SANDIA NATIONAL LABORATORIES
CIVILIAN RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE IMPLEMENTING PROCEDURE (QAIP)
QAIP 1-5

ESTABLISHING WORK AGREEMENTS

Revision 11

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Author: _____ 12/4/96
Date

Concurrence: _____ 12/4/96
QA Reviewer Date

Approval: _____ 12/4/96
Michaele C. Brady, SNL CRWM Lab Lead Date

12/4/96 Schelling & Horton

REVISION HISTORY

Revision	Summary
00	Total procedure formatted to requirements of QAIP 5-1, Rev. 01. This revision was done due to satisfy changes in QARD, Rev.4 requirements and QAIP 5-1, Rev.01.
01	This was a total revision of the procedures for the Task Definition Statement (TDS) procedure, which replaced the TDS, DIM, PDM, and ITM with Work Agreements. Work Agreements will be used to define interfaces internal to SNL and to specify and authorize work. This revision adapted the procedure to restructured organization, incorporated SNL project management and quality improvement ideas, simplified procedures, and replaced similar functions of TDS, DIM, PDM and ITM with a single vehicle, the Work Agreement.
02	This revision was a total rewrite which included clarification to the portion concerning review, issue and revision of work agreements and the records section. This revision was a result of the need to clarify minor problems found during the initial issue and incorporate new QARD requirements.
03	This revision revised section 4.1 to address QARD planning elements. This revision resulted from the need to interface with other implementing procedures.
04	This revision revised scope and purpose, and added upper tier and lower tier work agreement definitions.
05	This revision included sections 4.1 and 4.4 including changing work agreement elements list to specify how to identify what procedures apply to Supplier or Customer.
06	This revision included sections 1.0, 4.4, 4.6, and 6.0. The revision added work agreement change history, examples of editorial changes, and added a requirement to stop work when work agreement is incorrect. This revision addressed previously missing QARD requirements.
07	This revision was a total rewrite including reformatting the procedure to playscript, clarifying use of TPs, deleting personnel and assignments and adding a requirement to assure controlled documents are sent to the supplier. This revision was a general update to the procedure and it response to SNL YMP CARs 94-27 and 94-28.
08	This revision was a total rewrite and included incorporating ICN 01, deleting QAGR from the program, deleting requirements for TP and SNs which will be placed in other procedures, adding requirements for QA program grading to WAs and adding Appendix A. This revision resulted because of the need to clarify requirements for using TP and, and to clarify WA requirements and their use and to make QA grading more meaningful.

REVISION HISTORY
(Continued)

Revision	Summary
09	This revision include sections 4.1 and 6.0. The following changes were made, deleted the reference to QAIP 1-3 and 16-1, added the reference to OCRWM procedures AP16.1Q and AP-16.2Q after 07/02/95.
10	This revision was a total rewrite to incorporate new QARD requirements and to reformat according to QAIP 5-1, Rev.5. It also incorporated provisions for mandatory and non-mandatory review comments according to QAIP 6-3, per resolution of Deficiency Report YMQAD-96-D34.
11	Changes made to section 4.1 in response to Deficiency Report YM-96-D044. Added text requiring process detail to be included either in the content of lower-tier WAs or in the documentation (TPs, Scientific Notebooks, analysis documentation, etc.) resulting from the work. Added text requiring technical reviewers to verify same. Added reference to QAIP 2-6 in section 4.2. Changes made to sections 4.3 and 5.0 in response to Deficiency Report YM-96-D080. Clarified that the customer is the management level who authorizes expedited changes to WAs, provided a methodology for evaluating the effect of differences between temporary revisions and subsequent formal revisions and specified that memos or e-mail is to be used to notify affected parties of temporary revisions. Added record retention designations to section 5.0.

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1.0 PURPOSE

The purpose of this procedure is to implement Quality Assurance Requirements and Description (QARD) requirements for organizational interface control, work instructions, and planning. The procedure specifies the method for establishing Work Agreements (WAs), which shall be used for planning and directing Civilian Radioactive Waste Management (CRWM) work assigned to the Lab Lead for Sandia National Laboratories (SNL).

2.0 SCOPE

This procedure is applicable in the following cases:

- For all Work Breakdown Structure (WBS) elements, to establish interface information and direction between the Lab Lead and Task Managers (via upper-tier WAs).
- For activities subject to the Quality Assurance (QA) program;
- Where organizational interfaces (internal and external to SNL) are to be documented.
- Where work is to be specified via approved written procedures or instructions (lower-tier WAs), except for work for which Technical Procedures (TPs) are used.

Contracts issued to suppliers in accordance with QAIP 4-1 may be used instead of a WA if they contain level of detail equivalent to that specified herein.

3.0 DEFINITIONS

Customer - The individual responsible under this procedure for initiating a WA to have work performed by, or under the direction of, a Supplier. Customers are individuals certified and qualified as Principal Investigators (PIs) or higher for CRWM activities.

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3.0 DEFINITIONS, Continued

Data: Information developed as a result of scientific investigation activities, including information extracted from reference sources, and performance assessment analyses.

Discretionary Comment: Any comment that can be resolved by an editorial change or a minor change or any comment that the reviewer defines as discretionary.

Lower-tier WA: This WA is used to prescribe work in more detail than an upper-tier WA. These WAs are prepared by Task Managers or PIs to define and allocate specific work scope, identify graded QA and technical requirements, controls, deliverables, and acceptance criteria and communicate this information to support staff and contractors.

Mandatory Comment: Any comment that does not meet the definition of a discretionary comment.

Quality Assurance Review - A review to provide assurance that the WA being reviewed is consistent with SNL procedures, that appropriate QA requirements have been met, and that appropriate quality requirements have been incorporated in the WA.

Scientific Investigation - Any observation, identification, description, experimental study, or analysis and explanation of natural phenomena.

Supplier(s): The individual(s) whose organization(s) is responsible for performing the work specified in a WA. Suppliers are SNL employees, contractors, or other project participants certified and qualified to perform CRWM work.

Technical Review - A review of the WA by qualified personnel who are independent of the customer/supplier of the WA but have technical expertise equivalent to the customer/supplier. Technical reviews of WA are critical reviews and evaluations of the contents of the WA for applicability, correctness, adequacy, and completeness.

Upper-tier WA - This WA shall be used by the Lab Lead to define basic organizational interfaces, establish lines of communications, delegate responsibility and authority, allocate budget, and define high-level scope of work to Task Managers. Lower-tier WAs will be issued to provide a detailed work prescription. Because of their lack of detail, upper-tier WAs cannot be used to prescribe technical activities.

Work Agreement: A documented agreement between a Customer and Supplier that is used by SNL to establish, document, and control interfaces and to specify and authorize work to be performed for CRWM.

4.0 PROCEDURE

4.1 Preparing, Reviewing, and Approving a Work Agreement

Responsible Individual(s)	Step	Procedure
Customer	1	Obtains the document identifier from the Document Control staff.
	2	Prepares a draft WA that includes or references by number the following elements. Enters "NA" for any element that is not applicable WA ELEMENTS: 1) Agreement title, revision number, and WA identifier. 2) Customer name and organization. 3) Supplier(s) name and organization(s). 4) Dated technical and QA reviewer signature lines. 5) Dated Customer and Supplier approval signature lines. 6) Upper-tier WA number. 7) WBS 8) Charging case number(s). 9) Scope of work, objectives, and primary tasks. Shall describe or specify the work to be done, including the objectives to be achieved. Specify, as a minimum, the primary tasks to be accomplished. Specify roles and responsibilities of individuals, teams, or organizations. Shall specify any needed planning or coordination activities with organizations that will use the results of the work or that will provide input to the activities. Lower-tier WAs governing work subject to the QA Program must either, themselves, include the necessary process detail (e.g. sequential actions) required to perform the specified activities, or require that such process detail be specified or described in the documentation resulting from the work (e.g. TPs, Scientific Notebooks, analysis documentation, etc.).

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4.0 PROCEDURE, Continued

4.1 Preparing, Reviewing, and Approving a Work Agreement (continued)

Responsible Individual(s)	Step	Procedure
Customer (continued)	2 cont.	10) Quality Assurance - Shall identify the extent to which and manner in which the QA Program applies to the activities by specifying which procedures will be used to control the scope of work identified in item 9. (a) The determination as to which procedures are applicable shall be made using the process shown in Appendix A. (b) Documents whether the activity is applicable to the Q-List, Site Characterization, or Performance Assessment in the WA. (c) QAIPs 1-4, 17-1, AP-16.1Q, and AP-16.2Q are applicable to all SNL CRWM work and do not have to be listed in each WA. (d) Clearly indicates which procedures apply to the Customer's organization and which apply to the Supplier's organization. (e) Identifies QA program verifications to overview the work performed or the product produced and quality verification points and hold points. 11) Readiness review prerequisite. If the customer requires a readiness review to be performed, identifies at which point in the work. 12) Identification of, or provisions for, the identification of, required records and the recording of objective evidence of the results of the work performed. 13) Deliverable products. 14) Anticipated schedule. 15) Estimated budget.

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4.0 PROCEDURE, Continued

4.1 Preparing, Reviewing, and Approving a Work Agreement (continued)

Responsible Individual(s)	Step	Procedure
Customer (continued)	2 cont.	16) Training Requirements (identify what training is required for personnel doing work under the WA, for example, training to Technical Procedures and/or Administrative Procedures). 17) Any Customer additional requirements. Example: In cases where the WA governs analysis activities in which a model is used, the Customer may specify the model to be used and justify its selection. If the Supplier is selecting the model, the Customer will require that the supplier identify the model and justify its selection in the documentation provided as a result of the analysis. 18) Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished. Example: Models need to be validated. The WA will specify the appropriate qualitative acceptance criteria that indicate that the model accurately represents the actual physical phenomena. 19) History of WA revisions, e.g. previous WA number if this current WA replaces another WA with a different number.
	3	Identifies each technical organization affected by this WA and assures that all technical organizations are represented by the technical reviewer(s) in the review process.
	4	Submits draft WAs for technical review and QA review. Attaches any pertinent background information or data necessary for the reviewers. Note: When practical, the supplier's immediate manager conducts the technical review.
QA/Technical Reviewer(s)	5	Reviews the draft WA according to QAIP 6-3. Technical reviewers shall additionally verify that apparently adequate process detail is either included in the lower-tier WA itself, or that the WA requires such process detail in resulting documentation (see step 2, WA element 9 above).

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4.0 PROCEDURE, Continued

4.1 Preparing, Reviewing, and Approving a Work Agreement (continued)

Responsible Individual(s)	Step	Procedure
QA/ Technical Reviewer(s)	6	Forwards review documentation to the Customer.
	7	Signs and dates the WA to document the review and resolution of comments.
Supplier(s) / Customer	8	Signs and dates the WA to indicate concurrence with and commitment to the content. Note: Supplier should review that draft WA to ensure that the stated requirements can be met considering resources available.
Customer	9	Submits copies of completed Document and Review Comment forms (QAIP 6-3 Appendix A) for mandatory comments to the Local Records Receiving Organization.

4.2 Issuing a Work Agreement

Responsible Individual(s)	Step	Procedure
Customer	1	If the customer is not the Task Manager, reviews the WA and recommends training to the Task Manager. This may be done by completing a draft Training Assignment form(s) Appendix A, QAIP 2-5.
Task Manager	2	Reviews the WA and the training history of personnel affected by this WA including QAIPs, Technical Procedures, or Yucca Mountain Administrative Procedures (YAPs) in order to determine if personnel are certified (per QAIP 2-6) and have been trained on the applicable procedures specified in the WA.
	3	Assigns training to all responsible individuals working to the Work Agreement according to QAIP 2-5.
	4	Forwards Training Assignment form(s) to the customer for submittal.
Customer	5	Submits the WA to the Document Control staff for distribution as a controlled document per QAIP 6-1 and training assignment documentation per QAIP 2-5 to the Training Manager.

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4.0 PROCEDURE, Continued

4.2 Issuing a Work Agreement (continued)

Responsible Individual(s)	Step	Procedure
Document Control Staff	6	Distributes the WA as required by QAIP 6-1 and assures that controlled copies of implementing documents (QAIPs, TPs, etc.) identified on the Special Instructions Section of the Request for Distribution of a Controlled Document form are transmitted to the supplier.
Supplier(s)	7	Shall work in accordance with controlled copies of implementing documents (QAIPs, TPs, etc.) as identified in the WA.

4.3 Revising Work Agreements

Responsible Individual(s)	Step	Procedure
Customer		Note: The Customer is the "management level" who authorizes temporary revisions ("expedited changes") to Work Agreements.
	1	Authorizes, if necessary, temporary revisions in writing. In this situation, notifies affected parties of the content of the temporary revision by memorandum or e-mail. Processes a formal WA revision within 30 working days through the formal revision process. If the formal revision process results in a change that is different from the temporary revision, the results of the work activities performed under the temporary revision shall be evaluated by comparing those results with the projected results had the activities been performed as the formal revision specifies. The results of the evaluation will be documented and included in the record of the activities.
	2	If work cannot be accomplished as described in the WA, or accomplishment of such work would result in an undesirable situation, the work shall be stopped. Work shall not resume until the WA is revised.

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4.0 PROCEDURE, Continued

4.3 Revising Work Agreements (continued)

Responsible Individual(s)	Step	Procedure
Customer (Continued)	3	Prepares revisions, initiated by either the Customer or Supplier when necessary, when there is a change in one of the following areas: • deliverables, • scope of work, • supplier or customer, • QA requirements, • Acceptance criteria, • QA program verifications, or • QA records.
	4	Provides a description and rationale for each change per revision history shown in QAIP 5-1 and includes the revision history as part of the WA. Reviews the previous revisions each time a revision is made.
	5	Reviews technical organizations affected by the WA and assures that all technical organizations are represented by the technical reviewer(s) in the review process.
	6	Submits the draft revision to the WA for technical and QA review except for minor editorial changes. Minor editorial changes include correcting grammar or spelling, renumbering, changing titles or document numbers, or updating organizational titles that don't change responsibilities or typographic changes, changes to schedule or budget, or other changes that do not affect scope of work or quality, which can be approved by the Customer.
	7	Attaches any pertinent background information or data necessary for the reviewers.
QA/ Technical Reviewer(s)	8	Shall review the draft WA and resolve comments with the customer according to QAIP 6-3.
	9	Forwards review documentation to Customer.
	10	Signs and dates the WA to document the review and resolution of comments.

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4.0 PROCEDURE, Continued

4.3 Revising Work Agreements (continued)

Responsible Individual(s)	Step	Procedure
Supplier/Customer	11	Signs and dates the WA to indicate concurrence with and commitment to its content. Note: Supplier should review that draft WA to ensure that the stated requirements can be met considering resources available.
Customer	12	Submits copies of completed Document and Review Comment forms (QAIP 6-3 Appendix A) for mandatory comments to the Local Records Receiving Organization.

4.4 Closing a Work Agreement

Responsible Individual(s)	Step	Procedure
Customer	1	Completes and submits the Request for Distribution/Recall of a Controlled Document form to the Controlled Document staff.
	2	Submits any other records generated as a result of performing WA activities to the LRRO in accordance with the implementing document governing those records. These records include documentation of final actions negotiated between the customer and supplier(s) or changes to specified deliverables, if appropriate.

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5.0 RECORDS

QA records and record packages, including corrections and changes thereto, generated as a result of implementing this procedure shall be prepared and submitted to the Local Records Receiving Organization in accordance with QAIP 17-1 "Protecting, Preparing, and Submitting CRWM QA Records". The QA records, record package segments and record packages include:

- Original Work Agreement (LIFETIME)
- Work Agreement Revisions (LIFETIME)
- Completed Document Review and Comment Forms for Mandatory Comments (NONPERMANENT)
- Records documenting the effects of differences between temporary revisions and subsequent formal revisions (NONPERMANENT)

6.0 REFERENCES

QAIP 1-4	"Resolution of Quality Assurance Disputes"
QAIP 2-5	"Training"
QAIP 2-6	"Qualification and Certification of Personnel"
QAIP 4-1	"Procurement"
QAIP 5-1	"Quality Assurance Implementing Procedures"
QAIP 6-1	"Document Control System"
QAIP 6-3	"Conducting and Documenting Reviews of Documents"
QAIP 17-1	"Protecting, Preparing, and Submitting CRWM QA Records"
OCRWM AP-16.1Q	"Performance/Deficiency Reporting"
OCRWM AP-16.2Q	"Corrective Action and Stop Work"

7.0 APPENDICES

Appendix A: Classifying Activities and Applying QA Controls

APPENDIX A

CLASSIFYING ACTIVITIES AND APPLYING QA CONTROLS

1. **Determination of Importance**

The customer shall determine the Applicability of the QA Program as follows:

Using the Q-List and work description, check the specific relation, if any, of the activity to one or more of the following: *(The Q-List is a controlled document that is available with the QA staff.)*

a. Q-LIST-Determine if the activities covered the work agreement are related to one or more items on the CRWM Q-List. Such activities include design, procurement, construction, fabrication, production, handling, packaging, shipping storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, modification, decontamination, dismantling, decommissioning, and permanent closure. Such activities shall take on the same degree of importance as the item(s) to which they pertain, so are thereby subject to the QA Program.

b. SITE CHARACTERIZATION/PERFORMANCE ASSESSMENT - Determine if the activities covered by the work agreement are:

(1) related to sample collection,

(2) related to the collection and analysis of data to support performance confirmation or performance assessment, or

(3) providing data used to assess the potential dispersion of radioactive materials from the licensed facility.

If the work activity under consideration falls in any of the above categories, it is subject to the QA Program.

2. **Quality Assurance (Work Agreement Item 10)**

The Customer shall complete Item 10, by determining which elements are applicable, providing justification if not applicable, and listing the SNL procedure(s) or other implementing procedures e.g., OCRWM Administrative Procedures (APs) applicable to each element. The following shall be considered.

For items on the Q-List, related activities, and activities associated with site characterization data and samples, quality assurance controls (grading) shall be applied to the degree commensurate with the following:

a. Function or end use of the item, if applicable.
b. Consequence of failure (risk).
c. Importance of the data.
d. Complexity of design or fabrication of the item or design or implementation of the activity.
e. Reliability of the process.
f. Reproducibility of the results.
g. Uniqueness of the item or degree of standardization.
h. History of the item or service quality.
i. Necessity for special controls or processes.
j. Degree to which functional compliance can be demonstrated through inspection or test.