

DOE M 483.1-1

Approved: 1-12-01
Sunset Review: 1-12-03
Expiration: 1-12-05

DOE COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS MANUAL



U.S. DEPARTMENT OF ENERGY

Office of Science and Technology Policy Analysis

DISTRIBUTION:
All Departmental Elements

INITIATED BY:
Office of Science and
Technology Policy Analysis

**DOE COOPERATIVE RESEARCH
AND DEVELOPMENT AGREEMENTS MANUAL**

1. PURPOSE. This Manual provides detailed requirements to supplement DOE O 483.1, DOE COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS, dated 1-12-01, which establishes requirements for the performance of technology transfer through the use of Cooperative Research and Development Agreements (CRADAs).
2. REFERENCE. DOE O 483.1, DOE COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS, dated 1-12-01.
3. CONTACT. Questions concerning this Manual should be addressed to the Office of Science and Technology Policy Analysis at 202-586-3900.

BY ORDER OF THE SECRETARY OF ENERGY:



T.J. GLAUTHIER
Deputy Secretary

CONTENTS

	<u>Page</u>
1. INTRODUCTION	1
2. DEFINITIONS	1
3. JWS/CRADA PROCESS	2
4. TECHNOLOGY TRANSFER NOTIFICATIONS FOR EXCEPTIONAL SITUATIONS	2
 APPENDIXES	
A. JOINT WORK STATEMENT FORMAT	1
B. DOE MODULAR COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT	1

DOE COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS MANUAL

1. INTRODUCTION. The purpose of this Manual is to provide practical guidelines that will expedite the Cooperative Research and Development Agreement (CRADA) process. The Manual provides detailed information on Department of Energy (DOE) approval requirements and processing guidelines. This information has been developed to promote consistency among sites entering into CRADAs.

2. 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 personal property (equipment and supplies), capital equipment, work to be performed at either party's facilities, real property, or 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 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, assigning rights among the various parties.

3. JWS/CRADA PROCESS. 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 must be approved before a CRADA can be approved by DOE.

The DOE field program manager will review the JWS for compliance with Federal and agency regulations and guidelines. All issues and problems will be identified and resolved prior to approval. Appendix A, Joint Work Statement Format, presents the DOE JWS format to be

used for all CRADAs. This format is also to be used by contractors when developing multi-laboratory CRADAs. The Statement of Work approved in the JWS will be made an attachment to the CRADA. This JWS format may be supplemented by local field offices.

The Modular CRADA (Appendix B, DOE Modular Cooperative Research and Development Agreement) contains 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 office and should be consistent with this Manual. It is recognized that there are other models that have been developed through appropriate entities in DOE. These include the Short Form CRADA and the USIC CRADA models. If there is any question as to the validity of other models, consult with the Assistant General Counsel for Technology Transfer and Intellectual Property.

4. TECHNOLOGY TRANSFER NOTIFICATIONS FOR UNUSUAL CIRCUMSTANCES.

- a. 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.
- b. Notification Process. When concern arises about unusual circumstances in an existing or proposed CRADA activity, the operations/field office will notify the appropriate Secretarial Officers. These include, if different, the Lead Program Secretarial Officer, Cognizant Secretarial Officer, and Program Secretarial Officer. Members of the technology transfer working group can provide advice or guidance as to whether a particular concern should be reported to a Secretarial Officer.
- c. Notification Criteria. Some notification criteria are specifically addressed in this Manual or imposed by other Orders.
 - (1) The following criteria are examples of situations that each have a well-defined notification or approval process in place which identifies when higher management must be notified.
 - (a) Modular CRADA. Deviation from the double-underlined language in the Modular CRADA standard terms, conditions, and options, and the related Modular CRADA guidance.

- (b) Multi-laboratory CRADAs. These require notification of the relevant field offices, which are responsible for ensuring coordination and resolution of any conflicting or varying terms or arrangements.
 - (c) 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.
 - (d) Human or animal subject involvement.
 - 1 Human subject involvement. If the laboratory holds an assurance of compliance with human subject regulations, it may approve such activities; however, the field office 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.
 - 2 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.
 - (e) Environment, Safety and Health and National Environmental Policy Act. Normal considerations are handled within the standard process.
- (2) For all other circumstances the judgment and experience of field office personnel is the primary determiner of when notification should occur. DOE encourages early discussion among laboratories, field offices, and program offices to make this determination. The following are examples of circumstances under which Headquarters notification might be appropriate based on field office judgment:
- (a) foreign participation and issues;
 - (b) alternative benefits to U.S. manufacturing requirements having a potential for significant impact on the U.S. economy;
 - (c) size of activity and impact on the laboratory;
 - (d) large Funds-in from the partner;

- (e) activities that may involve unique or unusual health, safety, or environmental issues or a significant real or perceived potential environmental impact;
- (f) potential for major economic impact to the relevant industrial or commercial sector or for the appearance of inappropriate competition with the private sector; and
- (g) potential for significant political or media interest or significant public or private sector controversy.

JOINT WORK STATEMENT

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)

(NAME)
(City, State, Zip)
(Telephone Number)

3. Participant Type (check all that apply)

	Participant One	Participant Two
Foreign	G	G
University	G	G
Small Business	G	G
Large Business	G	G
State or Local Government	G	G
Not-for-Profit	G	G
National Laboratory	G	G

4. Funding Table

Funding Type	Year 1		Year 2		Year 3		Totals
	Funds-in	*In-kind	Funds-in	*In-kind	Funds-in	*In-kind	
Participant 1							
Participant 2							
Dept. of Energy							
Totals							
Federal Admin Charge if applicable							

Note: If applicable, the contractor has reviewed the participant(s) proposed in-kind contribution and based on **G experience, **G** financial analysis, and/or **G** sound business judgment has determined the estimated in-kind contribution(s) is/are reasonable.*

5. Identify the DOE mission area (**G** Energy, **G** Environmental Quality, **G** Science, **G** National Security, **G** 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: **G** Assists laboratory achieve programmatic scope, **G** adds new capability to the laboratory's core competencies, **G** enhances the laboratory's core competencies, **G** uses the laboratory's core competencies, and/or **G** 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 **G** Modular CRADA, **G** Short Form CRADA, **G** Multilab CRADA, **G** USIC, **G** other (identify)_____.

B. Special Considerations

1. Background Intellectual Property (e.g., inventions or copyrightable software, etc.)?
 Yes No
If yes, list (1) _____
(2) _____
(3) _____

2. Is the company interested in licensing Background Intellectual Property? Yes No
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 (explain)

5. The laboratory is responsible for obtaining OCI Certificates and will maintain in the file the completed OCI 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 (explain) No

6. Will export controlled and classified information be used or produced? Yes No
If yes, identify.

7. How was Fairness of Opportunity determined? Participant approached laboratory
 Participant responded to CBD Participant was contacted by laboratory after or during broad public announcement. *(Supporting documentation is to be maintained in CRADA file.)*

8. Did the Participant require any substantive/material changes to the laboratory-/field-approved modular CRADA and/or any changes to double-underlined language? Yes No
If yes, attach copies of the proposed modified articles, 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.

9. **Additional Notes:** If applicable, identify special considerations or comments.

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

**DOE-APPROVED COOPERATIVE RESEARCH AND
DEVELOPMENT AGREEMENT LANGUAGE AND GUIDANCE**

The Modular Cooperative Research and Development Agreement (CRADA) was developed to promote consistency throughout the Department of Energy (DOE). The Modular CRADA presents DOE-approved language, approved optional language, and guidance for each article.

CONTENTS

	<u>Page</u>
Introduction	1
Negotiating and Approving CRADAs	2
The Importance of Teamwork and Communication	3
 <u>DOE-APPROVED CRADA LANGUAGE AND GUIDANCE</u>	
TITLE OF CRADA	5
ARTICLE I: DEFINITIONS	7
ARTICLE II: STATEMENT OF WORK	11
ARTICLE III: TERM, FUNDING AND COSTS	13
ARTICLE IV: PERSONAL PROPERTY	17
ARTICLE V: DISCLAIMER	19
ARTICLE VI: PRODUCT LIABILITY	21
ARTICLE VII: OBLIGATIONS AS TO PROPRIETARY INFORMATION	25
ARTICLE VIII: OBLIGATIONS AS TO PROTECTED CRADA INFORMATION	29
ARTICLE IX: RIGHTS IN GENERATED INFORMATION	33
ARTICLE X: EXPORT CONTROL	35
ARTICLE XI: REPORTS AND ABSTRACTS	37
ARTICLE XII: PRE-PUBLICATION REVIEW	41
ARTICLE XIII: COPYRIGHTS	43
ARTICLE XIV: REPORTING SUBJECT INVENTIONS	47
ARTICLE XV: TITLE TO SUBJECT INVENTIONS	49
ARTICLE XVI: FILING PATENT APPLICATIONS	53
ARTICLE XVII: TRADEMARKS	55
ARTICLE XVIII: MASK WORKS	57
ARTICLE XIX: COST OF INTELLECTUAL PROPERTY PROTECTION	59
ARTICLE XX: REPORTS OF INTELLECTUAL PROPERTY USE	61
ARTICLE XXI: DOE MARCH-IN RIGHTS	63
ARTICLE XXII: U.S. COMPETITIVENESS	65
ARTICLE XXIII: ASSIGNMENT OF PERSONNEL	69
ARTICLE XXIV: FORCE MAJEURE	71
ARTICLE XXV: ADMINISTRATION OF THE CRADA	73
ARTICLE XXVI: RECORDS AND ACCOUNTING FOR GOVERNMENT PROPERTY	75
ARTICLE XXVII: NOTICES	77
ARTICLE XXVIII: DISPUTES	79
ARTICLE XXIX: ENTIRE CRADA AND MODIFICATIONS	81
ARTICLE XXX: TERMINATION	83
ARTICLE ____: PROJECT MANAGEMENT	85

CONTENTS (continued)

	<u>Page</u>
ARTICLE ____: ORDER OF PRECEDENCE	85
ARTICLE ____: WAIVER	86
ARTICLE ____: BACKGROUND INTELLECTUAL PROPERTY	86
Attachment 1: FOCI QUESTIONNAIRE FOR APPLICABLE COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS	87
Attachment 2: U.S. COMPETITIVENESS WORK SHEET	97
Attachment 3: ABSTRACT FORMAT DESCRIPTION	99