PNL AUDIT REPORT/CORRECTIVE ACTION
RESPONSES OF WESTINGHOUSE STANDARDS
LABORATORY

K. E. Harrison
L. M. Worden

DISCLAIMER

June 1993

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Prepared for
the U.S. Department of Energy
Contract DE-AC06-76RLO 1830

Pacific Northwest Laboratory
Richland, Washington 99352

MASTER

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AUG 09 1993

OSTI

Westinghouse
Hanford Company

NOTE:

IN PROCESS OF BEING REVIEWED BY

P.O. Box 1970 Richland, WA 99352

PNL AUDIT TEAM FOR ACCEPTANCE

June 23, 1993

RECEIVED

JUN 28 1993

L.M. Worden
6/29/93

9305213B-R1

L.M. WORDEN

L. M. Worden, Technical Group Leader (Acting)
Facilities & Procurement
Pacific Northwest Laboratory
Post Office Box 999
Richland, Washington 99352

Dear Mr. L. M. Worden:

QA VERIFICATION AUDIT OF WHC STANDARDS LABORATORY

Reference: Letter, L. M. Worden, PNL, to M. J. Charney, WHC, same
subject, dated June 3, 1993.

FINDING (1)

The written program was not always consistent with actual practices.

CORRECTIVE ACTION:

The manual has been completely revised to address the items in this finding. The 15 operating procedures have been reduced from 15 to 10. Twelve of the 14 items identified in this finding have been resolved. The remaining two items involving Records Management have been addressed and corrected through a submittal/approval of RIDS (Records Inventory Disposition Schedule) to Records Management (a draft copy is attached for your info).

ROOT CAUSE:

Recent turnover of management at WHC Standards Laboratory was a contributing factor in completing this corrective action.

IMPACT ON PNL & KEH:

No major negative impact on services provided.

FINDING (2)

4:1 rational requirement has been completed, this action item is considered closed.

FINDING (3)

Corner Load Testing of Balances documented on data sheet is complete, this action item is considered closed.

OBSERVATION A:

EAQA committed to review purchase requisitions with the Standard's Lab personnel to determine the need for supplier evaluations. This commitment was not coordinated with the QE who was assigned to support the Standard's Lab.

The cognizant EAQA personnel are now aware of the requirements and are reviewing the purchase requisitions.

B ?

OBSERVATION C:

The FY 1993 EAQA Surveillance Schedule has been rescoped to include a surveillance of the WHC Standards Lab in June 1993. An in-depth site-wide surveillance of the Standards Lab will be performed in August, 1993 by the QA Audit Program Administration/Site-Wide Surveillance Group.

Beginning with the FY 1994 Surveillance Schedule EAQA will schedule a monthly surveillance of the Standards Lab. Typical surveillance topics will include:

- o Performance based surveillances
- o Procedure verification
- o The review of Standards Lab procedures to verify compliance with contractual requirements
- o Environmental controls adequacy
- o Measurement Disciplines
- o Purchase Requisitions

The monthly EAQA surveillances beginning FY 1994 will provide adequate oversight of the WHC Standards Lab. Previously proposed joint surveillances performed by WHC/PNL/KEH will not be necessary in light of this increased oversight.

L. M. Worden
Page 3
June 23, 1993

9305213B-R1

OBSERVATION C:

On June 18, 1993 a meeting was held with Standards Lab Records Management Representative. Results from this meeting determined a rewrite/revision in the RIDS (Records Inventory Disposition Schedule) was necessary and is currently in the mail for all approvals. (a draft copy of Standards Lab RIDS is attached for your information)

Very truly yours,

Mary J. Charney, Acting Manager
Standards Laboratory

mjc

Attachment 1

cc: CA Carpenter - WHC
KL Chubb - WHC
JN Nansen - WHC
LD Salsberry - KEH
CR Wallskog - KEH

1. Agency or Contractor Westinghouse Hanford Company	RECORDS INVENTORY AND DISPOSITION SCHEDULE	2. Organization Code 55540
		Page 1 of 3

3. Organizational Unit Standards Laboratory	NSIN: L6-86 Bldg.: 3717B Room: 1 Area: 300
--	---

4. Approval Signatures	Records Management or RL Records Officer	Date
B. A. Holmberg	376-1353	
K. L. Chubb	376-3368	
Manager	Phone No.	
M. J. Charney	N/A	
File Custodian	System Analyst	Phone No.
	Date	

AGREEMENT: The above approving individuals agree that the disposal and retirement directions on this Records Inventory and Disposition Schedule (RIDS) are properly applied. It is further agreed that the directions of this inventory will be carried out as indicated, and if any changes are made to the inventory (including organization, file custodian, and manager changes; addition or deletion of records) the RIDS will be revised accordingly.

5. Record Category	6. File Unit and Description	7. Media	8. Vital Record	9. Disposal Authority	10. Retention Period	11. Cut-Off and Retirement Instructions
1	QUALITY ASSURANCE RECORDS Calibration Histories - - Records of calibrations performed by this organization instruments and equipment, including radiation detection instrument records accumulated in checking instrument and equipment against established standards and calibrations, and for making corrections to the equipment. Documentation covers equipment and instrument calibrations for WHC and all other DOE contractors.	P	N/A	DOE Order 1324.A DRS 1.7a1	Destroy when 75 years old.	Submit original to IRM for Record Disposition within 30 days of completion.

DRAFT COPY

1. Agency or Contractor Westinghouse Hanford Company		RECORDS INVENTORY AND DISPOSITION SCHEDULE					2. Organization Code 55540 Page 2 of 3	
5. Record Category	6. File Unit and Description	7. Media	8. Vital Record	9. Disposal Authority	10. Retention Period	11. Cut-Off and Retirement Instructions		
	Specific documentation includes the following: 1)Physical & Electrical Standards Lab Report Form and Data Sheets. 2)Notice of Discrepancy 3)Non-Conformance Report							
2	Calibration Procedures	P	N/A	DOE Order 1324.A DRS 1.7a1	Destroy when 75 yrs old.	Retain Superseded/Canceled copies for 2 years in fireproof/environmentally safe files. Submit to IRM for Records Disposition.		
	OTHER RECORD MATERIAL							
1	Corrective Action Documentation	P	N/A	2 Years	GRS 23.1	Destroy when 2 years old, or when no longer needed.		
2	Qualification and Training Records (In-House)	P	N/A	Destroy when 5 yrs old or 5 yrs after program completion.	GRS 1.29a1	Destroy in office when 5 years old or upon completion.		
3	Calibration Stamp Log	P	N/A	When no longer needed.	GRS 23.8	Destroy in office when no longer needed.		
4	General Operating Procedures	P	N/A	Destroy when superseded.	DOE Order 1324.2A DRS 5.a	Destroy in office when superseded (IRM 2257(13)).		

DRAFT COPY

1. Agency or Contractor Westinghouse Hanford Company		RECORDS INVENTORY AND DISPOSITION SCHEDULE		2. Organization Code 55540	
				Page 3 of 3	

5. Record Category	6. File Unit and Description	7. Media	8. Vital Record	9. Disposal Authority	10. Retention Period	11. Cut-Off and Retirement Instructions
	NON-RECORD MATERIAL					
1	Audit and Surveillance Reports	P	N/A	2 Years.	Nonrecord	Destroy in office (record held by sub-contractor, PNL-QA, WPPSS-QA, KAISER-QA.
2	Contractual Agreements and Statement of Work Packages	P	N/A	2 Years.	Nonrecord	Destroy in office (record held by sub-contractor, PNL-Contracts Administration, WPPSS-Contracts Administration, Kaiser - Contracts Administration.
3	Records Inventory and Records Disposition Schedule	P	N/A	1 Year	Nonrecord	Destroy in office (record copy retained by Records Holding)
4	Quality Assurance Records Transmittal and Receipts	P	N/A	1 Year	Nonrecord	Destroy in office (record copy retained by Records Holding)

DRAFT COPY

CORRESPONDENCE DISTRIBUTION COVERSHEET

Author	Addressee	Correspondence No.
M. J. Charney	L6-86	9305213B-R1

Subject: QA VERIFICATION AUDIT OF WHC STANDARDS LABORATORY

INTERNAL DISTRIBUTION

Approval	Date	Name	Location	w/att
		Correspondence Control	A3-01	X
		CA Carpenter	L6-35	
		KL Chubb	L6-86	
		JN Nansen	N1-71	
		LD Salsberry	E6-03	
		CR Wallskog	G7-21	
		Warden	P7-72	X

FOR APPROVAL OF		
Name	Approved	Date
BO Barnes (Author)	BO BARNES	6/4/93
JW Smith	<i>[Signature]</i>	6/3/93
KE Harrison	<i>[Signature]</i>	6/3/93
LD Salsberry (KEH)	<i>[Signature]</i>	6/4/93

Battelle

Pacific Northwest Laboratories
Battelle Boulevard
P.O. Box 999
Richland, Washington 99352
Telephone (509) 376-0579

June 3, 1993

PQE-LMW-197

Ms. M. J. Charney
Acting Manager, Standards Laboratory
Westinghouse Hanford Company
P.O. Box 1970
Richland, WA 99352

Dear Ms. Charney:

QA VERIFICATION AUDIT OF WHC STANDARDS LABORATORY

Thank you for the cooperation extended to Ken Harrison and Orie Barnes during the subject verification audit which was performed to determine if corrective actions were completed as stated in the responses to the June 1992 audit. A copy of the verification audit report is attached for your review. A written response is required within 10 working days after receipt of this letter.

Since a considerable amount of the corrective action remains to be performed, your response to this verification audit is expected to include continued and prompt attention to the corrective action you identified in your September 10, 1992 response to the audit report dated August 7, 1992. The audit team will track your completion of each corrective action item through surveillances and/or weekly followups.

Corrective action was to have been completed by December 31, 1992. Since no extension was requested, PNL and KEH considers the lack of WHC management support and QA oversight as significant conditions adverse to quality. Your response should be coordinated and based upon input from the Standards Laboratory, WHC Engineering Applications QA, and any other WHC organizations deemed appropriate.

If you have any questions, please contact Orie Barnes at 376-4842 or me at 376-0579.

Very Truly Yours,

[Signature]

L. M. Worden
Technical Group Leader (Acting)
Facilities & Procurement QE Group
Process Quality Department

LMW/BOB/cjb

Attachments

cc: CA Carpenter - WHC
KL Chubb - WHC
JN Nansen - WHC
LD Salsberry - KEH
CR Wallskog - KEH

bcc: FC Hood
RR LaBarge
CS Larmey
JE McGarrah
BL Sachs
Supp. Hist. File
File/LB

BATTELLE PACIFIC NORTHWEST LABORATORY

VERIFICATION AUDIT REPORT

Company: Westinghouse Hanford Corporation

Address: 3717B Building Telephone: 509 376-2100
300 Area
Richland, WA 99352

Report By: B. ORIE BARNES
Audit Team Leader (Acting)

Date: June 2, 1993

INTRODUCTION

KE Harrison

A QA verification audit of Westinghouse Hanford Company (WHC) Standards Laboratory was performed at the above location on May 5-6, 1993, by PNL Process Quality Department Representatives, BO Barnes and KE Harrison. The purpose of this audit was to verify if corrective actions were completed in response to a QA program audit performed during June 2-29, 1992.

The scope of the audit was limited to the June, 1992 audit findings and observations. The audit findings included:

- (1) the written program was not always consistent with actual practices,
- (2) documentation on rationale for deviating from 4:1 ratio was not adequate, and
- (3) calibration procedures and forms did not address corner loading calibration of balances.

The audit observations included:

- (1) evaluation of subcontractors calibrating WHC Standards Laboratory primary and secondary standards was not being performed,
- (2) WHC QA surveillances were not effective in detecting violations to operating procedure requirements, and
- (3) retention requirements for obsolete calibration procedures did not exist.

The corrective action statements were identified in WHC letter 92-56-726 from KL Chubb to KE Harrison dated September 10, 1992. This audit was based upon and performed to verify completion of those corrective action commitments.

The entrance meeting was held at 1:00 p.m. on May 5, 1993. Meeting attendees are listed on Attachment A. A followup meeting was held at 9:00 on May 27, 1993 to allow Standards Laboratory and EAQA staff an opportunity to respond to the findings and observations that remained open. The verification audit report, including the completed checklist, is available for review in the Supplier's History File, presently located in Room 2221, 337 Building, 300 Area.

EXECUTIVE SUMMARY OF RESULTS

The audit reviewed the progress of the Standards Laboratory towards completion of the corrective action for the June 1992 audit performed by PNL and KEH. The corrective action was scheduled to be completed by 12/31/92, but very little effort has been directed towards its completion.

It is the audit team's opinion that the Standards Laboratory has not received the necessary amount of management and QA support to ensure that the written program accurately defines daily activities.

The findings and observations from the June 1992 audit, when grouped with findings and observations from other past audits and surveillances, indicates the WHC Standards Laboratory's management system is not effective in the areas of surveillances, agreement between the operating procedures and current practices, and obtaining calibration services from evaluated suppliers.

VERIFICATION DETAILS

Based on the verifications performed the status of each finding and observation is noted below:

Finding No. 1 Corrective action is not complete.

The initial visit by the audit team on May 5, 1993 found the following: The written program (WHC-SP-0446) for the Standards Laboratory included 15 operating procedures. Most of the 14 items identified in this finding could have been addressed by revising the operating procedures. Six of the 15 operating procedures were in the process of being revised, but only one of the 14 items had been addressed (Item 1). Corrective action for the rest of the 14 items was not yet completed. It appears that the effort to date of revising six of the operating procedures has not been effective in addressing corrective action for Finding No. 1. Operating procedures presently being revised, should undergo another review to determine if any items of this finding can be addressed.

Standards Laboratory management has committed to revise the appropriate operating procedures and complete the corrective actions that are referenced in this finding. The auditors acknowledge that recent turnover of management at the WHC Standards Laboratory has contributed to the delay in completing corrective action. The audit team was asked to return on May 27, 1993 to review progress towards corrective action for this finding.

The visit by the audit team on May 27, 1993 found the following: The manual consisting of the 15 operating procedures (WHC-SP-0446) has been completely revised to address the items of this finding. The 15 operating procedures have been reduced to 10 operating procedures, and a review of these procedures shows that 12 of the 14 items identified in this finding have been satisfactorily resolved. The remaining two items involve records management and will be addressed at a later date.

Finding No. 2 Corrective action is complete and this finding is considered closed.

A desk operating procedure has been written to document a statement of how Standards Laboratory justifies their deviation from a 4:1 ratio of accuracy of the standard vs. the instrument being calibrated. The calibration report form has also been modified to include the 4:1 ratio deviation statement.

Finding No. 3 Corrective action is complete and this finding is considered closed.

The May 5, 1993 visit by the audit team found that no corrective action had been taken to date. The corrective action response stated that the performance and results of corner load testing of balances would be documented on the calibration data sheet.

The May 27, 1993 follow-up visit by the audit team found that the Standards Laboratory had included the necessary information for corner load testing on the form used for balance calibration reports.

Observation A Corrective action is not complete.

WHC Engineering Applications Quality Assurance (EAQA) submitted a proposal to WHC QA management in a letter dated November 20, 1992, as promised in the corrective action response. The proposal stated EAQA's position regarding the evaluation of suppliers performing calibrations for the Standards Laboratory. WHC response to this proposal has not been adequate. It appears that Standards Laboratory management have chosen to selectively impose the applicable QA requirements for supplier evaluations on the purchase requisitions. It appeared that WHC has not been evaluating suppliers not currently on the Evaluated Suppliers Listing, as stated in the November 20, 1993 letter.

Observation B Corrective action is not complete.

In a October 20, 1992 letter from JN Nansen to KL Chubb, EAQA committed to evaluate the scope of the current surveillance program and determine what appropriate topics were needed to cover oversight of the Standards Laboratory activities. The FY 1993 EAQA surveillance schedule included only two surveillances of the Standards Laboratory, and both cover calibration procedures. One of these surveillances was performed in December of 1992, and was limited to the review of several calibration procedures. The second surveillance is scheduled to cover the same scope as the first. WHC EAQA is not providing the necessary oversight that the Standards Laboratory requires. At a minimum, the surveillances should be addressing past weaknesses, such as previous audit findings or observations.

The audit team does not accept the response to date by EAQA that their surveillance planning has been rescoped to include review of weaknesses pointed

out by the previous audit.

In addition, EAQA committed to assess a proposal of joint WHC/PNL/KEH surveillances of Standards Laboratory activities, but the assessment has not been performed to date.

Observation C Corrective action is not complete.

The corrective action stated that obsolete calibration procedures would be held for seven years. This statement should be included as a record retention requirement on the Records Inventory Disposition Schedule (RIDS) for the Standards Laboratory. Corrective action for this observation is being coordinated with the parts of Finding No. 1 that deal with records management (see items 9 and 10 of Finding No. 1) and will be addressed at a later date.

CORRECTIVE ACTION

Your response to this report is requested by separate cover letter. The audit team will track the completion of each corrective action item through surveillances and/or weekly follow-ups. The first of these follow-ups was held at the Standards Laboratory on May 27, 1993. The Standards Laboratory and EAQA staff presented corrective action that addressed the open findings and observations. The audit team will respond to all follow-up corrective actions through separate correspondence.

Attachment A

[illegible]

INDEX OF AUDIT/~~SURVEY~~/SURVEILLANCE

COMPANY WHC Standards Laboratory

ADDRESS 3717B Bldg. 300 Area

PHONE 376-2202

DATE PERFORMED 6/2 - 29/92 BY CR Wallskog & KE Harrison

- 1.0 CORRECTIVE ACTION
- 2.0 REPORT
- 3.0 COMPLETED CHECKLIST
- 4.0 EXHIBITS
- 5.0 BACKGROUND
- 6.0 PR/RFP/PO

DATE REPORT COMPLETED 8/4/92

REMARKS Corrective action response was deemed acceptable
11/13/92

DATE CLOSED _____ BY _____

1.0 CORRECTIVE ACTION

Name	FOR APPROVAL OF Approved	Date
KE Harrison (Author)	<i>KE Harrison</i>	11/4/92
AH Friberg	<i>AH Friberg</i>	11-9-92
JW Smith	<i>JW Smith</i>	11-4-92

Battelle

Pacific Northwest Laboratories
Battelle Boulevard
P.O. Box 999
Richland, Washington 99352
Telephone (509)

376-0873

November 13, 1992

PQE-KEH-409

Mr. K. L. Chubb
Manager, Safeguards & Security
Westinghouse Hanford Company
Maintenance & Standards Laboratory
P. O. Box 1970
Richland, Washington 99352

Dear Mr. Chubb:

QA AUDIT OF WHC STANDARDS LABORATORY

Thank you for the latest response (letter dated September 10, 1992) to the findings and observations noted during the subject audit. The corrective action response is considered acceptable; a verification audit will be conducted during the first quarter of CY93 to verify corrective action completion.

Sincerely,

KE Harrison

K. E. Harrison
Technical Group Leader
Process Quality Department

bcc: FC Hood
RR LaBarge
JE McGarrah
JW Smith
Sup Hist File
File/LB

cc: AH Friberg - KEH
JN Nansen - WHC
CR Wallskog - KEH

KEH:ljc

Westinghouse
Hanford Company

Internal
Memo

From: Engineering Applications Quality Assurance
Phone: 6-8393 L6-35
Date: October 20, 1992
Subject: PNL/KEH AUDIT RESPONSE

38920-92-030

To: K. L. Chubb L6-86
cc: C. A. Carpenter L6-35
D. W. Smith L6-35
JNN LB/File

Based upon the recommendation resulting from the audit response discussion meeting held on October 15, we have modified our response to Observation B on the PNL/KEH audit.

Observation B: WHC Engineering Applications Quality Assurance (EAQA) will evaluate the scope of our current surveillance program and determine what appropriate topics are needed to cover oversight of the Standard Laboratories activities. EAQA will assess the proposal of WHC, PNL, and KEH conducting joint surveillances of these activities. EAQA still plans to conduct appropriate narrow scoped surveillances. This proposal assessment and new surveillance checklists will be completed by November 30, 1992.

Due to circumstances outside of our control, the completion date of September 11, 1992 in Observation A will be changed to November 12, 1992.

J. N. Nansen
Manager

kcr

Westinghouse
Hanford Company

P.O. Box 1970 Richland, WA 99352

September 10, 1992

92-56-726

K. E. Harrison, Technical Group Leader
Facilities & Procurement
Pacific Northwest Laboratory
Post Office Box 999
Richland, Washington 99352

Dear Mr. K. E. Harrison:

QA AUDIT OF WHC STANDARDS LABORATORY

Reference: Letter, K. E. Harrison, PNL, to K. L. Chubb, WHC, same subject, PQE-KEH-280, dated August 7, 1992 and the meeting held on October 15, 1992 at 3717B Building.

FINDINGS (1)

The written program was not always consistent with actual practices.

CORRECTIVE ACTION:

Review our written program and update to reflect actual practices with special attention to the fourteen (14) item's listed under **BACKGROUND**
SCHEDULED COMPLETION DATE: Review completed by 9/30/92. Rewrite of operational procedures by 12/31/92. (At this time four Procedures have been rewritten to be consistent with actual practices).

ROOT CAUSE:

In the best interest of the Standards Laboratory and it's customers, it was managements decision to move conservatively in the area of operational procedure changes.

IMPACT ON PNL & KEH:

No major negative impact on services provided.

FINDINGS (2)

The rationale for deviating from the requirement to maintain the 4:1 ratio between the calibrated item and the Standard was not documented on the calibration reports or in the operating procedures.

K. E. Harrison
Page 2 of 3
September 10, 1992

ROOT CAUSE

The written response to a previous audit explaining our deviating from the 4:1 ratio, was not added to the operating procedures scheduled for rewrite.

CORRECTIVE ACTION:

Our Laboratory will review its Standards as they are used and develop a statement justifying the deviation from a 4:1 ratio. This information will be documented on all calibration reports that require it.

SCHEDULED COMPLETION DATES:

Calibration Standards will be reviewed to the 4:1 requirements on a daily bases. Start date: 10/1/92

IMPACT ON PNL & KEH:

No major impact on services provided.

FINDINGS (3)

The Manufacturer's requirement for Corner Loading on balances was not addressed in Calibration documents and calibration report Forms/Procedures.

CORRECTIVE ACTION:

Provide space on data sheet's to document performance and results of Corner Load testing.

SCHEDULED COMPLETION DATE:

Added to data sheet by 12/30/92.

ROOT CAUSE:

Corner loading is presently checked on most electronic balances. Our calibration procedure reference the corner loading but our data sheets do not provide for proven performance.

IMPACT ON KEH & PNL:

No impact on calibration's performed.

K. E. Harrison
Page 3 of 3
September 10, 1992

OBSERVATION A:

Engineering Applications Quality Assurance (EAQA) will submit a proposal to Westinghouse Hanford Company (WHC) Quality Assurance (QA) management recommending that all suppliers of calibration services for primary and secondary standards for the WHC Standards Laboratory be evaluated in accordance with WHC-CM-4-2, QI 7.2. Management response to this proposal will establish the appropriate follow-on actions. The proposal will be submitted by September 11, 1992.

OBSERVATION B: See attached letter 10-20-92 from J.N. Nansen.

WHC EAQA will evaluate the scope of our current surveillance program and determine what appropriate topics are needed to adequately cover oversight of the Standards Laboratory activities. EAQA will revise the surveillance checklists accordingly. This will be completed by October 1, 1992.

OBSERVATION C:

Obsolete calibration procedures will be held for seven years.

Very truly yours,

K. L. Chubb, Manager
Maintenance & Standards Laboratory

slh

cc: SD Calvert - KEH
CA Carpenter - WHC
JA Johnston - KEH
JN Nansen - WHC
CR Wallskog - KEH

September 10, 1992

92-56-726

K. E. Harrison, Technical Group Leader
Facilities & Procurement
Pacific Northwest Laboratory
Post Office Box 999
Richland, Washington 99352

Dear Mr. K. E. Harrison:

QA AUDIT OF WHC STANDARDS LABORATORY

Reference: Letter, K. E. Harrison, PNL, to K. L. Chubb, WHC, same
subject, PQE-KEH-280, dated August 7, 1992.

FINDINGS (1)

The written program was not always consistent with actual practices.

CORRECTIVE ACTION:

Review our written program and update to reflect actual practices with
special attention to the fourteen (14) item's listed under BACKGROUND

SCHEDULED COMPLETION DATE: Review completed by 9/30/92. Rewrite of
operational procedures by 12/31/92. (At this time four Procedures have been
rewritten to be consistent with actual practices).

ROOT CAUSE:

Day to day improvements made in the Laboratory's operation are not being
incorporated into our operational procedures in a timely manner.

IMPACT ON PNL & KEH:

No major negative impact on services provided.

FINDINGS (2)

The rationale for deviating from the requirement to maintain the 4:1 ratio
between the calibrated item and the Standard was not documented on the
calibration reports or in the operating procedures.

Findings
September 10, 1992
Page 2 of 3

CORRECTIVE ACTION:

Our Laboratory will review its Standards as they are used and develop a statement justifying the deviation from a 4 to 1 ratio. This information will be documented on all calibration reports that require it.

SCHEDULED COMPLETION DATES:

Calibration Standards will be reviewed to the 4:1 requirements on a daily bases. Start date: 10/1/92

IMPACT ON PNL & KEH:

No major impact on services provided.

FINDINGS (3)

The Manufacturer's requirement for Corner Loading Calibration of balances was not addressed in Calibration documents and calibration report Forms/Procedures.

CORRECTIVE ACTION:

Provide space on data sheet's to document performance and results of Corner Loading testing.

SCHEDULED COMPLETION DATE:

Added to data sheet by 12/30/92.

ROOT CAUSE:

Corner loading is presently checked on most electronic balances. Our calibration procedure reference the corner loading but our data sheets do not provide for proven performance.

IMPACT ON KEH & PNL:

No impact on calibration's performed.

OBSERVATION A:

Engineering Applications Quality Assurance (EAQA) will submit a proposal to Westinghouse Hanford Company (WHC) Quality Assurance (QA) management recommending that all suppliers of calibration services for primary and secondary standards for the WHC Standards Laboratory be evaluated in accordance with WHC-CM-4-2, QI 7.2. Management response to this proposal will establish the appropriate follow-on actions. The proposal will be submitted by September 11, 1992.

Findings
September 10, 1992
Page 3 of 3

OBSERVATION B:

WHC EAQA will evaluate the scope of our current surveillance program and determine what appropriate topics are needed to adequately cover oversight of the Standards Laboratory activities. EAQA will revise the surveillance checklists accordingly. This will be completed by October 1, 1992.

OBSERVATION C:

Obsolete calibration procedures will be held for seven years.

Very truly yours,

A handwritten signature in dark ink, appearing to read 'K.L. Chubb', with a stylized flourish at the end.

K. L. Chubb, Manager
Maintenance & Standards Laboratory

slh

cc: SD Calvert - KEH
CA Carpenter - WHC
JA Johnston - KEH
JN Nansen - WHC
CR Wallskog - KEH

FOR APPROVAL OF		
Name	Approved	Date
JW Smith	<i>[Signature]</i>	8/6/92
JA Johnston (KEH)	<i>[Signature]</i>	8/7/92

Battelle

Pacific Northwest Laboratories
Battelle Boulevard
P.O. Box 999
Richland, Washington 99352
Telephone (509)

August 7, 1992

376-0873

PQE-KEH-280

Mr. K. L. Chubb
Manager, Safeguards & Security
Westinghouse Hanford Company
Maintenance & Standards Laboratory
P. O. Box 1970
Richland, WA 99352

Dear Mr. Chubb:

QA AUDIT OF WHC STANDARDS LABORATORY

Thank you for the cooperation extended to the joint audit team during the subject audit. A copy of the audit report is attached for your review and response.

Please provide a written response to each finding and observation within 30 days after receipt of this report. Your response must include identification of the root cause for each finding, including an evaluation of the impact of the findings upon completed work for PNL and KEH. Also, describe the corrective action (or being taken) to correct immediate problems and to prevent future occurrences, and the date completed or scheduled to be completed.

If you have any questions, please contact C. R. Wallskog at 376-6587 or me at 376-0873.

Sincerely,

[Signature]

K. E. Harrison
Technical Group Leader
Facilities & Procurement
Process Quality Department

bcc: FC Hood
BC King
RR LaBarge
JE McGarrah
JW Smith
Sup Hist File
File/LB

KEH:naj

Attachment

cc: SD Calvert - KEH
CA Carpenter - WHC
JA Johnston - KEH
JN Nansen - WHC
CR Wallskog - KEH

BATTELLE PACIFIC NORTHWEST LABORATORY

AUDIT REPORT

Company: Westinghouse Hanford Corporation
Address: 3717B Building Telephone: 509 376-2100
300 Area
Richland, WA 99352

Report Date: August 4, 1992

INTRODUCTION

A joint QA program audit was performed of Westinghouse Hanford Corporation Standards Laboratory at the above location from June 2-29, 1992, by PNL Quality Representative, KE Harrison and KEH Quality Representative, CR Wallskog. The audit purpose, scope, audit members and audit base are addressed in the audit plan (Attachment A). The entrance meeting was held at 8:30 a.m. on June 2, 1992, and the exit meeting was held at 8:30 a.m. on July 31, 1992. Meeting attendees are listed on Attachment B. The audit report, including the completed checklist, is available for review in the Supplier's History File, presently located in Room 2221, 337 Building, 300 Area.

EXECUTIVE SUMMARY OF RESULTS

There were three findings and three observations noted during the course of the audit. The audit findings related to: (1) The written program was not always consistent with actual practices, (2) Documentation on the rationale for deviating from 4:1 ratio, and (3) Calibration procedures and forms did not address corner loading calibration of balances. The controls directly associated with environmental control, handling and storage, nonconformances and corrective action, training and qualification of personnel, and performance and documentation of most calibrations appeared to be effectively administered.

OBSERVATIONS

Observations are described below. Observations indicate a weakness in a management program that could lead to a more serious deficiency if not corrected, but do not constitute a lack of compliance with applicable requirements.

FINDINGS

Findings are described in Attachment C to this report. Any lack of findings in a specific area is not considered an indication that deficiencies do not exist. WHC should continue its own evaluations to assure compliance and control of the management system to DOE-RL requirements and other Hanford Contractor's Statements of Work.

OBSERVATIONS

- A. When subcontractors were used to provide calibration services, there did not appear to be any system within the Hanford arena for tracking what impact (safety) subsequent calibrations would have on the final product or results. WHC Quality Assurance performs a formal evaluation of those subcontractors providing calibration services where the final product involves safety class 1 and 2 applications. It would appear that there needs to be a joint effort by WHC and other Hanford Contractors in resolving this question: What is the final use of an instrument (safety class application) calibrated by WHC Standards Laboratory using a standard that has been calibrated by a subcontractor?
- B. Surveillances performed by WHC Quality Assurance did not appear to verify implementation of the requirements in the operating procedures. There were several operating procedure requirement violations that could have been easily detected through the surveillance process.
- C. For historical purposes and for purposes of verification of past performance, there should be a designated interval for the retention of obsolete calibration procedures in the files.

CORRECTIVE ACTION

Corrective action will be addressed in a separate cover letter.

KEH:naj

Attachment

bcc: CA Carpenter - WHC
SD Calvert - KEH
FC Hood
JA Johnson - KEH
BC King
RR LaBarge
JE McGarrah
JN Nansen - WHC
JW Smith
D Wendel
Sup Hist File
File/LB

AUDIT PLAN

ATTACHMENT A

I. PURPOSE

To determine if WHC Standards Laboratory and WHC Quality Assurance are continuing to implement a calibration program in accordance with the requirements of the audit base (stated below); to determine the adequacy of WHC's internal procedures addressing these calibration programs, and to obtain corrective action for any findings or observations.

II. SCOPE

This audit is not intended to be inclusive of all quality-related requirements. However, most of the elements of a calibration program will be evaluated including, but not limited to, WHC's documented calibration program and control of reference standards.

III. AUDITORS

K. E. Harrison, PNL Audit Team Leader

C. R. Wallskog, KEH Lead Auditor

S. D. Calvert, KEH Lead Auditor

IV. AUDIT BASE

A. ASME NQA-1 - 1989 Quality Assurance Program Requirements for Nuclear Facilities

B. IEEE Std 498 - 1985 IEEE Standard Requirements for the Calibration Control of Measuring and Test Equipment used in Construction and Maintenance of Nuclear Power Generating Stations

C. PNL Statement of Work WHC-85-1

D. WHC Standards Operating Procedures

E. KEH Statement of Work

VI. AUDIT CONDUCT

A. The Entrance Interview is scheduled for 08:30 a.m. on 6/2/92.

Attendees: _____

- B. Use judgmental sampling in most cases; random samples may be used.
- C. Use checklist developed for this program.
- D. During the audit, add additional checks if deemed appropriate.
- E. Assure the audit is retraceable, obtain copies of documented "objective evidence", when appropriate.
- F. The exit interview is tentatively scheduled for 4:00 p.m., 6/4/92.

- 1. Discuss overview of audit results.
- 2. Discuss any discrepancies or areas of disagreement.
- 3. Discuss corrective action, if required.
- 4. Audit exit interview held on: _____

Attendees: _____

Prepared by:

KE Harrison

Date:

5/19/92

Pacific Northwest Laboratories

LESS QUALITY

~~CONFIDENTIAL~~ DEPARTMENT

6/2-

3717B

6/2/92

WHC STDs LABORATORY

ATTACHMENT B p1 of 2

PLEASE PRINT

[illegible]

Pacific Northwest Laboratories

~~4~~VERIFICATION DEPARTMENT

AUDIT DATES:

MEETING PLACE:

ENTRANCE/EXIT MEETING
TIME/DATE:

June 2-29, 1992

3717B 300 AREA

ORGANIZATION AUDITED/PROJECT:

ATTACHMENT B

WHC STDs LABORATORY

P2 of 2

PLEASE PRINT

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ATTACHMENT C

FINDINGS

AUDIT FINDING

Action Date: 30 working days after receipt Audit Finding No: 001

Supplier: WHC Standards Laboratory Audit Date: June 2-29, 1992

Audit Team Leader: K.E. Harrison Auditor: CR Wallskog

Audit Finding (Brief Summary) The written program was not always consistent with actual practices.

REQUIREMENT

1. "The Sandia Primary Standards Laboratory (PSL) is designated by DOE to provide auditing services for the Standards Laboratories of the DOE weapon complex and, at the request of DOE/RLO (Richland Operations), the Westinghouse Hanford Standards Laboratory ..." (WHC-SP-0446, Operating Procedure Requirements, Sec. 2, Rev. 3, Para. 4.1)
2. "Controlled distribution of Operating Procedures will be limited to the Standards Laboratory and to the responsible Contractor Quality Assurance organizations. Procedures will not be available for general distribution. The controlled distribution list is posted at the back of this Manual. Distribution of this Procedures Manual, any future revision or new procedures, shall be controlled by the current distribution listing. Operating Procedures shall be controlled by the Procedures Manual copy number, with receipt required (see receipt form, Attachment 1)." (WHC-SP-0446, Operating Procedure Requirements, Sec. 3, Rev. 3, Para. 4.1)
3. "A Calibration Procedure Log (see Attachment 1) shall be used to provide a listing of procedure numbers or other identifiers assigned to procedures. The Log shall identify the department using the procedure, the identifier, issue date, revision date or number, and other pertinent information." (WHC-SP-0446, Operating Procedure Requirements, Sec. 4, Rev. 2, Para. 4.2)
4. "Calibration Procedures prepared internally should use the following format or similar, as applicable to the device." (WHC-SP-0446, Operating Procedure Requirements, Sec. 4, Rev. 2, Para. 6.2)
5. "When Calibration Procedures are revised or replaced, the superseded procedure shall be removed from the files and replaced with the latest version. Preprinted Calibration Report Forms which reference the superseded procedure shall also be removed

from the files. An on-going effort shall be implemented to segregate obsolete procedures, manuals, etc., so that procedure control efforts can be directed to those that are current and in use."

(WHC-SP-0446, Operating Procedure Requirements, Sec. 4, Rev. 2, Para. 9.1-9.3)

6. "Use regular calibration label (A) for instruments meeting procedural or manufacturer's specifications consistent with the established recall interval at all points checked."
(WHC-SP-0446, Operating Procedure Requirements, Sec. 8, Rev. 6, Para. 4.1)
7. "A (2) denotes Out of Tolerance as received. A Notice of Discrepancy (NOD) must be issued. (See attached). Contact the custodian or Calibration Control Authority (CCA) for authorization to repair, adjust, or conditional accept before proceeding. Document the name of the person contacted on the NOD form. If contact cannot be made in a timely manner, obtain authorization to proceed from the Supervisor or Plant Engineer."
(WHC-SP-0446, Operating Procedure Requirements, Sec. 8, Rev. 6, Para. 3.3.2)
8. "When it is not feasible to place a calibration label directly on the equipment due to size or use restrictions, calibration status may be maintained by: 10.1.1 Use of a log sheet system, available for audit, and containing serial numbers or other identification which is visible on the equipment."
(WHC-SP-0446, Operating Procedure Requirements, Sec. 8, Rev. 6, Para. 10.1)
9. "A Records Inventory and Disposition Schedule (RIDS) for Quality Assurance Records shall be maintained in addition to the index. RIDS shall be reviewed periodically and updated as needed to meet existing program and regulatory requirements."
(WHC-SP-0446, Operating Procedure Requirements, Sec. 11, Rev. 2, Para. 5.2)

"Calibration reports and supporting records of Battelle owned M&TE shall not be destroyed without written authorization from the Battelle Quality Assurance Department."
(Battelle Statement of Work, WHC-85-1, Para. 4.0)
10. "A schedule shall be established with Documentation Services to transmit a record copy of Quality Assurance Records to permanent storage as soon as practicable. The normal retention period within the Standards Laboratory before transmittal for permanent storage shall be 60 days from approval or designated as a Quality Assurance Record requiring permanent storage."
(WHC-SP-0446, Operating Procedure Requirements, Sec. 11, Rev. 2, Para. 7.3)

11. "All instruments requiring calibration or service must be received by the Receiving/Shipping Clerk. All items must have a delivery tag attached with delivery contact, location, valid work order number, and supplementary information listed. Items without proper information supplied by the customer will be set aside until time allows for contacting the custodian and obtaining the necessary information to properly tag the item. The Job Sheet shall be attached to the instrument and the instrument placed on the storage shelves for the department which will perform the calibration."
(WHC-SP-0446, Operating Procedure Requirements, Sec. 12, Rev. 3, Para. 4.2, 4.6)
12. "Complete a Purchase Requisition [Form 54-7600-001 (6-88)] (Attachment 1).
Items sent to the vendor for NIST traceable calibrations must be clearly identified on the requisition with the words "NIST Traceable Certificate of Calibration Required."
Items shipped to the vendor for repair must be so identified on the requisition with words "For Repair Only - Calibration Not Required".
(WHC-SP-0446, Operating Procedure Requirements, Sec. 15, Rev. 2, Para. 3.1.1, 3.1.2, 3.2.2)
13. "Standards Laboratory General Operating Procedures shall be reviewed annually by the Supervisor to assure continued compliance with current requirements."
(WHC-SP-0446, Operating Procedure Requirements, Sec. 3, Rev. 3, Para. 5.1)
14. "Relative Humidity General 20% to 55% in all laboratories around controlled temperatures of 20 C and 23 C."
(WHC-SP-0446, Operating Procedure Requirements, Sec. 6, Rev. 2, Para. 3.6)

BACKGROUND

1. The relationship with Sandia Primary Standards Laboratory was terminated over two years ago.
2. There was no controlled distribution of documents as specified in Section 3, Paragraph 4.1.
3. The calibration procedures log book did not reflect current status. There was verification of twelve procedures written by the standards laboratory personnel; six were not listed in the log and two procedures listed in the log book did not reflect the correct issue date and revision number.

4. Thirty seven calibration procedures were reviewed; approximately 80% did not follow the suggested format or contain the required information listed for all bullets under this requirement (bullets 1-9). This situation had been noted in a previous audit (AUD-90-03, dated 3-21-90, Joint WHC and KEH Audit Team).
5. It was noted that obsolete procedures (manufacturer's Instructions or manuals) had not been removed when a WHC Laboratory Calibration Procedure superseded the then obsolete procedure. Preprinted calibration report forms were in the files which referenced obsolete/superseded procedures (revision numbers).
6. The use of WHC calibration labels for standards calibrated by external calibration agencies was not addressed in the operating procedures. The operating procedure addressed internally calibrated equipment only.
7. Contrary to this requirement (contact of the custodian or CCA), notice of discrepancy forms did not have the name of the person contacted.
8. There was no evidence that a log sheet had been used in the past; recommend that this no longer be reflected in the operating procedure.
9. The current Records Inventory and Disposition Schedule (RIDS) states a retention period "until item removed from service" which is not consistent with the current practice of records retention for an indefinite period (i.e., 75 years plus). The RIDS needs to reflect current practice and the RIDS or Operating Procedures need to address the Battelle SOW concerning destruction of calibration records on Battelle owned M&TE. RIDS should reference Siemens instead of Advanced Nuclear Fuel.
10. There was no record of an established schedule for records transmittal; records were transmitted when the box was full. Since current practice was to have records transmitted when the box was full, the second sentence does not appear to be relevant "The normal retention period within the Standards Laboratory before transmittal for permanent storage shall be 60 days from approval or designated as a Quality Assurance Record requiring permanent storage."
11. The delivery tag on ten items were checked for compliance to Sec. 12, Para. 4.2; eight items did not have the work order number documented. Exceptions to paragraph 4.6 need to be addressed such as dimensional, mass, and force M&TE. The Job Sheet was not always attached to the instrument and the instrument placed on the storage shelves.

12. There was a conflict in revision numbers between the requisition referenced in WHC-SP-0446 and the requisition in use. Recommend that the procedure state that a purchase requisition will be used (do not use a specific rev. number). Purchase requisitions sent to the vendor within the past year for NIST traceable calibrations did not contain the words "NIST Traceable Certificate of Calibration Required." Purchase requisitions sent to the vendor for repair were not identified with the words "For Repair Only - Calibration Not Required."
13. There did not appear to be objective evidence of an annual review of the Standards Laboratory General Operating Procedures by the supervisor. An annual review should have identified some of the aforementioned deficiencies.
14. The receiving/inspection area did not have a monitor for humidity.

AUDIT FINDING

Action Date: 30 working days after receipt Audit Finding No: 002

Supplier: WHC Standards Laboratory Audit Date: June 2-29, 1992

Audit Team Leader: K.E. Harrison Auditor: C.R. Wallskog

Audit Finding (Brief Summary) The rationale for deviating from the requirement to maintain the 4:1 ratio between the calibrated item and the standard was not documented on the calibration reports or in the operating procedures.

REQUIREMENT

"Standards shall have tolerances of at least four times better than those of the M&TE being calibrated. When the accuracy cannot be made four times better, the rationale for deviating from this requirement shall be justified in writing (e.g., limited by state-of-the-art)." (Battelle Statement of Work, WHC-85-1, Para. 2.2)

"Calibration standards shall have accuracies four times better than those of the M&TE being calibrated, unless limited by state of the art of availability of such standards. When the four to one (4:1) calibration requirements cannot be met, the accuracy of the standard used for the calibration shall be documented. The use of NIST proven comparison methods shall also be acceptable." (Kaiser LOI Dated 6/21/91, Para. 2.3)

BACKGROUND

There was a letter in the file that justified specific deviations from the subject requirement, but the corresponding operating procedures or individual calibration records did not reference the letter or have a statement justifying the deviation.

AUDIT FINDING

Action Date: 30 working days after receipt Audit Finding No: 003

Supplier: WHC Standards Laboratory Audit Date: June 2-29, 1992

Audit Team Leader: K.E. Harrison Auditor: C.R. Wallskog

Audit Finding (Brief Summary) The manufacturer's requirement for corner loading calibration of balances was not addressed in calibration documents and calibration report forms/procedures.

REQUIREMENT

"The Calibration Procedures shall provide sufficient instruction and information to enable qualified personnel to perform the calibration." (WHC-SP-0446, Operating Procedure Requirements, Sec. 4, Rev. 2, Para. 3.2)

"Written methods or procedures for calibrating M&TE shall be used to assure calibration technique uniformity." (Battelle Statement of Work, WHC-85-1, Para. 2.6)

BACKGROUND

On some balances the test for corner loading is essential in order to assure that the subject balance is capable of optimum performance. During the audit it was stated that corner loading was sometimes performed on balances, although this action was not documented. There was no evidence that provision had been made for corner loading calibration on the calibration documents or in the calibration procedures.

2.0 REPORT

Name	FOR APPROVAL OF Approved	Date
JW Smith	<i>[Signature]</i>	8/6/92
JA Johnston (KEH)	<i>[Signature]</i>	8/7/92

Battelle

Pacific Northwest Laboratories
Battelle Boulevard
P.O. Box 999
Richland, Washington 99352
Telephone (509)

August 7, 1992

376-0873

PQE-KEH-280

Mr. K. L. Chubb
Manager, Safeguards & Security
Westinghouse Hanford Company
Maintenance & Standards Laboratory
P. O. Box 1970
Richland, WA 99352

Dear Mr. Chubb:

QA AUDIT OF WHC STANDARDS LABORATORY

Thank you for the cooperation extended to the joint audit team during the subject audit. A copy of the audit report is attached for your review and response.

Please provide a written response to each finding and observation within 30 days after receipt of this report. Your response must include identification of the root cause for each finding, including an evaluation of the impact of the findings upon completed work for PNL and KEH. Also, describe the corrective action (or being taken) to correct immediate problems and to prevent future occurrences, and the date completed or scheduled to be completed.

If you have any questions, please contact C. R. Wallskog at 376-6587 or me at 376-0873.

Sincerely,

[Signature: K. E. Harrison]

K. E. Harrison
Technical Group Leader
Facilities & Procurement
Process Quality Department

bcc: FC Hood
BC King
RR LaBarge
JE McGarrah
JW Smith
Sup Hist File
File/LB

KEH:naj

Attachment

cc: SD Calvert - KEH
CA Carpenter - WHC
JA Johnston - KEH
JN Nansen - WHC
CR Wallskog - KEH

BATTELLE PACIFIC NORTHWEST LABORATORY

AUDIT REPORT

Company: Westinghouse Hanford Corporation
Address: 3717B Building Telephone: 509 376-2100
300 Area
Richland, WA 99352

Report Date: August 4, 1992

INTRODUCTION

A joint QA program audit was performed of Westinghouse Hanford Corporation Standards Laboratory at the above location from June 2-29, 1992, by PNL Quality Representative, KE Harrison and KEH Quality Representative, CR Wallskog. The audit purpose, scope, audit members and audit base are addressed in the audit plan (Attachment A). The entrance meeting was held at 8:30 a.m. on June 2, 1992, and the exit meeting was held at 8:30 a.m. on July 31, 1992. Meeting attendees are listed on Attachment B. The audit report, including the completed checklist, is available for review in the Supplier's History File, presently located in Room 2221, 337 Building, 300 Area.

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OBSERVATIONS

Observations are described below. Observations indicate a weakness in a management program that could lead to a more serious deficiency if not corrected, but do not constitute a lack of compliance with applicable requirements.

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Findings are described in Attachment C to this report. Any lack of findings in a specific area is not considered an indication that deficiencies do not exist. WHC should continue its own evaluations to assure compliance and control of the management system to DOE-RL requirements and other Hanford Contractor's Statements of Work.

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- A. When subcontractors were used to provide calibration services, there did not appear to be any system within the Hanford arena for tracking what impact (safety) subsequent calibrations would have on the final product or results. WHC Quality Assurance performs a formal evaluation of those subcontractors providing calibration services where the final product involves safety class 1 and 2 applications. It would appear that there needs to be a joint effort by WHC and other Hanford Contractors in resolving this question: What is the final use of an instrument (safety class application) calibrated by WHC Standards Laboratory using a standard that has been calibrated by a subcontractor?
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- C. For historical purposes and for purposes of verification of past performance, there should be a designated interval for the retention of obsolete calibration procedures in the files.

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KEH:naj

Attachment

bcc: CA Carpenter - WHC
SD Calvert - KEH
FC Hood
JA Johnson - KEH
BC King
RR LaBarge
JE McGarrah
JN Nansen - WHC
JW Smith
D Wendel
Sup Hist File
File/LB

AUDIT PLAN

ATTACHMENT A

I. PURPOSE

To determine if WHC Standards Laboratory and WHC Quality Assurance are continuing to implement a calibration program in accordance with the requirements of the audit base (stated below); to determine the adequacy of WHC's internal procedures addressing these calibration programs, and to obtain corrective action for any findings or observations.

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K. E. Harrison, PNL Audit Team Leader

C. R. Wallskog, KEH Lead Auditor

S. D. Calvert, KEH Lead Auditor

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E. KEH Statement of Work

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A. The Entrance Interview is scheduled for 08:30 a.m. on 6/2/92.

Attendees: _____

- B. Use judgmental sampling in most cases; random samples may be used.
- C. Use checklist developed for this program.
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- 2. Discuss any discrepancies or areas of disagreement.
- 3. Discuss corrective action, if required.
- 4. Audit exit interview held on: _____

Attendees: _____

Prepared by:

KE Harrison

Date:

5/19/92

Pacific Northwest Laboratories

Process Quality

~~CONFIDENTIAL~~ DEPARTMENT

AUDIT REPORT NO.

AUDIT DATES:

6/2-

MEETING PLACE:

37178

ENTRANCE/EXIT MEETING
TIME/DATE:

6/2/92

~~ORGANIZATION AUDITED/PROJECT:~~

WHC STDs LABORATORY

ATTACHMENT B p1 of 2

PLEASE PRINT

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ATTACHMENT C

FINDINGS

AUDIT FINDING

Action Date: 30 working days after receipt Audit Finding No: 001
Supplier: WHC Standards Laboratory Audit Date: June 2-29, 1992
Audit Team Leader: K.E. Harrison Auditor: CR Wallskog
Audit Finding (Brief Summary) The written program was not always consistent with actual practices.

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9. The current Records Inventory and Disposition Schedule (RIDS) states a retention period "until item removed from service" which is not consistent with the current practice of records retention for an indefinite period (i.e., 75 years plus). The RIDS needs to reflect current practice and the RIDS or Operating Procedures need to address the Battelle SOW concerning destruction of calibration records on Battelle owned M&TE. RIDS should reference Siemens instead of Advanced Nuclear Fuel.
10. There was no record of an established schedule for records transmittal; records were transmitted when the box was full. Since current practice was to have records transmitted when the box was full, the second sentence does not appear to be relevant "The normal retention period within the Standards Laboratory before transmittal for permanent storage shall be 60 days from approval or designated as a Quality Assurance Record requiring permanent storage."
11. The delivery tag on ten items were checked for compliance to Sec. 12, Para. 4.2; eight items did not have the work order number documented. Exceptions to paragraph 4.6 need to be addressed such as dimensional, mass, and force M&TE. The Job Sheet was not always attached to the instrument and the instrument placed on the storage shelves.

12. There was a conflict in revision numbers between the requisition referenced in WHC-SP-0446 and the requisition in use. Recommend that the procedure state that a purchase requisition will be used (do not use a specific rev. number). Purchase requisitions sent to the vendor within the past year for NIST traceable calibrations did not contain the words "NIST Traceable Certificate of Calibration Required." Purchase requisitions sent to the vendor for repair were not identified with the words "For Repair Only - Calibration Not Required."
13. There did not appear to be objective evidence of an annual review of the Standards Laboratory General Operating Procedures by the supervisor. An annual review should have identified some of the aforementioned deficiencies.
14. The receiving/inspection area did not have a monitor for humidity.

AUDIT FINDING

Action Date: 30 working days after receipt Audit Finding No: 002

Supplier: WHC Standards Laboratory Audit Date: June 2-29, 1992

Audit Team Leader: K.E. Harrison Auditor: C.R. Wallskog

Audit Finding (Brief Summary) The rationale for deviating from the requirement to maintain the 4:1 ratio between the calibrated item and the standard was not documented on the calibration reports or in the operating procedures.

REQUIREMENT

"Standards shall have tolerances of at least four times better than those of the M&TE being calibrated. When the accuracy cannot be made four times better, the rationale for deviating from this requirement shall be justified in writing (e.g., limited by state-of-the-art)." (Battelle Statement of Work, WHC-85-1, Para. 2.2)

"Calibration standards shall have accuracies four times better than those of the M&TE being calibrated, unless limited by state of the art of availability of such standards. When the four to one (4:1) calibration requirements cannot be met, the accuracy of the standard used for the calibration shall be documented. The use of NIST proven comparison methods shall also be acceptable." (Kaiser LOI Dated 6/21/91, Para. 2.3)

BACKGROUND

There was a letter in the file that justified specific deviations from the subject requirement, but the corresponding operating procedures or individual calibration records did not reference the letter or have a statement justifying the deviation.

AUDIT FINDING

Action Date: 30 working days after receipt Audit Finding No: 003

Supplier: WHC Standards Laboratory Audit Date: June 2-29, 1992

Audit Team Leader: K.E. Harrison Auditor: C.R. Wallskog

Audit Finding (Brief Summary) The manufacturer's requirement for corner loading calibration of balances was not addressed in calibration documents and calibration report forms/procedures.

REQUIREMENT

"The Calibration Procedures shall provide sufficient instruction and information to enable qualified personnel to perform the calibration." (WHC-SP-0446, Operating Procedure Requirements, Sec. 4, Rev. 2, Para. 3.2)

"Written methods or procedures for calibrating M&TE shall be used to assure calibration technique uniformity." (Battelle Statement of Work, WHC-85-1, Para. 2.6)

BACKGROUND

On some balances the test for corner loading is essential in order to assure that the subject balance is capable of optimum performance. During the audit it was stated that corner loading was sometimes performed on balances, although this action was not documented. There was no evidence that provision had been made for corner loading calibration on the calibration documents or in the calibration procedures.

FOR APPROVAL OF		
Name	Approved	Date
JA Johnston (KEH)	<i>JA Johnston</i>	5/20/92
JW Smith	<i>JW Smith</i>	5-20-92

Battelle

Pacific Northwest Laboratories
Battelle Boulevard
P.O. Box 999
Richland, Washington 99352
Telephone (509)

376-0873

May 21, 1992

PQE-KEH-180

Mr. K. L. Chubb, Manager
Safeguards & Security
Westinghouse Hanford Company
Maintenance & Standards Laboratory
P. O. Box 1970
Richland, WA 99352

Report

Dear Mr. Chubb:

QA AUDIT OF WHC STANDARDS LABORATORY

A joint QA audit of the WHC Standards Calibration Laboratory, by Pacific Northwest Laboratories and Kaiser Engineering Hanford, Quality Assurance Staff, is planned for June 2-4, 1992. The audit purpose, scope, audit members and audit base are addressed in the audit plan (Attachment A). The audit entrance meeting will be held at the WHC Standards Laboratory (300 Area-3717B Building) at 8:30 a.m., June 2, 1992.

Please contact me at 376-0873 if there are any comments or questions regarding the subject audit.

Sincerely,

K E Harrison

K. E. Harrison
Technical Group Leader
Facilities & Procurement QE Group
Process Quality Department

Attachment

KEH:naj

bcc: C Bosted - DOE
PH Bruce - KEH
CA Carpenter - WHC
SD Calvert - KEH
FC Hood
JA Johnston - KEH
BC King
RR LaBarge
JE McGarrah
JN Nansen - WHC
JW Smith
CR Wallskog - KEH
Sup Hist File
File/LB

+ WA Hinckley
Q

RECEIVED

MAY 21 1992

J W SMITH

Twenty-five years of science

for DOE and the Northwest

AUDIT PLAN

ATTACHMENT A

I. PURPOSE

To determine if WHC Standards Laboratory and WHC Quality Assurance are continuing to implement a calibration program in accordance with the requirements of the audit base (stated below); to determine the adequacy of WHC's internal procedures addressing these calibration programs, and to obtain corrective action for any findings or observations.

II. SCOPE

This audit is not intended to be inclusive of all quality-related requirements. However, most of the elements of a calibration program will be evaluated including, but not limited to, WHC's documented calibration program and control of reference standards.

III. AUDITORS

K. E. Harrison, PNL Audit Team Leader

C. R. Wallskog, KEH Lead Auditor

S. D. Calvert, KEH Lead Auditor

IV. AUDIT BASE

A. ASME NQA-1 - 1989 Quality Assurance Program Requirements for Nuclear Facilities

B. IEEE Std 498 - 1985 IEEE Standard Requirements for the Calibration Control of Measuring and Test Equipment used in Construction and Maintenance of Nuclear Power Generating Stations

C. PNL Statement of Work WHC-85-1

D. WHC Standards Operating Procedures

E. KEH Statement of Work

VI. AUDIT CONDUCT

A. The Entrance Interview is scheduled for 08:30 a.m. on 6/2/92.

Attendees: _____

- B. Use judgmental sampling in most cases; random samples may be used.
- C. Use checklist developed for this program.
- D. During the audit, add additional checks if deemed appropriate.
- E. Assure the audit is retraceable, obtain copies of documented "objective evidence", when appropriate.
- F. The exit interview is tentatively scheduled for 4:00 p.m., 6/4/92.

1. Discuss overview of audit results.

2. Discuss any discrepancies or areas of disagreement.

3. Discuss corrective action, if required.

4. Audit exit interview held on: _____

Attendees: _____

Prepared by:

KE Harrison

Date:

5/19/92

END

**DATE
FILMED**

9/29/93