

**U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT**

**PRESENTATION TO
THE NUCLEAR WASTE TECHNICAL REVIEW BOARD**

**SUBJECT: QUALITY ASSURANCE CRITERIA
APPLICABLE TO THE DESIGN
PROCESS**

PRESENTER: EDGAR H. PETRIE

**PRESENTER'S TITLE
AND ORGANIZATION: ACTING DIRECTOR, ENGINEERING AND DEVELOPMENT DIVISION
YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT**

**PRESENTER'S
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QA GRADING PROCESS

- **PROVIDE ACTIVITY IDENTIFICATION AND DEFINITION**
- **DETERMINE IF ACTIVITY IS ON QUALITY ACTIVITIES LIST OR PROJECT REQUIREMENTS LIST**
- **STATE IMPORTANCE TO PROJECT (i.e. WORKER RADIOLOGICAL SAFETY, OPERATIONAL RELIABILITY)**
- **IDENTIFY APPLICABLE QA CRITERIA**
- **PROVIDE JUSTIFICATION IF CRITERIA IS NOT APPLICABLE**
- **OBTAIN QUALITY REVIEW BOARD ACCEPTANCE**

**THE FOLLOWING CRITERIA WERE
IDENTIFIED BY THE AE THROUGH
THE QA GRADING PROCESS AND
ARE APPLICABLE TO ESF DESIGN
ACTIVITIES**

QUALITY ASSURANCE CRITERIA APPLICABLE TO THE DESIGN PROCESS

- 1 ORGANIZATION**
- 2 QA PROGRAM**
- 3 DESIGN CONTROL**
- 4 PROCUREMENT DOCUMENT CONTROL**
- 5 PLANS, PROCEDURES, INSTRUCTIONS AND
DRAWINGS**
- 6 DOCUMENT CONTROL**
- 7 CONTROL OF PURCHASED ITEMS AND SERVICES**
- 16 CORRECTIVE ACTION**
- 17 QA RECORDS**
- 18 AUDITS**
- 19 COMPUTER SOFTWARE**

QUALITY ASSURANCE CRITERIA APPLICABLE TO THE DESIGN PROCESS

CRITERION 1 - ORGANIZATION

REQUIRES:

- **ESTABLISHMENT OF LINES OF AUTHORITY**
- **DEFINITION OF FUNCTIONAL RESPONSIBILITIES**
- **DEFINITION OF LINES OF COMMUNICATION FOR GUIDANCE, DIRECTION AND CONTROL**
- **FULL DOCUMENTATION OF ORGANIZATIONAL ACTIONS**

QUALITY ASSURANCE CRITERIA APPLICABLE TO THE DESIGN PROCESS

CRITERION 2 - QUALITY ASSURANCE PROGRAM

REQUIRES:

- **ESTABLISHMENT OF A QA PROGRAM**
- **QA ORGANIZATIONAL INDEPENDENCE**
- **IDENTIFICATION OF QUALITY AFFECTING ITEMS OR ACTIVITIES**
- **IDENTIFICATION OF APPLICABLE QA CRITERIA**
- **IDENTIFICATION OF QA CONTROLS**
- **DOCUMENTED PERSONNEL QUALIFICATION**
- **TRAINING OF PERSONNEL**
- **TRAINING RECORDS**

QUALITY ASSURANCE CRITERIA APPLICABLE TO THE DESIGN PROCESS

CRITERION 3 - DESIGN CONTROL

REQUIRES:

- **DEFINITION OF DESIGN CONTROL PROCESS**
- **CONTROL OF DESIGN INPUTS**
- **DESIGN VERIFICATION**
- **ESTABLISHMENT OF CHANGE CONTROL MEASURES**
- **ARCHIVING OF DESIGN DOCUMENTATION**

QUALITY ASSURANCE CRITERIA APPLICABLE TO THE DESIGN PROCESS

CRITERION 4 - PROCUREMENT DOCUMENT CONTROL

REQUIRES:

- **APPLICABLE DESIGN BASES/REQUIREMENTS NECESSARY TO ASSURE QUALITY TO BE INCLUDED OR REFERENCED IN PROCUREMENT DOCUMENTS**
- **PROCUREMENT DOCUMENTS TO SPECIFY THAT SUPPLIERS HAVE AN ADEQUATE QUALITY ASSURANCE PROGRAM**

QUALITY ASSURANCE CRITERIA APPLICABLE TO THE DESIGN PROCESS

CRITERION 5 - PLANS, PROCEDURES, INSTRUCTIONS AND DRAWINGS

REQUIRES:

- **DESIGN ACTIVITIES TO BE CONDUCTED IN ACCORDANCE WITH APPROVED PLANS AND PROCEDURES**
- **IDENTIFICATION OF ACCEPTANCE CRITERIA FOR DESIGN PRODUCTS**
- **CONTROLLED CHANGES TO PLANS AND PROCEDURES**

QUALITY ASSURANCE CRITERIA APPLICABLE TO THE DESIGN PROCESS

CRITERION 6 - DOCUMENT CONTROL

REQUIRES:

- **CONTROL OF DESIGN GENERATED DOCUMENTS**
- **ESTABLISHMENT OF CRITERIA FOR CONTROL OF DESIGN INPUTS**
- **STATUS OF DESIGN GENERATED DOCUMENTS TO BE MAINTAINED**
- **DOCUMENTATION OF DESIGN CHANGES**

QUALITY ASSURANCE CRITERIA APPLICABLE TO THE DESIGN PROCESS

CRITERION 7 - CONTROL OF PURCHASED ITEMS AND SERVICES

REQUIRES:

- **CONTROL OF PROCUREMENT OF ITEMS AND SERVICES TO ASSURE CONFORMANCE WITH SPECIFIED REQUIREMENTS**

INCLUDES

- **SOURCE EVALUATION AND SELECTION**
- **OBJECTIVE EVIDENCE OF QUALITY (BY SUPPLIER)**
- **SOURCE INSPECTIONS/AUDITS**
- **EXAMINATION OF ITEMS/SERVICES UPON DELIVERY**

QUALITY ASSURANCE CRITERIA APPLICABLE TO THE DESIGN PROCESS

CRITERION 16 - CORRECTIVE ACTIONS

REQUIRES:

- **PROMPT IDENTIFICATION AND CORRECTION OF CONDITIONS ADVERSE TO QUALITY**
- **REMEDIAL ACTION**
- **IDENTIFICATION OF ROOT CAUSE OF CONDITION**
- **INVESTIGATIVE ACTION**
- **CORRECTIVE ACTION**
- **DOCUMENTATION OF ACTION TAKEN**

QUALITY ASSURANCE CRITERIA APPLICABLE TO THE DESIGN PROCESS

CRITERION 17 - QA RECORDS

REQUIRES:

- **DOCUMENTATION OF EVIDENCE OF COMPLIANCE TO QA REQUIREMENTS**
- **LEGIBLE AND IDENTIFIABLE RECORDS**
- **PROVISIONS FOR SUPPLEMENTING OR AMENDING RECORDS**
- **SUBMITTAL OF RECORDS TO APPROVED RECORDS FACILITY**

QUALITY ASSURANCE CRITERIA APPLICABLE TO THE DESIGN PROCESS

CRITERION 18 - AUDITS

REQUIRES:

- **AUDITS AND SURVEILLANCES OF QUALITY AFFECTING OR QUALITY RELATED DESIGN ACTIVITIES**

QUALITY ASSURANCE CRITERIA APPLICABLE TO THE DESIGN PROCESS

CRITERION 19 - COMPUTER SOFTWARE

REQUIRES:

- **DEVELOPMENT OF A COMPUTER SOFTWARE DEVELOPMENT AND CONTROL PROGRAM**
- **DEVELOPMENT OF A COMPUTER SOFTWARE QUALITY ASSURANCE PLAN**