INTERIM GENERAL GUIDANCE REGARDING UP TO THIRTY-YEAR PROTECTED CRADA INFORMATION

Pursuant to recent statutory changes to the Stevenson-Wydler Technology Innovation Act of 1980 by section 40322 of the Infrastructure Investment and Jobs Act (IIJA) (P.L. 117-58), NETL, Laboratory Contractors, and CRADA Participants may request extended protection for certain categories of Protected CRADA Information (PCI) for a period of more than five years but not to exceed thirty years from generation. For such requests, DOE must determine, in accordance with 15 U.S.C. § 3710a(c)(7)(B)(ii), that the nature of such PCI, "including nuclear technology, could reasonably require an extended period of that protection to reach commercialization." The parties may use the attached suggested template or similar documentation for these requests.²

To facilitate the required DOE determination, any request should provide the protection period requested and a reasonable written justification identifying the categories of PCI, including any software source code, and specific reasons for the extended protection period. These reasons may address factors such as the maturity of the technology, development timeframe, market and economic considerations, technical issues, national and economic security issues, e.g., risk of malign foreign actors acquiring PCI (and thus negatively impacting the ability of the Participant to commercialize the technology), or any other reason why the requested period of protection is reasonably required to reach full commercialization. The parties may include a technology commercialization plan to support their request, which may include a commercialization timeline and proposed contractual commitments to commercialize the technology in the U.S. The request should be directed to DOE, preferably to the DOE Contracting Officer (CO)³ with a copy to DOE Patent Counsel. The request should be coordinated with the cognizant DOE funding program as soon as practical. The request must be approved in writing by the DOE CO, DOE funding program, and DOE Patent Counsel.

DOE approval should not be unreasonably withheld if the request includes a description of the PCI categories and a reasonable justification to support that the requested period of protection to reach commercialization is required for such categories. However, DOE may approve a protection period that is different from the period requested (not to exceed thirty years) as long as the protection period is reasonably required for commercialization. In addition, DOE may require more detailed justification for its determination, in particular, for requests for protection periods of more than ten years. In reviewing the categories of PCI, DOE should consider the potential positive and negative consequences of protecting the information beyond five years, e.g., limited rights to disclose, publish, and disseminate such information during the protection period, and DOE program requirements, which may include factors other than commercialization, to ensure that DOE and the public's interests are appropriately protected.

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¹ If the Participant is using federal funds to perform at least some of the work, the terms of that federal funding agreement relating to the period of protection for Protected Data will apply. The protection period determination of the awarding office that issues such federal funding agreement controls. No other independent determination is required.

² DOE funding programs may issue blanket determinations that certain categories of technology under CRADAs be protected for more than five years using documentation similar to the attached suggested template with sufficient justification according to this guidance. However, blanket determinations with protection periods of twenty years or longer will also require GC-62 approval unless delegated to the cognizant DOE Patent Counsel.

³ For NETL, requests should be directed to the CRADA Administrative Contact.

DOE approval, as described above, may be provided as part of existing DOE field element CRADA/JWS approval processes.

The PCI protection period shall not relieve the parties of their obligations under Article VI, Rights in Subject Inventions, including the timely reporting and title election of subject inventions, and to the extent that there is any conflict between Article VI, Rights in Subject Inventions, and Article VII, Rights in Data, Article VI controls. If a Participant fails to timely report a Subject Invention, DOE may determine to decrease the protection period for PCI related to that Subject Invention.

Article VII, Rights in Data, Additional Language

If DOE authorizes a PCI protection period of more than five years as described above, the following changes should be made:

In paragraph (C), replace the phrase "For a period of _____ [not to exceed five years]" with "For a period of _____ [not to exceed five years] unless otherwise approved by DOE and identified below".

In addition, insert the following at the end of paragraph (C):

The following categories of Protected CRADA Information are subject to a protection period of more than five years from production (not to exceed thirty years) as authorized by 15 U.S.C. § 3710a(c)(7)(B)(ii). Any Protected CRADA Information not identified below is subject to the protection period identified above in this paragraph (C). Only the protection period for the following categories of Protected CRADA Information is modified. All other rights and obligations of Protected CRADA Information described in this Article apply. Such Protected CRADA Information must be designated and marked (identifying the protection period) according to this Article.

[List categories of Protected CRADA Information including the protection period approved by DOE – copied from the suggested request template in Attachment 2]

| Protection Period | Description of the Category of Protected CRADA Information | |
|-------------------|---|--|
| (Not to exceed 30 | | |
| years) | | |
| [Example: 10] | [Example only: Prototype equipment including design details and | |
| | drawings, specifications, pressure relief system design and | |
| | calculations, heat integration performance/study results] | |
| [Example: 10] | [Example only: Instrumentation and controls including specification | |
| | sheets, detailed instrumentation lists, sizing details, control drawings, | |
| | installation drawings] | |

[Suggested Template] Request for an Extended Period of Protection for Protected CRADA Information¹

This form should be completed by the Laboratory Contractor and CRADA Participant as described in the CRADA interim guidance. All text in blue should be replaced with the appropriate information and removed before the document is finalized.

1. Background

Section 40322 of the Infrastructure Investment and Jobs Act (IIJA) (P.L. 117-58) gives federal agencies, in part, the ability to authorize laboratory directors to extend existing data protection authority in cooperative research and development agreements (CRADAs) from a maximum of five years to up to thirty years from development "if the agency determines that the nature of the information protected against dissemination, including nuclear technology, could reasonably require an extended period of that protection to reach commercialization." 15 U.S.C. § 3710a(c)(7)(B)(ii).

This suggested form is intended to facilitate the required DOE determination and consideration of a request for a protection period of up to thirty years for Protected CRADA Information (PCI). DOE Laboratory Contractors and CRADA Participants may use this form or similar documentation on an interim basis as described in the guidance until DOE O 483.1B, *DOE Cooperative Research and Development Agreements* is revised.

2. DOE Funding Agreements

If the Participant is using federal funds to perform at least some of the work, the terms of that federal funding agreement with regard to the period of protection for Protected Data will apply. Please provide a list of such federal funding agreements (including award number) and the period of protection provided, or insert "None."

3. CRADA and Work Description

Identify the applicable CRADA(s) and provide a brief description of the Statement of Work for the CRADA(s).

4. Description of Categories of Protected CRADA Information, Requested Protection Period, and Justification

This extended data protection request must demonstrate to the satisfaction of DOE that the requested protection period is reasonably required for commercialization of the technology. The justification provided may address factors such as the maturity of the technology, development timeframe, market and economic considerations, technical issues, national and economic security issues, e.g., risk of malign foreign actors acquiring PCI (and thus negatively impacting the ability of the Participant to commercialize the technology), or any other reason why the requested

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¹ Please note that the justification provided in this suggested form may include information, e.g., Participant's Proprietary Information and information protectable under a federal funding agreement, that may be protected from disclosure under the Freedom of Information Act. The parties may mark such protected information, as appropriate.

period of protection is reasonably required for commercialization.

In a table or similar format below, please briefly list and describe the categories of Protected CRADA Information and the requested protection period for each category along with a brief justification. Additional justification can be provided in the next section.

| Protection | Description of the Category of Protected | Justification |
|----------------|---|---------------|
| Period (Not to | CRADA Information | |
| exceed 30 | | |
| years) | | |
| [Example: 10] | [Example only: Prototype equipment including | [INSERT] |
| | design details and drawings, specifications, | |
| | pressure relief system design and calculations, | |
| | heat integration performance/study results] | |
| [Example: 10] | [Example only: Instrumentation and controls | [INSERT] |
| | including specification sheets, detailed | |
| | instrumentation lists, sizing details, control | |
| | drawings, installation drawings] | |

5. Additional Justification

Please provide any additional justification to support that the requested protection period is reasonably required for commercialization of the technology. The parties may include a technology commercialization plan to support their request, which may include contractual obligations to support justification. For example, the commercialization plan may include one or more of the following to support justification: a commitment for commercial deployment in the U.S. first, annual software utilization reporting, annual commercialization reporting, a commitment to publish in the open scientific literature, and an agreement to assign any related intellectual property to DOE if substantial commercialization efforts cease.

6. Other Considerations

Add any other issues, considerations, or sensitivities (if known), not addressed in the sections above, or insert "N/A."

Note: DOE staff should strive to review and respond to complete Extended Data Protected Requests within 10 business days.

7. Determination

For the reasons stated above, DOE has determined that "the nature of the information protected against dissemination, including nuclear technology, could reasonably require an extended period of that protection to reach commercialization," in accordance with 15 U.S.C. § 3710a(c)(7)(B)(ii), and therefore this extended data protection request is granted. This determination is supported by the information and justification provided above. The Contracting Officer is respectfully requested to work with the Cognizant DOE Patent Counsel to implement the approved data protection in the above identified CRADA(s).

LABORATORY/CRADA PARTICIPANT REQUESTOR:

| [SIGNATURE] | | DAT | E | |
|---|-------|-------------|--------|----|
| [NAME, TITLE, AND ORGANIZATION] | | | | |
| DOE APPROVAL: | | | | |
| [SIGNATURE] | | DAT | E | |
| [NAME] | | | | |
| [TECHNOLOGY OFFICE DIRECTOR OR OPPOGRAM LEADERSHIP] | OTHER | APPROPRIATE | MEMBER | Ol |
| | | | | |
| [SIGNATURE] | | DAT | E | |
| [NAME] COGNIZANT DOE PATENT COUNSEL | | | | |

| [SIGNATURE] | DATE |
|----------------------------|------|
| [NAME] CONTRACTING OFFICER | |
| Attachments [INSERT] | |