and Energy has permitted the use of the S&E DEC for the rare Office of Fossil Energy funding opportunity announcements issued prior to June 7, 2021, that referenced a forthcoming DEC for U.S. manufacturing, including contract modifications for issued awards.

U.S. manufacturing requirements in federally-funded grants, cooperative agreements, and research and development contracts through the S&E DEC under the Bayh-Dole Act.

The new policy supports domestic job creation by ensuring that all innovations—including those relating to advanced batteries—developed with taxpayer dollars through DOE Science and Energy Programs are substantially manufactured in the U.S. Specifically, the S&E DEC authorizes inclusion of a U.S. Competitiveness provision, which requires substantial U.S. manufacture of products embodying DOE-funded subject inventions, in agreements funded by DOE Science and Energy Programs.

The S&E DEC optimizes and expands previous technology-specific DECs piloted since 2013 by Departmental programs such as the Office of Energy Efficiency and Renewable Energy and the Advanced Research Projects Agency-Energy.

What are the instructions/guidance of this FAL?

Sections

- A. Applicability
- B. Definitions
- C. Use of the S&E DEC
- D. Non-Use of the S&E DEC, i.e., Opt-Outs
- E. Notice of the S&E DEC in Funding Opportunity Announcements
- F. Incorporation of the U.S. Competitiveness Provision into Award Terms and Conditions and Class Deviation
 - a. The U.S. Competitiveness Provision
 - b. Administrative Changes to the U.S. Competitiveness Provision by DOE Programs
- G. Relationship to other DECs
- H. Program Reporting to the Under Secretary for Science and Energy
- I. Recipient Requests to Modify or Waive the U.S. Competitiveness Provision
- J. U.S. Economic Impact Monitoring and Recipient Engagement

A. <u>Applicability</u>

This FAL applies to funding opportunity announcements and funding agreements including financial assistance actions, e.g., financial assistance agreements, with Bayh-Dole entities, directed at least in part to R&D activities funded by DOE Science and Energy Programs. While the S&E DEC will be incorporated into applicable funding opportunity announcements, only Bayh-Dole entities are subject to the S&E DEC.

B. <u>Definitions</u>

As used in this FAL,

- 1. The term "Bayh-Dole entities" means any person, small business firm, or nonprofit organization, as such terms are defined in the Bayh-Dole Act, that is a party to a funding agreement.
- 2. The term "DOE Science and Energy Programs" means one or more DOE programs under the cognizance of DOE's Under Secretary of Science, Under Secretary of Energy,

combined Under Secretary for Science and Energy, or the Advanced Research Projects Agency-Energy (ARPA-E).

- 3. The term "DOE Science and Energy Technologies" means any Subject Invention, as defined by the Bayh-Dole Act, conceived or first actually reduced in the performance of work under a DOE funding agreement issued by DOE Science and Energy Programs.
- 4. The term "funding agreement" means any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government. Such term includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as herein defined.
- 5. The term "R&D activities" means experimental, developmental, or research work.

C. <u>Use of the S&E DEC</u>

DOE Science and Energy Programs shall use the S&E DEC by default in all fiscal year 2022 and after funding opportunity announcements and financial assistance actions directed at least in part to R&D activities.

D. Non-Use of the S&E DEC, i.e., Opt-Outs

DOE Science and Energy Programs may opt out of using the S&E DEC for particular financial opportunity announcements with written justification approved by appropriate program leadership and the cognizant CO with cognizant DOE patent counsel concurrence. The written justification may include the S&E DEC opt-out determination template, attached as Appendix 2, or similar documentation.

The opt-out determination template outlines factors which may support an opt-out and is only required for announcements where the S&E DEC is otherwise applicable and the DOE program wishes to deviate from the direction to use the S&E DEC. No opt-out is required for non-R&D activities which are not subject to this FAL.

DOE Science and Energy Programs must report S&E DEC opt-outs to the Under Secretary for Science and Energy on a quarterly basis as described in Section H.

E. <u>Notice of the S&E DEC in Funding Opportunity Announcements</u>

DOE Science and Energy Programs must provide notice of the S&E DEC in applicable funding opportunity announcements. Programs should use the default funding opportunity announcement language provided in Appendix 3 or a substantially similar version agreed to by the cognizant DOE Patent Counsel, funding program, and the cognizant Contracting Officer to promote consistency among DOE Science and Energy Programs.³

³ As described in the FOA language, Appendix 3, the S&E DEC, Appendix 1 (page 14), and 2 C.F.R. § 910.366(b), DOE Science and Energy Programs may require applicants to submit U.S. manufacturing plans. For purposes of the

F. <u>Incorporation of the U.S. Competitiveness Provision into DOE Award Terms and</u> <u>Conditions and Class Deviation</u>

a. The U.S. Competitiveness Provision

The S&E DEC authorizes the incorporation of a U.S. Competitiveness provision requiring substantial U.S. manufacture of DOE-funded subject inventions into the Intellectual Property provisions of applicable financial assistance agreements.

The new DOE award IP provisions including the U.S. Competitiveness provision are <u>available</u> <u>here</u>. DOE Science and Energy Programs shall consult with their cognizant DOE Patent Counsel on the appropriate IP provisions to include in an award as part of current award processes.

This FAL also includes a 2 C.F.R. § 910.362 class deviation, provided in Appendix 4, which includes minor technical amendments to allow DOE Patent Counsel to implement the S&E DEC in the appropriate award IP provisions.

b. Administrative Changes to the U.S. Competitiveness Provision

DOE Science and Energy Programs may seek to make technical or administrative changes to the U.S. Competitiveness provision, for example, to clarify funding agreement requirements, provide contact information, or to reduce requirements of the provision, as appropriate, while balancing the need for consistency across programs.

Programs may initiate this process through documentation similar to the opt-out determination in Appendix 2. Any change to the U.S. Competitiveness provision requires program approval at the Deputy Assistant Secretary (or equivalent) level and GC-62 concurrence. If approved, the funding opportunity announcement language in Appendix 3 must be updated to reflect any changes.

As needed, GC-62 may issue clarifying guidance or other administrative changes to the U.S. Competitiveness provision.

G. <u>Relationship to other DECs</u>

Existing DECs, <u>available here</u> for reference, remain in place and are available for applicable programs to use, subject to the direction in Section C. Programs should consult with their cognizant DOE Patent Counsel.

H. Program Reporting to the Under Secretary for Science and Energy

DOE Science and Energy Programs shall, in coordination with GC-62, report to the Under Secretary for Science and Energy on a quarterly basis one month after the end of each quarter beginning in February 2022 on the number of, and basis for, S&E DEC opt-outs in the previous

S&E DEC, such plans may be required in addition to, or, if the program approves, in lieu of, the U.S. Competitiveness provision, but the default policy for purposes of the S&E DEC is to include the U.S. Competitiveness provision.

quarter. After 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.

I. <u>Recipient Requests to Modify or Waive the U.S. Competitiveness Provision</u>

Detailed guidance for the receipt, review, and resolution of requests to waive or modify the U.S. Competitiveness provision is attached as Appendix 5.

J. U.S. Economic Impact Monitoring and Recipient Engagement

DOE's new, strengthened U.S. manufacturing policy implemented through the U.S. Competitiveness provision authorized by the S&E DEC is a critical and necessary tool to ensure the establishment and security of U.S. supply chains, the creation of U.S. jobs, and the advancement of DOE policy goals and missions. DOE, therefore, expects recipients to comply with the U.S. Competitiveness provision as part of the terms and conditions of applicable DOE awards. DOE funding programs take compliance issues—and their potentially detrimental effect on programmatic requirements and missions—seriously. DOE awards including the U.S. Competitiveness provision provide the Government with certain rights including the right to obtain title to subject inventions for breach of the provision.⁴

The U.S. Competitiveness provision gives DOE the ability to ensure that its rights are preserved in case of a transfer of control of the recipient. DOE review and oversight is particularly needed to protect against foreign entities acquiring rights to federally funded technologies through stock/asset purchases and bankruptcy proceedings and then moving the manufacturing of such technologies offshore (Appendix 1, page 9). In accordance with DOE's long-standing practice, this provision is intended to require DOE approval prior to the transfer of the subject inventions in cases where the U.S. economic interests described above and in the S&E DEC, e.g., Appendix 1, page 9, are present. If concerned about DOE's role in a change of ownership transaction, recipients should be encouraged to engage with DOE early in any such process so that DOE can determine the level of review required.

However, DOE is firmly committed to resolving 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.

DOE's waiver and modification process (Appendix 5) requires DOE and recipient engagement and communication on these issues. Accordingly, DOE strongly encourages recipients to bring potential compliance concerns and waiver or modification requests to the attention of the appropriate funding program as soon as practicable to ensure that DOE and the recipient have a full opportunity to resolve any issues or concerns promptly and in a mutually-agreeable manner.

⁴ In addition, DOE will continue to require annual utilization reports to monitor activities related to the commercialization of subject inventions, including licensing and jobs created. Any documents supplied to DOE as part of this engagement with recipients on U.S. impact and manufacturing will be protected from further disclosure to the maximum extent allowed by law.