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PNL-8749

PNL-MA-70 QA PLAN

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June 2, 1993

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Richland, Washington 99352

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PNL-MA-70 QA PLAN

CONCURRENCES AND APPROVAL:

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Date

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Date

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Quality Engineering, J. E. McGarrah (Concurrence)
P&HTG Group Leader

8-31-92
Date

PROJECT IMPACT LEVEL I

TITLE: QA Plan for INSTRUMENT CALIBRATION and EVALUATION PROGRAM

SCOPE: The Instrument and External Dosimetry (I&ED) Section provides the calibration service for all portable radiation monitoring measurement and test equipment (M&TE) used on the Hanford site. This responsibility is delineated in Hanford Site Services Handbook in the section entitled "Radiation Protection Instruments (Portable) and Dosimeters - Procurement Specification, Acquisition, Maintenance and Calibration". Evaluations of new equipment and calibration of some non-portable M&TE (e.g. hand and foot monitors) are also performed.

PNL Craft Services provides for the repair and servicing of radiation monitoring M&TE in accordance with the Statement of Work (SOW I&ED-91-1) issued to Craft Services by I&ED.

The portable instrument pool requires the operation of a complete radiation protection instrument program. This operation consists of procuring new and replacement instruments to national workmanship specifications; overseeing an instrument pickup and delivery service; keeping records; and surveying, decontaminating, maintaining, and calibrating instruments. In addition, the program includes maintaining traceability of radiological and electronic calibration systems to the National Institute of Standards and Technology (NIST); operating a program to service radiation protection emergency kits; modifying and updating written calibration procedures as new instruments are introduced and calibration techniques are improved; procuring, acceptance testing, calibrating, and distributing pencil dosimeters; performing specification development and acceptance testing on all instruments purchased for pool use or as required by Hanford contractors; and administering the Hanford Instrument Evaluation Committee (HIEC). New instruments from vendors are evaluated under this program.

CLIENT: Department of Energy

AUTHORIZING DOCUMENT: N/A (Service Activity) Project Number 98040

QA REQUIREMENT SPECIFICATION(S):

- ☒ ASME NQA-1 as delineated in PNL-MA-70
- ☐ Other

Impact Level I and II WBS element activities shall comply with the applicable requirements in Parts 1 and 3 of PNL-MA-70. Impact Level III task activities and all developmental work comply with the Good Practices Standard (GPS) located in Part 2 of PNL-MA-70. If quality-related activities other than those discussed in SCOPE are later performed, the appropriate PNL-MA-70 requirements and procedures shall be applied, unless specifically excluded.

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QA PROGRAM/ORGANIZATION:

The organizational relationship of the Instrument and External Dosimetry Section to the Health Physics Department, Life Sciences Center, and the Process Quality Department is provided in Attachment A. Changes to organizational structure and individual assignments will not require a QA Plan revision.

The PNL Quality Assurance Program conforms to the requirements of NQA-1 and is interpreted by Parts 1 and 3 of PNL-MA-70, Quality Assurance Manual. This QA Plan, LSC-10, Rev. 3, applies only to the Impact Level I and II task activities as designated by Attachment B. WBS elements identified as Impact Level III shall comply with the requirements of PNL-MA-70, Part 2, Good Practices Standard:

IMPACT LEVEL:

The overall Impact Level of this activity has been determined to be Impact Level I due to the Impact Level I task governed by this QA Plan. The Impact Level I task has been so designated because the instrumentation listed in Attachment C is used in the stacks and waste water streams to detect unacceptable levels of radiation. Their function has the potential of affecting offsite personnel. A second task which governs most of the routine calibrations performed has been determined to be Impact Level II since the instruments calibrated are used to detect on-site radioactive exposure of personnel and to control spread of radioactive materials. The impact level has been documented for the two activities covered by this QA Plan: "Routine Instrument Pool" and "Radiation Instrument Evaluation and Acceptance Testing". Further information is provided in the WBS Impact Level Matrix in Attachment B.

SPECIAL CLIENT REQUIREMENTS:

There are no Special Client Requirements imposed on the calibration program at this time.

OTHER REQUIREMENTS, DIRECTION OR PLANNING:

The following exclusions or limitations of applicability apply to the referenced PNL Administrative Procedure(s):

PAP-70-201: Authors of Calibrations Procedures in PNL-MA-563 shall be considered qualified to perform that procedure. This information shall be documented in the Laboratory Training Coordination training records.

PAP-70-206: The QA Requirements Evaluation Sheet required in PAP-70-206 has been modified to reflect the requirements of the site services charter being governed by this QA Plan. (see Attachment D)

PAP-70-401: All radiation monitoring M&TE must be procured from a Process Quality evaluated supplier.

PAP-70-601: This procedure does not apply to the calibration procedures maintained in PNL-MA-563. The calibration procedures shall be controlled and issued in accordance with procedure PNL-MA-563, 0.0.2. These controlled documents (procedures) shall be reviewed by qualified personnel and approved for use by the line manager. Management approval of the issuance of the procedures shall be indicated by a signature and date on the table of contents of PNL-MA-563. Each procedure shall be identified with an issue date. Additions and revisions to the technical procedures shall be incorporated into each of the controlled manuals by the Project Manager or his designee.

PAP-70-604: The calibration procedures are reviewed by at least one technical staff member and the Process Quality Representative in accordance with PNL-MA-563 procedure 0.0.1.

PAP-70-702, PAP-70-706, and PAP-70-1001: These procedures apply only to the workmanship inspections to be performed by the F&PTG. These inspection requirements shall be indicated on the Purchase Requisition for new instruments. They do not apply to other inspections performed on radiation monitoring M&TE purchased from vendors and instruments repaired or modified by PNL Craft Services. The inspection and tests (i.e., receiving inspection) shall be performed in accordance with the usual calibration procedures. The testing and calibration procedure used for this activity shall be considered equivalent to and used in place of an Inspection Test Instruction (ITI).

PAP-70-803: The controls for identification and control of portable radiation monitoring M&TE are documented in procedures in PNL-MA-563. Portable radiation monitoring M&TE shall be traceable to the last delivery location.

PAP-70-901: This procedure does not apply. There are no known controlled processes under this QA Plan.

PAP-70-902: This procedure does not apply. There are no known special processes under this QA Plan.

PAP-70-1101: PNL-MA-563 contains calibration procedures that govern the routine work performed under this QA Plan. Calibration procedures do not meet the format described in PAP-70-1101 but do meet the requirements delineated in PAP-70-1201. Special requests for calibrations of one-of-a-kind instruments may be performed according to the suppliers user's manual and documented in Laboratory Record Books.

PAP-70-1201, Sec. 3.4: The requirement states that "The Calibrator shall use standards that have accuracies that are at least four times better than those of the M&TE being calibrated." The calibration of radiation detection instrumentation is excluded from the "four times" better requirement since many radiation detection devices are capable of accuracies equivalent to that of the standard.

PAP-70-1201: Section 8.0 - Radiation Monitoring M&TE - This section of PAP-70-1201 applies to the activities of the I&ED Section governed under this QA Plan.

PAP-70-1201: Section 8.1 - The notification system for instruments overdue for calibration is described in PNL-MA-563, 1.0 (to be issued 10/92).

PAP-70-1201: Section 8.2 - The following is a clarification of the calibration records management:

HP-9000 Database: The calibrations performed by I&ED and repairs performed by PNL Craft Services are documented in the 318 Building HP-9000 computer database. The HP-9000 computer database is considered to be the permanent record. Additional information for the maintenance and back-up of the HP-9000 calibration database is available in procedure PNL-MA-563, 0.3.0.

Calibration Records: Prior to January 1993, the completed calibration record cards and data sheets shall be considered records and shall be transferred to DOE Records Storage as described under "Records Turnover" on page 7. After January 1993, the calibration cards for all instruments will function as trailer cards during the calibration or repair process. Calibration data and repair information shall be entered into the HP-9000 calibration database from the trailer cards at the end of each working day. Data sheets containing supplemental information to assist in the calibration process will continue to be utilized. All data necessary to corroborate the calibration of the instruments shall be entered into the database and the data sheets and calibration cards will not be maintained as records.

Traceability of Standards: Standards shall be traceable to the National Institute of Standards and Technology or other nationally recognized standards, derived from accepted values of natural physical constants, or derived by the ratio-type of self-calibration techniques (e.g., ohm's law). If none of these traceability steps is feasible, the basis for calibration shall be documented and approved by the cognizant manager.

PAP-70-1201: Section 8.4 - As-found readings obtained during the calibration of instruments returned from the field shall be entered into the calibration records database as described in Procedure PNL-MA-563, 0.3.0. Any readings outside limits established by the technical procedures shall be identified and the personnel in the field who last used the equipment shall be notified as required by PAP-70-1201, Section 8.4. It shall be indicated in the calibration database that the instrument has been to the

Portable Instrument Shop for repair. The repair information shall be entered into the calibration record database after the repair has been completed.

If the instrument is sent to the shop for repair upon receipt, no as-found readings can be recorded. This situation will be indicated in the calibration records on the database.

PAP-70-1701: The records generated by the program shall be maintained in accordance with PAP-70-1701 and documented accordingly on the Records Inventory and Disposition Schedule/File Index (RIDS). The following is a clarification on the application of PAP-70-1701:

RIDS: The RIDS shall be signed by the cognizant Quality Engineer.

Laboratory Record Books: Laboratory Record Books (LRBs) shall be used for recording one-of-a-kind or special request calibrations and dosimeter exposure parameters. The LRBs shall be used in accordance with PNL-MA-68, Records Management and Document Control. Laboratory Record Books shall be reviewed on a quarterly basis.

Records Turnover: Project records shall be transferred to Records Storage on an annual basis.

Instructions, Procedures, and Drawings

Activities that will require written procedures and/or instructions shall be determined by the activity manager. These procedures shall be controlled in PNL-MA-563 and shall include the following as a minimum:

- instrument identification (PNL-MA-563, 1.1)
- database back-up and control (PNL-MA-563, 0.3.0)
- out of limit detection, recording, and notice to user actions, if applicable (PNL-MA-563, each individual calibration procedure)
- personnel training (PNL-MA-563, 0.0.1)
- records maintenance and protection (PNL-MA-563, 0.3.1, to be issued)

Internal Audits

The work under this QA plan shall be audited by PNL Quality Verification on a regular basis.

— Line Management Direction
 === Project/Program QA Support
 ***** Calibration, Instrumentation, and Inspection Support

ORGANIZATION/KEY PERSONNEL

Department Manager: Health Physics - J.R. Johnson
 Line Organization: Cognizant Manager - D.M. Fleming
 Project Manager: T.J. Froelich
 Material Custodian: T.J. Froelich
 M&TE Custodian: E.J. Bard
 Database Steward: R. A. Fox (Dosimetry Research Section)
 Records Custodian: D.E. Linklater
 Quality Engineer: L.J. Ethridge

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Attachment B
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IMPACT LEVEL DESIGNATION

<u>WBS Element Title</u>	<u>Impact Level</u>			<u>Comments</u>
	<u>I</u>	<u>II</u>	<u>III</u>	
1. Management Task	X			Maintains RIDS Calibration Procedure Maintenance & Update
2. Environmental Monitoring Instrumentation				List of Instruments on Attachment C
2.A. Calibration of Instruments	X			
2.B. Procurement of Instruments	X			
3. Routine Instrumentation				
3.A Calibration of Instruments		X		
3.B Procurement of Instruments		X		
4. Hanford Instrument Evaluation Program				
4.A Routine Instrumentation			X	
4.B Non-Routine Instrumentation			X	
5. Instrument Manual Update			X	

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Attachment C
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LIST OF IMPACT LEVEL I
RADIATION DETECTION INSTRUMENTATION
Calibrated by I&ED

Alpha CAMs (Continuous Air Monitors)

CIS (Containment Isolation System)

Harshaw Water Monitors

NCD (Neutron Criticality Detector)

Stack Monitors

Tritium Monitors

QA REQUIREMENTS EVALUATION SHEET
Instrument Calibration and Evaluation Program

Date: _____ Applicable Work Order Number: _____

To: (Client's Primary Technical Contact) _____

From: (PNL Recipient) _____

Subject: _____

- ☐ A. PNL has been requested to perform the subject work for your organization. To date, PNL has not been informed of the QA requirements applicable to this work. Since this work is mandated by the Hanford Site Services Handbook it shall be conducted in accordance with PNL's QA Program, PNL-MA-70. The work shall be conducted under the necessary impact level as delineated by the project-specific QA Plan LSC-10. (Impact Level II requirements shall apply to instruments used for protection of on-site personnel or facilities. Impact Level I requirements shall apply to instruments used for detection or control of off-site release of radioactive materials).
- ☐ B. PNL has been requested to perform the subject work for your organization. PNL has been informed that this work is identified as QA Level _____. No additional QA requirements have been identified. The work shall be conducted under PNL-MA-70 and project-specific QA Plan LSC-10 with Impact Levels assigned according to the criteria shown in A. above.
- ☐ C. PNL has been requested to perform the subject work for your organization. It is PNL's understanding that this work will be governed solely by your policies and procedures and therefore, PNL's QA program does not apply.

☐ D. PNL has been requested to perform the subject work for your organization. Your work authorizing document identifies requirements that cannot be implemented by PNL at this time. Because the work is safety related and cannot be discontinued, the work will be performed as outlined in the attached document. Work will proceed unless you inform us, in writing, that work should be discontinued.

Required Distribution:

PNL Process Quality (P7-72)
Project/Activity File

Copy Appropriate Organization:

WHC Related Work: WHC QA, MSIN S1-52
KEH Related Work: KEH QA, MSIN E3-11
HEHF Related Work: HEHF QA, _____

A. Document No.: QA Plan LSC-10		Revision No.: 3	Effective Date of ICN: 10 / 20 / 92
Document Title: QA Plan for INSTRUMENT CALIBRATION and EVALUATION		Change Requested By: L.J. Ethridge	
Document's Original Author: T.J. Froelich			
B. Action: 1. Replace existing Page 5 with attached Page 3. 2. Replace existing Attachment D with attached Attachment D.			
C. Effect of Change: 1. Clarifies the qualification of technical staff members who are authors of calibration procedures. 2. The new section provides a mechanism to notify the customer when work order requirements could not be implemented by the Instrument Calibration and Evaluation Program.			
D. Reason for Change/Description of Change: 1. <u>Reason for Change:</u> Authors of procedures are considered the authority on the topic of the procedure and are therefore qualified to perform the work governed by that procedure without an additional training session. 1. <u>Description of Change:</u> A clarification to the application of PAP-70-201 has been added to the body of the QA Plan. 2. <u>Reason for Change:</u> WHC Audit IAA-92-013, Observation 1, stated that PNL did not have a mechanism in place to inform WHC when Work Orders directions or Letters of Instruction could not be implemented. 2. <u>Description of Change:</u> Another option was added to the QA Requirements Evaluation Sheet attached to the QA Plan.			
E. Approval Signatures (Please Sign and Date)		Type of Change: {Check (✓) one} (XX) Minor Change () Major Change	
Approval Authority: D.M. Fleming <i>D.M. Fleming</i>		Date: 10/15/92	
Other Approvals: T.J. Froelich <i>T.J. Froelich</i>		Date: 10/15/92	
L. J. Ethridge <i>L.J. Ethridge</i>		Date: 10/15/92	

**DATE
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9/28/93

END