University of California Lawrence Livermore National Laboratory

**NUCLEAR WASTE MANAGEMENT PROGRAM** 

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Subject:

CONTROL OF PURCHASED ITEMS AND SERVICES

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Yucca Mountain Project Leader

**Quality Assurance Manager** 

## 1.0 GENERAL REQUIREMENTS

Measures are established to assure that purchased material, equipment, and services conform to the procurement documents. These measures include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, audit, and examination of products upon delivery. Where required by code, regulation, or contract requirement, documentary evidence that material and equipment conform to the procurement requirements is available at the location where the material or equipment is to be used prior to installation or use of such material and equipment. This documentary evidence is retained under the control of the DOE Project Office QA Records Management System (QARMS) and is sufficient to identify the specific requirements, such as codes, standards, or specifications, that are met by the purchased material and equipment. Specific requirements for the control of purchased items and services are listed below.

### PROCUREMENT PLANNING

### 1.1.1 GENERAL

Procurement activities are planned and documented to assure a systematic approach to the procurement process. Procurement planning results in the documented identification of procurement methods and organizational responsibilities. LLNL-YMP Quality Assurance (QA) organization participation is provided for evaluation and selection of suppliers, verification of suppliers' activities and receiving inspections. Planning determines the following:

- o What is to be accomplished.
- o Who is to accomplish it.
- o How it is to be accomplished.
- o When it is to be accomplished.

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## 1.1.2 PROCUREMENT TIMING

To assure interface compatibility and a uniform approach to the procurement process, planning is accomplished as early as practicable and no later than at the start of those procurement activities that are required to be controlled.

# 1.1.3 PROCUREMENT METHODS

Planning results in the documented identification of the methods to be used in procurement activities, the sequence of actions and milestones that indicate the completion of these activities, and the preparation of applicable procedures prior to the initiation of each individual activity listed below. Planning provides for the integration of the following:

- o Procurement document preparation, review, and change control.
- o Selection of procurement sources.
- o LLNL-YMP control of supplier performance.
- o Verification (surveillance, inspection, or audit) activities by the LLNL-YMP, including notification for hold-and-witness points.
- o Control of nonconformances.
- o Corrective action.
- o Acceptance of item or service.
- o QA records.

### 1.2 SOURCE EVALUATION AND SELECTION

### 1.2.1 SELECTION OF SUPPLIERS

The selection of suppliers is based on evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents before the award of contract.

#### 1.2.2 SOURCE EVALUATION AND SELECTION MEASURES

Procurement source evaluation and selection measures are implemented by the LLNL-YMP and provide for identification of LLNL-YMP's responsibilities for determining supplier capability.

### 1.2.3 MEASURES FOR EVALUATION AND SELECTION OF PROCUREMENT SOURCES

Measures for evaluation and selection of procurement sources, and the results thereof, are documented and include one or more of the following items:

o Evaluation of the supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The supplier's history reflects current capability.

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- o Supplier's current quality assurance records supported by documented qualitative and quantitative information that can be objectively evaluated.
- o Supplier's technical and quality capability as determined by a direct evaluation of their facilities and personnel and the implementation of their QA program.

### 1.3 BID EVALUATION

### 1.3.1 EXTENT OF CONFORMANCE

Bid evaluation determines the extent of conformance to the procurement documents. This evaluation is performed by individuals or organizations designated to evaluate the following subjects, as applicable to the type of procurement:

- o Technical considerations.
- o QA requirements.
- o Supplier's personnel.
- o Supplier's production capabilities.
- o Supplier's past performance.
- o Alternates.
- o Exceptions.

# 1.3.2 RESOLUTION OF UNACCEPTABLE QUALITY ASSURANCE CONDITIONS

Before the award of the contract, the LLNL-YMP resolves or obtains commitments to resolve unacceptable quality assurance conditions resulting from the bid evaluation.

#### 1.4 SUPPLIER PERFORMANCE EVALUATION

## 1.4.1 INTERFACE MEASURES

The LLNL-YMP establishes measures to interface with the supplier. The measures include the following:

- o Documentation of the understanding between the LLNL-YMP and supplier of the provisions and specifications of the procurement documents.
- o Requiring the supplier to identify planning techniques and processes to be utilized in fulfilling procurement document requirements.
- o Reviewing supplier documents that are generated or processed during activities fulfilling procurement document requirements.

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- o Identifying and processing necessary change information. Measures to control changes in procurement documents are established, implemented and documented in accordance with the requirements of the LLNL-YMP QAPP.
- o Establishing methods of document information exchange between the LLNL-YMP and supplier.

## 1.4.2 VERIFICATION MEASURES

# 1.4.2.1 Extent of Verification

The LLNL-YMP establishes measures to verify supplier's performance, as deemed necessary by the LLNL-YMP. The measures establish the extent of source surveillance and inspection activities.

NOTE: When the LLNL-YMP utilizes another Yucca Mountain Project participating organization, the LLNL-YMP organization initiates a request to the DOE Project Office to conduct a surveillance of the organization performing the work. The surveillance is conducted to determine that the item or activity is being produced or performed in accordance with the LLNL-YMP requirements. These surveillances may utilize LLNL-YMP personnel as technical advisors at the DOE Project Office's discretion.

The extent of verification activities, including planning, are a function of the relative importance, complexity, and quantity of the item or services procured and the supplier's quality performance. Verification activities are accomplished by qualified personnel assigned to check, inspect, audit, or witness the suppliers' activities. These verification activities are conducted as early as practicable. However, LLNL-YMP verification activities do not relieve the supplier of their responsibilities for verification of quality achievement.

## 1.4.2.2 Record of Verification Activities

Activities performed to verify conformance to requirements of procurement documents are recorded. Source surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions are documented. These completed documents are considered QA records and are controlled in accordance with O33-YMP-R 17. The LLNL-YMP assures that this documentation is evaluated to determine the supplier's QA program effectiveness.

### 1.5 CONTROL OF DOCUMENTS GENERATED BY SUPPLIERS

Documents that are generated by suppliers are controlled, handled, and approved in accordance with documented procedures. Means are implemented to assure that the submittal of these documents is accomplished in accordance with the procurement document requirements. These measures provide for the acquisition, processing, and recorded evaluation of technical, inspection, and est data against acceptance criteria.

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## 1.6 ACCEPTANCE OF ITEM OR SERVICE

#### 1.6.1 METHODS FOR ACCEPTANCE

Methods are established for the acceptance of an item or service being furnished by the supplier. Prior to offering the item or service for acceptance, the supplier verifies that the item or service being furnished complies with the procurement requirements. Methods used to accept an item or related service from a supplier are either a supplier certificate of conformance, a source verification, a receiving inspection or post-installation test at the facility site, or a combination thereof. Requirements applicable to these methods of acceptance are listed below.

# 1.6.1.1 Certificate of Conformance

When a certificate of conformance is used, the following minimum criteria are met:

- o The certificate identifies the purchased material or equipment, such as by the purchase order number.
- o The certificate identifies the specific procurement requirements met by the purchased material or equipment, such as codes, standards, or other specifications. This is accomplished by including a list of the specific requirements or by providing at the point of receipt, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified include any approved changes, waivers, or deviations applicable to the subject material or equipment.
- o The certificate identifies any procurement requirements that have not been met, together with an explanation and the means by which to resolve the nonconformances.
- o The certificate is attested to by a person who is responsible for this QA function and whose function and position are described in the LLNL-YMP or supplier's QA program.
- o The certificate system, including the procedures to be followed in filling out a certificate and the administrative procedures for the review and approval of the certificates, are described in the LLNL-YMP or supplier's QA program.
- o Means are provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the supplier or independent inspection or test of the items. Such verification is conducted by the LLNL-YMP at intervals commensurate with the supplier's past quality performance.

# 1.6.1.2 Source Verification

if source verification is used, then it is performed at intervals that are consistent with the importance and complexity of the item or service, and it is implemented to monitor, witness, or observe activities.

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ource verification is implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon purchaser acceptance of source verification, documented evidence of acceptance is furnished to the receiving destination of the item, to the LLNL-YMP, and to the supplier.

## 1.6.1.3 Receiving Inspection

When receiving inspection is used, purchased items are inspected as necessary to verify their conformance to specified requirements, by taking into account source verification and audit documentation and the demonstrated quality performance of the supplier. Receiving inspections are performed in accordance with established procedures and inspection instructions to verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. Receiving inspections are coordinated with review of supplier documentation when procurement documents require such documentation to be furnished prior to the receiving inspection. Receiving inspections associated with engineered items are planned, performed, and documented in accordance with the requirements specified in 033-YMP-R 10, Para. 2.1, 4.0, 4.1, 6.1, 9.0 and 9.1. Personnel selected for receipt inspection activities have the experience or training commensurate with the scope, complexity, or special nature of the activities. When required, personnel are indoctrinated as to the technical objectives and requirements of the applicable codes and standards and the QA program elements that are applicable.

# ..6.1.4 Post-Installation Testing

When post-installation testing is used, post-installation test requirements and acceptance documentation are established mutually by both the LLNL-YMP and the supplier.

### 1.7 ACCEPTANCE OF SERVICES ONLY

### 1.7.1 PROCUREMENT OF SERVICES ONLY

In certain cases involving procurement of services only, such as third party inspections, engineering, and consulting; and installation, repair, overhaul, or maintenance work, the LLNL-YMP accepts the service by any or any combination of the following methods:

- o Technical verification of data produced.
- o Surveillance, audit, or both, with regard to the activity.
- o Review of objective evidence for conformance to the procurement document requirements such as certifications, stress reports, etc.

### 1.8 CONTROL OF SUPPLIER NONCONFORMANCES

### 1.8.1 METHODS

The LLNL-YMP and supplier establish and document methods for disposition of items and services that do not meet procurement document requirements. These methods include the following provisions:

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### 1.8.1.1 Evaluation

Provisions for evaluation of nonconforming items.

## 1.8.1.2 Submittal

Provisions are established for submittal of nonconformance notice by the supplier to the LLNL-YMP. These submittals include supplier recommended disposition (e.g., use as-is or repair) and technical justification. Nonconformances to the procurement requirements or LLNL-YMP approved documents, which consist of one or more of the items listed below are submitted to the LLNL-YMP. Approval of the recommended disposition is in accordance with documented procedures.

- o Technical or material requirement is violated.
- Requirement in supplier documents, which has been approved by the LLNL-YMP, is violated.
- Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.
- o The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

# 1.8.1.3 Disposition

Provisions for LLNL-YMP disposition of supplier recommendation.

## 1.8.1.4 Verification

Provisions for verification of the implementation of the disposition.

## 1.8.1.5 Records Maintenance

Provisions for maintenance of records of nonconformances that are submitted by the supplier.

### 2.0 COMMERCIAL-GRADE ITEMS

### 2.1 ALTERNATIVES

If a design requires commercial-grade items, then the following requirements are an acceptable alternative to other requirements of this section, except as noted in Paragraph 2.1.2 below and the requirements of 033-YMP-R 4. If a scientific investigation requires use of commercial-grade items, these items are controlled by the use of the following requirements (except Paragraph 2.1.1) and 033-YMP-R 4.

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# 2.1.1 IDENTIFICATION OF COMMERCIAL-GRADE ITEMS

Where the commercial-grade item is to be used as an integral part of the designed facility, it is identified in an approved design or design out-put document. An alternate commercial-grade item may be supplied if the cognizant organization provides verification that the alternate commercial-grade item will perform the intended function and meet the requirements applicable to both the replaced item and its application.

### 2.1.2 SOURCE EVALUATION AND SELECTION

Source evaluation and selection is in accordance with Paragraph 1.2, if it is determined necessary by the LLNL-YMP based on the complexity of the item and importance to safety.

### 2.1.3 PURCHASE ORDER

Commercial-grade items are identified in the purchase order by the manufacturer's published product description (e.g., the catalog number).

### 2.1.4 RECEIPT OF COMMERCIAL-GRADE ITEM

After receipt of a commercial-grade item, the LLNL-YMP determines that the following conditions have been met:

- o Damage was not sustained during shipment.
- o The item received was the item ordered.
- o Inspection, testing, or both, is accomplished by the LLNL-YMP, in accordance with written procedures, to assure conformance with the manufacturer's published requirements. If applicable, acceptance of the item is accomplished via the calibration program in accordance with the requirements of O33-YMP-R 12.
- o Documentation, as applicable to the item, was received and is acceptable.