February 16, 1989

AUDIT PLAN

Audit Number:	89-C-1
Audit Scope:	Center for Nuclear Waste Regulatory Analyses (CNWRA) program architecture
Audit Requirements:	To evaluate program architecture activities for compliance with applicable procedures
Activities to be Audited:	CNWRA Elements and Subelements
Audit Personnel:	R. E. Engelhardt, SwRI, Lead Auditor Mark Delligatti, NRC Observer Ken Hooks, NRC Observer
Organization to be Notified:	CNWRA
Applicable Documents:	Center Quality Assurance Manual, Sections i, 1, 2, 3, 5, 6, 15, 16, 17, 18, and 19; and Technical Operating Procedures, TOP-001, TOP-001-01, TOP-001-02 and TOP-001-03
Pre-Audit Meeting:	08:30, February 27, 1989 at CNWRA
Audit Content:	See attached checklist

Submitted by: _____
Robert E. Engelhardt, Lead Auditor

REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 1 Ref CQAM Page 1.5	Is the distribution of TOPs, QAPs, and APs controlled?	
Item 2 Ref CQAM Page 1.5	Have Operations Plans been prepared for each Element/Sub-element?	
Item 3 Ref CQAM Page 1.5	Do Operations Plans invoke specific quality requirements by referencing the CQAM?	

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EXAMPLE: S
EXAMPLE: U, O

REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 4 Ref CQAM Page 1.5	Do Operations Plans other than 1 year plans, reference TOPs, QAPs, and APs?	
Item 5 Ref CQAM Page 1.6	Has the SwRI Quality Assurance Committee provided oversight of the Center QA program?	
Item 6 Ref CQAM Page 1.6	Does the SwRI Quality Assurance Committee report regularly to the President of SwRI regarding the effectiveness of the Center QA program?	

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REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 7 Ref CQAM Para 1.2.2(1)	Has the approval of Element/Sub-element Operations Plans by the NRC been documented?	
Item 8 Ref CQAM Para 1.4.1(3)	Has the QAC made followup reviews of quality assurance audits and surveillances to determine that corrective action is timely and effective?	
Item 9 Ref CQAM Para 1.4.1(4)	Has the QAC performed a review of the Center quality assurance program at least once per calendar year?	

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REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 10 Ref CQAM Para 1.5	Has delegation of authority by an individual to persons other than his supervisor been documented?	
Item 11 Ref CQAM Para 2.3.2	Has the process used to change Center activities from QA Level 1 to QA Level 2 or 3 been documented?	
Item 12 Ref CQAM Para 2.5.1	Have applicable Center employees received QA indoctrination and training?	

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REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 13 Ref CQAM Para 3.4(3)	Are changes from approved design inputs, including the reason for the changes, identified, approved, documented and controlled?	
Item 14 Ref CQAM Para 3.5	Has design analysis been considered in the design of the Program Architecture?	
Item 15 Ref CQAM Para 3.6(1)	Has the Program Architecture been periodically evaluated by Program Architecture Review Committees?	

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REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 16 Ref CQAM Para 3.6(1)	Are the activities of the Program Architecture Review Committees controlled by Technical Operating Procedures?	
Item 17 Ref CQAM Para 3.6(8)	Does the Center Technical Director and the Director of Systems Engineering and Integration participate in the Program Architecture review process?	
Item 18 Ref CQAM Para 3.6(8)	Has the review of the various Element/Sub-element inputs been documented in the Center's transmittal to the NRC?	

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REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 19 Ref CQAM Para 5.3(2)	Does the Center QA Director review and approve QAPs, TOPs, Operations Plans, Project Plans, and the CQAM?	
Item 20 Ref CQAM Para 5.3(4)	Has the Systems Engineering Management Plan been approved by the Center President and the NRC Program Manager?	
Item 21 Ref CQAM Para 6.3(3)	Is the distribution of the CQAM, TOPs, QAPs, and APs controlled?	

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REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 22 Ref CQAM Para 6.3(3)	Is the assignment of new and revision numbers for documents controlled?	
Item 23 Ref CQAM Para 6.4.3(2)	Are Operations Plans and Project Plans approved by the Element/Sub-element Manager with written concurrence by the SE&I Director and Director of Quality Assurance?	
Item 24 Ref CQAM Para 6.4.5(2)	Are uncontrolled copies of Operations Plans and Project Plans marked for information only on the front page?	

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SwRI FORM QA 1-3

REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 25 Ref CQAM Para 6.5.6(1)	Are distribution lists for TOPs, QAPs and APs maintained by the Center Director of Administration?	
Item 26 Ref CQAM Para 6.8.1	Does the Center Director of Administration maintain a distribution list and evidence of distribution of the CQAM?	
Item 27 Ref CQAM Para 6.8.2	Does the Center Administrative Director maintain record copies of Operations Plans, Project Plans, TOPs, QAPs, and APs?	

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REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 28 Ref CQAM Para 15.3(1)	Does SwRI QA maintain a file of all Center Deviation and Nonconformance Reports (DNRs)?	
Item 29 Ref CQAM Para 15.4, 15.5	Are nonconforming items identified and segregated?	
Item 30 Ref CQAM Para 15.6.1(8)	Does the Center maintain a DNR file and sequentially number such DNRs?	

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SwRI FORM QA 1-3

REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 31 Ref CQAM Para 15.6.2(2)	Has the NRC Program Element Manager been notified of DNRs affecting the task and of the disposition by the Center?	
Item 32 Ref CQAM Para 16.4(7)	Are DNRs received by the Center QA Director within 10 working days after their preparation?	
Item 33 Ref CQAM Para 16.4(8)	Has the Center Director received audit finding corrective action statements within 30 days after the audit report is distributed?	

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| AUDIT CHECKLIST | Audit Report No. 89-C-1 | Page 12 of 26 |

REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 34 Ref CQAM Para 16.4(9)	Has the basis for closeout of corrective action on DNRs and audit open items been documented?	
Item 35 Ref CQAM Para 16.4(10)	Has the corrective action program been audited annually?	
Item 36 Ref CQAM Para 17.4.2	Are there hardcopy backups of electronic records and are these hardcopies certified as being bonafide copy of the electronic media?	

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REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 37 Ref CQAM Para 18.3(1), 18.4.2(1)	Has the Center QA Director prepared an audit plan specifying the audits to be performed? Has the schedule for internal audits been distributed to the President, Technical Director and the Director of SE&I?	
Item 38 Ref CQAM Para 18.4.2(2)	Has the Center QA Director prepared an audit schedule for vendor audits and distributed this schedule to the President, Technical Director, Director of SE&I and SwRI Manager of Quality Assurance?	
Item 39 Ref CQAM Para 18.4.4	Are lead auditors certified to ANSI N45.2.23 and have they been specified in writing by the Center QA Director?	

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REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 40 Ref CQAM Para 18.4.5(1)	Do audit reports contain the following: scope, auditor identification, persons contacted, summary of results, descriptions of nonconformances and recommendations for corrective action or improvements.	
Item 41 Ref CQAM Para 18.4.5(3)	Are audit reports submitted within 30 days?	
Item 42 Ref CQAM Para 18.4.5(4)	Does the Center QA Director receive corrective action resolution within 30 days after the report was received by the Element/Sub-element Manager or vendor?	

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SwRI FORM QA 1-3

REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 43 Ref TOP-001 Para A.4.1	Has the WSE&I issued work instructions to Element/Sub-element Managers regarding Program Architecture (PA) development?	
Item 44 Ref TOP-001 Para A.4.3	Do the Element/Sub-element Managers maintain professional data sheets or resumes on each individual recruited to address the WSE&I worksheets?	
Item 45 Ref TOP-001 Para A.4.4	Are worksheets associated with input to the WSE&I Sub-element identified by name of Element/Sub-element, person performing the work, by regulation or statute, or other identification?	

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REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 46 Ref TOP-001 Para A.4.5	Has a database administrator been designated, have administrative procedures been prepared for inputting to the PA database, and is the database "write protected"?	
Item 47 Ref TOP-001 Para A.4.6	Have Program Architecture Review Committees (PARCs) been selected by the WSE&I Sub-element Manager and concurred in by the Center Technical Director and Director of SE&I?	
Item 48 Ref TOP-001 Para A.4.6	Has the NRC CNWRA Program Manager been advised of the PARC schedule by the WSE&I Sub-element Manager?	

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REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 49 Ref TOP-001 Para A.4.6	Has the work of the PARC been documented in a written format with PARC members identified as voting or only participating?	
Item 50 Ref TOP-001 Para A.4.6	Are initial entries that are rejected from the PA database maintained in a separate electronic file?	
Item 51 Ref TOP-001 Para A.4.6	Does the Center maintain one paper copy and one electronic copy of submittals to the NRC?	

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REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 52 Ref TOP-001 Para A.4.6	Are records of the PARC proceedings maintained in the Center controlled files?	
Item 53 Ref TOP-001 Para A.4.6	Is there a documented PARC review at each step of process integration in the development of the PA?	·
Item 54 Ref TOP-001 Para A.4.6	Are changes to the database controlled by "write protection" subsequent to certification of each integration step?	

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REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 55 Ref TOP-001 Para A.4.7	Has Quality Assurance verified that TOP-001 is implemented and followed?	
Item 56 Ref TOP-001 Para A.4.8	Have Major Milestones been certified by a Quality Assurance review and provided to the NRC for review and comment?	
Item 57 Ref TOP-001 Para A.4.8	Have Center Intermediate Milestones been provided to the appropriate NRC office at the time the certified integrated products are transmitted to the NRC?	

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REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 58 Ref TOP-001 Para B.4.1	Have configuration control and change control procedures been developed for application to certified contents of the PA?	
Item 59 Ref TOP-001-01 Para 5.	If the WSE&I Sub-element Manager elects to select a subset of the content of the database for review and revision, is the subset selected, rationale for choosing the subset, approval of the Director of SE&I and the Technical Director, and concurrence of the NRC Program Manager documented?	
Item 60 Ref TOP-001-01 Para 5.	Is the work product of the PARC checked by the WES&I Sub-element Manager, Director of Quality Assurance, and the Technical Director and is this check documented?	

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REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 61 Ref TOP-001-01 Para 5.	Have changes to TOP-001-01 been "red lined", initialed, and distributed to affected parties?	
Item 62 Ref TOP-001-02 Para 1.	Has the review and revision of Milestone Number 12 data been completed by the PARC in accordance with TOP-001-01 thereby making TOP-001-02 effective?	
Item 63 Ref TOP-001-02 Para 1.	Have examples of the required content of each field been developed by the WES&I Sub-element and provided in the form of memoranda to the Elements/Sub-elements?	

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SwRI FORM QA 1-3

REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 64 Ref TOP-001-02 Para 5.9	Are activities of PARCs formed to revise the Program Architecture Database (PADB) controlled by work instructions?	
Item 65 Ref TOP-001-03 Para 5.4	If the WSE&I Sub-element Manager elects to complete the development of not more than two related key fields and their associated fields before submitting the information for verification, has the written concurrence of the Director of SE&I and the Technical Director been obtained before taking such action?	
Item 66 Ref TOP-001-03 Para 5.6	Has the PARC made recommendations for modification to the submitted PADP input information?	

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REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 67 Ref TOP-001-03 Para 5.7(2)	Does the PARC Chairman distribute hard copy of PADM to members of the PARC and retain a copy for file?	
Item 68 Ref TOP-001-03 Para 5.7(3)	Is there evidence that PARC members have reviewed submitted PADB information and have signed and dated their reviews?	
Item 69 Ref TOP-001-03 Para 5.7(4)	Have sets of review packages been provided to the Element/Sub-element Manager?	

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Item 70 Ref TOP-001-03 Para 5.7(5)	Has the Element/Sub-element Manager reviewed each comment and marked it either "accept" or "reject"?	
Item 71 Ref TOP-001-03 Para 5.7(7)	Has the reviewer signed and dated the hard copy of the revised review package?	
Item 72 Ref TOP-001-03 Para 5.7(9)	When the PARC Chairman is satisfied that all comments have been properly dispositioned and the revised submittal is complete has he marked the diskette label "accepted" and signed and dated the label?	

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SwRI FORM QA 1-3

REFERENCE DOCUMENT PARAGRAPH	AUDIT ELEMENT DESCRIPTION AND FINDINGS	STATUS
Item 73 Ref TOP-001-03 Para 5.7(9)	Has the PARC Chairman provided a complete hard copy file of the PADB input to the Director of Quality Assurance?	
Item 74 Ref TOP-001-03 Para 5.8	Has the development team prepared a checklist of regulatory text to be incorporated into at least one regulatory requirement and has this checklist been included in the associated file provided to the PARC Chairman?	
Item 75 Ref TOP-001-03 Para 5.9	Has the WSE&I Sub-element Manager and the Technical Director, with the assistance of the Manager of Quality Assurance conducted documented periodic checks of PARC verification activities?	

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Item 76 Ref TOP-001-03 Para 5.9	If the check of PARC verification activities is judged inadequate, has additional training or instruction been provided and have existing verifications been corrected?	
Item 77 Ref TOP-001-03 Para 6.1	Do the PADB input form templates include: the complete alphanumeric identifier for the PADB input, the name of the responsible Center Element/Sub-element Manager, the date of submission to the PARC, the name of the PARC Chairman, PARC review status and date, and QA review status and date?	
Item 78 Ref TOP-001-03 Para 6.2	Are filenames in MS-DOS format? Are they composed of eight digits the first three of which are the Manager's initials and the last are an Arabic sequence number while the extension is the file revision number?	
Item 79 Ref TOP-001-03 Para 8.	Is there either electronic or hardcopy objective evidence of QA verification of the acceptability of review and verification activities performed in accordance with this procedure?	

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SwRI FORM QA 1-3

89-C-1 PRE-AUDIT CONFERENCE ATTENDANCE LIST DATE: 2/27/89

NAME	DIV. NO.	TITLE	EXT. NO.
R. E. ENGELHARDT	30	LEAD AUDITOR	2802
Kenneth R Hooks		NRC	
MARE PELLICATTI		NRC	301-492-040
Tom Trbovich	QA	SwRI	3145
Amos E. Holt	30/17	V.P.	2076
ALLEN R. WHITING	CNWRA-20	Dir. S.E. & I	5156
BRUCE MABBITO	CNWRA-20	Dir. Center QA	5149
Henry F Garcia	CNWRA-30	DIR - Admin	5148
John E. Latz	CNWRA		5154
John L. Russell	CNWRA	MANAGER GEOLOGIC SETTING	5-183
WESLEY C. PATRICK	CNWRA	TECHNICAL DIRECTOR	5158

89-C-1 POST-AUDIT CONFERENCE ATTENDANCE LIST		DATE: 2/28/89	
NAME	DIV. NO.	TITLE	EXT. NO.
R. E. Engelhardt	30	Lead Auditor	2802
Kenneth R Hooks		NRC	
Mark S. Delligatti		NRC	
John E. Latz	CNWRA		5154
Bruce Mabrito	CNWRA	Dir. of Center QA	5149
D. Ted Romine	CNWRA	Sr Systems Engr	5208
Allen R. Whiting	CNWRA	Dir. S.E. & I.	5156
John T. Green	CNWRA	Dir. Admin	5149
Wesley C. Patrick	CNWRA	Tech. Director	5158
Thomas C. Tehranich	QA	QA Mgr	3145