



CHANGE NOTICE

CN No.: 9.0-0-1

Affected Document: 033-YMP-OP 9.0, "Control of Processes," Rev.0

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Approved by: N/A  
(Technical Area Leader) (Date)

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(YMP QA Manager) (Date)

Training Required:  
Yes  No

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(YMP Project Leader) (Date)

Currently Read as Follows:

1. Section 9.0.5.12: As published
2. Section 9.0.5.13: Presently numbered as 9.0.5.13

CHANGED TO READ:

1. Section 9.0.5.12: Delete
2. Section 9.0.5.13: Change paragraph number to 9.0.5.12

NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

NUCLEAR WASTE MANAGEMENT PROGRAM  
CONTROLLED COPY NO. 0100

Subject:

CONTROL OF PROCESSES

Approved:

Approved by: [Signature] 2/4/89 YMP Project Leader  
Approved by: [Signature] 1/19/89 YMP Quality Assurance Manager

### 9.0.1 PURPOSE

The purpose of this procedure is to identify the requirements and establish the responsibilities for the control of processes and "Special Processes" that are used on engineered items and scientific investigations which affect the quality of Project produced deliverables for the Yucca Mountain Project (YMP).

### 9.0.2 SCOPE

The general process control requirements specified by this procedure apply to engineered items and scientific investigations. The "Special Process" control requirements apply only to engineered items, the use of which, affect the quality of LLNL produced deliverables for the Yucca Mountain Project.

### 9.0.3 DEFINITIONS

Listed below are key terms and phrases used in this procedure.

**CONTROL MEASURE DOCUMENTS:** As used in this procedure means those documents that identify and specify the control measure requirements for specifically identified processes and "Special Processes".

**ENGINEERED ITEM:** Any structure, system, or component identified in design documents as being a functional part of the completed facility.

**PROCESS:** A procedure, method, or technique followed in the execution of a scientific investigation or the design or manufacture of an engineered item.

**SPECIAL PROCESS:** A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

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QUALIFICATION (PERSONNEL): The characteristics or abilities that are gained through education, training, or experience which are measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

QUALIFIED PROCEDURE: An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

#### 9.0.4. RESPONSIBILITIES

The Task Leader is responsible for:

- o Identifying the appropriate application and implementation of the requirements and instructions of this procedure.
- o Establishing and controlling the specific requirements for the qualification/certification of process procedures and personnel who use the "Special Process" procedure.
- o Assuring that required process and special process controls are passed on to contractors, subcontractors, and suppliers through appropriate specifications and drawings and other interface control documents.

The Technical Area Leader is responsible for:

- o Approval and disposition of processes and "Special Processes" procedures and submittal of the process control documents to appropriate distribution and Records Center.

The YMP Quality Assurance Manager or designee is responsible for:

- o Monitoring and assuring the effectiveness of the specified process controls, including review of the procedures and records for compliance to QA Program requirements.

#### 9.0.5 REQUIREMENTS

##### 9.0.5.1

The identification of and/or the need for a process or special process is addressed and documented as part of the work activity planning as prescribed in Procedure 033-YMP-QP 3.0, "Scientific Investigation Control".

##### 9.0.5.2

Control measures for process and special process are identified and documented. Procedure control requirements, as specified in Procedure 033-YMP-QP 5.0, "Technical Implementing Procedures" apply to process and special process procedures.

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#### 9.0.5.3

Documents used shall provide a means to identify process characteristics, attributes, variables, parameters and environmental conditions required to be controlled to attain a specified end result.

#### 9.0.5.4

Qualification requirements for a special process, special process procedures, equipment and personnel who will use the special process procedures are identified and compliance requirements prescribed in control measures documents.

#### 9.0.5.5

A master index of "Special Process Procedures" are received and maintained by the YMP Records Manager based on approved input provided by Technical Area Leaders.

#### 9.0.5.6

Acceptance criteria are established and specified for the qualifications of:

- o Special processes.
- o Special process procedures.
- o Personnel who use the procedures.

#### 9.0.5.7

Personnel assigned to use special process procedures are trained, qualified and certified in accordance with written procedures.

#### 9.0.5.8

Recognized industrial codes and standards are used where applicable and practical to establish special process control and qualification requirements.

#### 9.0.5.9

Welders and weld procedures are qualified prior to production to assure compliance of weldments to requirements of specifications, codes, standards, and regulations.

#### 9.0.5.10

Production welds and the weld process are monitored to assure that only qualified personnel and qualified procedures are used.

#### 9.0.5.11

Personnel performing nondestructive testing procedures, including those who witness the nondestructive testing application of others, are trained and qualified in accordance with the requirements of Procedure 033-YMP-QP 2.9, "Indoctrination and Training of Personnel" and Procedure 033-YMP-QP 2.10, "Qualification and Certification of Personnel".

#### 9.0.5.12

Special process procedures for QA Level I & II items or deliverables receive Yucca Mountain Project Office review and approval.

#### 9.0.5.13

Process development, qualification and use activities are monitored to assure compliance to established requirements.

### 9.0.6 PROCEDURE

#### 9.0.6.1

During the activity planning functions prescribed in Procedure 033-YMP-QP 3.0, "Scientific Investigation Control", all processes are identified and evaluated against the definition of "Special Process" and "Process" for application of this procedure's requirements.

#### 9.0.6.2

Procedure detail requirement for the development, preparation, qualification and use of process procedures are prescribed in a number of source documents:

- a) From work planning documents and procedure requirements established from implementation of Procedure 033-YMP-QP 3.0, "Scientific Investigation Test Control" prepared by the responsible Technical Area Leaders.
- b) From requirements established by Procedure 033-YMP-QP 5.0, "Technical Implementing Procedures".
- c) From applicable industrial Codes and Standards.
- d) From requirements prescribed in Scientific Investigation Plans (SIP) governing the process/special process activity.

#### 9.0.6.3

Process/special process specifications are prepared, reviewed and approved prior to start of qualification activities. This approved specification is treated as a controlled document and a Quality Assurance Record.

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#### 9.0.6.4

Process/special process qualification data and results are documented and independently reviewed for compliance to technical specification requirements and quality assurance program requirements.

#### 9.0.6.5

A Process/special process qualification report/record is prepared, reviewed, approved and submitted for distribution, and retention as a Quality Assurance Record.

#### 9.0.6.6

The responsible Technical Area Leader or designee notifies the YMP Records Manager of the qualification of a special process procedure for the following action:

- a) Inclusion of the identified special process procedure on the master index of special process procedures.
- b) Appropriate distribution of the special process procedure to users and records retention center.

#### 9.0.7 RETAINED DOCUMENTATION

Quality assurance records created by the implementing procedures are collected, stored, and maintained in accordance with procedure 033-YMP-QP 17.0, "Quality Assurance Records."

Quality assurance records are specified in the approved special process procedure and shall include but are not limited to:

- a) Master index of all special process procedures.
- b) Copies of each approved special process procedure specification.
- c) Copies of each qualified and approved special process procedure.
- d) Copies of special process procedure qualifications records.
- e) Copies of personal qualifications records.