IAEA/ANL
Interregional Training Course

Technical and Administrative Preparations Required for Shipment of Research Reactor Spent Fuel to Its Country of Origin

Argonne National Laboratory
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Lecture L.11.1

Quality Assurance

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MODULE 11

L.11.1

QUALITY ASSURANCE

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QUALITY ASSURANCE

SOURCE MATERIAL

QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR RESEARCH REACTORS ANSI/ANS - 15.8 1995

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CODE ON THE SAFETY OF NUCLEAR POWER PLANTS: QUALITY ASSURANCE IAEA SAFETY SERIES 50-C-QA (REV. 1) 1988

GRADING OF QUALITY ASSURANCE REQUIREMENTS - A MANUAL IAEA TECHNICAL REPORTS SERIES NO. 328

SOME DEFINITIONS

QUALITY ANS *THE DEGREE TO WHICH AN ITEM OR PROCESS MEETS OR EXCEEDS THE USER'S REQUIREMENTS AND EXPECTATIONS.*

IAEA *THE TOTALITY OF FEATURES AND CHARACTERISTICS OF AN ITEM OR SERVICE THAT BEAR ON ITS ABILITY TO SATISFY A DEFINED REQUIREMENT.*

QUALITY ASSURANCE ANS *THOSE PLANNED AND SYSTEMATIC ACTIONS* NECESSARY *TO PROVIDE ADEQUATE CONFIDENCE THAT THE STRUCTURE, SYSTEM OR COMPONENT WILL PERFORM SATISFACTORILY IN SERVICE.*

IAEA *ALL THOSE PLANNED AND SYSTEMATIC ACTIONS NECESSARY TO PROVIDE ADEQUATE CONFIDENCE THAT AN ITEM OR SERVICE WILL SATISFY GIVEN REQUIREMENTS FOR QUALITY.*

SOME DEFINITIONS (CONTINUED)

QUALITY CONTROL IAEA *THE VERIFICATION THAT THE REQUIRED QUALITY HAS BEEN ACHIEVED.*

MANAGEMENT ANS *THOSE PERSONS WITHIN THE RESEARCH REACTOR ORGANIZATION WHOSE RESPONSIBILITY AND AUTHORITY INCLUDE THE QUALITY ASSURANCE PROGRAM.*

IAEA *THAT ASPECT OF THE OVERALL MANAGEMENT FUNCTION THAT DETERMINES AND IMPLEMENTS THE QUALITY POLICY.*

SAFETY RELATED ITEMS ANS *THOSE PHYSICAL STRUCTURES, SYSTEMS, AND COMPONENTS WHOSE INTENDED FUNCTIONS ARE TO PREVENT ACCIDENTS THAT COULD CAUSE UNDUE RISK TO THE HEALTH AND SAFETY OF WORKERS AND THE PUBLIC OR TO THE RESEARCH REACTOR'S PROGRAMS; AND TO*

SOME DEFINITIONS (CONTINUED)

CONTROL OR MITIGATE THE CONSEQUENCES OF SUCH ACCIDENTS.

IAEA *ITEMS OR SYSTEMS IMPORTANT TO SAFETY WHICH ARE NOT SAFETY SYSTEMS.*

COMPONENTS OF A QA PLAN OR PROGRAM

A NUCLEAR POWER PLANT WILL HAVE AN INDEPENDENT QA ORGANIZATION HEADED BY A QA MANAGER WITH A STAFF. THE MANAGER OFTEN REPORTS TO A VICE PRESIDENT THROUGH THE PLANT SUPERINTENDENT.

A RESEARCH REACTOR FACILITY IS USUALLY OPERATED WITH A SMALL STAFF WHERE PERSONNEL PERFORM MULTIPLE FUNCTIONS. IT IS RARELY POSSIBLE TO HAVE A TOTALLY INDEPENDENT QA ORGANIZATION OR EVEN A QA MANAGER.

1. ORGANIZATION

SINCE SUPERVISORS (OPERATIONS, MAINTENANCE, HEALTH PHYSICS, ENGINEERING, ETC.) ARE RESPONSIBLE FOR THE WORK OF THEIR SECTIONS AND THEIR STAFFS, MAKE THESE SUPERVISORS RESPONSIBLE FOR THE QA PROGRAM IN THEIR SECTIONS.

APPOINT ONE OF THEM (USUALLY AN ENGINEER) TO BE THE QA COORDINATOR. THE REACTOR MANAGER SHOULD NOT BE THE COORDINATOR BECAUSE THE MANAGER WILL AUDIT THE PROGRAM FOR ITS EFFECTIVENESS AS A MANAGEMENT TOOL.

ALTHOUGH THE COORDINATOR MAY PREPARE A DRAFT OF THE QA PLAN, ALLOW THE SUPERVISORS TO ACTIVELY PARTICIPATE IN THE DEVELOPMENT OF THE PLAN IN ORDER TO MAKE IT THEIR PLAN.

ALLOW THE QA COORDINATOR TO REPORT THROUGH THE REACTOR MANAGER TO A LEVEL ABOVE THE MANAGER.

ARRANGE FOR INDIVIDUALS NOT DIRECTLY PERFORMING THE WORK TO VERIFY THAT QUALITY HAS BEEN ACHIEVED IN THE WORK.

DEVELOP A RESPONSIBILITY MATRIX.

DEVELOP A PLAN TO RESOLVE DIFFERENCES IN OPINION BETWEEN THE SUPERVISORS. THE REACTOR MANAGER MAY BE USED TO RESOLVE DIFFERENCES.

APPENDIX VI PRESENTS A SAMPLE QA PLAN WHICH INCORPORATES THESE ORGANIZATIONAL FEATURES.

2. QA PROGRAM

INCLUDE A STATEMENT CONCERNING THE GOALS OF THE PROGRAM. PROGRESS TOWARDS ACHIEVING THESE GOALS SHOULD BE MEASURABLE.

IN THE PROGRAM, IDENTIFY THE ITEMS AND ACTIVITIES TO WHICH IT APPLIES TAKING INTO ACCOUNT THE ITEM'S OR ACTIVITY'S IMPORTANCE TO SAFETY.

IF EXISTING PROCEDURES HAVE BEEN UTILIZED SATISFACTORILY, INCORPORATE THEM INTO THE PROGRAM.

CREATE QA FORMS WHICH WILL BE USED BY THE SUPERVISORS AND THEIR STAFFS FOR ALL WORK.

AN IMPORTANT FORM IS THE **WORK PERMIT** WHICH ACT AS A REVIEW OF ALL WORK.

FOR SHIPMENT OF IRRADIATED FUEL, PREPARE FORMS FOR EACH STEP IN THE PROCESS.

APPENDIX VI PRESENTS A REPRESENTATIVE PROGRAM AND INCLUDES SAMPLE QA FORMS AND SAMPLE FORMS FOR THE SHIPMENT OF IRRADIATED FUEL.

3. TRAINING

TRAINING IS NOT ALWAYS A SEPARATE PART OF THE PROGRAM. IT IS SOMETIMES INCLUDED IN CHAPTER 2.

PROVIDE FOR APPROPRIATE INDOCTRINATION AND TRAINING OF ALL INDIVIDUALS WHO PERFORM ACTIVITIES WHICH AFFECT QUALITY.

PROVIDE FOR TESTING OF TRAINED INDIVIDUALS.

PERIODICALLY MONITOR PERFORMANCE TO IDENTIFY PROGRESS TOWARDS REACHING GOALS AND TO IDENTIFY DEFICIENCIES.

VIOLATIONS OF PRACTICES SHOULD BE ADDRESSED AND DOCUMENTED, AS APPROPRIATE.

FOR INFREQUENTLY PERFORMED JOBS, PROVIDE RETRAINING BEFORE START.

APPENDIX VI PRESENTS A REPRESENTATIVE SECTION ON TRAINING AND INCLUDES SAMPLE QA FORMS.

4. DESIGN CONTROL

IN GENERAL, DESIGN CONTROL REFERS TO MODIFICATIONS TO A FACILITY AND THE CONSTRUCTION NECESSARY TO ACHIEVE THE MODIFICATION.

PROVIDE FOR AN INITIAL REVIEW TO DETERMINE IF CONFIGURATION CONTROL IS AN ISSUE.

PROVIDE FOR AN EARLY REVIEW TO DETERMINE IF THE REGULATORY BODY MUST BE INVOLVED.

PROVIDE FOR DESIGN VERIFICATION BY REVIEW OF PLANS BY MULTIPLE PERSONS AND COMMITTEES.

FOR SHIPMENT OF IRRADIATED FUEL, DESIGN CONTROL MAY BE IMPORTANT FOR:

INCREASING SIZE OF DOORWAYS.
INCREASING CAPACITY FOR FLOOR LOADING.
INCREASING CAPACITY FOR OVERHEAD CRANE.
NEW HANDLING TOOLS.
MODIFICATIONS TO ASSEMBLY STORAGE RACKS.
ADDITIONAL SECURITY DEVICES.

APPENDIX VI PRESENTS A REPRESENTATIVE SECTION ON DESIGN CONTROL AND INCLUDES SAMPLE QA FORMS. IF EXTENSIVE DESIGN IS INVOLVED, CONSULT IAEA STANDARDS AND ANS STANDARD FOR CONSIDERATION OF ALL FACTORS.

5. PROCUREMENT CONTROL

PROVIDE FOR QA CONTROL ON ALL PURCHASE ORDERS, REQUISITIONS AND CONTRACTS.

PROVIDE FOR VENDOR EVALUATION INCLUDING EVALUATION OF VENDOR'S QA PROGRAM.

FOR ITEMS IMPORTANT TO SAFETY, CONSIDER INDEPENDENT VERIFICATION OF VENDOR'S TEST RESULTS.

ESTABLISH CRITERIA FOR ACCEPTABILITY OF PRODUCTS AND PERFORM RECEIVING INSPECTIONS IN ACCORDANCE WITH WRITTEN PROCEDURES.

APPENDIX VI PRESENTS A REPRESENTATIVE SECTION ON PROCUREMENT CONTROL AND INCLUDES SAMPLE QA FORMS.

6. INSTRUCTIONS, PROCEDURES AND DRAWINGS

REQUIRE THAT ALL OPERATIONS BE PERFORMED ACCORDING TO WRITTEN, REVIEWED AND APPROVED PROCEDURES.

BASE THE EXTENT OF DETAIL IN A PROCEDURE ON THE COMPLEXITY OF THE TASK AND ITS IMPORTANCE TO SAFETY.

DOCUMENT THE PROCESS FOR MAKING CHANGES AND REVISIONS TO THE PROCEDURES.

PROVIDE A MECHANISM FOR CONTROL OF PROCEDURES SO THAT ONLY CURRENT, COMPLETE VERSION IS USED.

APPENDIX VI PRESENTS A REPRESENTATIVE SECTION ON PROCEDURES AND INCLUDES SAMPLE QA FORMS.

APPENDIX VII PRESENTS REPRESENTATIVE PROCEDURES FOR THE PROCESS OF RETURN OF IRRADIATED FUEL TO THE US.

7. DOCUMENT CONTROL

THE QA PLAN SHOULD DESCRIBE THE PROCESS FOR THE PREPARATION, REVIEW AND APPROVAL OF ALL DOCUMENTS.

THE QA COORDINATOR SHOULD ESTABLISH A MASTER LIST WITH THE CURRENT REVISION NUMBER FOR ALL DOCUMENTS WHICH ARE CONTROLLED. THESE ARE PROCEDURES, DRAWINGS, LICENSES, CERTIFICATES, ETC.

THE SUPERVISORS SHOULD BE ASSIGNED RESPONSIBILITY FOR ALL DOCUMENTS IN THEIR SPHERE OF RESPONSIBILITY. THE SUPERVISORS SHALL CONTROL THE DISTRIBUTION OF DOCUMENTS IN THEIR SECTIONS.

THE QA PLAN SHALL DESCRIBE THE PROCESS USED TO MAKE MAJOR CHANGES IN DOCUMENTS.

QA DOCUMENTATION FOR THE AS-BUILT FACILITY (INCLUDING FUEL ASSEMBLIES) MAY NOT MEET THE REQUIREMENTS OF THE QA PLAN DEVELOPED. HOWEVER, ALL AVAILABLE AS BUILT RECORDS SHOULD BE COLLECTED AND STORED ACCORDING TO THE REQUIREMENTS OF THE QA PLAN.

APPENDIX VI PRESENTS A REPRESENTATIVE SECTION ON DOCUMENT CONTROL AND INCLUDES SAMPLE QA FORMS.

8. CONTROL OF ITEMS

CONTROL OF ITEMS IS SOMETIMES CALLED MATERIAL CONTROL.

SAFETY RELATED PARTS, COMPONENTS OR ASSEMBLIES ARE CONTROLLED BY A "MATERIAL TAGGING PROGRAM".

THE APPLICATION AND REMOVAL OF TAGS, LABELS AND MARKINGS SHOULD BE CONTROLLED BY THE QA COORDINATOR.

QA FORMS SHOULD BE DEVELOPED FOR USE WITH THE TAGGING PROGRAM.

THE TAG FOR ITEMS WITH SPECIFIC SHELF LIFE SHALL STATE AN EXPIRATION DATE FOR THE ITEM.

THE CONTROL OF ITEMS SHOULD EXTEND TO HANDLING, STORAGE, SHIPPING AND MAINTENANCE.

APPENDIX VI PRESENTS A REPRESENTATIVE SECTION ON ITEM CONTROL AND INCLUDES SAMPLE QA FORMS.

9. CONTROL OF SPECIAL PROCESSES

A SPECIAL PROCESS IS ONE IN WHICH THE RESULTS ARE HIGHLY DEPENDENT ON THE CONTROL OF THE PROCESS OR THE SKILL OF THE PERSONNEL.

DO NOT BASE THE QA PLAN ON THE MOST DIFFICULT SPECIAL PROCESS AT THE FACILITY.

A SPECIAL PROCESS MAY BE PLACED IN AN APPENDIX TO THE QA PLAN IN ORDER TO INCORPORATE REQUIREMENTS BEYOND THE NORMAL QA PLAN.

THE PREPARATION FOR AND THE SHIPMENT OF IRRADIATED FUEL ASSEMBLIES IS A SPECIAL PROCESS.

CONSULTANTS ARE VERY OFTEN USED IN A SPECIAL PROCESS. THEIR RECOMMENDATIONS SHALL BECOME PART OF THE QA FILE. RESPONSIBILITY FOR ACCEPTANCE AND USE OF CONSULTANTS RECOMMENDATIONS RESTS WITH FACILITY STAFF.

ALTHOUGH THE SUPERVISORS PERFORM AS BEFORE, THE QA COORDINATOR AND/OR THE REACTOR MANAGER MAY BECOME MORE INVOLVED IN A SPECIAL PROCESS.

APPENDIX VI PRESENTS A REPRESENTATIVE SECTION ON SPECIAL PROCESS CONTROL AND INCLUDES SAMPLE QA FORMS. “APPENDIX G AND SECTION 11” IN APPENDIX VI ARE SPECIFIC TO FUEL ASSEMBLY SHIPMENTS.

10. INSPECTIONS AND TESTING

INCLUDES EXAMINATIONS, MEASUREMENTS AND TESTS.

WRITTEN INSPECTION AND TEST PROCEDURES WHICH INCLUDE ACCEPTANCE CRITERIA SHOULD BE USED.

INSPECTION PERSONNEL SHALL BE INDEPENDENT OF THE INDIVIDUALS PERFORMING THE ACTIVITY BEING INSPECTED.

INSPECTIONS AND TESTS WHICH FAIL SHALL BE REPORTED ON A "DISCREPANCY AND NONCONFORMANCE SHEET" WHICH BECOMES PART OF THE QA RECORD.

MEASURING AND TEST EQUIPMENT SHALL BE CONTROLLED AND CALIBRATED AT SPECIFIC INTERVALS.

WHEN MEASURING AND TEST EQUIPMENT IS FOUND TO BE OUT OF CALIBRATION, A DOCUMENTED REVIEW SHALL BE MADE TO DETERMINE THE VALIDITY OF PREVIOUS USES OF THE EQUIPMENT.

APPENDIX VI PRESENTS A REPRESENTATIVE SECTION ON INSPECTION AND TESTING AND INCLUDES SAMPLE QA FORMS.

11. NONCONFORMANCE CONTROL

ALL NONCONFORMING ITEMS IMPORTANT TO SAFETY SHALL BE IDENTIFIED AND TAGGED AS NONCONFORMING.

NONCONFORMING ITEMS SHOULD BE SEGREGATED.

SUCH ITEMS SHOULD BE REPAIRED OR DISPOSED OF.

REPAIRED ITEMS SHOULD BE SUBJECTED TO THE QA PROGRAM THE SAME AS A NEWLY PURCHASED ITEM.

NONCONFORMANCE MAY REQUIRE NOTIFICATIONS TO THE VENDOR, REGULATORY BODY, ETC.

APPENDIX VI PRESENTS A REPRESENTATIVE SECTION ON NONCONFORMANCE AND INCLUDES SAMPLE QA FORMS.

12. QA RECORDS

THE QA PROGRAM IS BASED UPON DOCUMENTED EVIDENCE THAT ALL ACTIVITIES HAVE BEEN PERFORMED WHICH AFFECT THE QUALITY OF SAFETY RELATED ITEMS.

DEVELOP A MATRIX WHICH SHOWS THE RECORDS WHICH MUST BE GENERATED, THE RETENTION PERIOD AND THE INDIVIDUAL RESPONSIBLE FOR THE RECORD.

RECORDS SHALL BE IDENTIFIABLE, EASILY RETRIEVABLE AND ARCHIVED.

THE RECORDS GENERATED DURING THE SHIPPING PROCESS (A SPECIAL PROCESS) SHALL BE MAINTAINED AS A PACKAGE.

APPENDIX VI PRESENTS A REPRESENTATIVE SECTION ON RECORDS AND INCLUDES SAMPLE QA FORMS. “APPENDIX G AND SECTION 11” IN APPENDIX VI ARE SPECIFIC TO FUEL ASSEMBLY SHIPMENTS.

13. QA AUDITS

PROVIDE FOR PERIODIC AUDITS OF PROGRAM.

CAREFULLY DEFINE THE SCOPE OF THE AUDIT.

AUDIT USING WRITTEN PROCEDURES AND CHECKLISTS.

FOR SELDOM USED PORTIONS OF THE PROGRAM (SPECIAL PROCESSES), AUDIT BEFORE USE.

DEVELOP PERFORMANCE INDICATORS FOR USE DURING THE AUDIT.

CONDITIONS REQUIRING CORRECTIVE ACTIONS SHALL BE PROMPTLY REPORTED TO THE APPROPRIATE MANAGEMENT.

APPENDIX VI PRESENTS A REPRESENTATIVE SECTION ON AUDITS AND INCLUDES SAMPLE QA FORMS.