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QAP NO. APC-011 REV. 0

RETURN TO REGULATORY CENTRAL FILES
ROOM 016

COBRA-SFS MAINTENANCE QA PLAN

D. R. Rector

March 1987

RETURN TO REGULATORY CENTRAL FILES
ROOM 016

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Pacific Northwest Laboratory
Richland, Washington 99352

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PREFACE

This QA Plan identifies the procedures which shall be used in transmitting, controlling and maintaining COBRA-SFS and supporting computer programs. The COBRA-SFS code is designed to perform thermal-hydraulic analysis of spent nuclear fuel storage systems and other generic heat transfer/fluid mechanic systems.

The QA Plan is outlined in form PAP-70-205, Exhibit 1, which is presented in Appendix A. This form identifies the key personnel, applicable sections from the PNL QA Manual (PNL-MA-70) and PNL Administrative Procedures (PAPs).

The applicable Software Control Procedures (SCPs) (Appendix B) for control and maintenance of the COBRA-SFS computer code are:

- SCP-70-312, Determination of Software Requirements
- SCP-70-314, Software Configuration Management
- SCP-70-315, Conversion Testing, Verification and/or Validation of Software
- SCP-70-317, Transfer of Software, Data and/or Documentation

The applicability of SCP procedures are determined by the requirements of procedure SCP-70-312, Exhibits 1 and 2 which are contained in Appendix C.

Copies of supporting PNL QA Manual sections and PAPs that are called out in the applicable SCPs are provided in Appendices D and E, respectively.

APPENDIX A

PNL ADMINISTRATIVE PROCEDURE 205, EXHIBIT 1

PNL-MA-70 QA PLAN

PROJECT IMPACT LEVEL II

TITLE: QA Plan for COBRA-SFS Computer Code Maintenance

SCOPE: This plan identifies the procedures which shall be used in transmitting, controlling and maintaining the COBRA-SFS and supporting computer programs. The COBRA-SFS code is designed to perform thermal-hydraulic analysis of spent nuclear fuel storage systems.

CLIENT: U. S. Department of Energy (CSFM-PO)

AUTHORIZING DOCUMENT: Code Evaluation and Qualification Project Plan (10557)

QA REQUIREMENT SPECIFICATION(S):

[x] ANSI/ASME NQA-1 as delineated in PNL-MA-70

[ ] Other

Impact Level I and II WBS element activities shall comply with the applicable requirements, as appropriate for the work being performed, in Parts 1 and 3 of PNL-MA-70. Impact Level III activities shall comply with the GPS Standards located in Part 2 of PNL-MA-70. This QA Plan also identifies client QA requirements, if applicable, and any client imposed exclusions or limitations to PNL procedure requirements. If other quality-related activities are later performed, the appropriate PNL-MA-70 requirements and procedures shall be applied, unless specifically excluded.

CONCURRENCES AND APPROVAL:

D. R. Rector — 9/1/87
Cognizant Manager (Concurrence) — Date

Quality Engineering (Concurrence) D.E. Ryder — Date

Line Manager (Approval) — Date

QA PROGRAM/ORGANIZATION:

Department Manager: Energy Sciences/B. M. Johnson
Section Manager: Fluid and Thermal Science/C. W. Stewart
Project Manager: D. R. Rector
Code Custodian: D. R. Rector
Records Custodian: D. R. Rector
Quality Engineer: V. C. Lauhala

IMPACT LEVEL:

All items are Impact Level II

SPECIAL CLIENT REQUIREMENTS:

A. Covered by Part(s) 1 and/or 3 of PNL-MA-70

Client Requirements	Where Covered
None	

SPECIAL CLIENT REQUIREMENTS: (Continued)

B. Not covered by Part(s) 1 and/or 3 of PNL-MA-70

None.

C. Client required exclusions or limitations of procedure applicability

None.

OTHER REQUIREMENTS, DIRECTION OR PLANNING:

Refer to SCP-70-312, Exhibit 1, Section VII.

When the project is closed out, all technical records shall be transferred to the PNL Records Center.

APPENDIX B

APPLICABLE SOFTWARE CONTROL PROCEDURES

CONTROLLED DOCUMENT
COPY NO. 000482

SOFTWARE CONTROL PROCEDURES

TITLE: SCP-70-312, DETERMINATION OF SOFTWARE REQUIREMENTS

1.0 APPLICABILITY

This is the initial procedure for addressing software quality assurance, and specifies requirements for:

- software design, development, documentation, review, control, testing and use
- control of data used as input to software
- transfer of software, data and/or documentation to and from the research project.

Details of applicability shall be determined by research project planning documents, sponsor requirements, and intended end-use of software.

This procedure applies to all software, with the exception of software used as part of measuring and test equipment (M&TE) which is covered by a separate procedure, software encompassed by a technical procedure that prescribes methods for data acquisition, word processing software, and operating system software.

This procedure applies when Impact Level I or II have been determined in accordance with PAP-70-208.

2.0 DEFINITIONS

This section contains definitions that are common to two or more software control procedures.

2.1 Acquired software and/or design documentation - Software and/or design documentation obtained by procurement or transfer from outside the research project.

2.2 Application - See application run.

2.3 Application run - Use of software to perform calculations or to manipulate data. Same as application.

2.4 Backup copy - A copy of a data file, software, etc., on magnetic media or as a computer listing that is retained in the event that the original copy is destroyed or lost.

2.5 Benchmarking - A type of verification in which a test problem (including input and output results) is used to assure correct model operation or to compare software.

Concurrence	Date	Approved	Date
N/A		N B Clark	9/5/86
Prepared by	**Date**	**QAD Concurrence**	**Date**
J A Mahaffey	7/23/86	C E Hughey	7/23/86

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SCP-70-312	0	OCT 1 1986	1	12

2.6 Class determination - Designation of software into a category. The selection of a category in turn determines other requirements.

2.7 Code - See software.

2.8 Code custodian - A person designated to be responsible for accomplishing the actions required for configuration management; this individual is generally the main point of contact and authority for a given computer code.

2.9 Computer model - Engineering/scientific software and data.

2.10 Configuration management - 1. A system for orderly control of software, including methods used for labeling, changing, and storing software and its associated documentation. 2. The systematic evaluation, coordination, approval or disapproval, and implementation of all approved changes in an item of software after establishment of its configuration management (taken from DOD-STD-480A).

2.11 Conversion testing - Testing performed to assure that calculated results obtained with software installed on a specific computer are consistent with results obtained on the computer on which the software was originally developed and tested.

2.12 Data - 1. Representation of facts/concepts in a formalized manner suitable for communication, interpretation or processing by human or automatic means. 2. Any representation such as characters or analog quantities to which meaning is or might be reassigned. 3. Same as input data, numeric data, output data.

2.13 Data base - A logically unified collection of information stored on magnetic media and maintained by a research project. Within the SCP series, a flat (sequential) file or a binary worksheet (e.g., from SAS or MINITAB) containing a collection of information in a fixed configuration is considered a data base when it is used as the information base for a research project.

2.14 Data base software - Software that handles storage and retrieval of information in a data base. This software is often known as a data base management system (DBMS). Analytical software (e.g., SAS or MINITAB) is regarded as data base software when it is used to manage a data base.

2.15 Data base steward - A person designated to be responsible for accomplishing the actions required for configuration management of a data base.

2.16 Deficiency - Failure to develop, document or implement effectively any applicable element of the QA program or project activity established by mutual agreement with the sponsor, or failure to follow established procedures.

2.17 Design documentation - 1. For engineering/scientific software, documentation of software design that includes a description of mathematical models and numerical methods, and a user's manual. 2. For support software, documentation of software that includes at a minimum a user's manual.

2.18 Design input - 1. Input to the software development process, including bases for software design, functional requirements, performance requirements, regulatory requirements, and codes and standards (taken from ANSI/ASME NQA-1-1983, Supplement 3S-1). 2. Also termed "software requirements specifications:" functions, performances, design constraints and attributes of software and external interfaces (taken from IEEE std 730-1984).

2.19 Documentation - Design documentation and exhibits, memos and/or other information used to assure traceability and reproducibility of software development, review, control, testing and use.

2.20 Engineering/scientific software - Software that reads input data, computes results and provides output calculations for use in performing an analysis or making an inference. Engineering/scientific software may be transferred from outside PNL or outside the research project, or it may be developed at PNL. Transferred software may be used as acquired, or it may be modified at PNL. (NOTE: Does not include system maintained software, such as LOTUS 1-2-3, RS/1, SAS, or DISSPLA, or command files written to utilize such software.)

2.21 Final Internal Development Review (FIDR) - A formal review process that compares modified or developed engineering/scientific software and its documentation to its design input and design documentation requirements, evaluates the technical validity of the software, and approves software for configuration control and verification and/or validation.

2.22 Hard copy - A computer-produced copy of information in human-readable form on paper or microfiche (as opposed to a copy on magnetic media in computer-readable form).

2.23 Incident - Any deviation from the planned or expected behavior of an activity or operation; or a course of events which has or may have a significant programmatic, safety, health, or environmental impact. Significant programmatic impacts include those associated with reliability, cost, schedule, data loss, or questions of data validity or analysis.

2.24 Independent technical review (ITR) - A documented critical review by qualified independent personnel to provide assurance that information is correct and satisfactory.

2.25 Internal testing - Informal testing of software that is performed during the development process. Internal testing does not replace verification but may be used to support the verification process.

2.26 Magnetic media - Tapes, discs or diskettes used to record and store information in computer-readable form.

2.27 Operating system software - A collection of software remaining permanently on a computer to provide overall coordination and control of the operation of the hardware. This collection includes compilers, link editors and similar software.

2.28 PAP - Acronym for PNL Administrative Procedure.

2.29 Project manager - A person designated as the manager of a research project. The term project manager also refers to those persons designated by the project manager to act on his/her behalf for specific activities.

2.30 Production software - Software for which the detailed design can be prespecified to a level of detail acceptable for development (as opposed to research software).

2.31 Program - See software.

2.32 QAD - Acronym for Quality Assurance Department.

2.33 Research project planning documents - Documents that specify agreements between PNL and a sponsor regarding the nature of work to be performed in a research project. Examples of these documents are the Project Management Plan (PMP), the Technical Program Plan (TPP), the Quality Assurance Plan (QA Plan), the Statement of Work (SOW), and the Field Task Proposal/Agreement (FTP/A).

2.34 Research software - Software for which the detailed design is being researched in the software development process, and for which comprehensive, accurate prespecification of design detail usually is not possible (as opposed to production software).

2.35 SCP - Acronym for software control procedure.

2.36 Secure storage - Controlled access, limited to individuals that are authorized for specific purposes.

2.37 Software - A sequence of instructions suitable for processing by a computer. Same as program, code.

2.38 Software development - The process by which new software (or a software segment) is created, including modification of the logic of existing software.

2.39 Stream of commands - A sequence of instructions executing system maintained software that is supplied by the user for an application run.

2.40 System maintained software - Software that is installed and maintained at the computer system level rather than at the user level, but that is peripheral to the operation of the hardware (e.g., commercial software such as LOTUS 1-2-3, RS/1, SAS, or DISSPLA).

2.41 Support software - 1. Software that may be easily and exactly verified, and that performs a simple function such as conversion of units, change in data format or plotting of data in support of engineering/scientific or system maintained software. 2. A stream of commands or sequence of streams of commands executed to utilize system maintained software, in which the system maintained software generates reportable results.

2.42 User's manual - Documentation of software that supplies information to the user to allow preparation of input and understanding of format and/or content of output.

2.43 Validation - 1. A demonstration that a computer model (data and software) adequately describes physical reality over the range of variables of interest. 2. Assurance that a model as embodied in a computer code is a correct representation of the process or system for which it is intended (taken from NUREG-0856).

2.44 Verification - 1. A demonstration that software correctly solves mathematical equations and performs the data processing it was designed to perform. 2. Assurance that a computer code correctly performs operations specified in a numerical model (taken from NUREG-0856).

2.45 Version - An item of software or documentation that is identifiably different from the original item.

3.0 RESPONSIBLE STAFF

Staff with responsibilities for implementing this procedure are:

- Project Manager
- Preparer of the Software Requirements Form

4.0 PROCEDURE

4.1 Introduction

4.1.1 Relationship of SCPs to NQA-1

This procedure provides the framework for compliance of the SCPs with ANSI/ASME NQA-1-1983, Quality Assurance Program Requirements for Nuclear Power Plants, Supplement 3S-1, Supplementary Requirements for Design Control. PNL is differentiating research software from production software, in that design input for production software is usually well defined. In the case of research software, the design process itself may be the primary objective of the research. Formal control of software need occur only after the design has been determined and the expected application has been specified. Freedom to try different algorithms and code pathways must be permitted during the formative stages of design. PNL has recognized this stage as research software design, where such freedom is permitted. This stage terminates with FIDR at which time the software and design documentation are baselined and placed under configuration management.

If the software is production software rather than research software, the SCPs have been designed as minimum requirements and provide the flexibility to require additional standards and specifications (e.g., IEEE-std-730-1984). In addition, the SCPs are designed to allow additions or exceptions to specific requirements either to accommodate equivalent means of maintaining traceability and reproducibility, or to tailor the stringency of requirements to the needs of a particular piece of software.

NQA-1 specifies that for hardware design control, the following shall be addressed:

- *design input*
- *design process, including design analysis*
- *design verification*
- *change control*
- *interface control*
- *documentation and records.*

These SCPs are an interpretation of these hardware requirements for software.

Design input is specified in research project planning documents and on the Software Requirements Form in Sections II, IV, V and VI of Exhibit 1 and Sections II through IV of Exhibit 2. *Design process* consists of development and internal testing of software, development of benchmark test cases, and documentation of software in accordance with design input. The design process complies with the requirements specified in research project planning documents and in the Software Requirements Form (Exhibit 1), and is finalized by the FIDR. The design input (requirements for the design process) receives an independent technical review (ITR). *Design analysis* is accomplished through an in-depth technical review in accordance with SCP-70-313, Final Internal Development Review of Software and Documentation. When the software and its design documentation have been approved by FIDR, configuration management of and changes to software and design documentation (including *change control*) are controlled by SCP-70-314, Software Configuration Management. The final phase before releasing software for use is *design verification*, which is accomplished by following SCP-70-315, Software Conversion Testing, Verification and/or Validation. Software-related aspects of *interface control* are handled by specific sections of SCPs. *Documentation* generated and required to be a record is specified in each SCP. *Records* are processed according to records control procedures.

Additionally, SCPs are provided to document and review application runs (SCP-70-316, Software Application Control), to transfer software or data to and from the research project (SCP-70-317, Transfer of Software, Data and/or Documentation), and to handle data base management (SCP-70-318, Control of Data Bases). SCP-70-318, Control of Data Bases, does not manage the data during its generation; ensuring quality and integrity of data during experimentation is controlled by a project-specific technical procedure. Rather, this procedure is meant to assure the integrity of the data during its analysis and/or use in modeling.

4.1.2 Reporting of Preliminary Results

The process of taking software from design input to design verification may be lengthy; thus, for purposes of providing research project progress to a sponsor, preliminary results may need to be reported.

The PROJECT MANAGER shall assure that any results reported to the sponsor using engineering/scientific software that has not been reviewed in accordance with SCP-70-313 (Final Internal Development Review of Software and Documentation) and verified in accordance with SCP-70-315 (Conversion Testing, Verification and/or Validation of Software) are clearly marked with the following:

Results are based on the use of unverified software. No assurance is expressed or implied as to the accuracy, completeness or usefulness of this information.

4.2 Preparation of the Software Requirements Form

4.2.1 For all software [except software used as part of measuring and test equipment (M&TE), software encompassed by a technical procedure that prescribes methods of data acquisition, word processing software and operating system software], the PREPARER of the Software Requirements Form shall designate one of the three classes of software by selection of the appropriate Software Requirements Form:

- Engineering/Scientific Software, Exhibit 1
- Support Software, Exhibit 2
- System Maintained Software, Exhibit 3.

Engineering/scientific or system maintained software can be used to generate reportable results. Support software must be used with engineering/scientific software, system maintained software, or another source of original data to produce reportable results.

Each application run of system maintained software used to generate reportable results requires creation and documentation of a stream of commands (e.g., command files to submit batch runs) tailored to the application. A stream of commands is written in the language of the system maintained software or in a programming language. All such streams of commands and interactions with software must be classed as support software.

4.2.2 The PROJECT MANAGER shall assure that a Software Requirements Form is completed for all research project software in the format of Exhibit 1, 2 or 3. Directions for completing each form are in italics on the form. The possible resulting sequences for applying the SCPs for software are indicated in the flowcharts given in Exhibits 1, 2, and 3. Exhibit 4 indicates the sequence of applying the SCPs for data used as input to software.

4.2.3 The PREPARER of the Software Requirements Form (Exhibit 1 or 2) shall indicate the appointments made in accordance with PAP-70-205, Quality Assurance Plans, as follows:

- code custodian in item 2
- data base steward in item 10, if appropriate.

4.2.4 The PREPARER of the Software Requirements Form (Exhibit 1 or 2) shall assure that the appropriate impact level is noted (see PAP-70-208, Impact Levels).

4.2.5 The PREPARER shall decide if any additions or exceptions to requirements (entire SCPs or parts of SCPs) are needed. If so, additions and exceptions and their explanations shall be recorded in one of the following:

- Section VII of Exhibit 1, for engineering/scientific software
- Section V of Exhibit 2, for support software
- Section III of Exhibit 3, for system maintained software

4.2.6 If software is proprietary, requirements that violate the software license shall not apply. Such exceptions to requirements shall be noted and explained in the additions and exceptions section of the appropriate Software Requirements Form (see Section 4.2.5).

4.3 Approval of the Software Requirements Form

4.3.1 The PREPARER shall review designation of software class, design input, design documentation requirements, testing options, and other applicable SCPs; shall assure completeness of the Software Requirements Form (Exhibit 1, 2 or 3); and shall indicate approval by signature and date. The PREPARER shall forward the approved form to the project manager.

4.3.2 The PROJECT MANAGER shall determine if an ITR of the Software Requirements Form (Exhibit 1 or 2) is to be performed in accordance with PAP-70-604, Independent Technical Review. If not, the Project Manager shall review the Software Requirements Form (Exhibit 1 or 2). At a minimum, either review shall evaluate the following:

- appropriateness of software class
- qualifications of code custodian and data base steward
- design input
- design documentation requirements
- testing options
- applicable SCPs
- completeness of the form.

The PROJECT MANAGER shall assure that the reviewer(s) signs and dates the approval section of the Software Requirements Form.

4.3.3 The PROJECT MANAGER shall provide an information copy of the reviewed Software Requirements Form to the QA Representative.

4.3.4 Upon final approval(s) of the Software Requirements Form (Exhibit 1, 2 or 3), the PROJECT MANAGER shall assure that a copy of the form is maintained as a research project record.

4.4 Identification of Design Input Requirements for Engineering/Scientific Software

Section 4.4 applies only if development or modification of engineering/scientific software and/or design documentation is required (see questions 8 and 9 on the Software Requirements Form, Engineering/Scientific Software, Exhibit 1).

4.4.1 The PREPARER of the Software Requirements Form, Engineering/Scientific Software (Exhibit 1), shall reference any design input specified in the research project planning documents by indicating document name and page in question 18, Section IV of the form.

4.4.2 If the following design input requirements are not addressed in research project planning documents, the PREPARER shall evaluate the need for their inclusion:

- bases for design (e.g., physical and chemical phenomena to be accounted for or known to be neglected; input or output formats)
- performance requirements (e.g., maximum CPU time, memory requirements)
- regulatory requirements (e.g., NUREG-0856 or other specified requirements)
- codes and standards (e.g., IEEE-std-730-1984).

Requirements for additional design input, including internal testing and benchmark test cases, shall be based primarily upon the intended end-use of software, its relative importance to research project results, and sponsor requirements. Exclusions shall be documented on the Software Requirements Form (Exhibit 1).

4.4.3 If additional design input is determined to be required, the PREPARER of the Software Requirements Form (Exhibit 1) shall attach the additional input and indicate in question 19, Section IV, that additional design input has been appended.

4.5 Identification of Design Documentation Requirements

Design documentation requirements (i.e., user's manual and mathematical models and numerical methods) shall be based primarily upon intended end-use of software, its relative importance to research project results, and sponsor requirements.

4.5.1 The PREPARER of the Software Requirements Form (Exhibit 1 or 2) shall determine design documentation requirements in Section V of Exhibit 1 or Section III of Exhibit 2. These sections are not applicable to acquired software requiring no development or modification, unless acquired design documentation is incomplete.

4.5.2 Design documentation for each software class shall include at a minimum the following:

- engineering/scientific software - mathematical models and numerical methods description, and user's manual. The specific items selected for inclusion are so indicated in Section V of the Software Requirements Form, Engineering/Scientific Software (Exhibit 1)

- support software - user's manual. The specific items selected for inclusion are so indicated in Section III of the Software Requirements Form, Support Software (Exhibit 2)

- system maintained software - available documentation for the particular software version.

4.5.3 The design documentation necessary to the FIDR (as determined by the PROJECT MANAGER and sponsor requirements) shall be completed before the FIDR. Delayed design documentation shall be specified in Section VII, Software Requirements Form, Exhibit 1 and shall be added by following SCP-70-314, Software Configuration Management.

4.6 SCPs Required for Engineering/Scientific Software

4.6.1 Engineering/scientific software shall be acquired in accordance with SCP-70-317, Transfer of Software, Data and/or Documentation; or PAP-70-401, Preparation, Review and Approval of Purchase Requisitions.

4.6.2 When development or modification is required for engineering/scientific software and/or design documentation, an FIDR shall be performed in accordance with SCP-70-313, Final Internal Development Review of Software and Documentation.

4.6.3 After completion of an FIDR, or after transfer if no modification or development occurs, all engineering/scientific software shall be configuration managed in accordance with SCP-70-314, Software Configuration Management.

4.6.4 All engineering/scientific software shall be tested in accordance with SCP-70-315, Conversion Testing, Verification, and/or Validation of Software. The tests that are performed shall, at a minimum, exercise the software options and the range of variables likely to be encountered in the application of the software. The testing shall include the following:

- all acquired engineering/scientific software shall be conversion tested

- all engineering/scientific software shall be verified. Verification shall be independent if prescribed in research project planning documents

- validation of engineering/scientific software shall be performed if prescribed in research project planning documents.

NOTE: SCP-70-315, Conversion Testing, Verification, and/or Validation of Software, may be implemented only after placing software under configuration management.

4.6.5 Use of engineering/scientific software shall be documented in accordance with SCP-70-316, Software Application Control.

4.7 SCPs Required for Support Software

4.7.1 Support software may be acquired in accordance with SCP-70-317, Transfer of Software, Data and/or Documentation; or PAP-70-401, Preparation, Review and Approval of Purchase Requisitions.

4.7.2 If support software is used repeatedly or by multiple users, it shall require configuration management in accordance with SCP-70-314, Software Configuration Management.

4.7.3 If support software is acquired, it shall be conversion tested in accordance with SCP-70-315, Conversion Testing, Verification and/or Validation of Software. If it is developed or modified, support software shall be verified in accordance with SCP-70-315, Conversion Testing, Verification, and/or Validation of Software.

4.7.4 Streams of commands (or sequences of streams of commands) used to execute system maintained software to generate reportable results shall be classed as support software and shall be verified in accordance with SCP-70-315, Conversion Testing, Verification, and/or Validation.

4.7.5 Use of support software shall be documented in accordance with SCP-70-316, Software Application Control, unless documented as part of an application run of engineering/scientific software.

4.8 SCPs Required for System Maintained Software

4.8.1 The PREPARER of the Software Requirements Form, System Maintained Software (Exhibit 3), shall assure that the name, supplier and version of system maintained software (e.g., commercial software such as LOTUS 1-2-3, RS/1, SAS, or DISSPLA) are specified on the form.

4.8.2 The PREPARER of the Software Requirements Form (Exhibit 3) shall indicate the available documentation and version on the form.

4.9 SCPs Required for Data

4.9.1 As shown in Exhibit 4, data shall be acquired from another research project at PNL or from outside PNL in accordance with SCP-70-317, Transfer of Software, Data and/or Documentation; PAP-70-401, Preparation, Review and Approval of Purchase Requisitions; or from open literature.

4.9.2 Data used in software development, testing or application shall be verified and configuration managed in accordance with SCP-70-318, Control of Data Bases; or data traceability and reproducibility shall be documented in accordance with SCP-70-316, Software Application Control.

4.9.3 The PREPARER of the Software Requirements Form (Exhibit 1 or 2) shall indicate the name of the data base steward appointed in accordance with PAP-70-205, Quality Assurance Plans, in

- item 10, Section II of Exhibit 1, for engineering/scientific software
- item 10, Section II of Exhibit 2, for support software.

4.10 Changing an Approved Software Requirements Form

After a Software Requirements Form has been approved, to make changes in to the form, the PROJECT MANAGER shall assure that a revised Software Requirements Form (Exhibit 1, 2 or 3) is issued in accordance with this SCP and receives the same level of approval(s) as the original Software Requirements Form. A revised Software Requirements Form shall be indicated by sequentially assigning a revision number, where the initial Software Requirements Form shall be designated Revision no. 0.

4.11 Reporting of Deficiencies

If the Software Requirements Form (Exhibit 1, 2 or 3) is determined to be deficient after being submitted as a research project record, the PROJECT MANAGER shall evaluate and document the deficiency in accordance with PAP-70-1502, Controlling Deviations from QA Requirements and Established Procedures.

SOFTWARE REQUIREMENTS FORM
ENGINEERING/SCIENTIFIC SOFTWARE

Revision no. _____
Impact Level 1 [ ] 2 [ ]

(Answer every question or, if appropriate for questions with a line in front of the question number, specify not applicable, N/A. If not otherwise specified, proceed to the next question in sequence.)

1) Software name (and version, if applicable) _____
2) Name of code custodian _____
3) Project title _____ Project no. _____
4) Function of this engineering/scientific software:

SECTION I: Determination of Required Software Control Procedures *(See p. 6 of this exhibit for a flowchart of the sequence.)*

5) Is this engineering/scientific software going to be acquired from outside PNL or from another PNL research project (with a different project number)?

___ yes

___ no *(Mark N/A on questions 6-8. Go to question 9.)*

__ 6) Identify software origin and version(s):

__ 7) Describe available software documentation and version(s):

__ 8) Will this engineering/scientific software and/or its design documentation be modified at PNL?

___ yes Required SCPs (in addition to SCP-70-312, Determination of Software Requirements) in order of application:

SCP-70-317, Transfer of Software, Data and/or Documentation *(to transfer software and its documentation)*
SCP-70-313, Final Internal Development Review of Software and Documentation
SCP-70-314, Software Configuration Management
SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
SCP-70-316, Software Application Control

(Indicate required SCPs in Section VI. Mark N/A on question 9. Go to question 10.)

___ no Required SCPs (in addition to SCP-70-312, Determination of Software Requirements) in order of application:

SCP-70-317, Transfer of Software, Data and/or Documentation *(to transfer software and its documentation)*
SCP-70-314, Software Configuration Management
SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
SCP-70-316, Software Application Control

(Indicate required SCPs in Section VI. Mark N/A on question 9. Go to question 10.)

__ 9) Is this engineering/scientific software and/or its design documentation going to be developed at PNL?

___ yes Required SCPs (in addition to SCP-70-312, Determination of Software Requirements) in order of application:

SCP-70-313, Final Internal Development Review of Software and Documentation
SCP-70-314, Software Configuration Management
SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
SCP-70-316, Software Application Control

(Indicate required SCPs in Section VI.)

___ no *(You have answered "no" to questions 5 and 9. You need to reevaluate whether you have chosen the correct software class. If the class is correct, either question 5 or question 9 must be answered by "yes.")*

SECTION II: Data Associated with this Engineering/Scientific Software

10) Will data or data base(s) be used to determine input for this engineering/scientific software?

___ yes The data base steward designated in accordance with PAP-70-205, Quality Assurance Plans, is:_____.

___ yes No data base steward is required because data base software will not be used. A flat (sequential) file or binary worksheet is used to input data to software.

___ no *(Mark N/A on question 11. Go to question 14.)*

__11). Will data or data base(s) be acquired from outside PNL or from another PNL research project (with a different project number)?

___ yes Required SCPs (in addition to those in Section I) in order of application:

SCP-70-317, Transfer of Software, Data and/or Documentation *(to transfer data and its documentation)*
SCP-70-318, Control of Data Bases

(Indicate required SCPs in Section VI.)

___ no Required SCP (in addition to those in Section I):

SCP-70-318, Control of Data Bases

(Indicate required SCP in Section VI. Mark N/A on questions 12 and 13. Go to question 14.)

__12) Identify origin of data or data base(s):

__13) Describe available documentation of data or data base(s) including version(s):

SECTION III: Determination of Options for SCP-70-315, Conversion Testing, Verification, and/or Validation of Software

__14) Is conversion testing required for this acquired engineering/scientific software? *(Applicable if engineering/scientific software is acquired from outside PNL or is being installed on a different computer or different operating system.)*

___ yes *(Indicate so under Section VI.)*

___ no

15) Is independent verification required?

___ yes *(Indicate so under Section VI.)*

___ "Independent" is defined to be verification by competent PNL individual(s) other than those from whom the work originated (they may be users, but they shall not have designed or developed the software).

___ "Independent" is defined to be verification by competent individual(s) outside PNL.

___ "Independent" is defined to be verification by:

___ no

16) Is validation required?

___ yes *(Indicate so under Section VI.)*

___ no

N/A 17) Left intentionally blank.

SECTION IV. Design Input *(applicable if answer to question 8 or 9 is "yes")*

__18) List research project planning documents (title and page numbers) containing design input (see Section 4.4.1):

__19) Is additional design input attached (see Section 4.4.2)?

___ yes

___ no

Explain any exclusions of items in Section 4.4.2:

SECTION V: Design Documentation *(applicable if answer to question 8 or 9 is "yes". Mark all items to be included.)*

20) Mathematical models and numerical methods descriptions shall include:

___ Design input (i.e., documentation of items 18 and 19)
___ Statement and description of the problem
___ Applicable assumptions and limitations (e.g., appropriateness of algorithms)
___ Numerical techniques/methods
___ Relevant discretized (or otherwise transformed numerical solution) equations and derivations
___ Numerical stability and accuracy of methods
___ Notation for variables and equations
___ Important computational characteristics
___ References and sources
___ Other _____

21) User's manual shall include:

___ Hardware requirements including computer type and operating system
___ Software listing (handwritten, computer generated or on microfiche)
___ Testing documentation relevant to Final Internal Development Review
___ Structure and organization of the software by flowchart, software design language, or other appropriate means
___ Data input and output information
___ Model and system interfaces
___ Coding standards
___ Sample and/or test problems
___ Input/output requirements (e.g., libraries and compilers)
___ Other _____

__22) Do research project planning documents or other contractual documents require compliance to a specific standard?

___ yes Identify the standard:

___ no

SECTION VI: Summary of Required SCPs

X SCP-70-312, Determination of Software Requirements
___ SCP-70-313, Final Internal Development Review of Software and Documentation
X SCP-70-314, Software Configuration Management
X SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
___ conversion testing
X verification (independent? ___ yes ___ no)
___ validation
X SCP-70-316, Software Application Control
___ SCP-70-317, Transfer of Software, Data and/or Documentation
___ software
___ document of software
___ data
___ documentation of data
___ SCP-70-318, Control of Data Bases

SECTION VII: Additions or Exceptions to Questions 1-22 *(attach additional pages if necessary)*

__23) Describe any additions or exceptions to the above:

__24) Provide explanations for additions or exceptions:

SECTION VIII: Approvals of Answers to Questions 1-24

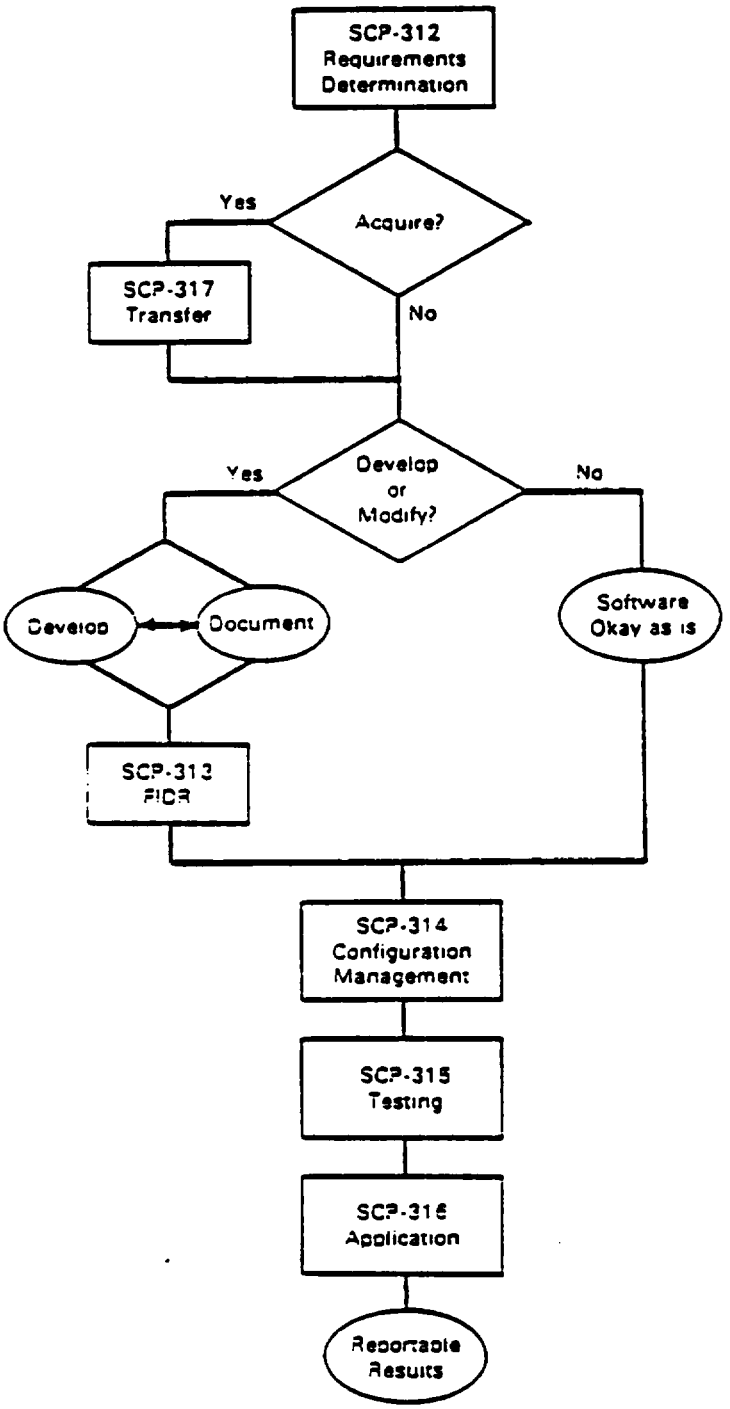
25) Prepared by:

_____
Signature Date

26) Approved by:

_____
Project Manager, or Independent Technical Reviewer (if required) Date

Engineering/Scientific Software



SOFTWARE REQUIREMENTS FORM
SUPPORT SOFTWARE
Revision no. _____
Impact Level 1 [ ] 2 [ ]

(Answer every question, or if appropriate for a question with a line in front of the question number, specify not applicable, N/A. If not otherwise specified, proceed to the next question in sequence.)

1) Software name (and version, if applicable) _____
2) Name of code custodian _____
3) Project title _____ Project no. _____
4) Function of this support software:

5) Is this support software a stream of commands used to execute system maintained software?

___ yes Identify name and version of system maintained software:

___ no

SECTION I: Determination of Required Software Control Procedures *(See p. 4 of this exhibit for a flowchart of the sequence.)*

6) Will this support software receive repeated use or be used by multiple users?

___ yes Required SCP (in addition to SCP-70-312, Determination of Software Requirements):

SCP-70-314, Software Configuration Management

(Indicate required SCP in Section IV.)

___ no

7) Is this support software going to be acquired from outside PNL or from another PNL research project (with a different project number)?

___ yes Required SCPs (in addition to SCP-70-312, Determination of Software Requirements) in order of application *(apply SCP-70-314 before SCP-70-315, if SCP-70-314 is required from question 6)*:

SCP-70-317, Transfer of Software, Data and/or Documentation *(to transfer software and its documentation)*
SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
SCP-70-316, Software Application Control

(Indicate required SCPs in Section IV.)

___ no Required SCPs (in addition to SCP-70-312, Determination of Software Requirements) in order of application *(apply SCP-70-314 first, if SCP-70-314 is required from question 6)*:

SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
SCP-70-316, Software Application Control

(Indicate required SCPs in Section IV. Mark N/A on questions 8 and 9. Go to question 10.)

__ 8) Identify software origin and version(s):

__ 9) Describe available software documentation and version(s):

SECTION II: Data Associated with this Support Software

10) Will data or data base(s) be used to determine input for this support software?

___ yes The data base steward designated in accordance with PAP-70-205, Quality Assurance Plans, is:_____.

___ yes No data base steward is required because data base software will not be used. A flat (sequential) file or binary worksheet is used to input data to software.

___ no *(Mark N/A on question 11. Go to question 14.)*

__11) Will data or data base(s) be acquired from outside PNL or from another PNL research project (with a different project number)?

___ yes Required SCPs (in addition to those in Section I) in order of application:

SCP-70-317, Transfer of Software, Data and/or Documentation (to transfer data and its documentation)
SCP-70-318, Control of Data Bases

(Indicate required SCPs in Section IV.)

___ no Required SCP (in addition to those in Section I):

SCP-70-318, Control of Data Bases

(Indicate the required SCP in Section IV. Mark N/A on questions 12 and 13. Go to question 14.)

__12) Identify origin of data or data base(s):

__13) Describe available documentation of data or data base and version(s):

SECTION III: Design Documentation *(Mark all items to be included.)*

14) User's manual shall include:

___ Hardware requirements including computer type and operating system
___ Software listing (handwritten, computer generated or on microfiche)
___ Testing documentation
___ Structure and organization of the software by flowchart, software design language, or other appropriate means
___ Data input and/or output information
___ Model and system interfaces
___ Coding standards
___ Sample and/or test problems
___ Input/output requirements (e.g., libraries and compilers)
___ Other _____

SECTION IV: Summary of Required SCPs

__X__ SCP-70-312, Determination of Software Requirements
_____ SCP-70-314, Software Configuration Management
__X__ SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
- _____ conversion testing
- __X__ verification
- _____ validation

__X__ SCP-70-316, Software Application Control
_____ SCP-70-317, Transfer of Software, Data and/or Documentation
- _____ software
- _____ documentation of software
- _____ data
- _____ documentation of data

_____ SCP-70-318, Control of Data Bases

SECTION V: Additions or Exceptions to Questions 1-14

__15) Describe any additions or exceptions to the above:

__16) Provide explanations for additions or exceptions:

__17) For the following ITRs, can independent be defined to be a review by technically competent PNL individual(s) other than the principal author of the work? [NOTE: Independent is otherwise defined to be a review by competent PNL individual(s) other than those from whom the work originated (they may be users, but they shall not have designed or developed the software).]

SCP-70-314: a review of a new version of software and/or design documentation?

___ yes
___ no

SCP-70-315: a review of testing and its documentation?

___ yes
___ no

SCP-70-316: a review of an application package before reporting results to a sponsor?

___ yes
___ no

SCP-70-318: a review of data base design, if such is required by the project manager?

___ yes
___ no

SECTION VI: Approvals of Answers to Questions 1-17

18) Prepared by:

_____

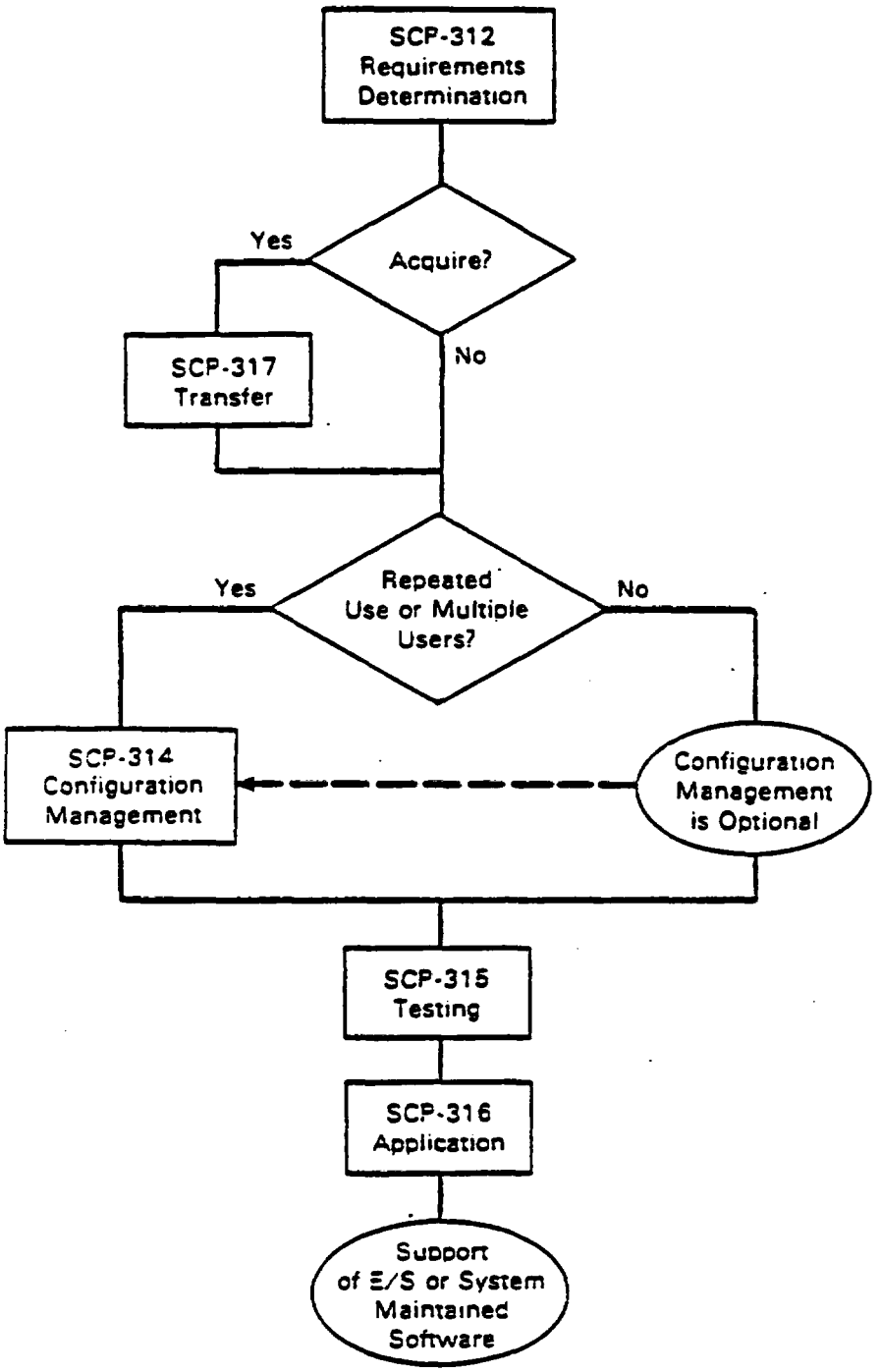
Signature Date

19) Approved by:

_____

Project Manager, or Independent Technical Reviewer (if required) Date

Support Software



SOFTWARE REQUIREMENTS FORM
SYSTEM MAINTAINED SOFTWARE
Revision no. _____

(Answer every question or, if appropriate for a question with a line in front of the question number, specify not applicable, N/A. If not otherwise specified, proceed to the next question in sequence.)

1) Software name (and version, if applicable) _____
2) Project title _____ Project no. _____
3) Function of this system maintained software:

4) Does this system maintained software require a stream of commands to execute various options?

___ yes *(Class each stream of commands as support software in accordance with Section 4.7.4.)*

___ no Explain:

SECTION I: Determination of Required Software Control Procedures *(See p. 4 of this exhibit for a flowchart of the sequence.)*

5) Is this system maintained software to be purchased or transferred?

___ Purchased. *(See PAP-70-401, Preparation, Review and Approval of Purchase Requisitions.)*

___ Transferred. Required SCP (in addition to SCP-70-312, Determination of Software Requirements):

SCP-70-317, Transfer of Software, Data and/or Documentation (to transfer software and its documentation)

(Indicate required SCP in Section III.)

___ Neither. (Software is already installed from previous purchase or transfer.)

6) Identify origin (vendor) of software and version(s):

7) Describe available software documentation and version(s):

Revision no. _____
Software name and version _____
Project name and no. _____

SECTION II: Summary of Required SCPs

__X__ SCP-70-312, Determination of Software Requirements
_____ SCP-70-317, Transfer of Software, Data and/or Documentation
_____ software
_____ documentation of software

SECTION III: Additions and Exceptions to Questions 1-7 *(attach additional pages if necessary)*

__ 8) Describe any additions or exceptions to the above:

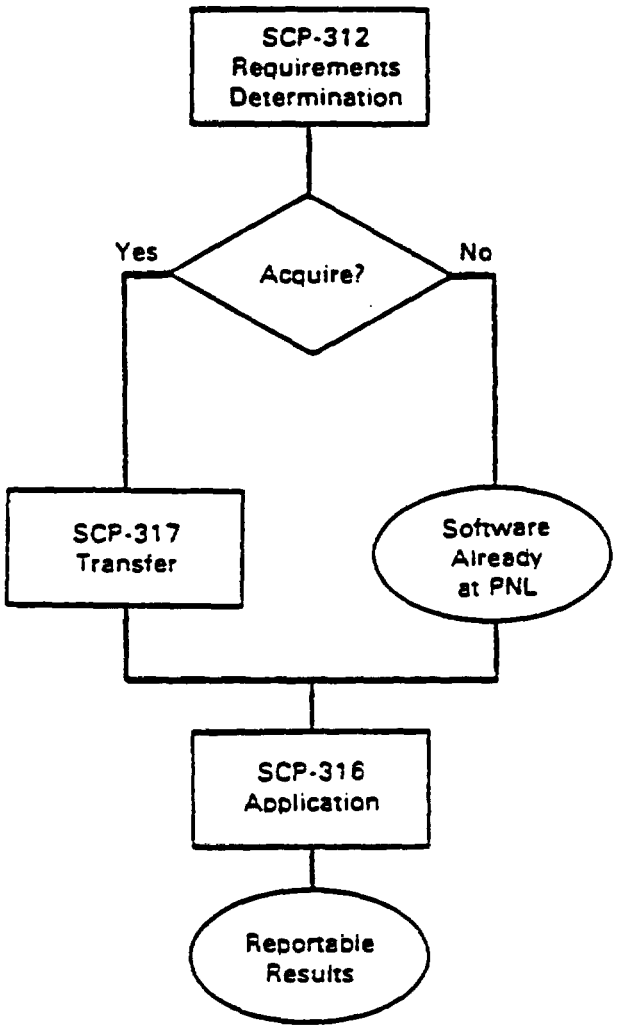
__ 9) Provide explanations for additions or exceptions:

SECTION IV: Approvals of Answers to Questions 1-9

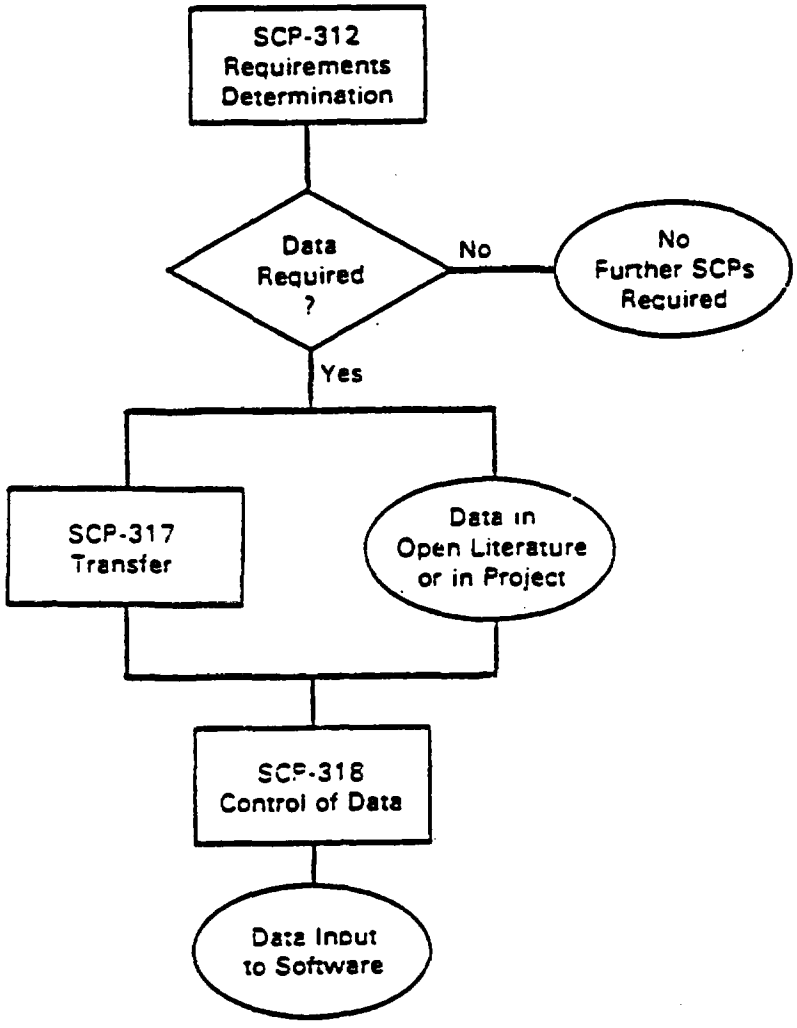
10) Prepared by:

_____
Signature Date

System Maintained Software



Input Data to Software
(to development, testing or application)



SOFTWARE CONTROL PROCEDURES

TITLE: SCP-70-314, SOFTWARE CONFIGURATION MANAGEMENT

1.0 APPLICABILITY

When selected on the Software Requirements Form in accordance with SCP-70-312, Determination of Software Requirements, this procedure applies to engineering/scientific software and designated support software.

For engineering/scientific software being developed or modified at PNL, this procedure shall apply after the base version of the software is established by the FIDR in accordance with SCP-70-313, Final Internal Development Review of Software and Documentation. Configuration management during development is optional but is highly recommended on large projects, especially those with several developers.

For acquired engineering/scientific software that needs no development or modification, this procedure shall apply after the class of the software has been determined or after the software has been transferred in accordance with SCP-70-317, Transfer of Software, Data and/or Documentation, if applicable.

For support software, this procedure shall apply if designated on the Software Requirements Form (see Exhibit 2 of SCP-70-312, Determination of Software Requirements). If support software is going to be used repeatedly or by multiple users, configuration management is recommended.

This procedure does not apply to system maintained software. However, a stream of commands used to execute system maintained software and classed as support software shall adhere to the configuration management requirements of that class.

Configuration management of data base software that is not classed as system maintained software is covered by this procedure.

2.0 DEFINITIONS

Terms used in this procedure are defined in SCP-70-312, Determination of Software Requirements.

3.0 RESPONSIBLE STAFF

Staff with responsibilities for implementing this procedure are:

- Project Manager
- Code Custodian
- User

Concurrence	Date	Approved	Date
N/A		R B Clark	9/5/86
Prepared by	**Date**	**QAD Concurrence**	**Date**
J A Mahaffey	7/14/86	P E Hughes	7/18/86

Procedure No.	Revision No.	Effective Date	Page	of
SCP-70-314	0	OCT 1 1986	1	9

4.0 PROCEDURE

4.1 Transfer of Software Items for Configuration Management

The PROJECT MANAGER shall assure that the software (in machine-readable form) and documentation described below are transmitted to the code custodian to be configuration managed. The PROJECT MANAGER shall assure that software and documentation are maintained as research project records.

4.1.1 Software documentation consists of the following:

- for developed or modified engineering/scientific software that has been approved by an FIDR, documentation shall include the FIDR package
- (Impact Level I only) for developed or modified support software, the documentation shall include the Software Requirements Form for Support Software and the user's manual
- for acquired engineering/scientific and/or support software documentation shall include the Software Requirements Form and all documentation transferred with the software.
- after initiation of configuration management, additional documentation shall include software testing documentation in accordance with SCP-70-315, Conversion Testing, Verification, and/or Validation of Software.

4.1.2 If not included as part of the software documentation, the PROJECT MANAGER shall assure that one or more benchmark test cases are developed to demonstrate correct model operation and provide for future comparison of software versions. Benchmark test cases are optional for support software.

4.2 Initiation of Configuration Management

4.2.1 On receipt of software and documentation described in Section 4.1, the CODE CUSTODIAN shall assign a unique version number to software and design documentation, and shall identify the software version and the associated document version on a Software Version Log in the format of Exhibit 1.

(Impact Level I only) On completion of each page of the Software Version Log, Exhibit 1, the PROJECT MANAGER shall assure that a copy is maintained as a research project record.

4.2.2 The CODE CUSTODIAN shall assure that the unique software version number is identified in the software listing and is printed in the engineering/scientific software output.

4.2.3 If the engineering/scientific software has not received a Final Internal Development Review and/or been verified, the CODE CUSTODIAN shall assure that the software listing and software output include the following:

Results are based on the use of unverified software. No assurance is expressed or implied as to the accuracy, completeness or usefulness of this information.

4.3 Maintenance of Software Items

4.3.1 The CODE CUSTODIAN shall create on magnetic media a backup of the master copy of the latest version of software, data files required to run the software, and other software records normally resident on the computer. For support software (e.g., streams of commands), hardcopy backup may be sufficient if manual reentry into the computer will produce a reliable copy.

4.3.2 The CODE CUSTODIAN shall control access to the master copy and backup copy in machine-readable form (except backup hard copies as noted in Section 4.3.1).

4.3.3 The CODE CUSTODIAN shall establish and maintain a Magnetic Media Log in the format of Exhibit 2 to identify and record the location of magnetic media items received or created by the code custodian for the purposes of configuration management, as follows:

- magnetic media items maintained onsite under physical control of the code custodian shall be logged with a unique log number and externally labeled with software name, version, creation date, and log number

- magnetic media items not under physical control of the code custodian (e.g., in an offsite library) shall be logged with the identifiers by which they may be accessed in the host computer system

- a list of contents (e.g., file directory) of each magnetic media item identified in the log shall be filed with the log until the item is erased or released

- when a magnetic media item is moved, released or erased, the action shall be recorded on the next numbered column under location/disposition and date.

(Impact Level I only) On completion of each page of the Magnetic Media Log, Exhibit 2, the PROJECT MANAGER shall assure that a copy is maintained as a research project record.

4.3.4 The CODE CUSTODIAN may release backup copies of magnetic media for reuse when they become obsolete (i.e., when a new master version and its backup are created).

4.3.5 The CODE CUSTODIAN shall maintain a backup copy all associated design documentation. The CODE CUSTODIAN shall maintain a working index of the design documentation, completed forms, logs, etc. and their location.

4.4 User Access Control

4.4.1 The PROJECT MANAGER may authorize the code custodian to grant onsite user access to configuration-managed software items.

4.4.2 The PROJECT MANAGER shall document authorization of offsite user access in a letter to those users, with copies to the code custodian and to research project records.

4.4.3 The CODE CUSTODIAN shall complete the Software User List (Exhibit 3) in the following manner:

- initial access to a software version shall be indicated in column 1 under software version/date of release
- as a user receives a new software version, the version identifier shall be noted on the next numbered column under software version/date of release
- when user access is terminated, the date of termination shall be noted under the appropriate column of software version/date of release.

4.4.4 (Impact Level I only) On completion of each page of the Software User List, the PROJECT MANAGER shall assure that a copy of the list is maintained as a research project record.

4.5 Problem Reporting and Change Requests

USERS may request changes to software and/or design documentation to correct errors, to add new features and models, or to modify existing features. The change request may be in the form of a letter, memo, telefax, telephone call, etc., or in the format of a Change Request Form, Exhibit 5, Part 1.

This section prescribes procedures for reporting and processing requests for software and design documentation changes. Note that procedures to create new versions of software are prescribed in Section 4.6. New versions of the design documentation are provided for in Section 4.7.

4.5.1 Upon receipt, the CODE CUSTODIAN shall document the request on the Change Request Form, Exhibit 4, Part 1, if not already in that format, and proceed as follows:

- if a software problem is being reported, Exhibit 4, Part 1 shall include a description of the problem and a listing of input for a test case that demonstrates the error (or sufficient information to allow a test case to be developed)
- if the information submitted is incomplete (e.g., lacks test case input) or illegible, the CODE CUSTODIAN shall request clarification or reject the change request and return the Change Request Form, Exhibit 4, to the originator without action.

4.5.2 When the change request is accepted for action, the CODE CUSTODIAN shall assign it a change request number and shall enter the number on the Change Request Form, Exhibit 4, and on the Software Change Request Log in the format of Exhibit 5. On completion of each page of the Software Change Request Log, Exhibit 5, the PROJECT MANAGER shall assure that a copy is maintained as a research project record.

4.5.3 If a software problem is being reported, the CODE CUSTODIAN shall assure that software is run using input supplied with or described in Part 1 of the Change Request Form, Exhibit 4, and that the appropriate action below is accomplished:

- if the error cannot be duplicated with the input provided or if it is found that the supplied input is in error, the CODE CUSTODIAN shall note this information on Part 2 of the Change Request Form, Exhibit 4, and under "Disposition" on the Software Change Request Log, Exhibit 5; and shall send a copy of the Change Request Form, Exhibit 4, to the user identified in Part 1 of the form and to research project records. No further action shall be required for the change request.

- if the error occurs as described in Part 1 of the Change Request Form, Exhibit 4, or if any other errors occur in the run, the CODE CUSTODIAN shall complete Part 2, sign and date the form, and forward the form and input and output to the project manager.

4.5.4 The PROJECT MANAGER shall review the Change Request Form, Exhibit 4, to assess the impact of the software problem, to determine disposition of the request, and to determine if users shall be notified. The project manager shall indicate the disposition of the request on Part 3, sign and date the form, and return the completed form to the code custodian.

4.5.5 The CODE CUSTODIAN shall enter the appropriate information from Part 3 of the Change Request Form, Exhibit 4, on the Change Request Log, Exhibit 5, and shall take the following actions as appropriate on the disposition as specified by the project manager:

- if the change request is approved, the CODE CUSTODIAN shall assure changes to the software and design documentation are developed in accordance with Sections 4.6 and 4.7, respectively

- if the requested change is disapproved, the CODE CUSTODIAN shall send a copy of the completed Change Request Form, Exhibit 4, to the originator. The PROJECT MANAGER shall assure that a copy is maintained as a research project record

- if users are to be notified of an error, the CODE CUSTODIAN shall assure that a copy of the Change Request Form, Exhibit 4, is sent to each person on the Software User List, Exhibit 3.

4.5.6 The CODE CUSTODIAN may notify users of and provide user access to interim corrections for software errors that have been processed in accordance with Sections 4.5.1 through 4.5.5 before formal release of a new version of the software. The CODE CUSTODIAN shall include a transmittal letter or memo stating that USERS assume all risks and responsibilities for use of software containing such interim corrections and that USERS shall modify the version identifier prescribed in Section 4.2.2 to reflect the changes installed and shall include the verification disclaimer specified in Section 4.2.3.

4.6 Creation of New Versions of Software

New versions of software are created to install one or a set of software error corrections or other changes that have been reported in Section 4.5. Section 4.7 describes the procedures for making corresponding revisions to the software design documentation.

4.6.1 To initiate creation of a new software version, the PROJECT MANAGER shall complete Part 1 of the New Version Report in the format of Exhibit 6 to identify the base version of the software to be revised, specify changes to be installed in the designated version, and select test cases to be used. In addition,

- only those changes reported and logged in accordance with Section 4.5 may be selected
- at a minimum, the test cases shall be comprised of the benchmark test cases (see Section 4.1.2) and input provided with the selected Change Request Forms, Exhibit 4
- additional test cases may be developed, as appropriate.

The PROJECT MANAGER shall transmit the New Version Report, Exhibit 6, with Part 1 completed to the code custodian.

4.6.2 On receipt of the New Version Report, Exhibit 6, the CODE CUSTODIAN shall assure that the following tasks are performed:

- assign a unique version identifier to the new version of software and enter it on the New Version Report, Exhibit 6
- provide access to the version of the software to be revised for the person(s) who will create the new version
- develop a revised version of the software that includes the selected changes and obtain a listing thereof
- obtain a computer-generated listing of software modifications that compares the revised version with the designated base version (e.g., using VAX/VMS DIFFERENCES, CDC's UPDATE, or BNW's WITNESS)

- perform application runs to test the revised version of the software on the designated computer system using the specified test cases

- develop revisions to design documentation as required by the selected change requests in accordance with Section 4.7.

4.6.3 The CODE CUSTODIAN shall assure that all additional software and design documentation errors discovered during software revision or testing are handled as new change requests in accordance with Section 4.5, and that revisions to correct them are included in the revised software and design documentation.

4.6.4 When the actions in Sections 4.6.2 and 4.6.3 are accomplished, the CODE CUSTODIAN shall complete Part 2 of the New Version Report, Exhibit 6, and shall deliver the listing of the revised version of software, listing of modifications, testing documentation, and design documentation revisions to the project manager for review in accordance with Section 4.8.

4.7 Creation of New Versions of Design Documentation

New versions of the design documentation corresponding to new versions of the software are created if the change requests selected in Part 1 of the New Version Report, Exhibit 6 (see Section 4.6.1), require documentation changes. In this case the actions in Sections 4.7.1 through 4.7.4 are performed concurrently with those in Sections 4.6.1 through 4.6.4. Design documentation may also be revised independently of software if significant changes are requested in Section 4.5.

4.7.1 To initiate creation of a new version of design documentation, the PROJECT MANAGER shall complete Part 1 of the New Version Report in the format of Exhibit 6 to identify the base versions of design documentation, and the revisions to be implemented. Only those changes reported and logged in Section 4.5, and typographical and minor editorial changes that clarify but do not change the meaning of the text, may be implemented and reviewed in accordance with Section 4.8.

The PROJECT MANAGER shall transmit the New Version Report with Part 1 completed to the code custodian.

4.7.2 On receipt of the New Version Report, Exhibit 6, the CODE CUSTODIAN shall assure that the following tasks are performed:

- a unique version identifier is assigned to the new design documentation and entered on the New Version Report, Exhibit 6

- a copy is obtained of the designated base version of design documentation to be revised

- a revised version of the design documentation is developed that includes the selected changes. The revised version may be in the form of a new document or a set of replacement pages, with replacement instructions, for the designated base version

- each page in the new design documentation or each replacement page is marked with the new version identifier to differentiate it from the designated base version.

4.7.3 The CODE CUSTODIAN shall assure that all additional errors (except typographical and minor editorial changes) in the design documentation discovered during the revision process are handled as new change requests in accordance with Section 4.5, and that these errors are corrected in the revised design documentation.

4.7.4 When the actions in Sections 4.7.2 and 4.7.3 are completed, the CODE CUSTODIAN shall complete Part 2 of the New Version Report, Exhibit 6, and shall deliver the draft revised design documentation or draft replacement pages and instructions to the project manager for review in accordance with Section 4.8.

4.8 Independent Technical Review of New Versions of Software and/or Design Documentation

4.8.1 The PROJECT MANAGER shall assure that an ITR of the new version of software and/or design documentation is conducted in accordance with PAP-70-604.

4.8.2 The PROJECT MANAGER shall designate items for review and include at a minimum the following:

- New Version Report, with Parts 1 and 2 completed

- copies of all Change Request Forms, Exhibit 4, for changes included in the new version

- documents developed in Section 4.6.2, including listings of revised software, listings of software modifications, testing documentation, and results of application runs used for testing

- revised design documentation or replacement pages and instructions developed in Section 4.7.2.

4.8.3 The criteria for approval of the ITR items designated in Section 4.8.2 shall be the following, at a minimum:

- satisfactory implementation of the designated requested changes

- conformance of revised software to design input specified on the Software Requirements Form

- conformance of revised design documentation to the requirements specified on the Software Requirements Form

- adequacy and correctness of testing of the revised software version, including input, input assumptions and results

- adherence of the software to the requirements for version identification in Section 4.2.2 and for the disclaimer statement in Section 4.2.3.

4.8.4 When the new version is approved for release by the ITR, the PROJECT MANAGER shall assure that Part 3 of the New Version Report, Exhibit 6, is completed and that copies of the New Version Report, the ITR Report, the new version of software and the new version of design documentation are transmitted to the code custodian and are also maintained as research project records.

4.9 Release of New Versions of Software and/or Design Documentation

4.9.1 On receipt of the new version of software and/or design documentation from the project manager, the CODE CUSTODIAN shall:

- indicate completion of each installed software change in the Software Change Request Log, Exhibit 5

- (Impact Level I only) identify the new version of software and/or design documentation and incorporated changes (by change request log numbers) in the Software Version Log, Exhibit 1

- create backup copies and identify new magnetic media items in the Magnetic Media Log, Exhibit 2, in accordance with Section 4.3

- notify users identified on the Software User List, Exhibit 3, of the availability of the new version of the software and/or design documentation.

4.9.2 If the user requests the new version of software and/or design documentation, the CODE CUSTODIAN shall update the next numbered column under software version/date of release in the Software User List, Exhibit 3.

4.10 Reporting of Deficiencies

If the documents produced by this procedure are found deficient, the PROJECT MANAGER shall evaluate and document the deficiencies with Deficiency Reports in accordance with PAP-70-1502, Controlling Deviations from QA Requirements and Established Procedures.

SOFTWARE VERSION LOG

Software name: _____

Design documentation title: _____

Project title and number: _____

SOFTWARE VERSION	DESIGN DOCUMENTATION VERSION(S)	CREATION DATE	DESCRIPTION (e.g., Change requests incorporated)

Page completion certified by:

_____

Code Custodian Date

MAGNETIC MEDIA LOG

Software name: _____

Project title and number: _____

MEDIA TYPE AND LOG NO.	DESCRIPTION OF CONTENTS (e.g., Software Version No.)	LOCATION/DISPOSITION AND DATE			
		1	2	3	4

Page completion certified by:

_____

Code Custodian Date

SOFTWARE USER LIST

Software name: _____

Project title and number: _____

NAME AND ADDRESS OF USER	SOFTWARE VERSION/DATE OF RELEASE				
	1	2	3	4	5

Page completion certified by:

_____

Code Custodian Date

Change Request Number _____
(To be entered by code custodian)

CHANGE REQUEST FORM

Software name and version: _____
Computer type and operating system: _____
Document title and version: _____

PART 1 - Person requesting code or document change or reporting problem

Submitted by Name: _____ Date submitted: _____
Address: _____ Telephone: _____
_____

Change(s) and/or problem(s) reported (If a software problem is being reported, include a description of input data that can be used to duplicate the error):

PART 2 - To be completed by the code custodian

___ Probable software error. ___ Probable documentation error. ___ No errors found.

Description/recommendation:

Request evaluated by:

_____
Code Custodian Date

PART 3 - To be completed by the project manager

1) Does this change affect previously reported information? ___ Yes ___ No

2) Should users (as identified on Software User List, Exhibit 3) be notified?
___ Yes ___ No, for the following reason(s):

3) Disposition of change request.
___ Approved ___ Disapproved
Comments/instructions:

Reviewed and approved by:

_____
Project Manager Date

SOFTWARE CHANGE REQUEST LOG

Software name: _____

Project title and number: _____

CHANGE REQUEST NO. (FROM EXHIBIT 3)	DATE REC'D.	REQUIRES DOCUMENTATION REVISION? (Y/N)	DISPOSITION			REVISED SOFTWARE/DESIGN DOCUMENTATION VERSION IDENTIFIER
			Accept	Reject	Date Users Notified	

Page completion certified by:

_____

Code Custodian Date

NEW SOFTWARE VERSION _____
NEW DOCUMENT VERSION _____
(To be entered by code custodian)

NEW VERSION REPORT

PART 1 - To be completed by the project manager

Base software name and version: _____

Computer type and operating system: _____

Base design documentation title and version: _____

Project title and number: _____

List change request numbers to be installed:

List the test case(s) to be used:

Reviewed and approved by:

_____

Project Manager Date

PART 2 - To be completed by the code custodian

Are additional software and/or design documentation changes required? If so, complete Part 1 of the Change Request Form, Exhibit 3, and note associated change request number(s) below.

NEW SOFTWARE VERSION _____
NEW DOCUMENT VERSION _____
(To be entered by code custodian)

NEW VERSION REPORT (CONTD)

PART 2 (contd) - To be completed by code custodian

Identify items submitted for ITR:

Reviewed and approved by:

_____

Code Custodian Date

PART 3 - To be completed by the project manager

The revised version of the software is approved for use. Release date: _____

Reviewed and approved by:

_____

Project Manager Date

CONTROLLED DOCUMENT
COPY NO. 000482

SOFTWARE CONTROL PROCEDURES

TITLE: SCP-70-315, CONVERSION TESTING, VERIFICATION, AND/OR VALIDATION OF SOFTWARE

1.0 APPLICABILITY

When selected on the Software Requirements Form in accordance with SCP-70-312, Determination of Software Requirements, this procedure applies to both engineering/scientific software that has been configuration managed in accordance with SCP-70-314, Software Configuration Management, and support software.

Application runs to test software shall be performed and documented in accordance with SCP-70-316, Software Application Control, if specified on the Software Requirements Form. Hand calculations (if applicable) shall be performed in accordance with PAP-70-301, Hand Calculation Documentation and Review.

2.0 DEFINITIONS

Only the definition unique to this procedure is included here. Other terms are defined in SCP-70-312, Determination of Software Requirements.

2.1 Testing - A general term for the purpose of this SCP, referring to conversion testing, verification, validation, or any combination thereof.

3.0 RESPONSIBLE STAFF

Staff with responsibilities for implementing this procedure are:

- Project Manager
- Testing Personnel
- Code Custodian

4.0 PROCEDURE

4.1 Requirements for Conversion Testing, Verification and/or Validation

4.1.1 The PROJECT MANAGER shall assure conversion testing, verification (including benchmarking), and/or validation required for engineering/scientific software and support software as indicated on the Software Requirements Form is performed. Testing is also required for modified versions of software created under configuration management.

4.1.2 The PROJECT MANAGER shall assure that testing personnel are qualified to test the software for the uses being evaluated.

Concurrence	Date	Approved	Date
N/A		R. B. Corlock	9/5/86
Prepared by	**Date**	**QAD Concurrence**	**Date**
J. A. Mahaffey	7-14-86	C. J. Hughes	7/18/86

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4.1.3 The CODE CUSTODIAN shall assure that testing personnel obtain the current version of software, design documentation, and documentation of any previous testing.

4.2 Preparation of the Software Testing Plan

4.2.1 TESTING PERSONNEL shall prepare a Software Testing Plan in the format of Exhibit 1. The Software Testing Plan, Exhibit 1, shall specify the testing documentation required, and the evaluation methods and acceptance criteria for review of testing. The tests that are performed shall, at a minimum, exercise the software options and the range of variables likely to be encountered in the application of the software.

4.2.2 The PROJECT MANAGER shall review the Software Testing Plan, Exhibit 1, for completeness and correctness, and shall indicate approval by signature and date.

4.3 Performance and Documentation of Testing

4.3.1 The TESTING PERSONNEL shall perform and document testing in accordance with the approved Software Testing Plan, Exhibit 1.

4.3.2 TESTING PERSONNEL shall complete and document application runs for testing in accordance with SCP-70-316, Software Application Control. Hand calculations in support of testing shall be documented in accordance with PAP-70-301, Hand Calculation Documentation and Review, if required by the applicable QA plan.

4.3.3 If a software error is discovered during testing, the TESTING PERSONNEL shall report the error to the code custodian in accordance with SCP-70-314, Software Configuration Management, and to the project manager who shall determine whether testing shall continue. If the error is so severe as to require a new software version, the testing shall not continue. In this case, the PROJECT MANAGER shall document that the Software Testing Plan is no longer applicable.

4.3.4 If testing shall not continue, TESTING PERSONNEL shall prepare a new testing plan in accordance with Section 4.2 for use with a corrected version of the software.

4.3.5 When testing is completed, TESTING PERSONNEL shall provide the project manager with testing documentation required by the Software Testing Plan, Exhibit 1.

4.4 Independent Technical Review of Testing

4.4.1 The PROJECT MANAGER shall assure that an ITR of the testing method and testing documentation required by the Software Testing Plan, Exhibit 1, is conducted in accordance with PAP-70-604, Independent Technical Review.

4.4.2 Evaluation methods and acceptance criteria for the review shall comply with the Software Testing Plan, Exhibit 1.

4.4.3 If applicable, the PROJECT MANAGER shall write a memo to the code custodian and users stating that the software is verified and the disclaimer notification shall be removed from subsequent output and listings. The PROJECT MANAGER shall assure that the memo is maintained as a research project record.

4.4.4 The PROJECT MANAGER shall assure that an approved testing results package consisting of the following is prepared:

- Software Testing Plan, Exhibit 1
- ITR Report.

The PROJECT MANAGER shall assure that a copy is maintained as a research project record, with a copy sent to the code custodian.

4.5 Reporting of Deficiencies

If the Software Testing Plan, Exhibit 1, testing results or documentation of testing are found to be deficient, the PROJECT MANAGER shall evaluate and document the deficiency in accordance with PAP-70-1502, Controlling Deviations from QA Requirements and Established Procedures.

SOFTWARE TESTING PLAN

Impact Level 1[ ] 2[ ]

1) Project title and number _____

2) Software name and version _____

3) Computer type and operating system _____

4) Purpose and scope of testing:

__ Testing of New Version __ Conversion testing __ E/S software verification __ E/S software validation __ Support software verification

_____
_____
_____
_____
_____

5) Tests to be run _____
_____
_____
_____
_____
_____

6) Evaluation methods _____
_____
_____

7) Acceptance criteria _____
_____
_____

8) Testing documentation required _____
_____
_____

9) Sponsor and/or additional requirements _____
_____
_____
_____

Reviewed and approved by:

10) _____
Preparer Date

11) _____
Project Manager Date

INSTRUCTIONS FOR COMPLETING SOFTWARE TESTING PLAN

1-2) Enter the project title and number and the software name and version on this page and any attached pages.

3) Enter the computer type and operating system on which the testing is to be performed (e.g., DEC VAX 11/780 with VMS; or CDC 7600 with LTSS).

4) Check the appropriate space and describe the purpose and scope of testing. NOTE: Software verification can encompass both conversion testing and verification.

5) Describe the application runs to be made in enough detail so that an equally competent person can reproduce them. Attach additional pages, if required. This description could consist of references to previous test documents, drawings, experimental test descriptions, run matrices, and other similar items. Input listings shall be attached, if necessary. The tests that are performed shall, at a minimum, exercise the software options and the range of variables likely to be encountered in the application of the software.

6-7) Describe the evaluation methods and acceptance criteria to be used by the independent technical reviewers. Attach additional pages, if required. Evaluation methods can include comparison of specific results with experimental data or hand calculations, with previous standard test case results, or with other software. Since acceptance criteria are the basis for reviewers to approve the testing results, they shall be quantified.

8) Describe testing documentation required (e.g., computer output).

9) Include specific sponsor requirements or other additional requirements for testing, evaluation or documentation. The Software Requirements Form or research project planning documents may be referenced here as appropriate.

10) The preparer shall sign this space and enter the date the Software Testing Plan, Exhibit 1, was prepared.

11) The project manager shall indicate approval of the Software Testing Plan, Exhibit 1, by signature and date.

CONTROLLED DOCUMENT
COPY NO. 000482

SOFTWARE CONTROL PROCEDURES

TITLE: SCP-70-317, TRANSFER OF SOFTWARE, DATA AND/OR DOCUMENTATION

1.0 APPLICABILITY

When selected on the Software Requirements Form in accordance with SCP-70-312, Determination of Software Requirements, this procedure applies to all software, data, and/or documentation that is transferred between PNL and sponsors or external contractors, and between research projects at PNL.

This procedure does not apply to transfer of software items obtained by purchase requisition under PAP-70-401, Preparation, Review and Approval of Purchase Requisitions.

2.0 DEFINITIONS

Only definitions unique to this procedure are included here. Other terms are defined in SCP-70-312, Determination of Software Requirements.

2.1 Custodian - A generic term for the purposes of this procedure that refers to either the code custodian or the data base steward, as applicable.

2.2 Receiver - An individual to whom software, data and/or documentation are transferred.

2.3 Request for Transfer (RFT) - A request for software, data, and/or documentation in the form of a letter, memo, telefax, etc.

2.4 Requester - An individual who submits a request for transfer of software, data and/or documentation.

3.0 RESPONSIBLE STAFF

Staff with responsibilities for implementing this procedure are:

- Project Manager
- Receiver of Request for Transfer
- Custodian
- Requester

Concurrence	Date	Approved	Date
N/A		[signature]	9/5/86
Prepared by	**Date**	**QAD Concurrence**	**Date**
[signature]	7/14/86	[signature]	7/18/86

Procedure No.	Revision No.	Effective Date	Page	of
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4.0 PROCEDURE

4.1 Transfer to Outside Contractors, Sponsors or to Another Research Project at PNL

4.1.1 A transfer is initiated when a REQUESTER submits a request for software, data and/or documentation to a PNL organization. A request may be in the form of a letter, memo, telefax, telephone call, etc., or may be in the format of a Request for Transfer form (RFT, Exhibit 1). If the request is not in the format of Exhibit 1, the RECEIVER shall record the request on an RFT, Exhibit 1, and forward it to the custodian.

4.1.2 On receipt of the RFT, Exhibit 1, the CUSTODIAN shall assure that the following activities are performed:

- a sequential control number is assigned to the RFT, Exhibit 1
- Part II of the RFT, Exhibit 1, is completed by specifying items to be included in the transfer package. When approved, the transfer package shall consist of the RFT, and items listed in Part II
- the RFT, Exhibit 1, is sent to the project manager for approval.

4.1.3 If the RFT, Exhibit 1, was not originated by the sponsor of the research project, the PROJECT MANAGER shall contact the sponsor (via letter or phone) to request approval for transfer. This contact shall be documented on the RFT. (NOTE: this approval is required even if another branch or office of the sponsoring organization requests software, data, and/or documentation.)

4.1.4 The PROJECT MANAGER shall review the RFT, Exhibit 1, and indicate approval or disapproval by signature and date on Part III of the RFT, Exhibit 1.

4.1.5 On receipt of project manager's approval of the RFT, Exhibit 1, the CUSTODIAN shall assure that the following activities occur:

- the transfer package as specified in Part II of the approved RFT, Exhibit 1, is prepared
- the approved RFT, Exhibit 1, and those items of the transfer package not transferred electronically are sent to the requester
- those items of the transfer package specified on the RFT, Exhibit 1, are transmitted by electronic means
- the requester of the transfer package is added to the Software User List in SCP-70-314, Software Configuration Management.

4.1.6 If the RFT, Exhibit 1, is disapproved by either the project manager or the sponsor, the CUSTODIAN shall assure that a letter is sent to the requester explaining the disapproval. A copy of the letter shall be attached and maintained as a research project record.

4.1.7 If there are problems with the transfer (e.g., incomplete package, damage enroute, etc.) as indicated by the requester by telephone, letter, telefax, or on the Acknowledgment of Receipt, Part IV of the RFT, Exhibit 1, the CUSTODIAN shall:

- document the steps taken to complete the transfer and final resolution on Part V of the RFT, Exhibit 1
- assure that additional transfers (if any) of the originally approved package are accomplished in accordance with Section 4.1.5
- assure that any other items requested are approved by submitting additional RFTs, Exhibit 1, in accordance with Section 4.1.3.

4.1.8 Upon successful completion of transfer, the CUSTODIAN shall maintain the RFT as a research project record.

4.2 Transfer from Outside PNL or from Another Research Project at PNL

4.2.1 The CUSTODIAN shall initiate a request for transfer of software, data and/or documentation from another research project in PNL or from a source outside PNL by completing Part I of the the RFT, Exhibit 1, and submitting it to the project manager for approval.

4.2.2 The PROJECT MANAGER shall review and approve the RFT, Exhibit 1, by signature and date on item 10 and return the RFT to the custodian. Item 11 does not require sponsor approval and should be marked N/A.

4.2.3 The CUSTODIAN shall assure that the approved RFT, Exhibit 1, is sent to the potential supplier of the software, data and/or documentation.

4.2.4 On receipt of the requested items, the CUSTODIAN shall assure that the contents coincide with the requirements specified on the RFT, Exhibit 1. If the items are not correct or are incomplete, the CUSTODIAN shall assure that a notice of contingency is sent to the supplier requesting the corrected items.

4.2.5 When transfer is complete (i.e., the items are correct, complete and accepted), the CUSTODIAN shall assure that the following occur:

- completion of successful transfer is documented on Part VI of the RFT, Exhibit 1
- the sender is notified of receipt of the transferred items, and a copy of the RFT, Exhibit 1, is maintained as a research project record.

4.3 Reporting of Deficiencies

If data, software and/or documentation are found to be deficient after being sent to a requester or received from another PNL research project, the PROJECT MANAGER shall evaluate and document the deficiencies in accordance with PAP-70-1502, Controlling Deviations from QA Requirements and Established Procedures.

Control No. _____

REQUEST FOR TRANSFER
(See instructions)

PART Ia: Please transfer the following described software, data and/or documentation to:

1) Name: _____
2) Address: _____
_____
_____
3) Phone number: _____

PART Ib, REQUESTED		PART II, TRANSFER PACKAGE	
4) Items Requested (include version # where appropriate):	Electronic Transfer	7) Items Transferred:	Electronic Transfer
_____	___	_____	___
_____	___	_____	___
_____	___	_____	___
_____	___	_____	___
_____	___	_____	___
_____	___	_____	___
_____	___	_____	___
_____	___	_____	___
_____	___	_____	___
_____	___	_____	___
_____	___	_____	___
5) Magnetic media type and format		8) Magnetic media type and format	
_____		_____	
_____		_____	
_____		_____	
_____		_____	
6) Reason for request		9) Explanation of differences	
_____		_____	
_____		_____	
_____		_____	
_____		_____	

PART III, APPROVAL OF TRANSFER

Reviewed and APPROVED/DISAPPROVED (circle one)

10) _____
Project Manager Date

11) _____
Sponsor Contact (for transfers from the research project) Date
APPROVED/DISAPPROVED (circle one)

REQUEST FOR TRANSFER
(See instructions)

PART IV, ACKNOWLEDGMENT OF RECEIPT

We request your acceptance of the software items, notification of any problems encountered during the installation or execution of the information on your computer, and any suggested modification which either corrects problems or might be of general utility. If the transfer package is acceptable, indicate your acceptance below. If the transfer package is unacceptable, provide an explanation of the problem and contact the addressee. Return a copy of this acknowledgment of receipt to:

12) _____
_____
_____
_____

Completed by requester:

13) __ Accepted __ Accepted, contingent upon comments

14) Comments _____
_____
_____
_____

15) _____
Requester Date

PART V, RESOLUTION OF PROBLEMS
(Completed by Custodian)

16) Action taken
_____
_____
_____
_____
_____
_____
_____

PART VI, COMPLETION OF TRANSFER

17) Transfer completion certified by:

_____
Custodian Date

_____
Project Manager Date

REQUEST FOR TRANSFER INSTRUCTIONS

PARTS Ia and Ib. The requester shall provide the following information to the the custodian:

1) The identity of the individual requesting the software, data and/or documentation.
2) The company and address of the individual.
3) The requester's phone number.
4) Software or data items requested: indicate electronic transfer, if applicable.
5) Type and format of magnetic media requested.
6) The reason for the request of the information.

PART II. The supplier or custodian preparing the transfer shall assign the corresponding control number from the Software/Data Transfer Log, Exhibit 2, and shall provide the following information:

7) Software or data items available to be supplied: indicate if electronic transfer is requested and possible.
8) The type and format of magnetic media to be supplied.
9) If software items or magnetic media type and format to be supplied differ from those requested, an explanation (included or attached). If there are none, indicate N/A.

PART III. The following are the required approvals for transfer:

10) The project manager indicates approval or disapproval of the RFT, Exhibit 1, by signature, date, and circling of either approved or disapproved.
11) The sponsor indicates approval or disapproval of the RFT, Exhibit 1, by signature, date, and circling of approved or disapproved. If sponsor approval is verbal or by letter, the project manager shall note such in item 11. The sponsor approval is required for transfers to other PNL research projects, to outside contractors, or to the sponsor, if the person or organization requesting the transfer is not the sponsor technical contact.

PART IV. The requester of the software, data and/or documentation shall provide the following:

12) Address for return of acknowledgment of receipt.
13) Status of acceptance of transferred software, data and/or documentation.
14) Explanatory comments regarding the transfer package, as necessary.
15) Signature of requester and date of signature.

PART V. Resolution of problems.

16) The custodian shall document actions taken to resolve any problem described in Item 14 above. If none, so state.

PART VI. Completion of transfer.

17) When the transfer is complete and/or all actions have been completed, the custodian and project manager shall indicate completion by signature and date.

APPENDIX C

SOFTWARE CONTROL PROCEDURE 312, EXHIBITS 1 AND 2

SOFTWARE REQUIREMENTS FORM
ENGINEERING/SCIENTIFIC SOFTWARE
Revision no. 0
Impact Level 1 [ ] 2 [X]

(Answer every question or, if appropriate for questions with a line in front of the question number, specify not applicable, N/A. If not otherwise specified, proceed to the next question in sequence.)

1) Software name (and version, if applicable) COBRA-SFS
2) Name of code custodian D. R. Rector
3) Project title Code Evaluation and Qualification Project no. 10557
4) Function of this engineering/scientific software:
   To perform thermal-hydraulic analysis of spent nuclear fuel storage systems.

SECTION I: Determination of Required Software Control Procedures *(See p. 6 of this exhibit for a flowchart of the sequence.)*

5) Is this engineering/scientific software going to be acquired from outside PNL or from another PNL research project (with a different project number)?

___ yes

_x_ no *(Mark N/A on questions 6-8. Go to question 9.)*

N/A 6) Identify software origin and version(s):

N/A 7) Describe available software documentation and version(s):

N/A 8) Will this engineering/scientific software and/or its design documentation be modified at PNL?

___ yes Required SCPs (in addition to SCP-70-312, Determination of Software Requirements) in order of application:

SCP-70-317, Transfer of Software, Data and/or Documentation *(to transfer software and its documentation)*
SCP-70-313, Final Internal Development Review of Software and Documentation
SCP-70-314, Software Configuration Management
SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
SCP-70-316, Software Application Control

(Indicate required SCPs in Section VI. Mark N/A on question 9. Go to question 10.)

___ no Required SCPs (in addition to SCP-70-312, Determination of Software Requirements) in order of application:

SCP-70-317, Transfer of Software, Data and/or Documentation *(to transfer software and its documentation)*
SCP-70-314, Software Configuration Management
SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
SCP-70-316, Software Application Control

(Indicate required SCPs in Section VI. Mark N/A on question 9. Go to question 10.)

___ 9) Is this engineering/scientific software and/or its design documentation going to be developed at PNL?

X yes Required SCPs (in addition to SCP-70-312, Determination of Software Requirements) in order of application:

SCP-70-313, Final Internal Development Review of Software and Documentation
SCP-70-314, Software Configuration Management
SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
SCP-70-316, Software Application Control

(Indicate required SCPs in Section VI.)

___ no *(You have answered "no" to questions 5 and 9. You need to reevaluate whether you have chosen the correct software class. If the class is correct, either question 5 or question 9 must be answered by "yes.")*

SECTION II: Data Associated with this Engineering/Scientific Software

10) Will data or data base(s) be used to determine input for this engineering/scientific software?

___ yes The data base steward designated in accordance with PAP-70-205, Quality Assurance Plans, is:_____.

___ yes No data base steward is required because data base software will not be used. A flat (sequential) file or binary worksheet is used to input data to software.

X no *(Mark N/A on question 11. Go to question 14.)*

N/A 11) Will data or data base(s) be acquired from outside PNL or from another PNL research project (with a different project number)?

___ yes Required SCPs (in addition to those in Section I) in order of application:

SCP-70-317, Transfer of Software, Data and/or Documentation *(to transfer data and its documentation)*
SCP-70-318, Control of Data Bases

(Indicate required SCPs in Section VI.)

___ no Required SCP (in addition to those in Section I):

SCP-70-318, Control of Data Bases

(Indicate required SCP in Section VI. Mark N/A on questions 12 and 13. Go to question 14.)

N/A 12) Identify origin of data or data base(s):

N/A 13) Describe available documentation of data or data base(s) including version(s):

SECTION III: Determination of Options for SCP-70-315, Conversion Testing, Verification, and/or Validation of Software

___ 14) Is conversion testing required for this acquired engineering/scientific software? *(Applicable if engineering/scientific software is acquired from outside PNL or is being installed on a different computer or different operating system.)*

X yes *(Indicate so under Section VI.)*

___ no

15) Is independent verification required?

___ yes *(Indicate so under Section VI.)*

___ "Independent" is defined to be verification by competent PNL individual(s) other than those from whom the work originated (they may be users, but they shall not have designed or developed the software).

___ "Independent" is defined to be verification by competent individual(s) outside PNL.

___ "Independent" is defined to be verification by:

X no

16) Is validation required?

X yes *(Indicate so under Section VI.)*

___ no

N/A 17) Left intentionally blank.

SECTION IV. Design Input *(applicable if answer to question 8 or 9 is "yes")*

__18) List research project planning documents (title and page numbers) containing design input (see Section 4.4.1):

Code Evaluation and Qualification Project Plan

__19) Is additional design input attached (see Section 4.4.2)?

_X_ yes NUREG-0856

___ no

Explain any exclusions of items in Section 4.4.2:

SECTION V: Design Documentation *(applicable if answer to question 8 or 9 is "yes". Mark all items to be included.)*

20) Mathematical models and numerical methods descriptions shall include:

___ Design input (i.e., documentation of items 18 and 19)
_X_ Statement and description of the problem
_X_ Applicable assumptions and limitations (e.g., appropriateness of algorithms)
_X_ Numerical techniques/methods
_X_ Relevant discretized (or otherwise transformed numerical solution) equations and derivations
___ Numerical stability and accuracy of methods
_X_ Notation for variables and equations
_X_ Important computational characteristics
_X_ References and sources
___ Other _____

21) User's manual shall include:

_X_ Hardware requirements including computer type and operating system
___ Software listing (handwritten, computer generated or on microfiche)
___ Testing documentation relevant to Final Internal Development Review
_X_ Structure and organization of the software by flowchart, software design language, or other appropriate means
_X_ Data input and output information
_X_ Model and system interfaces
___ Coding standards
_X_ Sample and/or test problems
___ Input/output requirements (e.g., libraries and compilers)
___ Other _____

__22) Do research project planning documents or other contractual documents require compliance to a specific standard?

___ yes Identify the standard:

_X_ no

Revision no. 0
Software name and version COBRA-SFS
Project name and no. Code Ev. + Qual - 10557

SECTION VI: Summary of Required SCPs

X SCP-70-312, Determination of Software Requirements
___ SCP-70-313, Final Internal Development Review of Software and Documentation
X SCP-70-314, Software Configuration Management
X SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
- X conversion testing
- ___ verification (independent? ___ yes ___ no)
- ___ validation

X SCP-70-316, Software Application Control
___ SCP-70-317, Transfer of Software, Data and/or Documentation
- ___ software
- ___ document of software
- ___ data
- ___ documentation of data

___ SCP-70-318, Control of Data Bases

SECTION VII: Additions or Exceptions to Questions 1-22 *(attach additional pages if necessary)*

___23) Describe any additions or exceptions to the above:

___24) Provide explanations for additions or exceptions:

SECTION VIII: Approvals of Answers to Questions 1-24

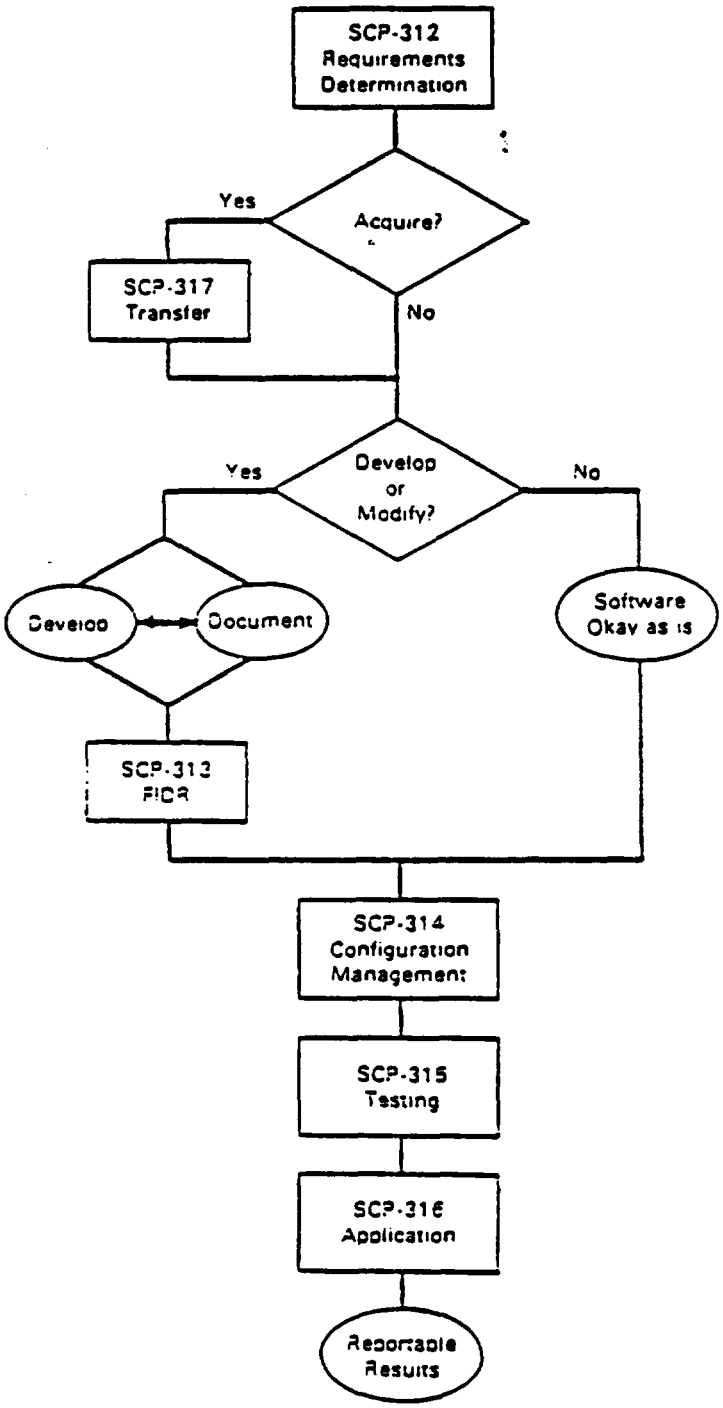
25) Prepared by:

Signature _____ Date

26) Approved by:

Project Manager, or Independent Technical Reviewer (if required) _____ Date

Engineering/Scientific Software



ATTACHMENT TO SCP-70-312, EXHIBIT 1, SECTION VII

The purpose of this QA plan is to outline the procedures to be used for transmission and maintenance of the COBRA-SFS code following its release. The following are exceptions to the previous questions:

1) A formal design review in accordance with SCP-70-313 was not required by the sponsor and was not performed.

2) Validation in accordance with SCP-70-315 was not performed. However, an extensive validation of the code was performed and is documented in PNL-6049, Vol. III. The computer runs and supporting information are stored on the LANL Central File Storage system (under DIR=/VAL) and on tape which is controlled by the project manager. (Attached is a list of the stored files.)

3) No changes have been made to COBRA-SFS (cycle 0) since validation was completed. Two sample benchmark test cases are identified in Section 7 of the COBRA-SFS User's Manual (PNL-6049, Vol. II).

4) Procedure SCP-70-317 shall not apply.

5) For the purposes of the Software Control Procedures, D. R. Rector is the project manager and designated code custodian.

6) For all Independent Technical Reviews (ITRs), independent shall be defined as by technically competent PNL individual(s) other than the principal author of the work.

VALIDATION RUNS

Text Case Description	LANL File Location	Backup Tape File
EMAD SINGLE ASSEMBLY	(DIR=/VAL/EMAD/OUT)	
helium, vert.	outhel.final	emadhel.out
air, vert.	outair.final	emadair.out
vacuum, vert.	outvac.final	emadvac.out
AGNS SINGLE ASSEMBLY	(DIR=/VAL/AGNS/OUT)	
air, vert.	outvert.final	agnsvert.out
air, horz.	outhor.final	agnshorz.out
air, inclined 25°	outinc.final	agnsincl.out
REA CONSOLIDATED BUNDLE	(DIR=/VAL/CONREA/OUT)	
nitrogen, horz.	outnit.final	connit.out
helium, horz.	outhel.final	conhel.out
REA 2023 CASK	(DIR=/VAL/REA/OUT)	
helium, vert.	outhel.final	reahel.out
air, vert.	outair.final	reaair.out
vacuum, vert.	outvac.final	reavac.out
CASTOR-1c CASK	(DIR=/VAL/CASTOR/OUT)	
helium, vert.	outhel.final	casthel.out
TN-24 CASK	(DIR=/VAL/TN/OUT)	
helium, vert.	outhelvert.final	tnvert.out
helium, horz.	outhelhor.final	tnhorz.out

SOFTWARE REQUIREMENTS FORM
SUPPORT SOFTWARE
Revision no. Ø
Impact Level 1 [ ] 2 [X]

(Answer every question, or if appropriate for a question with a line in front of the question number, specify not applicable, N/A. If not otherwise specified, proceed to the next question in sequence.)

1) Software name (and version, if applicable) RADX-1
2) Name of code custodian D. R. Rector
3) Project title Code Evaluation and Qualification Project no. 10557
4) Function of this support software:
   Input generator for COBRA-SFS

5) Is this support software a stream of commands used to execute system maintained software?

   ___ yes Identify name and version of system maintained software:

   X no

SECTION I: Determination of Required Software Control Procedures *(See p. 4 of this exhibit for a flowchart of the sequence.)*

6) Will this support software receive repeated use or be used by multiple users?

   X yes Required SCP (in addition to SCP-70-312, Determination of Software Requirements):

   SCP-70-314, Software Configuration Management

   (Indicate required SCP in Section IV.)

   ___ no

7) Is this support software going to be acquired from outside PNL or from another PNL research project (with a different project number)?

   ___ yes Required SCPs (in addition to SCP-70-312, Determination of Software Requirements) in order of application *(apply SCP-70-314 before SCP-70-315, if SCP-70-314 is required from question 6)*:

   SCP-70-317, Transfer of Software, Data and/or Documentation *(to transfer software and its documentation)*
   SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
   SCP-70-316, Software Application Control

   (Indicate required SCPs in Section IV.)

   X no Required SCPs (in addition to SCP-70-312, Determination of Software Requirements) in order of application *(apply SCP-70-314 first, if SCP-70-314 is required from question 6)*:

   SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
   SCP-70-316, Software Application Control

   (Indicate required SCPs in Section IV. Mark N/A on questions 8 and 9. Go to question 10.)

__ 8) Identify software origin and version(s):

__ 9) Describe available software documentation and version(s):

SECTION II: Data Associated with this Support Software

10) Will data or data base(s) be used to determine input for this support software?

___ yes The data base steward designated in accordance with PAP-70-205, Quality Assurance Plans, is:_____.

___ yes No data base steward is required because data base software will not be used. A flat (sequential) file or binary worksheet is used to input data to software.

_X_ no *(Mark N/A on question 11. Go to question 14.)*

N/A 11) Will data or data base(s) be acquired from outside PNL or from another PNL research project (with a different project number)?

___ yes Required SCPs (in addition to those in Section I) in order of application:

SCP-70-317, Transfer of Software, Data and/or Documentation (to transfer data and its documentation)
SCP-70-318, Control of Data Bases

(Indicate required SCPs in Section IV.)

___ no Required SCP (in addition to those in Section I):

SCP-70-318, Control of Data Bases

(Indicate the required SCP in Section IV. Mark N/A on questions 12 and 13. Go to question 14.)

N/A 12) Identify origin of data or data base(s):

N/A 13) Describe available documentation of data or data base and version(s):

SECTION III: Design Documentation *(Mark all items to be included.)*

14) User's manual shall include:

_X_ Hardware requirements including computer type and operating system
___ Software listing (handwritten, computer generated or on microfiche)
___ Testing documentation
___ Structure and organization of the software by flowchart, software design language, or other appropriate means
_X_ Data input and/or output information
___ Model and system interfaces
___ Coding standards
___ Sample and/or test problems
___ Input/output requirements (e.g., libraries and compilers)
_X_ Other Mathematical Model

SECTION IV: Summary of Required SCPs

X SCP-70-312, Determination of Software Requirements
X SCP-70-314, Software Configuration Management
X SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
- X conversion testing
- ___ verification
- ___ validation

X SCP-70-316, Software Application Control
___ SCP-70-317, Transfer of Software, Data and/or Documentation
- ___ software
- ___ documentation of software
- ___ data
- ___ documentation of data

___ SCP-70-318, Control of Data Bases

SECTION V: Additions or Exceptions to Questions 1-14

___15) Describe any additions or exceptions to the above:

___16) Provide explanations for additions or exceptions:

___17) For the following ITRs, can independent be defined to be a review by technically competent PNL individual(s) other than the principal author of the work? [NOTE: Independent is otherwise defined to be a review by competent PNL individual(s) other than those from whom the work originated (they may be users, but they shall not have designed or developed the software).]

SCP-70-314: a review of a new version of software and/or design documentation?

X yes
___ no

SCP-70-315: a review of testing and its documentation?

X yes
___ no

SCP-70-316: a review of an application package before reporting results to a sponsor?

X yes
___ no

SCP-70-318: a review of data base design, if such is required by the project manager?

___ yes
___ no

Revision no. Ø
Software name and version RADX-1
Project name and no. Code Ev + Qual - 10557

SECTION VI: Approvals of Answers to Questions 1-17

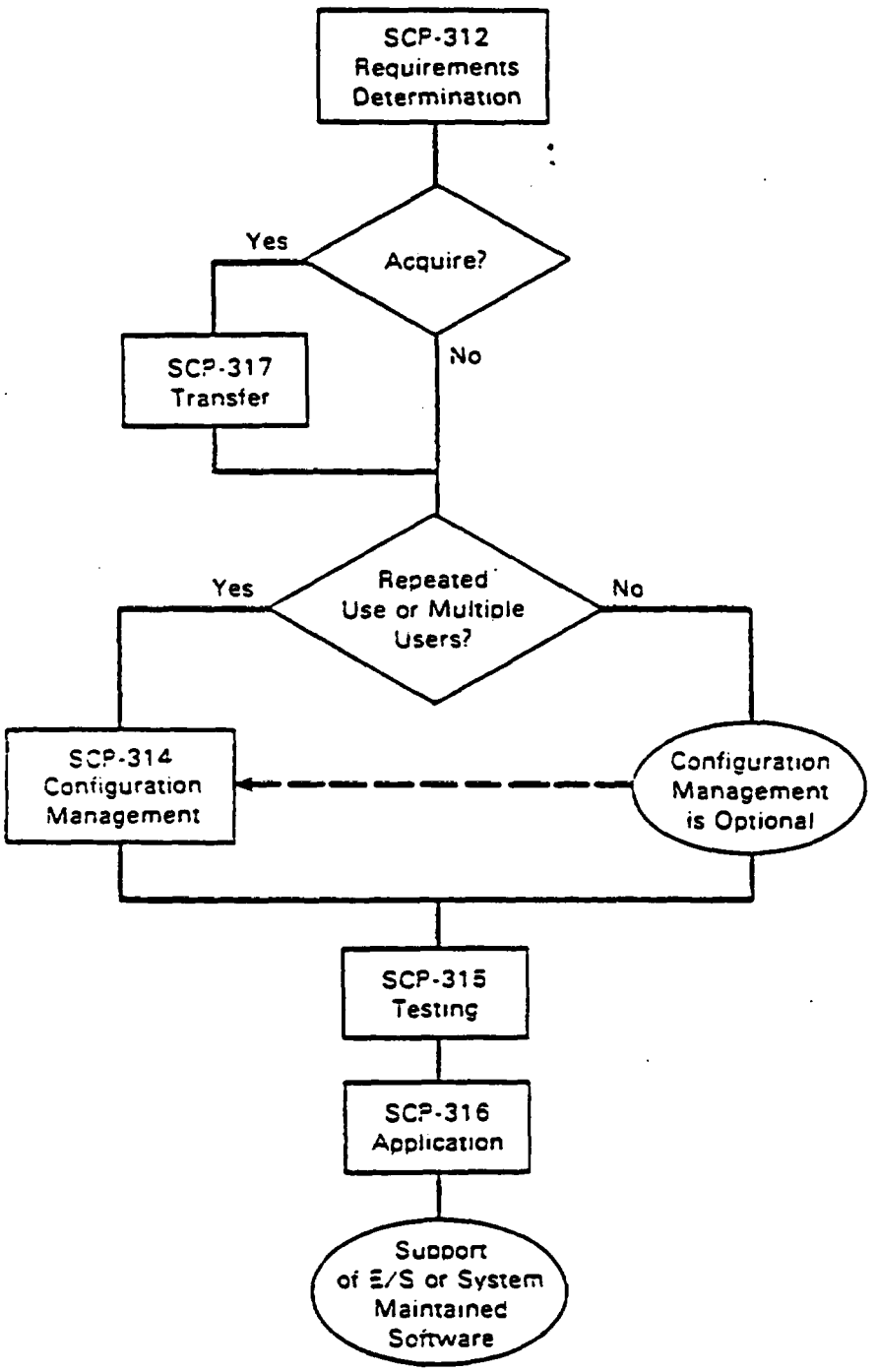
18) Prepared by:

Signature Date

19) Approved by:

Project Manager, or Independent Technical Reviewer (if required) Date

Support Software



APPENDIX D

SUPPORTING PNL QA MANUAL SECTIONS

1.1 ORGANIZATION

PURPOSE

Organizational responsibilities and interfaces are documented and communications between organizations are controlled to assure that quality-related responsibilities are clearly understood and are auditable. A formal stop work system is provided to assure that work is stopped when activities are not in substantial compliance with QA Program requirements or when corrective action is not implemented in a timely manner.

REQUIREMENTS

When fully applied, the methods in the administrative procedures and the responsibilities in this section meet the requirements of Basic Requirement 1 and Supplement 1S-1 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraphs.

External interfaces between PNL and sponsors, suppliers or Hanford Contractors shall be documented, as required, and communications between organizations appropriately controlled.

A stop work request shall be issued for activities not in substantial compliance to QA Program requirements or for activities for which corrective action is not implemented in a timely manner. Completion of appropriate corrective action shall be verified before a stop work request is lifted.

RESPONSIBILITIES

Responsibilities related to the Quality Assurance Program are defined in Management Guide 4.5, Quality Assurance, the various sections of this manual and the administrative procedures and other documents required by this manual. The significant management level responsibilities are summarized below:

Director, PNL

Ultimate management responsibility for the establishment and enforcement of PNL's quality assurance policy and program

Issuing management guides covering responsibility and authority

Assuring effective implementation of the quality assurance program

Delegating the authority and responsibility for establishing the QA Program to the Quality Achievement Director

Each Director and Manager

Assuring appropriate quality in research, construction and operations under their direction

Assuring their organization's compliance with QA requirements as specified in PNL-MA-70, QA plans and referenced procedures

Assuring that commitments to the sponsor are correct and are met, when responsible for projects or programs

Establishing, maintaining and managing technical and technical support staff, including training, qualifying and certifying when required

Arranging for adequate facilities and equipment needed to achieve quality objectives

Assuring that appropriate administrative procedures, technical procedures and instructions are approved and available

Assuring that work performed is consistent with agreements/commitments to the sponsor

Initiating corrective action within their areas of responsibility when deficiencies are noted

Quality Achievement Director

Approving revisions to the PNL quality assurance manuals and approving the PNL Administrative Procedures (PAPs)

Delegating to the Quality Assurance Department Manager the responsibility for administration and coordination of the QA Program

Quality Assurance Department Manager

Administering and coordinating the QA Program

Representing PNL on QA matters with sponsors

Developing and maintaining the QA Program for PNL as documented in the Quality Assurance Manual, PNL-MA-70, including reviewing and approving QA Procedures (QAPs) and concurring with all other administrative procedures for compliance with QA Program requirements

Interpreting QA Program requirements and determining appropriate application

Requesting and obtaining, in a timely manner, corrective action for activities not in compliance with QA Program requirements

Providing for audits and surveillance of the QA Program and obtaining corrective action as required

Issuing stop work requests on activities not in substantial compliance with QA Program requirements or activities for which corrective action is not implemented in a timely manner

Informing the Quality Achievement Director and the Director, PNL, of quality-related problems and obtaining resolution when required

Contracts Department Manager

Monitoring the sponsor contractual interface and resolving problems.

2.1 QA PROGRAM

PURPOSE

Planning of QA activities assists in the proper application of QA requirements to research projects, construction projects, services and facilities. Impact levels, based on the consequence of a potential error or failure, are used to assist in the selection of appropriate QA requirements to be included in QA plans and to be applied to each activity or item. QA plans are used to document the requirements from PNL's QA Program and any additional QA requirements from the sponsor that apply to work covered by the QA plan. Certain actions are required to be completed before a QA plan is closed-out to assure that outstanding QA-related action items are completed and records and test materials are properly stored or shipped. Monitoring and assessments by management are used to assess the scope, status and compliance to the PNL QA Program.

REQUIREMENTS

The PNL QA Program has been designed to be capable of meeting the basic requirements and supplements of ANSI/ASME NQA-1-1983 Edition, Quality Assurance Requirements for Nuclear Facilities, except as noted in specific sections of this manual. When fully applied, the methods in the administrative procedures and the requirements in this section meet NQA-1 Basic Requirement 2 except for the third paragraph which is addressed in Section 2.2. The significant requirements from the administrative procedures and this section are summarized in the following two paragraphs.

The impact level shall be determined using the criteria in Appendix I to this section, Impact Level Criteria, and QA plans shall be prepared, reviewed, approved, issued, implemented and, as needed, revised for all Impact Level I and Impact Level II research projects, services, Work Orders from Hanford Contractors, construction projects, modifications and facilities. The QA plans shall identify the requirements of the PNL QA Program and any additional QA requirements from the sponsor that apply to the work covered by the plan. Before a QA plan is closed-out, outstanding QA related action items shall be resolved, records shall be completed and transmitted as required and leftover or archival test material shall be shipped or disposed of.

Managers shall monitor the implementation of the QA Program within their organization. An assessment team appointed by the Director, PNL, shall assess the scope, status, adequacy and compliance to the PNL QA Program.

With the exception of determining and recording impact levels as required by this section, Part 1 of this manual and the administrative procedures do not apply to Impact Level III projects, items or activities. Impact Level III

projects, items and activities are covered by the Good Practices Standard in Part 2 of this manual.

RESPONSIBILITIES

Significant responsibilities include:

Cognizant Manager

Determining impact levels for research projects, service activities, Work Orders from Hanford Contractors, construction projects, modifications and facilities

Determining, or having determined, and approving impact levels for items and activities for Impact Level I or II projects, services and Work Orders from Hanford Contractors, and for construction projects, modifications and facilities if not determined by an A/E

Providing QA plans for Impact Level I or II projects, services, Work Orders from Hanford Contractors, construction projects, modifications and facilities

Obtaining the concurrence of the Quality Engineer and Quality Engineering Manager and the approval of his/her line manager on QA plans

Implementing, reviewing, revising and closing out QA plans

Department and Section Managers

Monitoring the implementation of the QA Program within their organizations

Approving QA plans, including impact levels therein, for cognizant managers that report to them

Director, PNL

Periodically initiating an assessment of the QA Program by an assessment team that is independent of the performance of the activities to be assessed and of the QAD

Reviewing and approving the report of the assessment team

Functional Directors

Concurring with and implementing any corrective actions resulting from the assessment report

Quality Achievement Director

Developing a corrective action plan for deficiencies and problems identified in assessment reports

Following-up on the corrective action plan for assessment reports and issuing a closeout report

Quality Assurance Department

Auditing the assignment of impact levels

Concurring with QA plans, revisions to QA plans and closeout of QA plans.

PROGRAM DESCRIPTION

The QA program as delineated in Part 1 of this manual is selectively applied to research and engineering technology projects and programs, construction projects, services, Work Orders from Hanford Contractors, modifications and facilities except for those projects and programs covered by PNL-MA-60, Quality Assurance Manual for License-Related Programs, and certain projects where the sponsor has specified compliance to Good Laboratory Practices regulations (e.g., 21CFR58, 40CFR792).

Items and activities classified as Impact Levels I or II, using the criteria in Appendix I of this section and administrative procedure PAP-70-208, Impact Levels, are covered by Part 1 of this manual and the associated administrative procedures. The methods and detailed responsibilities for the QA Program are included in a set of administrative procedures. A list of the procedures is in Appendix II. The specific procedures to be applied to a research project or program, construction project, service or facility covered by the QA Program are identified in a QA plan.

This section of the manual includes requirements for determining when a QA plan is required and documenting the decision when a QA plan is not required. This section also identifies some requirements for Impact Levels I and II construction projects to cover actions that occur before a QA plan is required to be issued.

QA PLANS

For Research Projects and Work Orders

The cognizant manager shall determine the impact level for all research projects and for activities covered by work orders from Hanford Contractors. Administrative procedure PAP-70-208 describes the methods used to determine impact levels (see Appendix I, Impact Level Criteria, for the criteria used).

The cognizant manager shall document the impact level and the reasons for the level, obtain his/her manager's approval on the document, and send an information copy to the Quality Assurance Department. For all projects that use a Risk Assessment form, the impact level and the reasons for the level should be recorded on the form before the form is routed for review and approval.

For Impact Level I or II projects and work orders from Hanford Contractors, a QA plan shall be implemented before work progresses beyond the planning stage.

QA plans shall be prepared and approved as described in administrative procedure PAP-70-205, Quality Assurance Plans, unless the sponsor requests a different QA program or a different QA plan format. Prior approval of the QAD Manager is required to use a different QA program. Prior approval of the Quality Engineering Manager is required to use a different QA plan format.

For Service Activities

Line managers with the assistance of a Quality Assurance Department representative shall at least annually review the services they provide and determine which services should have an Activity QA Plan. Work that is adequately covered by a Project QA Plan does not require an Activity QA Plan. However, an Activity QA Plan should normally be prepared for services that involve routine and repetitive tasks that can impact the quality of Impact Level I or II projects for which they provide services (e.g., an analytical chemistry lab performing "routine" analytical services for more than one PNL research project).

The review shall be documented in a letter from the line manager to his/her manager with a copy to the Quality Assurance Department. The letter shall include the planned issue date for any needed QA plans.

QA plans shall be prepared and approved as described in administrative procedure PAP-70-205, Quality Assurance Plans, unless the sponsor requests a different QA program or a different QA plan format. Prior approval of the QAD Manager is required to use a different QA program. Prior approval of the Quality Engineering Manager is required to use a different QA plan format.

Construction Projects

The impact level of construction projects shall be determined by the manager of the using PNL organization using the criteria in PAP-70-208. The impact level and the reason(s) for the level will be included in functional design criteria documents. QA plans for Impact Level I and II projects

shall be prepared and approved in a manner similar to that described in PAP-70-205, Quality Assurance Plans. The QA plan shall be prepared and approved early enough in the project so that appropriate requirements can be incorporated into the definitive design.

In addition to the above, the following documents that are issued before the definitive design stage is completed require the review and approval of a QA Representative prior to issuance or transmittal to DOE-RL for their use and may require the inclusion of appropriate QA program requirements:

- draft statements of work and draft advertisements for the "Commerce Business Daily" for use by DOE to obtain the services of offsite A/Es for DOE projects
- for DOE funded projects, the functional design criteria, conceptual design reports, statements of work or letters of instruction for the onsite A/E and project management plans
- for Battelle funded projects, the functional design criteria and conceptual design packages.

Impact levels and the reasons for the assigned levels are required in the functional design criteria and conceptual design documents.

Facility Modifications

For all modifications to a facility, the Building Manager shall determine the impact level for the modification using the criteria in PAP-70-208, Impact Levels, and include the impact level on the Engineering Request before forwarding the permit to Facilities Engineering. If the modification is designated as Impact Level I or II, the reason(s) for the impact level will be included in the information sent with the Engineering Request. Facilities Engineering shall review the impact level assigned and resolve any differences with the Building Manager. Impact levels shall also be noted on the Facility Modification Permit. For Impact Level I and II projects, a Modification QA Plan shall be prepared by Facilities Engineering, with the assistance of a QA Representative, before the design of the modification is started. The QA plan shall be prepared and approved in a manner similar to that described in PAP-70-205, Quality Assurance Plans.

Operating Facilities

Building Managers shall review the non-office buildings that they are responsible for and determine if any of the buildings are Impact Level I or II based on the criteria in PAP-70-208, Impact Levels. This review shall be documented

and shall include a schedule for the preparation of QA plans for Impact Level I and II facilities. Information copies shall be sent to Laboratory Safety, Facility Engineering and QAD. Facility QA Plans shall be prepared, with the assistance of a QA Representative, in a manner similar to that described in PAP-70-205, Quality Assurance Plans. Building Managers shall review significant changes in the use of their buildings to determine if changes, additions or deletions of Facility QA Plans are required.

APPENDIX I

IMPACT LEVEL CRITERIA

Impact Level I (IL I)

Impact Level I applies to items or systems in which failure could:

- result in (or increase the severity of) a release of radioactive, hazardous or toxic materials to the environment beyond established limits
- inhibit the detection of the release of radioactive, hazardous or toxic materials
- prevent control which would reduce the magnitude or consequence of a release of radioactive, hazardous or toxic materials
- result in other significant hazards to the public.

Also, if errors in the results reported to or items provided for use by a sponsor could result in any of the above conditions, the project will be classified as an Impact Level I project, unless the project is identified as an exploratory or scoping project.

Impact Level II (IL II)

Impact Level II applies to items or systems that are not Impact Level I and in which failure could:

- expose onsite personnel to radioactive, hazardous or toxic material beyond established limits
- involve significant safety concerns (Above Normal Risk) regarding equipment to be designed and/or fabricated and supplied to a sponsor or used offsite
- cause a major violation of regulatory requirements (e.g., ASME Code, EPA Standards)
- have a major impact on achievement of facility or program objectives (tests, operations, production, etc.)
- have a significant impact on the validity of reported data where the end user intends to rely on results in making significant business or operating decisions
- represent an extensive cost impact or unrecoverable schedule delay.

APPENDIX I

IMPACT LEVEL CRITERIA (CONTD)

Impact Level III

Impact Level III applies to all items or systems which are not Impact Level I or Impact Level II.

Notes

1. Classification shall be accomplished without consideration for redundancy provisions.

2. A project, service activity, facility, task, etc. shall be classified at the highest level of any included component or activity.

3. A component or activity of an Impact Level I or II project, activity or facility may be classified at a lower level than its parent project, activity, facility or system, providing the consequences of its failure satisfy the criteria for the lower classification.

APPENDIX II

PNL-MA-70 PROCEDURES

Number	Title
PAP-70-101	Communication and Commitment (Interface) Control
QAP-70-101	Stop Work Request
PAP-70-201	Indoctrination and Training
PAP-70-202	Management Assessment of QA Program Effectiveness
PAP-70-203	Qualification and Certification of Inspection/Test and NDT Personnel
PAP-70-205	Quality Assurance Plans
PAP-70-208	Impact Levels
QAP-70-204	QA Audit Personnel Qualification
PAP-70-301	Hand Calculations, General
PAP-70-302	Design Requirements, Definitions and Documentation
PAP-70-303	Design Analysis and Calculations
PAP-70-304	Performance of Design
PAP-70-305	Verification of Design
PAP-70-306	Release of Design Drawings and Documents
PAP-70-307	Design Controls for Fabrication and Construction
SCP-70-312	Determination of Software Requirements
SCP-70-313	Final Internal Development Review of Software and Documentation
SCP-70-314	Software Configuration Management
SCP-70-315	Conversion Testing Verification and/or Validation of Software
SCP-70-316	Software Application Control
SCP-70-317	Transfer of Software, Data and/or Documentation
SCP-70-318	Control of Data Bases
CAP-70-401	Preparation of RFPs and Award of Purchase Orders/Subcontracts
PAP-70-401	Preparation, Review and Approval of Purchase Requisitions
PAP-70-404	Obtaining Services Via Work Orders
PAP-70-501	Preparation, Review and Approval of Procedures
PAP-70-601	Document Control
PAP-70-602	Document Change Control
PAP-70-604	Independent Technical Review
PAP-70-605	Document Control - Furnished Documents
PAP-70-606	Peer Review

APPENDIX II

PNL-MA-70 PROCEDURES (CONTD)

Number	Title
CAP-70-701	Proposal Evaluation and Supplier/Subcontractor Selection and Purchase Order/Subcontract Administration (Post Award)
PAP-70-702	Preparation and Use of ITIs
PAP-70-704	Source Inspections, Tests and Surveillances
PAP-70-706	Receiving Inspection
QAP-70-701	Preaward Evaluations/Surveys
QAP-70-703	Material Overchecks
QAP-70-704	Supplier and Other Hanford Contractor Audits
QAP-70-705	Review of Supplier/Subcontractor Submitted Documents
PAP-70-801	Material Identification and Control (Testing and Experimentation)
PAP-70-803	Material Identification and Control
PAP-70-901	Control of Processes
PAP-70-902	Control of Special Processes
QAP-70-1001	Planning and Performing Surveillance
PAP-70-1101	Test/Analysis, Planning, Performance and Evaluation
PAP-70-1201	Calibration Control System
QAP-70-1201	Optimization of Calibration Intervals
PAP-70-1301	Handling, Storage and Shipping
PAP-70-1401	Inspection and Testing Status and Tagging
PAP-70-1501	Nonconformance Reports
PAP-70-1502	Controlling Deviations from QA Requirements and Established Procedures
PAP-70-1602	Corrective Action
PAP-70-1701	Records System
PAP-70-1704	Laboratory Record Books
QAP-70-1701	QAD Records
QAP-70-1801	Internal Audits

2.2 INDOCTRINATION AND TRAINING

PURPOSE

Staff members are instructed in the quality assurance program, including both PNL-MA-70 and the administrative procedures, to provide them with an understanding of the program and of their responsibilities for implementing it.

Staff members are selected and receive additional training and examination as necessary to assure that they will be qualified (and in some cases can be certified) to perform their quality related functions. Records are kept of personnel selection, training, qualification and certification to support determinations of the acceptability of the results of activities affecting quality; e.g., the validity of data.

REQUIREMENTS

When fully applied, the methods included in the administrative procedures for the instruction and training of PNL staff members meet the requirements related to training in Basic Requirement 2 (third paragraph) and Supplements 2S-1, 2S-2 and 2S-3 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraph.

Staff members who perform activities affecting quality shall receive instruction in the quality assurance program, with emphasis on their particular areas of activity. Staff members shall have the education, training and experience necessary to qualify them for the performance of their functions. Personnel who perform independent inspection or acceptance testing shall be certified on the basis of both initial and ongoing evaluations of their capability. Personnel who perform nondestructive testing for acceptance purposes shall be qualified and certified in accordance with SNT-TC-1A. Auditors shall be qualified to perform their particular auditing assignments. Lead Auditors shall be qualified, examined and certified for their ability to plan, lead, report and follow up on audits. Records of instruction and training activities shall be maintained.

RESPONSIBILITIES

Significant responsibilities include:

Laboratory Training Coordinator

Providing orientation in the quality assurance program

Coordinating the quality assurance training program

Maintaining quality assurance training program records

Project and Line Organization

Selecting personnel with the requisite education and experience

Determining staff members' training needs and assuring that the needs are met

Providing instructors and lesson plans for training courses, and conducting these courses

Providing on-the-job training and reading assignments

Determining and maintaining records of staff qualifications

Assigning work on the basis of staff qualifications

Quality Assurance Department

Determining the qualifications of staff members who perform independent inspection or acceptance testing, certifying these people and maintaining current records of their qualifications

Assuring that auditors are qualified for their auditing assignments

Evaluating and certifying Lead Auditors and maintaining current records of their qualifications.

3.2 COMPUTER SOFTWARE

PURPOSE

Controls are established over the development, modification, acquisition and use of software to assure that data produced by the software are valid representations of the natural or other phenomena being modeled. Software design inputs are developed and reviewed to provide a sound basis for the design process. Newly developed or modified software is reviewed to eliminate as many deficiencies as possible before testing and initiating configuration management. Software that has been developed, modified or acquired is tested to verify and validate its outputs. Configuration management, access control and physical protection are applied to protect the software against unauthorized changes, loss or deterioration. The application of software is approved, documented and reviewed to assure that the application is correct and that problems encountered are properly documented and resolved.

Data bases are controlled to assure that inputs are correct, modifications are made properly, data are protected, and deficiencies are documented, reported and resolved.

Software controls depend on the classification assigned to the software at the beginning of its development, or upon its acquisition. These controls have no direct relationship to the impact level of the software application.

REQUIREMENTS

When fully applied, the methods included in the administrative procedures for computer software control meet the requirements in Basic Requirement 3 and Supplement 3S-1 of NQA-1, as interpreted for software. The significant requirements from the administrative procedures are summarized in the following paragraphs. These requirements do not apply to software that is part of a purchased measuring and test equipment system, unless PNL changes the software.

Software shall be classified, and requirements for the software shall be determined based on its classification. Newly developed or modified software shall receive an independent technical review. Software shall be verified, and validated when required, through testing. Records of software configuration shall be maintained. Software shall be protected against uncontrolled changes and against loss or damage. Software applications shall be documented. Application problems shall be documented and resolved. Transfers of software to or from PNL shall be approved and documented.

Inputs to data bases shall be verified. Modifications to data bases shall be approved. Access to data bases shall be limited. Data bases shall be backed up. Deficiencies in data bases shall be documented and resolved.

RESPONSIBILITIES

Significant responsibilities include:

Using Organization

Classifying software and determining the requirements for its control

Obtaining and resolving independent technical review of newly developed software

Testing software to verify and validate it

Controlling software configuration

Protecting software and data bases

Approving and documenting software applications

Approving and documenting software transfers

Controlling inputs, modifications and access to data bases.

6.1 DOCUMENT CONTROL

PURPOSE

Documents that prescribe activities affecting quality; e.g., instructions, procedures and drawings; and changes to these are controlled in order to assure that the versions used are complete, correct, current and available at the location of the work. Controls include review, comment resolution, approval and distribution control.

Reviews, comment resolutions and approvals are performed to assure that the documents (including changes) are complete, correct and practical, satisfy the applicable requirements and include the appropriate quality assurance requirements.

Distribution is controlled to assure that document holders have the latest approved versions. Workplace copies are specially controlled to assure that they are at the workplace before and during the work, and that they are current.

Impact Level II technical procedures do not require independent technical reviews, formal comment resolutions or distribution control (except for workplace copies). Impact Level I technical procedures require all of these.

REQUIREMENTS

When fully applied, the methods included in the administrative procedures for the control of documents that prescribe activities affecting quality meet the requirements of Basic Requirement 6 and Supplement 6S-1 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraph.

Documents that prescribe activities affecting quality shall be reviewed by knowledgeable reviewers, including Quality Assurance personnel. Review comments shall be resolved. The documents shall be approved for issuance by designated approval authorities. Distribution of the documents shall be controlled. Workplace copies shall be at the workplace before and during the performance of work, and shall be replaced or updated with approved changes. Changes, except for editorial changes, shall be controlled in the same way as original documents.

RESPONSIBILITIES

Significant responsibilities include:

Director, Quality Achievement

Approving PNL Administrative Procedures (PAPs) for the Director, PNL

Quality Assurance Department

Controlling the review, comment resolution, approval and distribution list for administrative procedures

Approving Quality Assurance Procedures (QAPs)

Reviewing and concurring in drawings and procedures

Project and Line Organizations

Approving administrative procedures other than PAPs and QAPs

Approving drawings

Controlling drawings, technical procedures and test instructions

Assuring the availability and currentness of workplace copies of instructions, procedures and drawings

Document Control

Publishing and distributing administrative procedures, and maintaining their table of contents

Controlling the distribution of other documents as requested

All Staff Members

Adhering to approved instructions, drawings and procedures.

15.1 CONTROL OF NONCONFORMING ITEMS

PURPOSE

Controls are established for the documentation, control and disposition of nonconforming items to prevent their inadvertent use. Controls are also provided for the documentation of deviations from QA requirements and established procedures so that the deviations can be evaluated for impact on the integrity and validity of the work and corrective action taken to prevent future occurrences.

REQUIREMENTS

When fully applied, the methods included in the administrative procedures for control of nonconforming items and deviations from QA requirements and established procedures meet the requirements of Basic Requirement 15 and Supplement 15S-1 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraph.

Nonconforming items shall be identified, documented, controlled, evaluated and dispositioned. Deficiencies shall be documented, evaluated and resolved.

RESPONSIBILITIES

Significant responsibilities include:

Initiating Organization

Identifying, segregating or otherwise controlling and documenting nonconforming items

Withholding nonconforming items from use until approval of the disposition has been obtained and any necessary repair or rework done

Documenting deficiencies

Verifying and documenting that the disposition has been performed as directed

Using Organization

Determining the impact of a deficiency on research project results

Implementing corrective actions to resolve the deficiency

Identifying any project results affected by the deficiency and noting the location of corrected project results

Approving the disposition of nonconforming items

Contracts

Communicating deviation information to suppliers and obtaining dispositions

Quality Assurance Department

Verifying that reviewers have signed and dated each deficiency or nonconformance report and determining if additional reviews are required

Transmitting a copy of such documentation to the organization responsible for performance of the disposition

Verifying that disposition action has been taken, when appropriate

Periodically analyzing nonconformance reports for quality trends.

16.1 CORRECTIVE ACTION

PURPOSE

Significant conditions adverse to quality are reported and causes are determined. Corrective action is taken to minimize the likelihood of recurrence.

REQUIREMENTS

When fully applied, the methods included in the administrative procedures for addressing significant conditions adverse to quality meet the requirements in Basic Requirement 16 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraph.

Nonconformances and deviations shall be documented and corrected, and trend analysis shall be performed to identify significant conditions adverse to quality. Significant conditions adverse to quality may also be found through audits, management assessments or other means. Such conditions shall be documented, causes determined and corrective action taken to remove the causes.

Section 15.1 includes requirements for the correction of nonconformances and deficiencies. Section 18.1 includes requirements for corrective action resulting from audits.

The determination of when a condition adverse to quality is significant is partly a function of the impact level of the items including data that the condition affects or could affect in the future if not corrected.

RESPONSIBILITIES

Significant responsibilities include:

Cognizant Organization

Periodically evaluating documents received or initiated pertaining to nonconformances or deficiencies in their area of responsibility and reporting the results to the QAD Manager

Determining, implementing and completing the actions required in response to requests for corrective action

Obtaining the QAD Manager's concurrence on planned actions in response to corrective action requests

Documenting the completion of corrective actions for corrective action requests and providing a copy to QAD

Contracts

Processing corrective action requests through suppliers

Quality Assurance Department

Initiating a corrective action request when there is a significant condition adverse to quality

Concurring with the planned actions in response to corrective action requests

Verifying satisfactory corrective actions before closing out a corrective action request.

17.1 QUALITY ASSURANCE RECORDS

PURPOSE

Records of the performance of quality-related activities are controlled to assure that this information will be available for future reference. Records are physically protected or duplicated to prevent loss, damage or destruction. Records are indexed to assure their ready availability. Records are retained in accordance with established schedules to prevent premature destruction.

REQUIREMENTS

When fully applied, the methods included in the administrative procedures for the control and disposition of quality assurance records meet the requirements in Basic Requirement 17 and Supplement 17S-1 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraph.

For Impact Level I projects, designated PNL staff shall prepare a Project File Index of records with a retention classification of lifetime or nonpermanent. Retention periods for nonpermanent records shall be specified. Records shall then be accumulated and validated, and shall be indexed in accordance with the file index. Records shall be protected against loss, damage or determination. For Impact Level II projects, designated PNL staff shall maintain record files in accordance with the PNL Standard Filing System with the location of such records documented in a project management plan or centralized listing. For all Impact Level I/II projects PNL staff shall assure that quality-related records are protected from damage or loss.

RESPONSIBILITIES

Significant responsibilities include:

Records Generating Organization

Assuring that records are filed in accordance with the appropriate file index or filing system

Assuring that records are protected from damage or loss, authenticated before transmittal and traceable to the item or activity to which they apply

Preparing a Records and Inventory Disposition Schedule

Disposing of records in accordance with the governing schedule

PNL Records Management Office

Approving the Record Inventory and Disposition Schedule and appropriate project file index

Storing records in the PNL Records Center when required in governing documents

Assuring that records are dispositioned in accordance with requirements

Transmitting records to the sponsor when required.

18.1 AUDITS

PURPOSE

Audits are performed to verify compliance with all aspects of the quality assurance program and to determine where corrective action is needed. Timely corrective action is taken in order to correct the specific deficiencies identified and to prevent future occurrences of the same or similar deficiencies. Follow-up is performed to assure that timely and effective corrective action is taken in response to identified deficiencies.

REQUIREMENTS

When fully applied, the methods included in the administrative procedures for the audit function meet the requirements in Basic Requirement 18 and Supplement 18S-1 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraph.

Audits shall be systematically scheduled, planned, performed and reported. Written responses shall be provided to negative audit results by identifying the cause and noting corrective action measures taken or to be taken to prevent recurrence. Corrective action commitments shall be implemented and tracked. Performance of audits on organizations external to PNL shall be coordinated through the cognizant management or contract representative.

RESPONSIBILITIES

Significant responsibilities include:

Audited Organization

Investigating deficiencies from audits and identifying the cause

Defining, scheduling and implementing corrective actions for the cause and for the specific deficiency, including measures to prevent recurrence

Quality Assurance Department

Scheduling and performing audits

Reporting audit results to affected organizations

Reviewing audit responses for adequacy and reporting audit completion

Performing follow-up, as necessary, to verify completion of corrective action

Contracts

Arranging for the performance of audits of suppliers by PNL

Transmitting and receiving audit correspondence between the supplier and PNL

Obtaining corrective action from the supplier to audit findings.

APPENDIX E

SUPPORTING PNL ADMINISTRATIVE PROCEDURES

CONTROLLED DOCUMENT
COPY NO. 000482

PNL ADMINISTRATIVE PROCEDURES

TITLE: PAP-70-101, COMMUNICATION AND COMMITMENT (INTERFACE) CONTROL

1.0 APPLICABILITY

This procedure applies to both written and oral communications on technical and quality assurance matters between PNL and its sponsors. It also applies to commitments made by PNL to its sponsors, and vice versa.

This procedure applies to both multi-project programs and to single projects or activities. When this procedure is used on a single 1830 project, those requirements described for the Program Manager are the responsibility of the Cognizant Manager.

Communications with PNL suppliers and Hanford Contractors are described and controlled through the procurement document control series of procedures (PAPs 70-401 through 70-404, and CAPs 70-401 and 70-701) and through the series for control of purchased items and services (PAPs 70-702 through 70-706).

2.0 DEFINITIONS

None.

3.0 RESPONSIBLE STAFF

Staff responsible for implementing this procedure are:

- Cognizant Manager
- Program Manager
- Cognizant Contract Associate
- Contract Administrator

4.0 PROCEDURE

4.1 COGNIZANT MANAGERS shall ensure that all communications between PNL and sponsors are controlled and documented in accordance with Battelle policy and the requirements of the sponsor agreement.

4.2 COGNIZANT MANAGERS shall assure that project files contain documentation sufficient to constitute a full history and permit ready reconstruction of all actions for the purpose of:

- providing a complete background to assure informed decisions at each step

Concurrence	Date	Approved	Date
N/A		Stanley Goldsmith	10/10/86
Prepared by	**Date**	**QAD Concurrence**	**Date**
	10/9/86		10/10/86

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- providing information for reviews/audits
- furnishing essential facts in the event of inquiries/challenges by third parties (government agencies/auditors, litigation, etc.).

4.3 COGNIZANT MANAGERS shall ensure that no 1830 work or 1831 Government or Industrial contract work is performed prior to the issuance of an approved work authorization.

4.4 COGNIZANT MANAGERS shall:

- for 1830 Programmatic/Related Services, ensure that all commitments created subsequent to work authorization issuance are documented before activity is initiated to execute the commitment.
- for 1830 Work for Non-Federal Entities, ensure that no work in addition to or different from that specified in the sponsor agreement is performed prior to the modification of the sponsor agreement in accordance with the requirements of such agreement.
- for 1831 Government and Industrial Contracts, ensure that no work in addition to or different from that specified in the sponsor contract is performed prior to the modification of the sponsor contract in accordance with the requirements of such agreement.

4.5 The COGNIZANT MANAGER shall provide to the cognizant Program Manager all documentation required to be delivered to the sponsor.

4.6 The PROGRAM MANAGER shall obtain all required technical and quality assurance reviews/approvals of the deliverable documentation.

4.7 The PROGRAM MANAGER shall ensure that any noneditorial changes made to documentation to be delivered to the sponsor after the completion of initial technical and quality assurance reviews/approvals are resubmitted to the affected organizations.

4.8 The PROGRAM MANAGER shall provide a reproducible copy of the documentation delivered to the sponsor, as finally approved, to the Cognizant Manager for processing as a project record.

4.9 COGNIZANT MANAGERS shall identify those items in contracts, contract modifications, correspondence or other documents to be transmitted to the sponsor that either establish new commitments to the sponsor or satisfy previous ones. For Impact Level I projects, these commitments shall be registered in a Commitment Control Log (Exhibit 1) or in a computer data base that provides the same information as Exhibit 1. The Commitment Control Log may also be used to register commitments by the sponsor to PNL.

For Impact Level II projects, the commitments shall be documented and tracked, but use of the Commitment Control Log is not required.

4.10 The PROGRAM MANAGER or designee shall periodically, but not less frequently than monthly, review the status of commitments to the sponsors and take action as required. He/she shall also review the status of actions required of the sponsor (approvals, clearances, authorizations) and

- for 1830 Programmatic/Related Services, take action as necessary
- for 1830 Work for Non-Federal Entities, notify the Contract Services Contract Administrator of any problems
- for 1831 Government and Industrial Contracts, notify the Cognizant Contract Associate of any problems.

4.11 When notified of problems by a Program Manager, the CONTRACT ADMINISTRATOR, for 1830 Work for Non-Federal Entities, or the COGNIZANT CONTRACT ASSOCIATE, for 1831 Government and Industrial Contracts, shall take any necessary action, notify the Program Manager of the action and provide appropriate records for the project files.

COMMITMENT CONTROL LOG

Page _____

Program Manager _____

Document Name/No.	Date Issued	Commitment	Responsible Individual	Due Date	Date Completed	Closed Out by (initials)

CONTROLLED DOCUMENT
COPY NO. 000482

PNL ADMINISTRATIVE PROCEDURES

TITLE: PAP-70-201, INDOCTRINATION AND TRAINING

1.0 APPLICABILITY

This procedure describes the methods for planning, performing and documenting indoctrination and training for PNL staff performing activities affecting quality to assure that suitable proficiency is achieved and maintained.

The training requirements for inspection, test and NDT personnel are provided in PAP-70-203.

The training requirements for QA Lead Auditor and auditors are provided in QAP-70-204.

This procedure applies to impact Level 1 and 2 projects/activities with the exception as noted in paragraph 4.3.5.

NOTE: Paragraphs 1.0, 2.0, 3.0, 4.0, 4.1, 4.2, 4.3, and 4.5 apply to Level I and II projects/activities.

2.0 DEFINITIONS

2.1 Certification (staff) - The action of determining, verifying and attesting in writing to the qualifications of staff members.

2.2 Indoctrination and Training - This term, as used in this procedure, includes all of the actions necessary (e.g., formal training, on-the-job training, required reading assignments) to assure that personnel assigned to manage or perform activities affecting quality are instructed in the project's purpose, scope of work and implementation of the QA Plan, administrative and technical procedures and interfaces applicable to their work assignments.

2.3 Qualification - The characteristics or abilities gained through education, training or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

2.4 Technical Training - Training which is specific to a process or responsibility rather than to an administrative procedure and which is essential to a project or department.

Concurrence	Date	Approved	Date
N/A		Stanley P. Schmidt	9/29/86
Prepared by	**Date**	**QAD Concurrence**	**Date**
Michael J. Schmis	9-19-86	C. E. Hughley	9/19/86

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3.0 RESPONSIBLE STAFF

Staff responsible for implementing this procedure are:

- Laboratory Training Coordinator
- Line Manager
- Cognizant Manager
- Trainer
- Trainee
- Cognizant Staff
- QAD Representative

4.0 PROCEDURE

4.1 Orientation and Indoctrination

The LABORATORY TRAINING COORDINATOR, in coordination with the QAD Manager shall develop and maintain a generic PNL Quality Assurance (QA) Orientation and Indoctrination Program. This program will be a basic QA course, introducing concepts, policy and philosophy of quality-related activities at PNL including the purpose, scope and implementation of quality related manuals and administrative procedures.

4.2 Types of Training

This procedure recognizes four types of training.

4.2.1 Formal training is used where large amounts of detailed information must be presented, and where feedback, in the form of discussion or examination, is desired in order to determine the extent of understanding of the presentation. Assignments and completion of formal training shall be documented on the Training Assignment form (Exhibit 1, Page 1 of 4).

4.2.2 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 (Exhibit 6). Assignment and completion of OJT shall also be documented on the Training Assignment form (Exhibit 1, Page 4 of 4).

4.2.3 Briefings should be used in situations where the COGNIZANT MANAGER determines that the amount of material to be presented does not justify formal training. Briefing sessions shall be documented on the Briefing Documentation form (Exhibit 2), if the manager desires that such training be entered in the individual training record.

4.2.4 Required reading assignments designated by the COGNIZANT MANAGERS shall identify required reading/study of the applicable codes, standards and technical and administrative procedures and subsequent revisions. Reading assignments shall not be used as a substitute for

assigned training. Required reading assignments shall be documented on the required reading lists of the Training Assignment form for Administrative Procedures (Exhibit 1, Page 2 of 4) and Technical Training (Exhibit 1, Page 3 of 4), and upon completion of the applicable training assignment, the form forwarded to Laboratory Training Coordination.

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:

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

4.3.2 The COGNIZANT MANAGER shall assure that all personnel receive the appropriate indoctrination and training and that they are sufficiently qualified prior to their being allowed to work on activities affecting quality. Personnel discovered to be inadequately indoctrinated and trained shall be removed from the work being performed until adequate training has been completed.

4.3.3 The COGNIZANT MANAGER shall assure that personnel operating equipment and systems (e.g., autoclaves, other high pressure test systems and analytical measuring and test equipment) 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.

4.3.4 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 conduct work on activities affecting quality:

- 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

- after a significant change in a research project or activity organizational structure, scope of work, QA Plan, or procedures

- upon assignment of new personnel to a research project or activity.

4.3.5 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. For Impact Level I projects, this evaluation shall be documented on Exhibit 1 (Pages 1 and 4) as applicable.

NOTE: Paragraphs 4.4, 4.6, 4.7, 4.8, 4.9, 4.10, 4.11 and 4.12 are required for Level I projects/activities only.

4.4 Determining Training Requirements and Assigning Training

4.4.1 The COGNIZANT MANAGER shall prepare Training Assignment forms (Exhibit 1) for 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 (Exhibit 1, Page 4 of 4) 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 (Exhibit 6). Assignment and completion of OJT shall also be documented on the Training Assignment form (Exhibit 1, Page 4 of 4).

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 form shall be forwarded to Laboratory Training Coordination.

4.4.4 Cognizant Managers should contact the Laboratory Training Coordinator to discuss new needs for specific training that is not available.

a. If training is required, the requesting COGNIZANT MANAGER shall assign a trainer for development and presentation of the course.

b. The Laboratory Training Coordinator is available to assist the assigned trainer in the development of the desired training course.

4.5 Training Waivers

4.5.1 Managers may request exemption of some staff members from required technical training on the basis of equivalent training received. Waivers shall not be issued for required minimum training.

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.

4.5.3 COGNIZANT MANAGERS shall ensure that training waivers do not compromise the provisions of Section 4.3 of this procedure.

4.5.4 Training Waivers shall then be forwarded to the Laboratory Training Coordinator for review and entry into the individual training record.

4.6 Assignment and Qualification of Trainers

4.6.1 The COGNIZANT MANAGER shall assign trainers who are knowledgeable in the content of the training to conduct training.

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.

4.7 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.

4.8 Developing Lesson Plans

4.8.1 All formal training covering procedures contained in the PNL-MA-70 procedures manual shall be conducted in accordance with an approved lesson plan. Technical training (including technical procedures) may be conducted in accordance with an approved Training Plan (Exhibit 6). Lesson and Training Plans shall be developed by assigned trainers designated by COGNIZANT MANAGERS.

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 (Exhibit 5) Lesson Plan Preparation Guide and forms. Lesson Plan forms are available in the Laboratory Training Coordination Office.

4.8.3 Upon completion of a lesson plan, the TRAINER shall submit it to the Laboratory Training Coordinator, the cognizant Manager and the QA Department for review and approval, when appropriate.

4.8.4 Lesson Plans and Training Plans for QAD Requirements training (or that which includes QAD Requirements training) shall be approved by a QAD REPRESENTATIVE. If QAD requirements are not addressed (e.g., technical training only), the COGNIZANT MANAGER shall mark the QAD Representative signature space of the Lesson Plan with "N/A."

4.8.5 A master file of approved lesson plans shall be retained in Laboratory Training Coordination for future use and update.

4.8.6 The LABORATORY TRAINING COORDINATOR shall obtain distribution of all revisions, changes, additions or deletions to administrative procedures, manuals or QA plans that affect training.

a. The LABORATORY TRAINING COORDINATOR shall identify lesson plans that are affected by changes, revisions, additions or deletions to procedures, manuals, codes and standards and refer them to the Lesson Plan author and cognizant manager.

b. Changes to lesson plans shall be initiated by the assigned TRAINER and/or author, reviewed and approved by the same individuals and organizations who reviewed and approved the original version.

4.9 Conducting Training

4.9.1 Prior to conducting training, assigned TRAINERS shall review lesson plans or training plans for content and changes and obtain Training Attendance forms (Exhibit 3).

4.9.2 All COGNIZANT STAFF are responsible for attending assigned training sessions and completing additional training as required on their individual Training Assignment form.

4.9.3 For training, as agreed by the cognizant manager, the LABORATORY TRAINING COORDINATOR shall provide trainee survey forms which shall be completed by the TRAINEE and returned to the trainer.

a. The survey forms shall request trainee opinions as to the effectiveness of the presentation, adequacy of course content and recommendations for improvement, if any.

b. The TRAINER shall submit the completed survey forms to the Laboratory Training Coordinator following completion of the course.

c. The LABORATORY TRAINING COORDINATOR shall review the completed survey forms and, if a consensus of trainees' opinion so warrants, contact the cognizant trainer and/or trainer's manager for resolution of recommended improvement.

d. Selected courses may also be observed by a manager, Laboratory Training Coordinator or a designee, who shall also complete a survey form as in Item a. above.

4.10 Documenting Training

4.10.1 TRAINERS conducting the training shall use a Training Attendance form to document the completion of the assigned training. The TRAINER(S) shall also obtain credit for attending the training by checking the box by the trainer's signature on the attendance record for the initial training course.

4.10.2 Upon completion of the training course, the assigned TRAINER shall return the completed Training Attendance forms to Laboratory Training Coordination for use in updating individual training records.

4.10.3 Copies of documentation verifying satisfactory completion of required training courses presented by organizations outside of PNL shall be provided by the TRAINEE to Laboratory Training Coordination.

4.10.4 Briefing Documentation (Exhibit 2) shall be used by the COGNIZANT MANAGER to document attendance at informal training if the manager determines that the training should be recorded in the individual training record.

4.10.5 After verifying that the training has been completed, the COGNIZANT MANAGER shall sign the completion lines on applicable parts of the Training Assignment form and forward the original or a reproduced copy to the Laboratory Training Coordinator for incorporation in the individual training record.

4.10.6 Individual training records are located in the Laboratory Training Coordination Office. Information for description and records storage can be obtained through this office.

4.11 Requalification Training

The COGNIZANT MANAGER shall assure that all staff members requiring certification to specific standards, codes and regulations receive requalification training at time intervals prescribed by these standards, codes and regulations.

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.

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.

TRAINING ASSIGNMENT

FROM _____ DATE _____

TO _____ PAYROLL NUMBER _____

JOB/POSITION TITLE _____

PROJECT _____/DEPARTMENT _____

PART A (USE BLACK INK)

The items listed indicate the formal training in which you are required to participate.

(Project/Line Manager)

_____
Signature Date

Training Course	Rev. No.	Training Recommendation (✓) Prior to Job Performance	During Job Performance	Sign and Date When Completed

Upon completion: This assignment has been reviewed with _____ and to the best of my knowledge s/he has completed the assignment and adequately understands its content.

(Cognizant Project/Line Manager or Task Leader)

_____ _____
Signature Date Signature Date
Prior to Job Performance During Job Performance

(Forms shown in the exhibits are examples only. Forms are available from LTC. Page 1 of the Training Assignment form will include a list of available training courses.)

TRAINING ASSIGNMENT

FROM _____ DATE _____

TO _____ PAYROLL NUMBER _____

JOB/POSITION TITLE _____

PROJECT _____/DEPARTMENT _____

PART B (USE BLACK INK)

Required Reading/Administrative Procedures

You are assigned to read and understand the following Administrative Procedures.

1. Administrative Procedures (by number)	Rev. No.	Training Recommendation (✓) Prior to Job Performance	During Job Performance	Sign and Date When Completed
a)				
b)				
c)				
d)				
e)				
f)				
g)				
h)				
i)				
j)				
k)				

Note: If more Administrative Procedures need to be listed than space allows, use an additional Part B.

Upon completion: This assignment has been reviewed with _____ and to the best of my knowledge s/he has completed the assignment and adequately understands its content.

(Cognizant Manager or Task Leader)

Signature _____ Date _____
Prior to Job Performance

Signature _____ Date _____
During Job Performance

TRAINING ASSIGNMENT

FROM _____ DATE _____

TO _____ PAYROLL NUMBER _____

JOB/POSITION TITLE _____

PROJECT _____ /DEPARTMENT _____

PART C (USE BLACK INK)

Required Reading/Technical Training

You are assigned to read and understand the following Technical Training.

2. Document Title	Rev. No.	Training Recommendation (✓) Prior to Job Performance	During Job Performance	Sign and Date When Completed
a)				
b)				
c)				
d)				
e)				
f)				
g)				
h)				
i)				
j)				
k)				

Note: If more documents need to be listed than space allows, use an additional Part C.

Upon completion: This assignment has been reviewed with _____ and to the best of my knowledge s/he has completed the assignment and adequately understands its content.

(Cognizant Manager or Task Leader)

Signature _____ Date _____
Prior to Job Performance

Signature _____ Date _____
During Job Performance

TRAINING ASSIGNMENT

FROM _____ DATE _____

TO _____ PAYROLL NUMBER _____

JOB/POSITION TITLE _____

PROJECT _____ /DEPARTMENT _____

PART D (USE BLACK INK)

The items identified indicate the technical and on-the-job training in which you are required to participate.

(Project/Line Manager)

_____
Signature Date

Technical Training Description	Rev. No.	Training Recommendation (✓) Prior to Job Performance	During Job Performance	Sign and Date When Completed

Upon completion: This assignment has been reviewed with _____ and to the best of my knowledge s/he has completed the assignment and adequately understands its content.

(Cognizant Manager or Task Leader)

_____ _____
Signature Date Signature Date
Prior to Job Performance During Job Performance

BRIEFING DOCUMENTATION

PROJECT/DEPARTMENT _____ DATE _____

Briefing documentation is optional at the discretion of the project/line manager. The objective of the form is to document attendance at briefing sessions that are significant to quality of work activities.

DESCRIPTION OF BRIEFING

_____

_____

_____

_____

_____

(USE BLACK INK)

SIGNATURE	PRINTED NAME	PAYROLL NUMBER	PROJECT	DEPARTMENT

CONDUCTED BY _____ (Print) _____ (Signature) _____ (Date)

SUBMITTED BY PROJECT/LINE MANAGER _____ (Signature) _____ (Date)

TRAINING ATTENDANCE

LESSON PLAN NUMBER _____ REV. _____ DATE _____

LESSON PLAN TITLE _____

_____

OVERALL COURSE TIME _____ RETRAINING DATE _____

(USE BLACK INK)

SIGNATURE	PRINTED NAME	PAYROLL NUMBER	PROJECT	DEPARTMENT

CONDUCTED BY _____ _____
(Print Name) (Payroll Number)

_____ _____
(Signature) (Date)

☐ Check to obtain credit for trainer attendance (first time presented only).

TRAINING WAIVER
(USE BLACK INK)

PRINT NAME _____ _____
(Last) (First)

PAYROLL NUMBER _____

COURSE NO. _____

COURSE TITLE _____

_____

JUSTIFICATION FOR WAIVER (Attach documents of verification to this form)

_____

_____

_____

_____

_____

_____

Submitted by
PROJECT/LINE MANAGER

_____ _____ _____ _____
(Last) (First) (Signature) (Date)

Approved by
SECTION/DEPARTMENT MANAGER

_____ _____ _____ _____
(Last) (First) (Signature) (Completion Date)

Concurred by
QUALITY ASSURANCE DEPARTMENT

_____ _____ _____ _____
(Last) (First) (Signature) (Completion Date)

Reviewed and Filed by
LABORATORY TRAINING COORDINATOR

_____ _____ _____ _____
(Last) (First) (Signature) (Completion Date)

STAFF MEMBER SIGNATURE _____ DATE _____

TRAINING WAIVER INSTRUCTIONS

1) List printed name and date.

2) List payroll number.

3) List course number, if applicable.

4) List course title.

5) State the justification for waiver and attach any supporting documents.

6) All approval signatures are required before the training waiver is valid.

7) OAD forwards approved waiver to Laboratory Training Coordinator.

8) Laboratory Training Coordinator notifies cognizant project/line manager of approved waiver.

9) Staff member notified or waiver and signs "acknowledged."

LESSON PLAN PREPARATION GUIDE

1.0 Purpose of Lesson Plan

The lesson plan assists in organizing tasks, materials and aids needed to deliver a course. A good lesson plan gives a trainer confidence when in front of the trainees and helps to:

- Provide needed motivation
- Give proper emphasis to the various parts of the lesson
- Make sure all important information is included
- Use training aids effectively
- Ask questions at the proper time
- Stay on schedule
- Insure consistency of presentation from one instructor to another.

2.0 Lesson Plan Contents

Lesson plans shall contain the following information. For the convenience of the trainer, lesson plan forms may be obtained from Laboratory Training Coordination.

- Lesson Plan No. - This is established by Laboratory Training Coordination to provide a unique identifier for each course.

- Revision No. - This is for traceability of significant changes.

- Lesson Plan Title - Provide a descriptive title which identifies the course contents.

- Prepared By - The name of person who developed and authored the lesson plan.

- Technical Concurrence - Printed name and signature of staff who have a background in the field expressed in the lesson plan.

- Requesting Project/Line Manager Reviewed and Approved - Printed name and signature of individual who requested training course.

- Quality Assurance Department Reviewed and Approved - Printed name and signature to indicate concurrence on license-related training material.

- Laboratory Training Coordination Reviewed and Approved - Printed name and signature of Laboratory Training Coordinator to indicate approval of structural content and objective development.

2.2 Lesson Plan Update Sheet

For lesson plans which have been revised, an update sheet shall be inserted behind the cover sheet. The update sheet, and additional update sheets if necessary, shall contain the following information for the current and all previous revisions of the lesson plan:

- Lesson Plan No. - Reference the update sheet to the lesson plan.
- Revision No. - Current revision number of the affected lesson plan.
- Title - Lesson plan title for traceability
- Update No. - Numerical sequence of changes applicable to each revision.
- Update Summary - Description of the changes made to the lesson plan.
- Reference - Information, such as a procedural change, requiring the change to the lesson plan.
- Signature - Appropriate Project/Line Manager, Assigned Trainer and Laboratory Training Coordinator signatures and dates.

2.3 Lesson Plan Information

The body of the lesson plan shall contain the following information in the order given. Variations from the following content requirements are subject to the aforementioned review and approval.

- Lesson Plan No. - On each page, indicate the lesson plan number in the upper right hand corner and identify the page numbers as "Page __ of __."
- References - Identify source documents from which the content of the lesson plan was obtained.
- Instructional Aids - Provide a list of the items required by the trainer to perform the course, such a type of projector, blackboard, etc.
- Trainee Materials - Provide a list of information and/or materials required to be used by each trainee during the course, indicating any provided by the trainee and those furnished by the trainer.
- Course Objectives - Describe what the trainee should be able to do or know upon completion of the lesson plan.

- Time Allocation - Indicate the time required to deliver and complete the course, including examination time. If the course consists of multiple sessions, identify the length of each session and total time.

- Cycle - If attendance at the course is required to be repeated periodically, identify the cycle, e.g., annually, etc.

- Introduction - Identify the information to be conveyed to the trainees regarding the reason for the course, what the course will cover, and if applicable, how the trainees may be examined.

- Presentation - Identify the information to be presented within the training course which should achieve the Course Objective. For each element of information, provide the following:

  a. Trainer Activity - Describe the instructional or tutorial activity, i.e., view graph, flowchart, etc., required to meet the applicable objective.

  b. Outline of Instruction - List the information and instructions to be conveyed in outline form. This element of the lesson plan is important since it controls the flow of the lesson and provides information for subsequent trainers who may be required to present the source. It also identifies specific course material which may be subject to revision as a result of changes to reference material.

  c. Trainee Activity - Identify the activity or function required of the trainee, such as discussion participation, note-taking or simple attention.

  d. Test Item - Indicate the examination question or set of questions applied to the outlined course material.

- Summary - Describe the objectives and course material as they should be summarized at the completion of a lesson.

- Application - Identify the use of the lesson plan as it pertains to particular jobs or positions.

- Evaluation - Identify the value or worth of the lesson plan utilizing a trainer evaluation format available for your convenience in the Laboratory Training Coordination.

LESSON PLAN COVER SHEET

Lesson Plan No. _____ Revision No. _____

Lesson Plan Title: _____

Prepared By: _____ Date: _____

Technical Concurrence: _____ Date: _____

_____ Date: _____

Requesting Project/Line Manager
Reviewed and Approved: _____ Date: _____

Quality Assurance Department
Reviewed and Approved: _____ Date: _____

Laboratory Training Coordination
Reviewed and Approved: _____ Date: _____

LESSON PLAN UPDATE SHEET (A)

LESSON PLAN NO. _____ REVISION NO. _____

TITLE: _____

UPDATE NO.	UPDATE SUMMARY	REFERENCE	*SIGNATURE/DATE

*Signature of the appropriate Project/Line Manager/Responsible Trainer or Laboratory Training Coordinator indicates acknowledgment of the update.

LESSON PLAN INFORMATION SHEET (B)

LESSON PLAN NUMBER

COURSE OBJECTIVES

REFERENCES

INSTRUCTIONAL AIDS

TIME ALLOCATION

TRAINEE MATERIALS

CYCLE

LESSON PLAN INFORMATION SHEET (C)

TRAINER ACTIVITY	OUTLINE OF INSTRUCTION	TRAINEE ACTIVITY	TEST ITEM
	INTRODUCTION		
	PRESENTATION		

LESSON PLAN INFORMATION SHEET (D)

TRAINER ACTIVITY	OUTLINE OF INSTRUCTION	TRAINEE ACTIVITY	TEST ITEM

LESSON PLAN INFORMATION SHEET (E)

TRAINER ACTIVITY	OUTLINE OF INSTRUCTION	TRAINEE ACTIVITY	TEST ITEM
	SUMMARY		
	APPLICATION		
	EVALUATION		

TRAINING PLAN

PROJECT/ACTIVITY: _____

TRAINING PLAN NO.: _____

LESSON TITLE: _____

_____ Revision Number _____

TRAINING PLAN OUTLINE

Note: If additional outline information is required than space allows, use an attached sheet with the same format and add a note that an attachment has been added.

I. OBJECTIVES

II. PRESENTATION

III. SUMMARY

IV. EXAMINATION (options)

(please attach all demonstration or testing documentation)

Prepared by: _____ _____
Trainer Date

Approved by: _____ _____
QA Representative Date

Approved by: _____ _____
Project/Line Manager Date

TRAINING PLAN INSTRUCTIONS

1. Training Plans shall be used for technical on-the-job training sessions.

2. Identify project or activity.

3. Assign a Training Plan Number (this number should be unique to each Individual Training Plan, and prefixed by project number or by organization abbreviation, such as Comm. for Communications).

4. List the lesson title and revision number (if applicable).

5. Objectives - Describe what the trainee should be able to do or know upon completion of the lesson plan.

6. Presentation - Identify the information to be presented within the training plan which should achieve the Course Objective.

7. Summary - Describe the objectives and course material as they should be summarized at the completion of a lesson.

8. Examination - Attach any testing or examination documents to this Training Plan.

9. Complete the approval signatures.

CONTROLLED DOCUMENT
COPY NO. 000482

PNL ADMINISTRATIVE PROCEDURES

TITLE: PAP-70-202, MANAGEMENT ASSESSMENT OF QA PROGRAM EFFECTIVENESS

1.0 APPLICABILITY

This procedure describes the methods used by management above or outside the QA Department to regularly assess the scope, status, adequacy and compliance to applicable requirements of the QA Program as delineated in PNL-MA-70.

2.0 DEFINITIONS

None.

3.0 RESPONSIBLE STAFF

Staff responsible for implementing this procedure are:

- Department and Section Managers
- Director, PNL
- Assessment Team
- Director, Quality Achievement
- Functional Directors

4.0 PROCEDURE

4.1 Management Monitoring

DEPARTMENT and SECTION MANAGERS shall monitor the implementation of the QA Program within their organizations using methods such as the following:

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

These monitoring activities shall be documented using a memo to file or similar means.

Concurrence	Date	Approved	Date
N/A		Stanley Goldsmith	9/29/86
Prepared by	**Date**	**QAD Concurrence**	**Date**
J E Ruffin	9/15/86	C. E. Hughes	9/22/86

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4.2 Annual Assessment

4.2.1 Annually, the DIRECTOR, PNL, shall select and assign assessment team members.

a. The team shall consist of at least three (3) members.

b. Team members shall be independent of the performance of the activities to be assessed and of the QAD.

c. One (1) team member shall be designated as the assessment team leader and shall coordinate the planning, performance and documentation of the assessment.

NOTE: This assessment may be made at the same time and by the same team as the PNL-MA-60 assessment. However, separate plans and reports are recommended.

4.2.2 The ASSESSMENT TEAM shall prepare a plan for the assessment.

a. The plan shall be designed so as to assess the scope, status, and effectiveness of the QA Program and its compliance to ANSI/ASME NQA-1 as delineated in PNL-MA-70.

b. The plan shall include specific objectives. These should include a review of the resolution of problems identified in previous assessments.

c. The scope of the assessment shall be determined in terms of the organizations, activities and/or projects to be included. Particular attention should be given to areas of perceived weakness and to Impact Level I projects, items and activities.

d. Background information such as audit reports should be used to assist in determination of scope and specific objectives (Items b and c above).

e. A schedule for the assessment shall be provided.

f. The interviews to be conducted and the questions to be answered shall be determined.

g. The plan should be reviewed by the QAD Manager or the Director, Quality Achievement and due consideration given to their comments. However, the assessment shall remain independent of the QAD or the Director, Quality Achievement.

4.2.3 The ASSESSMENT TEAM shall conduct the assessment in accordance with the plan with changes as found necessary during the course of the assessment. Reviews of background information such as audit and surveillance reports, procedures, correspondence and trend analyses shall be used in addition to interviews.

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

- description of the assessment scope
- identification of persons contacted during the assessment
- summary of assessment results, including a statement on the adequacy and effective implementation of the QA Program requirements
- description of the deficiencies or problems found, in sufficient detail for corrective action to be formulated and taken. Appropriate recommendations should also be included.

4.2.5 The DIRECTOR, PNL, shall review and approve the report.

4.2.6 The DIRECTOR, QUALITY ACHIEVEMENT shall develop a corrective action plan that identifies the actions to be taken, the responsible functional directors and the dates for completion. The plan shall be concurred with by the responsible functional directors.

4.2.7 FUNCTIONAL DIRECTORS with action responsibilities shall implement the actions, provide monthly status information to the Director, Quality Achievement, and notify the Director, Quality Achievement when an action is complete and ready to be verified.

4.2.8 The DIRECTOR, QUALITY ACHIEVEMENT shall provide follow-up on the corrective action plan, including monthly status reporting and verification of the completion of actions. A closeout report shall be issued when all actions have been completed and verified.

CONTROLLED DOCUMENT
COPY NO. 000482

PNL ADMINISTRATIVE PROCEDURES

TITLE: PAP-70-205, QUALITY ASSURANCE PLANS

1.0 APPLICABILITY

This procedure describes the preparation, control and use of quality assurance (QA) plans. It is applicable to both projects and support activities.

A QA plan may cover an individual project, a group of similar projects or a group of projects with one sponsor. In addition, service groups and analytical centers not directly covered by project QA plans may establish activity QA plans to identify the requirements and procedures that they intend to meet.

This procedure contains both requirements and guidance. The guidance in Exhibit 3, Guidance to PNL-MA-70 Applicability, can assist in the selection of the applicable sections of PNL-MA-70 and Exhibit 4, Guidance to Administrative Procedure Applicability, can assist in selecting the corresponding procedures for the QA plans.

2.0 DEFINITIONS

None.

3.0 RESPONSIBLE STAFF

- Project Manager
- Cognizant Manager
- Quality Engineer
- Quality Engineering Manager
- Quality Engineering Technical Leader
- Line Manager
- Author
- Cognizant Staff

4.0 PROCEDURE

4.1 Preparation

4.1.1 When QA plans are required by the QA Manual, the COGNIZANT MANAGER shall:

- provide a specific QA plan or

Concurrence	Date	Approved	Date
N/A		C E Hughes for Stanley Goldsmith	10/6/86
Prepared by	**Date**	**QAD Concurrence**	**Date**
J G Ruffin	10/3/86	C E Hughes	10/6/86

Procedure No.	Revision No.	Effective Date	Page	of
PAP-70-205	0	OCT 1 1986	1	5

CONTROLLED DOCUMENT
COPY NO. _____ OK YGO

- issue a QA plan Addendum which references an existing QA plan that is issued, accurate and fully adequate for the project in question. The addendum applies the requirements in total to the new project. The QA Plan Addendum will use the QA plan number followed by a letter designated identifier (i.e., EP-33A).

4.1.2 The COGNIZANT MANAGER and QUALITY ENGINEER shall jointly determine the QA plan scope. Each QA plan shall have a clearly defined scope.

4.1.3 QA plans may make exclusions; e.g., certain phases of work may be excluded from some of the plan's requirements. Provisions for such exclusions are made in Exhibits 1, QA Plan, and 2, Instructions for Project QA Plan.

4.1.4 The COGNIZANT MANAGER or designee shall prepare the QA plan in accordance with Exhibits 1 and 2, using Exhibits 3, Guidance to PNL-MA-70 Applicability, and 4, Guidance to Administrative Procedure Applicability.

4.1.5 The determination of functional responsibilities, requirements, and applicability in items 8 through 14 of the plan exhibit shall be appropriate to:

- the scope of work and the potential consequences of errors or malfunctions on the final results
- the sponsor's requirements
- the need for operability and reliability of the equipment and facilities
- the need for continuity of the work.

4.2 Review and Approval

4.2.1 The QA plan draft shall be reviewed and commented upon by the COGNIZANT MANAGER and/or designees, the QUALITY ENGINEER and the QUALITY ENGINEERING MANAGER, or a QUALITY ENGINEERING TECHNICAL LEADER.

4.2.2 The QA plan AUTHOR shall resolve any comments and circulate the QA plan for concurrence and approval.

4.2.3 The COGNIZANT MANAGER, QUALITY ENGINEER and QUALITY ENGINEERING MANAGER shall concur, by signature and date, with the QA plan.

4.2.4 The LINE MANAGER shall approve, by signature and date, the QA plan.

4.3 Distribution

After approval, the COGNIZANT MANAGER shall prepare a distribution list which shall include as a minimum the Cognizant Manager, appropriate project or activity personnel, Quality Engineer, Quality Engineering Manager, QAD

and the PNL Records Manager. For Impact Level I QA plans, the COGNIZANT MANAGER shall transmit the plan and distribution list to Records Management, Document Control for issuance of the plan as a controlled document. For Impact Level II QA plans, the COGNIZANT MANAGER shall maintain a distribution list and assure that everyone on the list receives a copy of the QA plan and any revisions.

4.4 Staff Responsibilities

4.4.1 On receipt of the QA plan the COGNIZANT MANAGER shall:

- implement the requirements of the QA plan where the prescribed activities occur
- assure that project personnel governed by the requirements of the QA plan are cognizant of the QA plans requirements.

4.4.2 COGNIZANT STAFF shall assure that work performed is accomplished in accordance with the requirements of the QA plan.

4.4.3 COGNIZANT STAFF who are reassigned and no longer have a need for the QA plan shall return the plan to the cognizant manager or designated document distribution control.

4.5 Revisions and Interim Changes

4.5.1 COGNIZANT MANAGERS, with QE assistance, shall review their QA plans annually, normally at the beginning of the fiscal year, and revise them as necessary. The QA plans shall be revised or an interim change issued when one of the following occurs:

- a change in scope
- a major change in organization, requirements or responsibility -- Changes such as the following may not individually be major:
  - change in project personnel, other than the project manager
  - revisions to other QA plans that are incorporated by reference
  - recognition of additional major procurements or activities requiring certified inspection test personnel
  - superseding of applicable procedures.
- an accumulation of minor changes.

4.5.2 The COGNIZANT MANAGER shall determine whether the change is to be processed as an Interim Change Notice (ICN, see Exhibit 5) or as a revision. Revisions are required when the proposed changes are extensive, when four ICNs have been approved and issued since the last revision, or when a revision is needed to avoid confusion in the use of the QA plan.

4.5.3 The COGNIZANT MANAGER or designee shall initiate the required revisions or interim changes when necessary or as requested by the Quality Engineer.

a. Interim changes shall be made using the ICN form (Exhibit 5).

b. Revisions shall require a QA plan rewrite. Revised portions shall be identified within the document by a vertical line in the right margin.

c. Revisions and major interim changes shall be prepared, reviewed, approved and issued in accordance with subsections 4.1, 4.2 and 4.3.

d. Minor interim changes require the approval of the COGNIZANT MANAGER and the QUALITY ENGINEER. Minor changes are those that do not affect the scope or requirements of the QA plan. Examples include:

- correction of typographical or grammatical errors
- wording changes to improve understanding
- addition of missing information to assure that the document is interpreted correctly
- correction of obviously incorrect information
- changes listed in 4.5.1 as not individually being major.

All other changes are major.

4.6 QA Plan Closure

4.6.1 The COGNIZANT MANAGER, upon work completion or the superseding of the QA plan, and prior to QA plan closeout shall, as appropriate:

- resolve any outstanding action items, such as open NCR's, audit findings or Deficiency Reports
- complete the project or activity records and transmit reproducible copies to the PNL Records Management Office for transmittal to DOE-RL or other designated sponsors
- ship or otherwise dispose of leftover or archival test materials and samples.

4.6.2 The COGNIZANT MANAGER shall issue a memo to the Quality Engineering Manager, with QE concurrence, that the QA plan is closed, and the date of the closure.

NOTE: If records or materials are to be retained for an extended period of time after other activities are complete, the "closure" memo may leave the requirements and procedures for these records or materials in effect.

QAP No. _____ Rev. _____

Issue Date _____

Impact Level _____ Page ___ of ___

1. TITLE: QA Plan for _____

_____

2. SCOPE: _____

_____

_____

_____

_____

_____

_____

3. SPONSOR: _____

4. AUTHORIZING DOCUMENT: _____

5. QA REQUIREMENT SPECIFICATION(S):

[ ] ANSI/ASME NQA-1 as delineated in PNL-MA-70

[ ] Other (Specify) _____

_____

This QA plan identifies the requirements from PNL-MA-70 and from the sponsor, when applicable, to be met in the performance of quality affecting work within the scope of this plan. It also identifies the key personnel, the procedures and any special instructions. The identified PNL-MA-70 sections and procedures are those that are planned at that time. It other quality-related activities are later performed, the appropriate PNL-MA-70 requirements and procedures shall be applied to them irrespective of whether they appear herein, unless specifically excluded.

6. CONCURRENCES AND APPROVAL

_____

Cognizant Manager (Concurrence) Date

_____

Quality Engineer (Concurrence) Date

_____

Quality Engineering Manager (Concurrence) Date

_____

Line Manager (Approval) Date

QAP No. _____ Rev. ____
Page ___ of ___

7. OTHER APPLICABLE QA PLANS:

No.	Rev.	Title	Approval Date

Do the above QA Plans (Item 7) provide all the direction and information that would appear in Sections 8 through 14 of this QA Plan? [ ] Yes [ ] No [ ] NA

8. ORGANIZATION/KEY PERSONNEL:

Department/Manager _____
Section/Manager _____
Line Organization/Cognizant Manager _____
Project Manager _____
Task or Subtasks Leaders and Tasks or Subtasks
_____
_____
Material Custodian(s) _____
M&TE Custodian(s) _____
Code Custodian(s) _____
Data Base Steward(s) _____
Records Custodian(s) _____
Program Office Manager _____
Program Manager and Title _____
Quality Engineer _____
Others (Names and Function) _____
_____

9. APPLICABLE PNL-MA-70 Sections:

[X] 1.1 - Organization
[X] 2.1 - QA Program
[X] 2.2 - Indoctrination & Training
[ ] 3.1 - Design Control
[ ] 3.2 - Computer Software
[ ] 4.1 - Procurement Document Control
[ ] 4.2 - Work Package and Work Order Control
[X] 5.1 - Instructions, Procedure & Drawings
[X] 6.1 - Document Control
[ ] 7.1 - Control of Purchased Items and Services
[ ] 7.2 - Control of Work Package Items and Services
[ ] 8.1 - Identification & Control of Items
[ ] 9.1 - Control of Processes
[X] 10.1 - Inspection
[ ] 11.1 - Test Control
[ ] 12.1 - Control of M&TE
[ ] 13.1 - Handling, Storage & Shipping
[ ] 14.1 - Inspection, Test & Operating Status
[X] 15.1 - Control of Nonconforming Items
[X] 16.1 - Corrective Action
[X] 17.1 - Quality Assurance Records
[X] 18.1 - Audits
[ ] ____ - _____
[ ] ____ - _____

QAP No. _____ Rev. ____

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10. APPLICABLE ADMINISTRATIVE PROCEDURES

[ ]	PAP-70-101	[ ]	PAP-70-902	[ ]	SCP-70-312
[X]	PAP-70-201	[ ]	PAP-70-1101		SCP-70-313**
[X]	PAP-70-202	[ ]	PAP-70-1201		SCP-70-314**
[ ]	PAP-70-203	[ ]	PAP-70-1301		SCP-70-315**
[X]	PAP-70-205	[ ]	PAP-70-1401		SCP-70-316**
[X]	PAP-70-208	[X]	PAP-70-1501		SCP-70-317**
[ ]	PAP-70-301	[X]	PAP-70-1502		SCP-70-318**
[ ]	PAP-70-302	[X]	PAP-70-1602		
	PAP-70-303*	[X]	PAP-70-1701		
	PAP-70-304*	[ ]	PAP-70-1704	[ ]	_____
	PAP-70-305*			[ ]	_____
	PAP-70-306*			[ ]	_____
	PAP-70-307*	[ ]	CAP-70-401	[ ]	_____
[ ]	PAP-70-401	[ ]	CAP-70-701	[ ]	_____
[ ]	PAP-70-404			[ ]	_____
[X]	PAP-70-501			[ ]	_____
[X]	PAP-70-601	[X]	QAP-70-101	[ ]	_____
[X]	PAP-70-602	[X]	QAP-70-204	[ ]	_____
[ ]	PAP-70-604	[ ]	QAP-70-701	[ ]	_____
[ ]	PAP-70-605	[ ]	QAP-70-703		
[ ]	PAP-70-606	[ ]	QAP-70-704		
[ ]	PAP-70-702	[ ]	QAP-70-705		
[ ]	PAP-70-704	[X]	QAP-70-1001		
[ ]	PAP-70-706	[ ]	QAP-70-1201		
[ ]	PAP-70-801	[X]	QAP-70-1701		
[ ]	PAP-70-803	[X]	QAP-70-1801		
[ ]	PAP-70-901				

Note: This page may be updated, without revising PAP-70-205, in order to reflect the current list of procedures.

* Applicability determined by the requirements of PAP-70-302.
**Applicability determined by the requirements of SCP-70-312.

QAP No. _____ Rev. ____

Page ___ of ___

11. APPLICABLE TECHNICAL PROCEDURES

Number & Rev.	Title or Subject	Issue Date (Actual or Planned)

12. SPECIAL SPONSOR REQUIREMENTS

A. Covered by PNL-MA-70 and/or Administrative Procedures

Sponsor Requirement	Where Covered

QAP No. _____ Rev. ____

Page ___ of ___

12. SPECIAL SPONSOR REQUIREMENTS (CONTD)

B. Not covered by PNL-MA-70 or Administrative Procedures

Sponsor Requirement	Responsibility

13. EXCLUSIONS OR LIMITATIONS OF APPLICABILITY

14. OTHER REQUIREMENTS, DIRECTION OR PLANNING

INSTRUCTIONS FOR PROJECT QA PLAN

QA Plan Number - Supplied by Quality Engineering

Impact Level - The highest impact level of any items or activities covered by the QA plan. See PAP-70-208, Impact Levels, for criteria and method of determining impact levels.

1. Title - A descriptive title for the type of work to which this plan applies, e.g., "X-Ray Diffraction Analysis."

2. Scope - Identify the program, project(s), organizational component or activity to which this plan applies.

3. Sponsor - Identify the sponsor.

4. Authorizing Document - Identify the project funding document (when applicable). If not applicable enter "NA".

5. QA Requirement Specification - Check either or both boxes. Make an entry in "Other" when the sponsor has specified QA requirements in addition to those contained in PNL-MA-70.

6. Concurrences and Approval - These boxes shall be signed and dated when the QA Plan has been found acceptable.

7. Other Applicable QA Plans - List any other QA plan(s) that apply and are to be incorporated by reference. Exceptions or Qualifications to these plans should be in Item 13.

   a. If the answer to the question at the end of Item 7 is "yes," the remaining sections of this plan form may be omitted.

   b. If the answer to the question is "NA" (because of the absence of other applicable QA plans), the remaining sections shall be completed in accordance with these instructions.

   c. If the answer is "no" (i.e., other applicable QA plans exist, but do not completely cover this scope of work), supplemental information shall be provided so that the requirements are covered completely.

8. Organizational/Key Personnel - Identify the organization components and personnel as applicable.

9. Applicable PNL-MA-70 Sections - Check each section of PNL-MA-70 that contains requirements that are expected to be applicable to this program, project, organizational component or activity, guidance provided in Exhibit 3.

10. Applicable Administrative Procedures - Check the administrative procedures that are expected to be applicable.

11. Applicable Technical Procedures - List the applicable technical procedures, including their actual or planned issue dates.

INSTRUCTIONS FOR PROJECT QA PLAN

12. Special Sponsor Requirements

    a. Covered by PNL-MA-70 and/or Administrative Procedures - State and/or reference any special sponsor requirements that are satisfied through provisions in PNL-MA-70 or administrative procedures. Identify the section(s) in PNL-MA-70 or the subsection(s) or paragraph(s) in the administrative procedures that satisfy the requirement.

    b. Not covered by PNL-MA-70 and/or Administrative Procedures - State any special sponsor requirements that are not satisfied through provision in PNL-MA-70 or the administrative procedures. Identify the responsibility for meeting each requirement.

    Use continuation sheets for Items 12a and 12b as necessary.

13. Exclusions or Limitations of Applicability - It may not be appropriate to apply all of the controls specified by this plan to all phases of activity. Therefore, this section may be used to exclude or limit the applicability of specific requirements. Describe these exclusions or limitations and the work they affect. Use a continuation sheet as necessary.

14. Other Requirements, Direction or Planning - The following are requirements of PNL-MA-70 and the administrative procedures, and shall be addressed in this section as applicable:

    - identification of the impact level of the project and all of the reasons that would make part of the project Impact Level I or II -- The criteria and methods for determining impact levels are in PAP-70-208, Impact Levels. The fundamental reasons that a project or part of a project is Impact Level I or II are used in the determination of the impact levels for lower tier work.

    - identification of the impact level of any task, subtask, procurement, Work Order or Work Package fabrication or service, item or activity specifically identified in the QA plan, including the reason(s) for each Impact Level I or II identified

    - identification of any major, known procurements and significant or special procurement controls

    - identification of any activities that will require qualified and certified inspection personnel

    - identification of any known controlled processes to be performed within the organization covered by the QA plan

    - identification of any known special processes to be performed

    - the disposition of records

    - the disposition or archiving of leftover test materials, specimens, and samples.

    This section may also be used by the cognizant manager to provide any other appropriate direction. A continuation sheet shall be used as necessary.

GUIDANCE TO PNL-MA-70 APPLICABILITY

A. ALWAYS APPLICABLE

Section	Title
1.1	ORGANIZATION
2.1	QA PROGRAM
2.2	INDOCTRINATION AND TRAINING
5.1	INSTRUCTIONS, PROCEDURES AND DRAWINGS
6.1	DOCUMENT CONTROL
10.1	INSPECTION
15.1	CONTROL OF NONCONFORMING ITEMS
16.1	CORRECTIVE ACTION
17.1	QUALITY ASSURANCE RECORDS
18.1	AUDITS

B. POTENTIALLY APPLICABLE

Section	Title	Criteria for Applicability
3.1	DESIGN CONTROL	Required when design is performed
3.2	COMPUTER SOFTWARE	Required when research computer software is developed or used
4.1	PROCUREMENT DOCUMENT CONTROL	Required when purchase requisitions are to used, when purchase orders or subcontracts are to be issued
4.2	WORK PACKAGE AND WORK ORDER CONTROL	Required when Work Packages or Work Orders are to be issued external to the project organization

GUIDANCE TO PNL-MA-70 APPLICABILITY (CONTD)

B. POTENTIALLY APPLICABLE (CONTD)

Section	Title	Criteria for Applicability
7.1	CONTROL OF PURCHASED ITEMS AND SERVICES	Required when a purchase order, subcontract, ILA or MPO is to be issued
7.2	CONTROL OF WORK PACKAGE ITEMS AND SERVICES	Required when Work Packages or Work Orders are to be issued external to the project organization
8.1	IDENTIFICATION & CONTROL OF ITEMS	Required when quality-related items, test materials or samples are to be used
9.1	CONTROL OF PROCESSES	Required when processes are to be performed
11.1	TEST CONTROL	Required when testing other than receiving inspection of procured items is performed
12.1	CONTROL OF MEASURING & TEST EQUIPMENT	Required when M&TE is to be used for data collection, process control, determination of acceptability or nondata uses
13.1	HANDLING, STORAGE AND SHIPPING	Required when loss or damage to materials or equipment could affect quality objectives
14.1	INSPECTION, TEST & OPERATING STATUS	Required when items are to be inspected or tested for acceptance. When an item is found to be nonconforming. When inadvertent change could affect test results

GUIDANCE TO ADMINISTRATIVE PROCEDURE APPLICABILITY

A. ALWAYS APPLICABLE

Procedure	Title
PAP-70-201	Indoctrination and training
PAP-70-202	Management Assessment of QA Program Effectiveness
PAP-70-205	Quality Assurance Plans
PAP-70-208	Impact Levels
PAP-70-501	Preparation, Review and Approval of Procedures
PAP-70-601	Document Control
PAP-70-602	Document Change Control
PAP-70-1501	Nonconformance Reports
PAP-70-1502	Controlling Deviations from QA Requirements and Established Procedures
PAP-70-1602	Corrective Action
PAP-70-1701	Records System
QAP-70-101	Stop Work Request
QAP-70-204	QA Audit Personnel Qualification
QAP-70-1001	Planning and Performing Surveillance
QAP-70-1701	QAD Records
QAP-70-1801	Internal Audits

B. POTENTIALLY APPLICABLE

Procedure	Title	Criteria for Applicability
PAP-70-101	Communication and Commitment (Interface) Control	Required when interface control provisions are necessary
PAP-70-203	Qualification and Certification of Inspection/Test and NDT Personnel	Required for the performance of independent inspection or acceptance testing

GUIDANCE TO ADMINISTRATIVE PROCEDURE APPLICABILITY (CONTD)

B. POTENTIALLY APPLICABLE (CONTD)

Procedure	Title	Criteria for Applicability
PAP-70-301	Hand Calculation, General	Required when the project or the project manager requires the use of calculation controls
PAP-70-302	Design Requirements, Definition and Documentation	Required when the project involves design activities
*PAP-70-303	Design Analysis and Calculations	Required when the project involves design activities
*PAP-70-304	Performance of Design	Required when the project involves design activities
*PAP-70-305	Verification of Design	Required when the project involves design activities
*PAP-70-306	Release of Design Drawings and Documents	Required when the project involves design activities
*PAP-70-307	Design Controls for Fabrication and Construction	Required when the project involves design activites
PAP-70-401	Preparation, Review & Approval of Purchase Requisitions	Required when procurements are to take place on the project
PAP-70-404	Obtaining Services Via Work Orders	Required when services from PNL service groups or from other Hanford contractors is planned
PAP-70-604	Independent Technical Review	Required when procedures and/or reports will be generated
PAP-70-605	Document Control - Furnished Documents	Required when the project plans on controlling selected documents received from either a supplier and/or the sponsor

*Use is determined by PAP-70-302

GUIDANCE TO ADMINISTRATIVE PROCEDURE APPLICABILITY (CONTD)

B. POTENTIALLY APPLICABLE (CONTD)

Procedure	Title	Criteria for Applicability
PAP-70-606	Peer Review	Required when the project plans on producing documents that will require peer review
PAP-70-702	Preparation and use of ITI's	Required when receiving inspection or source inspection is planned
PAP-70-704	Source Inspections, Tests and Surveillance	Required when the project plans to require source inspection, tests or surveillance
PAP-70-706	Receiving Inspection	Required when independent receiving inspection is planned for procurement activities
PAP-70-801	Material Identification and Control (Testing and Experimentation)	Required when assured identification and traceability of test materials and samples are required
PAP-70-803	Material Identification and Control	Required when identification and control of items other than test materials and samples are required
PAP-70-901	Control of Processes	Required when improper performance of a process could affect data validity, other deliverables, cost of schedule
PAP-70-902	Control of Special Processes	Required when special processes will be used
PAP-70-1101	Test/Analysis Planning, Performance and Evaluation	Required when tests and/or analysis are to be performed for the project
PAP-70-1201	Calibration Control System	Required when measuring and test equipment is to be used on the project

GUIDANCE TO ADMINISTRATIVE PROCEDURE APPLICABILITY (CONTD)

B. POTENTIALLY APPLICABLE (CONTD)

Procedure	Title	Criteria for Applicability
PAP-70-1301	Handling, Storage and Shipping	Required when protection of items is required during handling, storage and shipping
PAP-70-1401	Inspection and Testing Status and Tagging	Required when hardware is to be used and will require physical evidence of status
PAP-70-1704	Laboratory Record Books	Required when Laboratory Record Books are to to be used on the project
CAP-70-401	Preparation of RFPs and Award of Purchase Orders/Subcontracts	Required when procurement actions are to be performed on the project
CAP-70-701	Proposal Evaluation, Supplier/ Subcontractor Selection and Purhcase Order/Subcontractor Administration (Post Award)	Required when procurement actions are to be performed on the project
QAP-70-701	Preaward Evaluations/Surveys	Required when the project plans on major procurements and/or subcontracts that might involve QA in a preaward survey
QAP-70-703	Material Overchecks	Required when the project plans on purchasing materials such as chemicals, metals, etc.
QAP-70-704	Supplier and Other Hanford Contractor Audits	Required when audits are planned for suppliers or Hanford Contractors
QAP-70-705	Review of Supplier/Subcontractor Submitted Documents	Required when the project plans on procuring items
QAP-70-1201	Optimization of Calibration Intervals	Required when the project is to use measuring & test equipment
SCP-70-312	Determination of Software Requirements	Required when computer software is to be developed or used on the project

GUIDANCE TO ADMINISTRATIVE PROCEDURE APPLICABILITY (CONTD)

B. POTENTIALLY APPLICABLE (CONTD)

Procedure	Title	Criteria for Applicability
*SCP-70-313	Final Internal Development Review of Software and Documentation	Required when computer software is to be developed on the project
*SCP-70-314	Software Configuration Management	Required when software is to be developed/used on the project
*SCP-70-315	Conversion Testing, Verification and/or Validation of Software	Required when software is to be developed/used on the project
*SCP-70-316	Software Application Control	Required when software is to be used on the project
*SCP-70-317	Transfer of Software, Data and/or Documentation	Required when software is to be developed/used on the project
*SCP-70-318	Control of Data Bases	Required when software data bases are to be used on the project

*Use is determined by SCP-70-312.

INTERIM CHANGE NOTICE (ICN)

ICN No. _____
Page 1 of ___

A. Doc. No. _____ Rev. No. ___ Doc. Title _____

Document's Author _____

Requested by _____ Date Issued _____

B. Type of Change and Approvals:

/__/ Minor Change QAD Concurrence _____ Date _____
Approval _____ Date _____

/__/ Major Change Reviews, _____ _____
Approvals & Dates _____ _____

Sponsor concurrence documented
by: _____

C. Reason for Change:

D. Description of Change (old text versus requested test):

** PLACE THIS ICN AT THE FRONT OF THE SUBJECT DOCUMENT **

CONTROLLED DOCUMENT
COPY NO. 000482

TITLE: PAP-70-208, IMPACT LEVELS

1.0 APPLICABILITY

PNL projects, activities, facilities and items shall be assigned impact levels according to the potential safety and/or technical consequences of a failure to accomplish goals. The type and degree of safety, management and administrative controls applied to, and resource requirements for, the project, task, activity facility or item are determined or guided by the assigned impact level.

This procedure describes the method of determining and applying impact levels to research and development projects, service activities, work orders, facilities and related activities. Project impact levels are determined and documented on the Proposal Prep Sheet as the project proposal is prepared. Tasks and items within an Impact Level I or II project or activity may be assigned a lower impact level than the project or activity. Criteria and requirements for the assignment of impact levels are provided in this procedure.

2.0 DEFINITIONS

none

3.0 RESPONSIBLE STAFF

Staff responsible for implementing this procedure are:

- project/cognizant manager
- line manager
- staff members
- technical representatives
- QA representatives
- Safety representative

4.0 PROCEDURE

4.1 Impact Level Assignment

4.1.1 The PROJECT MANAGER shall determine the impact level for all 1830 and 1831 projects using the criteria in Exhibit 1, Impact Level Criteria, as the project proposal is prepared and document this impact level on the Proposal Prep Sheet and the Project Impact Level Approval form, Exhibit 2.

Concurrence	Date	Approved	Date
Walter J. Cybley	FEB 12 1987	Stanley Goldsmith	2/12/87
Prepared by	**Date**	**QAD Concurrence**	**Date**
[illegible]	2/12/87	L. M. Shorden for C.E. Hughey	2/12/87

Procedure No.	Revision No.	Effective Date	Page	of
PAP-70-208	1	02/17/87	1	4

a. If the client has specified the Battelle impact level to be applied to the project, the PROJECT MANAGER shall not assign an impact level lower than that specified level. However, a higher impact level shall be assigned if required by the criteria in Exhibit 1, Impact Level Criteria.

b. On work orders received from Hanford Contractors without an impact level (or corresponding QA level), the PROJECT MANAGER shall contact the client and obtain the impact level and justification, unless the work order covers activities that, based on client concerns, are obviously Impact Level III (see Exhibit 1, Impact Level Criteria). Contact information shall be documented and retained as part of the project/activity records.

4.1.2 The COGNIZANT MANAGER shall determine the impact level for all service activities, facilities and related activities using the criteria in Exhibit 1, Impact Level Criteria. Documentation of the applicable impact level with the rationale and approval/concurrence signatures shall be retained as part of the activity records.

4.1.3 The approval and concurrence requirements for assigned impact level are shown in Exhibit 3, Impact Level Approval and Concurrence matrix.

4.2 Documentation of Impact Levels

4.2.1 The PROJECT MANAGER shall document the project impact level on the Project Impact Level Approval form (Exhibit 2) and assure that the required approvals and concurrences are obtained. The PROJECT MANAGER shall also document the project impact level on the Proposal Prep Sheet.

4.2.2 The COGNIZANT MANAGER shall document the impact level in the project/activity management plan or, when there is no management plan required, in the project/activity QA Plan. Documentation and content requirements for QA Plans are provided in PAP-70-205, QA Plans.

4.2.3 The COGNIZANT MANAGER shall not assign an impact level to a subtier task/activity that is higher than the impact level assigned to the project activity.

4.2.4 The COGNIZANT MANAGER may assign an impact level to subtier tasks/activities that is lower than the impact level assigned to the project/activity, provided that the consequences of a potential failure of that particular item/activity was not a factor in assigning the specific impact level to the project as a whole. In such cases, the subtier item/activity shall be assigned that same impact level.

a. The COGNIZANT MANAGER shall determine, or have determined, the impact level for any task, subtask, procurement, work

order fabrication or service, item or activity to be specifically identified in the QA Plan.

b. In determining subtier impact levels, the Exhibit 1, Impact Level Criteria, shall be used.

c. More than one impact level criteria may be applicable to a given project/activity.

4.3 Impact Levels Not in the QA Plan

4.3.1 STAFF MEMBERS may assign Impact Level III to any item/activity that is to be used exclusively on a project/activity previously classified as Level III project/activity. The Cognizant Manager's signature on the purchase requisition, work order, drawing, etc., is adequate documentation of determination.

4.3.2 If items/activities have not been assigned an impact level in an approved QA Plan, the COGNIZANT MANAGER shall determine the impact level, using the criteria in Exhibit 1, Impact Level Criteria. When the impact level assigned to a specific item/activity is lower than the impact level assigned to the project/activity as a whole, the rationale, approval and concurrence for such levels shall be documented and included in the project/activity file.

4.3.3 For any documents that include, or should include, an impact level, COGNIZANT MANAGERS, LINE MANAGERS, TECHNICAL REPRESENTATIVES, SAFETY REPRESENTATIVES and QA REPRESENTATIVES shall include in their review of the document a review of the impact level assigned.

4.4 Use of Impact Levels

4.4.1 STAFF MEMBERS should note that:

- impact levels are one of the factors used in the determination of quality assurance requirements, such as sample size, surveillance frequency and the need for verification

- Impact Level I and II items and activities are required to meet the requirements of the PNL-MA-70 Manual and its associated administrative procedures

- some administrative procedures apply additional requirements to Impact Level I items and activities that are not applied to Impact Level II

- quality assurance requirements for Impact Level III items and activities are provided in the Good Practices Standard for Level III Quality Assurance, Part 2 to PNL-MA-70

- impact levels are also used to determine the applicability of other, non QA specific, management control requirements. Refer to PNL Management Guide 3.0

- other Hanford Contractors use impact levels or QA levels, with their Level I and II based on criteria similar to those in Exhibit 1, Impact Level Criteria.

4.4.2 QA REPRESENTATIVES shall review documents specifying QA requirements to determine if the QA requirements are appropriate for the assigned impact level and for the functions to be performed by the item or activity.

IMPACT LEVEL CRITERIA

Impact Level I (IL-I)

Applies to projects, tasks, activities or items whose failure could:

A. Result in (or increase the severity of) a release of radioactive, hazardous or toxic material to the public or environs beyond established release limits.

B. Inhibit the detection of such release.

C. Prevent control, including safe shutdown, which would reduce the magnitude or consequence of such releases.

A project, task, activity or item is IL-I if:

1. its maximum inventory of radioactive and/or toxic materials would require classification as "high" or "moderate" hazard according to criteria presented in PNL-MA-44, Safety Review System Manual, or

2. it or its end product is:

   a. equipment, a system or a facility (or design, analysis or operation thereof) relied upon to prevent, detect or control an off-site release of radioactive or toxic materials exceeding established limits.

   b. a peripheral component, procedure or test which, through its presence or performance could prevent the proper functioning of IL-I equipment or systems.

   c. any activity where the activity itself, its deliverable or its application will be directly relied on establishing licensing or regulatory requirements.

   d. an offsite deliverable that will be required to meet licensing requirements.

Impact Level II (IL-II)

Applies to projects, tasks, activities or items whose failure could:

A. Expose on-site personnel to radioactive, hazardous or toxic material beyond established limits.

B. Cause a major impact in achievement of facility or program objectives (tests, operations, production).

IMPACT LEVEL CRITERIA

Impact Level II (IL-II) (cont'd)

A project, task, activity or item is IL-II if:

1. its maximum inventory of radioactive and/or toxic materials would require classification as a "low" hazard according to criteria presented in PNL-MA-44, Safety Review System Manual, or

2. it or its end product is:

   a. equipment, a system or a facility (or the design, analysis or operation thereof) relied upon to prevent an on-site release of radioactive or toxic materials exceeding established limits, or

   b. a peripheral component, procedure or test which through its presence or performance could prevent the proper functioning of IL-II equipment, or

3. it includes or involves significant hazards to personnel

4. it will be required to meet statutory requirements but will be used on-site only.

5. it includes activities where error or failure could cause a major impact in achievement of facility or program objectives. These include:

   a. critical path activities in major sponsor programs or line items, e.g., designs or analysis, or acquisitions of long lead time materials and equipment.

   b. activities whose deliverables will be critical to major decisions in such areas as business, economics or technology applications.

   c. activities where documentation of how the product or result was generated is required as part of the deliverable and/or to establish the acceptability or validity of the product or results.

   d. any activity designated by the cognizant director as being of sufficient potential concern as to warrant special management attention. Typical bases for such concern might include prior sponsor evaluations, Operations Directive commitments, public or scientific image, future market potential and sponsor requests.

Impact Level III (IL-III)

A project, task, activity, or item is IL-III if it does not meet the criteria for either IL-I or IL-II.

PROJECT IMPACT LEVEL APPROVAL

Provide the following project identification information. If the requested information is not applicable to the project enter N/A in the space provided.

Account No. _____ Rev./Amend No. _____

Proposal No. _____ Rev./Amend No. _____

Project Title: _____

Project Manager: _____

Lead Department Name: _____

PROJECT IMPACT LEVEL: [ ] Level I [ ] Level II [ ] Level III

The project scope/description and work to be performed has been reviewed and classified for its applicable impact level. The requirements and guidance provided in PAP-70-208 has been used to establish this project impact level. Documentation providing the rationale used to arrive at the above selected impact level is attached to this form. These documents shall be filed and maintained in the project files as a project record.

Impact Level Concurrence:

Project Manager: _____ Date: _____

Safety Representative: _____ Date: _____

QA Representative: _____ Date: _____

Management Approval:

Department Manager: _____ Date: _____
(IL-III Approval)

Center/Office Manager: _____ Date: _____
(IL-II Approval)

Cognizant Director: _____ Date: _____
(IL-I Approval)

Distribution:
- Project File
- Laboratory Safety
- Quality Assurance
- Center/Office Manager (IL-III)
- Cognizant Director (IL-II)

Impact Level
Approval and Concurrence
Matrix

Function	Approval*/Concurrence IL-I	IL-II	IL-III
Project Impact Level Assignment	Cognizant Director*	Center or Office Mgr*	Department Mgr*
	Project Mgr	Project Mgr	Project Mgr
	Safety	Safety	Safety
	Quality Engr	Quality Engr	Quality Engr
Activity Impact Level Assignment	Cognizant Director*	Center or Office Mgr*	Department Mgr*
	Activity Mgr	Activity Mgr	Activity Mgr
	Safety	Safety	Safety
	Quality Engr	Quality Engr	Quality Engr
Facility Impact Level Assignment	F & O Director*	Facilities Administration Manager*	Department Mgr*
	Facility Mgr	Facility Mgr	Facility Mgr
	Safety	Safety	Safety
	Quality Engr	Quality Engr	Quality Engr
	Safeguards & Security	Safeguards & Security	

* Indicates approval authority

Note: Subsequent to a project, activity or facility impact level approval any lower impact level assigned to a subtier activity or task does not require the same level of approval as shown above for that subtier assigned level. Approval should be as established in the Project Management Plan or equivalent plans for activities and facilities.

CONTROLLED DOCUMENT
COPY NO. 000482

PNL ADMINISTRATIVE PROCEDURES

TITLE: PAP-70-604, INDEPENDENT TECHNICAL REVIEW

1.0 APPLICABILITY

This procedure is applicable when a documented critical review by independent, qualified personnel is required to assure the technical adequacy, completeness and correctness of technical documents.

Independent Technical Reviews (ITRs) are required on deliverables of Impact Level I scientific or technical information such as letter and topical reports, and final research reports. In addition, an ITR shall be performed when specified by an administrative procedure, a QA Plan or by a manager responsible for approving the technical document prior to its use or delivery.

Technical documents prepared and clearly identified as "preliminary drafts," "working papers" or for "information only" do not require an ITR unless specified by the Project Manager or the approval authority.

The design and peer review processes are also independent technical reviews but of a different type and are described in administrative procedures for these activites.

2.0 DEFINITIONS

None.

3.0 RESPONSIBILITIES

Staff responsible for implementing this procedure are:

- Cognizant Manager
- Approval Authority
- Independent Technical Reviewer
- Designee
- QA Representative (QAR)

4.0 PROCEDURE

4.1 General

4.1.1 The COGNIZANT MANAGER responsible for PNL approval of the technical document, hereinafter referred to as the Approval Authority, shall

Concurrence	Date	Approved	Date
N/A		Stanley Goldsmith	9/18/86
Prepared by	**Date**	**QAD Concurrence**	**Date**
[illegible]	8/21/86	C E Hughey	9/3/86

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assure that required Independent Technical Reviews (ITRs) are accomplished in accordance with this procedure prior to document approval for release/issue.

4.1.2 The APPROVAL AUTHORITY shall designate, hereafter referred to as the Designee, an individual (usually the author, author's manager or task/technical leader) to resolve the ITR comments and correct the document.

4.1.3 When formal clearance is required, the ITR may be used in conjuction with or prior to and independent of the PNL clearance process. The PNL clearance process should be performed on the final draft of the document which results from the ITR process.

4.2 Selection of Reviewers

4.2.1 The APPROVAL AUTHORITY shall select Independent Technical Reviewers, hereafter referred to as Reviewers, who will be able to assure that the document is technically adequate, complete, and correct. Selection shall be based on:

- Technologies and disciplines represented in the document.
- Qualifications of the reviewers (resume on file with Project). Those selected shall have proven competence in the subject matter of the document, and shall have been given an adequate understanding of the requirements for and objectives of the technical document.
- Reviewer independence. Those selected shall be independent of the original work performed.
- Specialists, as applicable, in such functions as:
  - health
  - safety
  - environmental safeguards
  - licensing.
- Requirement from a governing document, the Approval Authority, or the QAD management to include a QA Representative (QAR). A QAR shall participate in ITRs of technical procedures.
- The normal clearance review procedures (Clearance of Reports, Speeches and Articles for Use Outside BNW) will not provide adequate assessment of the material.

4.2.2 Personnel outside the approval authority's organization may be appointed as Reviewers with the concurrence of their manager. Such concurrence need not be documented.

4.3 Preparation of Document Review Record

4.3.1 The APPROVAL AUTHORITY shall complete the top portion of the Document Review Record (DRR), Exhibit 1, and include the following additional information as appropriate and relevant to the ITR:

- Project name and number.
- Intended use of the document.
- Applicable requirements and references to be considered in evaluating technical quality:
  - 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) include:
  - specific criteria or requirements to be met
  - information indicating importance of the document
  - other documents or requirements affected
  - potential problems requiring consideration.
- Identification of the scope of each reviewer's review (i.e., limited to a section, topic, etc., or unlimited).

4.3.2 The APPROVAL AUTHORITY shall clearly identify the DRR as an "ITR" and forward a copy of the DRR, with a copy of the document to be reviewed, to each reviewer and the designee.

4.4 Performance of Review

4.4.1 REVIEWER(S) shall review documents within their scope of review responsibility in accordance with DRR instructions. They shall either verify that the documents are adequate, complete and correct, or shall identify and document any deficiency that requires a change to the technical document.

4.4.2 REVIEWER(S) shall verify that scientific reports or other deliverables meet the following criteria, as applicable:

- reported results are traceable to and consistent with recorded data
- data reduction has been accomplished correctly

- data are traceable to their origin and to reported analytical results
- the deliverable is consistent internally and with other reports
- inferences and conclusions are soundly based
- the deliverable satisfies program objectives.

4.4.3 REVIEWER(S) shall record the comments on the DRRs and mark it to indicate that the reviewer:

- "Concurs" indicates concurrence with the document as written. Typographical and grammatical errors may be noted.
- "Concurs, but with comments" indicates concurrence with the document, subject to resolution of comments.
  - The DESIGNEE shall consider these comments, and either assure that they are incorporated into the document or record the reason for not doing so.
  - The DESIGNEE shall document the resolution comments on the DRR.
  - The DESIGNEE shall be advise orally or provide an information copy of the closed-out DRR to the reviewer prior to document approval.
- "Do Not Concur" indicates that the reviewer has identified problems regarding concept, practice, implementation or responsibilities that render the document unacceptable. Comments reflecting these problems shall be identified with an asterisk.
  - Resolution of these comments is mandatory, and the reviewers written concurrance with the resolution required.
  - If the designee, reviewer and/or author cannot resolve the comments, the disagreement shall be referred to the approval authority for final disposition and documentation on the DRR.

4.4.4 Comments that, in the REVIEWER'S judgement, require documented resolution (as a minimum, those that are the basis for a "concur, but with comment" or "do not concur" disposition) shall be written on the DRR. Other comments may be either written on the DRR or noted on the document.

4.4.5 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.

4.4.6 On completion of the review, the REVIEWER shall sign the DRR and forward it to the designee.

4.5 Comment Resolution

4.5.1 The DESIGNEE shall upon receipt of reviewer comments, review and resolve the comments. The resolutions and REVIEWER'S, of the "Do Not Concur" comments, acceptance of the resolutions shall be recorded on the DRR.

4.5.2 Major changes resulting from resolution of one reviewer's comments shall necessitate a followup ITR if changes affect another reviewer's concurrence. The followup ITR may be limited to the affected section of the document.

4.5.3 When all DRR comments are resolved and required corrections to the document have been incorporated, the DESIGNEE shall prepare an ITR Report containing:

- a statement that all required reviews have been received and that comments have been satisfactorily resolved. Further, that it is the designee's opinion that the document fulfills its requirements and objectives
- a statement summarizing details of any controversial resolutions or minority opinions of which the approval authority should be cognizant
- a list of reviewers with attached, closed out DRRs, all signed by the designee, and by the reviewers when required
- a copy of the document prior to review and a copy of the document resulting from the ITR resolutions.

4.5.4 The DESIGNEE shall sign and date the ITR Report and shall obtain the concurrence signature of the cognizant QAR that all comments are resolved and document corrections incorporated.

4.5.5 The DESIGNEE shall route the ITR Report and attachments to the approval authority.

4.5.6 The PROJECT MANAGER shall assure that a copy of the ITR Report is included in the QA Records File.

CONTROLLED DOCUMENT
COPY NO. 000482

PNL ADMINISTRATIVE PROCEDURES

TITLE: PAP-70-1502, CONTROLLING DEVIATIONS FROM QA REQUIREMENTS AND ESTABLISHED PROCEDURES

1.0 APPLICABILITY

This procedure establishes methods for identifying, documenting, tracking, evaluating and correcting deviations from quality assurance requirements and established procedures.

When a deviation results in a nonconformance in deliverable reports, data or computer software, a Deficiency Report (DR) required by this procedure shall be initiated. When a deviation results in nonconforming hardware item(s), a Nonconformance Report (NCR) required by PAP-70-1501 shall be initiated and a DR is not required. However, a deviation documented on a DR and subsequently determined to also result in a nonconforming hardware item(s) shall also be documented and corrected on an NCR.

This procedure is also used to document and resolve Measuring and Test Equipment (M&TE) calibration discrepancies as described in PAP-70-1201, computer software discrepancies as described in Software Control Procedures (SCPs) and deficiencies identified by QAD surveillance as described in QAP-70-1001.

Impact Level considerations are covered in PAP-70-208.

2.0 DEFINITIONS

None.

3.0 RESPONSIBLE STAFF

Staff with responsibilities for implementation of this procedure are:

- Cognizant Manager
- QA Representative
- QAD Secretary

4.0 PROCEDURE

4.1 Identification

4.1.1 The identification of the need to initiate a Deficiency Report may originate from one or more of the following sources:

- PNL QA surveillance audit reports

Concurrence	Date	Approved	Date
N/A		Stanley Goldsmith	9/18/86
Prepared by	**Date**	**QAD Concurrence**	**Date**
K E Harrison	8-28-86	C E Hughes	9/3/86

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- sponsor QA surveillance or audit
- unplanned deviations from approved procedures during normal project activities
- PNL or sponsor technical reviews
- calibration and software discrepancies that impact project results.

4.1.2 When responding to or planning corrective action for one or more of the instances described in 4.1.1, the COGNIZANT MANAGER shall determine if the deficiency resulted in a nonconformance in deliverable reports, data or computer software or otherwise had an adverse effect on the validity or integrity of Project reported results. If so, the COGNIZANT MANAGER shall initiate a Deficiency Report (DR), Exhibit 1, by completing Parts 1 through 7 of the report form.

4.1.2.1 The COGNIZANT MANAGER shall request a DR number from the QAD Secretary who maintains a log of issued numbers and open/closed DRs.

4.1.2.2 A DR may be used to document and evaluate multiple deficiencies that are similar in nature and that are applicable to the same research project or task.

4.1.2.3 The COGNIZANT MANAGER shall indicate the Impact Level of the item involved in the deviation in block 5 of the DR. The Impact Level has usually been determined at an earlier date by an engineering or scientific evaluation of the results and consequences of a failure occurrence.

4.1.3 The COGNIZANT MANAGER shall forward a copy to the Quality Assurance Department.

4.2 Corrective Action

4.2.1 The COGNIZANT MANAGER shall determine the deficiency's impact upon activity or research project results, the corrective action required to resolve the deficiency and prevent recurrence, and shall notify affected organizations. This action shall be documented by completing Part 8 of the DR.

4.2.1.1 A copy of the DR shall be temporarily affixed to (or the DR number recorded on) the data sheet, laboratory record book, report, etc., for any project results that may be affected by the deficiency.

4.2.1.2 If required, initiate an Unusual Occurrence Report (UOR) and reference the UOR number on the DR.

4.2.1.3 When required by the sponsor, the COGNIZANT MANAGER shall obtain sponsor concurrence with the method selected to resolve the deficiency and the assessment of the deficiency's impact on project results.

4.2.2 The COGNIZANT MANAGER or designated alternate shall assure that:

- A notation is made of the location (e.g., laboratory record book page number) of the corrected project or activity results (if applicable) that replace the results in question
- The DR number is recorded on any data sheets, laboratory record book pages, etc., that are generated as a result of the deficiency report corrective action.

4.2.3 Upon completion of the evaluation, corrective action judgements, and sponsor contact (if required), the COGNIZANT MANAGER shall sign and date Part 9 of the DR.

4.2.4 The QA REPRESENTATIVE'S concurrence on the adequacy of corrective action to assure that QA requirements are satisfied shall be noted by signature and date in Part 10 of the DR. Follow-up action shall be taken by the QA REPRESENTATIVE to verify proper implementation of corrective action and to close out the corrective action in a timely manner. This concurrence and follow up shall be documented in Part 11 of the DR.

4.2.5 The COGNIZANT MANAGER shall distribute copies of closed out DRs as follows:

- DR Originator
- Project or Activity File (see 4.3.3)
- Project Quality Engineer
- QA Department.

4.3 Tracking and Reporting

4.3.1 The COGNIZANT MANAGER shall track DRs from issuance (receipt) through closeout to ensure prompt corrective action.

4.3.2 The COGNIZANT MANAGER shall assure that a reproducible copy of the completed DR and all attachments or references are processed as project records. When required by the sponsor, or when the deficiency has a significant effect on validity and integrity of project results or affects previously transmitted sponsor deliverables, a copy of the completed DR shall be provided to the cognizant Program Manager for transmittal to the sponsor.

4.3.3 A closed copy of the DR shall be permanently affixed to the data sheet or laboratory record book containing the project results in question, without obscuring any previously recorded information. Copies of the closed DR shall be distributed along with corrected project results to all parties who received incorrect project results.

DEFICIENCY REPORT

DR No. _____ Page _____ of _____

1. Date: _____ 2. Location _____

3. Discovered by: _____ (Name) Organization: _____

4. QA Plan No.: _____

Project Title: _____

5. Requirement and Source of Requirement (Document Title, No. and Revision):

6. Description of Deficiency:

Cause of Deficiency:

NCR Required? ☐ No ☐ Yes, NCR No. _____

7. Originator's Signature: _____ Date: _____

8. Evaluation and Corrective Action:

a. Effect of Deficiency on Validity and Integrity of Project Results (Check One):

☐ None ☐ Significant effect

Explain:

b. If Significant Effect, Location of Project Results Effected:

c. Corrective Action to Correct Deficiency:

d. Corrective Action to Preclude Recurrence:

e. Contact Sponsor: ☐ Yes ☐ No

If Yes:

Contacted _____ (Name) on _____ (Date) by _____ (Name)

Method: _____

Sponsor's Response:

IR/UOR Required? ☐ No ☐ Yes, No. _____

9. Cognizant Manager Signature _____ Date _____

10. Signature _____ Date: _____

11. Closeout/Corrective Action Complete: ☐ Yes ☐ No

Comments:

Signature: _____ Date: _____

Originator Fills in Parts 1 to 7
Manager Responsible for Corrective Action Fills in Parts 8 and 9
QA Concurrence with Disposition and Corrective Action, Parts 10 and 11

Copies to:
Cognizant Manager (Original)
Project Quality Engineer
QA Department
Originator
Project File

The form shown in this exhibit is an example only. Any revisions to the actual form will be incorporated in the next revision of this procedure.

CONTROLLED DOCUMENT
COPY NO. 000482

PNL ADMINISTRATIVE PROCEDURES

TITLE: PAP-70-1602, CORRECTIVE ACTION

1.0 APPLICABILITY

This procedure prescribes requirements and responsibilities for corrective action on conditions adverse to quality.

Conditions adverse to quality and corrective action taken are promptly identified in nonconformance reports (NCRs), deficiency reports (DRs), surveillance reports and audit findings in accordance with the following administrative procedures respectively, PAP-70-1501, PAP-70-1502, QAP-70-1001, QAP-70-704 and QAP-70-1801.

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.

2.0 DEFINITIONS

None.

3.0 RESPONSIBLE STAFF

Staff responsible for implementing this procedure are:

- Project Managers
- Cognizant Managers
- QAD Manager
- QA Staff
- QA Representative (CAR Originator)
- QAD Secretary
- QA Section Managers
- Buyer/Subcontract Specialist

4.0 PROCEDURE

4.1 Evaluation of Conditions Adverse to Quality

4.1.1 At a frequency not exceeding six (6) months, PROJECT MANAGERS shall perform an evaluation of NCRs, DRs, Surveillance Reports, audit

Concurrence	Date	Approved	Date
N/A		Stanley Goldsmith	9/18/86
Prepared by	**Date**	**QAD Concurrence**	**Date**
K E Harrison	8-29-86	C E Hughey	9/3/86

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findings and CARs pertaining to their areas of responsibility and which have been initiated during the period or remain open. This evaluation shall include all documented adverse conditions; identify any adverse quality trends with root causes and action taken and assess the effectiveness of action taken. The result of this evaluation shall be documented and reported to the QAD Manager for analysis and inclusion in a summary report.

4.1.2 The QAD MANAGER shall evaluate corrective action reports submitted by Project Managers and prepare a summary report. Copies of the report shall be provided to the PNL Directors and Program Managers, as appropriate, for review and assessment.

4.2 Identification of Significant Conditions Adverse to Quality

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 and to suppliers and Hanford Contractors for significant conditions adverse to quality. The following are considered significant conditions:

- conditions that are not corrected in a timely manner or are not anticipated to be corrected
- conditions where prior corrective action has not been effective
- recurrent or continuing conditions based on reviews and analyses
- conditions requiring corrective action that involve more than one functional group and/or project
- conditions which, if not immediately corrected, would result in acceptance of work being withheld or could result in a stop work request.

4.2.2 The QAD SECRETARY shall establish and maintain a log of CARs which identifies the CAR number, responsible manager, due date and status. The CAR status shall be updated based on input provided by the manager or Buyer/Subcontract Specialist responsible for implementing corrective action.

4.2.3 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), obtain QA SECTION MANAGER'S review (initial/date), and forward to QAD Manager for approval and issuance.

4.2.4 The QAD MANAGER shall review the draft CAR and if acceptable, identify the manager or Buyer/Subcontract Specialist responsible for corrective action, assign a due date, approve CAR, and forward to QA SECRETARY for distribution.

4.2.5 The QAD MANAGER shall report to the Project Sponsor QA Manager (and others 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.

4.2.6 The QAD SECRETARY shall assign the CAR a unique number, log the number and distribute the CAR to the Cognizant Manager or Buyer/Subcontract Specialist and others, as appropriate (e.g., Program Manager for forwarding to the sponsor).

4.2.7 CARs requiring action by suppliers and Hanford Contractors shall be routed through the QC Manager to the Buyer/Subcontract Specialist or Cognizant Manager for action with the supplier or contractor.

4.3 Response and Corrective Action for Corrective Action Requests

4.3.1 The COGNIZANT MANAGER shall identify, implement and complete the corrective action for internal CARs.

4.3.1.1 Review the CAR and, assisted by cognizant staff, determine the cause and extent of the noncompliant condition.

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:

- Extent - Identify other activities that may be or are being affected by the noncompliant condition
- Cause - Identify the root cause and position titles of personnel responsible for the noncompliant condition
- Contributing Factors - Identify any other factors that led to the noncompliant condition
- Results Expected - Identify the action taken to correct the noncompliant condition and the action taken or planned to preclude repetition
- Scheduled Completion Date - Identify the date the corrective action will be completed, not exceeding two (2) months from when the CAR is transmitted.

4.3.2 The BUYER/SUBCONTRACT SPECIALIST or COGNIZANT MANAGER is responsible for coordinating the CAR with the supplier or Hanford Contractor and for obtaining an appropriate response and commitment to corrective action. The CAR may be forwarded to the supplier or contractor for recording the cause and corrective action and signature/date or the BUYER/SUBCONTRACT SPECIALIST or COGNIZANT MANAGER shall obtain the required information, record it on the CAR and sign/date the CAR for the supplier or contractor.

4.3.3 The COGNIZANT MANAGER/BUYER/SUBCONTRACT SPECIALIST shall obtain the QAD Manager's concurrence, via the CAR Originator, on corrective action taken or to be taken.

4.3.4 The CAR ORIGINATOR shall review the response to a CAR within one week of receipt and forward to QAD Manager with recommendation on acceptability.

4.3.5 Supplier and Hanford Contractor CARs shall be forwarded to the QAD Manager via the QC Manager.

4.3.6 The QAD MANAGER shall determine acceptability of response/corrective action plan.

4.3.6.1 If acceptable, sign the QAD concurrence block on the CAR and return the CAR to the Cognizant Manager/Buyer/Subcontract Specialist.

4.3.6.2 If unacceptable, go to Step 4.4.3.

4.3.7 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.

4.4 Follow-Up and Close-Out of Corrective Action Requests

4.4.1 The CAR ORIGINATOR and/or QAD SECRETARY shall review status of open CARs periodically. If response or corrective action is overdue, go to Step 4.4.3.

4.4.2 The CAR ORIGINATOR shall verify implementation and completion of the corrective action plan. Verification of corrective action on supplier CARs shall be coordinated with the QC Manager.

4.4.2.1 If satisfactory, sign the "Corrective Action Verified" block on CAR, inform QAD Manager and forward to QAD Secretary for distribution of completed CAR. Have copies of completed CAR forwarded to the original distribution.

4.4.2.2 If unsatisfactory, go to Step 4.4.3.

4.4.3 The CAR ORIGINATOR shall discuss overdue or unsatisfactory response/action with the Cognizant Manager or Buyer/Subcontract Specialist and the QAD Manager.

4.4.3.1 If CAR is to be escalated, go to Step 4.4.4.

4.4.3.2 If CAR is not to be escalated, identify modified action plan and/or due date on or by attachment to the CAR. The modified action plan will require signature concurrence by the Cognizant Manager/Buyer/Subcontract Specialist and QAD Manager. Note new due date in CAR Log. Go to Step 4.4.2.

4.4.4 Where determined appropriate, the QAD MANAGER shall escalate a CAR to the next higher level of management.

4.4.4.1 Close-out prior CAR with notation that new CAR has been issued and record number of new CAR.

4.4.4.2 Prepare new CAR to next higher level of management (attach original CAR to new CAR). Go to Step 4.2.6.

4.4.5 The QAD SECRETARY shall establish and maintain a file of CARs and associated documentation.

4.4.6 The QAD MANAGER shall issue on a bimonthly basis, the status of outstanding CARs. As a minimum, the distribution of the status report shall include the Director, Quality Achievement and Directors whose organizations have outstanding CARs.

Battelle
Pacific Northwest Laboratories
P.O. Box 999
Richland, Washington 99352

CORRECTIVE ACTION REQUEST (From QAD)

TO: (Organization Name, Address, Phone No.)

NUMBER:

REPLY DUE:

PROJECT/CONTRACT NO.

1. DESCRIPTION: The following condition is brought to your attention. Complete Part 2 and return the form to _____

Initiated By/Date

Approved By/Title/Date

2. CAUSE AND CORRECTIVE ACTION: Indicate the cause if it can be determined and specify the corrective action taken or to be taken (including schedule) to correct the cause and to prevent recurrence of the problem.

Signature/Title/Date

3. BATTELLE QAD CONCURRENCE:

Signature/Title/Date

4. CORRECTIVE ACTION COMPLETED:

Signature/Title/Date

5. CORRECTIVE ACTION VERIFIED:

Signature/Title/Date

A-1060-052 (3-85)

The form shown in this exhibit is an example only. Any revisions to the actual form will be incorporated in the next revision of this procedure.

CONTROLLED DOCUMENT
COPY NO. 000482

PNL ADMINISTRATIVE PROCEDURES

TITLE: PAP-70-1701, RECORDS SYSTEM

1.0 APPLICABILITY

This procedure is applicable to PNL research projects, Service Groups, and program offices that generate records or produce data. This procedure establishes requirements for the identification, generation, maintenance, temporary storage and disposition of records by the research project and service group staffs.

The entry of information and maintenance of PNL Laboratory Record Books is described in PAP-70-1704, Laboratory Record Books.

This procedure does not include instructions for managing and controlling security classified research records.

2.0 DEFINITIONS

None.

3.0 RESPONSIBLE STAFF

Staff responsible for implementing this procedure are:

- Service Group Managers
- Project Manager
- Cognizant Managers
- Records Custodian
- Cognizant Staff (Originator)
- PNL Records Specialist
- PNL Records Manager
- PNL Records Center
- PNL Records Management Office
- Transportation Office
- Cognizant QE
- Task Leader
- Project Contributors

Concurrence	Date	Approved	Date
N/A		Stanley Goldsmith	9/18/86
Prepared by	**Date**	**QAD Concurrence**	**Date**
[illegible]	8/20/86	C E Hughes	9/3/86

Procedure No.	Revision No.	Effective Date	Page	of
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4.0 PROCEDURE

4.1 General

At the start of the project, the COGNIZANT MANAGER shall designate a Records Custodian to manage records in accordance with this procedure. The COGNIZANT MANAGER, assisted by the Cognizant QE, shall document the Records Transfer Schedule in the QA plan.

4.1.1 For Impact Level I projects, the RECORDS CUSTODIAN shall prepare a Project File Index (PFI) and necessary subindexes using the format of Exhibit 1, Project File Index - Example. For Impact Level II projects, the Records Custodian shall maintain files in accordance with Exhibit 2, with the location documented in a Project Management Plan (PMP) or centralized listing.

4.1.2 A standard classification system has been developed for organizing PNL records. The system, PNL Standard Filing System (Exhibit 2), provides fourteen (14) major (functional) classifications under which all records shall be organized. It is designed to promote uniform procedures and terminology among organizations as well as easy access to information in the files.

The system is alpha-numeric in structure and consists of three classification levels:

Level	Designation	Represented By
1	Major Classification	Capital letter A, B, N, T, etc.
2	Group Classification	A1, B3, N3, etc.
3	Subgroup Classification	A1.1, B3.2, etc.

The first two levels (major and group classification) are fixed and should not be modified. The subgroup classification (Level 3) may be used or modified as required to meet individual filing requirements.

NOTE: The subgroup classifications on Exhibit 2 have not been identified alpha-numerically and are listed as examples of subgroups to be considered in establishing project files.

4.1.3 Exhibit 1 is an example of a completed PFI showing application of the three classification levels for a set of records. The PFI should list only those record classifications that are applicable for organizing project records. Task/Subtask indexes and other sub-indexes to the PFI shall be established where necessary to subdivide files due to the scope of the project, organizations involved and volume or complexity of records generated. All indexes and sub-indexes shall be identified in the PFI by the RECORDS CUSTODIAN. Forms for preparing PFIs are available from the PNL Records Center.

NOTE: At the discretion of the PROJECT MANAGER and where there are project records that are specific to a particular task/subtask or discrete package of work (i.e., milestone, deliverable or experiment), it is permissible and recommended that such records be subdivided and filed in accordance with an index established for that specific task/subtask or discrete package of work.

4.1.4 When subindexes are prepared, the RECORDS CUSTODIAN should endeavor to reduce the number of redundant records that will ultimately be sent to storage. For example, several copies of a report may be distributed but only one index should list the report as a record. Conversely, the RECORDS CUSTODIAN shall assure that there is a file classification for each record generated.

4.1.5 The completed PFI including necessary task/subtask indexes shall be reviewed and concurred with by the PNL RECORDS MANAGER and, when required by the QA Plan, the COGNIZANT QE. The PFI shall be approved by the PROJECT MANAGER and the subindexes shall be approved by the COGNIZANT MANAGER or SERVICE GROUP MANAGER.

4.1.6 The RECORDS CUSTODIAN shall distribute copies of the PFI and subindexes to the PNL Records Management Office and other records custodians where project records are generated.

4.1.7 The RECORDS CUSTODIAN shall prepare the Records and Inventory Disposition Schedule (RIDS), Exhibit 3, and obtain the approval of the Cognizant Manager and the PNL Records Manager. Assistance in the preparation of the RIDS may be obtained from the PNL Records Center. The PNL RECORDS MANAGER shall distribute the RIDS as appropriate. A detailed listing or description of the files shall be incorporated in the RIDS.

NOTE: Exhibit 3, pages 1 and 2 shall be used on 1830 projects and pages 3 and 4 shall be used on 1831 projects.

4.2 Records Generation

4.2.1 COGNIZANT STAFF shall generate and maintain the records necessary to support their research activities in accordance with the appropriate file index and RIDS for the work being performed. Project contributors include PNL research staff as well as support groups such as the QAD and other service organizations.

4.2.2 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.

4.2.3 Corrections shall be made by:

- drawing a single line through the incorrect portion
- entering the correct information
- initialing and dating the correction
- recording the reason for the change, if not obvious.

4.2.4 The COGNIZANT MANAGER shall identify in the work package request those support Service Group records that are essential to fully document a specific research project.

4.2.5 SERVICE GROUP MANAGERS shall assure that the required project specific records (listed on the work package request) are transmitted to the research Project Manager as soon as the work has been completed.

4.2.6 All other Service Group records that are generic (non-project specific) shall be identified and organized in accordance with this procedure.

4.3 Records maintenance in Project (Working) Files

4.3.1 While in the working files, COGNIZANT STAFF shall assure that records are protected from damage or loss.

4.3.2 SERVICE GROUP MANAGERS shall assure that the required records (listed in the work package request) are transmitted to the Records Custodian as soon as the work has been completed.

4.3.3 All other Service Group records that are generic (non-project specific) shall be identified and organized in accordance with this procedure. Generic records shall be forwarded to the PNL Records Center on a periodic basis as established in the QA Plan.

4.4 Inspection of Completed Records

4.4.1 On receiving completed records from Project Contributors, the 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.

4.4.2 Any record judged by the 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 Records Custodian.

4.5 Transfer of Completed/Closed Records to Storage

4.5.1 The RECORDS CUSTODIAN shall assure that each record is traceable to the item or activity to which it applies.

NOTE: Records that are specific to a particular task/subtask or discrete work package may be bound in a book and handled as a single record. Loose leaf (three ring) notebooks are not acceptable.

4.5.2 The RECORDS CUSTODIAN shall assemble the appropriate records, prepare a Records Transfer/Data Input Form, Exhibit 4, and forward the original and two copies of the completed form to the PNL Records Management Office.

4.5.3 Upon approval by the PNL Records Specialist, the original and two copies of the transfer form shall be returned to the Records Custodian. The original and two copies of the form shall be placed in the lowest numbered box of the group.

4.5.4 The PNL RECORDS MANAGEMENT OFFICE shall arrange through the Transportation Office for pickup and delivery of the records.

4.5.5 Upon verifying receipt of the records in the PNL Records Center, the transfer form is signed and the original and one copy is returned to the PNL Records Management Office who shall keep one copy and return the second copy to the Records Custodian.

4.5.6 The RECORDS CUSTODIAN shall arrange for the final disposition of records with the PNL Records Manager prior to termination of the project.

4.6 Records Storage

When required by the QA Plan, the primary storage area shall be the PNL Records Center. When dual storage is required, the PNL RECORDS MANAGER shall arrange for the storage.

PROJECT FILE INDEX - EXAMPLE

Project Title (from statement of work)		Document No.
Name of Sponsor	Project No. (Acctg. or W.P.)	QA Plan No.
Project Manager	Records Custodian	

Retention Classification (Records are classified Lifetime unless specified otherwise by the sponsor)

( ) Lifetime

( ) Nonpermanent ( ) Long Term ( ) Short Term

Dual Storage Required

( ) Yes ( ) No

Frequency of Turnover to Sponsor

( ) Annually ( ) Every 2 years ( ) Other

Concurrence	Approval
Quality Engineer Date	
PNL Records Manager Date	Manager or Designee Date

Functional Classifications	Custodian	Location
A. ADMINISTRATION		
A1 Policy and Management		
A1.1-Program Planning (PPD)		
A1.2-Appraisals		
A1.3-Manpower Planning		
A2 Organization		
A2.1-Organization Charts		
A2.2-Project Staff Listing		
A3 Reports		
A3.1-Progress Reports		
A3.2-Inspection Reports		
A3.3-Milestones (Topical)		

The form shown in this exhibit is an example only. Any revisions to the actual form will be incorporated in the next revision of this procedure.

PROJECT FILE INDEX - EXAMPLE (CONTD)

Functional Classification	Custodian	Location
A4 Activities and Associations A4.1-Conferences		
C. COMMUNICATIONS (STAFF AND PUBLIC) C1 Staff Communications (Internal) C1.1-Delegations of Authority		
C3 Public Communication C3.1-News Releases C3.2-Technical Papers C3.3-Speeches/Articles C3.4-Clearances		
C5 General Correspondence		
F. FINANCE AND ACCOUNTABILITY F1 Budget F1.1-Planning F1.2-Preparation and Approval F1.3-Budget Reviews		
F2 Cost Accounting F2.1-Allocations F2.2-Cost Runs		
F3 Travel F3.1-Expense Reports		
F4 Property Accounting and Control		
F6 Auditing (other than QA)		
I. INDUSTRIAL SAFETY I1 Education and Training		
L. LEGAL AND CONTRACTS L1 Project Contract and Financial Agreements		
L2 Subcontracts/Consultants L2.1-Work Packages and Requests L2-2-Field Task Proposals/Agreements		
L5 Inventions and Patents		
N. PROCUREMENT N1 Purchase Order/Requisitions (arrange P.O. Number)		
N2 Work Packages		

PROJECT FILE INDEX - EXAMPLE (CONTD)

Functional Classification	Custodian	Location
N3 Identification and Control of Purchased Items N3.1-Operational/Maintenance Manuals N3.2-Service Logs N3.3-Used Materials (Scrap) N3.4-Nonconforming Items N3.5-Equipment and Material Disposition N3.6-Test Material in Storage		
N4 Identification and Control of Reference Test Material		
O. OTHER SERVICES O1 Records Management O1.1-Records Plan O1.1.1-Project Records Lists O1.1.2-Project Records Indices O1.1.3-Task/Subtask Indices O1.2-Records Transmittals/Receipts (to PNL Records Center) O1.3-Records Turnover/Receipts (to sponsor)		
O2 Document Control O2.1-Administrative Procedures/Manuals O2.2-Technical Procedures O2.3-Controlled Document List and Transmittal Documents O2.4-Concurrences/Issues Authority O2.5-Printing and Duplicating		
O3 Training Coordination O3.1-Training Schedules		
P. PERSONNEL P1 Personnel Folders (arrange alphabetically by name) P1.1-Qualification/Certification Records P1.2-Resumes P1.3-Position Descriptions P1.4-Training Records		
Q. QUALITY ASSURANCE Q1 Quality Assurance Plan Q2 Quality Assurance Audits and Responses Q3 Nonconformances and Corrective Action		

PROJECT FILE INDEX - EXAMPLE (CONTD)

Functional Classification	Custodian	Location
S. SECURITY S1 Clearances S2 Training		
T. TECHNICAL (Breakdown by subprojects, tasks, or classifications for individual projects T1 Research Project Planning and Appraisals T1.1-Sponsor Work Packages and Statement of Work T1.2-Data Collection Procedures		
T2 Laboratory Analysis and Tests T2.1-Analysis Methods/Techniques T2.2-Models		
T3 Technical Documentation T3.1-Hand Calculations T3.2-Peer Review T3.3-Graphics and Photography T3.4-Input/Output Sources		
T4 Design Documentation T4.1-Experimental Design and Setup T4.2-Schematics, Flowcharts and Logs		
T5 Computer Code Documentation T5.1-Computer Codes T5.2-Run Plans		
T6 Laboratory Record Books		
T7 Test Controls T7.1-Environmental T7.2-Equipment and Material T7.3-Test Records and Certifications		
T8 Basic Data Sheets/Logs		
T9 Technical Reports		
T10 Equipment Lists T10.1-Measures and Test Equipment T10.2-Operation/Maintenance Manuals T10.3-Test Records and Certification		
T12 Correspondence		

PNL STANDARD FILING SYSTEM

MAJOR CLASSIFICATIONS

A ADMINISTRATION
B BUSINESS DEVELOPMENT
C STAFF AND PUBLIC COMMUNICATIONS
F FINANCE AND ACCOUNTABILITY
I INDUSTRIAL SAFETY
L LEGAL AND CONTRACTS
M MARKETING
N PROCUREMENT
O OTHER SERVICES
P PERSONNEL
Q QUALITY ASSURANCE
R RADIATION PROTECTION
S SECURITY
T TECHNICAL

A ADMINISTRATION

A1 POLICY AND MANAGEMENT
- Objectives
- Program Planning
- Appraisals
- Goals
- Task Forces
- Committees & Boards
- Surveys - Studies
- Manpower Planning

A2 ORGANIZATION
- BMI
- BSRC
- Battelle Laboratories
  - (Laboratories in the U.S. & Abroad)
- DOE
- Hanford Contractors
- Other Companies

A3 REPORTS (Weekly, Monthly, Quarterly, Annual) (Internal - To be used as office business dictates)

A4 ACTIVITIES & ASSOCIATIONS
- Memberships (Societies, Panels, Etc.)
- Conferences
- Honors

A5 BUSINESS LIAISON
- BMI
- Battelle Laboratories
  - (Laboratories in the U.S. and abroad)
- DOE
- Hanford Contractors
- Other Companies
- Institutions

B BUSINESS DEVELOPMENT

B1 189's

B2 PREPROPOSALS (Research, Etc.)
- 1830
- Non-1830

B3 PROPOSALS (Research, Etc.)
- 1830
- Non-1830 (When a Proposal becomes a contract file in your company/ sponsor file)

C STAFF & PUBLIC COMMUNICATION

C1 STAFF COMMUNICATIONS
- Periodic Publications
- Other Publications
- Management Communications

C2 PUBLIC RELATIONS
- Programs
- Civic Projects
- Displays

C3 PUBLIC NEWS MEDIA
- News Releases
- Press—Radio—TV
- Magazines

C4 PAPERS-SPEECHES AND ARTICLES
- Clearances
- Technical Papers
- Speeches

C5 GENERAL CORRESPONDENCE

F FINANCE AND ACCOUNTABILITY

F1 BUDGETS AND FORECASTS
- Preparation
- Personnel Budgets
- Operating
- Budget Reviews
- Estimates

F2 COST ACCOUNTING
- Operating Costs
- Maintenance Costs
- Cost Allocations
- Cost Reduction

F3 TRAVEL
- Domestic
- Foreign

PNL STANDARD FILING SYSTEM (CONTD)

F4 PROPERTY ACCOUNTING AND CONTROL
- Onsite Plant and Equipment
- Offsite Equipment
- Special Equipment
- Physical Inventories
- Excess

F5 SPECIAL SOURCE MATERIAL ACCOUNTABILITY
- Procedures
- Transfers
- Schedules and Shipments
- Receipts

F6 AUDITS

F7 ADP
- Data Process Systems
- Word Process Systems

F8 GENERAL ACCOUNTING

F9 PAYROLL & TREASURY SERVICES

I INDUSTRIAL SAFETY

I1 SAFETY STANDARDS & PROCEDURES
- Codes and Specifications
- Hazards and Controls
- Emergency Procedures

I2 SAFETY REPORTS AND DATA
- Safety Meetings
- Safety Bulletins
- Injury Reports
- Inspections

I3 FIRE PROTECTION
- Emergency Procedures
- Inspections
- Programs
- Equipment

I4 INDUSTRIAL HEALTH
- First Aid

I5 EDUCATION AND TRAINING

L LEGAL AND CONTRACTS

L1 CONTRACTS - 1830
- Negotiations
- DOE Manual Chapters

L2 CONTRACTS-OTHER
- Negotiations
- Subcontractors
- Union Agreements
- Vendor Contracts
- Consultant Contracts

L3 CLAIMS AND SETTLEMENTS
- Litigation

L4 LEGISLATION
- Federal
- State
- Local

L5 INVENTIONS AND PATENTS
- Applications
- Invention Reports

L6 CONTRACT ACCOUNTABILITY

M MARKETING
- (break down into your group's technical marketing effort)

N PROCUREMENT

N1 PURCHASING - 1830
- Appropriations
- Purchase Requirements
- Purchase Orders (can be broken down further by person's name that is ordering)
- Specifications and Bids

N2 PURCHASING - OTHER
- Appropriations
- Purchase Requirements
- Purchase Orders
- Specifications and Bids

N3 PURCHASING INSTRUCTIONS AND PROCEDURES
- Special Materials

N4 SUPPLIERS AND CONTRACTORS
- Vendors
- Vendors-Performance
- Vendors-Surveys

N5 EQUIPMENT AND SUPPLIES
- Central Stores
- Expediting

O OTHER SERVICES

O1 RECORDS MANAGEMENT
- Records Inventory & Disposition Schedules
- Records Transfer Request

O2 FORMS CONTROL

O3 MAIL AND DUPLICATING
- Mail
- Duplicating

PNL STANDARD FILING SYSTEM (CONTD)

O4 TECHNICAL INFORMATION
- Classified Files
- Library
- Library Procurement

O5 GRAPHICS

O6 PHOTOGRAPHY

O7 TECHNICAL PUBLICATIONS

O8 EDITING/WRITING

P PERSONNEL

P1 EMPLOYMENT
- Recruiting
- Applications
- Requisitions
- Part-Time and Temporary Employees

P2 SALARY AND WAGE ADMINISTRATION
- Wage Rates
- Job Descriptions
- Reviews
- Overtime

P3 BENEFIT PLANS
- Insurance Plan
- Pension Plan
- Savings
- Vacations
- Federal and State (Social Security)

P4 ATTENDANCE AND ABSENCES

P5 PERFORMANCE AND CONDUCT
- Appraisals
- Awards
- Disciplinary Actions

P6 MILITARY STATUS

P7 PERSONNEL FOLDERS

P8 EDUCATION, TRAINING AND DEVELOPMENT
- Orientation
- Educational Programs
- Tuition Refunds

P9 LABOR RELATIONS
- Arbitration
- Grievances
- Seniority
- Strikes

Q QUALITY ASSURANCE

Q1 QA PROGRAM

Q2 QA AUDITS

Q3 UNUSUAL OCCURRENCES & EVENTS

Q4 INSPECTION & TEST EQUIPMENT

R RADIATION PROTECTION

R1 STANDARDS AND PROCEDURES
- Radiation Standards
- Radiation Procedures
- Emergency Procedures

R2 EXPOSURE MANAGEMENT
- Exposure Reports
- Radiation Incidents
- Exposure Control

R3 CONTAMINATION CONTROL
- Control Procedures
- Protective Clothing and Devices
- Monitoring

R4 WASTE MANAGEMENT
- Decontamination
- Contamination Disposal

R5 EDUCATION AND TRAINING

S SECURITY

S1 PROCEDURES
- Orientation
- Emergency

S2 CLEARANCES
- Personnel
- Passes

S3 SECURITY COMMUNICATIONS
- Security Meetings
- Bulletins

S4 SECURITY VIOLATIONS
- Infractions
- Investigations

S5 CLASSIFIED DOCUMENT CONTROL
- Receipts
- Inventories

S6 CLASSIFICATION-GENERAL AND POLICY
- Guides
- Bulletins

S7 EDUCATION AND TRAINING

T TECHNICAL
(break down into group's technical activities and interests)

DOE F 1324.10
(8-85)

RECORDS INVENTORY AND DISPOSITION SCHEDULE

OMB Control No
1910-1700 Number _____
1. PAGE 1 OF _____

2. ORGANIZATIONAL UNIT
Battelle Memorial Institute
Pacific Northwest Laboratory

3. DATE

4. APPROVAL SIGNATURES

Manager

~~Specialist~~ PNL Records Manager

Records File Custodian

Location of Records

5. ITEM NUMBER	6. FILING UNIT TITLE AND DESCRIPTION	7. RETENTION PERIOD	8. DISPOSAL AUTHORITY	9. CUT-OFF INSTRUCTIONS AND RETIREMENT PERIOD
	AGREEMENT:			
	The above approving officials agree that disposal and retirement directions on this Records Inventory and Disposition Schedule (RIDS) are properly applied. It is further agreed, that directions on this Inventory will be carried out as indicated and any changes to this Inventory will be made known to the Battelle Records Management Specialist.			

GPO 811 161

PAP-70-1701, Rev. 0
EXHIBIT 3
Page 1 of 4

The form shown in this exhibit is an example only. Any revisions to the actual form will be incorporated in the next revision of this procedure.

DOE F 1324.9
(8-85)

RECORDS INVENTORY AND DISPOSITION SCHEDULE – Continued

OMB Control No
1910-1700

5 PAGE _____ OF _____

5 ITEM NUMBER	6 FILING UNIT TITLE AND DESCRIPTION	7 RETENTION PERIOD	8 DISPOSAL AUTHORITY	9 CUT OFF INSTRUCTIONS AND RETIREMENT PERIOD

GPO 871-186

The form shown in this exhibit is an example only. Any revisions to the actual form will be incorporated in the next revision of this procedure.

Battelle
Pacific Northwest Laboratories

RECORDS INVENTORY AND DISPOSITION SCHEDULE - 1031

1 NUMBER _____
PAGE _____ OF _____

2 ORGANIZATIONAL UNIT

BATTELLE MEMORIAL INSTITUTE
PACIFIC NORTHWEST LABORATORY

3 DATE

4 APPROVAL SIGNATURES

Manager

Records Management Specialist

Records Custodian

Location of Records

AGREEMENT.

The above approving officials agree that disposal and retirement directions on this Records Inventory and Disposition Schedule (RIDS) are properly applied. It is further agreed, the directions on this Inventory will be carried out as indicated and any changes to this Inventory will be made known to the Battelle Records Management Specialist.

5 ITEM NUMBER	6 FILING UNIT TITLE AND DESCRIPTION	7 RETENTION PERIOD	8 DISPOSAL AUTHORITY	9 CUT OFF INSTRUCTIONS AND RETIREMENT PERIOD

BNW 1031 (7/1) 84-1

The form shown in this exhibit is an example only. Any revisions to the actual form will be incorporated in the next revision of this procedure.

Battelle
Pacific Northwest Laboratories

RECORDS INVENTORY AND DISPOSITION SCHEDULE - 1831 Continued

1. PAGE _____ OF _____

5 ITEM NUMBER	6 FILING UNIT TITLE AND DESCRIPTION	7 RETENTION PERIOD	8 DISPOSAL AUTHORITY	9 CUT OFF INSTRUCTIONS AND RETIREMENT PERIOD

BNW 1600 142 1 (1/68)

The form shown in this exhibit is an example only. Any revisions to the actual form will be incorporated in the next revision of this procedure.

CONTROLLED DOCUMENT
COPY NO. 000482

QUALITY ASSURANCE PROCEDURES

TITLE: QAP-70-101, STOP WORK REQUEST

1.0 APPLICABILITY

This procedure describes the method used by the QAD to issue a stop work request (SWR) both within and external to PNL.

2.0 DEFINITIONS

None.

3.0 RESPONSIBLE STAFF

- QAD Manager
- QAD Section Managers
- QAD Staff

4.0 PROCEDURE

4.1 Determination of Need for SWR

4.1.1 The QAD STAFF shall inform their manager of any significant conditions adverse to quality, including activities where required corrective actions are not being taken in a timely manner, that they identify during their daily assignments.

4.1.2 The cognizant QAD SECTION MANAGERS shall routinely review the following documentation originated in their area of responsibility and bring all significant conditions adverse to quality to the attention of the QAD Manager, including the severity of the conditions and the corrective actions already scheduled or in progress:

- audit reports
- corrective action requests
- deficiency reports
- nonconformance reports
- results of source inspections and tests
- surveillance reports.

4.1.3 The QAD MANAGER shall make an evaluation and determine whether or not to issue a SWR. SWRs should be issued for activities not in substantial compliance with QA program requirements or activities for which corrective action is not implemented in a timely manner. Generally a

Concurrence	Date	Approved	Date
N/A		C E Hughes	9/29/86
Prepared by	**Date**	**QAD Concurrence**	**Date**
J G Ruffin	9/26/86	C E Hughes	9/29/86

Procedure No.	Revision No.	Effective Date	Page	of
QAP-70-101	0	OCT 1 1986	1	3

SWR should not be issued unless other appropriate means have been exhausted, e.g., surveillance reports or deficiency reports. However, the QAD MANAGER may elect to issue a SWR as a first means to correct an unsatisfactory condition if circumstances warrant.

4.1.4 The QAD MANAGER shall inform the responsible manager of the adverse conditions justifying stop work and shall endeavor to reach agreement on required corrective action. If the QAD Manager and the responsible manager cannot agree on the appropriate corrective action and schedule, the QAD MANAGER shall immediately escalate the condition and recommend corrective action to higher management for action.

4.1.5 Prior to requesting work to be stopped, the QAD MANAGER shall review the justification for the SWR with the Quality Achievement Director.

4.2 Issuing a SWR

4.2.1 The QAD MANAGER shall issue all SWRs using a memo, letter or form that contains the following information:

- a SWR number indicating the year and the chronological number of the SWR (e.g., 1985-3 is the 3rd SWR issued in 1985)
- a description of the affected program/project/work element
- the reason for the SWR
- the conditions required before the SWR will be lifted
- a statement that it is the addressee's responsibility to assure that work is stopped and corrective action is taken in a timely manner
- a request that the addressee notify the QAD Manager in writing of the corrective actions to be taken for the QAD Manager's acceptance or resolution
- a request that the addressee notify the QAD Manager when the accepted corrective action has been completed.

4.2.2 The SWR shall be addressed to the manager, supplier or Hanford Contractor responsible for performance of the work with copies to the appropriate line, program and project managers and directors.

4.2.2.1 When a SWR is to be issued to a supplier, the SWR (and subsequent correspondence) shall be sent to Procurement/Subcontracts for processing to the supplier.

4.2.2.2 When a SWR is to be issued to another Hanford Contractor, the SWR (and subsequent correspondence) shall be processed through the project/program manager.

4.3 Lifting of SWRs

4.3.1 If the proposed corrective action is acceptable, the QAD MANAGER shall notify the addressee. If the proposed action is not acceptable, a resolution must be made.

4.3.2 When notified by the responsible manager or by Procurement/ Subcontracts that corrective action has been completed, the QAD MANAGER shall have the implementation verified prior to lifting the SWR.

4.3.3 When a SWR is lifted, the QAD MANAGER shall send written notification to all original recipients and a copy to the QAD Record Files. The notification will include the corrective actions that were completed.

4.3.4 The QAD MANAGER shall maintain a file of correspondence on all SWRs issued.