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ESSENCE OF QA

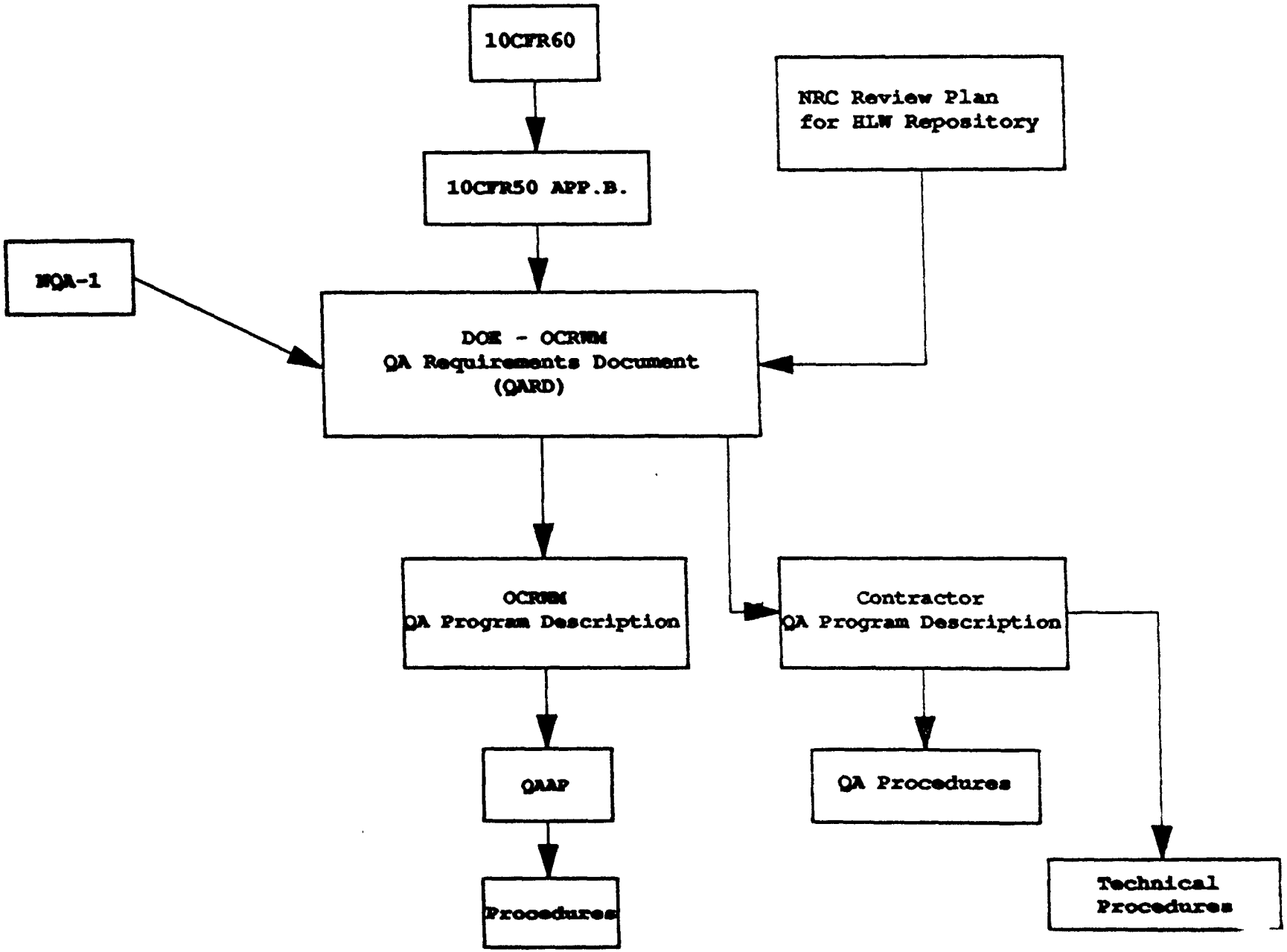
PLAN ACTIVITIES (AND DOCUMENT PLANNING PROCESS).

FOLLOW THE PLAN (AND DOCUMENT THE WORK PROCESS).

DOCUMENT RESULTS.

AUDIT TO VERIFY ADEQUACY OF ABOVE STEPS, AND DOCUMENT AUDITS.

HIERARCHY OF HLW QA PROGRAM



LEVELS OF SPECIFICITY IN QA REQUIREMENTS

10 CFR PART 60, SUBPART G

10 CFR PART 50, APPENDIX B

NRC REVIEW PLAN

NRC REQUIREMENTS

NUREGS

NQA-1

DOE REQUIREMENTS

OCRWM QAR

OCRWM QAPD

PARTICIPANT QAPP

YMPO QUALITY MANAGEMENT PROCEDURES

PARTICIPANT QA PROCEDURE(S)

PARTICIPANT TECHNICAL PROCEDURE(S)

SCIENTIFIC INVESTIGATION (ACTUAL WORK)

18 CRITERIA OF 10 CFR PART 50, APPENDIX B

I. ORGANIZATION

II QUALITY ASSURANCE PROGRAM

III DESIGN CONTROL

IV PROCUREMENT DOCUMENT CONTROL

V. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

VI. DOCUMENT CONTROL

VII. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

VIII. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

CONTINUED

CONTINUED

18 CRITERIA OF 10 CFR PART 50, APPENDIX B

IX. CONTROL OF SPECIAL PROCESSES

X. INSPECTION

XI. TEST CONTROL

XII. CONTROL OF MEASURING AND TEST EQUIPMENT

XIII HANDLING, STORAGE AND SHIPPING

XIV. INSPECTION, TEST, AND OPERATING STATUS

XV. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

XVI. CORRECTIVE ACTION

XVII QUALITY ASSURANCE RECORDS

XVIII. AUDITS

TRANSLATION OF 10 CFR PART 50, APPENDIX B REQUIREMENTS
AS APPLIED TO SCIENTIFIC (FIELD) INVESTIGATIONS

CRITERION III, DESIGN CONTROL (FIELD CHANGES)

"DESIGN CHANGES, INCLUDING FIELD CHANGES, SHALL BE SUBJECT TO DESIGN CONTROL MEASURES COMMENSURATE WITH THOSE APPLIED TO THE ORIGINAL DESIGN AND BE APPROVED BY THE ORGANIZATION THAT PERFORMED THE ORIGINAL DESIGN UNLESS THE APPLICANT DESIGNATES ANOTHER RESPONSIBLE ORGANIZATION."

"NQA-1-1986, DESIGN CONTROL (FIELD CHANGES)

"DESIGN CHANGES, INCLUDING FIELD CHANGES, SHALL BE GOVERNED BY CONTROL MEASURES COMMENSURATE WITH THOSE APPLIED TO THE ORIGINAL DESIGN."

CONTINUED..

NNWSI/88-9, REV.2, SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL

"1.6.1 DOCUMENTATION

THERE ARE TWO METHODS WHICH CAN BE USED FOR THE QUALITY ASSURANCE, DOCUMENTATION AND CONTROL OF SCIENTIFIC WORK. THESE ARE THE SCIENTIFIC NOTEBOOK SYSTEM AND THE TECHNICAL IMPLEMENTING PROCEDURE SYSTEM.

THE SCIENTIFIC NOTEBOOK SYSTEM WILL GENERALLY BE USED BY QUALIFIED INDIVIDUALS WHO ARE USING A HIGH DEGREE OF PROFESSIONAL JUDGEMENT, TRIAL AND ERROR METHODS, OR DEVELOPING THE METHODOLOGY BY WHICH AN ACTIVITY WILL BE ACCOMPLISHED. WHEN THE SCIENTIFIC NOTEBOOK SYSTEM IS USED, THE STUDY PLAN OR SCIENTIFIC INVESTIGATION PLANNING DOCUMENT SHALL BE THE CONTROLLING DOCUMENT USED TO PERFORM THE ACTIVITY SINCE IT DESCRIBES THE PROPOSED APPROACH OR GENERAL PROCEDURE FOR ACCOMPLISHING THE WORK.

WHAT DOES THIS EXAMPLE SHOW

THERE IS A GENERAL REQUIREMENT IN 10 CFR PART 50, APPENDIX B, CRITERION III, FOR CONTROL OF DESIGN ACTIVITIES.

OCRWM QAPD SAYS SCIENTIFIC INVESTIGATIONS ARE DESIGN ACTIVITIES AND WILL BE CONTROLLED.

NNWSI/88-9 SAYS SCIENTIFIC NOTEBOOKS CAN BE USED FOR NON-REPETITIVE WORK REQUIRING A HIGH DEGREE OF PROFESSIONAL JUDGEMENT OR TRIAL AND ERROR METHODS. IN SUCH CASES, THE CONTROL IS PROVIDED BY THE STUDY PLAN OR SCIENTIFIC INVESTIGATION PLANNING DOCUMENT. USE OF DETAILED TECHNICAL PROCEDURES IS NOT REQUIRED.

NRC PERCEPTIONS OF QA

10 CFR PART 50, APPENDIX B QA PROGRAM CAN BE IMPLEMENTED ON EARTH SCIENCES, BASED ON EXPERIENCE WITH NUCLEAR POWER PLANT SITE INVESTIGATIONS. NRC QA REQUIREMENTS ARE SUFFICIENTLY GENERAL TO PERMIT ADEQUATE FLEXIBILITY IN SCIENTIFIC INVESTIGATIONS.

IMPLEMENTING PROCEDURES AT THE WORKING LEVEL ARE BEST DEFINED BY EXPERIENCED SCIENTISTS/ENGINEERS WHO UNDERSTAND THE INTENT OF QA REQUIREMENTS.

THE APPLICATION OF A MEANINGFUL QA PROGRAM TO ANY COMPLEX ACTIVITY WILL REQUIRE SUCCESSIVE ITERATIONS.

KEY: X = ADDRESSES/REQUIRES
NA = NOT APPLICABLE
◯ = NO RESPONSIBILITY

APPENDIX B CRITERIA	QARD	QAPD	USGS	LLNL	REECO	LANL	FSN	SNL	H&N	CNWRA
I. ORGANIZATION	X	X	X	X	X	X	X	X	X	X
II. QA PROGRAM	X	X	X	X	X	X	X	X	X	X
III. DESIGN CONTROL	X	X	X	X	◯	X	X	X	DESIGN ONLY	X
IV. PROCUREMENT DOCUMENT CONTROL	X	X	X	X	X	X	X	X	REECO DOES PROCUR.	TWCORP. SECT. VII
V. INSTRUCTIONS, PROCEDURES & DRAWINGS	X	X	X	X	X	X	X	X	X	X
VI. DOCUMENT CONTROL	X	X	X	X	X	X	X	X	X	X
VII. CONTROL OF PURCHASED MAT., EQUIP. & SERV.	X	X	X	X	X	X	X	X	REECO DOES PROCUR.	X
VIII. IDENT. & CONTROL OF MAT., PARTS & COMP.	X	X	X	X	X	X	ENGINEERING ITEMS ONLY	X	X	X
IX. CONTROL OF SPECIAL PROCESSES	X	NA	NA	X	X	X	X	X	X	X
X. INSPECTION	X	NA	NA	X	X	NA	X	X	X	NA
XI. TEST CONTROL	X	NA	NA	X	X	NA	X	X	X	NA
XII. CONTROL OF MEASURING & TEST EQUIPMENT	X	X	X	X	X	X	X	X	X	X
XIII. HANDLING, STORAGE AND SHIPPING	X	X	X	X	X	X	X	X	X	X
XIV. INSPECTION, TEST, AND OPERATING STATUS	X	NA	NA	X	X	NA	NA	X	X	NA
XV. NONCONFORMING MATERIALS, PARTS OR COMPONENTS	X	X	X	X	X	X	X	X	X	X
XVI. CORRECTIVE ACTION	X	X	X	X	X	X	X	X	X	X
XVII. QUALITY ASSURANCE RECORDS	X	X	X	X	X	X	X	X	X	X
XVIII. AUDITS	X	X	X	X	X	X	X	X	X	X
XIX. COMPUTER SOFTWARE	X	X	APP-H	APP-H	APP-H	APP-H	SEC. 3	APP-H	APP-C	
XX. SCIENTIFIC INVESTIGATIONS	APP-A	APP-A	SEC. 3	SEC. 3	◯	SEC. 3	SEC. 3	SEC. 3	NA	

APPENDIX B CRITERIA DIFFER FROM DOE TERMINOLOGY