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See Pocket 1 for encl. LPDR - (2)
WM - 10
PDR - 11

DEPARTMENT OF ENERGY
RICHLAND OPERATIONS OFFICE

BASALT WASTE ISOLATION PROJECT

FINAL QUALITY ASSURANCE AUDIT PLAN

AUDIT NO. 8701

Audit of Battelle Memorial Institute Pacific Northwest Laboratory
Quality Assurance Program for BWIP

January 5-8, 1987

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Docket No. _____
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FINAL AUDIT PLAN 8701

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APPENDIX A

PRE-AUDIT RESEARCH DATA

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AUDIT CHECKLIST

FINAL AUDIT PLAN

AUDIT NO. 8701, AUDIT OF PNL, JANUARY 5-8, 1986

SCOPE

The audit is intended to cover all QA program elements applicable to Basalt Waste Isolation Project (BWIP) activities currently in progress at Battelle Memorial Institute's Pacific Northwest Laboratory (PNL). Active PNL BWIP tasks are shown by work breakdown structure number in Table 1, Audit Scope for DOE-RL QA Audit 8701 of PNL.

AUDIT TEAM

The audit team is led by DOE-RL and consists of team members from DOE-RL's Basalt Waste Isolation Division (Technical Advisors), Quality Systems Division (QSD), Management Analysis Company (MAC), DOE Office of Geologic Repositories (OGR) and Rockwell Hanford Operations (Rockwell). Team members and audit responsibility assignments are shown in Table 1.

BACKGROUND

PNL is a division (Pacific Northwest Laboratory) of Battelle Memorial Institute. The Institute was founded to provide a pool of creative scientific and engineering talent to perform applied research and development for industrial and institutional sponsors. PNL, which primarily (but not exclusively) serves sponsors with interests in the northwest region of the contiguous United States, is organized to address the technical areas listed in Figure 1. PNL work related to Hanford Reservation activities is covered under a blanket contract with DOE's Richland Operations Office (DOE-RL), which specifies unnamed services for DOE-RL and the various site contractors. Individual PNL projects are defined in Statements of Work (SOWs) and funded through work authorizations.

When the need for a particular project (discrete task or set of closely related tasks) is identified, PNL appoints a Project Manager (PM) who plans the project and prepares a proposed SOW and a project QA plan. Project planning and SOW preparation include consultation with the sponsor's technical contact person. The SOW is reviewed for technical content, compatibility with PNL's mission and resources, and appropriateness of QA and other commitments. After in-house approval, the SOW is submitted to the sponsor, where another set of technical, business and QA reviews is conducted and the SOW is approved. Work authorization (i.e., authorization to perform work and charge expenditures against the SOW) is issued separately by the sponsor.

PNL's approach to quality assurance is based on two sets of quality assurance administrative procedures (QA manuals) -- one for license related work and one for work that is not related to NRC licensing. The license related QA manual is designated MA-60. In addition to MA-60, PNL has generated two

volumes (to date) of department and technical procedures for various types of technical work on license related projects.

For each such license related project, the QA plan (QAP) identifies which of the eighteen criteria of 10 CFR 50 Appendix B (specified as requirements in consensus standard ANSI/ASME NQA-1) apply. In addition, each QAP describes any exceptions or clarifications that are necessary for those requirements.

AUDIT OBJECTIVES

The audit is intended to provide data that can be used to answer the following generic questions:

1. Does PNL have an approved QA program in place for basalt waste isolation project work (i.e., have their QA manual and QA administrative procedures been approved by Rockwell)?
2. Is their QA program, as defined by their QA manual and QA administrative procedures, adequate and responsive to project QA program requirements (i.e., the Basalt Quality Assurance Requirements Document [BQARD])?
3. Is their QA program being implemented; are they complying with the QA manual, QA administrative procedures and applicable technical procedures?
4. Are applicable elements of the QA program achieving the intended results?

It should be noted that QA program results involve (a) technical validity, and (b) credibility of applied controls.

Technical validity is to be addressed in this audit by the technical members of the team, who are charged with evaluating the adequacy of processes used to assure/verify technical quality, correctness and/or validity of the work.

Credibility is to be verified by the QA members of the team as they evaluate compliance with procedures and documentation of activities and results.

In particular, this audit is expected to determine the current baseline of program implementation, taking into account the delta already known to PNL through internal audits and surveillances, the September audit by the Salt Repository Project Office (SRPO) and the Rockwell appraisal program. In addition, the audit is intended to identify any remaining delta (between the existing baseline and a program fully responsive to latest requirements), if there is such a delta.

RELATION OF AUDIT TO ROCKWELL APPRAISAL RESULTS

Rockwell recently performed an extensive "program management appraisal", part of which addressed PNL's QA program. The appraisal process, as defined by Rockwell, was supposed to provide a subjective assessment of the adequacy of

the QA program and the "management capability" of project participants to implement their programs. The appraisal directive called for reliance on the experience of the appraisers and subjective judgement, rather than use of objective evidence. Results of the present audit will be based on examination of objective evidence. It is expected that comparison of results obtained by these two different approaches will enable DOE to "calibrate" the conclusions Rockwell has drawn from its appraisal.

AUDIT BASIS

Table 2 displays ongoing BWIP work at PNL (by work breakdown structure) versus applicable QA program elements. The table shows what program elements should apply to the work, in the judgment of the audit team, considering requirements specified in the BQARD and DOE-RL policy for meeting those requirements, as stated in the BWI Project Quality Assurance Plan (DOE-RL Document 86-06). The table indicates those differences that exist between team judgments and the elements called out as applicable by PNL in the SOWs and PNL project QAPs. Differences are attributed to the fact that the SOWs and QAPs were issued prior to the time the BQARD and the BWI Project QA Plan were issued for project implementation.

Table 3 shows PNL project managers and principal contributors for the work breakdown structure tasks that are to be audited.

DATA ON ACTIVITIES TO BE AUDITED

Appendix A indicates the pre-audit research each audit subteam accomplished during audit preparation and summarizes results of their research.

SCHEDULE OF AUDIT ACTIVITIES

Table 4 shows the planned schedule of audit activities.

CHECKLIST

The checklist for this audit is attached as Appendix B to this plan. Each of the PNL activities identified in Table 1 will be audited against a truncated checklist -- i.e., a subset of the Appendix B checklist, consisting of those QA program elements and critical features that apply to the activity.

FIGURE 1. AREAS OF PNL ACTIVITIES

APPLIED PHYSICS
EARTH AND ENVIRONMENTAL SCIENCES
LIFE SCIENCES
MATERIALS AND CHEMICAL SCIENCES
HANFORD ENVIRONMENT
NATIONAL SECURITY TECHNOLOGY
REACTOR TECHNOLOGY
WASTE TECHNOLOGY
ENGINEERING TECHNOLOGY
TECHNOLOGY PLANNING AND ANALYSIS

TABLE 1. AUDIT SCOPE FOR DOE-RL QA AUDIT 8701 OF PNL

| PROJECT TASKS | NUMBER | AUDITOR | TECH ADVISOR /TEAM |
|--|-----------------|--------------------------------------|--------------------|
| TOTAL SYSTEM PERFORMANCE ASSESSMENT | L1E | Smirardo/Newby | Knepp A |
| Verification and Benchmark Codes | L1E2 | | Knepp |
| WASTE FORM AND MATERIALS TESTING | L2D | Marcella/Bohn/Litz | Furman B |
| Solubility/Sorption Studies | L2D3P/ L3E2B | | Furman |
| Hydrotherm Material Testing | L2D4P | | Furman |
| GEOCHEMISTRY | L3E | O'Brien/Welsch | Furman D |
| Organic Analysis of Groundwater and Drilling and Leachate | L3E2A | | Furman |
| Organic Analysis of Sodium Bentonite Packing Materials | L2D3R | | Furman |
| U/TH Disequilibrium | L3E2C | | Furman |
| ENVIRONMENTAL STUDIES PROGRAM | L3G/L3H | Subramanian | Whitfield E |
| MANAGEMENT AND INTEGRATION | L9A | Williams | Hoe/Madsen F |
| PROJECT CONTROL | L9C | Williams | Hoe/Madsen |
| QUALITY ASSURANCE | L9D | Sandall/Stonecker/ Kasch/Thompson | ---- G |

TABLE 2. ONGOING PNL WORK versus QA PROGRAM ELEMENT

(FROM AUDIT HANDBOOK)

| ELEMENT | L2D3P/ | | | | | | L3G/ L3H |
|---|--------|-------|-------|-------|-------|-------|-------------|
| | L1E2 | L3E2B | L2D4P | L3E2A | L2D3R | L3E2C | L9D |
| 1.2 Internal Organization For QA | | | | | | | DX |
| 1.3 Designation of Functional Responsibilities | | | | | | | DX |
| 1.6 Organizational Interface Control | | | | | | | X |
| 2.1 Program Description | X | X | X | X | X | X | X |
| 2.4 Controlled Conditions | | | | | | | |
| 2.5 Training and Indoctrination | X | X | X | X | X | X | X |
| 2.6 Personnel Qualification | | | | | | | X |
| 2.7 Management Assessment of Program Effectiveness | | | | | | | |
| 3.1B Control of Inputs | R | R | R | | | | |
| 3.2B Control of Planning Process | R | R | R | R | R | R | R |
| 3.3B Technical Verification of Planning and Test Procedures | R | R | R | R | R | R | R |
| 3.4B Planning and Test Procedures Change Control | R | R | R | R | R | R | R |
| 5.1 Procedures | X | X | X | X | X | X | X |
| 5.2 Procedure Compliance | X | X | X | X | X | X | X |

LEGEND: X = Required by NQA-1 and Review Plan
 R = Required by Review Plan but not by NQA-1
 A = Was Required by NQA-1, but Review Plan moved requirement to 3B

TABLE 2. ONGOING PNL WORK versus QA PROGRAM ELEMENT

| ELEMENT | L2D3P/ | | | | | | | L3G/ L3H |
|--|--------|-------|-------|-------|-------|-------|-----|-------------|
| | L1E2 | L3E2B | L2D4P | L3E2A | L2D3R | L3E2C | L9D | |
| 6.1 Controlled Document List(s) | | | | | | | X | |
| 6.2 Unique Identification of Controlled Documents | | | | | | | X | |
| 6.3 Document Review | X | X | X | X | X | X | X | X |
| 6.4 Document Approval/ Issue Controls | X | X | X | X | X | X | X | X |
| 6.5 Document Change Controls | X | X | X | X | X | X | X | X |
| 6.6 Distribution Controls | X | X | X | X | X | X | X | X |
| 8.1 Identification System(s) for Items/Samples | | X | X | X | X | X | | X |
| 8.2 Item/Sample Controls | | X | X | X | X | X | | X |
| 8.3 Verification of Item/ Sample Identity Prior To Use | | X | X | X | X | X | | X |
| 11.3 Test Procedures | A | A | A | A | A | A | | A |
| 11.4 Test Documentation and Records | X | X | X | X | X | X | | X |
| 11.5 Evaluation of Test Results | X | X | X | X | X | X | | X |
| 12.1 M&TE Selection | | X | X | X | X | X | | X |
| 12.2 Calibration Controls | | X | X | X | X | X | | |
| 12.3 M&TE Handling and Storage | | X | X | X | X | X | | |

LEGEND: X = Required by NOA-1 and Review Plan
 R = Required by Review Plan but not by NOA-1
 A = Was Required by NOA-1, but Review Plan moved requirement to 3B

TABLE 2. ONGOING PNL WORK versus QA PROGRAM ELEMENT

| ELEMENT | L2D3P/ | | | | | | | L3G/ L3H |
|--|--------|-------|-------|-------|-------|-------|-----|-------------|
| | L1E2 | L3E2B | L2D4P | L3E2A | L2D3R | L3E2C | L9D | |
| 12.4 Traceability of M&TE Usage | | X | X | X | X | X | | X |
| 12.5 Impact Evaluation for Out of Calibration Incidents | | X | X | X | X | X | | X |
| 13.3 Marking/Labeling of Containers/Packages | | X | X | X | X | X | | X |
| 14.1 Inspection/Test Status Indicating System | | X | X | X | X | X | | |
| 15.1 Distinguishing Identification of Nonconforming Items | | X | X | X | X | X | X | X |
| 15.2 Nonconformance Reporting | | X | X | X | X | X | X | X |
| 15.3 Evaluation/Disposition Controls | | X | X | X | X | X | X | |
| 15.4 Nonconformance Closeout | | X | X | X | X | X | X | |
| 16.1 Identifying/Reporting/Correction of Conditions Adverse to Quality | X | X | X | X | X | X | X | |
| 16.2 Evaluation of Potential Impact/Significance | X | X | X | X | X | X | X | |
| 16.3 Determination of Cause (Significant Problems) | X | X | X | X | X | X | X | |
| 16.4 Action to Prevent Recurrence | X | X | X | X | X | X | X | |
| | | | | | | | | |

LEGEND: X = Required by NQA-1 and Review Plan
R = Required by Review Plan but not by NQA-1
A = Was Required by NQA-1, but Review Plan moved requirement to 3B

TABLE 2. ONGOING PNL WORK versus QA PROGRAM ELEMENT

| ELEMENT | L2D3P/ | | | | | | | L3G/ L3H |
|--|--------|-------|-------|-------|-------|-------|-----|-------------|
| | L1E2 | L3E2B | L2D4P | L3E2A | L2D3R | L3E2C | L9D | |
| 16.5 Documentation and Reporting to Management | X | X | X | X | X | X | X | |
| 16.6 Follow-up | | | | | | | X | |
| 17.1 Designation of Documents To Become Records | X | X | X | X | X | X | X | X |
| 17.2 Control of Working Documents | X | X | X | X | X | X | X | X |
| 17.3 Authentication/Validation of Completed Documents | X | X | X | X | X | X | X | X |
| 17.5 Traceability Between Record and Activity | X | X | X | X | X | X | X | X |
| 17.7 Control of Changes to Formal Record | X | X | X | X | X | X | X | X |
| 17.8 Record Submittal Controls | X | X | X | X | X | X | X | X |
| 18.1 Audit Scheduling | | | | | | | X | |
| 18.2 Audit Preparation/ Team Selection | | | | | | | X | |
| 18.3 Audit Performance/ Documentation | | | | | | | X | |
| 18.4 Audit Reporting | | | | | | | X | |
| 18.5 Resolution/Corrective Action for Adverse Findings | | | | | | | X | |
| 18.6 Audit Follow-up | | | | | | | X | |
| 18.7 Audit Records | | | | | | | X | |

LEGEND: X = Required by NQA-1 and Review Plan
 R = Required by Review Plan but not by NQA-1
 A = Was Required by NQA-1, but Review Plan moved requirement to 3B

TABLE 3. PNL TASK ASSIGNMENTS

| WBS NUMBER | TASK | PROJECT MANAGER | PROJECT OE |
|-----------------|--|--------------------|---------------|
| L1E2 | Codes Verification and Benchmark | M. J. Budden | V. C. Lauhala |
| L2D3P/ L3E2B | Solubility/Sorption Studies | L. L. Ames | R. Cuello |
| L2D4P | Hydrothermal Material Testing | J. R. Burnell | S. L. English |
| L3E2A/ L2D3R | Organic Analysis: Groundwater, etc. | A. P. Toste | S. L. English |
| L3E2C | U/Th Disequilibrium | J. C. Lau | S. L. English |
| L9D | Quality Assurance | C. Hughey | |
| L3G/L3H | Environmental Licensing Support | T. L. Page | R. Cuello |

**TABLE 4. SCHEDULE OF AUDIT ACTIVITIES
FOR PNL AUDIT 8701/DOE-RL QA**

DAY 1, Monday (1/5/87)

| | |
|---------|--|
| 9:00 am | Formal Pre-audit Briefing (Auditors and Observers) |
| 3:00 pm | Entrance Meeting |

DAY 2, Tuesday (1/6/87)

| | | | | | |
|--------------------|-------------------|---------------------|-----------------------|--------------|--------------|
| 8:00 am - 8:30 am | Audit Team Caucus | | | | |
| 8:30 am - 12:00 pm | 1E2 Team A | 2D3P/3E2B Team B | 3E2A/2D3R Team D * | 9A Team F | 9D Team G |
| 1:00 pm - 3:30 pm | | 2D4P Team B | 3E2A/2D3R Team D * | 9A Team F | 9D Team G |
| 3:30 pm - 4:30 pm | Audit Team Caucus | | | | |

DAY 3, Wednesday (1/7/87)

| | | | | | |
|--------------------|-------------------|----------------|--------------|--------------|-----------------------|
| 8:00 am - 8:30 am | Audit Team Caucus | | | | |
| 8:30 am - 12:00 pm | 9C Team F | 3E2C Team D | 3G Team E | 9D Team G | 2D3P/3E2B Team B * |
| 1:00 pm - 3:30 pm | 9C Team F | 3E2C Team D | 3G Team E | 9D Team G | 2D4P Team B * |
| 3:30 pm - 4:30 pm | Audit Team Caucus | | | | |

DAY 4, Thursday, (1/8/87)

| | |
|--------------------|--|
| 8:00 am - 12:00 pm | Finish auditing/prepare audit findings |
| 1:00 am - 3:00 pm | Audit Team Caucus |
| 3:00 pm | Exit Interview |

NOTE: * Without Technical Advisor

AUDIT PLAN 8701

APPENDIX A

AUDIT TEAM BRIEFING AGENDA AND INSTRUCTIONS

SUMMARY OF PRE-AUDIT
RESEARCH RESULTS

PRE-AUDIT TEAM BRIEFING AGENDA

GENERAL INTRODUCTION: RJSK

The PNL role in the project (DFC-technical/scientific)

How PNL is turned on

How PNL manages projects and defines QA programs

Audit Objectives

Audit approach

Team caucuses and evaluation

SPECIFIC INTRODUCTION:

How the audit is organized (subteams, SOW coverage, QA organization, coverage, project management coverage, technical coverage)

How audit preparation was conducted:

- o Identification and acquisition of SOWs, manuals, QAPs, etc.
- o Identification of QA program elements against SOWs
- o Identification of responsible personnel vs. SOWs
- o History research (audits, CARs, surveillance reports)
- o Checklist preparation
- o Assembly of checklist packages

SUBTEAM BRIEFINGS:

SANDALL

NEWBY

BOHN

O'BRIEN

SUBRAMANIAN

MARCELLA

WILLIAMS

SCHEDULE OF AUDIT ACTIVITIES: SMIROLD

PRE-AUDIT BRIEFING - NOTES AND QUESTIONS FOR SUBTEAMS

The formal pre-audit briefing is intended to provide all team members and observers with (a) a clear, comprehensive understanding of what the audit team is doing, how we are doing it, who is doing what, (b) what work is going on at PNL, who is doing and managing it, (c) PNL's history as it relates to this audit, and (d) what we expect to get out of the audit.

The spokesman for each subteam is expected to provide a clear picture of those PNL activities the subteam will be auditing, what the subteam's part of the audit will address, and any special things they will be checking on or concerned with.

At the end of the briefing, everyone in attendance should leave feeling thoroughly familiar with the PNL operation, the BWIP work now underway at PNL, and what the whole audit team is going to do.

The attached material describes what each subteam should present. Please use viewgraphs and/or flipcharts as necessary to make a thoroughly professional presentation.

GENERAL:

Discuss each SOW for which your subteam is responsible. Take us through the answers to the following questions one at a time. But start your presentation by telling us what SOWs your subteam is responsible for, supplying the following introductory information:

INTRODUCTORY:

1. Who is on your subteam? If you are on more than one subteam during the audit, who makes up each of the subteams?
2. What SOW(s) will your subteam cover? List the SOWs by topic, rather than by SOW number.
3. What is your schedule for covering each of the SOWs (if more than one)?

SPECIFIC: (Give the following information about one SOW at a time - if you have more than one)

1. What does the SOW require PNL to do?
2. Who is the PNL Project Manager for that SOW.
3. Who is (are) the principal contributor(s)?
4. What work is presently going on?

5. What QA program elements do you believe should apply to that work?
6. Does your preliminary identification of applicable QA program provisions match what PNL shows in the QA plan? If no, what are the differences?
7. Keeping in mind the fact that the SOWs and QAPs were probably written before the BOARD (and therefore the NRC Review Plan) was imposed, do differences between your list of applicable QA requirements and those called out in the SOW and/or QAP boil down to the fact that those documents are out of date?
8. What is the history of this activity?
 - a. Any previous audit findings, including the most recent audit by SRP0?
 - b. Any CARs or other problem reports (including any generated during the past year by PNL QA)?
9. What evidence related to corrective action promised for the problems mentioned in 8 do you plan to look at?
10. Did the checklist preparation activity, and your subsequent review of the checklist(s) for your SOWs, reveal any areas PNL does not have procedural coverage for?
11. What documents and other specific kinds of evidence will you be examining?
12. Where is the work being done that you are to audit? If an observer accompanies your subteam, are there any escort implications?

PRE-AUDIT BRIEFING

INTRODUCTION

- SUBTEAM MEMBERS:

1. W. B. WILLIAMS — LEAD AUDITOR
2. J. S. TRENT — TECHNICAL ADVISOR

- ACTIVITIES

- L1E2 — VERIFICATION AND BENCHMARKING
OF HEAT TRANSFER AND FLUID
FLOW CODES — SOFTWARE ONLY

SCHEDULE:

DROP FROM AUDIT SCOPE

WHY?

HISTORY

- MID '85 — SOFTWARE CONTROLS CONSIDERED
 INADEQUATE
- LATE '85 — SOFTWARE CONTROLS ADDED TO
 QA PLANS AS ATTACHMENTS
- EARLY '86 — SRPO AND PNL TASK FORCE TO
 DEVELOP SOFTWARE CONTROL
 PROCEDURES (SCPs)
- SCPs TRIED OUT ON SRPO SOWs —
 CONSIDERED INADEQUATE

HISTORY (continued)

MID '86 — TASK FORCE REWROTE THE SCPs.
NEW SCPs ISSUED JUNE 1986

— IMPLEMENTED FOR SRPO WORK
WITHOUT FURTHER CHANGES

TODAY — ONLY BWIP CANDIDATE FOR
AUDIT FOR COMPLIANCE TO
SCPs IS L1E2

— THE WORK ON L1E2 HAS NOT
PROGRESSED FAR ENOUGH FOR
AUDIT OF SOFTWARE TO BE
PRACTICAL

PREVIOUS AUDIT HISTORY

- SRO AUDIT SEPTEMBER 1986 FOUND:

LACK OF TRAINING TO PROCEDURE
NOT FOLLOWING PROCEDURES

THIS WILL BE COVERED BY OTHER
AUDITORS DURING THIS AUDIT
OF BWIP ACTIVITIES

TEAM "A" PRE-AUDIT BRIEFING

INTRODUCTION

- SUBTEAM "A" MEMBERS:

- | | | | |
|----|----------------|---|-------------------|
| 1. | C. A. SMIRLODO | — | LEAD AUDITOR |
| 2. | T. A. NEWBY | — | AUDITOR |
| 3. | A. J. KNEPP | — | TECHNICAL ADVISOR |

INTRODUCTION (continued)

- ACTIVITY:

L1E2 — VERIFICATION AND BENCHMARKING OF
HEAT TRANSFER AND FLUID FLOW CODES

SCHEDULE

| <u>DAY</u> | <u>DATE</u> | <u>TIME</u> | <u>ACTIVITY</u> |
|------------|-------------|-------------|-----------------|
| MONDAY | 1/5/87 | 3:00 | ENTRANCE MTG |
| TUESDAY | 1/6/87 | 8:30-12:00 | L1E2 |
| | | 1:00-3:00 | L1E2 |
| WEDNESDAY | 1/7/87 | 8:30-12:00 | L1E2 |
| | | 1:00-3:00 | L1E2 |
| THURSDAY | 1/8/87 | 3:00 | EXIT MTG |

SPECIFIC INFORMATION — L1E2

1. OBJECTIVE OF STUDIES

- COMPLETE VERIFICATION AND BENCHMARKING OF THE COMPUTER CODE "CHAINT"
- EVALUATE THE MONTE CARLO DIRVER CODE "PACSTAT" (ADDED OBJECTIVE)
- EVALUATE TWO MONTE CARLO COMPUTER CODES: "PORMC-SF" AND "CHAINT-MC"

2. RESULTS OF STUDIES

- WILL BE USED IN NUMERICAL MODELS FOR MAKING LONG-TERM PREDICTIONS OF POST CLOSURE REPOSITORY PERFORMANCE

SPECIFIC INFORMATION — L1E2 (continued)

3. PNL PROJECT MANAGER

- M. J. BUDDEN

4. PRINCIPAL CONTRIBUTORS

- M. J. BUDDEN — PROJECT MANAGER
- M. G. PIEPHO — SENIOR RESEARCH SCIENTIST
- V. C. LAUHALA — QUALITY ENGINEER

SPECIFIC INFORMATION — L1E2(continued)

5. CURRENT ACTIVITIES

- FINALIZE REPORTS ON "PACSTAT" AND "CHAINT"
- VERIFICATION AND BENCHMARKING OF "CHAINT—MC"
- TESTING OF BENCHMARK CODES

ACTIVITY HISTORY

1. AUDIT

- PNL A-86-04-10-60

DATE: APRIL 4, 1986

FINDINGS: 1) TRAINING
2) PROJECT RECORDS PLANNING

OBSERVATIONS: NONE

AUDIT HISTORY (continued)

2. SURVEILLANCES

- PNL • 4 SURVEILLANCES (3/11/86 – 8/14/86)
- 3 SATISFACTORY
 - 1 UNSATISFACTORY – (CLOSED 4/11/86)

DOCUMENTS TO BE EXAMINED

1. SOW — L1E2
2. QA PLAN — EPD-163
3. OPERATING PROCEDURES AND INSTRUCTIONS
4. PLANNING DOCUMENTS
5. LABORATORY RECORD BOOKS AND
SUPPORTING DOCUMENTS
6. TEST REPORTS
7. TECHNICAL ANALYSES AND EVALUATIONS

DOCUMENTS TO BE EXAMINED (continued)

8. PROJECT RECORDS LIST AND FILE
9. MONTHLY REPORTS
10. CORRESPONDENCE

LOCATION OF AUDIT

PNL MATH BUILDING

REQUIRES A "Q" CLEARANCE OR AN ESCORT

QAAUD-AB

TEAM "B" PRE-AUDIT BRIEFING

INTRODUCTION

- SUBTEAM "B" MEMBERS:

- | | | | |
|----|----------------|---|-------------------|
| 1. | T. J. MARCELLA | — | LEAD AUDITOR |
| 2. | J. A. BOHN | — | AUDITOR |
| 3. | H. B. LITZ | — | AUDITOR |
| 4. | M. J. FURMAN | — | TECHNICAL ADVISOR |

INTRODUCTION (continued)

- ACTIVITIES:

- L2D3P — BASALT RADIONUCLIDE SOLUBILITY AND SORPTION STUDIES FOR THE ENGINEERED BARRIERS DEPARTMENT
- L3E2B — RADIONUCLIDE SORPTION STUDIES FOR THE SITE DEPARTMENT
- L2D4P — HYDROTHERMAL MATERIALS TESTING IN 325 BUILDING HOT-CELL AND TRACER-TEST FACILITIES

SCHEDULE

| <u>DAY</u> | <u>DATE</u> | <u>TIME</u> | <u>ACTIVITY</u> |
|------------|-------------|-------------|-----------------|
| MONDAY | 1/5/87 | 3:00 | ENTRANCE MTG |
| TUESDAY | 1/6/87 | 8:30-12:00 | L2D3P/L3E2B |
| | | 1:00-3:30 | L2D4P |
| WEDNESDAY | 1/7/87 | 8:30-12:00 | L2D3P/L3E2B |
| | | 1:00-3:30 | L2D4P |
| THURSDAY | 1/8/87 | 3:00 | EXIT MTG |

SPECIFIC INFORMATION – L2D3P/L3E2B

1. OBJECTIVE OF STUDIES

- PROVIDE INFORMATION ON CHEMICAL INTERACTIONS OF RADIONUCLIDES WITH GROUNDWATER, BASALT AND BARRIER MATERIALS

2. RESULTS OF STUDIES

- WILL CONTRIBUTE TO PRELIMINARY WASTE PACKAGE DESIGN (L2D3P)
- DATA ON GEOCHEMICAL EVOLUTION OF BASALT GROUNDWATERS (L3E2B)

SPECIFIC INFORMATION — L2D3P/L3E2B (continued)

3. PNL PROJECT MANAGER

- L. L. AMES

4. PRINCIPAL CONTRIBUTORS

- L. L. AMES — PROJECT MANAGER
- R. CUELLO — QUALITY ENGINEER
- D. CATALDO — SERVICE MANAGER

SPECIFIC INFORMATION — L2D3P/L3E2B (continued)

5. CURRENT STUDIES/TESTS

- TECHNETIUM SORPTION/DESORPTION
(TI 080186E6/L2D3P)

GEOMEDIA: RCE-4

TEMPERATURE: 85° C ± 5° C

GROUNDWATER: SYNTHETIC GR-4

- STRONTIUM SORPTION/DESORPTION
(TI 102486S3/L3E2B)

GEOMEDIA: RCFT AND COFT

TEMPERATURE: 50° C

GROUNDWATER: SYNTHETIC GR-4

- URANIUM SORPTION/DESORPTION
(TI 081886S3/L3E2B)

GEOMEDIA: RCFT AND COFT

TEMPERATURE: 50° C

GROUNDWATER: SYNTHETIC GR-4

ACTIVITY HISTORY

1. AUDITS

- PNL A-86-09-33-60
DATE: SEPTEMBER 25, 1986
FINDINGS: NONE
OBSERVATIONS: NONE
- DOE-SRPO PNL-86-14-E
DATE: SEPTEMBER 25, 1986
FINDINGS: 1) TRAINING
2) PROCEDURES
3) CORRECTIVE ACTION
4) AUDITS
OBSERVATIONS: 5

ACTIVITY HISTORY (continued)

2. SURVEILLANCES

- PNL
- 30 SURVEILLANCES (1/27/86 – 10/27/86)
 - 26 SATISFACTORY
 - 4 UNSATISFACTORY
(ALL RESOLVED AND CLOSED)

- DOE
- QSB-041 (8/26/86)
 - SATISFACTORY

3. PNL DEFICIENCY REPORTS

- 22 DRs ISSUED (7/9/86 – 12/9/86)
- ALL DRs RESOLVED AND CLOSED

4. NCRs/CARs

- NONE ISSUED

DOCUMENTS TO BE EXAMINED

1. SOWs - L2D3P, L3E2B
2. QA PLAN - ENV-21
3. LABORATORY RECORD BOOKS
4. AUDIT, SURVEILLANCE, AND DEFICIENCY REPORTS
5. M&TE RECORDS
6. TEST MATRIX
7. TEST INSTRUCTIONS

DOCUMENTS TO BE EXAMINED (continued)

8. PURCHASED MATERIALS ANALYSIS
9. TEST MATERIALS IN STORAGE RECORDS
10. USED TEST MATERIAL ARCHIVED RECORDS
11. INDEPENDENT TECHNICAL REVIEW DOCUMENTATION
12. PROJECT RECORDS LIST
13. MONTHLY REPORTS
14. CORRESPONDENCE

LOCATION OF AUDIT

PNL LIFE SCIENCE LABORATORY, LSL-1 AND
LSL-2, 300 AREA OF THE HANFORD RESERVATION

ESCORT WITH "3" BADGE REQUIRED

TEAM "D" PRE-AUDIT BRIEFING

INTRODUCTION

- SUBTEAM "D" MEMBERS:

- | | | | |
|----|---------------|---|-------------------|
| 1. | R. P. O'BRIEN | — | LEAD AUDITOR |
| 2. | K. R. WELSCH | — | AUDITOR |
| 3. | M. J. FURMAN | — | TECHNICAL ADVISOR |

INTRODUCTION (continued)

- ACTIVITIES:

L3E2A — ORGANIC ANALYSES OF GROUNDWATER
AND DRILLING MUD LEACHATE

L2D3R — ORGANIC ANALYSES OF SODIUM BENTONITE
PACKING MATERIALS

L3E2C — URANIUM/THORIUM DISEQUILIBRIUM IN
BASALT GROUNDWATER:
IN-SITU RETARDATION COEFFICIENTS

SCHEDULE

| <u>DAY</u> | <u>DATE</u> | <u>TIME</u> | <u>ACTIVITY</u> |
|------------|-------------|--|---|
| MONDAY | 1/5/87 | 3:00 | ENTRANCE MTG |
| TUESDAY | 1/6/87 | 8:30-12:00 1:00- 3:30 3:30- 4:30 | L3E2A/L2D3R TEAM CAUCUS |
| WEDNESDAY | 1/7/87 | 8:30-12:00 1:00- 3:30 3:30- 4:30 | L3E2C TEAM CAUCUS |
| THURSDAY | 1/8/87 | 8:00-12:00 1:00- 3:00 3:00 | AUDIT WRAPUP TEAM CAUCUS EXIT MEETING |

QAAUD-3D

SPECIFIC INFORMATION — L3E2C

1. OBJECTIVE OF STUDIES

- DEVELOPMENT AND APPLICATION OF APPROVED ANALYTICAL AND SAMPLING METHODS TO DETERMINE IN-SITU RADIONUCLIDE CONCENTRATIONS, RETARDATION PARAMETERS, REDOX CONDITIONS AND COLLOID EFFECTS IN THE MAJOR BWIP BASALT AQUIFER SYSTEMS

SPECIFIC INFORMATION — L3E2C (continued)

2. RESULTS OF STUDIES

- ESTABLISH U AND TH CONCENTRATIONS AND THEIR DECAY CHAIN MEMBERS IN GROUND—WATERS AND SELECTED CORE SAMPLES
- ESTABLISH RETARDATION FACTORS RELATIVE TO SOLUABLE COMPONENTS
- DEFINE REDOX STATE OF ENVIRONMENT
- DETERMINE IN—SITU DISTRIBUTION COEFFICIENTS (K_d) — SORPTION AND DESORPTION IN OXIC AND ANOXIC ENVIRONMENT

SPECIFIC INFORMATION — L3E2C (continued)

2. RESULTS OF STUDIES (continued)

- OBSERVE KINETICS — RATE OF SORPTION AND DESORPTION
- ESTABLISH VALIDATION OF LAB VERSUS FIELD STUDY
- RADIONUCLIDE TRANSPORT BY SOLUTION OR COLLOIDS
- DETERMINE THE GEOCHEMICAL — GEOLOGICAL STABILITY OF THE SITE

SPECIFIC INFORMATION — L3E2C

(continued)

3. PNL PROJECT MANAGER

- J. C. LAUL

4. PRINCIPAL CONTRIBUTORS

- | | |
|--------------------|---------------------------|
| • J. C. LAUL | — PROJECT MANAGER |
| M. R. SMITH | — TASK LEADER (II, V, VI) |
| P. O. JACKSON | — TASK LEADER (III, VI) |
| S. L. ENGLISH | — QA ENGINEER |
| J. S. SCHMITT | — CHEMICAL TECHNICIAN |
| G. G. BRODACZYNSKI | — CHEMICAL TECHNICIAN |
| L. L. DAHLMAN | — CHEMICAL TECHNICIAN |

SPECIFIC INFORMATION — L3E2C (continued)

5. CURRENT STUDIES/TESTS

- 9 SEPARATE TASKS IN SOW
- DOING DATA EVALUATION AND REPORT WRITING ON PREVIOUS WORK
- RE-EVALUATING WORK SCOPE DUE TO BUDGET REDUCTIONS

ACTIVITY HISTORY

1. AUDITS

- PNL A-86-02-04-60
RESOLVED AND CLOSED
- DOE-SRPO PNL-86-14-E
RESOLVED AND CLOSED

2. SURVEILLANCES

- 11 SURVEILLANCES (CLOSED)

3. PNL DEFICIENCY REPORTS

- 2 DRs (86-32, 86-82)
- 86-32 REMAINS OPEN
- 86-82 CLOSED

DOCUMENTS TO BE EXAMINED

1. ANALYTICAL DATA SHEETS
2. AUDITS
3. COMPUTER CODES
4. CORRECTIVE ACTION
5. DOCUMENT CONTROL
6. INCIDENTS
7. LABORATORY RECORD BOOKS

DOCUMENTS TO BE EXAMINED (continued)

8. M&TE LIST AND CALIBRATION RECORDS
9. MASTER FILE INDEX
10. MATERIALS/STORAGE/HANDLING
11. MONTHLY PROGRESS REPORTS
12. NON CONFORMANCES
13. PERSONNEL QUALIFICATION
AND TRAINING
14. PROCEDURES

DOCUMENTS TO BE EXAMINED (continued)

- 15. PROCUREMENT
- 16. PROJECT RECORDS LIST
- 17. PURCHASE ORDERS
- 18. RADIATION WORK
- 19. RECORDS MANAGEMENT
- 20. QA SURVEILLANCE REPORTS
- 21. SAMPLE CONTROL

DOCUMENTS TO BE EXAMINED (continued)

22. TECHNICAL DOCUMENTATION

23. TECHNICAL REPORTS

24. TEST RECORDS

LOCATION OF AUDIT

L3E2C — TRAILER 6, 3708 BUILDING,
329 BUILDING/300 AREA OF THE
HANFORD RESERVATION

ESCORT WITH "3" BADGE REQUIRED

L3E2A/L2D3R — PNL LSL-2 BUILDING

ESCORT WITH MINIMUM
OF "W" BADGE

TEAM "E" PRE-AUDIT BRIEFING

INTRODUCTION

- SUBTEAM "E" MEMBERS:

1. T. K. SUBRAMANIAN — AUDITOR
2. S. C. WHITFIELD — TECHNICAL ADVISOR

- ACTIVITY

L3G/L3H — ENVIRONMENTAL LICENSING SUPPORT (ELS)

SPECIFIC INFORMATION

1. ENVIRONMENTAL AND SOCIOECONOMIC MONITORING

- PNL MANAGER — T. L. PAGE
- QE — R. CUELLO

2. REQUIREMENT

NWPA SECTION 113(a)

... TO THE EXTENT PRACTICABLE...
AND IN CONSULTATION WITH ... STATE
AND TRIBE CONDUCT... SITE...
ACTIVITIES IN A MANNER THAT
MINIMIZES ... SIGNIFICANT ADVERSE
ENVIRONMENTAL IMPACTS IDENTIFIED...
IN EAs SUBMITTED.

ELS: SCOPE OF WORK

1. DOCUMENT PREPARATION

- PROGRAM PLAN
- REGULATORY COMPLIANCE PLAN
- EMMP, SMMP AND PERIODIC REPORTS

2. SUPPORT INTERACTIONS WITH STATE AND INDIAN TRIBES

3. IMPLEMENTATION

- SURVEYS AND "AUDIT" OF ENGINEERING PRACTICES
- MONITORING

AUDIT FOCUS

1. PAST AUDIT FINDING AREAS

- CONTROLS FOR TECHNICAL REVIEWS OF REPORTS
- TRANSFER OF RECORDS TO PNL RECORDS CENTER
- DOCUMENTATION FOR PEER REVIEW

2. TECHNICAL

- SAMPLING DESIGN
- COLLECTION METHODOLOGIES
- EXPERTISE OF TECHNICAL STAFF

3. TRADITIONAL QA PROGRAM ELEMENTS

TEAM "F" PRE-AUDIT BRIEFING

INTRODUCTION

- SUBTEAM "F" MEMBERS:

1. W. B. WILLIAMS — LEAD AUDITOR
2. R. J. HOE — TECHNICAL ADVISOR
3. J. L. MADSEN — TECHNICAL ADVISOR

INTRODUCTION (continued)

- ACTIVITIES

L9A1 — MANAGEMENT AND INTEGRATION

L9C3 — PROJECT CONTROL

NOTE: THIS IS NOT A FORMAL
PORTION OF THE AUDIT.
THIS IS A MANAGEMENT
ASSESSMENT WHICH WILL
BE CONDUCTED IN PARALLEL
WITH THE AUDIT.

- RESULTS WILL BE REPORTED
SEPARATELY FROM THE EXIT
MEETING
- NO RESULTS WILL BE INCLUDED
IN THE AUDIT REPORT

SCHEDULE

| <u>DAY</u> | <u>DATE</u> | <u>TIME</u> | <u>ACTIVITY</u> |
|------------|-------------|-------------|-----------------|
| MONDAY | 1/5/87 | 3:00 | ENTRANCE MTG |
| TUESDAY | 1/6/87 | 8:30—12:00 | L9A1 |
| | | 1:00— 3:30 | L9A1 |
| WEDNESDAY | 1/7/87 | 8:30—12:00 | L9C3 |
| | | 1:00— 3:30 | L9C3 |
| THURSDAY | 1/8/87 | 8:30—12:00 | COMPL. INTVWS |
| | | 1:00— 3:00 | TEAM CAUCUS |
| | | 3:00 | EXIT MEETING |

PNL ORGANIZATION

PROGRAMMATIC

- W. D. RICHMOND
W. W. BALLARD
D. J. BRADLEY

RESEARCH

- J. T. A. ROBERTS
J. L. STRAALSUND
R. S. KEMPER
D. G. COLES
J. R. BURNELL

PROJECT SUPPORT

- R. J. HALL
R. M. MADISON
C. FRANKS
B. A. GRASHER

ACTIVITY HISTORY

- ROCKWELL COMPLETED A MANAGEMENT APPRAISAL NOVEMBER 1986. NO DEFICIENCIES. BUT.....
MEASURED ONLY MANAGEMENT CAPABILITY OF PNL TO DO THE JOB — NOT THE MANAGEMENT COMPLIANCE TO REQUIREMENTS

DOCUMENTS TO BE EXAMINED

1. CONTRACT DE-AC06-76RL01830
2. OPERATIONS DIRECTIVE — FY 1987 INTERIM
3. MANAGEMENT GUIDELINES
4. RESEARCH PROJECT MANAGEMENT MANUAL
(MA-95)
5. QUALITY ASSURANCE MANUAL (MA-60)

DOCUMENTS TO BE EXAMINED (continued)

6. PROJECT PROCEDURES
7. STATEMENTS OF WORK FOR L9A1, L9C3
AND TECHNICAL PROGRAM PLAN
8. WORK ORDERS

LOCATION OF AUDIT

PSL BUILDING, RO BUILDING AND SIGMA 1
BUILDING, 300 AREA OF THE HANFORD
RESERVATION

MINIMUM OF "W" BADGE AT THE PSL AND RO
BUILDINGS — ESCORT REQUIRED IN THE
300 AREA

TEAM "G" PRE-AUDIT BRIEFING

INTRODUCTION

- SUBTEAM "G" MEMBERS:

- | | | | |
|----|-----------------|---|--------------|
| 1. | B. K. SANDALL | — | LEAD AUDITOR |
| 2. | B. D. SLONECKER | — | AUDITOR |
| 3. | O. O. THOMPSON | — | AUDITOR |
| 4. | C. K. KASCH | — | AUDITOR |

INTRODUCTION (continued)

- ACTIVITY:

L9D — QUALITY ASSURANCE DEPARTMENT
(L9D IS ONLY AN ADMINISTRATIVE
ACCOUNT FOR CHARGING ALL QA
ORGANIZATION ACTIVITIES FOR
BWIP.)

SCHEDULE

| <u>DAY</u> | <u>DATE</u> | <u>TIME</u> | <u>ACTIVITY</u> |
|------------|-------------|----------------------------------|---|
| MONDAY | 1/5/87 | 3:00 | ENTRANCE MTG |
| TUESDAY | 1/6/87 | 8:30—12:00 1:00— 3:30 | QA DEPT. |
| WEDNESDAY | 1/7/87 | 8:30—12:00 1:00— 3:30 | QA DEPT. |
| THURSDAY | 1/8/87 | 8:30—12:00 1:00— 3:00 3:00 | FINISH INTRV TEAM CAUCUS EXIT MTG |

AREAS TO BE AUDITED

1. QA DEPARTMENT

- QUALITY ENGINEERING
- QUALITY CONTROL
- QA AUDITS

2. TRAINING AND CERTIFICATION

- QA PERSONNEL
- PNL TRAINING DEPARTMENT
(AS APPLICABLE)

AREAS TO BE AUDITED (continued)

3. DOCUMENTATION

- AUDIT/INSPECTION
- DEFICIENCY AND CLOSE-OUT RECORDS
- QA PLANS
- QA DOCUMENT REVIEWS
- CORRECTIVE ACTION
- QA PROCUREMENT ACTIVITY

SPECIFIC INFORMATION

1. PNL QA DEPARTMENT MANAGER

- C. E. HUGHEY

2. QA PRINCIPAL CONTRIBUTORS

- L. M. WORDEN — MANAGER QUALITY
ENGINEERING SECTION
- D. E. RYDER — MANAGER QUALITY CONTROL
SECTION
- N. C. FRANK — MANAGER QA AUDITS SECTION

ACTIVITY HISTORY

1. AUDITS

- PNL INTERNAL

20 BWIP AUDITS

DATE: OCTOBER 1986 — DECEMBER 1986

- SRPO/DOE — JOINT AUDIT

DATE: SEPTEMBER 25, 1986

FINDINGS: 4

OBSERVATIONS: 5

- ROCKWELL

NONE — STOP WORK ORDER CURTAILED SCHEDULE

ACTIVITY HISTORY (continued)

2. SURVEILLANCES

PNL

- 180 SURVEILLANCES
(JANUARY 1986 — NOVEMBER 1986)

DOE

- 1 SURVEILLANCE (AUGUST 26, 1986)
- SATISFACTORY (NO CORRECTIVE ACTION REQUIRED)

ROCKWELL

- 10 SURVEILLANCES
- 2 UNSATISFACTORY
(RESOLVED AND CLOSED)

ACTIVITY HISTORY (continued)

3. DEFICIENCY REPORTS

PNL

- 22 DEFICIENCY REPORTS
(JULY 9, 1986 — DECEMBER 9, 1986)
- ALL RESOLVED AND CLOSED

DOCUMENTS TO BE EXAMINED

1. PNL ADMINISTRATIVE PROCEDURES (PAP)
2. QUALITY ASSURANCE PROCEDURES (QAP)
3. QUALITY ASSURANCE MANUAL (PNL-MA-60)

LOCATION OF AUDIT

SIGMA 1 BUILDING — 3000 AREA

ESCORT AND VISITOR BADGE FOR C. K. KASCH,
O. O. THOMPSON

B. K. SANDALL WILL FUNCTION AS ESCORT
B. D. SLONECKER HAS CLEARANCE

AUDIT PLAN 8701

APPENDIX B

AUDIT CHECKLIST

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
|---------|---------|---------|-----------------------|
| _____ | _____ | _____ | Sheet _____ of _____ |
| _____ | _____ | _____ | |
| _____ | _____ | _____ | |

PROGRAM ELEMENT: 1.6 ORGANIZATIONAL INTERFACE CONTROL

PURPOSE:

- a) To prevent failure to make important decisions because of uncertainty concerning allocation of authority and/or responsibility.
- b) To prevent unauthorized exercise of authority.
- c) To ensure appropriate response to direction from authorized authority.

IMPLEMENTATION CRITERIA:

Procedural definition of interfaces and interface protocols in place and implemented.

REQUIREMENT # 2 **PROCEDURE NO.** PAP-101 **REV** 0 **PARA** 4.1, 4.5

4.1 PROGRAM MANAGER

- o Approve correspondence pertaining to scope, budget, commitments, schedule or changes to each that is submitted to the sponsor.

4.2 PROJECT MANAGER

- o Serve as the research project's technical contact with the sponsor and all research project participants.

4.4 QAO MANAGER

- o Serve as the QAO contact with the sponsor

4.5 QAO REPRESENTATIVE

- o Review for concurrence, correspondence that contains QA requirements/commitments or QA submittals.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 1.6 ORGANIZATIONAL INTERFACE CONTROL

AUDIT NO. 8701

Sheet **of**

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
|---------|---------|---------|-----------------------|
| _____ | _____ | _____ | Sheet _____ of _____ |
| _____ | _____ | _____ | |
| _____ | _____ | _____ | |

PROGRAM ELEMENT: 2.1 PROGRAM DESCRIPTION

PURPOSE:

To ensure integrity of the QA program throughout the project/operation.

IMPLEMENTATION CRITERIA:

Responsibility and authority assignments readily identified in program documentation.

REQUIREMENT # 1 PROCEDURE NO. PAP 205 REV 0 PARA 5.1.1

DETERMINATION OF QA PLAN NEED AND SCOPE

5.1.1 Quality Assurance (QA) plans are required for all projects that are to be performed in accordance with PNL-MA-60, Quality Assurance Manual for License-Related Programs, except when the nature of the work to be performed is such that, at most, the only QA program controls that could be applied to the project are those of records management (Section 17). Examples of such work are literature searches, or similar paper studies, and consulting services.

The project manager who determines that a QA plan is not required shall document this decision in a memorandum to his or her line manager. Justification for the decision, based on the criteria of the preceding paragraph, shall be included. If records management procedures are applicable, this shall be stated. The memorandum shall also contain a commitment to the effect that if the scope of the project should change to include activities that might be subject to QA programmatic controls, the project manager will reconsider the need for a QA plan with Quality Assurance, and provide one if necessary. The memorandum shall be concurred in by the Quality Engineering Manager.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.1 PROGRAM DESCRIPTION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
|---------|---------|---------|-----------------------|
| _____ | _____ | _____ | Sheet _____ of _____ |
| _____ | _____ | _____ | |
| _____ | _____ | _____ | |

PROGRAM ELEMENT: 2.1 PROGRAM DESCRIPTION

PURPOSE:

To ensure integrity of the QA program throughout the project/operation.

IMPLEMENTATION CRITERIA:

Responsibility and authority assignments readily identified in program documentation.

REQUIREMENT # 2 PROCEDURE NO. PAP 205 REV 0 PARA 5.3.2

5.3.2 The cognizant manager and the quality engineer shall conduct a readiness review after preparatory activities have been completed and any required approval of the plan by the sponsor has been received. The review shall address the completeness of preparations for the initial phases of activity, but need not consider later phases. Examples of preparation to be reviewed, as appropriate, include:

- a) Issuance of required procedures
- b) Completion of necessary training
- c) Project records list established
- d) Laboratory record books (LRBs) issued, when required
- e) Approval of any referenced QA plans or work order statements of work.

As appropriate, the review may also include the physical readiness of facilities and equipment, and the provision of file indexes.

When both parties are satisfied with the outcome of the review, the quality engineer shall transmit a formal memo to the program manager stating that the preparations have been satisfactorily completed. The program manager may then release funding for implementation of the project or program.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.1 PROGRAM DESCRIPTION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
|---------|---------|---------|-----------------------|
| _____ | _____ | _____ | Sheet _____ of _____ |
| _____ | _____ | _____ | |
| _____ | _____ | _____ | |

PROGRAM ELEMENT: 2.1 PROGRAM DESCRIPTION

PURPOSE:

To ensure integrity of the QA program throughout the project/operation.

IMPLEMENTATION CRITERIA:

Responsibility and authority assignments readily identified in program documentation.

REQUIREMENT # 3 PROCEDURE NO. PAP 205 REV 0 PARA 5.5.2

5.5.2 The cognizant manager shall provide the required amendments or revisions or interim changes either on his or her own initiative or at the request of the quality engineer. Interim changes shall be made using the ICN form. Revisions shall be made by rewriting the plan. Both revisions and major interim changes shall be prepared, reviewed, approved, and issued in accordance with Sections 5.2 and 5.2. Minor interim changes require the approval of the line manager and the concurrence of the Quality Engineering Manager.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.1 PROGRAM DESCRIPTION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
|---------|---------|---------|-----------------------|
| _____ | _____ | _____ | Sheet _____ of _____ |
| _____ | _____ | _____ | |
| _____ | _____ | _____ | |

PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

PURPOSE:

- a) To ensure that suitable proficiency of personnel performing activities important to safety is achieved and maintained.
- b) To ensure that activities important to safety are performed the way management believes they are being performed (pertains to both assurance oriented and technical procedures and instructions).

IMPLEMENTATION CRITERIA:

- a) Training records complete and accurate.
- b) Affected personnel are knowledgeable about procedures that affect them and are in compliance.

REQUIREMENT # 1 PROCEDURE NO. PAP 201 REV 2 PARA 4.3.1

4.3 ESTABLISHMENT OF COMPETENCY

4.3.1 The COGNIZANT MANAGER shall assign personnel who have the appropriate education and experience and shall have such personnel, who perform activities affecting quality, prepare written summaries of their education and experience. This documentation may be a recent resume or any other form of documentation as long as the following information is included and is sufficiently recent to substantiate the current assignments:

- o applicable dates
- o education completed (e.g., degree and major)
- o work experience (employer and major responsibilities)
- o licenses and certifications
- o related training and qualifications

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
|---------|---------|---------|-----------------------|
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PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

PURPOSE:

- a) To ensure that suitable proficiency of personnel performing activities important to safety is achieved and maintained.
- b) To ensure that activities important to safety are performed the way management believes they are being performed (pertains to both assurance oriented and technical procedures and instructions).

IMPLEMENTATION CRITERIA:

- a) Training records complete and accurate.
- b) Affected personnel are knowledgeable about procedures that affect them and are in compliance.

REQUIREMENT # 2 PROCEDURE NO. PAP 201 REV 0 PARA 4.3.3

4.3.3, first paragraph should read:

The COGNIZANT MANAGER shall assure that personnel operating equipment and systems while performing tests to gather data, have demonstrated their capability to correctly and safely operate the equipment and systems.

- a) The COGNIZANT MANAGER shall document an individual's competency by signing and dating a document (e.g., a memo) that states that the individual has demonstrated to the manager's satisfaction, the capability to correctly and safely operate the equipment and systems, and shall forward such documentation to Laboratory Training Coordination, with copies to applicable managers.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

PURPOSE:

- a) To ensure that suitable proficiency of personnel performing activities important to safety is achieved and maintained.
- b) To ensure that activities important to safety are performed the way management believes they are being performed (pertains to both assurance oriented and technical procedures and instructions).

IMPLEMENTATION CRITERIA:

- a) Training records complete and accurate.
- b) Affected personnel are knowledgeable about procedures that affect them and are in compliance.

REQUIREMENT # 3 PROCEDURE NO. PAP 201 REV 0 PARA 4.3.4

4.3.4 The COGNIZANT MANAGER shall review assigned staff's education, experience and competency documentation and shall periodically determine the indoctrination and training needed for the assigned staff. This evaluation shall be documented as applicable and shall occur:

- o At the start of a new research project or activity (i.e., after each research project's scope of work has been approved by PNL and the sponsor) and annually thereafter
- o After a significant change in a research project or activity organizational structure, scope of work, QA Plan, or procedures
- o Upon assignment of new personnel to a research project or activity.

NOTE: LINE MANAGERS of PNL staff not assigned to a project or activity but who perform activities affecting quality shall perform a comparable function to that described above for their staff.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

PURPOSE:

- a) To ensure that suitable proficiency of personnel performing activities important to safety is achieved and maintained.
- b) To ensure that activities important to safety are performed the way management believes they are being performed (pertains to both assurance oriented and technical procedures and instructions).

IMPLEMENTATION CRITERIA:

- a) Training records complete and accurate.
- b) Affected personnel are knowledgeable about procedures that affect them and are in compliance.

REQUIREMENT # 4 PROCEDURE NO. PAP 201 REV 2 PARA 4.4.1

4.4.1 The COGNIZANT MANAGER shall prepare Training Assignment forms for the individual staff and indicate completion of training as either prior to job performance or during job performance. The Laboratory Training Coordinator is available to assist in developing and determining training requirements and to provide information on past training history for staff members.

- a) The Training Assignment shall include training on the research or activity project's scope of work (including technical objectives), organization and QA Plan.
- b) The Training Assignment shall include required reading/study of the applicable codes and standards and the applicable Administrative and Technical Procedures and subsequent changes or revisions.
- c) On-the-job training (OJT) shall be used whenever the trainee is required to demonstrate proficiency in a process or skill or where supervised experience in the process is determined to be necessary prior to allowing the individual to work independently. OJT shall be prepared, approved and administered using the Training Plan. Assignment and completion of OJT shall also be documented on the Training Assignment form.

NOTE: LINE MANAGERS of PNL staff not assigned to a project but who perform activities affecting quality shall perform a comparable function to that described above for their staff.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

PURPOSE:

- a) To ensure that suitable proficiency of personnel performing activities important to safety is achieved and maintained.
- b) To ensure that activities important to safety are performed the way management believes they are being performed (pertains to both assurance oriented and technical procedures and instructions).

IMPLEMENTATION CRITERIA:

- a) Training records complete and accurate.
- b) Affected personnel are knowledgeable about procedures that affect them and are in compliance.

REQUIREMENT # 5 **PROCEDURE NO.** PAP 201 **REV** 2 **PARA** 4.4.2, 4.4.3, 4.5.2

- 4.4.2 A copy of each staff member's Training Assignment form (without completion of sign-offs) shall be forwarded to Laboratory Training Coordination. The original Training Assignment form shall be given to the trainee to record completed training. Completion of individual training requirements shall be documented by the COGNIZANT STAFF by signing and dating the applicable blank on the individual's Training assignment form.
- 4.4.3 The COGNIZANT MANAGER shall review the Training Assignment form with each staff member and signify completion by signing and dating the applicable blank. The original/copy of the form shall be forwarded to Laboratory Training Coordination.
- 4.5.2 Training Waivers (Exhibit 4) shall be initiated by the COGNIZANT MANAGER and submitted with supporting documents. Approvals shall be obtained as indicated on the Training Waiver form.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

PURPOSE:

- a) To ensure that suitable proficiency of personnel performing activities important to safety is achieved and maintained.
- b) To ensure that activities important to safety are performed the way management believes they are being performed (pertains to both assurance oriented and technical procedures and instructions).

IMPLEMENTATION CRITERIA:

- a) Training records complete and accurate.
- b) Affected personnel are knowledgeable about procedures that affect them and are in compliance.

REQUIREMENT # 6 **PROCEDURE NO.** PAP 201 **REV** 0 **PARA** 4.6.2, 4.6.3, 4.8.3

- 4.6.2 COGNIZANT MANAGERS shall assure that assigned trainers, for trainer qualification, perform and complete at least one of the following requirements.
 - a) Attend LTC-002 "Trainers' Training" course offered by Laboratory Training Coordination.
 - b) Attend LTC-003 "Lesson Plan Preparation" course offered by Laboratory Training Coordination.
- 4.6.3 Satisfactory completion of the Trainers' Training Course shall be documented by LABORATORY TRAINING COORDINATION in the individual training records.
- 4.8.2 QAD REPRESENTATIVE (usually a QE) shall participate in the planning of the QAD Program requirements to be included. Lesson plans shall be prepared in accordance with Lesson Plan Preparation Guide and forms. Lesson Plan forms are available in the Laboratory Training Coordination Office.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

PURPOSE:

- a) To ensure that suitable proficiency of personnel performing activities important to safety is achieved and maintained.
- b) To ensure that activities important to safety are performed the way management believes they are being performed (pertains to both assurance oriented and technical procedures and instructions).

IMPLEMENTATION CRITERIA:

- a) Training records complete and accurate.
- b) Affected personnel are knowledgeable about procedures that affect them and are in compliance.

REQUIREMENT # 7 PROCEDURE NO. PAP 201 REV 2 PARA 4.12.1

4.12 RETRAINING

- 4.12.1 An assessment of the need for retraining shall be made by the LABORATORY TRAINING COORDINATOR in consultation with the cognizant manager, author or assigned trainer on all changes (deletions, additions, revisions) to procedures, manuals, standards and codes which have a significant impact on lesson plan objectives.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

AUDIT NO. 8701

Sheet **of**

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

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OA PLAN

AUDIT NO. 8701

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PROGRAM ELEMENT:

2.5 INDOCTRINATION AND TRAINING

PURPOSE:

- a) To ensure that suitable proficiency of personnel performing activities important to safety is achieved and maintained.
- b) To ensure that activities important to safety are performed the way management believes they are being performed (pertains to both assurance oriented and technical procedures and instructions).

IMPLEMENTATION CRITERIA:

- a) Training records complete and accurate.
- b) Affected personnel are knowledgeable about procedures that affect them and are in compliance.

REQUIREMENT # 8 PROCEDURE NO. PAP 201 REV 2 PARA 4.7

4.7 SCHEDULING OF TRAINING

The LABORATORY TRAINING COORDINATOR shall periodically issue a schedule of training courses which comprises the various courses offered at PNL. Schedules of existing training courses, as well as new courses required, will be developed through the joint efforts of cognizant managers and the Laboratory Training Coordinator.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

PURPOSE:

- a) To ensure that suitable proficiency of personnel performing activities important to safety is achieved and maintained.
- b) To ensure that activities important to safety are performed the way management believes they are being performed (pertains to both assurance oriented and technical procedures and instructions).

IMPLEMENTATION CRITERIA:

- a) Training records complete and accurate.
- b) Affected personnel are knowledgeable about procedures that affect them and are in compliance.

REQUIREMENT # 9 PROCEDURE NO. TCP 202 REV 0 PARA 4.2.4

4.2.4 Master (original) copies of superseded or cancelled Lesson Plans shall be clearly marked or stamped "superseded" or "cancelled," marked for retention and forwarded to the PNL Records Center for the inactive file.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

AUDIT NO. 8701

Sheet **of**

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

PURPOSE:

- a) To ensure that suitable proficiency of personnel performing activities important to safety is achieved and maintained.
- b) To ensure that activities important to safety are performed the way management believes they are being performed (pertains to both assurance oriented and technical procedures and instructions).

IMPLEMENTATION CRITERIA:

- a) Training records complete and accurate.
- b) Affected personnel are knowledgeable about procedures that affect them and are in compliance.

REQUIREMENT # 10 PROCEDURE NO. TCP 202 REV 0 PARA 4.5

4.5 RECORDS TRANSMITTAL

Training records, collected by LABORATORY TRAINING COORDINATION shall be duplicated and transmitted to the PNL Records Center.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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| _____ | _____ | _____ | |

PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

PURPOSE:

- a) To ensure that suitable proficiency of personnel performing activities important to safety is achieved and maintained.
- b) To ensure that activities important to safety are performed the way management believes they are being performed (pertains to both assurance oriented and technical procedures and instructions).

IMPLEMENTATION CRITERIA:

- a) Training records complete and accurate.
- b) Affected personnel are knowledgeable about procedures that affect them and are in compliance.

REQUIREMENT # 11 **PROCEDURE NO.** PAP 201 **REV** 2 **PARA** 4.12.2

4.12.2 The LABORATORY TRAINING COORDINATOR shall prepare a report from the training file identifying individual staff members requiring retraining. The report shall be forwarded to cognizant managers for scheduling attendance at the next available course.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

PURPOSE:

- a) To ensure that suitable proficiency of personnel performing activities important to safety is achieved and maintained.
- b) To ensure that activities important to safety are performed the way management believes they are being performed (pertains to both assurance oriented and technical procedures and instructions).

IMPLEMENTATION CRITERIA:

- a) Training records complete and accurate.
- b) Affected personnel are knowledgeable about procedures that affect them and are in compliance.

REQUIREMENT # 12 PROCEDURE NO. PAP 201 REV 2 PARA 4.4.3

4.4.3 The COGNIZANT MANAGER shall review the Training Assignment form with each staff member and signify completion by signing and dating the applicable blank. The original/copy of the form shall be forwarded to Laboratory Training Coordination.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.5 INDOCTRINATION AND TRAINING

AUDIT NO. 8701

Sheet **of**

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

PURPOSE:

- a) To ensure that work whose quality depends on qualification of personnel performing the work meets quality objectives.

IMPLEMENTATION CRITERIA:

Procedures defining the system(s) for required personnel qualification are in place and being implemented.

REQUIREMENT # 1 PROCEDURE NO. PAP 201 REV 2 PARA 4.3.1

4.3.1 The COGNIZANT MANAGER shall assign personnel who have the appropriate education and experience and shall have such personnel, who perform activities affecting quality, prepare written summaries of their education and experience. This documentation may be a recent resume or any other form of documentation as long as the following information is included and is sufficiently recent to substantiate the current assignments:

- o Applicable dates
- o Education completed (e.g., degree and major)
- o Work experience (employer and major responsibilities)
- o Licenses and certification
- o Related training and qualifications.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

PURPOSE:

- a) To ensure that work whose quality depends on qualification of personnel performing the work meets quality objectives.

IMPLEMENTATION CRITERIA:

Procedures defining the system(s) for required personnel qualification are in place and being implemented.

REQUIREMENT # 2 PROCEDURE NO. PAP 201 REV 2 PARA 4.3.3(a)

- 4.3.3(a) The COGNIZANT MANAGER shall document an individual's competency by signing and dating a document (e.g., a memo) that states that the individual has demonstrated to the manager's satisfaction, the capability to correctly and safely operate the equipment and systems, and shall forward such documentation to Laboratory Training Coordination, with copies to applicable managers.

AUDIT CHECKLIST PART C-1 0A PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

PURPOSE:

- a) To ensure that work whose quality depends on qualification of personnel performing the work meets quality objectives.

IMPLEMENTATION CRITERIA:

Procedures defining the system(s) for required personnel qualification are in place and being implemented.

REQUIREMENT # 3 PROCEDURE NO. PAP 201 REV 0 PARA 4.6.2

4.6.2 COGNIZANT MANAGERS shall assure that assigned trainers, for trainer qualification, perform and complete at least one of the following requirements.

- a) Attend LTC-002 "Trainers' Training" course offered by Laboratory Training Coordination.
- b) Attend LTC-003 "Lesson Plan Preparation" course offered by Laboratory Training Coordination.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

PURPOSE:

- a) To ensure that work whose quality depends on qualification of personnel performing the work meets quality objectives.

IMPLEMENTATION CRITERIA:

Procedures defining the system(s) for required personnel qualification are in place and being implemented.

REQUIREMENT # 4 PROCEDURE NO. PAP 203 REV 0 PARA 5.1.1

5.1 DETERMINATION TO USE INSPECTION AND TEST PERSONNEL

- 5.1.1 The Project Manager in conjunction with the cognizant Quality Engineer shall designate during the preparation and review of the QA Plan those activities that will require the use of qualified/certified inspection/test personnel. Examples include PNL procured or produced items that require:
- o Receiving inspection/testing that involves use of precision measuring and test equipment
 - o Weld inspection
 - o Source inspection or surveillance
 - o In-process inspection or witness of a hydro test, load test, etc.
 - o Final inspection or witness of an acceptance test.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

PURPOSE:

- a) To ensure that work whose quality depends on qualification of personnel performing the work meets quality objectives.

IMPLEMENTATION CRITERIA:

Procedures defining the system(s) for required personnel qualification are in place and being implemented.

REQUIREMENT # 6 PROCEDURE NO. PAP 203 REV 0 PARA 5.7.1

5.7 PHYSICAL

- 5.7.1 The Quality Control Manager is responsible to subject all personnel who are being qualified/certified in accordance with this procedure to an annual eye examination. Personnel shall be capable of reading Jaeger Chart J-2 letters at 15" distance, in at least one eye, either uncorrected or with corrective lenses. Color vision shall also be verified on personnel who must be able to distinguish colors as part of the inspection/test to be performed. Exhibit 2 provides the means to document the required eye examination. When practicable, the eye examination shall be accomplished by Hanford Environmental Health Foundation (HEHF).

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

PURPOSE:

- a) To ensure that work whose quality depends on qualification of personnel performing the work meets quality objectives.

IMPLEMENTATION CRITERIA:

Procedures defining the system(s) for required personnel qualification are in place and being implemented.

REQUIREMENT # 7 PROCEDURE NO. PAP 203 REV 0 PARA 5.10.1

5.10 CERTIFICATION OF QUALIFICATION

- 5.10.1 The Quality Control Manager shall sign the Certification Record after initial evaluation and tri-annual reevaluation.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

PURPOSE:

- a) To ensure that work whose quality depends on qualification of personnel performing the work meets quality objectives.

IMPLEMENTATION CRITERIA:

Procedures defining the system(s) for required personnel qualification are in place and being implemented.

REQUIREMENT # 8 PROCEDURE NO. OAP 204 REV 1 PARA 4.2.3

- 4.2.3 The LEAD AUDITOR shall include a signed statement in the records for each audit stating that the auditors were competent, received project specific orientation and were independent of the activities they audited. As appropriate, the record shall identify auditors that received a review of ANSI/ASME NQA-1 and PNL's procedures related to auditing and auditing techniques.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

AUDIT NO. 8701

Sheet **of**

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

PURPOSE:

- a) To ensure that work whose quality depends on qualification of personnel performing the work meets quality objectives.

IMPLEMENTATION CRITERIA:

Procedures defining the system(s) for required personnel qualification are in place and being implemented.

REQUIREMENT # 9 PROCEDURE NO. OAP 204 REV 1 PARA 4.3.1

4.3 QUALIFICATION OF LEAD AUDITORS

- 4.3.1 The prospective LEAD AUDITOR shall have verifiable evidence that a minimum of ten (10) credits have been accumulated when credits are awarded per 4.3.1.1 through 4.3.1.4.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

PURPOSE:

- a) To ensure that work whose quality depends on qualification of personnel performing the work meets quality objectives.

IMPLEMENTATION CRITERIA:

Procedures defining the system(s) for required personnel qualification are in place and being implemented.

REQUIREMENT # 10 PROCEDURE NO. OAP 204 REV 1 PARA 4.5.3

- 4.5.3 The cognizant QAD SECTION MANAGER shall sign and date the "Record of Lead Auditor Qualification Maintenance" form, as evidence of having reviewed the record of qualification maintenance and supporting documents. This shall be done annually in order to maintain qualification.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

AUDIT NO. 8701

Sheet **of**

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

PURPOSE:

- a) To ensure that work whose quality depends on qualification of personnel performing the work meets quality objectives.

IMPLEMENTATION CRITERIA:

Procedures defining the system(s) for required personnel qualification are in place and being implemented.

REQUIREMENT # 11 PROCEDURE NO. OAP 204 REV 1 PARA 4.5.4

4.5.4 The QA SYSTEMS AND AUDITS MANAGER shall monitor the performance of Lead Auditors and annually review each Lead Auditor's qualifications and may:

- o Extend the qualification
- o Require retraining, or
- o Require requalification.

These evaluations shall be documented on the "Record of Lead Auditor Qualification" form.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

PURPOSE:

- a) To ensure that work whose quality depends on qualification of personnel performing the work meets quality objectives.

IMPLEMENTATION CRITERIA:

Procedures defining the system(s) for required personnel qualification are in place and being implemented.

REQUIREMENT # 12 PROCEDURE NO. OAP 204 REV 1 PARA 4.5.5

4.5.5 The QA SYSTEMS AND AUDITS MANAGER shall also maintain a list of personnel qualified to act as Lead Auditors.

4.5.5.1 This list will be kept in the QAD training files and shall be updated/reviewed annually.

4.5.5.2 The QA SYSTEMS AND AUDITS MANAGER shall also maintain a file on each lead auditor which contains copies of all documentation supporting qualification, certification and maintenance (e.g., certification, reviews, examinations).

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

PURPOSE:

- a) To ensure that work whose quality depends on qualification of personnel performing the work meets quality objectives.

IMPLEMENTATION CRITERIA:

Procedures defining the system(s) for required personnel qualification are in place and being implemented.

REQUIREMENT # 13 PROCEDURE NO. PAP 203 REV 0 PARA 5.5.1

- 5.5.1 The Quality Control Manager shall initially determine the capabilities of a candidate for certification by a suitable evaluation of the candidate's education, experience, training, and by one or more of the following methods:
- o A comprehensive test (e.g., visual, basic, method and specific)
 - o A capability demonstration of the intended area of qualification (e.g., visual weld inspection, receiving dimensional inspection, etc.).

NOTE: The capability demonstrated shall be documented in Block 5 of Exhibit 1.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

PURPOSE:

- a) To ensure that work whose quality depends on qualification of personnel performing the work meets quality objectives.

IMPLEMENTATION CRITERIA:

Procedures defining the system(s) for required personnel qualification are in place and being implemented.

REQUIREMENT # 14 PROCEDURE NO. PAP 203 REV 0 PARA 5.6.4

- 5.6.4 The QC Manager, cognizant Quality Engineers, and Project Managers shall assure that only personnel currently listed on the Maintenance Log are used for inspection/testing.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

PURPOSE:

- a) To ensure that work whose quality depends on qualification of personnel performing the work meets quality objectives.

IMPLEMENTATION CRITERIA:

Procedures defining the system(s) for required personnel qualification are in place and being implemented.

REQUIREMENT # 15 PROCEDURE NO. PAP 203 REV 0 PARA 5.6.2

- 5.6.2 The Quality Control Manager shall initiate the Maintenance Log for inspection/test personnel to be distributed on a quarterly basis to the other Section and Project Managers. This Maintenance Log will be used to prevent expirations from occurring and to help avoid use of unqualified personnel. The Quality Control Manager shall maintain the Master Copy.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 2.6 PERSONNEL QUALIFICATION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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|---------|---------|---------|-----------------------|
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PROGRAM ELEMENT: 3.2B CONTROL OF DATA ACQUISITION PLANNING PROCESS

PURPOSE:

- a) To ensure that approved data needs are accurately reflected in data used for site characterization.
- b) To ensure that data used for site characterization has experimental error minimized to greatest degree feasible.
- c) To permit data acquisition test planning verification.
- d) To make it possible to reconstruct the test planning process and rationale.

CRITICAL FEATURES:

System specifying the data acquisition planning and documentation process.

REQUIREMENT # 1 PROCEDURE NO. PAP 1101 REV 1 PARA 4.1.1., 4.1.2., 4.1.3

The PROJECT MANAGER or designated alternate shall prepare a description of work which defines and documents the planned testing efforts in a research project planning document (PMP, TPP, SOW, etc.). Tests that are planned to be conducted in support of such activities as data acquisition, evaluation of analytical processes, generation of test data or items and Special Post-Receiving Inspections or testing of items performed in house shall be summarized in the research project planning document.

The QA REPRESENTATIVE shall review, prior to issue, all research project planning documents to assure that the appropriate QA system requirements have been included.

The PROGRAM MANAGER shall obtain sponsor approval of the research project planning documents (TPPs, FTPAs and SOW).

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 3.2B CONTROL OF DATA ACQUISITION
PLANNING PROCESS

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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|---------|---------|---------|-----------------------|
| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 3.2B CONTROL OF DATA ACQUISITION PLANNING PROCESS

PURPOSE:

- a) To ensure that approved data needs are accurately reflected in data used for site characterization.
- b) To ensure that data used for site characterization has experimental error minimized to greatest degree feasible.
- c) To permit data acquisition test planning verification.
- d) To make it possible to reconstruct the test planning process and rationale.

CRITICAL FEATURES:

System specifying the data acquisition planning and documentation process.

REQUIREMENT # 2 PROCEDURE NO. PAP 1101 REV 1 PARA 4.2.1

The PROJECT MANAGER shall assure that Technical Procedures are identified, prepared and approved and shall define the methods of gathering needed information, including:

- o test objectives and requirements based upon sponsor and technical requirements delineated in the sponsor-approved research project planning documents
- o scope of tests (including characteristics to be tested)
- o justification
- o test method
- o prerequisite test conditions and provisions for assuring prerequisites have been met (checklists, etc.)
- o acceptance/rejection criteria for data, including required levels of precision and accuracy
- o methods of data analysis
- o expected results
- o needed Measurement and Testing Equipment (M&TE), and calibration requirements and provisions for assuring necessary monitoring is performed
- o other appropriate equipment needed

(CONTINUED)

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 3.2B CONTROL OF DATA ACQUISITION PLANNING PROCESS (CONTINUED)

PURPOSE:

- a) To ensure that approved data needs are accurately reflected in data used for site characterization.
- b) To ensure that data used for site characterization has experimental error minimized to greatest degree feasible.
- c) To permit data acquisition test planning verification.
- d) To make it possible to reconstruct the test planning process and rationale.

CRITICAL FEATURES:

System specifying the data acquisition planning and documentation process.

REQUIREMENT # 2 (CONTINUED) PROCEDURE NO. PAP 1101 REV 1 PARA 4.2.1

- o use of trained and qualified personnel who meet the requirements for performing experimental testing
- o schedule
- o environmental requirements
- o condition of test equipment and item to be tested
- o provisions for data acquisition/internal review
- o special handling and/or storage requirements (as appropriate)
- o mandatory inspection hold points (as appropriate)
- o provisions for indicating the current status of testing, activities, including the inspections of such activities, and any nonconformances
- o format of reports (as necessary)
- o references
- o QA Plan.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 3.2B CONTROL OF DATA ACQUISITION
PLANNING PROCESS

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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|----------------|----------------|----------------|------------------------------|
| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 3.3B TECHNICAL VERIFICATION OF DATA ACQUISITION PLANNING AND PROCEDURES

PURPOSE:

- a) To reduce the risk of acquiring inferior or invalid data, failing to obtain needed data, compromising other data acquisition activities, or compromising the site.
- b) To ensure that the data acquisition planning process is credible.
- c) To ensure that data acquisition processes produce valid, useable data while preserving site integrity.

CRITICAL FEATURES:

- b) Controls for documentation of the data acquisition planning verification process, including verification scope, verifier competence and independence and resolution of issues raised during verification.

REQUIREMENT # 1 PROCEDURE NO. PAP 604 REV 0 PARA 4.0

The APPROVAL AUTHORITY shall assure that required Independent Technical Reviews (ITRs) are accomplished in accordance with this procedure prior to document approval for release/issue or delivery to the sponsor.

- o The APPROVAL AUTHORITY shall select reviewer(s) who will be able to assure that the document is technically adequate, complete and correct.
- o The APPROVAL AUTHORITY shall complete the top portion of the Document Review Record (DRR) and include or attach the following information as appropriate and relevant to the ITR:
 - project name and number
 - intended use of document
 - applicable requirements and references to be considered
 - special instructions needed by reviewer(s)
 - identification of the reviewers and the scope of each reviewer's review (i.e., limited or total document)
- o When other data or information outside of the furnished review material is used to substantiate a comment, the reference material shall be documented and/or attached to the DRR.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 3.3B TECHNICAL VERIFICATION OF DATA ACQUISITION PLANNING AND PROCEDURES

PURPOSE:

- a) To reduce the risk of acquiring inferior or invalid data, failing to obtain needed data, compromising other data acquisition activities, or compromising the site.
- b) To ensure that the data acquisition planning process is credible.
- c) To ensure that data acquisition processes produce valid, useable data while preserving site integrity.

CRITICAL FEATURES:

- b) Controls for documentation of the data acquisition planning verification process, including verification scope, verifier competence and independence and resolution of issues raised during verification.

REQUIREMENT # 1 (CONTINUED) PROCEDURE NO. PAP 604 REV 0 PARA 4.0

- o On completion of the review, the REVIEWER shall sign and date the DRR, initial each page and forward the DRR to the designee.
- o The DESIGNEE shall obtain completed DRRs from all reviewers and shall review and resolve the comments.
- * o The QA REPRESENTATIVE shall review the ITR Report for assurance that reviews have been accomplished, comments resolved and procedures followed. If acceptable, indicate concurrence by signature and date on the report.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 3.3B TECHNICAL VERIFICATION OF DATA
ACQUISITION PLANNING AND PROCEDURES

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 3.3B TECHNICAL VERIFICATION OF DATA ACQUISITION PLANNING AND PROCEDURES

PURPOSE:

- To reduce the risk of acquiring inferior or invalid data, failing to obtain needed data, compromising other data acquisition activities, or compromising the site.
- To ensure that the data acquisition planning process is credible.
- To ensure that data acquisition processes produce valid, useable data while preserving site integrity.

CRITICAL FEATURES:

- Control of identification, by group doing data acquisition planning, of the method(s) used for verification of the planning (i.e., independent review or peer review).

REQUIREMENT # 1 PROCEDURE NO. PAP 604 REV 0 PARA 4.3.1

The APPROVAL AUTHORITY shall complete the top portion of the DRR, Exhibit 1, and include or attach the following information as appropriate and relevant to the ITR: • • •

- applicable requirements and references to be considered in evaluating technical quality (e.g., sponsor requirements, research data, design inputs, drawings and specifications, procedures and instructions, laboratory record books, software documentation, software verification documents, calculations, codes and standards)
- special instructions needed by reviewer(s) (e.g., specific criteria or requirements to be met, information indicating importance of the document, other documents or requirements affected, and potential problems requiring consideration) • • •

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 3.3B TECHNICAL VERIFICATION OF DATA
ACQUISITION PLANNING AND PROCEDURES

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet **of**

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/NBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 3.3B TECHNICAL VERIFICATION OF DATA ACQUISITION PLANNING AND PROCEDURES

PURPOSE:

- a) To reduce the risk of acquiring inferior or invalid data, failing to obtain needed data, compromising other data acquisition activities, or compromising the site.
- b) To ensure that the data acquisition planning process is credible.
- c) To ensure that data acquisition processes produce valid, useable data while preserving site integrity.

CRITICAL FEATURES:

- b) Controls for documentation of the data acquisition planning verification process, including verification scope, verifier competence and independence and resolution of issues raised during verification.

REQUIREMENT # 2 PROCEDURE NO. PAP 1102 REV 1 PARA 4.2.11
PAP 604 REV 0 PARA 4.5.5

4.2.11 The QA REPRESENTATIVE shall review the PRCR for assurance that reviews have been accomplished, comments resolved and procedures followed. If acceptable, indicate concurrence by signature and date on the report.

4.5.5 The QA REPRESENTATIVE shall review the ITR Report for assurance that reviews have been accomplished, comments resolved and procedures followed. If acceptable, indicate concurrence by signature and date on the report.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 3.3B TECHNICAL VERIFICATION OF DATA
ACQUISITION PLANNING AND PROCEDURES

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 3.4B CONTROL OF CHANGES TO DATA ACQUISITION PLANNING AND PROCEDURES

PURPOSE:

To reduce the risk that a planning or procedural change will compromise validity of test results, produce data that fails to correspond to specified data needs, compromise other planned data acquisition, compromise the site integrity, introduce indeterminate uncertainties into data acquisition activities or compromise the credibility of data acquisition controls.

CRITICAL FEATURES:

- a) System for ensuring verification of data acquisition planning changes commensurate with verification of the original planning.

REQUIREMENT # 1 **PROCEDURE NO.** PAP 602 **REV** 0 **PARA** 5.3.3

The document's author shall route the Interim Change Request/Notice (ICR/N) to the organizations that performed the original technical, QA and approval reviews.

- a) The reviews and approvals shall be documented by signature
- b) The reviewers shall have access to pertinent background data or information upon which to base their approval.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 3.4B CONTROL OF CHANGES TO DATA
ACQUISITION PLANNING AND PROCEDURES

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 3.4B CONTROL OF CHANGES TO DATA ACQUISITION PLANNING AND PROCEDURES

PURPOSE:

To reduce the risk that a planning or procedural change will compromise validity of test results, produce data that fails to correspond to specified data needs, compromise other planned data acquisition, compromise the site integrity, introduce indeterminate uncertainties into data acquisition activities or compromise the credibility of data acquisition controls.

CRITICAL FEATURES:

- ^b/_A System for ensuring verification of data acquisition planning changes commensurate with verification of the original planning.

REQUIREMENT # 1 PROCEDURE NO. PAP 602 REV 0 PARA 5.3.3

The document's author shall route the ICR/N to the organizations that performed the original technical, QA and approval reviews.

- The reviews and approvals shall be documented by signature
- The reviewers shall have access to pertinent background data or information upon which to base their approval.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 3.4B CONTROL OF CHANGES TO DATA
ACQUISITION PLANNING AND PROCEDURES

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 3.4B CONTROL OF CHANGES TO DATA ACQUISITION PLANNING AND PROCEDURES

PURPOSE:

To reduce the risk that a planning or procedural change will compromise validity of test results, produce data that fails to correspond to specified data needs, compromise other planned data acquisition, compromise the site integrity, introduce indeterminate uncertainties into data acquisition activities or compromise the credibility of data acquisition controls.

CRITICAL FEATURES:

- c) If field changes to data acquisition procedures are permitted, a system providing for control of such changes.

REQUIREMENT # 1 **PROCEDURE NO.** _____ **REV** _____ **PARA** _____

Are field changes to Test Procedures and Test Instructions allowed? If so, what control measures and/or procedures control the practice?

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 3.4B CONTROL OF CHANGES TO DATA
ACQUISITION PLANNING AND PROCEDURES

AUDIT NO. 8701

CRITICAL FEATURE: c)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

SUBTEAM

CAP/WBS

QA PLAN

AUDIT NO. 8701

Sheet of

PROGRAM ELEMENT:

5.1 PRESCRIPTION OF ACTIVITIES

PURPOSE:

- a) To ensure the ability to reconstruct any activity important to safety.
- b) To ensure that agreed-upon (authorized) methods and approaches are used in performance of activities within the scope of the QA program.

IMPLEMENTATION CRITERIA:

Written instructions, procedures or drawings, as appropriate, in place (i.e., reviewed, approved and issued to affected activities) in all activities audited).

REQUIREMENT # 1 PROCEDURE NO. PNI-MA-60 REV 3/22/85 PARA 5.1.1.1

Activities affecting quality shall be prescribed by and performed in accordance with documented procedures and instructions of a type appropriate to the circumstances.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 5.1 PRESCRIPTION OF ACTIVITIES

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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| _____ | _____ | _____ | Sheet _____ of _____ |
| _____ | _____ | _____ | |
| _____ | _____ | _____ | |

PROGRAM ELEMENT: 5.1 PRESCRIPTION OF ACTIVITIES

PURPOSE:

- a) To ensure the ability to reconstruct any activity important to safety.
- b) To ensure that agreed-upon (authorized) methods and approaches are used in performance of activities within the scope of the QA program.

IMPLEMENTATION CRITERIA:

Written instructions, procedures or drawings, as appropriate, in place (i.e., reviewed, approved and issued to affected activities) in all activities audited.

REQUIREMENT # 2 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 5.1.1.2

PROCEDURES AND INSTRUCTIONS SHALL:

- o prescribe controls over activities affecting quality to an extend consistent with their importance
- o provide for accomplishment of activities under suitably controlled conditions which include the use of appropriate equipment, suitable environmental conditions and assurance that prerequisites have been satisfied
- o provide for any special controls, processes, test equipment, tools and skills to attain the required quality and verification of quality
- o include or reference appropriate quantitative and qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished, and
- o provide for necessary records that furnish documentary evidence of quality.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 5.1 PRESCRIPTION OF ACTIVITIES

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 5.2 COMPLIANCE WITH INSTRUCTIONS, PROCEDURES AND DRAWINGS

PURPOSE:

- a) To ensure that work is done the way management believes it is being done.
- b) To ensure that methods or approaches can be reconstructed for purposes of problem analysis, program improvement, etc.

CRITICAL FEATURES:

- a) Procedure review, approval and distribution process that supports turn-around needs of line activities.

REQUIREMENT # 1 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 6.1.1.1

Documents that specify quality requirements or prescribe activities affecting quality shall be reviewed, approved, issued and controlled to assure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the activity is performed.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 5.2 COMPLIANCE WITH INSTRUCTIONS,
PROCEDURES AND DRAWINGS

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 5.2 COMPLIANCE WITH INSTRUCTIONS, PROCEDURES AND DRAWINGS

PURPOSE:

- a) To ensure that work is done the way management believes it is being done.
- b) To ensure that methods or approaches can be reconstructed for purposes of problem analysis, program improvement, etc.

CRITICAL FEATURES:

- a) Procedure review, approval and distribution process that supports turn-around needs of line activities.

REQUIREMENT # 2 PROCEDURE NO. PNI-MA-60 REV 3/22/85 PARA 6.1.1.1.g

Establishment and maintenance of distribution lists for controlled documents to assure distribution to locations where the activity is performed prior to commencing the work.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 5.2 COMPLIANCE WITH INSTRUCTIONS,
PROCEDURES AND DRAWINGS

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
|---------|---------|---------|-----------------------|
| _____ | _____ | _____ | Sheet _____ of _____ |
| _____ | _____ | _____ | |
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PROGRAM ELEMENT: 5.2 COMPLIANCE WITH INSTRUCTIONS, PROCEDURES AND DRAWINGS

PURPOSE:

- a) To ensure that work is done the way management believes it is being done.
- b) To ensure that methods or approaches can be reconstructed for purposes of problem analysis, program improvement, etc.

CRITICAL FEATURES:

- a) Procedure review, approval and distribution process that supports turn-around needs of line activities.

REQUIREMENT # 3 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 6.1.2.2.e

Documented QAD review and concurrence with documents with respect to quality-related aspects and for assurance that documents fully comply with PNL-MA-60 and applicable QA Plans.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 5.2 COMPLIANCE WITH INSTRUCTIONS,
PROCEDURES AND DRAWINGS

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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| _____ | _____ | _____ | |

PROGRAM ELEMENT: 5.2 COMPLIANCE WITH INSTRUCTIONS, PROCEDURES AND DRAWINGS

PURPOSE:

- a) To ensure that work is done the way management believes it is being done.
- b) To ensure that methods or approaches can be reconstructed for purposes of problem analysis, program improvement, etc.

CRITICAL FEATURES:

- b) Management measures that keep personnel aware of the need for procedural compliance.

REQUIREMENT # 1 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 2.1.3.1

PNL management shall regularly assess the adequacy for that part of the QA program, for which they are responsible and shall assure its effective implementation.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 5.2 COMPLIANCE WITH INSTRUCTIONS,
PROCEDURES AND DRAWINGS

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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| _____ | _____ | _____ | |

PROGRAM ELEMENT: 5.2 COMPLIANCE WITH INSTRUCTIONS, PROCEDURES AND DRAWINGS

PURPOSE:

- a) To ensure that work is done the way management believes it is being done.
- b) To ensure that methods or approaches can be reconstructed for purposes of problem analysis, program improvement, etc.

CRITICAL FEATURES:

- b) Management measures that keep personnel aware of the need for procedural compliance.

REQUIREMENT # 2 PROCEDURE NO. PAP-202 REV 2 PARA 5.1.2

Department and section managers with license-related research projects shall monitor the implementation of the QA Program within their organizations using methods such as the following. The monitoring activities shall be documented using a log or similar means:

- o interviews and walkthrough inspections, including interviews of Project Managers and project staff, reviews of project records, and inspections of project facilities and equipment
- o discussions of quality-related problems in staff meetings
- o attendance at audit closeout meetings and reviews of audit reports
- o inclusion of Quality matters in agendas for project review meetings
- o reviews of Trend Reports.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 5.2 COMPLIANCE WITH INSTRUCTIONS,
PROCEDURES AND DRAWINGS

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet **of**

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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| _____ | _____ | _____ | |
| _____ | _____ | _____ | |

PROGRAM ELEMENT: 5.2 COMPLIANCE WITH INSTRUCTIONS, PROCEDURES AND DRAWINGS

PURPOSE:

- a) To ensure that work is done the way management believes it is being done.
- b) To ensure that methods or approaches can be reconstructed for purposes of problem analysis, program improvement, etc.

CRITICAL FEATURES:

- b) Management measures that keep personnel aware of the need for procedural compliance.

REQUIREMENT # 3 PROCEDURE NO. PAP-202 REV 2 PARA 5.2

Annually, the Director, PNL, shall select and assign assessment team members according to the following:

- o the team shall consist of at least three members
- o team members shall be independent of the performance of the activities to be assessed and of the QAD.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 5.2 COMPLIANCE WITH INSTRUCTIONS,
PROCEDURES AND DRAWINGS

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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| _____ | _____ | _____ | |

PROGRAM ELEMENT: 5.2 COMPLIANCE WITH INSTRUCTIONS, PROCEDURES AND DRAWINGS

PURPOSE:

- a) To ensure that work is done the way management believes it is being done.
- b) To ensure that methods or approaches can be reconstructed for purposes of problem analysis, program improvement, etc.

CRITICAL FEATURES:

- b) Management measures that keep personnel aware of the need for procedural compliance.

REQUIREMENT # 4 PROCEDURE NO. PAP-202 REV 2 PARA 5.2.4

The assessment team shall prepare a report of the assessment, addressed to the Director, PNL. It shall include the following information:

- o description of the assessment scope
- o identification of persons contacted during the assessment
- o summary of assessment results, including a statement on the adequacy and effective implementation of the QA Program requirements.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 5.2 COMPLIANCE WITH INSTRUCTIONS,
PROCEDURES AND DRAWINGS

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | OA PLAN | AUDIT NO. <u>8701</u> |
|---------|---------|---------|-----------------------|
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PROGRAM ELEMENT: 6.1 IDENTIFICATION OF DOCUMENTS TO BE CONTROLLED
(CONTROLLED DOCUMENT LIST, FOR EXAMPLE)

PURPOSE:

- a) To ensure that only legitimate data is used in performance of activities important to safety, or to describe systems/facilities important to safety.
- b) To be sure that all documents used in activities important to safety, or that describe systems/facilities important to safety, are accounted for.

CRITICAL FEATURES:

System for authorized, up-to-date listing of controlled documents and of types of documents that are to be controlled.

REQUIREMENT # 1 PROCEDURE NO. PAP 601 REV 0 PARA 5.1.1

Document Control Procedure Matrix, provides a matrix of the documents to be controlled and the administrative procedure in which the document control responsibilities and requirements are described.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 6.1 IDENTIFICATION OF DOCUMENTS TO BE AUDIT NO. 8701
CONTROLLED (CONTROLLED DOCUMENT LIST,
FOR EXAMPLE)

Sheet ____ of ____

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 6.2 SYSTEM(S) FOR UNIQUELY IDENTIFYING
CONTROLLED DOCUMENTS

AUDIT NO. 8701

Sheet **of**

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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|---------|---------|---------|-----------------------|
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PROGRAM ELEMENT: 6.2 SYSTEM(S) FOR UNIQUELY IDENTIFYING CONTROLLED DOCUMENTS

PURPOSE:

To ensure only correct and current documents are used or referenced.

CRITICAL FEATURES:

System for serially numbering documents.

REQUIREMENT # 1 PROCEDURE NO. PAP 601 REV 0 PARA 5.1.4

The distribution authority shall mark copies of controlled documents by stamping the coversheet in red ink with the facsimile shown in Figure 1. The original should be retained unstamped to allow subsequent copies to be made as needed.

CONTROLLED DOCUMENT
COPY NO. _____

Figure 1. Controlled Document Stamp

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
|---------|---------|---------|-----------------------|
| _____ | _____ | _____ | Sheet _____ of _____ |
| _____ | _____ | _____ | |
| _____ | _____ | _____ | |

PROGRAM ELEMENT: 6.3 DOCUMENT REVIEW

PURPOSE:

To assure document adequacy and accuracy.

CRITICAL FEATURES:

Document review process that includes documentation of review comments and comment resolution.

REQUIREMENT # 1 PROCEDURE NO. PAP 501 REV 2 PARA 4.1.2, 4.3.4

- o When a new procedure or a procedure revision is determined to be necessary, the APPROVAL AUTHORITY shall appoint an author and establish a schedule, as necessary, for preparation, review, approval and issuance. The author shall be competent in the subject matter of the procedure. The procedure shall be available for use before commencing work. For PTs and TIs, the APPROVAL AUTHORITY shall also assure the designation of a Technical Procedure Coordinator (TPC).
- o The AUTHOR shall resolve each comment, i.e., indicate the response to it on the DRR. He shall sign and date the "Comments Resolved By" block and shall change the procedure in accordance with the comment resolutions. Where the reviewer had indicated a Do Not Concur disposition, the AUTHOR shall obtain the reviewer's concurrence with the resolutions. Any continuing nonconcurrence shall be referred to the APPROVAL AUTHORITY for final resolution.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 6.3 DOCUMENT REVIEW

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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|---------|---------|---------|-----------------------|
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| _____ | _____ | _____ | |

PROGRAM ELEMENT: 6.4 DOCUMENT APPROVAL/ISSUE CONTROL(S)

PURPOSE:

- a) To provide clear evidence of the authoritative nature of procedural and technical instruction.
- b) To prevent use of unauthorized instructions or descriptions of systems/facilities/data important to safety or waste isolation.

CRITICAL FEATURES:

- a) System that identifies authorized approval levels or positions.

REQUIREMENT # 1 PROCEDURE NO. PAP 501 REV 2 PARA EXHIBIT 1

| <u>Procedure Type</u> | <u>Approval Authority</u> |
|-------------------------------------|--|
| ADMINISTRATIVE PROCEDURES | |
| PNL Administrative Procedures | Quality Achievement Director |
| Contracts Administrative Procedures | Legal and Contracts Director |
| Design Control Procedures | Facilities and Operations Director |
| Quality Assurance Procedures | OAD Manager |
| Records Center Procedures | Management Systems and Administration Director |
| Software Control Procedures | Research Director |
| Training Coordination Procedures | Research Director |
| Training Coordination Procedures | Quality Achievement Director |
| TECHNICAL PROCEDURES | Cognizant Line Manger |
| TEST INSTRUCTIONS | Project Manager |

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 6.4 DOCUMENT APPROVAL/ISSUE CONTROL (S)

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet **of**

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED: .

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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| _____ | _____ | _____ | |

PROGRAM ELEMENT: 6.4 DOCUMENT APPROVAL/ISSUE CONTROL (S)

PURPOSE:

- a) To provide clear evidence of the authoritative nature of procedural and technical instruction.
- b) To prevent use of unauthorized instructions or descriptions of systems/facilities/data important to safety or waste isolation.

CRITICAL FEATURES:

- b) System that controls the release of controlled documents.

REQUIREMENT # 1 PROCEDURE NO. PAP 501 REV 0 PARA 4.3.8, 4.3.10

4.3.8 The APPROVAL AUTHORITY shall approve the procedure. If it is a revision to an existing Administrative Procedure (AP), the APPROVAL AUTHORITY may also authorize its release for use before receiving final sponsor approval.

4.3.10 Upon receipt of the sponsor's approval, or as provided in 4.3.8, the QAD Procedure Coordinator (QADPC) shall assign the Effective Date and send the procedure to Document Control for publication in accordance with PAP-601. The effective date should normally be within a week after it is expected that the procedure will be issued and any training completed.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 6.4 DOCUMENT APPROVAL/ISSUE CONTROL(S)

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 6.5 DOCUMENT CHANGE CONTROLS

PURPOSE:

To ensure that work important to safety is not compromised through use of improper information or lack of timely updates, corrections or other revisions.

CRITICAL FEATURES:

System for controlled document change control, including review by same organizations (or disciplines) that reviewed the original.

REQUIREMENT # 1 PROCEDURE NO. PAP 602 REV 0 PARA 5.3.3

The documents author shall route the Interim Change/Request Notice (ICR/N) to the organizations that performed the original technical, QA and approval reviews.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 6.5 DOCUMENT CHANGE CONTROLS

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
|---------|---------|---------|-----------------------|
| _____ | _____ | _____ | Sheet _____ of _____ |
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PROGRAM ELEMENT: 6.6 DISTRIBUTION CONTROLS

PURPOSE:

To ensure that correct, up-to-date documents are available for use where needed.

CRITICAL FEATURES:

- a) System for control of distribution that ensures that legitimate users of controlled documents receive controlled copies.

REQUIREMENT # 1 PROCEDURE NO. PAP 601 REV 0 PARA 5.2.1, 5.2.2

5.2.1 The distribution authority shall assign to each controlled document a copy number and shall distribute copies to the personnel responsible for the work covered by the document's content.

- a) The distribution shall be performed using a Controlled Document Transmittal form.
- b) The distribution authority shall retain the transmittal form original so that it may be used to acknowledge receipt of the documents by the recipient.
- c) A copy of each controlled document shall be distributed to the PNL Records Center.

5.2.2 Upon receipt of controlled documents, the recipient shall:

- o destroy all superseded documents
- o sign and date the receipt acknowledged column of the transmittal form
- o return the transmittal form to the distribution authority when the action required by the transmittal form has been completed
- o return the controlled document to the distribution authority when no longer involved in the research project(s) requiring implementation of the subject document.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 6.6 DISTRIBUTION CONTROLS

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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| _____ | _____ | _____ | Sheet _____ of _____ |
| _____ | _____ | _____ | |
| _____ | _____ | _____ | |

PROGRAM ELEMENT: 6.6 DISTRIBUTION CONTROLS

PURPOSE:

To ensure that correct, up-to-date documents are available for use where needed.

CRITICAL FEATURES:

- b) System for maintaining controlled document distribution lists current.

REQUIREMENT # 1 PROCEDURE NO. PAP 601 REV 0 PARA 5.1.3

The distribution authority shall prepare a Controlled Document List (CDL) of the documents to be distributed under their area of responsibility.

- a) Exhibit 3 provides the form and content to be used for the CDL.
- b) The CDL shall be revised whenever an applicable document is issued or revised. When several documents are being issued or revised within a short period of time (e.g., one week), the CDL may be revised periodically (e.g., weekly) instead of each time a controlled document is issued or revised.
- c) The CDL shall include documents planned to be issued at a later date and the revision status shall be indicated as To Be Issued (TBI).

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 6.6 DISTRIBUTION CONTROLS

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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| _____ | _____ | _____ | |
| _____ | _____ | _____ | |

PROGRAM ELEMENT: 6.7 SYSTEM(S) FOR ASCERTAINING DOCUMENT STATUS
(ISSUE/REVISION LISTS, FOR EXAMPLE)

PURPOSE:

To ensure that work reflects correct version of requirements.

CRITICAL FEATURES:

- a) System that enables controlled document user to readily determine the change status of any controlled document about to be used, or in use.

REQUIREMENT # 1 PROCEDURE NO. PAP 601 REV 0 PARA EXHIBIT 3

CONTROLLED DOCUMENT LIST (CDL)

Page 1 of _____

The attached pages provide a listing of the controlled documents maintained and distributed by (Organization/Research Project) in accordance with PNL Administrative Procedure PAP-601, Document Control. This list is maintained for the above mentioned organization/research project by (Name of distribution authority or designee).

This list is complete and includes the latest status of each listed document as of (date).

(Distribution Authority or Designee)
Signature

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 6.7 SYSTEM(S) FOR ASCERTAINING DOCUMENT AUDIT NO. 8701
STATUS (ISSUE/REVISION LISTS, FOR
EXAMPLE)

CRITICAL FEATURE: a) Sheet ____ of ____

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 8.1 SPECIFICATION OF ITEM/MATERIAL/SAMPLE IDENTIFICATION METHODS

PURPOSE:

- a) To prevent inadvertent use of incorrect material.
- b) To ensure that the source of items/materials/samples can be identified.

CRITICAL FEATURES:

System(s) for identification (marking, tagging, labelling, etc.) items and samples.

REQUIREMENT # 1 PROCEDURE NO. PAP 801 REV 2 PARA 4.2

RECEIPT OF TEST MATERIAL

The MATERIAL CUSTODIAN shall receive test materials for the project in accordance with the following:

- o Initiate a Test Materials Inventory Sheet (TMIS) in accordance with Exhibit 1. He or she shall also enter it into the log in accordance with Exhibit 1, page 3 of 3, when a log is used.
- o Examine the packaging. If damaged, contact the cognizant staff member for direction.
- o Determine whether any special handling or storage requirements for the material have been specified. If so, apply them.
- o Verify that required documentation is provided; e.g., certified material test reports from outside suppliers or laboratory reports.
- o Verify that the material or its container is marked, labeled or tagged with the material's identification, and that this matches the identification on the accompanying documentation.
- o Verify that material ordered against specific requirements meets the acceptance criteria for those requirements.
- o If material is deficient, initiate an NCR and apply a hold tag in accordance with PAP-1501, Nonconformance Reports.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 8.1 SPECIFICATION OF ITEM/MATERIAL /
SAMPLE IDENTIFICATION METHODS

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 8.1 SPECIFICATION OF ITEM/MATERIAL/SAMPLE IDENTIFICATION METHODS

PURPOSE:

- a) To prevent inadvertent use of incorrect material.
- b) To ensure that the source of items/materials/samples can be identified.

CRITICAL FEATURES:

System(s) for identification (marking, tagging, labelling, etc.) items and samples.

REQUIREMENT # 2 PROCEDURE NO. PAP 801 REV 2 PARA 4.3

IDENTIFICATION AND STORAGE OF TEST MATERIAL

The MATERIAL CUSTODIAN shall identify, store, handle, and protect the materials within his or her custody.

The materials shall be uniquely identified. Physical identification of the item or its container shall be used to the maximum extent possible. Where physical identification is impractical or insufficient, tags, physical separation, procedural control, or other means shall be used, providing that traceability between the actual item and its records is maintained. Identification markings, when used, shall be clear, legible, permanent, and not detrimental to the material.

Materials shall be traceable to appropriate documents, such as procurement documents, test reports, drilling logs, melt reports, or nonconformance reports.

The materials shall be clearly separated so as to prevent misidentification with other materials and/or cross contamination.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 8.1 SPECIFICATION OF ITEM/MATERIAL /
SAMPLE IDENTIFICATION METHODS

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 8.2 CONTROL OF ITEMS/MATERIALS/SAMPLES

PURPOSE:

- a) To reduce the risk of using, or basing site characterization conclusions on, incorrect or unidentifiable items/materials/samples.
- b) To ensure credibility of items/material/and samples used to characterize the site.
- c) To ensure that pedigree of items/material and samples can be traced to prove credibility of site characterization.

CRITICAL FEATURES:

- a) System(s) for controlled transfer of custody of items and/or samples.

REQUIREMENT # 1 PROCEDURE NO. PAP-801 REV 2 PARA 4.4

TRANSMITTALS OF SPECIMENS AND SAMPLES

COGNIZANT STAFF MEMBERS shall make transmittals of material in accordance with the following:

- o A MATERIAL CUSTODIAN who issues material shall record the transmittal on the TMIS and prepare a Material Identification Card (MIC) in accordance with Section 5.6 and Exhibit 2.
- o A COGNIZANT STAFF MEMBER (other than a material custodian) who transmits specimens or samples shall record the complete identification of the material and the recipient in a document of record such as an LRB and prepare an MIC.
- o When new test material is produced in processing operations, the COGNIZANT STAFF MEMBER shall record the material's identification in a document of record and present the material and supporting documentation to the material custodian (see 5.2).

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 8.2 CONTROL OF ITEMS/MATERIALS/SAMPLES

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 8.2 CONTROL OF ITEMS/MATERIALS/SAMPLES

PURPOSE:

- a) To reduce the risk of using, or basing site characterization conclusions on, incorrect or unidentifiable items/materials/samples.
- b) To ensure credibility of items/material/and samples used to characterize the site.
- c) To ensure that pedigree of items/material and samples can be traced to prove credibility of site characterization.

CRITICAL FEATURES:

- a) System(s) for controlled transfer of custody of items and/or samples.

REQUIREMENT # 2 PROCEDURE NO. PAP-801 REV 2 PARA 4.6

MATERIAL IDENTIFICATION CARDS

COGNIZANT STAFF MEMBERS who have possession of specimens and samples shall make use of MICs as follows:

- o All specimens or samples shall have unique identifiers and shall be identifiable to MICs that accurately describe their current chemical and physical condition. MICs on samples are first required when the samples are removed from the test apparatus or environment. A single MIC may be used for a group of related specimens or samples provided that they are kept close together, and that the MIC identifies them all.
- o The MIC shall identify the cognizant staff member who has authority over the material. This is usually the scientist in charge of the test in which the material has been or will be run. It is usually not the service group individual who may have temporary possession of the material for such services as specimen preparation or sample analysis.
- o MICs shall be kept with or in close proximity to the materials they represent.
- o When material on an MIC is separated (e.g., part of a sample is sent to an analytical center) either the MIC shall be duplicated or new ones shall be written so that each increment of material has an MIC with it. This requirement, however, does not apply to the portions of samples that an analytical center uses for analysis.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 8.2 CONTROL OF ITEMS/MATERIALS/SAMPLES

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 8.2 CONTROL OF ITEMS/MATERIALS/SAMPLES

PURPOSE:

- a) To reduce the risk of using, or basing site characterization conclusions on, incorrect or unidentifiable items/materials/samples.
- b) To ensure credibility of items/material/and samples used to characterize the site.
- c) To ensure that pedigree of items/material and samples can be traced to prove credibility of site characterization.

CRITICAL FEATURES:

- b) System(s) for maintaining the custody history of items and/or samples.

REQUIREMENT # 1 PROCEDURE NO. PAP-801 REV 2 PARA 4.2

The MATERIAL CUSTODIAN shall receive test materials for the project in accordance with the following:

- o Maintain a record file for the material on each TMIS, including documentation received with the material and any additional analytical reports obtained by the cognizant staff member.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 8.2 CONTROL OF ITEMS/MATERIALS/SAMPLES

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 8.2 CONTROL OF ITEMS/MATERIALS/SAMPLES

PURPOSE:

- a) To reduce the risk of using, or basing site characterization conclusions on, incorrect or unidentifiable items/materials/samples.
- b) To ensure credibility of items/material/and samples used to characterize the site.
- c) To ensure that pedigree of items/material and samples can be traced to prove credibility of site characterization.

CRITICAL FEATURES:

- b) System(s) for maintaining the custody history of items and/or samples.

REQUIREMENT # 2 **PROCEDURE NO.** PAP-801 **REV** 2 **PARA** 4.3

At least annually, storage areas shall be inspected to verify that materials on open TMISs are present, any required in-storage maintenance has been performed, storage and environmental controls have been maintained, and markings remain legible. Disposition shall be made of materials that have gone past their specified retention period. Markings whose legibility has been impaired shall be restored or replaced.

After all of the material covered by a TMIS is gone, the MATERIAL CUSTODIAN shall sign and date the final transmittal block. The TMIS shall be delivered to the project manager or records custodian for incorporation into the records system.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 8.2 CONTROL OF ITEMS/MATERIALS/SAMPLES

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 8.2 CONTROL OF ITEMS/MATERIALS/SAMPLES

PURPOSE:

- a) To reduce the risk of using, or basing site characterization conclusions on, incorrect or unidentifiable items/materials/samples.
- b) To ensure credibility of items/material/and samples used to characterize the site.
- c) To ensure that pedigree of items/material and samples can be traced to prove credibility of site characterization.

CRITICAL FEATURES:

- b) System(s) for maintaining the custody history of items and/or samples.

REQUIREMENT # 3 PROCEDURE NO. PAP-801 REV 2 PARA 4.7

RETENTION AND DISPOSAL

The COGNIZANT STAFF MEMBER shall provide direction to the material custodian, analytical center manager, or others in the possession of analyzed samples or other leftover materials for the disposition of these materials. Such direction shall be in accordance with any sponsor requirements, QA plan commitments, safety requirements, or other governing requirements. Actual disposition shall be in accordance with this direction and the following:

- o Materials of no further use may be discarded.
- o Any materials to be retained shall be identified, stored, handled, and protected in accordance with the requirements of 4.3.1.1 through 4.3.1.7.
- o Any required archiving shall be in accordance with PAP-802, Test Material and Sample Archiving.
- o Material to be shipped to the sponsor or elsewhere shall be identified and packaged so as to prevent damage or deterioration. An MIC and any other documents pertinent to the materials shall accompany the shipment. Examples of such documents include analytical reports, handling or storage instructions and expiration dates for limited lifetime materials.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 8.2 CONTROL OF ITEMS/MATERIALS/SAMPLES

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 8.2 CONTROL OF ITEMS/MATERIALS/SAMPLES

PURPOSE:

- a) To reduce the risk of using, or basing site characterization conclusions on, incorrect or unidentifiable items/materials/samples.
- b) To ensure credibility of items/material/and samples used to characterize the site.
- c) To ensure that pedigree of items/material and samples can be traced to prove credibility of site characterization.

CRITICAL FEATURES:

- d) System(s) for verifying that limited life items, materials or samples are appropriately identified and labelled (or otherwise made obvious to personnel using them or responsible for their storage).

REQUIREMENT # 1 PROCEDURE NO. PAP-801 REV 2 PARA 4.3

The MATERIAL CUSTODIAN shall stamp or annotate any TMIS for material that has a limited calendar or operating lifetime as "Limited Life Material. Expires _____." The date of expiration shall be entered. Where possible, the material or its container shall be marked or tagged with the same information. As a minimum, the material shall be flagged as limited life material.

Upon expiration, the MATERIAL CUSTODIAN shall discard the material unless instructed otherwise by the Project Manager. A hold tag shall be attached to any material that is not discarded, or to its container, or shall be displayed at the hot cell, etc., in which the material is kept. An NCR shall be prepared and dispositioned in accordance with PAP-1501, if further use of the material is to be made. Holds, Discards and NCRs shall be noted on the TMIS.

After all of the material covered by a TMIS is gone, the MATERIAL CUSTODIAN shall sign and date the final transmittal block. The TMIS shall be delivered to the project manager or records custodian for incorporation into the records system.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 8.2 CONTROL OF ITEMS/MATERIALS/SAMPLES

AUDIT NO. 8701

CRITICAL FEATURE: d)

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QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 8.2 CONTROL OF ITEMS/MATERIALS/SAMPLES

PURPOSE:

- a) To reduce the risk of using, or basing site characterization conclusions on, incorrect or unidentifiable items/materials/samples.
- b) To ensure credibility of items/material/and samples used to characterize the site.
- c) To ensure that pedigree of items/material and samples can be traced to prove credibility of site characterization.

CRITICAL FEATURES:

- d) System(s) for verifying that limited life items, materials or samples are appropriately identified and labelled (or otherwise made obvious to personnel using them or responsible for their storage).

REQUIREMENT # 2 PROCEDURE NO. PAP-801 REV 2 PARA 4.5

RECEIPT, STORAGE AND CHECKING OF SPECIMENS AND SAMPLES

COGNIZANT STAFF MEMBERS of specimens and samples, shall verify the material identification and that the lifetimes of any lifetime materials have not expired. They shall enter the receipt into an LRB (unless the same LRB is being used by both the transmitter and the recipient) or a sample logbook. The entry shall include the material identification and description and a reference to applicable documents such as Requests for Analytical Services.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 8.2 CONTROL OF ITEMS/MATERIALS/SAMPLES

AUDIT NO. 8701

CRITICAL FEATURE: d)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: **8.2 CONTROL OF ITEMS/MATERIALS/SAMPLES**

PURPOSE:

- a) To reduce the risk of using, or basing site characterization conclusions on, incorrect or unidentifiable items/materials/samples.
- b) To ensure credibility of items/material/and samples used to characterize the site.
- c) To ensure that pedigree of items/material and samples can be traced to prove credibility of site characterization.

CRITICAL FEATURES:

- e) System(s) for checking that items, materials or samples are within their life limits prior to use.

REQUIREMENT # 1 PROCEDURE NO. PAP-801 REV 2 PARA 4.5

COGNIZANT STAFF MEMBERS shall verify the identification of specimens prior to the start of a test. The verification shall include checking that any limited lifetime materials are within their lifetime. The verification shall be documented in the appropriate document of record.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

WAM ELEMENT: 8.2 CONTROL OF ITEMS/MATERIALS/SAMPLES

AUDIT NO. 8701

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Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

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Is the activity complying with the requirement? YES ☐ NO ☐

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AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 8.3 SYSTEM(S) FOR VERIFICATION OF ITEM/
MATERIAL/SAMPLE IDENTIFICATION PRIOR
TO USE

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 10.1 VERIFICATION/INSPECTION PLANNING

PURPOSE:

To assure that completed QL I or QL II work conforms to specific requirements.

CRITICAL FEATURES:

- a) Procedures for determining and specifying inspection or other verification requirements.

REQUIREMENT # 1 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 10.1.3.1

Assure that inspections of procured and/or PNL produced items are planned, performed and documented to verify compliance to specifications.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 10.1 VERIFICATION/INSPECTION PLANNING

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 10.1 VERIFICATION/INSPECTION PLANNING

PURPOSE:

To assure that completed QL I or QL II work conforms to specific requirements.

CRITICAL FEATURES:

- a) Procedures for determining and specifying inspection or other verification requirements.

REQUIREMENT # 2 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 10.1.3.2

Assure that the documentation of inspections identifies characteristics, methods, and acceptance criteria, and that objective evidence of inspection results is properly recorded.

(Note: It is expected that inspection planning will have to specify what the inspection documentation is to include.)

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 10.1 VERIFICATION/INSPECTION PLANNING

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 10.1 VERIFICATION/INSPECTION PLANNING

PURPOSE:

To assure that completed QI I or QI II work conforms to specific requirements.

CRITICAL FEATURES:

- a) Procedures for determining and specifying inspection or other verification requirements.

REQUIREMENT # 3 PROCEDURE NO. OAP-1001 REV 1 PARA 4.1

QC REPRESENTATIVES shall prepare semiannual plans for surveillances of Procurement/Subcontracts and Craft Services to assure control of the activity and compliance to requirements. Activities, locations, and requirements shall be selected for surveillance based upon prior observations, the nature of the activity or guidance from a QAD Section Manager. A copy of the plan shall be provided to the QC Manager for review and approval.

The QUALITY ENGINEERS shall prepare quarterly plans for surveillances to assure control of activities and compliance to requirements throughout the duration of an activity or project. Selection of activities, locations, and QA requirements for surveillance shall be based on QA plan commitments, prior observations, the nature of the activity or project, guidance from a QAD Section Manager or request from the Cognizant Manager. A copy of the quarterly plan shall be provided to the cognizant QE Technical Leader, prior to the start of the quarter, for review and approval.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 10.1 VERIFICATION/INSPECTION PLANNING

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 10.1 VERIFICATION/INSPECTION PLANNING

PURPOSE:

To assure that completed QL I or QL II work conforms to specific requirements.

CRITICAL FEATURES:

- b) System for ensuring that detailed planning is prepared for required inspections and/or other verification.

REQUIREMENT # 1 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 10.1.4.3

Assure that a combination of inspection and planned surveillance is performed in a systematic manner to assure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 10.1 VERIFICATION/INSPECTION PLANNING
CRITICAL FEATURE: b)

AUDIT NO. 8701
Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 10.1 VERIFICATION/INSPECTION PLANNING

PURPOSE:

To assure that completed QL I or QL II work conforms to specific requirements.

CRITICAL FEATURES:

- b) System for ensuring that detailed planning is prepared for required inspections and/or other verification.

REQUIREMENT # 2 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 10.1.6.1

Assure that required inservice inspections or surveillance of facilities, equipment, and systems are planned, executed, and documented by the PNL Craft Services Maintenance group necessary to assure test continuity and validity.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 10.1 VERIFICATION/INSPECTION PLANNING

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 10.2 IN-PROCESS VERIFICATION/INSPECTION

PURPOSE:

To assure that the process produces the intended results.

CRITICAL FEATURES:

- a) System for determining that required inspections and/or other verifications have been performed in accordance with applicable detailed planning/instructions.

REQUIREMENT # 1 **PROCEDURE NO.** PNL-MA-60 **REV** 3/22/85 **PARA** 10.1.4.4

Assure controls for the above in-process inspections and planned surveillance, when required, are established and documented for the coordination and sequencing of these activities at established hold/witness points during successive stages of the conducted process.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 10.2 IN-PROCESS VERIFICATION/INSPECTION AUDIT NO. 8701
CRITICAL FEATURE: a) Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

SUBTEAM

CAP/WBS

QA PLAN

AUDIT NO. 8701

Sheet of

PROGRAM ELEMENT:

10.2 IN-PROCESS VERIFICATION/INSPECTION

PURPOSE:

To assure that the process produces the intended results.

CRITICAL FEATURES:

- a) System for determining that required inspections and/or other verifications have been performed in accordance with applicable detailed planning/instructions.

REQUIREMENT # 2 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 10.1.4.2

Assure that in-process inspection and planned surveillance of PNL produced items, when necessary, are accomplished using the methods of PAP-702 and OAP-1001.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 10.2 IN-PROCESS VERIFICATION/INSPECTION AUDIT NO. 8701

CRITICAL FEATURE: a) Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 10.2 IN-PROCESS VERIFICATION/INSPECTION

PURPOSE:

To assure that the process produces the intended results.

CRITICAL FEATURES:

- a) System for determining that required inspections and/or other verifications have been performed in accordance with applicable detailed planning/instructions.

REQUIREMENT # 3 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 10.1.5.3

Assure completed items are inspected for the following as required to verify the quality and conformance of the item to specified requirements:

- o completeness
- o markings
- o calibration
- o adjustments
- o protection from damage
- o other characteristics

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 10.2 IN-PROCESS VERIFICATION/INSPECTION AUDIT NO. 8701
CRITICAL FEATURE: a) Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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| _____ | _____ | _____ | |

PROGRAM ELEMENT: 10.2 IN-PROCESS VERIFICATION/INSPECTION

PURPOSE:

To assure that the process produces the intended results.

CRITICAL FEATURES:

- b) System(s) for verifying that inspectors and/or verifiers were independent.

REQUIREMENT # 1 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 10.1.1.1

Assure inspection personnel performing inspections of procured or PNL produced items do not report directly to the immediate supervisors who are responsible for performing the work being inspected. These personnel may be obtained via subcontract with outside agencies.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 10.2 IN-PROCESS VERIFICATION/INSPECTION

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 10.3 ACCEPTANCE OR FINAL VERIFICATION/INSPECTION

PURPOSE:

- a) To assure that the final product or service meets the specified requirements.
- b) To arrive at a conclusion regarding conformance of the item or service to specified requirements.

CRITICAL FEATURES:

- a) System for establishing and documenting acceptance criteria for completed work.

REQUIREMENT # 1 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 10.1.5.2

Assure final inspections include a records review (including surveillance results) of the results and resolution of nonconformances identified by prior inspections and that conclusions are reached and documented regarding conformance of the item to specified requirements.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 10.3 ACCEPTANCE OR FINAL VERIFICATION/ AUDIT NO. 8701
INSPECTION

CRITICAL FEATURE: a) Sheet ____ of ____

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

SUBTEAM CAP/WBS QA PLAN AUDIT NO. 8701
Sheet ____ of ____

PROGRAM ELEMENT: 10.3 ACCEPTANCE OR FINAL VERIFICATION/INSPECTION

PURPOSE:

- a) To assure that the final product or service meets the specified requirements.
- b) To arrive at a conclusion regarding conformance of the item or service to specified requirements.

CRITICAL FEATURES:

- a) System for establishing and documenting acceptance criteria for completed work.

REQUIREMENT # 2 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 10.1.5.4
REQUIREMENT # 3 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 10.1.5.5
REQUIREMENT # 4 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 10.1.5.6

1. Assure all quality records have been examined for adequacy and completeness.
2. Assure acceptance of the item has been documented and approved by authorized personnel.
3. Assure that the item is reinspected or retested if modified, repaired or replaced subsequent to final inspection.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 10.3 ACCEPTANCE OR FINAL VERIFICATION/ AUDIT NO. 8701
INSPECTION

CRITICAL FEATURE: a) Sheet ____ of ____

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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| _____ | _____ | _____ | Sheet _____ of _____ |
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PROGRAM ELEMENT: 10.3 ACCEPTANCE OR FINAL VERIFICATION/INSPECTION

PURPOSE:

- a) To assure that the final product or service meets the specified requirements.
- b) To arrive at a conclusion regarding conformance of the item or service to specified requirements.

CRITICAL FEATURES:

- b) System for ensuring that completed work is evaluated against established acceptance criteria.

REQUIREMENT # 1 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA Applicability

The requirements of this section apply to inspections and surveillances to verify conformance of procured or PNL produced items and activities to specified requirements.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 10.3 ACCEPTANCE OR FINAL VERIFICATION/ AUDIT NO. 8701
INSPECTION

CRITICAL FEATURE: b) Sheet ____ of ____

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

SUBTEAM

CAP/WBS

QA PLAN

AUDIT NO. 8701

Sheet _____ of _____

PROGRAM ELEMENT:

10.3 ACCEPTANCE OR FINAL VERIFICATION/INSPECTION

PURPOSE:

- a) To assure that the final product or service meets the specified requirements.
- b) To arrive at a conclusion regarding conformance of the item or service to specified requirements.

CRITICAL FEATURES:

- b) System for ensuring that completed work is evaluated against established acceptance criteria.

REQUIREMENT # 2 PROCEDURE NO. PNL-WA-60 REV 3/22/85 PARA 10.1.4.5

Assure surveillance activities are performed of the Research Project activities in a systematic manner to assure that control of the activities and compliance to requirements are being achieved throughout the duration of the project.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 10.3 ACCEPTANCE OR FINAL VERIFICATION/
INSPECTION

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 11.3 TEST PROCEDURES [SEE ELEMENT 3.4B FOR R&D TEST PROCEDURE CONTROLS]

PURPOSE:

- a) To ensure the ability to reconstruct any test activity.
- b) To ensure that agreed-upon (authorized) methods and approaches are used in performance in the test.

CRITICAL FEATURES:

System for test procedure review, to include verification that:

1. Test objective is stated,
2. Prerequisites are specified, and
3. Instrumentation requirements are specified.

REQUIREMENT # 1 PROCEDURE NO. PAP 1101 REV 1 PARA 4.2.2

Technical Procedures and Test Instructions shall be complete to the extent that another qualified individual may, at a later date reproduce the test results, if deemed necessary.

NOTE: Test planning and test procedure preparation is evaluated under Program Element 3.4B. This checklist is intended for the evaluation of test instructions and their compliance with test procedures.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 11.3 TEST PROCEDURES [SEE ELEMENT 3.4B
FOR R&D TEST PROCEDURE CONTROLS]

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 11.3 TEST PROCEDURES [SEE ELEMENT 3.4B FOR R&D TEST PROCEDURE CONTROLS]

PURPOSE:

- a) To ensure the ability to reconstruct any test activity.
- b) To ensure that agreed-upon (authorized) methods and approaches are used in performance in the test.

CRITICAL FEATURES:

System for test procedure review, to include verification that:

1. Test objective is stated,
2. Prerequisites are specified, and
3. Instrumentation requirements are specified.

REQUIREMENT # 2 PROCEDURE NO. PAP 502 REV 2 PARA 4.6

PREPARATION OF TEST INSTRUCTIONS

AUTHORS shall prepare TIs as necessary in order to establish the specific parameters for individual test runs or experiments that are to be conducted according to a Technical Procedure -- typically a Test Procedure. Requirements for the TIs are as follows:

- a) They shall be labelled as Test Instructions and shall identify their parent TP and the particular test run or experiment to which they apply.
- b) They shall identify the Impact Level of the test or experiment.
- c) They shall include signatures and dates of the author and approval authority.
- d) They shall include any applicable qualitative or quantitative acceptance criteria for determining that the prescribed activities have been satisfactorily accomplished.
- e) They shall not contravene any requirements of the parent TP.
- f) Since they will become record documents, they shall be typed or written or printed legibly in ink.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 11.3 TEST PROCEDURES [SEE ELEMENT 3.4B
FOR R&D TEST PROCEDURE CONTROLS]

AUDIT NO. 8701

Sheet **of**

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 11.4 TEST DOCUMENTATION/RECORDS

PURPOSE:

- a) To ensure that R&D data evaluation and interpretation can be accurately related to data sources and data acquisition methods and conditions.
- b) To ensure that the R&D data acquisition process can be reconstructed from the record.

CRITICAL FEATURES:

System for verifying that:

1. Specified test prerequisites were met,
2. Specified instrumentation was used,
3. Instrumentation was within specified calibration period (where applicable),
4. Specified test environment and set-up existed,
5. Test data were recorded as required, and
6. Test anomalies and/or deviations from the test procedure were documented.

REQUIREMENT # 1 PROCEDURE NO. PAP 1101 REV 1 PARA 4.3.1

COGNIZANT STAFF MEMBERS shall:

- o Perform the tests in accordance with the requirements and methods contained in the Technical Procedures and the applicable Test Instructions. The COGNIZANT MANAGER shall monitor tests, as required, and document their monitoring activities, as appropriate, in the LRB or the Technical Procedure/Test Instructions.
- o Document the test results, or acquisition of data generated, in the manner specified in the Technical Procedure and/or Test Instructions

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 11.4 TEST DOCUMENTATION/RECORDS

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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| _____ | _____ | _____ | |

PROGRAM ELEMENT: 11.4 TEST DOCUMENTATION/RECORDS

PURPOSE:

- a) To ensure that R&D data evaluation and interpretation can be accurately related to data sources and data acquisition methods and conditions.
- b) To ensure that the R&D data acquisition process can be reconstructed from the record.

CRITICAL FEATURES:

System for verifying that:

1. Specified test prerequisites were met,
2. Specified instrumentation was used,
3. Instrumentation was within specified calibration period (where applicable),
4. Specified test environment and set-up existed,
5. Test data were recorded as required, and
6. Test anomalies and/or deviations from the test procedure were documented.

REQUIREMENT # 2 PROCEDURE NO. PAP 1101 REV 1 PARA 4.3.2

Included in the test results documentation shall be:

- o Reference to the procedure and instruction used
- o Identification of the material or process tested
- o Test date
- o Name of tester or data recorder
- o Type(s) of observation
- o Test results and acceptability
- o Action taken with respect to any identified unexpected results, discrepancies and nonconformances
- o Identity of the person evaluating the data or results for conformance to accept criteria
- o Signature and date of person who performed the work/recorded the data.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 11.4 TEST DOCUMENTATION/RECORDS

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 11.5 TEST RESULTS EVALUATION

PURPOSE:

- To verify that acquired data from R&D testing meets data acquisition requirements specified in test planning.
- To ensure that testing actually provided valid response to all test requirements.

CRITICAL FEATURES:

- System for ensuring that responsible testing agency evaluates test results to verify that the test produced the specified data under specified conditions.

REQUIREMENT # 1 PROCEDURE NO. PAP 1101 REV 1 PARA 4.4.1

The PROJECT MANAGER or designated alternate shall assure that test results and data are evaluated to determine conformance with the acceptance criteria specified in the Technical Procedures.

- Test results and data shall be evaluated by personnel authorized by the Project Managers who have the technical expertise to perform the evaluation and did not prepare the document being reviewed.
- The evaluation shall be documented by the dated signature of the EVALUATOR on the test results documentation.
- The PROJECT MANAGER also may initiate an Independent Technical Review as required to satisfy project requirements.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 11.5 TEST RESULTS EVALUATION

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet _____ **of** _____

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | OA PLAN | AUDIT NO. <u>8701</u> |
|---------|---------|---------|-----------------------|
| _____ | _____ | _____ | Sheet _____ of _____ |
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PROGRAM ELEMENT: 11.5 TEST RESULTS EVALUATION

PURPOSE:

- a) To verify that acquired data from R&D testing meets data acquisition requirements specified in test planning.
- b) To ensure that testing actually provided valid response to all test requirements.

CRITICAL FEATURES:

- a) System for ensuring that responsible testing agency evaluates test results to verify that the test produced the specified data under specified conditions.

REQUIREMENT # 2 PROCEDURE NO. PAP 1101 REV 1 PARA 4.5

REPORTING RESULTS

- 4.5.1 When a formal report is to be issued, the PROJECT MANAGER or designated alternate shall prepare a report incorporating the data resulting from performance of the test, and conclusions drawn from evaluation of the test data.
- 4.5.2 The PROJECT MANAGER shall initiate an Independent Technical Review and determine if a Peer Review of the formal report is required.
- 4.5.3 All documents that provide objective evidence of test planning, performance and evaluation shall be processed as research project records by the PROJECT MANAGER.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 11.5 TEST RESULTS EVALUATION

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 11.5 TEST RESULTS EVALUATION

PURPOSE:

- a) To verify that acquired data from R&D testing meets data acquisition requirements specified in test planning.
- b) To ensure that testing actually provided valid response to all test requirements.

CRITICAL FEATURES:

- b) System for ensuring that test results are evaluated by the organization that specified the test requirements.

REQUIREMENT # 1 PROCEDURE NO. PAP-1101 REV. 1 PARA 4.4.1

The PROJECT MANAGER or designated alternate shall assure that test results and data are evaluated to determine conformance with the acceptance criteria specified in the Technical Procedures.

- a) Test results and data shall be evaluated by personnel authorized by the Project Manager who have the technical expertise to perform the evaluation and did not prepare the document being reviewed.
- b) The evaluation shall be documented by the dated signature of the EVALUATOR on the test results documentation.
- c) The PROJECT MANAGER also may initiate an Independent Technical Review as required to satisfy project requirements.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 11.5 TEST RESULTS EVALUATION

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 11.5 TEST RESULTS EVALUATION

PURPOSE:

- a) To verify that acquired data from R&D testing meets data acquisition requirements specified in test planning.
- b) To ensure that testing actually provided valid response to all test requirements.

CRITICAL FEATURES:

- b) System for ensuring that test results are evaluated by the organization that specified the test requirements.

REQUIREMENT # 2 PROCEDURE NO. PAP-1101 REV 1 PARA 4.5.2

The PROJECT MANAGER shall initiate an Independent Technical Review and determine if a Peer Review of the forma report is required.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 11.5 TEST RESULTS EVALUATION

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 12.1 M&TE SELECTION

PURPOSE:

To maximize the ability to measure required parameters with the desired accuracy and precision.

CRITICAL FEATURES:

System for control of instrumentation selection, including consideration of:

1. Accuracy, precision, stability, reliability and ruggedness needs,
2. Appropriateness for intended application, and
3. Performance in similar applications (where applicable).

REQUIREMENT # 1 PROCEDURE NO. PAP 1201 REV 2 PARA 4.2, 4.1.2

4.1 SELECTION/CATEGORIZATION OF M&TE INTO LEVELS OF USE

4.1.1 The COGNIZANT MANAGER shall assure that the Measuring and Test Equipment (M&TE) are selected and then categorized into levels of use.

4.1.2 Calibrated M&TE selection shall be based on the following measurement requirements:

- o proper type of M&TE
- o range
- o accuracy
- o tolerance
- o precision.

NOTE: M&TE should have an accuracy of at least 4 times better than the specified tolerances being measured.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 12.1 M&TE SELECTION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 12.1 M&TE SELECTION

PURPOSE:

To maximize the ability to measure required parameters with the desired accuracy and precision.

CRITICAL FEATURES:

System for control of instrumentation selection, including consideration of:

1. Accuracy, precision, stability, reliability and ruggedness needs,
2. Appropriateness for intended application, and
3. Performance in similar applications (where applicable).

REQUIREMENT # 2 PROCEDURE NO. PNL-MA-60 REV 3/22/86 PARA 1A

M&TE shall be:

selected and controlled to assure that it is the proper type, range, accuracy, and tolerance to accomplish the required function.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 12.1 M&TE SELECTION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 0A PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 15.2 NONCONFORMANCE REPORTING

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 12.2 CALIBRATION CONTROLS

PURPOSE:

To ensure that the full design accuracy and precision of the M&TE is realized and to reduce probable error of measurement.

CRITICAL FEATURES:

- a) System for ensuring calibration against standards traceable to nationally recognized standards (this does not necessarily mean NBS standards), or basis of calibration documented.

REQUIREMENT # 1 PROCEDURE NO. PNL-MA-60 REV 0 PARA 2A,B,C

Standards used for calibrating M&TE shall:

- o have accuracies of at least four times better than those of the M&TE being calibrated, unless limited by state of the art -- When the accuracy is not four times better, the rationale for deviating from this requirement shall be justified and documented.
- o have an established history of stability.
- o have known valid relationships to nationally recognized standards (National Bureau of Standards or equivalent) or accepted values of natural physical constants and shall be traceable through certificates, reports, or data sheets attesting to the calibration date, calibration facility, unique control/ID number, traceability methods(s), and other data that shows conformance to accuracy requirements (except natural physical constants).

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 12.2 CALIBRATION CONTROLS

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 12.2 CALIBRATION CONTROLS

PURPOSE:

To ensure that the full design accuracy and precision of the M&TE is realized and to reduce probable error of measurement.

CRITICAL FEATURES:

- b) System for verifying that instrumentation is within its calibration period prior to use.

REQUIREMENT # 1 **PROCEDURE NO.** PAP 1201 **REV** 2 **PARA** 4.6.1

Before use of M&TE, the USER shall assure that the M&TE:

- ☐ Is properly labeled
- ☐ Is within its calibration period
- ☐ Has not been damaged or degraded
- ☐ Is properly suited for the intended purpose.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 12.2 CALIBRATION CONTROLS

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

SUBTEAM

CAP/WBS

QA PLAN

AUDIT NO. 8701

Sheet of

PROGRAM ELEMENT:

12.2 CALIBRATION CONTROLS

PURPOSE:

To ensure that the full design accuracy and precision of the M&TE is realized and to reduce probable error of measurement.

CRITICAL FEATURES:

- c) System for ensuring correct data where the duration of instrumentation use will take it past its calibration-due date (where such situations may arise).

REQUIREMENT # 1 PROCEDURE NO. PAP 1201 REV 2 PARA 4.8.3

A Waiver of Calibration can be initiated when there is a planned departure from requirements such as an extended calibration interval. M&TE requiring a waiver shall not be used until approval by the appropriate technical representative and QA Representative.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 12.2 CALIBRATION CONTROLS
CRITICAL FEATURE: c)

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 12.3 M&TE HANDLING AND STORAGE

PURPOSE:

To reduce the risk of introducing unknown or unrecognized measurement error.

CRITICAL FEATURES:

Controls for safe storage and handling of M&TE.

REQUIREMENT # 1 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 12.1.8

M&TE and Standards shall be maintained and controlled to assure consistent results of acceptable accuracy. The following controls shall be considered:

- o environmental controls (both during calibration and maintenance).
- o M&TE which is consistently found out-of-calibration shall be evaluated as to probable cause and corrective action taken.
- o a calibration shall be performed if the equipment is suspected of malfunctioning or the accuracy is questioned.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 12.3 M&TE HANDLING AND STORAGE

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 12.4 TRACEABILITY OF USE

PURPOSE:

To make it possible to identify data from an M&TE device later found to have been out of calibration (or otherwise unreliable) and to reduce the risk of placing good data (measured by other devices) in question unnecessarily.

CRITICAL FEATURES:

System for documenting M&TE use, providing traceability from results to device used and from device to its applications (to what it has been used on).

REQUIREMENT # 1 PROCEDURE NO. PAP 1201 REV 2 PARA 4.4.4

- o Level 1 and Level 2 M&TE calibration records shall be maintained close to the work area.
- o The Level 2 M&TE calibration record shall be in a Laboratory Record Book, log sheets, Battelle Calibration Record Card, or other method(s) traceable to the equipment and data collected.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 12.4 TRACEABILITY OF USE

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 12.5 IMPACT EVALUATION OF OUT-OF-CALIBRATION INCIDENTS

PURPOSE:

- a) To minimize the risk of unknowingly using invalid data.
- b) To minimize the risk of using equipment or other articles whose conformance to requirements may be in doubt.

CRITICAL FEATURES:

System for determining useability of results obtained from a measuring device during any period when it might have been out of calibration (when it is discovered to be out of calibration).

REQUIREMENT # 1 PROCEDURE NO. PNI-MA-60 REV 3/22/85 PARA 12.1.1.4

The calibration discrepancy system shall define the methods for reporting, evaluating, and recalibrating potentially damaged M&TE or M&TE found to be out of calibration. The system shall include the following requirements:

- o an evaluation shall be made and documented to assess the validity and acceptability of measurements performed since the last calibration -- When there is impact on the data one or more of the following shall be accomplished:
 - a. data appropriately downgraded.
 - b. inspection or tests repeated on items previously inspected/tested.
 - c. data qualified in a manner acceptable to the sponsor.

out-of-calibration M&TE shall be tagged or segregated and not used until they have been recalibrated.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 12.5 IMPACT EVALUATION OF
OUT-OF-CALIBRATION INCIDENTS

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 12.5 IMPACT EVALUATION OF OUT-OF-CALIBRATION INCIDENTS

PURPOSE:

- a) To minimize the risk of unknowingly using invalid data.
- b) To minimize the risk of using equipment or other articles whose conformance to requirements may be in doubt.

CRITICAL FEATURES:

System for determining useability of results obtained from a measuring device during any period when it might have been out of calibration (when it is discovered to be out of calibration).

REQUIREMENT # 2 PROCEDURE NO. PAP 1201 REV 1 PARA 4.1

The following document shall be forwarded to D. C. Manager for on-going evaluation and recommendations:

- o reports of calibration (stds. lab).
- o notice of discrepancy from stds. lab.
- o nonconforming reports.
- o calibration discrepancy tags.
- o WSL-18 recall master file - stds. lab.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 12.5 IMPACT EVALUATION OF
OUT-OF-CALIBRATION INCIDENTS

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 14.1 INSPECTION AND TEST STATUS INDICATING SYSTEM(S)

PURPOSE:

To reduce the risk of permitting an existing defect to go undetected when it should have been detected by a specified inspection or test (i.e., to reduce the risk of misplaced confidence).

CRITICAL FEATURES:

- a) Inspection and test documentation system that ensures that inspection or test status (i.e., inspection(s) and/or test(s) required, inspection(s) and/or test(s) completed, and acceptance status) is maintained in a controlled manner, such as logs or computers, clearly and readily traceable to the affected item, material or sample.

REQUIREMENT # 1 PROCEDURE NO. PAP 1401 REV 1 PARA 4.1, 4.2

4.1 STATUS INDICATORS

The following tags shall be considered "status indicators" and shall be used as applicable:

- o Hold Tag - Yellow
- o Accept Tag - Green

The following documents shall also be considered "status indicators" and shall be used as applicable:

- o Nonconformance Report (NCR)
- o Inspection/Test Instructions (ITIs)
- o Deficiency Report (DR).

In addition, status may be indicated on documents such as Test Procedures, Test Instructions and in Laboratory Record Books.

4.2 CONTROL OF STATUS INDICATORS

Hold Tags shall be issued, as required, by the QUALITY ASSURANCE REPRESENTATIVE

Acceptance Tags shall be issued to cognizant staff by the QUALITY ASSURANCE REPRESENTATIVE

When attaching status indicators COGNIZANT STAFF shall sign and date the status indicator to assure traceability to the individual or specific activity.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 14.1 INSPECTION AND TEST STATUS
INDICATING SYSTEM(S)

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 15.1 DISTINGUISHING IDENTIFICATION FOR NONCONFORMING ITEMS/MATERIALS/SAMPLES

PURPOSE:

To reduce the risk that an item or sample recognized as questionable or nonconforming will be "lost" in the system before the observed condition is corrected.

CRITICAL FEATURES:

Identification system.

REQUIREMENT # 1 PROCEDURE NO. PAP 1501 REV 1 PARA 4.1.1

IDENTIFICATION AND CONTROL OF NONCONFORMING ITEMS

When a hardware item (including a received sample) or an associated document is found to be nonconforming to requirements specified in an approved document (e.g., drawing, specification, work order or other controlled document), COGNIZANT STAFF discovering the nonconformance shall:

- o Notify the QA Representative (QE) of the NCR, or the Hold pending NCR initiation if QE assistance is needed for correction.
- o Attach a Hold Tag to the item. The tag may be used to control more than one (1) item if all items are kept together and are identified on the tag.
- o Segregate the nonconforming item(s) from acceptable items by placing them in clearly identified and designated hold areas, when practical, and withhold from use until an approved disposition is completed.
- o Use other precautions to preclude inadvertent use of a nonconforming item when segregation is impractical or impossible due to physical conditions such as size, weight or access limitations
- o Identify the custodian of the nonconforming items on the tag to indicate responsibility for preventing use of the items until completion of required actions.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 15.1 DISTINGUISHING IDENTIFICATION FOR AUDIT NO. 8701
NONCONFORMING ITEMS/MATERIALS/SAMPLES

Sheet ____ of ____

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☒ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 15.2 NONCONFORMANCE REPORTING

PURPOSE:

To reduce the risk that the observed nonconformance will escape the attention of affected (and responsible) parties.

CRITICAL FEATURES:

Reporting system.

REQUIREMENT # 1 PROCEDURE NO. PAP 1501 REV 1 PARA 4.1.2

Subsequently, the COGNIZANT STAFF shall:

- o Obtain a Nonconformance Report (NCR) number from the QA Department Secretary and initiate a Nonconformance Report.
- o Mark the Hold Tag to identify it as a "Nonconforming Material Hold," reference the NCR number and date on the tag, and include a brief description of the nonconformance.
- o Notify his or her manager of any nonconformances perceived to need an Incident Report (IR) or an Unusual Occurrence Report (UOR).
- o Immediately notify the Buyer/Subcontract Specialist of the nonconformance if the nonconformance involves an item received from a supplier or the cognizant manager if the nonconformance originated during other work on a work package or work order.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 15.2 NONCONFORMANCE REPORTING

AUDIT NO. 8701

Sheet **of**

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 15.3 EVALUATION/DISPOSITIONING CONTROLS

PURPOSE:

- a) To ensure that the potential impact of nonconformances is correctly assessed.
- b) To ensure that dispositions do not jeopardize the integrity of site characterization or of repository design/construction/operation.

CRITICAL FEATURES:

- a) Specified evaluation and dispositioning authority.

REQUIREMENT # 1 (Page 1 of 3) PROCEDURE NO. PAP-1501 REV 1 PARA 4.2.4.3

Evaluation and Disposition

A QA REPRESENTATIVE shall review the NCR for concurrence to the non-conformance and the need to initiate an Incident Report (IR) or Unusual Occurrence Report (UOR). If an IR or UOR is required, verify that the IR or UOR number is referenced on the NCR. Notify the Technical Representative responsible for the technical requirements affected by the NCR.

The TECHNICAL REPRESENTATIVE of the Line or Project Manager responsible for the item and the QA REPRESENTATIVE shall determine a recommended disposition and if additional reviews (may include material review meetings) for approval and concurrence of the disposition are necessary.

COGNIZANT STAFF performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

When the recommended disposition involves either Accept As Is, Conditional Accept or Repair, the NCR shall include a technical justification. Nonconformances to design requirements dispositioned Accept As Is or Repair shall be subject to design control measures commensurate with those applied to the original design. The as-built records, if such records are required, shall reflect the accepted deviation.

Reworked items shall be reexamined and documented in accordance with the applicable procedures or inspection test instructions and in accordance with the original acceptance criteria.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

SUBTEAM _____ CAP/WBS _____ QA PLAN _____ AUDIT NO. 8701
Sheet _____ of _____

PROGRAM ELEMENT: 15.3 EVALUATION/DISPOSITIONING CONTROLS

CRITICAL FEATURES:

- a) Specified evaluation and dispositioning authority.

REQUIREMENT # 1 (Page 2 of 3) PROCEDURE NO. PAP-1501 REV 1 PARA 4.2.4.3

Repaired items shall be reexamined and documented in accordance with alternate acceptance criteria to assure that the capability of the item to obtain valid data, function reliability, and operate safely is not impaired.

When the NCR disposition involves action to be taken with a supplier, the cognizant Buyer/Subcontract Specialist shall be sent a copy of the NCR so that appropriate action can be taken to resolve the nonconformance. Conditional Accept and Accept As Is dispositions will not be used when further action is requested from a supplier. When the NCR disposition involves action to be taken with a supplier/subcontractor, the cognizant Buyer/Subcontract Specialist shall be contacted to coordinate the disposition. When the NCR disposition involves action to be taken by PNL personnel, the cognizant manager(s) shall be contacted to coordinate the disposition and to verify their capability to perform the required disposition.

Instructions for accomplishing the disposition shall be specified in the NCR and the organization(s) responsible shall be identified.

A preliminary disposition (e.g., reinspect or retest, obtain required or corrected data or continue work activities on nonconforming item(s) pending a specified action or hold point) may be used to assist in determining a final disposition. Preliminary dispositions shall be identified on the NCR and a final disposition is required for each. (The final disposition that do not result in a nonconformance shall be indicated on the NCR as Accept.)

The QA REPRESENTATIVE shall initiate a Corrective Action Request (CAR) to achieve corrective action for significant conditions adverse to quality. Reference the CAR number on the NCR.

After completion of all required reviews, the QA REPRESENTATIVE shall:

- o verify that all reviewers have signed and dated the NCR.
- o make a copy of the NCR for follow-up
- o transmit a copy of the NCR to the organization(s) responsible for performance of the disposition -- if the NCR disposition involves a purchased item, send a copy of the NCR to the Buyer/Subcontract Specialist for procurement files and action.

When required by the sponsor, nonconformance reports with dispositions of "Accept As Is", "Conditionally Accept", and "Repair", that have a significant effect on the quality of sponsor deliverables, shall be provided to the cognizant Program Manager for transmittal to the sponsor for concurrence before performing the disposition.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

SUBTEAM CAP/WBS QA PLAN

AUDIT NO. 8701

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PROGRAM ELEMENT: 15.3 EVALUATION/DISPOSITIONING CONTROLS

CRITICAL FEATURES:

- a) Specified evaluation and dispositioning authority.

REQUIREMENT # 1 (Page 3 of 3) PROCEDURE NO. PAP-1501 REV 1 PARA 4.2.4.3

Accomplishment of Disposition

The ORGANIZATION(S) RESPONSIBLE FOR PERFORMANCE OF THE DISPOSITION shall accomplish the action as indicated by the NCR Disposition/Instructions or coordinate any changes with the cognizant staff who approved the NCR. On completion of the action, the responsible organization(s) shall notify the NCR originator.

The cognizant BUYER/SUBCONTRACT SPECIALIST shall advise and obtain concurrence of the Technical Representative in the course of action taken or to be taken by the supplier on the recommended disposition. The BUYER/SUBCONTRACT SPECIALIST may transmit the NCR directly to the supplier or transmit the equivalent information through other means and shall document all NCR action(s) taken and any responses from the supplier.

The NCR ORIGINATOR (or designee) shall assure the timely accomplishment of the disposition by periodically checking its progress.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 15.3 - EVALUATION/DISPOSITIONING CONTROLS
CRITICAL FEATURE: a)

AUDIT NO. 8701
Sheet ____ of ____

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 15.3 EVALUATION/DISPOSITIONING CONTROLS

PURPOSE:

- a) To ensure that the potential impact of nonconformances is correctly assessed.
- b) To ensure that dispositions do not jeopardize the integrity of site characterization or of repository design/construction/operation.

CRITICAL FEATURES:

- b) Specified groundrules for permissible dispositions.

REQUIREMENT # 1 (Page 1 of 2) PROCEDURE NO. PAP-1501 REV 1 PARA 4.2.2

The TECHNICAL REPRESENTATIVE of the Line or Project Manager responsible for the item and the QA REPRESENTATIVE shall determine a recommended disposition and if additional reviews (may include material review meetings) for approval and concurrence of the disposition are necessary.

COGNIZANT STAFF performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

When the recommended disposition involves either Accept As Is, Conditional Accept or Repair, the NCR shall include a technical justification. Nonconformances to design requirements dispositioned Accept As Is or Repair shall be subject to design control measures commensurate with those applied to the original design. The as-built records, if such records are required, shall reflect the accepted deviation.

Reworked items shall be reexamined and documented in accordance with the applicable procedures or inspection test instructions and in accordance with the original acceptance criteria.

Repaired items shall be reexamined and documented in accordance with alternate acceptance criteria to assure that the capability of the item to obtain valid data, function reliability, and operate safely is not impaired.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

SUBTEAM CAP/WBS QA PLAN

AUDIT NO. 8701

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PROGRAM ELEMENT: 15.3 EVALUATION/DISPOSITIONING CONTROLS

PURPOSE:

- a) To ensure that the potential impact of nonconformances is correctly assessed.
- b) To ensure that dispositions do not jeopardize the integrity of site characterization or of repository design/construction/operation.

CRITICAL FEATURES:

- b) Specified groundrules for permissible dispositions.

REQUIREMENT # 1 (Page 2 of 2) PROCEDURE NO. PAP-1501 REV 1 PARA 4.2.2

When the NCR disposition involves action to be taken with a supplier, the cognizant Buyer/Subcontract Specialist shall be sent a copy of the NCR so that appropriate action can be taken to resolve the nonconformance. Conditional Accept and Accept As Is dispositions will not be used when further action is requested from a supplier. When the NCR disposition involves action to be taken with a supplier/subcontractor, the cognizant Buyer/Subcontract Specialist shall be contacted to coordinate the disposition. When the NCR disposition involves action to be taken by PNL personnel, the cognizant manager(s) shall be contacted to coordinate the disposition and to verify their capability to perform the required disposition.

Instructions for accomplishing the disposition shall be specified in the NCR and the organization(s) responsible shall be identified.

A preliminary disposition (e.g., reinspect or retest, obtain required or corrected data or continue work activities on nonconforming item(s) pending a specified action or hold point) may be used to assist in determining a final disposition. Preliminary dispositions shall be identified on the NCR and a final disposition is required for each. (The final disposition that do not result in a nonconformance shall be indicated on the NCR as Accept.)

The QA REPRESENTATIVE shall initiate a Corrective Action Request (CAR) to achieve corrective action for significant conditions adverse to quality. Reference the CAR number on the NCR.

After completion of all required reviews, the QA REPRESENTATIVE shall:

- o verify that all reviewers have signed and dated the NCR.
- o make a copy of the NCR for follow-up
- o transmit a copy of the NCR to the organization(s) responsible for performance of the disposition -- if the NCR disposition involves a purchased item, send a copy of the NCR to the Buyer/Subcontract Specialist for procurement files and action.

When required by the sponsor, nonconformance reports with dispositions of "Accept As Is", "Conditionally Accept", and "Repair", that have a significant effect on the quality of sponsor deliverables, shall be provided to the cognizant Program Manager for transmittal to the sponsor for concurrence before performing the disposition.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 15.3 EVALUATION/DISPOSITIONING CONTROLS AUDIT NO. 8701
CRITICAL FEATURE: b) Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 15.3 EVALUATION/DISPOSITIONING CONTROLS

PURPOSE:

- a) To ensure that the potential impact of nonconformances is correctly assessed.
- b) To ensure that dispositions do not jeopardize the integrity of site characterization or of repository design/construction/operation.

CRITICAL FEATURES:

- c) System for handling dispositions of "use-as-is" or "repair" under design control procedures (i.e., written technical justification and independent technical review).

REQUIREMENT # 1 PROCEDURE NO. PAP-1501 REV 1 PARA 4.2.2.2
4.2.2.4
4.2.2.6
4.2.2.7

When the recommended disposition involves either Accept As Is, Conditional Accept or Repair, the NCR shall include a technical justification. Nonconformances to design requirements dispositioned Accept As Is or Repair shall be subject to design control measures commensurate with those applied to the original design. The as-built records, if such records are required, shall reflect the accepted deviation.

Repaired items shall be reexamined and documented in accordance with alternate acceptance criteria to assure that the capability of the item to obtain valid data, function reliability, and operate safely is not impaired.

Instructions for accomplishing the disposition shall be specified in the NCR and the organization(s) responsible shall be identified.

A preliminary disposition (e.g., reinspect or retest, obtain required or corrected data or continue work activities on nonconforming item(s) pending a specified action or hold point) may be used to assist in determining a final disposition. Preliminary dispositions shall be identified on the NCR and a final disposition is required for each. (The final disposition that do not result in a nonconformance shall be indicated on the NCR as Accept.)

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 15.3 EVALUATION/DISPOSITIONING CONTROLS AUDIT NO. 8701
CRITICAL FEATURE: c) Sheet ____ of ____

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | OA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 15.3 EVALUATION/DISPOSITIONING CONTROLS

PURPOSE:

- a) To ensure that the potential impact of nonconformances is correctly assessed.
- b) To ensure that dispositions do not jeopardize the integrity of site characterization or of repository design/construction/operation.

CRITICAL FEATURES:

- d) System for providing instructions and acceptance criteria for "repair" dispositions.

REQUIREMENT # 1 PROCEDURE NO. PAP-1501 REV 1 PARA 4.2.2.2,4.2.2.4
4.2.2.6,4.2.2.7

When the recommended disposition involves either Accept As Is, Conditional Accept or Repair, the NCR shall include a technical justification. Nonconformances to design requirements dispositioned Accept As Is or Repair shall be subject to design control measures commensurate with those applied to the original design. The as-built records, if such records are required, shall reflect the accepted deviation.

Repaired items shall be reexamined and documented in accordance with alternate acceptance criteria to assure that the capability of the item to obtain valid data, function reliability, and operate safely is not impaired.

Instructions for accomplishing the disposition shall be specified in the NCR and the organization(s) responsible shall be identified.

A preliminary disposition (e.g., reinspect or retest, obtain required or corrected data or continue work activities on nonconforming item(s) pending a specified action or hold point) may be used to assist in determining a final disposition. Preliminary dispositions shall be identified on the NCR and a final disposition is required for each. (The final disposition that do not result in a nonconformance shall be indicated on the NCR as Accept.)

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 15.3 EVALUATION/DISPOSITIONING CONTROLS AUDIT NO. 8701
CRITICAL FEATURE: d) Sheet ____ of ____

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 15.4 NONCONFORMANCE CLOSEOUT

PURPOSE:

To ensure that specified dispositions are accomplished correctly.

CRITICAL FEATURES:

System for documented verification that dispositions were carried out as specified and that specified acceptance criteria were met.

REQUIREMENT # 1 PROCEDURE NO. PAP-1501 REV 1 PARA 4.3.4.3

Accomplishment of Disposition

The ORGANIZATION(S) RESPONSIBLE FOR PERFORMANCE OF THE DISPOSITION shall accomplish the action as indicated by the NCR Disposition/Instructions or coordinate any changes with the cognizant staff who approved the NCR. On completion of the action, the responsible organization(s) shall notify the NCR originator.

The cognizant BUYER/SUBCONTRACT SPECIALIST shall advise and obtain concurrence of the Technical Representative in the course of action taken or to be taken by the supplier on the recommended disposition. The BUYER/SUBCONTRACT SPECIALIST may transmit the NCR directly to the supplier or transmit the equivalent information through other means and shall document all NCR action(s) taken and any responses from the supplier.

The NCR ORIGINATOR (or designee) shall assure the timely accomplishment of the disposition by periodically checking its progress.

Verification and Closeout

The NCR ORIGINATOR (or designee) shall verify whether the disposition was performed as described and in accordance with the instructions provided on the NCR.

- If a disposition is to be changed, the QA REPRESENTATIVE shall determine the additional reviews that are required in accordance with the Evaluation Disposition and Accomplishment of Disposition paragraphs. The changed disposition and justification shall be recorded in Block 17 of the NCR and titled "Final Disposition/Justification."
- Evidence of the reviews shall be indicated by initialling and dating in Block 22 of the NCR.

Follow-up action shall be taken by the QA REPRESENTATIVE to verify proper implementation of corrective action and to close out the corrective action on significant nonconformances.

When satisfied that all necessary action has been performed, the NCR ORIGINATOR (or designee) shall:

- o remove the Hold Tag(s)
- o sign and date the NCR and forward it to the QA REPRESENTATIVE for distribution.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 15.4 NONCONFORMANCE CLOSEOUT

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | OA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 16.1 IDENTIFICATION, REPORTING AND CORRECTION
OF CONDITIONS ADVERSE TO QUALITY

PURPOSE:

- a) To ensure that recognized problems are not permitted to remain in the system.
- b) To ensure that sources (causes) of conditions significantly adverse to quality do not continue to contribute to the same or similar significant adverse conditions.

CRITICAL FEATURES:

- a) System for flagging conditions adverse to quality upon discovery. -

REQUIREMENT # 1 PROCEDURE NO. PAP 1501 REV 1 PARA 4.1.1

IDENTIFICATION AND CONTROL OF NONCONFORMING ITEMS

When a hardware item (including a received sample) or an associated document is found to be nonconforming to requirements specified in an approved document (e.g., drawing, specification, work order or other controlled document), COGNIZANT STAFF discovering the nonconformance shall:

- o Notify the QA Representative (QE) of the NCR, or the Hold pending NCR initiation if QE assistance is needed for correction.
- o Attach a Hold Tag to the item. The tag may be used to control more than one (1) item if all items are kept together and are identified on the tag.
- o Segregate the nonconforming item(s) from acceptable items by placing them in clearly identified and designated hold areas, when practical, and withhold from use until an approved disposition is completed.
- o Use other precautions to preclude inadvertent use of a nonconforming item when segregation is impractical or impossible due to physical conditions such as size, weight or access limitations
- o Identify the custodian of the nonconforming items on the tag to indicate responsibility for preventing use of the items until completion of required actions.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 16.1 IDENTIFICATION, REPORTING AND
CORRECTION OF CONDITIONS ADVERSE
TO QUALITY

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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| _____ | _____ | _____ | |

PROGRAM ELEMENT: 16.1 IDENTIFICATION, REPORTING AND CORRECTION
OF CONDITIONS ADVERSE TO QUALITY

PURPOSE:

- a) To ensure that recognized problems are not permitted to remain in the system.
- b) To ensure that sources (causes) of conditions significantly adverse to quality do not continue to contribute to the same or similar significant adverse conditions.

CRITICAL FEATURES:

- b) System(s) for reporting conditions adverse to quality.

REQUIREMENT # 1 PROCEDURE NO. PAP-1602 REV 0 PARA 1.0, 4.2.5

This procedure prescribes requirements and responsibilities for corrective action on conditions adverse to quality. • • •

Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition shall be documented and reported to immediate management and upper levels of management for review and assessment by a Corrective Action Request (CAR) administered in accordance with this procedure.

The QAD MANAGER shall report to the Project Sponsor QA Manager (and others, if required by sponsor) as soon as possible but not later

than five (5) calendar days from the date that there is a determination of a significant condition adverse to quality.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 16.1 IDENTIFICATION, REPORTING AND CORRECTION
OF CONDITIONS ADVERSE TO QUALITY

PURPOSE:

- a) To ensure that recognized problems are not permitted to remain in the system.
- b) To ensure that sources (causes) of conditions significantly adverse to quality do not continue to contribute to the same or similar significant adverse conditions.

CRITICAL FEATURES:

- c) System(s) for ensuring that conditions adverse to quality are corrected upon notification that they exist.

REQUIREMENT # 1 PROCEDURE NO. PAP-1601 REV 1 PARA 4.1.4.b

If a reportable incident is determined to have occurred, the QAD MANAGER shall evaluate the need for a Stop Work Request. If required, the Stop Work Request shall be issued before PNL approval of the IR.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 16.1 IDENTIFICATION, REPORTING AND
CORRECTION OF CONDITIONS ADVERSE
TO QUALITY

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 16.1 IDENTIFICATION, REPORTING AND CORRECTION
OF CONDITIONS ADVERSE TO QUALITY

PURPOSE:

- a) To ensure that recognized problems are not permitted to remain in the system.
- b) To ensure that sources (causes) of conditions significantly adverse to quality do not continue to contribute to the same or similar significant adverse conditions.

CRITICAL FEATURES:

- c) System(s) for ensuring that conditions adverse to quality are corrected upon notification that they exist.

REQUIREMENT # 2 PROCEDURE NO. PAP-1602 REV 0 PARA 4.3.1.2

The COGNIZANT MANAGER shall identify, implement and complete the corrective action for internal CARs. • • •

- Results Expected - Identify the action taken to correct the noncompliant condition and the action taken or planned to preclude repetition • • •

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 16.1 IDENTIFICATION, REPORTING AND
CORRECTION OF CONDITIONS ADVERSE
TO QUALITY

AUDIT NO. 8701

CRITICAL FEATURE: c)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 16.2 EVALUATION OF POTENTIAL IMPACT/SIGNIFICANCE

PURPOSE:

- a) To ensure that conditions significantly adverse to quality receive prompt, meaningful attention.
- b) To ensure that nonsignificant conditions adverse to quality are not permitted to dilute project resources through excessive attention.
- c) To reduce the risk of permitting work that the observed condition rendered questionable or invalid to remain in the system.

CRITICAL FEATURES:

- a) System for evaluating conditions adverse to quality for significance.

REQUIREMENT # 1 PROCEDURE NO. PAP 1602 REV 0 PARA 4.2.1.

The QA STAFF shall routinely review nonconformance reports, deficiency reports and audit findings and determine the need to issue CARs to appropriate levels of management, suppliers and Hanford Contractors for significant conditions adverse to quality. The following are considered significant conditions:

- o conditions that are not corrected in a timely manner or are not anticipated to be corrected
- o conditions where prior corrective action has not been effective
- o recurrent or continuing conditions based on reviews and analyses
- o conditions requiring corrective action that involve more than one functional group and/or project
- o conditions which, if not immediately corrected, would result in acceptance of work being withheld or could result in a stop work request.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 16.2 EVALUATION OF POTENTIAL
IMPACT/SIGNIFICANCE

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 16.2 EVALUATION OF POTENTIAL IMPACT/SIGNIFICANCE

PURPOSE:

- a) To ensure that conditions significantly adverse to quality receive prompt, meaningful attention.
- b) To ensure that nonsignificant conditions adverse to quality are not permitted to dilute project resources through excessive attention.
- c) To reduce the risk of permitting work that the observed condition rendered questionable or invalid to remain in the system.

CRITICAL FEATURES:

- b) System for evaluating the possible impact of conditions adverse to quality on affected work (both prior and ongoing work).

REQUIREMENT # 1 PROCEDURE NO. PAP 1602 REV 0 PARA 4.3.1.2

Complete the CAR and return it to the QAD Manager as soon as practical, but no later than the response due date established by the QAD Manager. The response to the CAR shall include the following information: • • •

- o Extent - Identify other activities that may be or are being affected by the noncompliant condition • • •

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 16.2 EVALUATION OF POTENTIAL
IMPACT/SIGNIFICANCE

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | OA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 16.3 DETERMINATION OF CAUSE OF SIGNIFICANT PROBLEMS

PURPOSE:

To reduce the risk that a condition capable of causing a significant problem will remain unrecognized in the project.

CRITICAL FEATURES:

System for documented investigation into root cause of significant problems.

REQUIREMENT # 1 PROCEDURE NO. PAP 1602 REV 0 PARA 4.3.1.2

Complete the CAR and return it to the OAD Manager as soon as practical, but no later than the response due date established by the OAD Manager. The response to the CAR shall include the following information: • • •

- o Cause - Identify the root cause and position titles of personnel responsible for the noncompliant condition
- o Contributing Factors - Identify any other factors that led to the noncompliant condition • • •

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 16.3 DETERMINATION OF CAUSE
OF SIGNIFICANT PROBLEMS

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 16.4 ACTION TO PREVENT RECURRENCE AND CORRECT ADVERSE EFFECTS

PURPOSE:

- a) To prevent a recognized condition capable of causing significant problems from remaining in the system.
- b) To assure that adverse effects caused on previous work by the condition do not remain in the system without correction.

CRITICAL FEATURES:

- a) System for documented preventive action plans for significant problems after determination of root cause.

REQUIREMENT # 1 PROCEDURE NO. PAP 1602 REV 0 PARA 4.3

RESPONSE AND CORRECTIVE ACTION FOR CORRECTIVE ACTION REQUESTS

The COGNIZANT MANAGER shall identify, implement and complete the corrective action for internal CARs... • • •

- o Results Expected - Identify the action taken to correct the noncompliant condition and the action taken or planned to preclude repetition • • •

The QAD MANAGER shall determine acceptability of response/corrective action plan.

- o If acceptable, sign the QAD concurrence block on the CAR and return the CAR to the Cognizant Manager/Buyer/Subcontract Specialist.
- o If unacceptable, go to Step 4.4.3.

For internal CARs, the COGNIZANT MANAGER shall sign/date the "Corrective Action Completed" block on the CAR and forward the form to the CAR Originator when the corrective action is complete. For external CARs, the BUYER/SUBCONTRACT SPECIALIST or COGNIZANT MANAGER shall perform this function or have the supplier or Hanford Contractor sign/date the CAR verifying completion.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 16.4 ACTION TO PREVENT RECURRENCE
AND CORRECT ADVERSE EFFECTS

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 16.5 DOCUMENTATION, REPORTING TO MANAGEMENT

PURPOSE:

- a) To reduce the risk of inadequate, inappropriate corrective action.
- b) To reduce the risk of inability to direct corrective action at identified institutional causes or upper management deficiencies.
- c) To prevent organizational isolation of corrective action for problems that have or may have broader implications.

CRITICAL FEATURES:

System for reporting significant problems to responsible upper management, including (in real time):

1. Existence of problem
2. Root cause
3. Proposed preventive action
4. Action implemented.

REQUIREMENT # 1 PROCEDURE NO. PAP 1602 REV 0 PARA 4.2.3, 4.2.5

A QA REPRESENTATIVE (CAR Originator) shall draft a CAR (Exhibit 1) upon identification of a condition that falls into one of the above categories (Paragraph 4.2.1 -- QA Staff), obtain QA SECTION MANAGER'S review (initial/date), and forward to QAD Manager for approval and issuance.

The QAD MANAGER shall report to the Project Sponsor QA Manager (and others, if required by sponsor) as soon as possible but not later than five (5) calendar days from the date that there is a determination of a significant condition adverse to quality.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 16.5 DOCUMENTATION, REPORTING
TO MANAGEMENT

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/YBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: - ... 16.6: Follow-up

PURPOSE:

- a. To reduce the risk that defined corrective action for problems may not be implemented.
- b. To ensure that recurrences of significant problems do not remain undetected.

CRITICAL FEATURES:

- a. System for verifying implementation of preventive action plan.

REQUIREMENT # 1 PROCEDURE NO. PAP 1602 REV 0 PARA 4.4.2

The CAR ORIGINATOR shall verify implementation and completion of the corrective action plan. Verification of corrective action on supplier and Hanford Contractor CARs shall be coordinated with the QC Manager.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 16.6 FOLLOW-UP

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 16.6 FOLLOW-UP

PURPOSE:

- a) To reduce the risk that defined corrective action for problems may not be implemented.
- b) To ensure that recurrences of significant problems do not remain undetected.

CRITICAL FEATURES:

- b) System for evaluating effectiveness of preventive action.

REQUIREMENT # 1 PROCEDURE NO. _____ REV _____ PARA _____

This Critical Feature is not specifically addressed in PNL procedures. The Auditor should ask, "How does management evaluate the effectiveness of preventative actions taken? "If these actions are taken, what is the frequency?"

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 16.6 FOLLOW-UP

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 17.1 DESIGNATION OF DOCUMENTS/DOCUMENT TYPES
DESTINED TO BECOME RECORDS

PURPOSE:

To ensure that personnel know what documents/document types to submit for incorporation in the formal record (the collection or set of individual records for the plant or project) and to define the boundaries of the formal record.

CRITICAL FEATURES:

- a) An approved listing of documents and/or document types that are required to be retained as QA records. (NOTE: May be a computer data base, provided it is readily accessible to organizational units that generate documents.)

REQUIREMENT # 1 PROCEDURE NO. PAP-1701 REV 1 PARA 4.1.1

Records Identification

At the start of the project, the PROJECT MANAGER shall prepare a Project Records List (PRL) identifying the types of records to be generated during project activities.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.1 DESIGNATION OF DOCUMENTS/
DOCUMENT TYPES DESTINED
TO BECOME RECORDS

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.1 DESIGNATION OF DOCUMENTS/DOCUMENT TYPES
DESTINED TO BECOME RECORDS

PURPOSE:

To ensure that personnel know what documents/document types to submit for incorporation in the formal record (the collection or set of individual records for the plant or project) and to define the boundaries of the formal record.

CRITICAL FEATURES:

- a) An approved listing of documents and/or document types that are required to be retained as QA records. (NOTE: May be a computer data base, provided it is readily accessible to organizational units that generate documents.)

REQUIREMENT # 2 PROCEDURE NO. PAP-1701 REV 1 PARA 4.1.3

The PROJECT MANAGER shall obtain the concurrence of the cognizant QA on the PRL, sign and date the PRL and include a copy in project records.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.1 DESIGNATION OF DOCUMENTS/
DOCUMENT TYPES DESTINED
TO BECOME RECORDS

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.1 DESIGNATION OF DOCUMENTS/DOCUMENT TYPES
DESTINED TO BECOME RECORDS

PURPOSE:

To ensure that personnel know what documents/document types to submit for incorporation in the formal record (the collection or set of individual records for the plant or project) and to define the boundaries of the formal record.

CRITICAL FEATURES:

- a) An approved listing of documents and/or document types that are required to be retained as QA records. (NOTE: May be a computer data base, provided it is readily accessible to organizational units that generate documents.)

REQUIREMENT # 3 PROCEDURE NO. OAP-1701 REV 1 PARA 4.1.1

Project - specific documents are listed as Exhibit 1, QAD generated documents.

Note: No verification or response is required for this requirement.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.1 DESIGNATION OF DOCUMENTS/
DOCUMENT TYPES DESTINED
TO BECOME RECORDS

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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| | | | |

PROGRAM ELEMENT: 17.1 DESIGNATION OF DOCUMENTS/DOCUMENT TYPES
DESTINED TO BECOME RECORDS

PURPOSE:

To ensure that personnel know what documents/document types to submit for incorporation in the formal record (the collection or set of individual records for the plant or project) and to define the boundaries of the formal record.

CRITICAL FEATURES:

- a) An approved listing of documents and/or document types that are required to be retained as QA records. (NOTE: May be a computer data base, provided it is readily accessible to organizational units that generate documents.)

REQUIREMENT # 4 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 17.2.1.2

The Project Manager shall determine with the sponsor the need for retention of the test material or sample, and a listing prepared for these items and their corresponding documentation.

Note: Records associated with these test materials or samples fall under the purview of requirements 1, 2, 3 of this Program Element.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.1 DESIGNATION OF DOCUMENTS/
DOCUMENT TYPES DESTINED
TO BECOME RECORDS

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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| _____ | _____ | _____ | |

PROGRAM ELEMENT: 17.1 DESIGNATION OF DOCUMENTS/DOCUMENT TYPES
DESTINED TO BECOME RECORDS

PURPOSE:

To ensure that personnel know what documents/document types to submit for incorporation in the formal record (the collection or set of individual records for the plant or project) and to define the boundaries of the formal record.

CRITICAL FEATURES:

- a) An approved listing of documents and/or document types that are required to be retained as QA records. (NOTE: May be a computer data base, provided it is readily accessible to organizational units that generate documents.)

REQUIREMENT # 5 PROCEDURE NO. PAP-802 REV 0 PARA 4.3

The Project Manager shall identify the test materials and samples to be archived. Sponsor approval of this determination shall be obtained through the Program Manager, as required.

Note: Records associated with these test materials or samples fall under the purview of requirements 1, 2, 3 of the Program Element.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.1 DESIGNATION OF DOCUMENTS/
DOCUMENT TYPES DESTINED
TO BECOME RECORDS

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | OA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.1 DESIGNATION OF DOCUMENTS/DOCUMENT TYPES
DESTINED TO BECOME RECORDS

PURPOSE:

To ensure that personnel know what documents/document types to submit for incorporation in the formal record (the collection or set of individual records for the plant or project) and to define the boundaries of the formal record.

CRITICAL FEATURES:

- b) A system that ensures that organizational units check for existence or record requirements when receiving or generating new documents.

REQUIREMENT # 1 PROCEDURE NO. PAP-1701 REV 1 PARA 4.1.1

At the start of the project, the PROJECT MANAGER shall prepare a Project Records List (PRL) identifying the types of records to be generated during project activities. Exhibit 1, Project Records List - Example, is an example of a PRL and is the format to be used. (*See 17.1 a 1*)

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.1 DESIGNATION OF DOCUMENTS/
DOCUMENT TYPES DESTINED
TO BECOME RECORDS

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.1 DESIGNATION OF DOCUMENTS/DOCUMENT TYPES
DESTINED TO BECOME RECORDS

PURPOSE:

To ensure that personnel know what documents/document types to submit for incorporation in the formal record (the collection or set of individual records for the plant or project) and to define the boundaries of the formal record.

CRITICAL FEATURES:

- b) A system that ensures that organizational units check for existence or record requirements when receiving or generating new documents.

REQUIREMENT # 2 PROCEDURE NO. PAP-1701 REV 1 PARA 4.2.2

The PROJECT RECORDS CUSTODIAN shall prepare a Project File Index (PFI) and necessary subindexes based on the approved PRL.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.1 DESIGNATION OF DOCUMENTS/
DOCUMENT TYPES DESTINED
TO BECOME RECORDS

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet ____ of ____

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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| _____ | _____ | _____ | |

PROGRAM ELEMENT: 17.1 DESIGNATION OF DOCUMENTS/DOCUMENT TYPES
DESTINED TO BECOME RECORDS

PURPOSE:

To ensure that personnel know what documents/document types to submit for incorporation in the formal record (the collection or set of individual records for the plant or project) and to define the boundaries of the formal record.

CRITICAL FEATURES:

- b) A system that ensures that organizational units check for existence or record requirements when receiving or generating new documents.

REQUIREMENT # 3 PROCEDURE NO. PAP-1701 REV 1 PARA 4.3.1

COGNIZANT STAFF shall generate and maintain the records necessary to support their research activities in accordance with the appropriate file index for the work being performed. Project Contributors include PNL research staff as well as support groups such as the QAD and other service organizations.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.1 DESIGNATION OF DOCUMENTS/
DOCUMENT TYPES DESTINED
TO BECOME RECORDS

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND OF COMPLETED DOCUMENTS
PRIOR TO COMPLETION OF RECORD PACKAGES

PURPOSE:

- a) To ensure that the formal record is complete.
- b) To prevent loss or destruction of documents intended to become part of the formal record.
- c) To ensure that records in the formal record are usable.

CRITICAL FEATURES:

- a) Procedures for protecting and keeping track of documents (that are destined to become QA records) while they are still working documents.

REQUIREMENT # 1 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 17.1.2.4

All personnel, as records are generated, shall assure they are protected against damage, deterioration and loss.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND
OF COMPLETED DOCUMENTS PRIOR TO
COMPLETION OF RECORD PACKAGES

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND OF COMPLETED DOCUMENTS
PRIOR TO COMPLETION OF RECORD PACKAGES

PURPOSE:

- a) To ensure that the formal record is complete.
- b) To prevent loss or destruction of documents intended to become part of the formal record.
- c) To ensure that records in the formal record are usable.

CRITICAL FEATURES:

- a) Procedures for protecting and keeping track of documents (that are destined to become QA records) while they are still working documents.

REQUIREMENT # 2 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 17.1.2.5

The Project Records Custodian shall generate an inventory of records within two (2) months after record generation.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND
OF COMPLETED DOCUMENTS PRIOR TO
COMPLETION OF RECORD PACKAGES

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND OF COMPLETED DOCUMENTS PRIOR TO COMPLETION OF RECORD PACKAGES

PURPOSE:

- a) To ensure that the formal record is complete.
- b) To prevent loss or destruction of documents intended to become part of the formal record.
- c) To ensure that records in the formal record are usable.

CRITICAL FEATURES:

- a) Procedures for protecting and keeping track of documents (that are destined to become QA records) while they are still working documents.

REQUIREMENT # 4 PROCEDURE NO. PAP-1704 REV 1 PARA 4.2.1

The PROJECT MANAGER shall determine and document:...

- o Whether Lab Record Books (LRBs) are to be issued by the Technical Information Section directly to research project participants or to the Project Manager for reassignment to individual participants.
- o The name of each LRB Custodian and assigned LRB number.
- o The expected location for each LRB (e.g., office Sigma V/512, lab. Sigma V/510, etc.)
- o The designated LRB Reviewer(s) responsible for reviewing entries (including data) in each LRB.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND
OF COMPLETED DOCUMENTS PRIOR TO
COMPLETION OF RECORD PACKAGES

AUDIT NO. 8701

CRITICAL FEATURE: a).

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND OF COMPLETED DOCUMENTS
PRIOR TO COMPLETION OF RECORD PACKAGES

PURPOSE:

- a) To ensure that the formal record is complete.
- b) To prevent loss or destruction of documents intended to become part of the formal record.
- c) To ensure that records in the formal record are usable.

CRITICAL FEATURES:

- a) Procedures for protecting and keeping track of documents (that are destined to become QA records) while they are still working documents.

REQUIREMENT # 5 PROCEDURE NO. PAP-1704 REV 1 PARA 4.5.1

Lab Record Books (LRBs) shall be stored in metal file cabinets or otherwise protected from damage when not directly in use. Records shall not be left unprotected overnight, holidays, vacations, or weekends.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND
OF COMPLETED DOCUMENTS PRIOR TO
COMPLETION OF RECORD PACKAGES

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND OF COMPLETED DOCUMENTS
PRIOR TO COMPLETION OF RECORD PACKAGES

PURPOSE:

- a) To ensure that the formal record is complete.
- b) To prevent loss or destruction of documents intended to become part of the formal record.
- c) To ensure that records in the formal record are usable.

CRITICAL FEATURES:

- a) Procedures for protecting and keeping track of documents (that are destined to become QA records) while they are still working documents.

REQUIREMENT # 6 **PROCEDURE NO.** OAP-1701 **REV** 1 **PARA** 4.1.4

While in the working (QAD staff files) state, QAD staff shall ensure that the records are protected from damage and loss.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND
OF COMPLETED DOCUMENTS PRIOR TO
COMPLETION OF RECORD PACKAGES

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND OF COMPLETED DOCUMENTS PRIOR TO COMPLETION OF RECORD PACKAGES

PURPOSE:

- a) To ensure that the formal record is complete.
- b) To prevent loss or destruction of documents intended to become part of the formal record.
- c) To ensure that records in the formal record are usable.

CRITICAL FEATURES:

- a) Procedures for protecting and keeping track of documents ^{/samples} (that are destined to become QA records) while they are still working documents ^{/samples}.

REQUIREMENT # 8 PROCEDURE NO. PAP-801 REV 2 PARA 4.3.1

The MATERIAL CUSTODIAN shall store, handle, and protect the test materials and samples within his or her custody.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND
OF COMPLETED DOCUMENTS PRIOR TO
COMPLETION OF RECORD PACKAGES

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND OF COMPLETED DOCUMENTS
PRIOR TO COMPLETION OF RECORD PACKAGES

PURPOSE:

- a) To ensure that the formal record is complete.
- b) To prevent loss or destruction of documents intended to become part of the formal record.
- c) To ensure that records in the formal record are usable.

CRITICAL FEATURES:

- a) Procedures for protecting and keeping track of documents *or samples* (that are destined to become QA records) while they are still working documents *or samples*.

REQUIREMENT # 9 PROCEDURE NO. PAP-802 REV 0 PARA 4.3

The PROJECT MANAGER shall identify the materials to be archived upon sponsor approval.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND
OF COMPLETED DOCUMENTS PRIOR TO
COMPLETION OF RECORD PACKAGES

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND OF COMPLETED DOCUMENTS PRIOR TO COMPLETION OF RECORD PACKAGES

PURPOSE:

- a) To ensure that the formal record is complete.
- b) To prevent loss or destruction of documents intended to become part of the formal record.
- c) To ensure that records in the formal record are usable.

CRITICAL FEATURES:

- b) Procedures for safeguarding and maintaining inventory control of completed documents prior to their transmittal for processing into the formal record.

REQUIREMENT # 1 **PROCEDURE NO.** N/A **REV** N/A **PARA** N/A

What methods are employed by PNL to safeguard and maintain inventory control of completed documents prior to their transmittal for processing into the formal record.

NOTE: Methods should include;

- o Access control
- o Logs or other inventory means

NOTE: This critical feature applies to Research Records, Lab Record Books and QAD Records.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND
OF COMPLETED DOCUMENTS PRIOR TO
COMPLETION OF RECORD PACKAGES

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND OF COMPLETED DOCUMENTS PRIOR TO COMPLETION OF RECORD PACKAGES

PURPOSE:

- a) To ensure that the formal record is complete.
- b) To prevent loss or destruction of documents intended to become part of the formal record.
- c) To ensure that records in the formal record are usable.

CRITICAL FEATURES:

- samples*
- b) Procedures *for* safeguarding and maintaining inventory control of completed documents *prior* to their transmittal for processing into the formal record.

REQUIREMENT # 2 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 17.2.1.2

The PROJECT MANAGER shall determine with the sponsor the need for retention of the identified, controlled test material or sample and classify it as directed by the sponsor into one of the following categories:

- 1) Dispose
- 2) Retain for specified period
- 3) Retain until transmitted to sponsor.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND
OF COMPLETED DOCUMENTS PRIOR TO
COMPLETION OF RECORD PACKAGES

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND OF COMPLETED DOCUMENTS
PRIOR TO COMPLETION OF RECORD PACKAGES

PURPOSE:

- a) To ensure that the formal record is complete.
- b) To prevent loss or destruction of documents intended to become part of the formal record.
- c) To ensure that records in the formal record are usable.

CRITICAL FEATURES:

- (or samples that whose analysis has been completed)*
- b) Procedures for safeguarding and maintaining inventory control of completed documents prior to their transmittal for processing into the formal record.

REQUIREMENT # 3 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 17.2.1.2

The PROJECT MANAGER and MATERIAL CUSTODIAN are responsible for test materials and samples needing to be retained, and must determine environmental controls and handling requirements needed to maintain the item in the order to prevent damage, loss and deterioration.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND
OF COMPLETED DOCUMENTS PRIOR TO
COMPLETION OF RECORD PACKAGES

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet ____ of ____

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND OF COMPLETED DOCUMENTS PRIOR TO COMPLETION OF RECORD PACKAGES

PURPOSE:

- a) To ensure that the formal record is complete.
- b) To prevent loss or destruction of documents intended to become part of the formal record.
- c) To ensure that records in the formal record are usable.

CRITICAL FEATURES:

- (on of samples upon which work has been completed)*
- b) Procedures *for* safeguarding and maintaining inventory control of completed documents prior to their transmittal for processing into the formal record.

REQUIREMENT # 4 PROCEDURE NO. PAP-801 REV 2 PARA 4.1.2

The PROJECT MANGER shall use or specify facilities having the following attributes for material control:

- o Necessary environmental control, special procedures and special equipment for handling, storage, packaging, shipping and presentation to prevent damage loss and/or deterioration by environmental conditions.
- o Means to prevent unauthorized access to stored materials.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND
OF COMPLETED DOCUMENTS PRIOR TO
COMPLETION OF RECORD PACKAGES

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND OF COMPLETED DOCUMENTS PRIOR TO COMPLETION OF RECORD PACKAGES

PURPOSE:

- a) To ensure that the formal record is complete.
- b) To prevent loss or destruction of documents intended to become part of the formal record.
- c) To ensure that records in the formal record are usable.

CRITICAL FEATURES:

- (on of samples upon which necessary work is complete)*
- b) Procedures for safeguarding and maintaining inventory control of completed documents prior to their transmittal for processing into the formal record.

REQUIREMENT # 5 PROCEDURE NO. PAP-801 REV 2 PARA 4.3.1

The MATERIAL CUSTODIAN shall store, handle and protect the materials within his or her custody.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.2 CONTROL OF WORKING DOCUMENTS AND
OF COMPLETED DOCUMENTS PRIOR TO
COMPLETION OF RECORD PACKAGES

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.3 COMPLETED DOCUMENT CHECKING, RECORD AUTHENTICATION/VALIDATION

PURPOSE:

To ensure that documents (or other record materials) incorporated in the record are true (authentic) records of the plan/project, and that the formal record is completed and correct.

CRITICAL FEATURES:

System(s) that make it possible to determine by inspection of any document in the formal record system that the document is authentic (e.g., may be by authorized signature, by evidence properly relating the document to an organization authorized to generate documents of the observed type, etc.)

REQUIREMENT # 1 PROCEDURE NO. PAP-1701 REV 1 PARA 4.3.2

Records shall be considered valid records only if initialed or signed and dated by authorized personnel or otherwise authenticated. This authentication may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization. Records may be originals or reproduced copies.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.3 COMPLETED DOCUMENT CHECKING.
RECORD AUTHENTICATION/VALIDATION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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| _____ | _____ | _____ | |

PROGRAM ELEMENT: 17.3 COMPLETED DOCUMENT CHECKING, RECORD AUTHENTICATION/VALIDATION

PURPOSE:

To ensure that documents (or other record materials) incorporated in the record are true (authentic) records of the plan/project, and that the formal record is completed and correct.

CRITICAL FEATURES:

System(s) that make it possible to determine by inspection of any document in the formal record system that the document is authentic (e.g., may be by authorized signature, by evidence properly relating the document to an organization authorized to generate documents of the observed type, etc.)

REQUIREMENT # 2/3 PROCEDURE NO. PAP-1704 REV 1 PARA 4.6.1

When requested by the PROJECT RECORDS CUSTODIAN, COGNIZANT STAFF shall submit reproducible copies of all Lab Record Book (LRB) pages and supporting documents completed since the last submittal (including the review) to the Project Records Custodian. Each sheet shall be signed, dated and identified with the LRB number and shall have been reviewed by the LRB Reviewer.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.3 COMPLETED DOCUMENT CHECKING.
RECORD AUTHENTICATION/VALIDATION

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.5 TRACEABILITY BETWEEN RECORD AND ITEM/ACTIVITY

PURPOSE:

To ensure that the individual record can be put in correct project context in subsequent use of, or reference to, the formal record, and as a means of providing retrieval access to the body of records associated with particular items or activities.

CRITICAL FEATURES:

Procedures that cause document initiators to enter information (such as task numbers, title, references, initiating entity, etc, as appropriate) on the documents to provide clear identification with the item and/or activity with which the documents are associated.

REQUIREMENT # 1 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 17.1.2.4

All personnel shall assure that all records generated are traceable to the item(s) or activities to which they apply.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.5 TRACEABILITY BETWEEN RECORD
AND ITEM/ACTIVITY

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.5 TRACEABILITY BETWEEN RECORD AND ITEM/ACTIVITY

PURPOSE:

To ensure that the individual record can be put in correct project context in subsequent use of, or reference to, the formal record, and as a means of providing retrieval access to the body of records associated with particular items or activities.

CRITICAL FEATURES:

Procedures that cause document initiators to enter information (such as task numbers, title, references, initiating entity, etc, as appropriate) on the documents to provide clear identification with the item and/or activity with which the documents are associated.

REQUIREMENT # 2 PROCEDURE NO. PAP-1701 REV 1 PARA 4.3.1

COGNIZANT STAFF shall generate and maintain the records necessary to support their research activities in accordance with the appropriate file index for the work being performed. Project Contributors include PNL research staff as well as support groups such as the QAD and other service organizations.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.5 TRACEABILITY BETWEEN RECORD
AND ITEM/ACTIVITY

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.5 TRACEABILITY BETWEEN RECORD AND ITEM/ACTIVITY

PURPOSE:

To ensure that the individual record can be put in correct project context in subsequent use of, or reference to, the formal record, and as a means of providing retrieval access to the body of records associated with particular items or activities.

CRITICAL FEATURES:

Procedures that cause document initiators to enter information (such as task numbers, title, references, initiating entity, etc, as appropriate) on the documents to provide clear identification with the item and/or activity with which the documents are associated.

REQUIREMENT # 3 PROCEDURE NO. PAP-1701 REV 1 PARA 4.6.1

The PROJECT RECORDS CUSTODIAN shall assure each record is traceable to the item or activity to which it applies by recording in the upper right corner of the document the QA Plan No. and Revision, the index identification number and the alpha-numeric file classification (i.e., major, group, and subgroup classification).

NOTE: This requirement applies to records prior to transfer to storage.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.5 TRACEABILITY BETWEEN RECORD
AND ITEM/ACTIVITY

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.5 TRACEABILITY BETWEEN RECORD AND ITEM/ACTIVITY

PURPOSE:

To ensure that the individual record can be put in correct project context in subsequent use of, or reference to, the formal record, and as a means of providing retrieval access to the body of records associated with particular items or activities.

CRITICAL FEATURES:

Procedures that cause document initiators to enter information (such as task numbers, title, references, initiating entity, etc, as appropriate) on the documents to provide clear identification with the item and/or activity with which the documents are associated.

REQUIREMENT # 4 PROCEDURE NO. PAP-1704 REV 1 PARA 4.2.3

The LAB CUSTODIAN shall:

- o Identify the project number and title and applicable task/subtask numbers, if appropriate.
- o Describe the work covered in the first entry in the book and, as applicable, the name of the sponsor, work order/statement of work number and objectives of the work.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.5 TRACEABILITY BETWEEN RECORD
AND ITEM/ACTIVITY

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.5 TRACEABILITY BETWEEN RECORD AND ITEM/ACTIVITY

PURPOSE:

To ensure that the individual record can be put in correct project context in subsequent use of, or reference to, the formal record, and as a means of providing retrieval access to the body of records associated with particular items or activities.

CRITICAL FEATURES:

Procedures that cause document initiators to enter information (such as task numbers, title, references, initiating entity, etc, as appropriate) on the documents, to provide clear identification with the item and/or activity with which the documents are associated.

or samples
GR

REQUIREMENT # 5 PROCEDURE NO. PNL-MA-60 REV 3/22/85 PARA 4.3.1

The MATERIAL CUSTODIAN shall identify the materials or samples within his or her custody.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.5 TRACEABILITY BETWEEN RECORD
AND ITEM/ACTIVITY

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 17.7 CONTROLS OVER CORRECTIONS TO THE FORMAL RECORD

PURPOSE:

- a) To prevent the use of information from the record that has been determined to be in error.
- b) To prevent unauthorized or fraudulent manipulation of information in the formal record.
- c) To protect the integrity and credibility of the formal record.

CRITICAL FEATURES:

- a) System(s) for preparing, reviewing, approving and issuing corrections to documents that have already been incorporated into the formal record.

REQUIREMENT # 1 PROCEDURE NO. N/A REV N/A PARA N/A

What Document Control System does PNL employ for preparation, review, approval, and issuance of corrections to documents that have already been incorporated into the formal record?

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.7 CONTROLS OVER CORRECTIONS
TO THE FORMAL RECORD

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.7 CONTROLS OVER CORRECTIONS TO THE FORMAL RECORD

PURPOSE:

- a) To prevent the use of information from the record that has been determined to be in error.
- b) To prevent unauthorized or fraudulent manipulation of information in the formal record.
- c) To protect the integrity and credibility of the formal record.

CRITICAL FEATURES:

- b) System for ensuring that record retrieval will produce the corrected version of any document to which corrections have been made after incorporation of the document in the formal record.

REQUIREMENT # N/A PROCEDURE NO. _____ REV _____ PARA _____

This Critical Feature is not addressed in the procedures.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.7 CONTROLS OVER CORRECTIONS
TO THE FORMAL RECORD

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.7 CONTROLS OVER CORRECTIONS TO THE FORMAL RECORD

PURPOSE:

- a) To prevent the use of information from the record that has been determined to be in error.
- b) To prevent unauthorized or fraudulent manipulation of information in the formal record.
- c) To protect the integrity and credibility of the formal record.

CRITICAL FEATURES:

- c) A system that ensures that superseded (pre-correction) versions of documents that have been corrected cannot be mistaken for the correct version if they are retrieved.

REQUIREMENT # N/A PROCEDURE NO. _____ REV _____ PARA _____

This Critical Feature is not addressed in the procedures.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.7 CONTROLS OVER CORRECTIONS
TO THE FORMAL RECORD

AUDIT NO. 8701

CRITICAL FEATURE: c)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.8 RECORD SUBMITTAL/RECEIPT CONTROLS

PURPOSE:

- a) To ensure that records the submitting entity believes are being transmitted are in fact transmitted.
- b) To ensure that submitted documents are received by the record processing organization.

CRITICAL FEATURES:

- a) A system that ensures that the submitting entity knows what documents it has submitted for record processing.

REQUIREMENT # 1 PROCEDURE NO. PAP-1701 REV 1 PARA 4.6.3

Upon approval by the PNL Records Specialist, the original and two copies of the transfer form shall be returned to the Project Records Custodian. The original and two copies of the form shall be placed in the lowest numbered box of the group.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.8 RECORD SUBMITTAL/RECEIPT CONTROLS

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.8 RECORD SUBMITTAL/RECEIPT CONTROLS

PURPOSE:

- a) To ensure that records the submitting entity believes are being transmitted are in fact transmitted.
- b) To ensure that submitted documents are received by the record processing organization.

CRITICAL FEATURES:

- a) A system that ensures that the submitting entity knows what documents it has submitted for record processing.

REQUIREMENT # 4 PROCEDURE NO. RCP-1704 REV 0 PARA 5.3

TURNOVER TO SPONSOR

On ensuring that the turnover package is complete, the PROJECT MANAGER shall sign the transmittal letter, and the records shall be delivered to the sponsor in accordance with shipping instructions provided by the sponsor. The recipient of the records shall be requested to acknowledge receipt of the records.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.8 RECORD SUBMITTAL/RECEIPT CONTROLS

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 17.8 RECORD SUBMITTAL/RECEIPT CONTROLS

PURPOSE:

- a) To ensure that records the submitting entity believes are being transmitted are in fact transmitted.
- b) To ensure that submitted documents are received by the record processing organization.

CRITICAL FEATURES:

- a) A system that ensures that the submitting entity knows what documents it has submitted for record processing.

REQUIREMENT # 5 PROCEDURE NO. PAP-801 REV 2 PARA 4.7.1

The COGNIZANT STAFF MEMBER is responsible to assure that the material(s) or sample(s) to be shipped to the sponsor shall be identified and that any other documents pertinent to the materials/samples shall accompany the shipment.

AUDIT CHECKLIST PART C-1 DA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.8 RECORD SUBMITTAL/RECEIPT CONTROLS

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.8 RECORD SUBMITTAL/RECEIPT CONTROLS

PURPOSE:

- a) To ensure that records the submitting entity believes are being transmitted are in fact transmitted.
- b) To ensure that submitted documents are received by the record processing organization.

CRITICAL FEATURES:

- b) A system that ensures that the record processing activity verifies that it received the documents the submitting entity transmitted.

REQUIREMENT # 1 PROCEDURE NO. RCP-1702 REV 0 PARA 5.0

The records received at the PNL Records Center from research projects shall be inspected to verify that they agree with the transfer documents and then catalogued for storage. Duplicate copies requested by the project originator shall be made at this time. The records shall then be placed in storage containers in project file order by record category as identified on the Master File Index.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.8 RECORD SUBMITTAL/RECEIPT CONTROLS

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.8 RECORD SUBMITTAL/RECEIPT CONTROLS

PURPOSE:

- a) To ensure that records the submitting entity believes are being transmitted are in fact transmitted.
- b) To ensure that submitted documents are received by the record processing organization.

CRITICAL FEATURES:

- b) A system that ensures that the record processing activity verifies that it received the documents the submitting entity transmitted.

REQUIREMENT # 2 PROCEDURE NO. RCP-1702 REV 0 PARA 5.1

Records received from the Research Project Records Custodian shall be examined to verify that they agree with the Records Transfer Form, prepared in accordance with PAP-1703, Records Transmittal to PNL Records Center. Any discrepancies shall be resolved with the Research Project Records Custodian, according to requirements specified in PAP-1703, Records Transmittal to PNL Records Center. Any discrepancies shall be resolved with the Research Project Records Custodian.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.8 RECORD SUBMITTAL/RECEIPT CONTROLS

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.8 RECORD SUBMITTAL/RECEIPT CONTROLS

PURPOSE:

- a) To ensure that records the submitting entity believes are being transmitted are in fact transmitted.
- b) To ensure that submitted documents are received by the record processing organization.

CRITICAL FEATURES:

- c) A system for the record processing activity to confirm receipt of the transmitted documents, or to apprise the submitting entity of any discrepancies between submittal manifest and contents of the submitted package.

REQUIREMENT # 2 PROCEDURE NO. PAP-1701 REV 1 PARA 4.5.1

On receiving completed records from Project Contributors, the PROJECT RECORDS CUSTODIAN shall inspect the records for legibility, traceability to the item or activity to which they apply, and that they have been validated (i.e., initialed and dated, or signed and dated by an authorized person), verify that the transferred records match the corresponding PFI or subindex and ensure that any discrepancies are corrected.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.8 RECORD SUBMITTAL/RECEIPT CONTROLS
CRITICAL FEATURE: c)

AUDIT NO. 8701
Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 17.8 RECORD SUBMITTAL/RECEIPT CONTROLS

PURPOSE:

- a) To ensure that records the submitting entity believes are being transmitted are in fact transmitted.
- b) To ensure that submitted documents are received by the record processing organization.

CRITICAL FEATURES:

- c) A system for the record processing activity to confirm receipt of the transmitted documents, or to apprise the submitting entity of any discrepancies between submittal manifest and contents of the submitted package.

REQUIREMENT # 3 PROCEDURE NO. PAP-1701 REV 1 PARA 4.5.2

Any record judged by the PROJECT RECORDS CUSTODIAN to be deficient shall be returned to the Originator or authorized individual for correction.

- a. The Originator shall obtain any needed data, reviews or signatures.
- b. Corrected records shall be returned to the Project Records Custodian.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 17.8 RECORD SUBMITTAL/RECEIPT CONTROLS

AUDIT NO. 8701

CRITICAL FEATURE: c)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 18.1 AUDIT SCHEDULING

PURPOSE:

To ensure that the audit program provides project management timely, comprehensive visibility of QA program effectiveness.

CRITICAL FEATURES:

- a) A system for ensuring that all elements of the QA program are audited at regular intervals. (NOTE: All QA program elements and all project activities within the scope of the project QA program.)

REQUIREMENT # 1 PROCEDURE NO. OAP 1801 REV 2 PARA 4.1.2

- 4.1.2 The QA&A MANAGER shall prepare and approve an audit schedule covering a six-month period. QA Audits shall be scheduled in a manner to provide coverage and coordination with ongoing Quality Assurance program activities.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 18.1 AUDIT SCHEDULING

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 18.1 AUDIT SCHEDULING

PURPOSE:

To ensure that the audit program provides project management timely, comprehensive visibility of QA program effectiveness.

CRITICAL FEATURES:

- a) A system for ensuring that all elements of the QA program are audited at regular intervals. (NOTE: All QA program elements and all project activities within the scope of the project QA program.)

REQUIREMENT # 2 PROCEDURE NO. OAP 1801 REV 2 PARA 4.1.3

4.1.3 The QAS&A MANAGER shall also consider and include as appropriate generic audits which include:

- o Activities (e.g., design reviews, peer reviews)
- o Organizations (e.g., Records, Procurement, Subcontracts)
- o Projects (both sponsor required and non-sponsor required)
- o Job titles (e.g., Section Mangers, Records Specialists)
- o Laboratories (e.g., all laboratories in 329 Building, all laboratories in EPD, all analytical labs).

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 18.1 AUDIT SCHEDULING

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 18.1 AUDIT SCHEDULING

PURPOSE:

To ensure that the audit program provides project management timely, comprehensive visibility of QA program effectiveness.

CRITICAL FEATURES:

- b) A system that ensures the audit schedule is accomplished, and that provides documented rationale for justified changes to, or deviations from, the approved audit schedule.

REQUIREMENT # 1 PROCEDURE NO. OAP 1801 REV 2 PARA 4.1.2

The audit schedule shall be reviewed and updated approximately every three months. A copy shall be forwarded to the QAD files. In addition, when required, audit schedules and audit schedule revisions shall be submitted to the sponsor.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 18.1 AUDIT SCHEDULING

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 18.2 AUDIT PREPARATION, PLANNING, TEAM SELECTION

PURPOSE:

To ensure adequacy of coverage and validity of the audit process.

CRITICAL FEATURES:

- a) A system for audit team selection that ensures that the composite experience and capabilities represented on the team are commensurate with the nature of the activities to be audited.

REQUIREMENT # ~~1~~
2 PROCEDURE NO. OAP 1801 REV 2 PARA 4.2.4

- 4.2.4 The LEAD AUDITOR shall make a statement in the audit plan that the assigned personnel have experience commensurate with the scope, complexity or special nature of the activities to be audited, and have received the orientation and training required in QAP-204 (QA Audit Personnel Qualification).

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 18.2 AUDIT PREPARATION, PLANNING,
TEAM SELECTION

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 18.2 AUDIT PREPARATION, PLANNING, TEAM SELECTION

PURPOSE:

To ensure adequacy of coverage and validity of the audit process.

CRITICAL FEATURES:

- b) A system for audit preparation that includes adequate research into relevant historical information and ongoing work in the affected activities to ensure full coverage of applicable QA program implementation.

REQUIREMENT # 1 PROCEDURE NO. OAP 1801 REV 2 PARA 4.3.1

- 4.3.1 Prior to initiating an audit, the LEAD AUDITOR shall review the QA Plan to determine sponsor requirements and contact the appropriate Quality Engineers (QEs) to determine the present work being performed, any changes in the scope or tasks, and the applicable QA requirements. If necessary, cognizant managers may also be contacted. During the review, the LEAD AUDITOR will assess the need for an audit, and the impact of nonperformance, based on past audits and level of task activities.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 18.2 AUDIT PREPARATION, PLANNING,
TEAM SELECTION

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 18.2 AUDIT PREPARATION, PLANNING, TEAM SELECTION

PURPOSE:

To ensure adequacy of coverage and validity of the audit process.

CRITICAL FEATURES:

- b) A system for audit preparation that includes adequate research into relevant historical information and ongoing work in the affected activities to ensure full coverage of applicable QA program implementation.

REQUIREMENT # 2 PROCEDURE NO. OAP 1801 REV 2 PARA 4.3.4

- 4.3.4 In preparing for an audit, the LEAD AUDITOR shall examine nonconformance reports, surveillance reports, deficiency reports, and previous audit reports to identify areas of concern.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 18.2 AUDIT PREPARATION, PLANNING,
TEAM SELECTION

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐
PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐
EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 18.2 AUDIT PREPARATION, PLANNING, TEAM SELECTION

PURPOSE:

To ensure adequacy of coverage and validity of the audit process.

CRITICAL FEATURES:

- c) A system for ensuring that audit team members are thoroughly familiar with what they are to audit and what kinds of evidence they must examine.

REQUIREMENT # 1 PROCEDURE NO. QAP 1801 REV 2 PARA 4.2.3

4.2.3 Prior to the audit, the LEAD AUDITOR shall provide orientation and training to assigned personnel in accordance with QAP-204 (QA Audit Personnel Qualification).

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 18.2 AUDIT PREPARATION, PLANNING,
TEAM SELECTION

AUDIT NO. 8701

CRITICAL FEATURE: c)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | OA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 18.3 AUDIT PERFORMANCE, DOCUMENTATION

PURPOSE:

To ensure competent examination and evaluation of evidence, and to ensure the ability to reconstruct the audit process and conclusions.

CRITICAL FEATURES:

- b) Comprehensive checklists with definitive questions.

REQUIREMENT # 1 PROCEDURE NO. OAP 1801 REV 2 PARA 4.4.1

4.4 AUDIT CHECKLIST OR PROCEDURE

- 4.4.1 Elements selected for audit shall be evaluated against requirements specified in procedures or checklists. The LEAD AUDITOR shall designate which written procedure or checklist shall be used as a basis for the audit.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 18.3 AUDIT PERFORMANCE, DOCUMENTATION

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet **of**

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 18.3 AUDIT PERFORMANCE, DOCUMENTATION

PURPOSE:

To ensure competent examination and evaluation of evidence, and to ensure the ability to reconstruct the audit process and conclusions.

CRITICAL FEATURES:

- b) Comprehensive checklists with definitive questions.

REQUIREMENT # 2 PROCEDURE NO. OAP 1801 REV 2 PARA 4.4.2

- 4.4.2 When the audit is based on written procedures or a previously prepared checklist, the LEAD AUDITOR shall assure that the revision being used is appropriate for the time frame of the work being examined.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 18.3 AUDIT PERFORMANCE, DOCUMENTATION

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 18.3 AUDIT PERFORMANCE, DOCUMENTATION

PURPOSE:

To ensure competent examination and evaluation of evidence, and to ensure the ability to reconstruct the audit process and conclusions.

CRITICAL FEATURES:

- b) Comprehensive checklists with definitive questions.

REQUIREMENT # 3 PROCEDURE NO. OAP 1801 REV 2 PARA 4.4.3

- 4.4.3 Each set of audit checklist questions shall have a cover sheet containing: audit title, audit number, names of team members, and the dated signatures of the LEAD AUDITOR and participating AUDITORS. In addition, the audit checklist questions shall be prepared before the audit and reviewed for adequacy by the LEAD AUDITOR. This review shall be indicated on the checklist cover sheet.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 18.3 AUDIT PERFORMANCE, DOCUMENTATION

AUDIT NO. 8701

CRITICAL FEATURE: b)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 18.3 AUDIT PERFORMANCE, DOCUMENTATION

PURPOSE:

To ensure competent examination and evaluation of evidence, and to ensure the ability to reconstruct the audit process and conclusions.

CRITICAL FEATURES:

- c) Clearly defined groundrules for interpretation and evaluation of evidence.

REQUIREMENT # 1 PROCEDURE NO. OAP 1801 REV 2 PARA 4.7.1

AUDIT REPORT PREPARATION

- 4.7.1 The LEAD AUDITOR shall review the audit results and notes and use judgment in deciding which findings to include in the audit report as adverse findings and observations.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 18.3 AUDIT PERFORMANCE, DOCUMENTATION

AUDIT NO. 8701

CRITICAL FEATURE: c)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

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PROGRAM ELEMENT: 18.4 AUDIT REPORTING

PURPOSE:

To inform project management of QA program effectiveness, provide a basis for corrective action or program improvement, and ensure a credible formal record of QA audit results.

CRITICAL FEATURES:

Reporting system and groundrules that ensure objective statement of audit results and the bases for audit conclusions.

REQUIREMENT # 1 PROCEDURE NO. OAP 1801 REV 2 PARA 4.7.2.1

4.7.2.1 The audit report shall consist of a Audit Cover Sheet over a memorandum to the audited manager. The memo shall include paragraphs covering Introduction, Summary of Results (Executive Summary) and Need for Response and Closure; and shall provide detailed descriptions of each finding or observation as documented on the enclosed AFS or AOS.

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 18.4 AUDIT REPORTING

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 18.5 RESOLUTION OF, CORRECTIVE ACTION FOR, ADVERSE FINDINGS

PURPOSE:

To ensure effective QA program elements/control systems.

CRITICAL FEATURES:

A system for resolution of adverse audit findings that ensures timely, meaningful corrective action.

REQUIREMENT # 1 PROCEDURE NO. OAP 1801 REV 2 PARA 4.7.2

4.7.2.3 Documentation of CORRECTIVE ACTION shall include:

- o The identification of the root cause of each finding and evaluation of the impact of the findings upon completed work
- o A check/verification to assure that other areas/items that might have similar problems have been examined
- o The action taken to correct the problems identified in the Audit Report as well as those discovered during the check of other areas/items
- o The identification of what action will be taken to prevent future occurrences
- o The person responsible and the completion date for each item.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 18.5 RESOLUTION OF, CORRECTIVE ACTION
FOR, ADVERSE FINDINGS

AUDIT NO. 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 18.6 AUDIT FOLLOW-UP

PURPOSE:

- a) To reduce the risk that project decisions may be made, or actions taken, based on the belief that promised (and accepted) preventive actions are in place, when in fact they are not.
- b) To reduce the risk that management will believe a recognized significant problem has been eliminated when, in fact, it is recurring because the preventive action was not effective.

CRITICAL FEATURES:

- a) A formal system for verifying that approved corrective action for adverse audit findings is implemented in accordance with commitments.

REQUIREMENT # 1 PROCEDURE NO. OAP 1801 REV 2 PARA 4.11.3

4.11.3 The LEAD AUDITOR shall:

- o Assure a tracking system for audit findings is established so that all findings are appropriately addressed and a data base is provided to trend audit findings
- o Track corrective action due dates
- o Send a copy of the Audit Corrective Action Response to the QAD files and if not already done, route an informational copy to the QAD Manager, Quality Engineering Manager, QC Manager, and cognizant Quality Engineer
- o Schedule follow-up audit or request surveillance through the QE Manager, as appropriate, for any areas of significant noncompliance (findings)
- o Report to the QAS&A Manager any areas of recurring noncompliance
- o Record confirmation of completion of corrective actions by signing and dating the original Audit Finding Sheet or Audit Observation Sheet in the lower right hand corner. Send completed copies of AFSs and AOSs to the QAD Audit file. Originals shall be sent to the Project/Line Manager for placement in their record files.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 18.6 AUDIT FOLLOW-UP

AUDIT NO. 8701

CRITICAL FEATURE: a)

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES:

AUDIT CHECKLIST PART C-1 QA PROGRAM IMPLEMENTATION

| SUBTEAM | CAP/WBS | QA PLAN | AUDIT NO. <u>8701</u> |
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PROGRAM ELEMENT: 18.7 AUDIT DOCUMENTATION/RECORDS

PURPOSE:

To ensure the ability to reconstruct the rationale upon which audit conclusions are based and to reach independent conclusions as to the effectiveness of the audit program.

CRITICAL FEATURES:

A system for verifying that the required items of audit documentation are submitted for QA record processing.

REQUIREMENT # 1 PROCEDURE NO. OAP 1801 REV 2 PARA 4.13.3

4.13.3 The original Audit Report and original response correspondence shall be kept by the auditee and filed as project records in accordance with PAP-1701 and PAP-1702.

AUDIT CHECKLIST PART C-1 OA PROGRAM IMPLEMENTATION

PROGRAM ELEMENT: 18.7 AUDIT DOCUMENTATION/RECORDS

AUDIT NO: 8701

Sheet of

QUESTIONS:

- 1) Do the contacted personnel know and understand the requirement? YES ☐ NO ☐

PERSONNEL INTERVIEWED:

- 2) Is the activity complying with the requirement? YES ☐ NO ☐

EVIDENCE EXAMINED:

DISCREPANCIES: