

SUBJECT: DOE COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

1. PURPOSE.

- a. To establish Department of Energy (DOE) policy, requirements, and responsibilities for the oversight, management, and administration of Cooperative Research and Development Agreement (CRADA) activities at DOE facilities.
- b. To provide practical guidelines that will expedite the CRADA process.
- c. To make certain through the use of CRADAs, consistent with the terms of the DOE Facility Contract or delegation of authority, DOE and its facilities will—
 - (1) facilitate the efficient and expeditious development, transfer, and exploitation of Federally owned or originated technology to non-DOE entities for the public benefit and to enhance the accomplishment of DOE missions;
 - (2) leverage DOE resources, through its programs and facilities, through partnering; and
 - (3) ensure fairness of opportunity, protect the national security, promote the economic interests of the United States, and provide a variety of means to respond to private-sector concerns and interests about facility technology partnering activities
- d. To ensure that DOE and its facilities—
 - (1) carry out CRADA activities in accordance with applicable laws and authorities; and
 - (2) ensure consistent development and application of policy and procedures in planning and conducting CRADA activities at DOE facilities; and ensure the availability of timely and accurate CRADA data and information to monitor, evaluate, and describe DOE CRADA activities.

2. CANCELLATIONS. DOE O 483.1A, DOE *Cooperative Research and Development Agreements*, dated 11-06-13. Cancellation of a directive does not, by itself, modify or otherwise affect any contractual regulatory obligation to comply with the directive. Contractor Requirements Documents (CRDs) that have been incorporated into a contract remain in effect throughout the term of the contract unless and until the contract or regulatory commitment is modified to either eliminate requirements that are no longer applicable or substitute a new set of requirements.

3. APPLICABILITY.

- a. Departmental Applicability. Except for the equivalencies/exemptions in paragraph 3.c., the provisions of this Order apply to all Departmental organizational elements negotiating and entering into CRADAs performed under Title 15 United States Code (U.S.C.), Section 3710a. Government-Owned, Contractor-Operated (GOCO) facility contractors, also referred to as Management and Operating (M&O) contractors are authorized to enter into CRADAs by inclusion of the Department of Energy Acquisition Regulation (DEAR) 970.5227-3, Technology Transfer Mission clause. Government-Owned, Government-Operated (GOGO) facilities are authorized to enter into CRADAs by delegation of authority.
- b. The Administrator of the National Nuclear Security Administration (NNSA) will assure that NNSA employees comply with their responsibilities under this directive. Nothing in this directive will be construed to interfere with the NNSA Administrator's authority under section 3212(d) of Public Law (P.L.) 106-65 to establish Administration-specific policies, unless disapproved by the Secretary.
- c. Contractors. Except for the equivalencies/exemptions in paragraph 3.c., the Contractor Requirements Document (CRD), Attachment 1, sets forth requirements of this Order that apply to contracts that include the CRD. The CRD must be included in all DOE facility contracts under which contractors negotiate and enter into CRADAs under the National Competitiveness Technology Transfer Act of 1989.
- d. Equivalencies/Exemptions for DOE O 483.1B. Equivalencies and Exemptions to this Order are processed in accordance with DOE O 251.1C, Departmental Directives Program, and its successors.

4. REQUIREMENTS.

The following policies and requirements must be applied in carrying out the CRADA program.

- a. The proposed work is expected to result in a benefit consistent with the program missions at the facility and the facility's mission as established by the cognizant secretarial officer (CSO).
- b. The proposed work represents a collaboration with one or more non-Federal parties in specified research or development efforts that is consistent with the missions of the facility or facilities (in multi-laboratory CRADA activities). The non-Federal party contribution must be more than financial and/or equipment or the development of a statement of work, that is, the non-federal party must collaborate. One hundred percent (100%) funds-in CRADA are permissible and may be entered into by DOE Facilities, as long as there is

collaboration and the DOE Facility Contractor informs the non-Federal party of the availability of alternate forms of technology partnering mechanisms in accordance with the Contractor's contract with DOE. Any questions regarding the various collaboration requirements described in this Order should be directed to the Assistant General Counsel for Technology Transfer and Intellectual Property who will consult with the appropriate DOE program offices.

- c. In conducting its CRADA activities, the facility must prepare procedures and take all reasonable measures to ensure widespread notice of availability of technologies suited for transfer and for opportunities for exclusive licensing and joint research arrangements.
- d. Activities must be conducted in a manner that does not compromise the national security, economic, or environmental interests of the United States.
- e. Export control reviews must be performed in accordance with facility contracts and DOE policy. CRADA activities can result in information and technologies that may be subject to export controls. This export-controlled information (ECI) may or may not also fall under such categories as Classified information or Unclassified Controlled Nuclear Information (UCNI). The information and/or technology may become ECI at any stage. Information and data that are commercially valuable may be developed, including some that may have intellectual property rights associated with it. Consistent with applicable statutes, such information may be considered for protection from public dissemination, for a period not to exceed 5 years after development of information, to retain its commercial value and provide an incentive for its commercial application. Any protectable information generated or exchanged as a result of this CRADA will be marked, handled, and safeguarded in accordance with all applicable federal laws, rules, regulations and DOE Orders or directives, including but not limited to, the Trade Secrets Act (18 U.S.C. §1905), the Freedom of Information Act (FOIA) (5 U.S.C. §552), DOE's implementing FOIA regulations at 10 C.F.R. Part 1004, the Federal Technology Transfer Act (15 U.S.C. §3710a(c)), and DOE Order 471.3, Admin Chg. 1, Identifying and protecting Official Use Only Information. In accordance with these rules, certain information transmitted pursuant to a CRADA may qualify for protecting from disclosure under FOIA.
- f. DOE employees, in accordance with applicable law and the provisions of facility contracts, must protect properly marked proprietary information and data provided by private-sector collaborators and non-Federal parties in the conduct of CRADA activities.
- g. Non-Federal parties (also referred to as "Participants") are permitted to use funds previously obtained from federal sources as its contribution to fund a project, provided such use is consistent with the underlying Funding

Agreement. However, when Federal funds are being used by a non-Federal party special considerations must be taken into account including:

- (1) whether the non-Federal party's previous award contains authority for special data protection that justifies enhanced protection of information generated under the CRADA (i.e. protection of Protected CRADA Information) or in the alternative, limits data protection to a period of protection less than that provided under 15 U.S.C. § 3710a;
- (2) any potential inconsistencies in the U.S. Competitiveness clauses between the non-Federal party's award and the DOE Model CRADA language;
- (3) in case of inconsistencies between the non-Federal party's award and the CRADA, include a statement that indicates which agreement controls or ensure that such inconsistencies are addressed during negotiations;
- (4) whether the non-Federal party has clear election rights to inventions made under its previous award. .

5. RESPONSIBILITIES.

- a. Under Secretary for Science and Energy, in Consultation with the Under Secretary for Nuclear Security, as appropriate.
 - (1) Recommends, establishes and coordinates policy and provides overall guidance, subject to the Secretary's direction, for CRADA activities, and recommends appropriate delegations of authority for carrying out such policy and guidance.
 - (2) Serves as the focal point and provide leadership for developing policies and procedures, resolving CRADA partnering issues, and ensuring effective implementation of existing policies.
- b. The Technology Transfer Coordinator, in consultation with the Technology Transfer Policy Board.
 - (1) Develops policy and recommends procedures for the conduct, and is responsible for the coordination, of CRADA activities at DOE facilities.
 - (2) Provides an interagency coordination point for CRADA activities at DOE facilities, as appropriate.
 - (3) Provides guidance to Cognizant Secretarial Officers (CSO) for the preparation and submission of reports, such as the annual DOE Report to Congress on technology partnering program activities.

- (4) Coordinates the preparation of annual facility technology partnering program reports.
 - (5) Coordinates and conducts training, in coordination with the Head of Field Element, of DOE field personnel responsible for oversight of the Contractors' technology transfer programs to ensure consistent development and application of policy and procedures in planning and conducting CRADA activities at DOE facilities.
- c. Cognizant Secretarial Officers (CSO).
- (1) Exercise primary oversight, management, and administrative responsibility for CRADA activities at facilities under their cognizance.
 - (2) For facilities under their cognizance, provide general guidance in accordance with the terms of the facility contract or delegation of authority.
 - (3) Ensure the availability of timely and accurate data and information about CRADAs from facilities under their cognizance for satisfying DOE reporting and information requirement.
 - (4) Ensure that Heads of Field Element complete an appraisal of the performance of the CRADA activities under its cognizance on an established periodicity.
- d. Program Secretarial Officers (PSO).
- (1) Exercise primary programmatic responsibility for the implementation of CRADA activities for their programs.
 - (2) Support the CSO in the execution of the CSO's institutional responsibilities, by providing programmatic, mission area, and technical expertise in the resolution of CRADA issues.
- e. Assistant General Counsel for Technology Transfer and Intellectual Property.
- (1) Provides legal counsel to Departmental elements on all matters relating to intellectual property (including patents, copyrights, and technical data) and transfer of those rights to the private sector in accordance with established legal authorities, including from Department laboratories, and provides legal counsel on issues related to the CRADA program including questions regarding the various requirements presented in this Order.
 - (2) Establishes policy on intellectual property rights, advises and provides guidance on intellectual property provisions for CRADAs, and approves

waivers of patent rights and of any disposition of other intellectual property rights.

f. Heads of Field Elements.

- (1) Oversee CRADA activities conducted in DOE facilities under their purview. In this capacity, heads of field elements are accountable to the CSO.
- (2) Ensure that federal staff and the Contractors under their purview effectively carry out appropriate CRADA activities in accordance with applicable laws, regulations, Departmental directives and delegations of authority.
- (3) Develop and implement local procedures for the review and approval of CRADA activities consistent with legislation, Departmental directives, and contractual commitments and objectives.
- (4) In coordination with the CSO and PSOs, conduct reviews and appraisals of CRADA activities under their cognizance.
- (5) Notify appropriate Headquarters elements in accordance with the notification criteria in Attachment 9 of this Order and guidance from the CSO.
- (6) Ensure adequate Contractor review and appropriate DOE engagement in proposed CRADA activities involving human and/or animal subjects for compliance with the established regulations and Departmental directives for protection of these subjects, as appropriate.
- (7) Ensure that CRADA activities under their purview are effectively conducted in accordance with applicable security, safeguards, and classification and controlled unclassified information policies, as appropriate.
- (8) Ensure the Contractor appropriately notifies the Office of Intelligence and Counterintelligence of any CRADA agreements involving intelligence activities
- (9) Ensure adequate DOE and Contractor review of CRADA activities for compliance with applicable environmental, safety, and health requirements, including requirements of the National Environmental Protection Act, as appropriate, and to determine the applicability of 10 CFR Part 851 (Worker Safety and Health Program) to CRADA activities.
- (10) Consistent with the policies and procedures of the Department regarding CRADA activities, establish performance goals and measures to assess

performance and effectiveness of local CRADA processes and impacts of subsequent improvements and/or additional requirements.

- (11) Ensure periodic review and appraisal of CRADA activities.
- (12) Ensure that summary information is maintained sufficient to respond to reporting requirements and to respond to requests for information from DOE Headquarters or outside entities.
- (13) Notify cognizant Contracting Officers of those contracts that must include the Contractor Requirements Document.

g. Office of Intelligence and Counterintelligence.

- (1) Establishes procedures for the review of all CRADA activities concerning intelligence and intelligence-related programs.
- (2) Approves all CRADA activities for intelligence-related programs.
- (3) Establishes procedures for the review of CRADA activities involving classified and/or controlled unclassified technology. The list of sensitive subjects is maintained by the Office of Defense Nuclear Nonproliferation.
- (4) Establishes procedures for the review CRADA activities involving foreign Participants.

h. Contracting Officers. Once notified, incorporate the CRD into the affected contracts.

6. REFERENCES.

- a. Stevenson-Wydler Technology Innovation Act of 1980, Public Law 96-480 (15 U.S.C. 3701 et seq.), established Offices of Research and Technology Applications (ORTAs) at federal laboratories.
- b. Bayh-Dole Act of 1980, Public Law 96-517 (35 U.S.C. 200 et seq.), gives small businesses and nonprofit contractors the right to elect title to inventions made under funding agreements, with the Government retaining a license; provides for march-in rights and U.S. preference; and contains provisions relating to licensing of inventions.
- c. Section 152 of the Atomic Energy Act of 1954, Public Law 83-703 (42 U.S.C. 2182), addresses the disposition of title to inventions useful in the production or utilization of special nuclear material or atomic energy made under DOE contracts, etc., and the process for waiving title to such inventions to contractors.

- d. Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974, Public Law 93-577 (42 U.S.C. 5908), addresses the disposition of title to nonnuclear inventions made under DOE contracts, etc., and the process for waiving title to such inventions to contractors.
- e. Executive Order 12591, dated April 10, 1987, "Facilitating Access to Science and Technology," requires that Executive departments and agencies, to the extent permitted by law, transfer Federally funded technology to the commercial sector and specifically addresses GOGOs entering into CRADAs and licensing, assigning, and waiving intellectual property developed under such CRADAs.
- f. Section 31 of the Atomic Energy Act of 1954, Public Law 83-703 (42 U.S.C. 2051), provides for the dissemination of scientific and technical information.
- g. Freedom of Information Act, Public Law 89-487 (5 U.S.C. 552 et seq.), provides for public access to Federal agency records, which would include records containing scientific and technical information created with Federal funding.
- h. Trademark Clarification Act of 1984, Public Law 98-620, extended the contractors' right to elect title to inventions provided by the Bayh-Dole Act to DOE's GOCO Contractors.
- i. Federal Technology Transfer Act of 1986, Public Law 99-502, authorizes CRADAs for GOGOs, establishes the Federal Laboratory Consortium for Technology Transfer, and allows GOGO laboratories to negotiate licensing agreements for inventions made at its laboratories.
- j. National Competitiveness Technology Transfer Act of 1989, Public Law 101-189, establishes technology transfer as a laboratory mission and permits GOCOs to enter into CRADAs.
- k. National Technology Transfer and Advancement Act of 1995, Public Law 104-113, provides the CRADA collaborating party an option for reasonable compensation when appropriate to choose an exclusive license for a pre-negotiated field of use in any invention made in whole or in part by a laboratory employee under the CRADA.
- l. National Defense Authorization Act of 1999, Public Law 105-261, provides for the Secretary of Energy to impose a Federal Administrative Charge (which includes any depreciation and imputed interest charges) in an amount not to exceed 3 percent of the full cost incurred in carrying out the research and activities on behalf of non-Departmental persons and entities.

- m. Technology Transfer Commercialization Act of 2000, Public Law 106-404, directs the Secretary of Energy to require the Contractors to appoint a technology partnership ombudsman to hear and help resolve complaints from outside organizations regarding the policies and actions of the laboratory with respect to technology partnerships.
- n. Title X Section 1001 of Energy Policy Act of 2005 (EPACT 2005) (Public Law 109-58) calls for the appointment of the Technology Transfer Coordinator to serve as the principal advisor to the Secretary of Energy on all matters relating to the technology transfer and commercialization. EPACT 2005 also stipulates that the Secretary shall establish a Technology Transfer Working Group to coordinate technology transfer activities occurring at the National Laboratories and single-purpose research facilities.
- o. On February 28, 2011, the Secretary of Energy signed a Secretarial Policy Statement on Technology Transfer at DOE facilities. The Policy Statement is designed to help guide and strengthen DOE's technology transfer efforts and to heighten awareness of the importance of technology transfer activities throughout DOE. DOE may issue updated Policy Statements from time to time.
- p. Section 3196(a) of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001, Public Law 106-398, streamlines the approval process for CRADAs at GOCO facilities by authorizing federal agencies to substitute an annual strategic plan for individual joint work statements.
- q. Presidential Memorandum—Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses, Oct 28, 2011.
- r. Section 3120 of National Defense Authorization Act for Fiscal Year 2013, directing the Secretary of Energy and the Administrator of NNSA, to the extent practicable, to streamline the approval process for Cooperative Research and Development Agreements.
- s. DOE O 241.1B, *Scientific and Technical Information Management*, dated 12-13-10, provides requirements and responsibilities for the appropriate management and reporting of scientific and technical information.
- t. DOE O 471.3, Admin Chg 1, *Identifying and Protecting Official Use Only Information*, dated 1-13-11, and DOE M 471.3-1, Admin Chg 1, *Manual for Identifying and Protecting Official Use Only Information*, dated 1-13-11, establish requirements for DOE program to identify, mark, and protect documents containing such information.

- u. 10 CFR Part 1045, Nuclear Classification and Declassification - establishes the Government-wide policies and procedures for implementing sections 141 and 142 of the Atomic Energy Act of 1954 for classifying and declassifying RD (restricted data) and FRD (formally restricted data) and implements those requirements of Executive Order 13526 concerning NSI that affect the public.
- v. Executive Order 13526, *Classified National Security Information* prescribes the Government-wide system for classifying, safeguarding, and declassifying NSI.
- w. DOE O 475.2B, *Identifying Classified Information*, dated 11-3-14, establishes requirements for managing the DOE program including details for classifying and declassifying information, documents, and material classified under the Atomic Energy Act [Restricted Data, Formerly Restricted Data, and Transclassified Foreign Nuclear Information] or Executive Order 13526 [National Security Information], so that it can be protected against unauthorized dissemination.
- x. 10 CFR Part 1017, Identification and Protection of Unclassified Controlled Nuclear Information--establishes Government-wide policies and procedures for implementing the requirements of section 148 of the Atomic Energy Act of 1954 concerning the identification and protection of certain unclassified but sensitive Government information concerning atomic energy defense programs.
- y. DOE O 471.1B, *Identification and Protection of Unclassified Controlled Nuclear Information*, dated 3-1-10, establishes requirements for managing the DOE program for identifying and protecting UCNI.

7. DEFINITIONS.

- a. Amendment. A change to a DOE-approved Joint Work Statement (JWS)/CRADA document
- b. Funds-In. Monies provided by a Participant(s) to a DOE Contractor for a CRADA project.
- c. In-Kind Contributions. Noncash contributions provided by the Participant or contractor. In-kind contributions must include collaboration in the research and development efforts of the CRADA and may also include personnel, services, facilities, equipment, intellectual property and other resources. Work may be performed at either party's facilities and include services that are directly beneficial, specifically identifiable, and necessary for performance of the project. In-kind contributions generally do not include work performed prior to execution of the CRADA.

- d. Joint Work Statement. A proposal prepared for a Federal agency by the director of a Government-Owned, Contractor-Operated (GOCO) facility (or his/her delegate) describing the purpose, scope, schedule, and estimated cost of a proposed CRADA; assigning responsibilities among the agency, Contractor, and any other party or parties to the proposed agreement; and, to the extent known, describing the allocation of rights among the various parties.
- e. Cognizant Secretarial Officer. The Assistant Secretary/Director responsible for a bounded set of facilities or laboratories.
- f. Cooperative Research and Development Agreement (CRADA). Any agreement between one or more Federal facilities and one or more non-Federal parties under which the Government, through its facilities, provides personnel, services, facilities, equipment, intellectual property, or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, intellectual property, or other resources toward the conduct of specified research or development efforts which are consistent with the mission of the facility; except that such terms do not include a procurement contract or cooperative agreement.
- g. DOE Facility. Government-owned laboratory or production facility or other facility operated under DOE program cognizance.
- h. Heads of Field Elements. Federal managers of field elements and directors of GOGOs. Heads of field elements that have line accountability for all site program/project execution and contract management. Field element can refer to operations office, integrated support center, field office or site office.
- i. DOE Facility Contractor. Entity that operates and maintains a DOE facility under contract with, and for the benefit of, DOE and has the responsibility and authority to conduct technology partnering activities.
- j. Licensing. The transfer of less than ownership rights in intellectual property, such as a patent or a software copyright, to permit its use by the licensee.
- k. Program Secretarial Officer. An Assistant Secretary/Director who funds work at a particular site or laboratory via a “customer” relationship with the field element.
- l. Technology Transfer Coordinator. Principal advisor to the Secretary on all matters relating to technology transfer and commercialization. This office was created under Title X, Section 1001 of the Energy Policy Act of 2005.

- m. Technology Transfer Policy Board. Board consisting of representatives of DOE Program Offices, the Office of General Counsel, and other parts of DOE that, in consultation with the Technology Transfer Coordinator, develop DOE policy on technology transfer.
8. CONTACT. For information about this Order, contact the Office of the Assistant General Counsel for Technology Transfer and Intellectual Property at 202-586-2802.

BY ORDER OF THE SECRETARY OF ENERGY:



ELIZABETH SHERWOOD-RANDALL
Deputy Secretary

CONTRACTOR REQUIREMENTS DOCUMENT
DOE O 483.1B, *DOE COOPERATIVE RESEARCH AND*
DEVELOPMENT AGREEMENTS

Regardless of the performer of the work, the Contractor is responsible for complying with the requirements of this Contractor Requirements Document (CRD). The contractor is responsible for flowing down the requirements of this CRD to subcontractors at any tier to the extent necessary to ensure the contractor's compliance with the requirements.

In addition to the requirements set forth in this CRD, contractors are responsible for complying with Attachments 2-9 to DOE O 483.1B referenced in and made a part of this CRD and which provide program requirements and/or information applicable to contracts in which this CRD is inserted.

Contractors must:

1. Establish and maintain a management system, including policy and procedures that ensures Cooperative Research and Development Agreement (CRADA) activities requirements are satisfied.
2. Develop in conjunction with the Heads of Field Elements appropriate performance measures for CRADA activities and support DOE's oversight and conduct of appraisals.
3. Submit to the DOE Contracting Officer, CRADAs and Joint Work Statements (JWSs) for review and approval, or in the alternative, appropriate certification for a request for a preliminary determination to work at the Contractor's own risk (the process for which is described in Attachment 2)..
4. Ensure proposed work involving human and/or animal subjects are in compliance with established regulations as well as coordinated in accordance with program, and contractual requirements for protection of these subjects.
5. Ensure projects are in compliance with DOE environmental, safety, and health requirements, including the National Environmental Protection Act, and 10 CFR Part 851 (Worker Safety and Health Program), if applicable..
6. Ensure projects are protected in accordance with applicable security, safeguards, and classification and controlled unclassified information policies and procedures, including the site security plan or supplemental security plan specific to a project, as well as CRDs for other Departmental directives governing the identification and protection of classified and controlled unclassified information.
7. Ensure contractor employees protect proprietary information and data provided by private sector collaborators and Participants in the conduct of CRADA activities as well as any generated data marked in accordance with the CRADA provisions. Any protectable data generated or exchanged as a result of this CRADA will be marked, handled, and safeguarded in accordance with all applicable federal laws, rules, regulations and DOE

Orders or directives, including but not limited to, the Trade Secrets Act (18 U.S.C. §1905), the Freedom of Information Act (FOIA) (5 U.S.C. §552), DOE's implementing FOIA regulations at 10 C.F.R. Part 1004, the Federal Technology Transfer Act (15 U.S.C. §3710a(c)), and DOE Order 471.3, Identifying and protecting Official Use Only Information

8. Request DOE approval for construction when that construction cost estimate exceeds the general plant project threshold. Approval by the cognizant Secretarial Officer and the Chief Financial Officer is required prior to initiation of work which exceeds the threshold.
9. Maintain a project summary listing of information on each active CRADA project.
10. Maintain project file information documenting policy compliance.
11. Provide a final technical report, appropriately marked, to DOE's Office of Scientific and Technical Information, at the completion or termination of the CRADA.
12. Submit information on CRADAs as part of the annual Federal Laboratory technology transfer report.
13. For CRADAs involving foreign participation, consult with the United States Trade Representative (USTR) as contractually required.
14. Non-Federal parties (also referred to as "Participants") are permitted to use funds previously obtained from federal sources to finance a project. However, when Federal funds are being used by a non-Federal party, such use must be consistent with the underlying Funding Agreement and special considerations must be taken into account including:
 - a. whether the non-Federal party's previous award contains authority for special data protection that justifies enhanced protection of information generated under the CRADA (i.e. protection of Protected CRADA Information) or in the alternative, limits data protection to a period of protection less than that provided under 15 U.S.C. § 3710a;
 - b. any potential inconsistencies in the U.S. Competitiveness clauses between the non-Federal party's award and the DOE Model CRADA language;
 - c. in case of inconsistencies between the non-Federal party's award and the CRADA, include a statement that indicates which agreement controls or ensure that such inconsistencies are addressed during negotiations; and
 - d. whether the non-Federal party has clear election rights to inventions made under its previous award.

ATTACHMENT 2

This Attachment provides information and/or requirements associated with DOE O 483.1B as well as information and/or requirements applicable to contracts in which the associated CRD (Attachment 1 to DOE O 483.1B) is inserted.

JWS/CRADA PROCESS

Procedures for review and approval of Contractor CRADAs are developed and implemented by the DOE field elements. The JWS is intended to be the primary tool for ensuring that the Contractor and DOE have a common understanding of the purpose, scope, schedule, and cost of work for a CRADA. DOE's approval of a JWS sets the parameters within which the contractor may negotiate the CRADA. A JWS may be approved before the corresponding CRADA is approved by DOE. Alternatively, a Contractor may submit the JWS and the corresponding CRADA together for approval simultaneously.

The DOE field element Contracting Officer will review the JWS for compliance with Federal and agency regulations and guidelines and approve the JWS pursuant to DOE policy. The DOE field element Contracting Officer may require concurrence from program managers, financial officer, legal and other reviewers pursuant to field office procedures. All issues and problems will be identified and resolved prior to approval. Attachment 6 (Joint Work Statement Format), presents the DOE JWS format to be used for all CRADAs. This format is also to be used by the Contractors when developing multi-laboratory CRADAs. The Statement of Work based on the work summary approved in the JWS will be made an annex to the CRADA. This JWS format may be supplemented by local field elements.

The DOE Model CRADA (Attachment 3) and Alternate Clauses, Additional Articles and General Guidance (Attachment 4) contain the approved language to be used in a CRADA. Once a CRADA has been approved, any amendment to the CRADA, other than a no-cost extension, requires DOE approval. The mechanics for the approval of such an amendment shall be developed by the cognizant field element and should be consistent with this Order. It is recognized that other models may be developed through appropriate entities in DOE. These include the Model Short Form CRADA (Attachment 5). If there is any question as to the validity of other models, Departmental elements should consult with the Assistant General Counsel for Technology Transfer and Intellectual Property.

The Contractor may begin work at its own risk on a CRADA prior to the CRADA being approved by submitting a request for a preliminary determination to the Contracting Officer and by providing advanced funding. The Contractor may request a preliminary determination that the proposed CRADA scope of work is consistent with its contract and the DOE mission. The Contracting Officer will use his/her best efforts to provide such a determination within three (3) business days. Such a request shall include a JWS (if not previously approved) and a certification that the CRADA contains terms and conditions previously approved by DOE with no deviations.

Upon such a determination from the Contracting Officer, the Contractor may begin work under the CRADA at the Contractor's risk pending final approval of the CRADA documentation. The

Contractor must submit the CRADA signed by both the Contractor and the Participant, to the Contracting Officer for approval within (10) business days of the preliminary determination.

The Contractor shall be responsible for providing adequate advance payment for CRADA work conducted after a preliminary determination has been made consistent with procedures defined in the Department's Financial Management Handbook. All costs associated with the performance of work under a preliminary determination are the responsibility of the Contractor as no Federal funds will be used to fund any work conducted under a preliminary determination. In addition, for any obligations or liabilities arising due to Contractor's work under a preliminary determination, the Contractor is entirely at risk and the Government shall bear no risk.

The Contractor shall not request, and the Contracting Officer shall not approve a Contractor's request, to begin work in advance of approval of the JWS and CRADA document if the Contractor, Contractor's parent, member, subsidiary, or other entity in which the Contractor, Contractor's parent, member or subsidiary has an equity interest is a party funding work in connection with the CRADA. Approval to work at the Contractors own risk shall not be granted for work with a Participant that is foreign owned or controlled, or which is using funds from a foreign source.

Cognizant Secretarial Officers may (but are not required to) place a reasonable cap (e.g. \$2M) on the amount of cost and/or liability that will be incurred by a Contractor arising from work performed during the period between a Contracting Officer's preliminary determination and a Contracting Officer's final approval of the work.

ATTACHMENT 3

This Attachment provides information and/or requirements associated with DOE O 483.1B as well as information and/or requirements applicable to contracts in which the associated CRD (Attachment 1 to DOE O 483.1B) is inserted.

DOE MODEL CRADA

This DOE Model CRADA (Attachment 3) and Alternate Clauses, Additional Articles and General Guidance (Attachment 4) are to be used by both the Laboratory and Participant to negotiate a final CRADA. DOE expects most laboratories to propose a Laboratory Model CRADA that will be approved by the cognizant DOE Head of Field Element, or if delegated to the cognizant Contracting Officer. These Laboratory Model CRADAs would be tailored from the DOE Model CRADA to specific M&O Contract and Contractor requirements. And for these reasons, each Laboratory Model CRADA may include additional articles, alternate clauses and/or custom language. Negotiations with a potential CRADA Participant would begin with the Laboratory Model CRADA and, if necessary, be modified appropriately using clauses from Attachment 4. For example, if the project involved the creation of software or trademarks, the appropriate clauses would be added to the Laboratory Model CRADA. Also, some laboratories may want more detail in Export Control Article or publication reviews (both in Attachment 4) as the standard language for that Laboratory Model CRADA.

Double underline clauses and phrases require Assistant General Counsel for Technology Transfer and Intellectual Property approval to modify or remove.

Submission of the JWS in accordance with the Joint Work Statement Format (Attachment 6) and the Laboratory CRADA will follow DOE policy and DOE field element requirements. Identification of specific Alternate Clauses, Additional Articles and General Guidance (Attachment 4) to be used in projects that deviate from the Laboratory Model CRADA will assist the cognizant DOE field element in reviewing/approving the CRADA package.

DOE MODEL CRADA

*STEVENSON-WYDLER (15 U.S.C. 3710a)
COOPERATIVE RESEARCH AND DEVELOPMENT
AGREEMENT (hereinafter "CRADA") No. _____*

BETWEEN

under its U.S. Department of Energy

Contract No. _____ (hereinafter "Contractor"),

AND

(hereinafter "Participant"),

both being hereinafter jointly referred to as the "Parties."

ARTICLE I: DEFINITIONS

- A. *"Background Intellectual Property" means the Intellectual Property identified by the Parties in Annex __, Background Intellectual Property, which was in existence prior to or is first produced outside of this CRADA, except that in the case of inventions in those identified items, the inventions must have been conceived outside of this CRADA and not first actually reduced to practice under this CRADA to qualify as Background Intellectual Property.*
- B. *"Contracting Officer" means the DOE employee administering the Contractor's DOE contract.*
- C. *"DOE" means the Department of Energy, an agency of the Federal Government.*
- D. *"Generated Information" means information, including data, produced in the performance of this CRADA.*
- E. *"Government" means the Federal Government of the United States of America and agencies thereof.*
- F. *"Intellectual Property" means patents, trademarks, copyrights, mask works, Protected CRADA Information, and other forms of comparable property rights protected by Federal law and foreign counterparts, except trade secrets.*
- G. *"Proprietary Information" means information, including data, which is developed at private expense outside of this CRADA, is marked as Proprietary Information, and embodies (i) trade secrets or (ii) commercial or financial information which is*

privileged or confidential under the Freedom of Information Act (5 U.S.C. 552 (b)(4)).

- H. *“Protected CRADA Information” means Generated Information which is marked as being Protected CRADA Information by a Party to this CRADA and which would have been Proprietary Information had it been obtained from a non-Federal entity.*
- I. *“Subject Invention” means any invention of the Contractor or Participant conceived or first actually reduced to practice in the performance of work under this CRADA.*

ARTICLE II: STATEMENT OF WORK, TERM, FUNDING AND COSTS

- A. *The Statement of Work is attached as Annex A.*
- B. *Notices: The names, postal addresses, telephone and email addresses for the Parties are provided in the Statement of Work. Any communications required by this CRADA, if given by postage prepaid first class U.S. Mail or other verifiable means addressed to the Party to receive the communication, shall be deemed made as of the day of receipt of such communication by the addressee, or on the date given if by email. Address changes shall be made by written notice and shall be effective thereafter. All such communications, to be considered effective, shall include the number of this CRADA.*
- C. *The effective date of this CRADA shall be the latter date of (1) the date on which it is signed by the last of the Parties or (2) the date on which it is approved by DOE. The work to be performed under this CRADA shall be completed within _____ months/years from the effective date.*
- D. *The Participant’s estimated contribution is \$_____, of which \$_____ is fund-in to the Laboratory. The Government’s estimated contribution, which is provided through the Contractor’s contract with DOE, is \$_____, subject to available funding.*

ARTICLE III: PERSONAL PROPERTY

All tangible personal property produced or acquired under this CRADA shall become the property of the Participant or the Government, depending upon whose funds were used to obtain it unless identified in the Statement of Work as being owned by the other Party. Personal property shall be disposed of as directed by the owner at the owner’s expense. All jointly funded property shall be owned by the Government. The Participant shall maintain records of receipts, expenditures, and the disposition of all Government property in its custody related to the CRADA.

ARTICLE IV: DISCLAIMER

THE GOVERNMENT, THE PARTICIPANT, AND THE CONTRACTOR MAKE NO EXPRESS OR IMPLIED WARRANTY AS TO THE CONDITIONS OF THE RESEARCH OR

ANY INTELLECTUAL PROPERTY, GENERATED INFORMATION, OR PRODUCT MADE OR DEVELOPED UNDER THIS CRADA, OR THE OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE RESEARCH OR RESULTING PRODUCT. NEITHER THE GOVERNMENT, THE PARTICIPANT, NOR THE CONTRACTOR SHALL BE LIABLE FOR SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES ATTRIBUTED TO SUCH RESEARCH OR RESULTING PRODUCT, INTELLECTUAL PROPERTY, GENERATED INFORMATION, OR PRODUCT MADE OR DEVELOPED UNDER THIS CRADA.

ARTICLE V: PRODUCT LIABILITY

Except for any liability resulting from any negligent acts, willful misconduct or omissions of the Contractor and the Government, the Participant indemnifies the Government and the Contractor for all damages, costs, and expenses, including attorney's fees, arising from personal injury or property damage occurring as a result of the making, using, or selling of a product, process, or service by or on behalf of the Participant, its assignees, or licensees, which was derived from the work performed under this CRADA. In respect to this article, neither the Government nor the Contractor shall be considered assignees or licensees of the Participant, as a result of reserved Government and Contractor rights. The indemnity set forth in this paragraph shall apply only if the Participant shall have been informed as soon and as completely as practical by the Contractor and/or the Government of the action alleging such claim and shall have been given an opportunity, to the maximum extent afforded by applicable laws, rules, or regulations, to participate in and control its defense, and the Contractor and/or the Government shall have provided all reasonably available information and reasonable assistance requested by the Participant. No settlement for which the Participant would be responsible shall be made without the Participant's consent unless required by final decree of a court of competent jurisdiction.

ARTICLE VI: RIGHTS IN SUBJECT INVENTIONS

Wherein DOE has granted the Participant and the Contractor the right to elect to retain title to their respective Subject Inventions, and wherein the Participant has the option to choose an exclusive license, for reasonable compensation, for a pre-negotiated field of use to the Contractor's Subject Inventions,

- A. *Each Party shall have the first option to elect to retain title to any of its Subject Inventions and that election shall be made: (1) for the Participant, within 12 months of disclosure of the Subject Invention to DOE or (2) for the Contractor, within the time period specified in its prime contract for electing to retain title to Subject Inventions. However, such election shall occur not later than 60 days prior to the time when any statutory bar might foreclose filing of a U.S. Patent application. The electing Party has one year to file a patent application after such election unless any statutory bar exists. If a Party elects not to retain title to any of its Subject Inventions or fails to timely file a patent application, the other Party shall have the second option to elect to obtain title to such Subject Invention within one year of*

notification and file a patent application within one year after such election, or no less than 30 days prior to a statutory bar, if any.

- B. The Parties agree to assign to DOE, as requested by DOE, the entire right, title and interest in any country to each Subject Invention where the Parties (1) do not elect pursuant to this article to retain/obtain such rights, or (2) elect to retain/obtain title to a Subject Invention but fail to have a patent application filed in that country on the Subject Invention or decide not to continue prosecution or not to pay any maintenance fees covering the Subject Invention. If DOE is granted a patent on Participant's Subject Invention, the Participant may request a non-exclusive license and DOE will determine whether to grant such license pursuant to statutory authority.*
- C. The Parties acknowledge that the Government retains a nonexclusive, nontransferable, irrevocable, paid-up license to practice or to have practiced for or on behalf of the United States every Subject Invention under this CRADA throughout the world. The Parties agree to execute a Confirmatory License to affirm the Government's retained license.*
- D. The Parties agree to disclose to each other each Subject Invention which may be patentable or otherwise protectable under U.S. patent law. The Parties agree that the Contractor and the Participant will disclose their respective Subject Inventions to DOE and each other within two (2) months after the inventor first discloses the Subject Invention in writing to the person(s) responsible for patent matters of the disclosing Party.*

These disclosures should be in sufficiently complete technical detail to convey a clear understanding, to the extent known at the time of the disclosure, of the nature, purpose, and operation of the Subject Invention. The disclosure shall also identify any known actual or potential statutory bars, e.g., printed publications describing the Subject Invention or the public use or "on sale" of the Subject Invention. The Parties further agree to disclose to each other any subsequently known actual or potential statutory bar that occurs for a Subject Invention disclosed but for which a patent application has not been filed. All Subject Invention disclosures shall be marked as confidential under 35 U.S.C. 205.

- E. The Parties agree to include within the beginning of the specification of any U.S. patent applications and any patent issuing thereon (including non-U.S. patents) covering a Subject Invention, the following statement: "This invention was made under a CRADA (identify CRADA number) between (name the Participant) and (name the laboratory) operated for the United States Department of Energy. The Government has certain rights in this invention."*
- F. The Parties acknowledge that DOE has certain march-in rights to any Subject Inventions in accordance with 48 CFR 27.304-1(g) and 15 U.S.C. 3710a(b)(1)(B) and (C).*

- G. *The Participant agrees to submit, for a period of five (5) years from the date of termination or completion of this CRADA and upon request of DOE, a nonproprietary report no more frequently than annually on efforts to utilize any Intellectual Property arising under the CRADA including information regarding compliance with U.S. Competitiveness provision of this CRADA.*

ARTICLE VII: RIGHTS IN DATA

- A. *The Parties agree that they shall have no obligations of nondisclosure or limitations on their use of, and the Government shall have unlimited rights in, all Generated Information produced and information provided by the Parties under this CRADA, except for restrictions on data provided for in this Article or data disclosed in a Subject Invention disclosure being considered for Patent protection.*
- B. *PROPRIETARY INFORMATION: Each Party agrees to not disclose Proprietary Information provided by the other Party to anyone other than the CRADA Participant, Contractor and its subcontractors (if any) performing work under this CRADA without written approval of the providing Party, except to Government employees who are subject to the statutory provisions against disclosure of confidential information set forth in the Trade Secrets Act (18 U.S.C. 1905). Government employees shall not be required to sign non-disclosure agreements due to the provisions of the above-cited statute.*

If Proprietary Information is orally disclosed to a Party, it shall be identified as such, orally, at the time of disclosure and confirmed in a written summary thereof, appropriately marked by the disclosing Party, within ____ days as being Proprietary Information.

All Proprietary Information shall be protected for a period of ____ years from the effective date of this CRADA, unless such Proprietary Information becomes publicly known without the fault of the recipient, shall come into recipient's possession without breach by the recipient of any of the obligations set forth herein, can be demonstrated by the recipient by written record that it is known prior to receipt from disclosing party, is disclosed by operation of law, or is independently developed by recipient's employees who did not have access to such Proprietary Information.

- C. *PROTECTED CRADA INFORMATION: Except where a Participant's Federal funding agreement prohibits such protection, each Party may designate and mark as Protected CRADA Information any Generated Information produced by its employees, which meets the definition in Article I and, with the agreement of the other Party, so designate any Generated Information produced by the other Party's employees which meets the definition in Article I. All such designated Protected CRADA Information shall be appropriately marked.*

For a period of ____ [not to exceed 5 years] from the date Protected CRADA Information is produced, the Parties agree not to further disclose such information and to use the same degree of care and discretion, but no less than reasonable care

and discretion, to avoid disclosure, publication or dissemination of such information to a third party, as the Party employs for similar protection of its own information which it does not desire to disclose, publish, or disseminate except:

- (1) as necessary to perform this CRADA;*
- (2) as published in a patent application or an issued patent before the protection period expires;*
- (3) as provided in Article X [REPORTS AND PUBLICATIONS];*
- (4) as requested by the DOE Contracting Officer to be provided to other DOE facilities for use only at those DOE facilities solely for Government use only with the same protection in place and marked accordingly..*
- (5) when a specific maximum time period for delaying the public release of data is authorized in the terms of a Government funding agreement used to fund this CRADA and that maximum period is shorter than the time period set forth in this Article for protecting Protected CRADA Information;*
- (6) to existing or potential licensees, affiliates, customers, or suppliers of the Parties in support of commercialization of the technology with the same protection in place. Disclosure of the Participant's Protected CRADA Information under this subparagraph shall only be done with the Participant's consent; or*
- (7) as mutually agreed to by the Parties in advance.*

The obligations of this paragraph shall end sooner for any Protected CRADA Information which shall become publicly known without fault of either Party, shall come into a Party's possession without breach by that Party of the obligations of paragraph above, or shall be independently developed by a Party's employees who did not have access to the Protected CRADA Information. Federal Government employees who are subject to 18 USC 1905 may have access to Protected CRADA Information and shall not be required to sign non-disclosure agreements due to the provisions of the statute.

- D. COPYRIGHT: The Parties may assert Copyright in any of their Generated Information. Assertion of Copyright generally means to enforce or give an indication of an intent or right to enforce such as by marking or securing Federal registration. Copyrights in co-authored works by employees of the Parties shall be held jointly, and use by either Party shall be without accounting.*

For all Generated Information, the Government has for itself and others acting on its behalf, a royalty-free, nontransferable, nonexclusive, irrevocable worldwide copyright license to reproduce, prepare derivative works, distribute copies to the

public, and perform publicly and display publicly, by or on behalf of the Government, in all copyrightable works produced in the performance of this CRADA, subject to the restrictions this Article places on publication of Proprietary Information and Protected CRADA Information.

The Parties agree that no computer software will be created under this CRADA. If the scope of work changes to create computer software, then the CRADA will be amended accordingly.

The Parties agree to place Copyright and other notices, as appropriate for the protection of Copyright, in human-readable form onto all physical media, and in digitally encoded form in the header of machine-readable information recorded on such media such that the notice will appear in human-readable form when the digital data are off loaded or the data are accessed for display or printout.

ARTICLE VIII: U.S. COMPETITIVENESS

The Parties agree that a purpose of this CRADA is to provide substantial benefit to the U.S. economy.

- A. *In exchange for the benefits received under this CRADA, the Participant therefore agrees to the following:*
- (1) *Products embodying Intellectual Property developed under this CRADA shall be substantially manufactured in the United States, and*
 - (2) *Processes, services, and improvements thereof which are covered by Intellectual Property developed under this CRADA shall be incorporated into the Participant's manufacturing facilities in the United States either prior to or simultaneously with implementation outside the United States. Such processes, services, and improvements, when implemented outside the United States, shall not result in reduction of the use of the same processes, services, or improvements in the United States.*
- B. *The Contractor agrees to a U.S. Industrial Competitiveness clause in accordance with its prime contract with respect to any licensing and assignments of its Intellectual Property arising from this CRADA, except that any licensing or assignment of its intellectual property rights to the Participant shall be in accordance with the terms of paragraph A of this Article.*

ARTICLE IX: EXPORT CONTROL

THE PARTIES UNDERSTAND THAT MATERIALS AND INFORMATION RESULTING FROM THE PERFORMANCE OF THIS CRADA MAY BE SUBJECT TO EXPORT CONTROL LAWS AND THAT EACH PARTY IS RESPONSIBLE FOR ITS OWN COMPLIANCE WITH SUCH LAWS. EXPORT LICENSES OR OTHER AUTHORIZATIONS FROM THE U.S. GOVERNMENT MAY BE REQUIRED FOR THE EXPORT OF GOODS,

TECHNICAL DATA OR SERVICES UNDER THIS AGREEMENT. THE PARTIES ACKNOWLEDGE THAT EXPORT CONTROL REQUIREMENTS MAY CHANGE AND THAT THE EXPORT OF GOODS, TECHNICAL DATA OR SERVICES FROM THE U.S. WITHOUT AN EXPORT LICENSE OR OTHER APPROPRIATE GOVERNMENTAL AUTHORIZATION MAY RESULT IN CRIMINAL LIABILITY.

ARTICLE X: REPORTS AND PUBLICATIONS

- A. *The Parties agree to produce the following deliverables and provide to DOE Office of Scientific and Technical Information (OSTI):*
- (1) *an initial abstract suitable for public release at the time the CRADA is executed;*
 - (2) *a final report, upon completion or termination of this CRADA, to include a list of Subject Inventions; and*
 - (3) *other scientific and technical information in any format or medium that is produced as a result of this CRADA that is useful to the Government or the public as specified by and upon request from DOE no later than two years from submission of the final report to OSTI.*

The Parties acknowledge that the Contractor has the responsibility to timely provide the above information to OSTI. Furthermore, item (2) above should also be provided to the DOE field office.

- B. *The Parties agree to secure pre-publication review from each other wherein the non-publishing Party shall provide within 30 days any written objections to be considered by the publishing Party.*
- C. *The Parties agree that neither will use the name of the other Party or its employees in any promotional activity, such as advertisements, with reference to any product or service resulting from this CRADA, without prior written approval of the other Party.*

ARTICLE XI: FORCE MAJEURE

No failure or omission by the Contractor or the Participant in the performance of any obligation under this CRADA shall be deemed a breach of this CRADA or create any liability if the same shall arise from any cause or causes beyond the control of the Contractor or the Participant, including but not limited to the following, which, for the purpose of this CRADA, shall be regarded as beyond the control of the Party in question: Acts of God, acts or omissions of any government or agency thereof, compliance with requirements, rules, regulations, or orders of any governmental authority or any office, department, agency, or instrumentality thereof, fire, storm, flood, earthquake, accident,

acts of the public enemy, war, rebellion, insurrection, riot, sabotage, invasion, quarantine, restriction, transportation embargoes, or failures or delays in transportation.

ARTICLE XII: DISPUTES

The Parties shall attempt to jointly resolve all disputes arising from this CRADA. In the event a dispute arises under this CRADA, the Participant is encouraged to contact Contractor's Technology Partnerships Ombudsman in order to further resolve such dispute before pursuing third-party mediation or other remedies. If the Parties are unable to jointly resolve a dispute within 60 days, they agree to submit the dispute to a third-party mediation process that is mutually agreed upon by the Parties. To the extent that there is no applicable U.S. Federal law, this CRADA and performance thereunder shall be governed by the laws of the State of _____, without reference to that state's conflict of laws provisions.

ARTICLE XIII: ENTIRE CRADA, MODIFICATIONS, ADMINISTRATION AND TERMINATION

- A. *This CRADA with its annexes contains the entire agreement between the Parties with respect to the subject matter hereof, and all prior representations or agreements relating hereto have been merged into this document and are thus superseded in totality by this CRADA.*
- B. *Any agreement to materially change any terms or conditions of this CRADA or the annexes shall be valid only if the change is made in writing, executed by the Parties hereto, and approved by DOE.*
- C. *The Contractor enters into this CRADA under the authority of its prime contract with DOE. The Contractor is authorized to and will administer this CRADA in all respects unless otherwise specifically provided for herein. Administration of this CRADA may be transferred from the Contractor to DOE or its designee with notice of such transfer to the Participant, and the Contractor shall have no further responsibilities except for the confidentiality, use and/or nondisclosure obligations of this CRADA.*
- D. *This CRADA may be terminated by either Party upon ___ days written notice to the other Party. If Article III provides for advance funding, this CRADA may also be terminated by the Contractor in the event of failure by the Participant to provide the necessary advance funding.*

In the event of termination by either Party, each Party shall be responsible for its share of the costs incurred through the effective date of termination, as well as its share of the costs incurred after the effective date of termination, and which are related to the termination.

FOR CONTRACTOR:

BY _____

TITLE _____

DATE _____

FOR PARTICIPANT:

BY _____

TITLE _____

DATE _____

ATTACHMENT 4

This Attachment provides information and/or requirements associated with DOE O 483.1B as well as information and/or requirements applicable to contracts in which the associated CRD (Attachment 1 to DOE O 483.1B) is inserted.

TAILORABILITY, ALTERNATE CLAUSES, ADDITIONAL ARTICLES AND GENERAL GUIDANCE

I. Tailorability

GENERAL GUIDANCE:

In unique situations, where the standard terms and conditions of a CRADA are not workable, field elements may modify, add to or remove certain standard terms and conditions. Any changes to the standard terms and conditions must be covered by and not conflict with DOE's statutory CRADA authority, not conflict with the terms of the applicable M&O contract, and be approved by the cognizant DOE CO with concurrence from DOE Patent Counsel.

Unique situations include, but are not limited to, transactions that lack a great deal of human collaboration or those with certain federal flow-down requirements. In extraordinary situations, a third-party agreement may be entered into under DOE's CRADA authority as long as it is appropriately covered by, and not in conflict with statutory CRADA requirements or the terms of the applicable M&O contract, and is approved by the cognizant DOE CO with concurrence from DOE Patent Counsel.

As DOE develops or approves changes to the standard terms and conditions of a

CRADA that may apply, or might be useful at more than one facility, it will endeavor to post such examples on the Office of Technology Transitions website to make such examples more widely available, although their use will still be subject to Contracting Officer approval.

OPTIONAL ADDITIONAL LANGUAGE TO ADDRESS FEDERAL FLOWDOWNS:

The Facility Contractor's performance of the SOW shall be conducted consistent with the terms and conditions of its M&O Contract with DOE, and is subject only to the terms and conditions of the CRADA and the terms and conditions of the M&O Contract. If the Participant's funding is secured through an agency award (such as a SBIR, STTR, Cooperative Agreement or Federal Contract), the Contractor and Participant should determine whether the terms and conditions of the agency award, including the intellectual property terms and conditions and any flow-down provisions, conflict with the terms and conditions of the CRADA. The Participant should seek guidance or a variance from the agency issuing the award regarding any perceived or actual conflicts. However, the Contractor and Participant may request changes in the CRADA to address any perceived or actual conflicts between the CRADA and the agency award. Any changes to the CRADA must be covered by and not conflict with DOE's statutory CRADA authority, not conflict with the terms of the applicable M&O contract, and be approved by the

cognizant DOE CO with concurrence from DOE Patent Counsel. All costs associated with these types of changes must be reimbursed by the Participant.

II. ALTERNATE CLAUSES

In addition to the guidance in the Tailorability section above, Laboratories can replace clauses in the DOE Model CRADA or Laboratory Model CRADA with language from this Attachment as appropriate. These clauses are pre-approved by DOE and rarely require specific DOE approval. Use of one of these pre-approved clauses is encouraged as it will speed up the review and approval process for the CRADA by the DOE field office.

ARTICLE I: DEFINITIONS

These definitions may be added when appropriate:

ADDITIONAL DEFINITION: Affiliate

Any of the following definitions for Affiliate can be used when the CRADA is with a consortium or the CRADA Participant is a subsidiary or parent company. The CRADA may be appropriately modified to extend the rights and responsibilities to Affiliates (particularly regarding intellectual property).

“Affiliate” means any entity in which the Participant owns or controls, directly or indirectly, at least 50% of the voting stock or equity.

“Affiliate” means the member companies of _____ [consortium] and any entity designated by such a member company, in which the member company owns or controls, directly or indirectly, at least 50% of the voting stock or equity.

“Affiliate(s)” of a Party means any company, partnership or other legal entity that directly or indirectly controls, is controlled by, or is under common control with a Party hereto, either (1) by direct or indirect ownership of over 50 percent of the outstanding shares of the entity or the party, or (2) by directly or indirectly having the right to designate over 50 percent of its directors or in the case of any entity other than a corporation, persons exercising similar authority.

ADDITIONAL DEFINITION: Foreign Interests

When the need for a foreign ownership, control, or influence (FOCI) review has been determined to exist and where Article IX, Export Control, has been appropriately modified, the following two definitions should be added:

“Foreign Interest” is defined as any of the following:

- (1) A foreign government or foreign government agency;*
- (2) Any form of business enterprise organized under the laws of any country other than the United States or its possessions;*

- (3) *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 person; or*
- (4) *Any person who is not a U.S. citizen.*

“Foreign ownership, control, or influence (FOCI)” means the situation where the degree of ownership, control, or influence over a Participant by a foreign interest is such that a reasonable basis exists for concluding that compromise of classified information or special nuclear material, as defined in 10 CFR Part 710.5, may result.

ADDITIONAL DEFINITION: Laboratory Tangible Research Products

If Laboratory Tangible Research Products (LTRP) are likely to be developed in the CRADA, this definition and an alternate Personal Property provision (Article III) may be used.

“Laboratory Tangible Research Products” or “LTRP” means tangible material results of research that: (i) can be used for replication, reproduction, evaluation or confirmation of the research effort, or to evaluate its potential commercial utility; (ii) are not materials generally commercially available; and (iii) were made by one or more of the Parties in the performance of this CRADA. LTRP includes, without limitation, “Laboratory Biological Materials,” which is a biological material that can be replicated or reproduced, such as plasmids, deoxyribonucleic acid molecules, ribonucleic acid molecules, living organisms of any sort and their progeny, including viruses, prokaryote and eukaryote cell lines, transgenic plants and animals, and any derivatives or modifications thereof or products produced through their use or associated biological products.

ADDITIONAL DEFINITION: Other Protected Data

The following definition may be added if the CRADA involves Federal funding (from DOE or other agencies) that allows restrictions on release and marking of data (an additional paragraph in Article VII Rights in Data references this definition):

“Other Protected Data” means data first produced in the performance of an award, contract, or other agreement with DOE or another federal agency which is marked as being protected from public disclosure or other uses for a particular period time in accordance with that award, contract, other agreement or other statutory authority.

ALTERNATE DEFINITIONS: These alternate definitions may be used if desired:

“Intellectual Property” means patents, copyrights, trademarks and mask works protected by Federal law and foreign counterparts, except trade secrets.

“Proprietary Information” means information, including data, which embodies (i) trade secrets or (ii) commercial or financial information which is privileged or confidential under the Freedom of Information Act (5 U.S.C. 552 (b)(4)), either of which is developed at private expense outside of this CRADA and which is marked as Proprietary Information.

GENERAL GUIDANCE:

A definition section must include definitions for DOE Contracting Officer, DOE, Generated Information, Subject Invention, and any other terms that would be used in the CRADA. Additional definitions can be added based on the scope of work performed under the CRADA. The definitions for Trademark and Mask Works are located in the Additional Articles section below.

The definition for Background Intellectual Property (see Attachment 3, Article I) may not be all-inclusive (e.g., pre-existing invention disclosures, which may become Subject Inventions if reduced to practice under the CRADA, or copyrighted software). It is essential that the existence of this additional Background Intellectual Property be brought to the attention of the Participant before the CRADA is signed. This can be done by either changing the definition or by using a separate article on Background Intellectual Property to recognize such Background Intellectual Property. Additionally, it should be made clear either in an annex listing Background Intellectual Property or in one of the separate articles on Background Intellectual Property, if used, that the only Background Intellectual Property that need be identified is that necessary to perform the CRADA or practice the results of the CRADA, as appropriate.

ARTICLE II: STATEMENT OF WORK, TERM, FUNDING AND COSTS

ALTERNATE LANGUAGE: The following paragraph can be used for paragraph C for CRADAs where the Participant will send advance funds to the Contractor.

The effective date of this CRADA shall be the latter date of (1) the date on which it is signed by the last of the Parties, (2) the date on which it is approved by DOE, or (3) the date on which the advance funding referred to in this Article is received by the Contractor. The work to be performed under this CRADA shall be completed within _____ months/years from the effective date.

ALTERNATE LANGUAGE: The following paragraph can be used for paragraph D for CRADAs where the Participant will provide 100% funds for the CRADA. It is understood that the CRADA must include elements of collaboration between the Parties when Participant provides all the funding for the CRADA.

The Participant’s estimated contribution is \$ _____ .

ADDITIONAL PARAGRAPH: Advance Payment and Funding

The following provides advance payment funding requirements to be included in paragraph E. They are all consistent with current DOE policy on requiring advance payments, as elaborated in the DOE's Financial Management Handbook, Chapter 13. Contract specialists will need to consult the handbook for the latest information.

FUNDING REQUIREMENTS:

- (1) *Provision to be used for most Participants, where the work (for Participant's funds-in share) is greater than \$25,000 and will last longer than 60 days.*

The Participant shall provide to the Contractor, prior to any work being performed, a budgetary resource sufficient to cover anticipated work that will be performed for the Participants directly funded share for the first billing cycle. In addition, the Participant shall provide 60 days of additional funding to ensure that funds remain available for the Participants directly funded share for subsequent billing cycles.

A billing cycle is the period of time between billings, usually 30 days. The billing cycle is complete when the customer is billed for services rendered. However, with Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) Awards described under Chapter 13 of the Financial Management Handbook, the maximum funding that can be collected from the Participant may not exceed 30 days of work to be performed under the contract. Please see Chapter 13 for additional requirements and funding available for these types of awards.

- (2) *Provision where the Participant's contribution in direct funds to the contractor is \$25,000 or less or where the work will be completed in 60 days or less:*

The Participant shall provide Contractor full funding prior to beginning work covered by those funds.

However, with Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) Awards described under Chapter 13 of the Financial Management Handbook, the maximum funding that can be collected from the Participant may not exceed 30 days of work to be performed under the contract. Please see Chapter 13 for additional requirements and funding available for these types of awards.

- (3) *Additional Funding Requirements*

Field CFOs or Site Offices may require additional advance payments to account for estimated termination costs or other costs as appropriate for individual projects.

- (4) *No DOE budgetary resources under this CRADA shall be utilized to fund work directly to CRADA Participant.*

Exceptions to Funding Requirements

Exceptions to DOE's normal advance funding requirements can be found under Chapter 13 of the Financial Management Handbook.

GENERAL GUIDANCE:

The CRADA must include a Statement of Work, which must include a technical description of the scope encompassed by the proposed CRADA, including tasks, the party responsible for the tasks, and a list of deliverables (reports, prototypes, etc.). The Statement of Work should also include who the principal investigators for each party will be; the contact information for official notices unless an Additional Article For NOTICES (below) is added to the CRADA; who will provide what funds, personnel, services, and property; who will do what reporting on the work; and procedures for interaction between the parties to accomplish the Statement of Work, which is the objective of the CRADA. The parties may also wish to set forth levels of commitment to the CRADA, in terms of full-time equivalent numbers of various staff and personnel classifications.

Any Proprietary Information included in the Statement of Work should be clearly marked. However, Proprietary Information should not be included in the Statement of Work unless the parties consider it absolutely necessary to define the work. The name of the Participant cannot be considered proprietary. Cooperative research performed in CRADAs involves industrial Participants that have information which they consider to be of commercial value. Such commercially valuable information could possibly be divulged in the formal CRADA document, including the incorporated Statement of Work. Because taxpayer funds are used in the Government share of CRADAs, it is possible that there will be requests for public release of the formal CRADA document. Commercially valuable information that the Participant considers sensitive should not routinely be included in the CRADA, including the accompanying Statement of Work, unless specifically needed. Should DOE receive a request for public release of the formal CRADA document, only business-sensitive or proprietary information that qualifies under 5 U.S.C. 552(b)(4) will be exempt from release after appropriate review.

In accordance with this order, each CRADA must provide a benefit consistent with the program missions at the facility and the facility mission established by the Cognizant Secretarial Officer and must involve collaboration between the CRADA Participant and the DOE laboratory). CRADAs supported by 100% direct funds-in from the Participant must also include elements of in-kind contributions by the Participant.

There must be a statement of funding for the CRADA, showing the estimated contributions of the parties. The statement must clearly state that the Government's estimated contribution is provided through the contractor's contract with DOE and is subject to available funding, except for 100% funds-in CRADAs, for which there is no Government contribution. The statement may indicate that the Participant's contributions are also subject to availability of

funds and should include provisions that describe the obligations of the parties relative to exceeding the estimated costs. If the cost of the CRADA exceeds the estimated contributions, then CRADA will need to be amended to increase the amounts.

The statement of funding must include a provision addressing advance payment requirements whenever there are “funds-in” from the Participant. The contractor may not agree to waive advance payments unless the contractor is using its own funds (e.g., from royalties, award/management fees or non-Federal corporate funds). The contractor may, however, negotiate variations to the standard advance payment requirement for small businesses and others, consistent with Chapter 13 of DOE’s Financial Management Handbook.

Program officers and Cognizant Secretarial Officers may provide supplemental guidance on funding and other issues to the Head of the Field Element to help avoid surprises and ensure effective coordination of CRADAs and management of multi-year resource requirements. For example, there could be specific requirements to get either written approval from, or provide written notice to, the Cognizant Secretarial Officer and/or the appropriate program office for 100% funds-in CRADAs involving more than \$1 million dollars total effort per year.

Under current DOE policy, funds previously obtained from Federal sources can be used to finance a non-Federal Participant’s share of a project. One of the purposes of CRADAs is to stimulate private investment in collaborations with laboratories. It is important that the overall program be supported with significant private funds. However, DOE generally is unconcerned if the funds for the Participant’s share of a specific CRADA come ultimately from some other Federal program, so long as the decision process for obtaining those funds precedes the final CRADA negotiation and the obtaining of those funds complies with the rules of that process. If the funds come from some other part of the Department, extra care must be taken to ensure that there is no real or apparent conflict of interest and that there is fairness of opportunity.

Other contractual obligations of the Participant with respect to the Government are not overridden by this CRADA.

ARTICLE III: PERSONAL PROPERTY

ALTERNATE LANGUAGE: Any of the following options could be used instead.

OPTION 1:

All tangible personal property produced or acquired under this CRADA (specifically excluding Intellectual Property rights, Background Intellectual Property, and Proprietary Information) shall become the property of the Participant or the Government, depending upon whose funds were used to obtain it. Personal property shall be disposed of as directed by the owner at the owner’s expense. There shall not be any jointly funded property under this CRADA except by the mutual agreement of the Parties. The Participant shall maintain records of receipts, expenditures, and the disposition of all Government property in its custody related to the CRADA.

OPTION 2:

Participant shall have title to any tangible personal property the Contractor produces or acquires using solely the Participant's funds under this CRADA whose cost is greater than \$5,000 (unless identified otherwise in Annex A). The Government shall have title to all other tangible personal property produced or acquired by the Contractor. The Participant shall maintain records of receipts, expenditures, and the disposition of all Government property in its custody related to the CRADA and with a value greater than \$5,000.

OPTION 3: Laboratory Tangible Research Products (LTRP)

Definition of Laboratory Tangible Research Products (LTRP) should be added to Article I if using this option

Participant shall have title to any tangible personal property the Contractor produces (other than Laboratory Tangible Research Products) or acquires using solely the Participant's funds under this CRADA whose cost is greater than \$5,000, unless identified otherwise in Annex A. The Government shall have title to all other tangible personal property produced or acquired by the Contractor. The Participant shall maintain records of receipts, expenditures, and the disposition of all Government property with a value greater than \$___ in its custody related to the CRADA

ADDITIONAL PARAGRAPH: Transferring Title of Property

Personal property provided by the Participant for use in this CRADA may be permanently transferred to Government ownership, so long as the Parties mutually agree to such transfer, and an appropriate DOE or other Federal agency program representative verifies that the personal property would have continuing value to Government-funded research efforts.

ADDITIONAL PARAGRAPH: Inspecting Government Property

Where Government property will be under the Participant's control, Contractors should include language regarding periodic access, inspection, inventory, and records of the property. In such a case, the Contractor may choose to add the following language:

The Participant shall, with reasonable notice, grant to the Government and to the Contractor periodic access to Participant's premises during regular business hours for the purposes of inspection of CRADA-related Government property in its custody.

GENERAL GUIDANCE:

There must be agreement among the parties as to who will retain what tangible property, if any is to be obtained, acquired, produced, or modified in the course of the CRADA. Remember that Government property disposal regulations pertain to any property in which Government money is involved.

ARTICLE IV: DISCLAIMER

GENERAL GUIDANCE:

There must be a disclaimer of express or implied warranties as to the conduct of the research. This statement should be in the form of a Uniform Commercial Code (UCC)-type disclaimer, which should be conspicuous in the CRADA so as to meet the standards of due notice. One way to do this is to use bold type, all capital letters, or to have an especially large type font specifying the disclaimer.

ARTICLE V: PRODUCT LIABILITY

OPTION 1: Use of Hold Harmless Provision

As an alternate to using the standard language for product liability, a hold harmless provision may be substituted therefor, such as the following:

Except for any liability resulting from any negligent acts or omissions of the Contractor or the Government, the Participant agrees to hold harmless the Government and the Contractor for all damages, costs, and expenses, including attorney's fees, arising from personal injury or property damage occurring as a result of the making, using, or selling of a product, process, or service by or on behalf of the Participant, its assignees, or licensees, which was derived from the work performed under this CRADA.

OPTION 2: States and State Agencies

Most U.S. States prohibit indemnification obligations. Furthermore, State Agencies and State colleges or universities do not commercialize technology, but license it to third parties. Therefore, the following clause may be used when the CRADA involves a U.S. State, a State Agency, a State college or university, or a political subdivision of a State or an agency thereof:

For licenses granted or assignment made by the Participant to any third party in Intellectual Property derived from the work performed under this CRADA, such licenses or assignments shall include the requirement that the third party shall indemnify the Government, Contractor, and Participant for all damages, costs, and expenses, including attorneys' fees, arising from personal injury or property damage occurring as a result of the making, using, or selling of a product, process, or service by or on behalf of such third party, its assignees, or licensees, provided, however, such third parties shall not be required to indemnify the Government, Contractor or Participant for any negligent acts or omissions made by the Government, Contractor or Participant respectively.

OPTION 3: Purchase of Product Liability Insurance

The Participant or the Contractor may agree to purchase and maintain adequate product liability insurance to protect the Government and the Contractor against product liability claims. The cost for this insurance shall not be charged directly or indirectly to the Government. Product liability insurance is appropriate for CRADAs when there is a high risk of personal injury or property damage from using the product, process, or service derived from work performed under the CRADA. An example of a suitable provision is:

The (Participant, Contractor, or Parties) agree to obtain and maintain product liability insurance in the amount of \$_____ during the life of this CRADA and subsequently for the life of any products, processes, or services resulting from work under the CRADA. The Government and the Contractor shall be covered against any claims for product liability as a result of this insurance. A copy of this product liability insurance policy shall be provided to both the Government and the Contractor, including any material modifications thereto, including any notices of termination.

OPTION 4: Public Domain or Not Commercialized

If the Participant will either put all intellectual property developed under the CRADA in the public domain (such as publishing the data and inventions, or releasing the information or not marking as Protected CRADA Information) or does not plan to commercialize, the following statement can be used in place of a Product Liability clause:

The Participant agrees that all of its Intellectual Property generated under this Agreement will be placed in the public domain (with the appropriate disclaimer) or the results will be a product, process, or service unlikely to be commercialized. Therefore, a standard Product Liability provision where the Participant would indemnify the Contractor and the Government is not included in this CRADA.

GENERAL GUIDANCE:

If the results of the research covered by the CRADA are restricted in any way for the purpose of commercialization (such as through patents, copyrights, or Protected CRADA Information), or if there is a specific, identifiable laboratory technology being transferred, there must be a provision that indemnifies the Contractor and the Government from all costs related to personal injury and property damage that may result from the Participant's commercialization and use of a product, process, or service. The protection should usually take the form of the above provision on product liability.

Special situations may provide for use of Option 4 where standard product liability provision is not used. Since the Contractor would license its Intellectual Property under its M&O Contract requiring product liability protection, this option is limited to the Participant

agreeing not to commercialize its intellectual property. The following are examples of use of this option:

- (1) When the results will be a product, process, or service unlikely to be commercialized (e.g., basic research), circumstances must be such that they justify the exclusion of the product liability indemnity provision from the CRADA. Such determinations will be made on a case-by-case basis and will be supported by facts indicating there is little or no potential risk of liability to the Government or the Contractor. Approval from the DOE Contracting Officer will be required when this occurs.
- (2) When the results are to be placed totally in the public domain (i.e., no Protected CRADA Information or Intellectual Property) and accompanied by a DOE-approved disclaimer; if the purpose of the CRADA is to provide information which is intended to be placed in the public domain with an appropriate disclaimer *provision, a product liability provision need not be used.*

NOTE: If during the CRADA project, the Participant finds that the results will be a product, process, or service to be commercialized, then the CRADA can be amended to include a standard Product Liability clause. If the CRADA is completed, the Participant will need to execute a side agreement for product liability to protect the Contractor and Government.

If the Participant is a state entity (e.g. U.S. state university or college), the phrase “to the extent permitted by [name of state] State law” may be added to the beginning of the clause in the DOE Model CRADA. This is only permissible per letter from the state Attorney General for particular states, this provision may be suitably modified or deleted with DOE Contracting Officer approval after conferring with cognizant DOE Patent Counsel.

ARTICLE VI: RIGHTS IN SUBJECT INVENTIONS

PARAGRAPH A: The Contractor, with approval of cognizant DOE Patent Counsel, may tailor its own Laboratory Model CRADA language for providing rights for the Participant and Contractor regarding ownership of Subject Inventions in lieu of the standard version in the CRADA. The invention rights provisions in a CRADA should insure timely reporting and patenting of Subject Inventions. As prudence dictates modifying any deadlines (e.g. reporting) contained in the clause to better implement changes in the laws, the Assistant General Counsel for Technology Transfer and Intellectual Property will provide model language.

ADDITIONAL PARAGRAPH: Joint Inventions can also be addressed in Paragraph A by adding the following clause:

For Subject Inventions that are joint Subject Inventions of the Contractor and the Participant, title to such Subject Inventions shall be jointly owned by the Contractor and the Participant.

ADDITIONAL PARAGRAPH: Requiring Cooperation in Preparing Patent Applications:

If a patent application is filed by the non-inventing Party (“Filing Party”), the inventing Party shall reasonably cooperate and assist the Filing Party, at the Filing Party’s expense, in executing a written assignment of the Subject Invention to the Filing Party and in otherwise perfecting the patent application, and the Filing Party shall have the right to control the prosecution of the patent application. The Parties shall agree among themselves as to who will file patent applications on any joint Subject Invention.

ADDITIONAL PARAGRAPH: Cross Licensing Provision

Each Party grants the other Party a nonexclusive, transferable, irrevocable, paid-up license to practice or to have practiced for or on behalf of that Party every Subject Invention arising out of this CRADA throughout the world, with a right to grant sublicenses of no greater scope to others.

ADDITIONAL PARAGRAPH: Commercializing In Different Countries

When it is appropriate for each party to lead commercialization in different countries, and the paragraphs regarding filing of patent applications and costs have been addressed, the following provisions may be added.

- (1) *The Contractor grants to Participant an exclusive, royalty-free license, including the right to sublicense, in each patent application filed in _____[country] on any Contractor Subject Invention and any resulting patent in _____[country] from such patent application in which the Contractor acquires title. The Participant grants to Contractor an exclusive, royalty-free license, including the right to sublicense, in each patent application filed in the United States on any Participant Subject Invention and any resulting patent in the United States from such patent application in which the Participant acquires title.*
- (2) *Each Party grants to the other Party a nonexclusive, transferable irrevocable, paid-up license to practice or to have practiced for or on behalf of that Party every Subject Invention arising out of this CRADA in any country other than _____[country] or the United States, with a right to grant sublicenses of no greater scope to others.*

ADDITIONAL LANGUAGE: Laboratory Subcontracts

If the Contractor will be issuing subcontracts to perform work listed in the Statement of Work of the CRADA, and where the subcontracts are not funded with Federal funds or are otherwise subject to exceptional circumstances (e.g. 37 C.F.R. 401.3), there should be a paragraph addressing the Participant's option for a field-of-use license in the subcontractor's subject inventions in compliance with National Technology Transfer and Advancement Act of 1995 (see General Guidance section below regarding the ACT). Also, the Contractor should ensure that similar requirements are in the subcontract with the Subcontractor.

The following definitions should be added to Article I:

“Subcontractor” means a subcontractor of the Contractor or Participant at any tier.

The following paragraph should be added to this Article:

For each Subject Invention made by a Subcontractor of the Contractor performing work under this CRADA, Participant shall have the option during and for a period of _____ months after the Subject Invention of the Contractor's Subcontractor is reported to DOE and Contractor, to obtain a license within the field of use that Participant and Contractor have agreed upon. The license shall be on reasonable terms and conditions agreed upon by Participant and the Subcontractor, including the payment of negotiated license fees and royalties.

General Guidance: If Federal funds (from Contractor or Participant's funds-in) are used and no exceptional circumstance exists (e.g. 37 C.F.R. 401.3), Bayh-Dole applies such that the subcontractor does not have to provide an exclusive license to Participant. If the Subcontractor does not qualify under Bayh-Dole (i.e., large business), then a patent waiver may need to be issued by DOE Patent Counsel.

ALTERNATE LANGUAGE: Exclusive License to Participant.

The Parties can modify the standard preamble to this Article by replacing “and wherein the Participant has the option to choose an exclusive license, for reasonable compensation, for a pre-negotiated field of use to the Contractor's Subject Invention” with the following:

The Participant acknowledges that the Contractor has offered to the Participant the option to choose an exclusive license for a pre-negotiated field of use for reasonable compensation for any Subject Invention made in whole or in part by a Contractor employee.

ADDITIONAL LANGUAGE: Exclusive License to Participant.

The following options can be used as Additional Paragraphs defining the length of time that the Participant has to notify the Contractor of exercising the exclusive right:

OPTION 1:

The Participant has the option for ____ (insert a time period of not less than 6 months) after Contractor Subject Invention is disclosed to the Participant to choose an exclusive license in Contractor's Subject Inventions in the field of use of _____ (insert the field of use negotiated between the Parties).

OPTION 2:

During the term of this CRADA and for a period of 6 months after the termination or completion of the CRADA, the Participant shall have the opportunity, pursuant to 15 U.S.C. 3710a, to obtain a license to Contractor's Subject Inventions. In particular, the Participant shall have the option to obtain, up to and including, an exclusive license to Contractor's Subject Inventions within a defined field of use on agreed-upon reasonable terms and conditions, including the payment of negotiated license fees and royalties.

OPTION 3:

In Annex ____, the Parties have negotiated greater rights in the Contractors Subject Inventions pursuant to 15 U.S.C. 3710a.

OPTION 4:

The Participant has the option for ____ (insert a time period) plus a period of not more than 6 months after completion or termination of this CRADA to choose an exclusive license in Contractor's Subject Inventions in the field of use of _____ (insert the field of use negotiated between the Parties).

ADDITIONAL LANGUAGE: Background Intellectual Property

Usually, a list of the Background Intellectual Property (BIP) is attached to the CRADA as an Annex and referenced in the definition for BIP. This provides an easy way to amend the list as the CRADA progresses and also might be protectable under FOIA. Since the notice of existing BIP is to inform the Participant of existing technology that might need to be licensed to practice Subject Inventions, the language below can be modified such that only the Contractor is required to provide a list of BIP. The Parties can add the following paragraph to reference the Annex and remove the annex reference in the definition:

Each Party may use the other Party's Background Intellectual Property identified in Annex ____ of this CRADA solely in performance of research under the Statement of Work. This CRADA does not grant to either Party any option, grant, or license to commercialize, or otherwise use the other Party's Background Intellectual Property. Licensing of Background Intellectual Property, if agreed to by the Parties, shall be the subject of separate licensing agreements between the Parties.

Each Party has used reasonable efforts to list all relevant Background Intellectual Property, but Background Intellectual Property may exist that is not identified.

Neither Party shall be liable to the other Party because of failure to list Background Intellectual Property.

GENERAL GUIDANCE:

The CRADA must include an article which sets forth the allocation of rights to Subject Inventions between the parties. Through a class waiver at each laboratory, DOE has provided the Participant with title to inventions made by employees of the Participant. These class waivers extended the March-In Rights to Participant's Subject Inventions. The terms and conditions of that waiver have been effectively changed by P.L. 104-113 (the National Technology Transfer Act of 1995, hereinafter in this guidance, the "ACT") to include a field of use license granted to the Participant in Subject Inventions made in whole or in part by the contractor and the Government license and march-in rights contained in the ACT. The article must indicate that DOE retains rights for Subject Inventions for which a party to the CRADA does not file patent applications or maintain patents. The article must also provide that the Government retains a nonexclusive, nontransferable, irrevocable, paid-up license to practice or to have practiced for or on behalf of the United States every Subject Invention under the CRADA throughout the world. (Authority: 35 U.S.C. 202(c)(2) for DOE's nonprofit management and operating contractors entering into CRADAs and by DOE policy for other management and operating contractors and CRADA Participants.)

It is a statutory requirement that the Participant be offered an exclusive license in Contractor's Subject Inventions. This should be documented in the preamble or by using one of the options above. This may be used in conjunction with other language allocating invention rights where the Contractor retains title to its inventions. In some cases a Participant may not want the CRADA to include the option to choose the field of use license. To ensure that it is documented that the statutorily required option has been offered in those cases, it is suggested that a pre-agreement notice or other correspondence with a potential Participant provide a notice to the Participant about the option. In this situation, the Contractor should include an acknowledgment of the notice in the CRADA.

In addition, Subcontractors to the Contractor may be required to offer the Participant an exclusive license in their Subject Inventions pursuant to exceptional circumstances, such as in 37 C.F.R. 401.3. Similarly, where the subcontract is not funded with Federal funds and the subcontractor receives title to Subject Inventions under a patent waiver pursuant to 10 C.F.R. 784, the waiver of patent rights may be conditioned on granting such option to the Participant.

The exclusive license itself, per the ACT, may be only in exchange for reasonable compensation, when appropriate, and subject only to reasonable terms and conditions associated with obtaining reasonable compensation, for example, minimum annual royalty payments, objective performance obligations, contributions to the costs of prosecution and litigation to maintain a patent and other commercially reasonable terms, shall satisfy the statutory requirement of "for reasonable compensation." Failure of the Participant to fulfill any of its obligations in the negotiated exclusive license is cause for termination of such license and not in violation of the ACT. Although these are the types of terms that may be reasonable in appropriate circumstances, DOE does not require that any or all of these terms

be a condition of the license in all circumstances. Additionally, the exclusive license may be limited to a negotiated field of use. In accordance with the ACT, the license must provide the Participant with the right of enforcement under Chapter 29 of Title 35 U.S.C.

The Contractor should document the terms of the option and whether the option was exercised or not.

Paragraph G requires future reporting of use of intellectual property, which would most likely be commercialization of patents. The Participant should recognize that the Department has a need to measure economic outcomes of CRADAs and the Department through the Contractor may request long-term economic data (e.g., the results of commercializing products, processes, or services based on the CRADA, compliance with US Competitiveness provision of Article VIII). Such follow-up surveys are already being done for R&D 100 award-winning technologies without intruding into sensitive market or financial information. Measurement of the outcomes of cooperative research, both for the Department and for the Participant, is a very important aspect of the Department's Technology Partnerships activity. Examples of the types of long-term economic data that could be sought include jobs created/lost/retained, increases in market share, and sales increases. Surveys would be done in such a way that answers are provided in broad categories (i.e., 1-50 jobs created, etc.) in a "check-the-box" approach. Mechanisms used to gather the information could include customer surveys, third-party personal interviews, and third-party studies commissioned by the Department. The Department has decided on 5 year period since implementation of the intellectual property developed under the CRADA may take several years and the impact of such use may not be realized until 5 years has passed. However, this period may be reduced with DOE Contracting Officer approval where the Participant openly demonstrates why a shorter time is more appropriate based on the research being performed under the CRADA. Likewise, the Contracting Officer may increase the period in cases where a DOE programmatic need arises.

ARTICLE VII: RIGHTS IN DATA

ALTERNATE LANGUAGE: For Paragraph A:

- A. *The Parties and the Government shall have unlimited rights in all Generated Information produced or provided by a Party under this CRADA, except for information which is: (a) disclosed in a Subject Invention disclosure being considered for patent protection, (b) protected as a mask work or (c) marked as being copyrighted or as Protected CRADA Information or as Proprietary Information.*

PROPRIETARY INFORMATION:

ALTERNATE LANGUAGE: for Paragraph B.

OPTION 1:

- B. PROPRIETARY INFORMATION: Each Party agrees not to disclose Proprietary Information provided by the other Party to anyone other than the CRADA Participant and Contractor without written approval of the providing Party, except to Government employees who are subject to 18 U.S.C. 1905. To the extent that any Generated Information discloses or duplicates Proprietary Information, such Generated Information shall be marked and treated as Proprietary Information.*

Disclosures of Proprietary Information to DOE employees shall occur only on site at the Contractor's facilities unless mutually agreed upon by the Parties. The Contractor and DOE shall limit their respective internal disclosure of Proprietary Information to those employees or agents having a need to know such information

OPTION 2:

- B. PROPRIETARY INFORMATION: All information marked as Proprietary Information shall be protected by the recipient as Proprietary Information for a period of _____ years from receipt of such Proprietary Information when clearly dated, otherwise from the effective date of this CRADA, unless, as shown by the recipient, such Proprietary Information becomes publicly known without the fault of the recipient, comes into recipient's possession from a third party without an obligation of confidentiality on the recipient, is independently developed by recipient's employees who did not have access to such Proprietary Information, is released by the disclosing Party to a third party without restriction, or is released for disclosure with the written consent of the disclosing Party.*

OPTION 3: No Proprietary Information.

If the Parties agree that no Proprietary Information will be shared between the Parties in order to perform the tasks in the Statement of Work, the following language could be used. However, the following clause can be replaced by amending the CRADA if the Parties decide to share proprietary information during the performance of the project:

- B. PROPRIETARY INFORMATION: The Parties agree that no Proprietary Information will be shared between the Parties.*

ADDITIONAL PARAGRAPHS:

Any of following additional paragraphs can be added to Paragraph B of the Article:

- (1) *Proprietary Information in tangible form shall be returned to the disclosing Party or destroyed with a certificate of destruction submitted to the disclosing Party upon termination or expiration of this CRADA, or during the term of this CRADA upon request by the disclosing Party.*
- (2) *All Proprietary Information shall be returned to the provider thereof at the conclusion of this CRADA at the provider's expense.*
- (3) *In no case shall the Contractor provide Proprietary Information of the Participant to any person or entity for commercial purposes, unless otherwise agreed to in writing by the Participant.*
- (4) *Notwithstanding the provisions of this paragraph B, both Parties agree that a subcontractor identified in the Statement of Work may receive Proprietary Information to the extent necessary to perform the activities assigned to the subcontractor as set forth in the Statement of Work provided that the subcontractor agrees in writing to comply with the requirements set forth in this Article.*

GENERAL GUIDANCE REGARDING PROPRIETARY INFORMATION:

The definition in Article I (complying with the Freedom of Information Act (5 U.S.C. 552) and Stevenson-Wydler statute (15 U.S.C. 3710 a(c)(7)(A)), clearly indicates that Proprietary Information is “information embodying trade secrets developed outside the CRADA at private expense.” The contractor cannot negotiate away the right of a Government employee, subject to 18 U.S.C. 1905, to see Proprietary Information. The contractor should seek additional rights to Proprietary Information at the DOE laboratory where program needs require rights greater than those prescribed in the CRADA clauses (e.g., including limiting the period in which Proprietary Information is maintained as proprietary when such information is retained by the contractor). Such disclosure to the Government may require marking with both Proprietary Information and OUO as required under DOE O 471.3 Identifying and Protecting Official Use Only Information.

The obligations of the parties with regard to Proprietary Information should require that all such materials be sufficiently identified and marked so that the personnel involved in the project will have no trouble understanding what materials are to be protected. The parties should stipulate whether the contractor will return such materials, destroy them, or keep them at the end of work on the CRADA. If information could not be protected as a valid trade secret, or commercial or financial information, it should not be protected under the CRADA.

If the parties will be using software, biological materials, specimen materials, equipment, or other tangible personal property which a party wants to protect as proprietary, such items should be included in the definition of Proprietary Information to ensure such protection. Additional materials can be found at 48 CFR 927.400. In certain projects, a separate Material Transfer Agreement (MTA) or software license may be appropriate to protect the

parties and define the use of such items. Reference to the existence of such MTA or license may be appropriate within the CRADA or Statement of Work.

The Parties may wish to return Proprietary Information before the conclusion of the CRADA, when such information is no longer needed for CRADA work.

The Parties may want to address situations in which Proprietary Information is in electronic form and cannot necessarily be returned to the providing Party or completely destroyed without incurring considerable expenses. For example, electronic communications such as emails are often stored in backup files, tapes, or otherwise be part of a party's permanent business records. The Parties may agree to exempt these types of files or tapes.

PROTECTED CRADA INFORMATION

ALTERNATE LANGUAGE: Fundamental Research under Export Control Law

Some University M&O Contractors have many foreign employees and students and comply with export control law through the fundamental research safe-harbor. Also, Part 734.8(c) of the Export Administration Regulation extends the "fundamental research" designation to FFRDCs (Federally Funded Research and Development Centers) and the language below regarding "higher education" can be appropriately modified. In either case, the Participant may want to protect its own data. Therefore, the first paragraph of this subsection in the DOE Model CRADA could be replaced with the following paragraph where only the Participant's generated information is marked:

Except where a Participant's funding agreement prohibits such protection, the Participant may designate and mark as Protected CRADA Information any Generated Information produced by its employees, which meets the definition in Article I. Because the Contractor is part of an institution of higher education and intends to conduct its activities as fundamental research under the U.S. Export Administration Regulations, the Contractor does not intend to mark any of its Generated Information as Protected CRADA Information. All such designated Protected CRADA Information shall be appropriately marked.

ALTERNATE LANGUAGE: Last subparagraph of this Paragraph C could be replaced with the following:

The obligations of this paragraph shall end sooner for any Protected CRADA Information which shall become publicly known without fault of either Party, shall be independently developed outside of the CRADA by a Party's employees who did not have access to the Protected CRADA Information, or is disclosed through a product released by the Participant. If recipient receives any information independently developed by a third party without any obligation of confidentiality which is similar to Protected CRADA Information, disclosure by recipient of such third party information shall not be a breach of this CRADA.

ALTERNATE LANGUAGE: Subcontractor's Data

If some of the CRADA is done by subcontractors, the following changes can be made:

The following definitions should be added to Article I:

“Subcontractor” means a subcontractor of the Contractor or Participant at any tier.

The following paragraph should be added to the Rights in Data Article:

Each Party may designate and mark as Protected CRADA Information any Generated Information produced by its employees or Subcontractors, which meets the definition in Article I and, with the agreement of the other Party, so designate any Generated Information produced by the other Party's employees or Subcontractors which meets the definition in Article I. All such designated Protected CRADA Information shall be appropriately marked.

ADDITIONAL LANGUAGE: Other Protected Data Category. The definition for Other Protected Data must be added to Article I when this provision is used in the CRADA.

OTHER PROTECTED DATA: The Participant may designate data delivered to the Contractor by the Participant as Other Protected Data provided the data meets the definition of Article I and the data is marked in accordance with the award, contract, or other agreement that provides for the protection of the data. The Contractor shall comply with the markings to the extent that the markings are authorized by the award, contract, other agreement, or statutory authority.

GENERAL GUIDANCE REGARDING PROTECTED CRADA INFORMATION:

The wording of the definition for Protected CRADA Information should be along the lines of the Stevenson-Wydler statute (15 U.S.C. 3710a(c)(7)(B)) and placed in the Definitions article to support the substantive clause on protecting this information. The CRADA must include a requirement that designated Protected CRADA Information be appropriately marked. The Contractor cannot negotiate away the right to share Protected CRADA Information with Government employees covered under 18 U.S.C. 1905. Also, the Contractor cannot negotiate away DOE's right to share Protected CRADA Information with other DOE facilities having the same protection in place without the approval of the DOE field element office responsible for the CRADA. Such disclosure to the Government or other DOE facilities may require marking with both Protected CRADA Information and OOU as required under DOE O 471.3 Identifying and Protecting Official Use Only Information. Any delivery to DOE of Protected CRADA Information will be to implement the following policy: (a) ensure that anticipated DOE mission benefit is received from CRADAs; (b) avoid duplication of expense and effort; (c) help to advance technology; and (d) enable DOE to meet statutory requirements to disseminate information after the expiration of the withholding period.

Software may be marked as Protected CRADA Information, but that restriction only applies to the source code. Software has been exempted from the requirement of getting approval

from the Contracting Officer to share with other GOGOs and/or M&O Contractors. The new software copyright provision (see below) requires deposit of CRADA generated software in OSTI/ESTSC and therefore the object code can be shared under the Government's copyright license.

The parties should negotiate the respective responsibilities for marking Generated Information that meets the definition of Protected CRADA Information and the obligations that will attach to such information. Generated Information that is marked Protected CRADA Information cannot be protected for more than the statutory maximum of 5 years from the date it is produced. The determination as to which Generated Information is to be marked as Protected CRADA Information shall be made when the Generated Information is produced, not at the end of the CRADA. Also, 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 protection of data should apply (i.e., the time period in the Federal funding agreement is the maximum allowed to mark information as Protected CRADA Information) even if such protections under the CRADA could be greater than the terms of the Federal funding. The parties shall embody the rights and obligations in an appropriate legend. The parties should negotiate the term for which it will be protected and the obligations of the parties with regard to such Protected CRADA Information. The Contractor may license its Protected CRADA Information as long as it doesn't violate the release restrictions set forth in this article. If no protection is needed or when protection is no longer permitted, the parties should quickly publish the Generated Information when possible.

Per DOE Directive DOE O 241.1B, Generated Information in the form of final reports or other scientific and technical information (STI) that is marked as Protected CRADA Information and final reports or STI for which no protection is needed should be submitted to DOE's Office of Scientific and Technical Information.

The parties should also be careful to appropriately mark as Protected CRADA Information in human-readable form onto all physical media and in digitally encoded form in all machine-readable information.

COPYRIGHTS

ALTERNATE LANGUAGE: The first paragraph containing the rights of the Parties with regards to copyright can be replaced with the following:

Each Party shall have the first option to assert copyright in works authored by its employees. Copyrights in co-authored works by employees of the Parties shall be held jointly, and use by either Party shall be without accounting. A Party electing not to assert copyright in a work authored by its employees agrees to assign such copyright to the other Party upon the request of, and at the expense of, the other Party.

ALTERNATE LANGUAGE: Technical Manual, Film and Digital Media

The first paragraph could be replaced with the following if the Parties intend the copyrighted work to be contained within a Technical Manual, book, film, digital media, etc. However, the rights of the Parties could be defined in this paragraph instead of using an Annex.

All Participant and Contractor copyrights to original information for which authorship takes place during the performance of work under this CRADA shall be owned and licensed as set forth in Annex ___ subject to any obligation of protection as required in this article.

COMPUTER SOFTWARE: If the CRADA will develop Computer Software, then the computer software definition should be added to Article I and paragraph (D) replaced in its entirety as follows:

In Article I, add a definition for Computer Software as follows:

“Computer Software” means (i) computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and (ii) recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

In the Rights in Data Article, replace the entire section (D) COPYRIGHT with the following:

(D) **COPYRIGHT:** *The Parties may assert Copyright in any of their Generated Information. Assertion of Copyright generally means to enforce or give an indication of an intent or right to enforce such as by marking or securing Federal registration. Copyrights in co-authored works by employees of the Parties shall be held jointly, and use by either Party shall be without accounting.*

COMPUTER SOFTWARE: *For all Computer Software produced in the performance of this CRADA, the Parties shall provide an Announcement Notice, AN 241.4 Software Announcement Notice, along with providing the source code, the executable object code and the minimum support documentation needed by a competent user to understand and use the Computer Software to DOE’s Energy Science and Technology Software Center (ESTSC) via www.osti.gov/estsc. The source code of the Computer Software may be marked as Protected CRADA Information in accordance with this Article; however, the Government’s use of the executable object code is governed by the applicable license below.*

[The Parties can negotiate ownership and license rights to software and other copyrighted generated data developed under this CRADA.]

COMMENT: Many Laboratories may want to negotiate license rights in a separate agreement because use of software under a license will extend beyond the completion of the CRADA. The Laboratory should ensure that if there is an exclusive license to the Participant, that there is a right to license to third parties similar to march-in rights when Participant isn't commercializing the Laboratory's software. Therefore the Laboratory may want to use the following suggested statement:

Under a separate agreement, the Contractor will grant the Participant a license in Contractor's Computer Software. If the grant is for an exclusive license, the separate agreement will include "march-in rights."

For Generated Information that is Copyrighted Computer Software produced by a Party, the Party shall inform DOE's ESTSC when it abandons or no longer commercializes the Copyrighted Computer Software. Until such notice to ESTSC, the Government has for itself and others acting on its behalf, a royalty-free, nontransferable, nonexclusive, irrevocable worldwide copyright license to reproduce, prepare derivative works, and perform publicly and display publicly, by or on behalf of the Government. (narrow license) After the Party owning the Copyrighted Computer Software abandons or no longer commercializes the Copyrighted Computer Software, the Government has for itself and others acting on its behalf, a royalty-free, nontransferable, nonexclusive, irrevocable worldwide copyright license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government. (broad license)

For all other Generated Information where a Party asserts copyright in copyrightable works produced in the performance of this CRADA, the Government has for itself and others acting on its behalf, a royalty-free, nontransferable, nonexclusive, irrevocable worldwide copyright license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government, subject to the restrictions this Article places on publication of Proprietary Information and Protected CRADA Information.

The Parties agree to place Copyright and other notices, as appropriate for the protection of Copyright, in human-readable form onto all physical media, and in digitally encoded form in the header of machine-readable information recorded on such media such that the notice will appear in human-readable form when the digital data are off loaded or the data are accessed for display or printout.

GENERAL GUIDANCE REGARDING COPYRIGHT:

DOE authorizes the Participant and the contractor to assert copyright in Generated Information. The parties must grant to the United States an irrevocable, paid-up copyright license to any and all works that come out of the project and may be copyrightable.

For Computer Software, the Government retains a narrow license (without the right to distribute copies to the public) that will become a broad license after the Participant decides to abandon or not commercialize the software. However, there may be circumstances where DOE Program may require the broad license only (or Open Source Software distribution) for programmatic reasons and the above double underlined language will need to be appropriately modified by DOE Patent Counsel. The Contractor shall follow section (e)(1)(i) of M&O Contract clause 970.5227-24 Rights in Data-Technology Transfer (formally DEAR 970.5227-2) that allows “the Contractor to copyright data first produced under a CRADA...as described in the individual CRADA.” Therefore, no DOE Program approval is necessary and only reporting requirements to Patent Counsel and ESTSC apply. The Contractor shall follow its M&O Contract clauses regarding abandoning the commercialization of any software generated under the CRADA. The parties may also negotiate reciprocal licenses among themselves. As an alternative, the parties can agree as part of the CRADA to negotiate the software license rights each party is to receive upon the production and copyright of software under the CRADA. The contractor must ensure that all copyrighted works are available to other DOE contractors for Governmental purposes. Except for computer software, any restriction on the Government and others acting by or on behalf of the Government of the right to prepare derivative works or the right to use any copyrighted Generated Information must also be approved by the Contracting Officer of the cognizant DOE field element with concurrence by DOE Patent Counsel. All Computer Software, whether copyrighted or not, must be deposited in ESTSC. The Parties may mark Computer Software as Protected CRADA Information (PCI); however, that protection extends only to the source code. The Government retains a narrow license in the object code to be used for Government purposes. When the PCI protection expires (if applicable), the Government can use the source code under the narrow license.

Copies of all Participant generated computer software on which copyright protection will be asserted must be delivered to the ESTSC by the Participant. If the contractor and Participant agree to protect computer software for 5 years by marking it as Protected CRADA Information, the applicability of the DOE march-in rights will most likely be delayed for such period unless there is a clear indication that the Participant refuses to commercialize the computer software generated by the Contractor under the CRADA in which the Participant has an exclusive license. Most likely, an exclusive license of Contractor’s software would be covered under a separate agreement and should include march-in rights where the Participant is required to commercialize or the Contractor may license to third parties. The Participant should be given a right of appeal this march-in right. If the Participant is only granted a non-exclusive license in Contractor’s computer software, then the Contractor may license the software non-exclusively to third parties.

ARTICLE VIII: U.S. COMPETITIVENESS

OPTION 1: Use of a DOE approved Net Benefit Statement (NBS).

As discussed below in the general guidance section, when approved by DOE a Net Benefit Statement may be used in lieu of the standard U.S. competitiveness language in paragraph A. The NBS may be incorporated through a modification of the standard U.S.

competitiveness language in paragraph A or by replacing paragraph A in its entirety with the following or similar statement.

- A. *A plan for providing net benefit to the U.S. economy is attached in Annex*
_____.

OPTION 2: Substitution of “Subject Invention” for “Intellectual Property.”

Subject to DOE approval, the requirements set forth at paragraph A may be limited to Subject Inventions. When approved, “Intellectual Property” in paragraph A should be replaced with “a Subject Invention.”

When requesting DOE approval, the Contractor should explain the type of Intellectual Property anticipated to be developed under the CRADA and any relevant information that would help DOE determine the impact of the request. The use of this option is likely appropriate when it would harmonize the CRADA terms with the terms of a related funding agreement. The use of this option may be appropriate when subject inventions and non-invention IP are anticipated to be generated. The use of this option is unlikely to be approved when no subject inventions are anticipated because no benefit would be provided to the U.S. economy and industrial competitiveness. When no subject inventions are anticipated and the Participant has concerns with the standard U.S. competitiveness language, the Participant should pursue a NBS rather than this option.

ADDITIONAL PARAGRAPH: If the Participant wants the option to submit a NBS in the future, the following paragraph can be added.

If the Participant is willing to commit to paragraph A, but would like the option to submit a NBS after considering the impact of commercializing the Intellectual Property developed under the CRADA, this language may be added as an additional paragraph C:

- C. *If the Participant later finds that it cannot meet the requirements of Paragraph A above, the Participant will submit a plan for providing net benefit to the US economy to DOE. If such plan is approved by DOE, it shall be incorporated into this CRADA by an amendment to be executed by the Parties. If the CRADA is completed or terminated and DOE approves of the plan, the DOE Contracting Officer shall issue an approval letter.*

GENERAL GUIDANCE:

DOE has invested billions of dollars in the capabilities and resources at DOE laboratories. To increase the return on the taxpayers’ investment, the Government seeks to transfer technology to companies with significant manufacturing and research facilities in the United States to provide short- and long-term benefits to the U.S. economy and the industrial competitiveness of such companies. Therefore, in selection of CRADA Participants, it is DOE’s long established policy to give preference to business units located in the United States which agree to substantially manufacture resulting technology in the United States. For more information on DOE’s policy on U.S. competitiveness, see the Memorandum dated

February 10, 1993 from the Director of Technology Utilization and the Memorandum dated March 17, 2011 from the Secretary of Energy.

The CRADA must include the standard U.S. competitiveness language in paragraph A or one of the two options above. The preference is to use the standard U.S. competitiveness language in paragraph A that requires any products embodying any Intellectual Property resulting from the performance of the CRADA be manufactured substantially in the United States. Therefore, the standard U.S. competitiveness language in paragraph A must be the laboratories' opening negotiating position for all CRADAs unless an approved Class NBS applies to the transaction

Where a CRADA Participant is unable or unwilling to agree to the standard U.S. Competitiveness language in paragraph A, the Contractor may request a Net Benefit Statement (NBS). If approved, the NBS can replace or modify the standard U.S. competitiveness language in paragraph A. The NBS identifies specific contractual commitments made by the Participant to benefit the U.S. economy and industrial competitiveness. The process for negotiating and approval the use a NBS is the following:

- (1) During CRADA negotiations, Participant and Contractor should review the standard U.S. competitiveness language in paragraph A. If Participant agrees to the standard U.S. competitiveness language in paragraph A, then the language should be included in the CRADA.
- (2) If the Participant is unable or unwilling to agree to the standard language, the Contractor should determine whether a class NBS applies. Class NBSs are discussed further below. If Participant agrees to the class NBS, then the class NBS should be included in the CRADA. When the CRADA is forwarded for review and approval to the cognizant DOE Patent Counsel or the designated DOE Field Office personnel responsible for technology transfer matters (hereinafter, the Reviewing Office), the Contractor must inform the Reviewing Office of the use of the class NBS and demonstrate that the use of the class NBS is appropriate.
- (3) If no class NBS applies or the Participant will not agree to the class NBS, then the Contractor should provide the Participant with a U.S. Competitiveness Questionnaire (See Attachment 8) or other form that has been approved by DOE. Once the Questionnaire is completed, the Contractor or the Participant should submit it to the Reviewing Office. The completed Questionnaire contains a proposed NBS and information that will help DOE review the adequacy of the proposed NBS.
- (4) The Reviewing Office will review the proposed NBS to determine whether it contains specific contractual commitments by the Participant to benefit the U.S. economy and industrial competitiveness. If it does not or additional information is necessary, the Reviewing Office will work with the Participant, directly or through the Contractor, depending on the preference of the Participant, to address any issues with the proposed NBS.

- (5) Once the proposed NBS is considered legally sufficient by the Reviewing Office, the Reviewing Office will present the proposed NBS, along with any other documents deemed necessary, to the appropriate DOE program organization.
- (6) If the DOE program organization accepts the NBS, the Reviewing Office will so inform the Contractor and the Contractor will incorporate the NBS into the CRADA for DOE approval. If the DOE program organization requires changes to the NBS, the Reviewing Office will communicate those changes to the Participant. If the Participant accepts those changes, the NBS will be finalized and incorporated into the CRADA. The Reviewing Office will continue working with the DOE program organization and the Participant through subsequent revisions, if necessary, to reach a mutually agreeable NBS. The Reviewing Office will make best efforts to act upon the NBS (and subsequent revisions) within 5 working days of receipt. If a DOE program organization finds that a NBS is unacceptable after negotiation, the parties may seek resolution from the Cognizant Secretarial Officer.

Special Circumstance: 100% funds-in CRADAs

The DOE program organization may consider the funding structure as a formal, yet non-determinative, factor when evaluating the sufficiency of the NBS. If a Participant wishes to have the DOE program organization consider the NBS in light of the funding structure of a 100% funds-in CRADA, the Contractor must submit written confirmation to the Reviewing Office that the Participant was informed of the full range of funds-in partnership options available at the Laboratory and the IP disposition for each option. This confirmation may take the form of the certification used for Agreements to Commercialize Technology (ACT), or another form of written confirmation agreed to by the Laboratory and the Reviewing Office. When confirmed, the Reviewing Office will inform the DOE program organization that the CRADA is 100% funds-in and that the funding structure can be considered when evaluating the NBS.

Class Net Benefits Statements

Occasions may arise where similarly situated participants may benefit by accepting the terms of a class NBS. DOE may implement class NBSs that may cover multiple participants at multiple Laboratories. Class NBSs may be drafted either upon request of one or more Laboratories or participants, or at DOE's own initiative. Class NBSs may be drafted to cover participants in a particular program, for example the Lab-Embedded Entrepreneurship Program, or certain technologies, such as those within a particular DOE Technology Office. Class NBSs should further DOE programmatic goals, for instance, by providing incentives for broad participation in a DOE program in which participants engage the Laboratories via CRADAs. Participants must be defined, must meet certain eligibility requirements, and must acknowledge acceptance of the class NBS in writing (email is sufficient). Participants that do not accept the terms of the NBS are free to negotiate individual NBSs, however, the participants should be informed that such negotiations will likely delay finalization of the CRADA.

The Assistant General Counsel for Technology Transfer and Intellectual Property will coordinate

the drafting of class NBSs with the appropriate DOE program organization. A class NBS may be one or more commitments listed in paragraph A in lieu of the standard U.S. competitiveness language, an attachment to the CRADA, or incorporated throughout the CRADA by modifications made to other Articles of CRADA, such as in the International Basic Science CRADA. Each class NBS must be approved by the Assistant General Counsel for Technology Transfer and Intellectual Property and concurred by the Director of the cognizant DOE program organization. Further, the Cognizant Secretarial Officer must concur if the NBS covers more than one DOE program organization or if the Assistant General Counsel for Technology Transfer and Intellectual Property deems such concurrence necessary. DOE Patent Counsel in the field offices may assist with drafting and negotiating class NBSs and will disseminate final class NBSs to affected Laboratories.

The Secretary empowered the General Counsel to prepare guidance on streamlining the NBS process. To that end, the General Counsel may issue further guidance updating or supplementing the foregoing procedure.

When CRADAs involve foreign entities, additional factors must be addressed. Under Executive Order 12591, when considering whether to enter into a CRADA with a foreign company, and after reference to information from the U.S. Trade Representative (USTR), appropriate consideration must be given to (1) whether the foreign company and/or its government permit and encourage U.S. entities to enter into similar agreements on a comparable basis; (2) whether the foreign government has policies to protect Intellectual Property rights; and (3) when the research will involve or produce technologies subject to U.S. national security export controls, whether the foreign government has adequate measures to protect the transfer of the technology to prohibited locations. Consideration of the first factor is also required under 15 U.S.C. 3710a(c)(4)(B). Also, if the funds come from some other part of the Department, extra care must be taken to ensure that U.S. Competitiveness is handled in a manner consistent with such Department funding. For example, if a DOE Cooperative Agreement to the CRADA Participant has unique U.S. Competitiveness provision, the CRADA with the Participant should reference such provision. Similarly if the project is occurring under an International Agreement or Treaty, the U.S. Competitiveness provision should be consistent with such International Agreement or Treaty.

ARTICLE IX: EXPORT CONTROL

ADDITIONAL PARAGRAPH: Classified Information.

The following approved language was developed to address foreign ownership, control, or influence issues with respect to the Participant. It should only be used for those CRADAs involving access to classified information, access to special nuclear materials, or unescorted access to security areas of Departmental facilities. If the CRADA involves access to classified information, access to special nuclear materials, or unescorted access to security areas of Departmental facilities, the requirements of the Atomic Energy Act of 1954, as amended, must be met, this article of the CRADA should be retitled "Export Control/Foreign Ownership and Control," and language pertaining to FOCI should be added along with the Definitions for Foreign Interests and FOCI. The completed FOCI

questionnaire attached hereto as Attachment 7 must be completed by the Participant and included as an annex to the CRADA.

The Participant has a continuing obligation to provide the Contractor written notice of any changes in the nature and extent of foreign ownership, control, or influence over the Participant which would affect the Participant's answers to the previously completed FOCI certification.

ALTERNATE LANGUAGE: Some University M&O Contractors have many foreign employees and students. They strictly limit data developed onsite to be technology that would meet Department of Commerce's Export Administration Regulations (EAR) Section 99 designation. As such, it would be considered fundamental research and there would be no restrictions on its publications. The following language may be used:

The parties understand that materials and information resulting from the performance of this CRADA may be subject to export control laws and that each party is responsible for its own compliance with such laws.

Participant acknowledges that the Contractor has many foreign employees and students. The Participant agrees that the Contractor will conduct this project as fundamental research with no restrictions on publication. Accordingly, the Contractor does not intend to mark any of its Generated Information as Protected CRADA Information and the Participant agrees not to direct the Contractor to create export controlled information and not to transfer to Principal Investigator or to other employees or students of the Contractor any Proprietary Information or Protected CRADA Information that is export controlled under the Export Administration Regulations, the International Traffic in Arms Regulations, or 10 CFR 810.

GENERAL GUIDANCE:

There must be an export control warning statement to warn the parties that material and information resulting from the CRADA may be export controlled. This statement should be conspicuous, like the Uniform Commercial Code-like disclaimer.

ARTICLE X: REPORTS AND PUBLICATIONS

ALTERNATE LANGUAGE: Paragraph B-- a more detailed review process for approving publications can be used:

The Parties anticipate that their employees may wish to publish technical developments and/or research findings generated in the course of this CRADA. On the other hand, the Parties recognize that an objective of this CRADA is to provide business advantages to the Participant. In order to reconcile publication and business concerns, the Parties agree to a review proposed public disclosures as follows:

1. *Each Party ("Submitter") shall submit to the other Party ("Recipient"), in advance, proposed written and oral publications pertaining to work under the CRADA. Proposed oral publications shall be submitted to the Recipient in the*

form of a written presentation synopsis and a written abstract.

2. *The Recipient shall provide a written response to the Submitter within 30 days, either objecting or not objecting to the proposed publication. The Submitter shall consider all objections of the Recipient and shall not unreasonably refuse to incorporate the suggestions and meet the objections of the Recipient. The proposed publication shall be deemed not objectionable, unless the proposed publication contains the Recipient's Proprietary Information, Protected CRADA Information, export controlled information for which the Submitter does not have an appropriate license or exclusion from U.S. export control laws, or material that would create potential statutory bars to filing the United States or corresponding foreign Patent applications. In the event an objection is raised because of a potential statutory bar, the Recipient shall file its patent application within _____ days of making such objection, after which time the Submitter is free to publish.*

GENERAL GUIDANCE:

The CRADA must include a provision setting forth the required minimum deliverables of a publically releasable abstract and final report. Other deliverables pertaining to the specific project are normally contained in the Statement of Work; however, some intellectual property might be useful to the Government or the public and should be delivered to the DOE Office of Scientific and Technical Information (OSTI) for distribution if DOE requests such delivery. CRADA reports should fully cover and describe the research done under the CRADA, incorporating technical data as needed to support conclusions, and including Protected CRADA Information as appropriate. Where the Participant and/or the contractor identifies that such reports contain Protected CRADA Information, the reports will be properly marked with a restrictive legend identifying the agreed-to period of withholding from public disclosure per DOE Directive DOE O 241.1B. Such reports shall be furnished to OSTI for Departmental use only and be withholdable for the stated withholding period as materials exempt from Subchapter II of Chapter 5 of Title 5, United States Code. The contractor must ensure that adequate deliverables are provided to OSTI to ensure that the results of DOE-approved CRADAs are made known to other DOE contractors for DOE program needs. Additional information on providing information to OSTI is available at www.osti.gov/stip. Information and suggested best practices on marking CRADA reports to identify the agreed-to period of withholding from public disclosure is available at www.osti.gov/stip/access/crada.

A publication review provision must be included in the CRADA. The pre-publication review process must consider the protection of rights to filing U.S. and foreign patent applications, since any disclosure may be a bar to filing.

ARTICLE XI: FORCE MAJEURE

GENERAL GUIDANCE:

A force majeure clause stating that neither party will be liable for unforeseeable events beyond its reasonable control must be included in the CRADA.

ARTICLE XII: DISPUTES

If the Parties want to include a more detailed description of resolving disputes, the following options could be used as additional paragraphs added to the standard paragraph:

OPTION 1: Mediation

After the Parties have consulted with the Technology Partnership Ombudsman in accordance with the paragraph above, the Parties can initiate mediation, which shall commence within 30 days of selection of the mediator and shall be held in a mutually convenient location. The mediator's role shall be to facilitate an agreement between the Parties, based on their mutual interests. The Parties agree to share the costs of mediation equally.

Neither Party will be prevented from resorting to a judicial proceeding if (1) good faith efforts to resolve the dispute have been unsuccessful or (2) interim relief from a court is necessary to prevent serious injury. To the extent that there is no applicable U.S. Federal law, this CRADA and performance thereunder shall be governed by the law of the State of_____.

OPTION 2: DOE Contracting Officer Determination

After the Parties have consulted with the Technology Partnership Ombudsman in accordance with the paragraph above, the Parties can have the dispute decided by the DOE Contracting Officer, who shall reduce his/her decision to writing within 60 days of receiving in writing the request for a decision by either Party to this CRADA. The DOE Contracting Officer shall mail or otherwise furnish a copy of the decision to the Parties. The decision of the DOE Contracting Officer is final unless, within 120 days, the Participant brings an action for adjudication in a court of competent jurisdiction in the State of_____. To the extent that there is no applicable U.S. Federal law, this CRADA and performance thereunder shall be governed by the law of the State of_____.

OPTION 3: Arbitration

After the Parties have consulted with the Technology Partnership Ombudsman in accordance with the paragraph above and have mutually agreed not to enter into mediation, the Parties can request to have the dispute settled by arbitration conducted in the State of _____ in accordance with the then current

and applicable rules of the American Arbitration Association. Judgment upon the award rendered by the Arbitrator(s) shall be nonbinding on the Parties.

OPTION 4: Litigation

After the Parties have consulted with the Technology Partnership Ombudsman in accordance with the paragraph above and are unable to jointly resolve the dispute, the Parties can seek resolution through a judicial proceeding. Neither Party will be prevented from resorting to a judicial proceeding if (1) good faith efforts to resolve the dispute have been unsuccessful or (2) interim relief from a court is necessary to prevent serious injury. To the extent that there is no applicable U.S. Federal law, this CRADA and performance thereunder shall be governed by the law of the State of _____. Any and all litigation involving disputes, claims, or either Party's rights and duties under or arising as a result of this CRADA shall be brought in a court of competent jurisdiction in the State of _____.

GENERAL GUIDANCE:

The standard Disputes clause in the agreement must be included in all CRADAs. DOE believes that contacting the Laboratory Technology *Partnership Ombudsman* is essential in resolving disputes quickly and efficiently. If the *Technology Partnership Ombudsman* is unsuccessful in assisting the parties in resolving the conflict, the parties should attempt to settle disputes by mediation or by DOE Contracting Officer before entering into binding or nonbinding arbitration and/or seeking adjudication in a court of competent jurisdiction. It is strongly recommended that the contractor seek to include an intermediate step after it attempts to directly resolve the dispute with the Participant before going to court.

If mediation is undertaken, it is recommended that the confidentiality provisions of the Alternative Dispute Resolution Act be incorporated into the agreement to mediate. Sample agreements are available from the DOE Office of Conflict Prevention and Resolution. If the parties decide to replace mediation with another form of Alternative Dispute Resolution, such as a neutral evaluation or mini-trial, the DOE Office of Conflict Prevention and Resolution can provide information and guidance on these processes.

It is DOE policy (See DOE General Counsel Issues Arbitration Guidance for M&O Contractors) that mediation is the principal method of alternate dispute resolution. However, there is currently no legal prohibition on M&O contractors including binding arbitration clauses in their contracts with others. It often will be a good idea to include arbitration clauses as a means of limiting the risk of litigation which is often more time consuming and expensive than arbitration. The Department of Energy, including NNSA, does however "regulate" the use of arbitration once a dispute has arisen under our Contractor Legal Management Requirements. However, agreement to arbitrate should generally be consistent with the Administrative Dispute Resolution Act and Department guidance. When a decision to arbitrate is made, a statement fixing the maximum award amount should be agreed to.

ARTICLE XIII: ENTIRE CRADA, MODIFICATIONS, ADMINISTRATION AND TERMINATIONS

ALTERNATE LANGUAGE: Administration

The following paragraph could be used for paragraph C:

The Contractor enters into this CRADA under the authority of its prime contract with DOE. The Contractor is authorized to and will administer this CRADA in all respects unless otherwise specifically provided for herein. Administration of this CRADA may be transferred from the Contractor to DOE or its designee as a successor to Contractor who is assuming responsibilities for the facilities managed by Contractor with notice of such transfer to the Participant, and the Contractor shall have no further responsibilities except for the confidentiality, use and/or nondisclosure obligations of this CRADA. This CRADA shall be binding upon and inure to the benefit of the Parties, and their respective successors and assignees.

ADDITIONAL LANGUAGE: Surviving Clauses

The following clause may be added to section D.

The confidentiality, use, and/or non-disclosure obligations of this CRADA shall survive any termination of this CRADA, as well as provisions of this CRADA which would naturally survive termination or expiration of this CRADA.

GENERAL GUIDANCE:

The CRADA must include an article stating that all the terms and conditions of the CRADA are entirely contained within the CRADA and its annexes (for example, Statement of Work). Subsequent modifications to the CRADA must acknowledge or supersede this statement.

The CRADA should include a termination clause. The termination clause may also reference to Funding and Costs Article, in so far as to clearly state that “failure of the Participant to provide the necessary advance funding, or to promptly pay the invoices rendered by the contractor is cause for termination of the CRADA.”

When the contractor is entering into a CRADA with a division or subsidiary of another corporation, it may be desirable to add a statement to the signatory line of the Participant stating that the person attests that he/she has the legal authority to bind the company to all the terms and conditions of the CRADA.

III. ADDITIONAL ARTICLES

The following articles may be added depending on the scope of work and Contractor obligations:

ARTICLE __ : LABORATORY SITE ACCESS, SAFETY AND HEALTH

As a precondition to performing work at CONTRACTOR Laboratory, Participant must complete all CONTRACTOR Site Access documents and requirements. Participant shall take all reasonable precautions in activities carried out under this Agreement to protect the safety and health of others and to protect the environment. Participant must comply with all applicable safety, health, access to information, security and environmental regulations and the requirements of the Department and CONTRACTOR, including the specific requirements of the Laboratory. In the event that the Participant fails to comply with said regulations and requirements, CONTRACTOR may, without prejudice to any other legal or contractual rights, issue an order stopping all or any part of Participant's activities at the Laboratory.

GENERAL GUIDANCE:

If the Participant or any subcontractors are going to perform work under the CRADA at the Laboratory, the Participant shall follow the Laboratory site access, safety and health protocols. Therefore, this article should be added accordingly.

ARTICLE __ : TRADEMARKS

If trademarks are contemplated to be created under the CRADA, the following definitions should be added to Article I:

“Trademark” means a distinctive mark, symbol, or emblem used in commerce by a producer or manufacturer to identify and distinguish its goods or services from those of others.

“Service Mark” means a distinctive word, slogan, design, picture, symbol, or any combination thereof, used in commerce by a person to identify and distinguish its services from those of others.

The following language may be used for this article.

The Parties may seek to obtain Trademark/Service Mark protection on products or services generated under this CRADA in the United States or foreign countries. [The ownership and other rights relating to this Trademark shall be as mutually agreed to in writing by the Parties.] The Parties hereby acknowledge that the Government shall have the right to indicate on any similar goods or services produced by or for the Government that such goods or services were derived from and are a DOE version of the goods or services protected by such Trademark/ Service Mark, with the Trademark and the owner thereof being specifically identified. In addition, the Government shall have the right to use such Trademark/Service Mark in print or communications media

OPTION:

The following language is an option for the bracketed language in the above paragraph:

The Party originating the Trademark/Service Mark on products or services generated under this CRADA in the United States or foreign countries shall have the full right, title, and interest in such Trademark or Service Mark subject only to the Government's retained right to use the mark on any similar goods or services as set forth below.

OPTION:

If the CRADA Participant objects to the Government's retention of any right to use any trademark owned by the Participant because the Participant has no right to perform a quality review or inspection of the DOE version of the trademarked goods, the following sentence may be added to the end of the above standard language paragraph, if desired:

Where the Government indicates on goods that such goods were derived from goods protected by a Trademark/Service Mark, the Government will also indicate that the Trademark owner has had no right to perform a quality review/inspection of the DOE version of the goods.

GENERAL GUIDANCE:

By approving a CRADA, DOE authorizes the contractor and the Participant to assert trademark protection for products or services arising out of the performance of that CRADA. The parties shall acknowledge the Government's right to indicate the relationship between the goods and services it produces and those protected by trademark/service mark in appropriate circumstances. The parties may negotiate between themselves any licensing rights they desire, consistent with the Government's license.

Trademarks for jointly developed products or services should be addressed in the CRADA. One way to do so is to specify that any trademarks in generated products or services jointly attributable to contractor and Participant employees shall be jointly owned by the contractor and the Participant.

ARTICLE ___ : MASK WORKS

If mask works are contemplated to be created under the CRADA, the following definition should be added to Article I:

"Mask Work" means a series of related images, however fixed or encoded, having or representing the predetermined, three-dimensional pattern of metallic, insulating, or semiconductor material present or removed from the layers of a semiconductor chip

product and in which series the relation of the images to one another is that each image has the pattern of the surface of one form of the semiconductor chip product.

The following language may be used for this article.

The Parties may seek to obtain legal protection for Mask Works fixed in semiconductor products generated under this agreement as provided by Chapter 9 of Title 17 of the United States Code. [The rights to any Mask Work covered by this provision shall be as mutually agreed to in writing by the Parties.] The Parties hereby acknowledge that the Government or others acting on its behalf shall retain a nonexclusive, paid-up, worldwide, irrevocable, nontransferable license to reproduce, import, or distribute the covered semiconductor product by or on behalf of the Government, and to reproduce and use the Mask Work by or on behalf of the Government.

OPTION:

The following language is an option for the bracketed language in the above paragraph:

The allocation of rights to Mask Works will be commensurate with the distribution of Copyrights under Article VII, paragraph D of this CRADA.

GENERAL GUIDANCE:

By approving a CRADA, DOE authorizes the contractor and the Participant to assert mask work protection for semiconductor chip products first produced during the performance of the CRADA. The parties shall grant to the Government and others acting on its behalf an irrevocable, paid-up license to use any of these covered products. The parties may negotiate between themselves any licensing rights they desire, consistent with the Government's license.

Jointly developed semiconductor chip materials may be registered for protection; this should be addressed in the CRADA. One way to address this is to specify that any mask works fixed in semiconductor chip products generated under the CRADA and jointly attributable to contractor and Participant employees shall be jointly owned by the contractor and the Participant.

ARTICLE ___ : ASSIGNMENT OF PERSONNEL

If personnel from either party will work at the others facility, this Article may be added to the CRADA:

- A. *Each Party may assign personnel to the other Party's facility as part of this CRADA to participate in or observe the research to be performed under this CRADA. Such personnel assigned by the assigning Party shall not during the period of such assignments be considered employees of the receiving Party for any purpose.*
- B. *The receiving Party shall have the right to exercise routine administrative and*

technical supervisory control of the occupational activities of such personnel during the assignment period and shall have the right to approve the assignment of such personnel and/or to later request their removal by the assigning Party.

- C. *The assigning Party shall bear any and all costs and expenses with regard to its personnel assigned to the receiving Party's facilities under this CRADA. The receiving Party shall bear facility costs of such assignments.*

OPTION: More Complete Recitation of the Exclusions in Paragraph A

- A. *Each Party may assign personnel to the other Party's facility as part of this CRADA. Such personnel assigned by the assigning Party to participate in or observe the research to be performed under this CRADA shall not during the period of such assignments be considered employees of the receiving Party for any purposes, including but not limited to any requirements to provide workers' compensation, liability insurance coverage, payment of salary or other benefits, or withholding of taxes.*

OPTION: More Complete and Explicit Recitation of Costs for Paragraph C

- C. *The assigning Party shall bear any and all costs and expenses with regard to its personnel assigned to the receiving Party's facilities under this CRADA. The receiving Party shall bear the costs of providing an appropriate work space, access to a telephone, use of laboratory, manufacturing or other work areas as appropriate, and any other utilities and facilities related to such assignments.*

ADDITIONAL PARAGRAPH: Observe Working Hours of Host Facility

The assigning Party's employees and agents shall observe the working hours, security and safety rules, and holiday schedule of the receiving Party while working on the receiving Party's premises. The receiving Party shall have the reasonable right to approve the assignment of personnel or request their removal by the assigning Party.

OPTION: Contractor Annex

If Employees of the Participant are required to visit the Contractor's facility, the Participant agrees to the conditions in Annex ____.

GENERAL GUIDANCE:

If it is anticipated that personnel may be assigned back and forth between the facilities, a provision for such assignments must be included in the CRADA so that such assignments of personnel can be easily facilitated during the course of the CRADA. The contractors should ensure that, when this article is being discussed, the Participants are given copies of contractor regulations, procedures, policies, and practices for entrance of outside personnel to work in the laboratories and/or facilities, especially where foreign Participants are

involved. DOE facilities must comply with U.S. export and security laws when receiving assigned foreign national Participant personnel.

ARTICLE __: NOTICES

If Parties want Notices to be in the CRADA instead of the Statement of Work, this Article may be added:

Any communications required by this CRADA, if given by postage prepaid first class U.S. Mail or other verifiable means addressed to the Party to receive the communication, shall be deemed made as of the day of receipt of such communication by the addressee, or on the date given if by verified facsimile. Address changes shall be made by written notice and shall be effective thereafter. All such communications, to be considered effective, shall include the number of this CRADA.

The addresses, telephone numbers, email and facsimile numbers for the Parties are as follows:

1. For CONTRACTOR:

U.S. Mail Only:

FedEx, UPS, Freight

a. FORMAL NOTICES AND COMMUNICATIONS, COPIES OF REPORTS

Attn: Tel:

Email:

b. PROJECT MANAGER, REPORTS, COPIES OF FORMAL NOTICES AND COMMUNICATIONS

Attn: Tel:

Email:

2. For PARTICIPANT:

U.S. Mail Only:

FedEx

UPS, Freight

a. FORMAL NOTICES AND COMMUNICATIONS, COPIES OF REPORTS

Attn: Tel:

Email:

b. *PROJECT MANAGER, REPORTS, COPIES OF FORMAL NOTICES AND COMMUNICATIONS*

Attn: Tel:

Email:

GENERAL GUIDANCE:

If the Contractor does not want to have the notices in the Statement of Work, then delete paragraph B of Article II and add this Article to the CRADA for communications among the parties to the CRADA for invoicing and receipt of funds, as well as other notices under the CRADA. For funds-in CRADAs a billing and/or an invoice address for the Participant can be added, if needed.

ARTICLE __ : PROJECT MANAGEMENT

- A. *Each Party shall assign and identify in writing a project manager prior to the start of the CRADA. Either Party may change its project manager by providing written notification to the other Party. Each project manager shall be responsible for coordinating all matters relating to this CRADA, any Statement of Work hereunder, and all other related matters between the Parties. All communications between the Parties relating to this CRADA shall take place between the project managers.*
- B. *Project managers for this CRADA are as follows:*
- for CONTRACTOR: _____*
- for PARTICIPANT: _____*

The Parties will use reasonable efforts to manage the disclosure of Proprietary Information or Protected CRADA Information through the project managers or their designees; however, failure to do so will not cause any marked Proprietary Information or any marked Protected CRADA Information to lose the protection afforded by Articles VII and VIII.

GENERAL GUIDANCE:

This additional article has been approved for use if desired. This information could be combined with the NOTICES Article and be retitled as “Notices and Project Management.”

ARTICLE __ : ORDER OF PRECEDENCE

In the event of a conflict between the provisions of the annexes and those of this CRADA, this CRADA shall prevail.

ARTICLE __ : WAIVER

The failure of the Contractor or the Participant at any time to enforce any provisions of this CRADA or to exercise any right or remedy shall not be construed to be a waiver of such provisions or of such right or remedy or of the right of the Contractor or the Participant thereafter to enforce each and every provision, right, or remedy.

ARTICLE __ : BACKGROUND INTELLECTUAL PROPERTY

Usually, a list of the Background Intellectual Property (BIP) is attached to the CRADA as an annex. However, the Parties could agree to add an Article to the CRADA as follows and this can be modified to have only the Contractor report its BIP:

The Contractor and the Participant have identified and agreed that the following Background Intellectual Property may be used in the performance of work under this CRADA and may be needed to practice the results of this CRADA:

Contractor's Background Intellectual Property: _____

Participant's Background Intellectual Property: _____

The Contractor and the Participant represent that the above-identified Background Intellectual Property is available for licensing as of the effective date of this CRADA.

Each Party has used reasonable efforts to list all relevant Background Intellectual Property, but Intellectual Property may exist that is not identified. Neither Party shall be liable to the other Party because of failure to list Background Intellectual Property.

ATTACHMENT 5

This Attachment provides information and/or requirements associated with DOE O 483.1B as well as information and/or requirements applicable to contracts in which the associated CRD (Attachment 1 to DOE O 483.1B) is inserted.

MODEL SHORT FORM CRADA

This Model Short form CRADA is designed to be offered to entities as means for streamlining and simplifying the CRADA process for certain circumstances. In order to ensure expedited CRADA development and approval, this document must be adopted in its entirety, as written, by both/all parties with no exceptions. The language of this document is pre-approved by DOE; however, the DOE field office can approve minor changes specific to a Laboratory or other facility. The goal is for uniformity across the DOE complex with this CRADA with limited differences between Laboratories and other facilities.

The Short Form CRADA may be offered to entities that meet the following criteria:

- A. *The Participant should be clearly advised that this CRADA must be adopted in its entirety, as written, by both/all parties and, at the same time, advised of the alternative to use the DOE Model CRADA if the total terms of the Short Form CRADA are not agreeable.*
- B. *The dollar value of the entire project (including amendments) does not exceed \$500,000. This dollar value may be periodically adjusted by the HQ Office of Procurement Policy (MA).*

The Short Form CRADA package will be subject to the same process used for DOE Model CRADA package review and approval at the cognizant DOE field element.

Guidance for the DOE Model CRADA applies to clauses unchanged in the Short Form CRADA.

For each project, a Statement of Work (SOW) is required that details the nature, scope, roles, responsibilities, and costs of activities to be conducted by both parties together with an estimated timeline for completion of identified tasks. The SOW will be incorporated into the CRADA as Annex A.

Financial Considerations:

- A. *Federal Administrative Charge is applicable to entities as provided for by DOE Order 522.1;*
- B. *In Article II paragraph D, DOE's Cognizant Site CFO's per Chapter XIII of the Financial Management Handbook will provide approval/concurrence before the DOE Contracting Officer approves any advance payments of less than 60 days;*

C. *All of the funding provisions/requirements in Attachment 4 apply to the DOE Short Form CRADA. Please see Attachment 4 for more guidance on the following provisions:*

- (1) *Requirements for SBIR/STTR awards;*
- (2) *Full funding requirements for awards that are \$25,000 or less or where the work will be completed in 60 days or less;*
- (3) *Additional funding requirement for termination costs or other expenses for individual projects as determined by the Field CFOs;*
- (4) *Statement that no budgetary resources shall be utilized to fund work for CRADA partners; and*
- (5) *Exceptions to funding requirements as provided for in Chapter 13 of DOE's Financial Management Handbook.*

The Department of Energy has opted to utilize the following agreement, which is uniform across the Departmental facilities, for small value transactions. Except for minor modifications to the terms of this agreement made by CONTRACTOR, most changes will require approval by the DOE Contracting Officer, WHICH WILL LIKELY DELAY THE START DATE OF THE PROJECT. If substantive changes are required, the DOE Model CRADA may be more appropriate due to the increased flexibility such agreements afford.

STEVENSON-WYDLER (15 USC 3710a)

*SHORT-FORM COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
(hereinafter "CRADA") NO. _____*

BETWEEN

under its U.S. Department of Energy Contract

No. . (Hereinafter "Contractor")

AND

_____ *(hereinafter "Participant") both*

being hereinafter jointly referred to as the "Parties"

ARTICLE I: DEFINITIONS

- A. *"Government" means the United States of America and agencies thereof.*
- B. *"DOE" means the Department of Energy, an agency of the United States of America.*
- C. *"Contracting Officer" means the DOE employee administering the Contractor's DOE contract.*
- D. *"Generated Information" means information produced in the performance of this CRADA.*
- E. *"Proprietary Information" means information which is developed at private expense outside of this CRADA, is marked as Proprietary Information, and embodies (i) trade secrets or (ii) commercial or financial information which is considered privileged or confidential under the Freedom of Information Act (5 USC 552 (b)(4)).*
- F. *"Protected CRADA Information" means Generated Information which is marked as being Protected CRADA Information by a Party to this CRADA and which would have been Proprietary Information had it been obtained from a non-federal entity.*
- G. *"Subject Invention" means any invention of the Contractor or Participant conceived of or first actually reduced to practice in the performance of work under this CRADA.*
- H. *"Intellectual Property" means patents, trademarks, copyrights, mask works, Protected CRADA Information and other forms of comparable property rights protected by Federal law and other foreign counterparts.*

ARTICLE II: STATEMENT OF WORK, TERM, FUNDING AND COSTS

- A. *Annex A is the Statement of Work.*
- B. *The effective date of this CRADA shall be the latter date of (1) the date on which it is signed by the last of the Parties or (2) the date on which it is approved by DOE. The work to be performed under this CRADA shall be completed within _____ months/years from the effective date.*
- C. *The Participant's estimated contribution is \$ _____, which includes \$ _____ funds-in. The Government's estimated contribution, which is provided through Contractor's contract with DOE, is \$ _____, subject to available funding.*
- D. *[Reserve paragraph if Participant is not providing funding to Contractor.] For CRADAs that include (non-Federal) funding on a funds-in basis, the Participant shall provide Contractor, prior to any work from being performed, a budgetary resource sufficient to cover the anticipated work that will be performed during the first billing cycle. In addition, the Participant shall provide 60 days of additional funding to ensure that funds remain available for project during subsequent billing cycles. Failure of*

Participant to provide the necessary advance funding is cause for termination of this CRADA in accordance with the Termination article of this CRADA. A billing cycle is the period of time between billings, usually 30 days. The billing cycle is complete when the customer is billed for services rendered.

ARTICLE III: PERSONAL PROPERTY

Any tangible personal property produced or acquired in conducting the work under this CRADA shall be owned by the Party paying for it. There will be no jointly funded property. Personal property shall be disposed of as directed by the owner at the owner's expense.

ARTICLE IV: DISCLAIMER:

THE GOVERNMENT, THE PARTICIPANT, AND THE CONTRACTOR MAKE NO EXPRESS OR IMPLIED WARRANTY AS TO THE CONDITIONS OF THE RESEARCH OR ANY INTELLECTUAL PROPERTY, GENERATED INFORMATION, OR PRODUCT MADE OR DEVELOPED UNDER THIS CRADA, OR THE OWNERSHIP, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF THE RESEARCH OR RESULTING PRODUCT. NEITHER THE GOVERNMENT, THE PARTICIPANT, NOR THE CONTRACTOR SHALL BE LIABLE FOR SPECIAL, CONSEQUENTIAL OR INCIDENTAL DAMAGES.

ARTICLE V: PRODUCT LIABILITY

Except for any liability resulting from any negligent acts, or willful misconduct or omissions of Contractor or Government, Participant agrees to hold harmless the Government and the Contractor for all damages, cost and expenses, including attorney's fees, arising from personal injury or property damage as a result of the making, using, or selling of a product, process or service by or on behalf of the Participant, its assignees or licensees, which was derived from the work performed under this CRADA.

ARTICLE VI: RIGHTS TO SUBJECT INVENTIONS

The Parties agree to promptly disclose in writing to each other every Subject Invention in sufficient detail to comply with the provisions of 35 USC §112 well before any statutory bars may arise under 35 USC §102. Each Party shall have the first option to retain title to any of its Subject Inventions. If a Party elects not to retain title to any of its Subject Inventions, then the other Party shall have the option of electing to retain title to such Subject Inventions under this CRADA. The Participant has the option to choose an exclusive license, for reasonable compensation, in a pre-negotiated field of use to the Contractor's Subject Inventions.

The Parties acknowledge that the DOE may obtain title to each Subject Invention reported under this Article for which a patent application is not filed, a patent application is not prosecuted to issuance, or any issued patent is not maintained by either Party to this CRADA. The Government shall retain a nonexclusive, non-transferable, irrevocable, paid-up license to practice, or to have practiced, for or on its behalf all Subject Inventions throughout the world.

For Subject Inventions conceived or first actually reduced to practice under this CRADA which are joint Subject Inventions made by the Contractor and the Participant, title to such Subject Inventions shall be jointly owned by the Contractor and the Participant.

The Parties acknowledge that the DOE has certain march-in rights to any Subject Inventions in accordance with 48 CFR 27.304-1(g) and 15 USC 3710a(b)(1)(B) and (C).

ARTICLE VII: RIGHTS IN DATA

A. *The Parties and the Government shall have unlimited rights and each of them shall have a right to use all Generated Information produced by, or information provided to, the Parties under this CRADA which is not marked as being Protected CRADA Information or Proprietary Information.*

B. Proprietary Information:

Each Party agrees to not disclose properly marked Proprietary Information provided by the other Party to anyone other than the providing Party without the written approval of the providing Party, except to Government employees who are subject to 18 USC 1905.

C. Protected CRADA Information:

Each Party may designate and mark as Protected CRADA Information (PCI) any qualifying Generated Information produced by its employees. For a period of ___ years [not to exceed five years] from the date it is produced, the Parties agree not to further disclose such PCI except as necessary to perform this CRADA or as requested by the DOE Contracting Officer to be provided to other DOE facilities for use only at those DOE facilities with the same protection in place and marked accordingly. Government employees who are subject to 18 USC 1905 may have access to PCI.

D. Cessation of Obligations Regarding PCI and Proprietary Information:

The obligations relating to the disclosure or dissemination of Protected CRADA Information and Proprietary Information shall end if any such information becomes known without fault of either party, or if such information is developed independently by a Party's employees who had no access to the PCI or Proprietary Information.

E. Copyright:

The Parties may assert copyright in any of their Generated Information. The Parties hereby acknowledge that the Government or others acting on its behalf shall retain a nonexclusive, royalty-free, worldwide, irrevocable, non-transferable license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government, all copyrightable works produced in the performance of this CRADA, subject to the restrictions this CRADA places on publication of Proprietary Information and Protected CRADA Information.

[This paragraph can be deleted if no software is produced] If a Party copyrights computer software produced in the performance of this CRADA, the Party will provide the source code, object code, and expanded abstract, and the minimum support documentation needed by a competent user to understand and use the software to DOE's Energy Science and Technology Software Center (ESTSC) via www.osti.gov/estsc. The Party shall inform ESTSC when it abandons or no longer commercializes the computer software. Until such notice to ESTSC, the Government has for itself and others acting on its behalf, a royalty-free, nontransferable, nonexclusive, irrevocable worldwide copyright license to reproduce, prepare derivative works, and perform publicly and display publicly, by or on behalf of the Government. (narrow license) After the Party owning the Computer Software abandons or no longer commercializes the Computer Software, the Government has for itself and others acting on its behalf, a royalty-free, nontransferable, nonexclusive, irrevocable worldwide copyright license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government. (broad license)

ARTICLE VIII: U.S. COMPETITIVENESS

The Parties agree that a purpose of this CRADA is to provide substantial benefit to the U.S. economy.

- A. *In exchange for the benefits received under this CRADA, the Participant therefore agrees to the following:*
- (1) Products embodying Intellectual Property developed under this CRADA shall be substantially manufactured in the United States, and*
 - (2) Processes, services, and improvements thereof which are covered by Intellectual Property developed under this CRADA shall be incorporated into the Participant's manufacturing facilities in the United States either prior to or simultaneously with implementation outside the United States. Such processes, services, and improvements, when implemented outside the United States, shall not result in reduction of the use of the same processes, services, or improvements in the United States.*
- B. *The Contractor agrees to a U.S. Industrial Competitiveness clause in accordance with its prime contract with respect to any licensing and assignments of its Intellectual Property arising from this CRADA, except that any licensing or assignment of its intellectual property rights to the Participant shall be in accordance with the terms of paragraph A of this Article.*

ARTICLE IX: EXPORT CONTROL

EACH PARTY IS RESPONSIBLE FOR ITS OWN COMPLIANCE WITH EXPORT CONTROL LAWS AND REGULATIONS. EXPORT LICENSES OR OTHER AUTHORIZATIONS FROM

THE U.S. GOVERNMENT MAY BE REQUIRED FOR THE EXPORT OF GOODS, TECHNICAL DATA OR SERVICES UNDER THIS AGREEMENT. THE PARTIES ACKNOWLEDGE THAT EXPORT CONTROL REQUIREMENTS MAY CHANGE AND THAT THE EXPORT OF GOODS, TECHNICAL DATA OR SERVICES FROM THE U.S. WITHOUT AN EXPORT LICENSE OR OTHER APPROPRIATE GOVERNMENTAL AUTHORIZATION MAY RESULT IN CRIMINAL LIABILITY.

ARTICLE X: REPORTS AND ABSTRACTS

The Parties agree to produce the following deliverables: an initial abstract suitable for public release; and a final report, to include a list of Subject Inventions. It is understood that the Contractor has the responsibility to provide this information at the time of its completion to the DOE Office of Scientific and Technical Information. The Participant agrees to provide the above information to the Contractor to enable full compliance with this Article.

The Parties agree to submit, for a period of five years from the expiration of this CRADA and, upon request of DOE, a non-proprietary report no more frequently than annually on the efforts to utilize any Intellectual Property arising under the CRADA.

Use of the name of a Party or its employees in any promotional activity, with reference to this CRADA, requires written approval of the other Party.

ARTICLE XI: FORCE MAJEURE

Neither Party will be liable for unforeseeable events beyond its reasonable control.

ARTICLE XII: DISPUTES

The Parties shall attempt to jointly resolve all disputes arising from this CRADA. In the event a dispute arises under this CRADA, the Participant is encouraged to contact Contractor's Technology Partnership Ombudsman in order to further resolve such dispute before pursuing third-party mediation or other remedies. If the Parties are unable to jointly resolve a dispute within a reasonable period of time, they agree to submit the dispute to a third-party mediation process that is mutually agreed upon by the Parties. To the extent that there is no applicable U.S. Federal law, this CRADA and performance thereunder shall be governed by the laws of the State of _____, without reference to that state's conflict of laws provisions.

ARTICLE XIII: ENTIRE CRADA, MODIFICATIONS AND TERMINATION

This CRADA with its annexes contains the entire agreement between the Parties in performing the research described in the Statement of Work (Annex A) and becomes effective on the later date of either the date the last Party signs the document or receipt of advance funding, if any. Any agreement to materially change any terms or conditions of the CRADA and annexes shall be

valid only if the change is made in writing, executed by the Parties hereto, and approved by DOE.

This CRADA may be terminated by either Party with _____ days written notice to the other Party. If Article II provides for advance funding, this CRADA may also be terminated by the Contractor in the event of failure by the Participant to provide the necessary advance funding. Each Party will be responsible for its own costs arising out of or as a result of this termination. The obligations of any clause of this CRADA that were intended to survive the expiration of the period of performance, for example, confidentiality, use and/or non-disclosure obligations, shall also survive any termination of this CRADA.

FOR CONTRACTOR:

BY _____

TITLE _____

DATE _____

FOR PARTICIPANT:

BY _____

TITLE _____

DATE _____

ATTACHMENT 6

This Attachment provides information and/or requirements associated with DOE O 483.1B as well as information and/or requirements applicable to contracts in which the associated CRD (Attachment 1 to DOE O 483.1B) is inserted.

JOINT WORK STATEMENT FORMAT

JWS/CRADA # _____

Project Title: _____

Submittal Date: _____

A. Data Table

1. Summary/OSTI Abstract:
2. Participant(s) Name and Address
(NAME)
(Mailing or Street Address) (City, State, Zip)
(Telephone Number)
3. Participant Type (check all that apply)

	Participant One	Participant Two
Foreign	<input type="checkbox"/>	<input type="checkbox"/>
University	<input type="checkbox"/>	<input type="checkbox"/>
Small Business	<input type="checkbox"/>	<input type="checkbox"/>
Large Business	<input type="checkbox"/>	<input type="checkbox"/>
State or Local Government	<input type="checkbox"/>	<input type="checkbox"/>
Not-for-Profit	<input type="checkbox"/>	<input type="checkbox"/>
National Laboratory	<input type="checkbox"/>	<input type="checkbox"/>

4 Funding Table

	Year 1		Year 2		Year 3		Totals
Funding Type	Funds-in	*In-kind	Funds-in	*In-kind	Funds-in	*In-kind	
Participant 1							
Participant 2							
Dept. of Energy							
Totals							
**FAC							

**Note: If applicable, the contractor has reviewed the Participant(s) proposed in-kind contribution and based on ___experience, ___financial analysis, and/or ___sound business judgment has determined the estimated in-kind contribution(s) is/are reasonable.*

***Federal Administrative Charge—state amount if included in Funds-in amount above. If FAC is waived, put amount in parentheses. See DOE Order 522.1 for more information on FAC.*

5. Identify the DOE mission area (___ Energy, ___ Environmental Quality, ___ Science, ___ National Security, ___ Other) that will benefit from this CRADA. If other, please explain.
6. How does the proposed CRADA benefit DOE, Participant, and U.S. Taxpayer? (Some facilities require textual explanation; others provide a checklist for each stakeholder. An example follows.)

EXAMPLE:

DOE Benefit: ___ Assists laboratory in achieving programmatic scope, ___ adds new capability to the laboratory’s core competencies, ___ enhances

the laboratory's core competencies, ___ uses the laboratory's core competencies, and/or ___ enhances U.S. competitiveness by utilizing DOE-developed intellectual property and/or capabilities.

7. DOE Program Manager:

Telephone No.
8. B&R Code and/or FWP Number
9. The Proposed CRADA will be based upon DOE Model CRADA, Short Form CRADA, Multilab CRADA, other (identify)

B. Special Considerations

1. Background Intellectual Property (e.g., inventions or copyrightable software, etc.)?
 Yes No. If yes, list:
2. Is the Participant interested in licensing Background Intellectual Property?
 Yes No. If yes, please identify any known impediments for such licensing:
3. Are human or animal subjects involved in this project?
 Yes No

(If yes, before the CRADA can be executed, approvals must be obtained from the Institutional Review Board or the Animal Care and Use Committee.)
4. Have all necessary environmental, safety, health and quality (NEPA) reviews been satisfactorily completed?
 Yes No (If No, explain)
5. The laboratory is responsible for obtaining Conflict of Interest (COI) Certificates and will maintain in the file the completed COI Certificates for each employee with a substantial role in this CRADA. Are there any organizational or personal conflict of interest issues associated with this CRADA?
 Yes (If Yes, explain) No
6. Will export controlled and classified information be used or produced?
 Yes (If Yes, explain) No
7. How was Fairness of Opportunity determined? ___ Participant approached laboratory ___ Participant responded to FBO (Federal Business Opportunity) ___ Participant was contacted by laboratory after or during broad public announcement.
(Supporting documentation is to be maintained in CRADA file.)

8. For 100% funds-in CRADAs, the Participant has been notified of other types of technology transfer agreements (e.g. Work for Others).
 Yes No N/A
9. Did the Participant require any substantive/material changes to the laboratory/field-approved DOE Model CRADA and/or any changes to double-underlined language?
 Yes No
If yes, attach copies of the proposed modified articles (changes should be highlighted in CRADA if it is also submitted with the JWS), and (if applicable) Participant's U.S. Competitiveness worksheet/justification. If requested by the Contracting Officer, the Contractor will provide justification for modified articles in writing.
10. Is this a request for a preliminary determination to proceed at Contractor's own risk?
 Yes No.
By checking yes, the Contractor certifies that the CRADA to be submitted for DOE approval contains terms and conditions previously approved by DOE with no deviations.
11. **Additional Notes:** If applicable, identify special considerations or comments.

If applicable, add approval signature blocks for DOE and the Contractor.

ATTACHMENT 7

This Attachment provides information and/or requirements associated with DOE O 483.1B as well as information and/or requirements applicable to contracts in which the associated CRD (Attachment 1 to DOE O 483.1B) is inserted.

CRADA WITH FOREIGN-OWNED OR CONTROLLED ENTITY

Part A below is to be completed by proposed Participants in technology transfer agreements involving Participant access to classified information or special nuclear materials or unescorted access to security areas of Departmental facilities. This information is requested in accordance with provisions of the Atomic Energy Act of 1954, as amended. Part B of this Attachment is to be completed by the Laboratory for notifying DOE.

DOE field elements are required to include a foreign ownership, control, or influence (FOCI) review as part of their security review of CRADAs involving Participant access to classified information, access to special nuclear materials (special nuclear materials shall mean quantities as defined in 10 CFR Part 710) or unescorted access to security areas within Departmental facilities. If a CRADA does not involve access to classified information, special nuclear materials, or secure facilities, a FOCI review is not required to meet the Department's national security obligations as mandated by the Atomic Energy Act of 1954, as amended. If an individual has the ability and/or opportunity to obtain access to classified information or matter by being in a place where such information or matter is accessible, and, if the security measures which are in force do not *prevent* the gaining of access to the classified information or matter, the FOCI review must be completed regardless of whether the CRADA involves classified matter or information

In those cases requiring a FOCI review, DOE must receive the prospective Participant's response to the eleven FOCI questions, including required additional information and the certification, prior to approval of the CRADA. These materials should be submitted as early as possible to the normal Joint Work Statement/CRADA contact at DOE, for referral to the Safeguards and Security point of contact so that the FOCI review process may be initiated expeditiously. If the field element receives a proposed Joint Work Statement prior to submission of the needed responses to the FOCI questions, or a proposed CRADA prior to completion of the FOCI review and resolution of outstanding issues, the field element must decide whether to return the Joint Work Statement or CRADA for further information or to disapprove it. In general, no CRADA involving access to classified information, access to special nuclear materials, or unescorted access to security areas of Departmental facilities will be approved until the FOCI review is complete and all FOCI issues are resolved. One option, available at field element discretion, is to phase the work in such a way that unclassified activities are initiated in an earlier phase than those requiring access to classified information, special nuclear materials, or security areas of Departmental facilities. Approval of unclassified phases of the work could precede the completion of the FOCI determination. Approval of phases of the work involving classified information, special nuclear materials, or unescorted access to security areas of Departmental facilities must await the FOCI determination and resolution of any FOCI issues. The field element may

require additional justification from Laboratory to address the risk associated with terminating a CRADA between phases.

Implementation of the FOCI review should be done in a manner which ensures that DOE meets the statutory deadlines for processing Joint Work Statements and CRADAs. Information submitted by the Participant as required pursuant to the FOCI review shall be treated by the Laboratory and by DOE, to the extent permitted by law, as business or financial information submitted in confidence to be used solely for purposes of evaluating FOCI. Nothing in this guidance relieves the obligation to address other considerations such as export control or U.S. competitiveness issues. Broad concerns about existing U.S. competitiveness policies and procedures should be brought to the DOE Technology Transfer Committee for discussion.

For CRADAs involving access to classified information or special nuclear materials or unescorted access to security areas of Departmental facilities, the CRADA must contain provisions which ensure that changes in the Participant's FOCI status are promptly reported over the term of the agreement. If a Participant reports such changes or if more than 5 years have passed since any previous FOCI determination, the Laboratory shall forward that information to DOE according to its established procedures for FOCI review. Certain changes in the FOCI status of the Participant in an approved CRADA could result in direction from security organizations that access of the Participant to classified information, special nuclear materials, or security areas of Departmental facilities be limited. The authority to limit access is inherent in operative DOE Orders. If the Participant becomes subject to FOCI and cannot, or chooses not to, avoid or mitigate the FOCI problem, and the Participant's access to classified information is essential to continuation of the collaborative work, the Laboratory shall provide notice of termination and expedite the orderly shutdown of collaborative work.

**A. FOCI QUESTIONNAIRE FOR APPLICABLE
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS**

Instructions:

- I. For the purposes of this questionnaire, a foreign interest is defined as any of the following:
 - A. A foreign government or foreign government agency;
 - B. Any form of business enterprise organized under the laws of any country other than the United States or its possessions;
 - C. Any form of business enterprise organized or incorporated under the laws of the U.S., or a State or other jurisdiction within the U.S., which is owned, controlled, or influenced by a foreign government, agency, firm, corporation or person; or
 - D. Any person who is not a U.S. citizen.

- II. If your organization has not previously submitted responses to the following questions, then provide the information requested herein. Answer each question in either the yes or no space. If the answer to any of the questions is yes, provide the detailed information requested in the attached *Guidelines for Completing the FOCI Certification* for that specific question. Information which responds to these questions and which has been previously submitted to a Government agency may be resubmitted for this questionnaire if the information is accurate, complete, and current.
- III. If you own other entities, you must provide consolidated information for all your wholly- and majority-owned subsidiaries (foreign and domestic). If you are owned by a parent organization, it must also complete a FOCI certification which should be submitted along with your certification.
- IV. Each FOCI representation must also include the following supporting information:
- A. Identification of all your organization's owners, officers, directors and executive personnel, including their names; social security numbers; citizenship; titles of all positions they hold within your organization; and clearances they possess, if any, and the name of the agency(ies) which granted the clearances.
 - B. Your organization's latest annual report and the Securities and Exchange Commission Form 10-K. If you are a privately held company or a subsidiary of another corporation and cannot provide these documents, the appropriate official within your organization (e.g., chief financial officer, treasurer, or secretary) must provide the following consolidated financial information for all wholly and majority-owned subsidiaries and affiliates: assets, current and total; liabilities, current and total; stockholders' equity; revenue and net income; and the amount of revenue derived from foreign interests.
- V. The certification of the FOCI questionnaire must be signed by an individual who can legally do so for the Participant and may include an owner, officer, or director.

QUESTIONS:

1. Does a foreign interest own or have beneficial ownership in 5% or more of your organization's voting securities?
 Yes No
2. Does your organization own 10% or more of any foreign interest?
 Yes No

3. Do any foreign interests have management positions such as directors, officers, or executive personnel in your organization?
 Yes No

4. Does any foreign interest control or influence, or is any foreign interest in a position to control or influence the election, appointment, or tenure of any of your directors, officers, or executive personnel?

5. Does your organization have any contracts, binding agreements, understandings, or arrangements with a foreign interest(s) that cumulatively represent 10% or more of your organization's gross income?
 Yes No

6. Is your organization indebted to foreign interests?
 Yes No

7. Does your organization derive any income from sensitive countries included on the attached list?
 Yes No

8. Is 5% or more of any class of your organization's securities held in "Nominee shares," in "street names," or in some other method which does not disclose beneficial ownership of equitable title?
 Yes No

9. Does your organization have interlocking directors with foreign interests?
 Yes No

10. Are there any citizens of foreign countries employed by, or who may visit, your offices or facilities in a capacity which may permit them to have access to classified information or a significant quantity of special nuclear material?
 Yes No

11. Does your organization have foreign involvement not otherwise covered in your answers to the above questions?

CERTIFICATION: Check one:

- () I certify that the entries made herein are accurate, complete, and current to the best of my knowledge and belief and are made in good faith.
- () I certify that the information requested herein has been previously submitted to the Department of Energy as required for a facility clearance and that the information in the previous submission is accurate, complete, and current for the purposes of this Cooperative Research and Development Agreement.

CERTIFIED BY:

_____ : NAME OF PARTICIPANT REPRESENTATIVE

_____ : TITLE

_____ : STREET ADDRESS

_____ : CITY, STATE, ZIPCODE, COUNTRY

_____ : SIGNATURE & DATE

GUIDANCE FOR COMPLETING FOCI CERTIFICATION

Question Number 1. Does a foreign interest own or have beneficial ownership in 5% of more of your organization's voting securities?

Identify the percentage of any class of shares or other securities issued which are owned by foreign interests, listed by country. If you answered "Yes" and have received from an investor a copy of Schedule 13D or Schedule 13G filed by the investor with the Securities and Exchange Commission, you are to attach a copy of Schedule 13D or Schedule 13G.

Question Number 2. Does your organization own 10% or more of any foreign interest?

If your answer is "Yes", furnish the name of the foreign interest, address by country, and the percentage owned. For each employee occupying a position with the foreign firm, provide the following information:

1. Complete name.
2. Citizenship.
3. Titles of positions within the foreign entity.
4. Clearances, if any, they possess, and by whom those clearances were granted.
5. To what extent the employees are involved in the operations of the foreign facilities.

6. Whether or not any of these individuals will, by virtue of their position, knowledge, or expertise, require access to Department of Energy classified information.

If the employees possess DOE clearances, or are in the process of being cleared, and hold positions with foreign interests, they need to complete the attached "Representative of Foreign Interest Statement" for each such firm.

Does your organization have branch or sales offices or other facilities, or are you qualified to do business as a foreign corporation in any other countries? If the answer is "Yes" list all.

What percentage of your organization's gross income is derived from your foreign subsidiaries or affiliates?

Question Number 3. Do any foreign interests have management positions such as directors, officers, or executive personnel in your organization?

Furnish details concerning the identity of the foreign interest and the position(s) held in your organization, to include the amount of time the individual spends at your facility. If the individual spends less than full time at your facility, provide information on how and where the rest of his/her time is spent.

Question Number 4. Does any foreign interest control or influence, or is any foreign interest in a position to control or influence the election, appointment, or tenure of any of your directors, officers, or executive personnel?

Identify the foreign interest(s) and furnish details concerning the control or influence. If the individuals have been excluded from access to Department of Energy classified information by Board resolution or corporate exclusion, an official (signed and dated) copy of such exclusion must be submitted with this package.

Question Number 5. Does your organization have any contracts, binding agreements, understandings, or arrangements with a foreign interest(s) that cumulatively represent 10% or more of your organization's gross income?

Furnish the name of the foreign interest, country, and nature of agreement or involvement. If there is no ownership involved in these arrangements, provide details along the same lines of information required for Question Number 2. Certification should be made as to whether or not the agreements are:

1. Purely commercial in nature.
2. Involve defense procurement.
3. Involve classified information.
4. Involve sensitive countries.

Provide the amount of revenue derived from foreign sources. This should be provided by country. Also, state the time frame, e.g., fiscal year ending December 31, 1992, during which the revenue was derived. This should include revenue from all foreign sources, e.g., subsidiaries, equity income derived from your interest in less than wholly owned subsidiaries, export sales, divestitures to foreign interests, royalties from licensing and patent agreements, dividends from foreign stock holdings, and investment or real estate. Compliance with export license requirements and international traffic in arms regulations (ITAR) requirements must be acknowledged, if applicable.

In addition, due to the political sensitivity of some countries, the Department of Energy requires that you provide the following information if you derive revenue and have other understandings or arrangements with sensitive countries:

1. The amount of international and export revenue.
2. The type of service or product provided (be specific—show whether they are commercial in nature or involve defense procurement).
3. Compliance with export license and ITAR requirements, if applicable.
4. Any other involvement not covered by the prior two elements of the question.

NOTE: Information provided must be audited information, and NOT MORE THAN ONE YEAR OLD.

Question Number 6. Is your organization indebted to foreign interests?

Report all lines of credit your organization has with foreign interests even if there is no current indebtedness. Provide the following information:

1. The amount and type of indebtedness.
2. If any debentures are convertible, explain under what circumstances.
3. The name(s) of the lending institution(s) and the country(ies) in which they are located.
4. What collateral, if any, has been furnished or pledged.
5. The total line of credit available from these lending institutions.
6. What percentage of your current assets does this indebtedness represent?
7. If you have a worldwide line of credit available, what is the total line of credit available from foreign sources?

NOTE: If you own other entities, you must provide consolidated information for all of your wholly and majority-owned subsidiaries (foreign and domestic).

B. DOE NOTIFICATION BY LABORATORY

Guidance: The Laboratory must notify the servicing DOE/NNSA field element as early as possible about the pending CRADA and submit a completed Certification (above) along with the following information:

CRADA Title:

Parties: [Identify lab/Participant]

Foreign Ownership Information: [Identify name of company; type of company/line of work; nature of foreign ownership and/or foreign control; location of company; location of corporate office, if different; subsidiaries; number of employees.]

Purpose: [Briefly explain purpose of CRADA. Include specific expertise of company and how that expertise relates to this CRADA. Include brief statement on work that each Party will be doing.]

Funding: [Will Participant contribute funds-in and in-kind? Are there DOE Program funds involved? OFA funds?]

Benefits: [Explain benefits to DOE/NNSA program(s).]

Trade Rep. Review: [Identify date of completion/decision and any issues. If a decision has not been received, state the USTR decision is pending and provide date that agreement was submitted to USTR for review.]

National Security Issues: [Provide classification review results. Does the CRADA involve any sensitive or Military Critical Technologies? ITAR-controlled information?]

Fairness of Opportunity: [Provide sufficient information to confirm that U.S. companies have been given an equal opportunity to participate in a similar CRADA.]

U.S. Competitiveness: [For a CRADA with a foreign-owned and/or foreign-controlled Participant, it's not enough to get the Participant to sign up to Article XXII. The labs need to meet all legal requirements and also understand the political and public risks involved in partnering in the technology area and with the specific Participant. The labs need to fully understand how the Participant plans to meet the Article XXII requirements and provide that info here. Some factors to consider include: What is the deliverable, e.g., product, process, service? What are their commercialization plans? What are their plans for manufacturing? Does the Participant have manufacturing facilities and, if so, where? Do they have U.S. facilities, manufacturing plants, suppliers? What are their licensing plans for commercialization? What is their foreign vs. U.S. market for product, process service?]

Export Control Determination: [State if there are foreign nationals who may be part of Contractor's and/or the Participant's project team and discuss that determination in light of the export review results.]

CRADA Deviations: [State whether or not changes have been negotiated in the DOE Model CRADA language. A sample statement is as follows: (Participant name) has negotiated a number of changes to the standard DOE Model CRADA language. This language has been reviewed and approved by the legal counsel of Contractor and is being reviewed by (name of DOE/NNSA field element).]

M&O Contractor POC: [Name, e-mail and phone]

Field Element Recommendation: [Leave blank]

Field Element POC: [Leave blank]

GUIDANCE FOR DOE NOTIFICATION:

If the proposed Participant is foreign-owned or foreign-controlled, the M&O Contractor needs to pay special attention to the following factors:

1. Export control determination;
2. Classification review results;
3. Coordination and approval for foreign nationals who would be part of the Participant's project team; and U.S. Competitiveness pertaining to:
 - a. Deliverables under the agreement;
 - b. How Participant is going to meet U.S. Competitiveness requirements; and
 - c. Whether or not Participant has the ability or plans to manufacture in the U.S.

Additionally, the M&O Contractor must comply with the following requirements:

1. Notify the servicing DOE/NNSA field element as early as possible about the pending CRADA and submit the completed DOE Notification.
2. Review information available at the U.S. Trade Representative web page (<http://www.ustr.gov>).
 - a. The M&O Contractor should consider the following factors in their review:
 - (a) Does the foreign government permit U.S. agencies, organizations and other U.S. persons to enter into cooperative R&D agreements?

- (b) Does the foreign government have policies to protect U.S. intellectual property rights?
 - b. The documents to review include the following:
 - (a) USTR Inventory of Foreign Trade Barriers: The National Trade Estimate Report found at (www.ustr.gov/about-us/press-office/reports-and-publications)
 - (b) The most recent USTR Special 301 Review: (www.ustr.gov/about-us/press-office/reports-and-publications)
 - (c) Any other relevant information, such as past USTR opinions on countries in light of new reports.
- 3. Seek DOE Contracting Officer approval of the proposed CRADA. The Contracting Officer may require the M&O Contractor to obtain input from the US Trade Representative before reaching a decision. Information provided to the Contracting Officer must contain, but are not limited to the following:
 - a. Nature of foreign ownership/control of the Participant (e.g., foreign-owned, U.S.-controlled; U.S.-owned, foreign-controlled; foreign-owned, foreign-controlled; etc.)
 - b. Information from obtained from USTR web site and answers to questions from paragraph 2(a), above.
 - a. Results of classification and export control reviews.
 - d. Fairness of Opportunity (FOO) checklist with sufficient information to confirm that U.S. companies have been given equal opportunities to participate in a similar CRADA.
 - e. Any other information that the Contracting Officer feels is required to make a decision.

ATTACHMENT 8

This Attachment provides information and/or requirements associated with DOE O 483.1B as well as information and/or requirements applicable to contracts in which the associated CRD (Attachment 1 to DOE O 483.1B) is inserted.

U.S. COMPETITIVENESS / NET BENEFIT STATEMENT

The Government, authorizing CRADAs, is seeking to transfer technology to companies with significant manufacturing and research facilities in the United States in a way that will provide short- and long-term benefits to the U.S. economy and the industrial competitiveness of such companies.

The preferred benefit to the U.S. economy is the creation and maintenance of manufacturing capabilities and jobs within the United States.

If the Participant(s) can't agree, as part of the CRADA, to substantially manufacture any products, use any processes, or perform any services in the United States incorporating or resulting from inventions, copyrights, mask works, or protectable data arising from the CRADA work in which the Participant(s) has some commercial rights, then the Participant(s) must furnish a description (hereinafter A Net Benefit Statement) of specific economic or other benefits to the U.S. economy that are related to the commercial use by Participant(s) of the technology being funded under the CRADA and that are commensurate with the Government's contribution to the proposed work.

The above-described agreement and/or Net Benefit Statement will be provided by the laboratory to the DOE field element according to the latest Net Benefit Statement Guidance.

QUESTIONNAIRE FOR CRADA PARTICIPANT

The standard terms and conditions of a DOE Model CRADA include the U.S. Competitiveness provision, which reads:

In exchange for the benefits received under this CRADA, the Participant therefore agrees to the following:

- 1. Products embodying Intellectual Property developed under this CRADA shall be substantially manufactured in the United States, and*
- 2. Processes, services, and improvements thereof which are covered by Intellectual Property developed under this CRADA shall be incorporated into the Participant's manufacturing facilities in the United States either prior to or simultaneously with implementation outside the United States. Such processes, services, and improvements,*

when implemented outside the United States, shall not result in reduction of the use of the same processes, services, or improvements in the United States.

If you cannot agree to this provision as written, then part of the process for finalizing your CRADA will include developing legally binding language acceptable to DOE that commits you to provide some other benefit to the U.S. economy, which will then be made a part of your agreement in lieu of the standard clause.

At the end of this document, you will provide a statement for an alternate benefit to the US economy (referred to as Net Benefit Statement), which will be incorporated into the CRADA as an annex. The following questions will assist you in developing an acceptable Net Benefit Statement that will be reviewed and approved by DOE.

Title and number of CRADA:

Contact Person (e.g., Patent Counsel), phone number, and e-mail address:

Briefly describe your business model. The description may include plans for manufacturing domestically and offshore. Briefly explain why you need to manufacture in the locations you discuss.

Future Benefits to the U.S. economy when creating and implementing Intellectual Property developed under the CRADA:

What work under CRADA do you plan to do in the U.S.? Work may include manufacturing, R&D, administration. If you have built or will build a plant or R&D facility, what is the capacity and approximate number and type of employees? What is the timeframe of the U.S.-based work? Will you begin work in the U.S. right away, with later global diversification, or will the work be spread over several locations for the entire period of the CRADA? Will your efforts result in the creation of new U.S. jobs? If so, describe them.

Participant makes the following specific commitments to U.S. investment:

(You may list these in bullet or numbered form, or in paragraph form. Be aware that DOE will require specific commitments. You may include existing or planned facilities in the U.S. (if so, please describe what they'll be and how many and what type of employees they may have)). Also, the projected timeline for building and operating the facilities.

How will your work under the CRADA further the U.S. development of the technology?

What commitments do you make to significantly reinvest profits from the commercialization of the intellectual property resulting from the work under this CRADA in the U.S. economy?

What other benefits will your work have on the U.S. economy?

Such benefits may include one or more of the following:

- Direct or indirect investment in U.S.-based plant and equipment.
- Creation of new and/or higher-quality U.S.-based jobs.
- Enhancement of the domestic skills base.
- Further domestic development of the technology.
- Significant reinvestment of profits in the domestic economy.
- Positive impact on the U.S. balance of payments in terms of product and service exports as well as foreign licensing royalties and receipts.
- Appropriate recognition of U.S. taxpayer support for the technology; e.g., a quid-pro-quo commensurate with the economic benefit that would be domestically derived by the U.S. taxpayer from U.S.-based manufacture.
- Cross-licensing, sublicensing, and reassignment provisions in licenses which seek to maximize the benefits to the U.S. taxpayer.

The following Net Benefit Statement will be incorporated into the CRADA:

[The Net Benefit Statement should be based on the answers to the above questions and provide a specific commitment on the part of the Participant to provide some significant net benefit to the U.S. economy in lieu of substantial U.S. manufacture.]

ATTACHMENT 9

This Attachment provides information and/or requirements associated with DOE O 483.1B as well as information and/or requirements applicable to contracts in which the associated CRD (Attachment 1 to DOE O 483.1B) is inserted.

TECHNOLOGY TRANSFER NOTIFICATIONS FOR UNUSUAL CIRCUMSTANCES

1. Background. DOE and its laboratory system are involved in large numbers of technology transfer activities. Most proceed smoothly and significantly benefit the Department, the private sector, and the nation as a whole. Some activities result in exceptional success, which DOE may want to promote. Other activities involve unusual circumstances (real or perceived issues that can attract significant attention), which need to be communicated to higher levels in DOE management.
2. Notification Process. When concern arises about unusual circumstances in an existing or proposed CRADA activity, the field element will notify the appropriate Secretarial Officers. These include, if different, the Cognizant Secretarial Officer, and Program Secretarial Officer. Cognizant Secretarial Officers can provide advice or guidance as to whether a particular concern should be reported to a Secretarial Officer.
3. Notification Criteria. Some notification criteria are specifically addressed in this Order or imposed by other Orders.
 - a. The following are examples of situations that require a well-defined notification or approval process to be in place so that higher management will be notified.
 - (1) DOE Model CRADA. Deviation from the double-underlined language in the DOE Model CRADA standard terms, conditions, and options, and the related DOE Model CRADA guidance.
 - (2) Multi-laboratory CRADAs. These require notification of the relevant field elements, which are responsible for ensuring coordination and resolution of any conflicting or varying terms or arrangements.
 - (3) Sensitive technologies. Projects related to sensitive technologies (as outlined in the Sensitive Subjects List available from the Nuclear Transfer and Supplier Policy Division, NN-43), nuclear applied technologies, or work involving export controlled information require the relevant approvals.
 - (4) Human or animal subject involvement.
 - (a) Human subject involvement. If the laboratory holds an assurance of compliance with human subject regulations, it may approve such activities; however, the field element must be notified. If the laboratory does not hold an assurance of

compliance (either Department of Health and Human Services or DOE), the Office of Science must approve the activities. If the Participant will be performing the human subject testing, the Contractor will notify DOE Head of Field Element and Contracting Officer of such activity before executing the CRADA.

- (b) Animal subject involvement. If the laboratory has an institutional animal care and use committee, it may approve such activities; however, the field office must be notified. If the laboratory does not have an institutional animal care and use committee, it is not authorized to conduct research activities involving animals. If the Participant will be performing the animal subject testing, the Contractor will notify the DOE Head of Field Element and Contracting Officer of such activity before executing the CRADA.
- (5) Environment, Safety and Health and National Environmental Policy Act. Normal considerations are handled within the standard process.
- (6) For all other circumstances the judgment and experience of DOE field element personnel is the primary determiner of when notification should occur. DOE encourages early discussion among laboratories, field elements, and program offices to make this determination. The following are examples of circumstances under which Headquarters notification might be appropriate based on field judgment.
- (7) foreign participation and issues;
- (8) alternative benefits to U.S. manufacturing requirements having a potential for significant impact on the U.S. economy;
- (9) size of activity and impact on the laboratory;
- (10) large funds-in from the Participant;
- (11) activities that may involve unique or unusual health, safety, or environmental issues or a significant real or perceived potential environmental impact; potential for major economic impact to the relevant industrial or commercial sector or for the appearance of inappropriate competition with the private sector; and
- (12) potential for significant political or media interest or significant public or private sector controversy.