GPU Nuclear

AUDIT REPORT

Audit No. O-COM-90-16 Audit Dates August 27-28, 1990

Program/Activity Roche Biomedical

PURPOSE:

This audit was conducted to verify the capability of the Research Triangle Park facility of Roche Biomedical Laboratories to comply with the requirements of existing purchase orders with other Roche facilities, and, to conduct an investigation into the false negative laboratory result on a blind QC sample (A303-762).

ATTENDEES:

Name	Title	Representing
D. Aichele (2)	GCMS Supervisor	Roche Biomed Lab
P. Childs, PhD (1,2,3)	Director Toxicology, Resch Park	Roche Biomed Lab
N. Coates (2)	Screening Supervisor	Roche Biomed Lab
D. Corbett (1,2,3)	Lead Auditor	GPUN
R. Ebert (1,2,3)	Technical Specialist	GPUN
B. Flora, PhD (1,2)	Assist. Dir. Toxicology	Roche Biomed Lab
J. Gourley (2)	First Shift Supervisor	Roche Biomed Lab
J. Irving (1,2)	Co-Dir. Toxicology, Resch Park	Roche Biomed Lab
N. Lewis (1,2,3)	Technical Specialist	GPUN (NADE)
J. Venet (2)	Medical Director	GPUN

(1) - Attended Pre-Audit Conference (8/27/90)
(2) - Contacted During Audit (8/27-28/90)
(3) - Attended Post-Audit Conference (8/28/90)

SUMMATION:

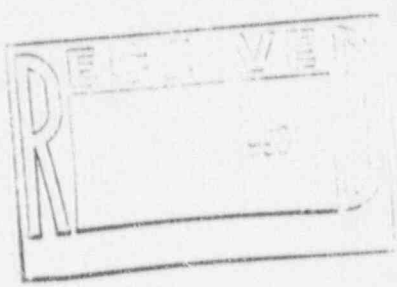
Roche Biomedical Laboratories' Research Triangle park facility has established a program of procedures and controls to provide satisfactory analyses of urine samples for drugs. The program was found to be incomplete in that there were not written procedures for all areas required by the Department of Health and Human Services (DHHS). Refer to Finding 1 of 1. The lack of procedures for checking the accuracy and reproducibility of automatic pipettes and for determining the screening control values of the Olympus 500 Analyzer were compensated for by actual practices, which met the intent of the requirement to have written procedures.

	Signature	Title	Date
Originator		Audit Team Leader	10/2/90
Concurred By		QA Audit Manager	10/3/90
Approved By		Mgr., QA Prog. Dev. & Audit	10/3/90
Audit Package Complete		Audit Team Leader/Manager	

6160-90-205
October 3, 1990

cc: B.W. Alatary - Corp. QA PD&A Mgr.
P.R. Clark - President
W.D. County - TMI QA Audit Manager
R.W. Ebert - Special Projects Mgr.
R.D. Fenton - Director, Human Resources
P.B. Fiedler - Director, Nuclear Assurance
E.E. Fitzpatric - Director, Oyster Creek
R.P. Germann - NSAD Director/Ombudsman
G.M. Gurican - Engineer
H.D. Hukill, Jr. - Director, TMI-1
J. Knubel - Licensing & Reg. Affairs Dir.
R.L. Long - Director Corporate Services
D.W. MacFarlane - Oyster Creek QA Audit Manager
R.S. Markowski - Mgr. Corp. QA Program Development & Audit
C.A. Mascari - Director QA
C.J. Paczolt - Mfg. Assurance Mg.
M.B. Roche - Director, TMI-2
S.S. Singleton - Mgr. HR/Program Development
J.L. Sullivan - Chairman, GORBS
J.L. Venet - Mgr. Medical Services
J.F. Wilson - Legal Services Director

File: O-COM-90-16
CARIRS



Because of an administrative oversight by DHHS, Roche Biomedical Laboratories did not have a certification for the Research Triangle Park facility at the commencement of the audit. One was provided from DHHS before the audit was completed.

Based upon the data examined and the processes observed, the audit team could not attribute the false negative result of QC sample A303-702 to Roche Biomedical Laboratories.

REFERENCES:

Mandatory Guidelines for Federal Workplace Testing Programs. (53FR11970)

DETAILED DISCUSSION:

Certification:

The audit team requested to examine the certification documents from DHHS showing that they had been successfully evaluated as capable of meeting the scientific and technical requirements of DHHS. Roche produced a letter from the contractor for DHHS, RTI (dated 5/15/90), stating that they had given preliminary approval to transfer the existing certification from the Burlington, NC facility to their new facility at Research Triangle Park, NC. This approval was conditional pending successful completion of the next scheduled NCLP inspection. The team asked to see the final approval of the certification and was shown an entry in the Federal Register (55FR27505) dated 7/3/90 listing the Research Triangle Park facility as a certified laboratory, but, no written certification had been received from DHHS. Roche contacted DHHS during the audit and requested a copy of the certification. This was provided prior to the completion of the audit.

Capability:

The audit team examined documents and equipment operating procedures to verify that Roche Biomedical Laboratories is capable of testing for at least the following five classes of drugs:

1) Marijuana
2) Cocaine
3) Opiates
4) Amphetamines
5) Phencyclidine.

Roche Biomedical Laboratories utilizes the Olympus AU500 screening equipment for preliminary screening of urine samples. This equipment uses the EMIT test required by DHHS. The confirmatory testing is performed using Gas Chromatograph/Mass Spectroscopy (GCMS) in accordance with DHHS requirements. Demonstration of the laboratories ability to produce accurate results with the equipment was demonstrated to DHHS during the laboratory certification process. Records were available at the Research Triangle Park facility to document this.

Personnel:

The audit team examined resumes and training documents to verify that Roche personnel met the requirements of paragraph 2.3 of 53FR11970, "Mandatory Guidelines for Federal Workplace Testing Programs."

The position described as "Day-to-Day Management" is filled jointly by Dr. Paula Childs and Mr. John Irving. Dr. Childs is a certified forensic toxicologist by the American Board of Toxicology (Certificate #168). She holds a Ph.D in chemistry from Tufts University and is a certified Laboratory Director in New York and Connecticut. These qualifications are sufficient to satisfy DHHS requirements. Mr. Irving received a MS degree in Chemistry from Buchnell University. In addition, he has twenty years of experience in the Navy drug testing program which includes analytical experience, supervising laboratory technicians, managing a Navy drug testing lab, serving as Head of the Navy Drug Testing Program and Acting Chief of the Testing Branch for the National Institute on Drug Abuse. These qualifications have been interpreted by DHHS as being equivalent to the requirements contained in 53FR11970.

The position described as "Day-to-Day Operations and Supervision of Analysts" is filled by several persons on three shifts. The qualifications of each of the shift supervisors and those of the GCMS and Screening Supervisors were reviewed. Each held a BS degree in an appropriate science. Training records indicated that they had been trained in the subjects required by DHHS.

The remaining personnel in the laboratory must possess training and skills for the tasks assigned. The qualifications of one analyst were reviewed and were considered appropriate for the tasks performed.

Training files contained the information necessary to document each person's qualifications and meet DHHS requirements.

Quality Assurance/Quality Control:

The audit team examined documents and interviewed personnel to verify that Roche Biomedical had a documented program that encompasses all aspects of the laboratory analytical process. Procedures were found, and were considered appropriate, which addressed the following:

a. Chain of custody.
b. Security.
c. Reporting of results.
d. Validation of analytical procedures.

Analytical procedures are validated initially by DHHS as part of the certification process and on an ongoing basis in order to maintain the certification. Internal QC practices by Roche continually check the validity of results produced. For example, each batch of fifty samples submitted for initial testing includes the following quality controls;

a. Two positive controls fortified with drugs at the cutoff level.
b. Four urine blanks containing no drugs.
c. One positive blind sample.

The blanks are analyzed to assure that carryover does not cross contaminate samples.

The quality control samples described above constitute approximately 12% of all samples analyzed. This meets the minimum of 10% required by 53FR11970.

The sequence of quality control samples submitted for GCMS analysis includes:

a. An instrument setup standard.
b. A calibration standard.
c. A threshold control standard at 40-50% of the cutoff concentration.
d. A cutoff level control with a concentration of 20% above the cutoff level.
e. A high level control at twice the cutoff level.

In addition, each analytical run includes a blank urine sample and a quality control standard obtained commercially from Hycor.

These quality controls meet laboratory requirements contained in 53FR11970.

Security and Chain of Custody:

Security provisions were reviewed during the walkthrough of the Laboratory. Access to each of the sample handling areas is separately controlled by key card readers with an access code. Individuals who prepare samples do not have access to the areas where samples are analyzed and vice versa. Only selected management has access to multiple areas. All visitors are escorted at all times. Security was considered acceptable.

The chain of custody process was observed during a walkthrough of the receiving area, assessioning area and analysis laboratories. The samples are brought to the assessioning area in bins from the receiving area. The samples are unpacked onto a table where no other materials or activities are present. The bottles are examined for any shipping damage or other anomalies and are logged and bar coded. Each time a sample is drawn from the original bottle, a peel off bar code is applied from the internal control label on the bottle. The automated analytical results are automatically recorded against the bar code. This eliminates the chance of transcription errors. In the event that the bar code label were applied to the wrong bottle and a positive result on the screening were attributed to the wrong individual, the confirmatory testing would reveal the error unless the same mislabeling error occurred twice; an unlikely event.

Documentation:

Documentation required by 53FR11970 is maintained for a minimum of two years in a file room with access limited by a key card and access code system. Records of specimens under legal challenge are retained indefinitely. The file shelves are open front with the files stored in vertical folders. The room is fully sprinklered and has smoke detection with a central alarm station. The combustibles, aside from the files, are minimal. Additional file locations exist at other Roche facilities, but, were not reviewed as part of this audit.

Standard Requirements:

The audit team examined performance documents to verify that performance testing is part of the continuing assessment of Roche Biomedical Laboratories. Performance testing is done under the NCLP certification maintenance program required by 53FR11970. The laboratory is scheduled to receive 6 challenges per year where samples containing known quantities mixed with samples with no drugs are submitted by a DHHS contractor. The results of this analysis determine whether the laboratory certification is continued or not.

Performance Test Specimen Composition:

The audit team examined performance documentation to verify that performance test specimens contain those drugs and metabolites which the laboratory must be capable of assaying in concentration ranges that allow detection by commonly used techniques. Performance test specimens for the 4th cycle testing dated 8/20/90 were found to be spiked with the following drug classes and their metabolites:

Marijuana - 109 and 17 ng/ml.
Cocaine - 349, 185 and 176 ng/ml.
Opiates - 389 ng/ml.
Amphetamines - 550, 497, 1560, 5000, 218 and 817 ng/ml.
Phencyclidine - 36 ng/ml.

Evaluation of Performance:

The audit team reviewed test results of periodic evaluations administered by a DHHS contractor laboratory. Roche Biomedical Laboratories had completed four cycles of performance testing since obtaining their initial certification at the Burlington, NC facility in December 1989. (The certification was transferred to the Research Triangle Park facility by DHHS in April, 1990.) Reports of their performance were reviewed for the last two cycles. The facility received scores of 93.3% and 100% on screening tests. On the confirmatory testing, Roche received scores of 100% on both cycles. A score of at least 90% is required in order to maintain the certification. Roche successfully analyzed 100% of the total drug challenges within +/- 20%, or 2 standard deviations. Roche did not have any values in the two cycles which differed from the actual level by more than 50% from the reference group mean (i.e. other certified laboratories participating in the ongoing evaluation program.)

Additional Requirements:

A limited review was conducted of Roche analytical procedures to verify that they included the requirements of 53FR11970. The review only include skimming the format to assure that the required topics were addressed. This was because Roche considers the procedures to be proprietary and would not permit them to be reviewed outside of their offices. Therefore, a thorough review could not be performed. However, the analytical procedures did address the required topics, as far as could be determined by the method of review dictated by circumstances.

Of a greater concern than the format of the procedures, was a lack of procedures for checking the accuracy and reproducibility of automatic pipettes. In addition, Roche did not have procedures for checking the critical operating characteristics of analytical balances and there were no procedures for establishing the screening control values for the Olympus 500 Analyzer. These procedures are specifically required in order to be a DHHS certified laboratory. Yet, Roche did not have written procedures in place and they are a DHHS certified laboratory. Refer to Finding 1 of 1. This leads the auditor to conclude that GPUN must be very cautious in relying too heavily upon the DHHS certification process as a guarantee that the laboratory is capable of meeting DHHS requirements. Despite the fact that no written procedures existed for accomplishing the above functions, the activities were being performed in what appeared to be a technically supportable manner. The method was prescribed by forms which were not subjected to a documented review and approval process. Records existed to document that the activity had been conducted.

High Purity drug standards are obtained from commercial suppliers such as Research Triangle Institute (RTI), Altech, USP, and Sigma. Certificates of quality indicating the lot number were available from all of the suppliers except Sigma. These should be requested from the supplier as a matter of course when ordering standards, especially when the supplier does not provide them automatically. Refer to Recommendation 1.

Drug standards are labeled with the dates on which they are received and opened. The Quality Control group prepares stock, intermediate and calibration standards by diluting weighed amounts of the drug to a known volume of solvent. A unique lot number is assigned to each standard and the preparation date is recorded in the GC/MS Standard and Control Book.

Standard solutions are labeled as to the content, concentration preparation date and expiration date.

Calibration standards are dispensed into sample tubes which are refrigerated until needed in the laboratory. The preparation dates and expiration dates are recorded in the GC/MS Standards and Control Book, which serves as the control.

Class A glass volumetric pipettes are used to prepare stock, intermediate and calibration solutions.

A Mettler AE200 analytical balance is used to weigh high purity drugs during the preparation of stock solutions. The balance was last serviced in June 1990 by a vendor. The next service is due in May 1991. The laboratory has a set of National Bureau of Standards (NBS) class S weights to check the accuracy of the balance on a more frequent basis, but, there were no records to indicate that this had been done. A further check showed that there were no written procedures to perform this periodic check. Refer to Finding 1 of 1.

Automatic Eppendorf pipets are checked by gravimetric procedures every calendar quarter. Records indicated that two pipets (10-100 microliter #4710/27773 and 10-100 microliter #27818) had failed the accuracy checks. However, They were still in use by the laboratory for the addition of internal standards to samples. Further review showed that there was no written procedure for verifying the accuracy of automatic pipets or what to do if one failed an accuracy check. Refer to Finding 1 of 1.

Investigation of False Negative Test 5/7/90 (Sample 127-706-0068):

During this audit, the team investigated the circumstances surrounding a false negative drug test reported by Roche Biomedical Laboratories. From interviews with personnel and a review of the records available from the Research Triangle Park, NC facility, the team was able to determine the following facts:

On 4/13/90, Elsoly Laboratory, a contract laboratory for GPUN, prepared a standard batch of urine containing THC, a marijuana derivative. The batch was certified by Elsoly as containing 172 ng/ml.

On 4/16/90, Northwest Toxicology certified the batch as containing 167 ng/ml.

At some time after 4/13/90, Elsoly prepared a sample from the THC batch for GPUN to submit to Roche Biomedical Laboratories as a blind QC check. This was done by the Oyster Creek Medical Department and the blind sample was submitted with a batch of real urine samples using a false name and social security number. The blind sample was indistinguishable from the real samples to Roche Biomedical.

On 5/7/90, Roche Biomedical screened the batch of urine samples from GPUN by EMIT. The chain of custody form identified the QC sample bottle as A303763. The sample prepared from the bottle was assigned an assessioning number of 127-706-0068. Upon analyzing the sample, it was found to contain 90 ng/ml: below the cutoff for THC of 100 ng/ml. Roche had analyzed the sample in a batch which contained a calibration sample every 50 samples. These samples verify the performance and accuracy of the analysis. The last two numbers of the assession number assigned by Roche indicate the sequence of analysis. The calibration samples immediately before and after the QC blind sample were #50 and #100 respectively. The results of the calibration samples were within acceptable tolerances. The QC blind sample submitted by GPUN was #68 in the sequence.

On 5/8/90, the GPUN Medical Review Officer, Dr. Moraldo, telephoned the Roche Laboratory Director, Dr. Flora, and notified him of the false negative result. Dr. Flora agreed to retest the sample using the confirmatory (and more accurate) GC/MS.

On 5/9/90, Roche found the sample to contain 95 ng/ml by GC/MS. This was still below the cutoff of 100 ng/ml. At the same time, Elsoly reanalyzed the original batch still in their possession using GC/MS and found it to contain 142 ng/ml.

On 5/28/90, Elsoly reanalyzed the original batch by GC/MS and found it to contain 205 ng/ml.

Roche Biomedical sent a portion of the QC blind sample to Elsoly Laboratory for analysis and Elsoly Laboratories sent a sample of the original batch to Roche Biomedical. On 6/14/90, Elsoly reported in a letter to Roche Biomedical that the sample was screened at <100 ng/ml and was found to contain 109 ng/ml by GC/MS. On 6/14/90, Roche Biomedical reported in a letter to Elsoly Laboratory that the batch was found to contain 153 ng/ml.

Interviews with Dr. Flora and the current Director of the Roche facility, Dr. Childs, indicated that the loss of concentration from the THC spiked urine sample from the time that Elsoly prepared it until Roche analyzed it might be explained by the fact that THC is not stable under the conditions encountered as part of the normal sample handling process. According to Dr. Childs, THC can precipitate to the bottom of the container. It can become suspended in froth if the sample is shaken too vigorously. It can decompose at room temperature over a period of time. It can plate onto the container, especially when frozen and thawed, as GPUN sometimes does with QC samples.

Based upon the facts outlined above and the interviews conducted, the audit team concluded the following:

1. The QC sample submitted by GPUN spiked with THC decreased in concentration by approximately 77 ng/ml from the original 172ng/ml to 95 ng/ml.

2. Roche Biomedical properly reported the results of the blind QC sample as negative based upon the analytical results.

3. The reliability of the analytical results appears to be high, based upon the results of the calibration samples before and after analyzing the QC blind sample. In addition, consistent results were later obtained by both Roche Biomedical and Elsoly Laboratories using GC/MS.

RECOMMENDATIONS

Quality Assurance does not require a response to these recommendations. However, Corporate policy requires that an internal Division/Department memo documenting your disposition of these recommendations should be written to file.

	RECOMMENDATION	RESPONSIBLE ORGANIZATION
1.	Assure that certificates of quality for drug standards are provided by the supplier by requiring it in the purchase order.	Roche Biomedical
2.	Improve the visibility of the trending of data by proceduralizing the trending program. For example, compare the result of QC blind samples with actual results.	Roche Biomedical
3.	Assure that the last two procedures remaining to be reviewed and signed by the new Director are completed prior to the final date of turnover (9/1/90).	Roche Biomedical

GPU Nuclear	Audit Finding	Audit No.: O-COM-90-16	Date: 08/28/90
		Criteria No.: III	Finding 1 of 1
Facility/Functions: ROCHE BIOMEDICAL LABORATORIES			Page 1 of 1

Requirement: The individual responsible for day to day management is responsible for the laboratory having a procedure manual which is complete. (Section 2.3(a)(5) of 53FR11982). Automatic pipettes shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter. (Section 2.4(n)(3) of 53FR11984,. There shall be written procedures and a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks and instructions for major trouble shooting and repair. There shall be written procedures for actions to be taken when systems are out of acceptable limits or errors detected. (Section 2.4 (n)(4) of 53FR11984)

FINDING: Contrary to the above, there were no procedures for checking accuracy and reproducability of automatic pipettes. In addition, analytical balances do not have approved procedures for checking critical operating characteristics. There are no procedures for determining the screening control values of the Olympus 500 Analyzer. (Note: Two automatic pipettes were found to have failed the manufacturer's tolerences for accuracy during a calibration check and were not removed from service.)

Potentially Reportable: ☐ Yes ☒ No	Severity Level: V	
Cognizant Group/Activity: RESEARCH TRIANGLE PARK, NC	Auditor: DJ Corbett	
ACKNOWLEDGING FINDING — Signature: Keith D. Chitty	Date: 08/28/90	Response Due: 09/27/90
ACTION PARTY CORRECTIVE ACTION	You are requested to respond by memorandum. The following three items are to be included in your response: 1. The CAUSE of the deficiency, including the EXTENT of the problem. 2. The ACTION TAKEN by you to prevent recurrence. 3. The EFFECTIVE DATE of implementation of corrective action. (If time required to implement corrective action exceeds 30 days, you are requested to identify what INTERIM CORRECTIVE ACTION is to be taken to assure that the QA Program is not compromised.)	
	Send response to: R.S. Markowski Manager QA Program Development and Audit	
	~~Send copy of response to: Director of audited organization (GPUN internal audits only):~~	
RESPONSE EVALUATION	Accepted/Rejected:	
	Audit Team Leader Signature:	Date:
CLOSE-OUT	Audit Team Leader Signature:	Date:

N65092 (01-87)

GPU Nuclear

Quality Deficiency Report

RECNO ____
REV ____
DATE ____
RECTYPE 002-01
LOCATION ____
RETENTION PERMANENT

Unit: Oyster Creek

QDR No.: 90-025

1. INITIATION

Initiated by: J. Venet — Dept: Medical Di: — Date/Time: 5/18/90 - 2pm
Responsibility: Roche Labs c/o W. Sienon — Dept: Contracts — Notified Date: 5/18/90 - 2:30pm

REQUIREMENT

10 CFR 26, App. A, Subpart B, Section 2.8(e)(4
The licensee shall investigate, or shall refer to DHHS for investigation any unsatisfactory performance testing result and based on this investigation, the laboratory shall take action to correct the cause of the unsatisfactory performance test result. A record shall be made of the investigative findings and the corrective action taken by the laboratory and that record shall be dated and signed by the individuals responsible for the day-to-day management and operation of the HHS certified laboratory. Then the licensee shall send the document to the NRC as a report of the unsatisfactory performance testing incident within 30 days. The NRC shall ensure notification of the finding to DHHS.

DEFICIENCY

A blind sample sent to Roche Laboratories contained 172 ng/ml of THC(positive). This value was reported on the certificate of analysis by the supplier of the specimen, Elsohly Labs. Roche Labs reported this sample as negative ,i.e. <100 ng/ml.

RECEIVED
JUN - 7 [illegible]

2. EVALUATION AND VALIDATION (IF EVALUATED AS POTENTIALLY REPORTABLE, NOTIFY UNIT MANAGEMENT; NOTIFY AND SEND COPY OF QDR TO LICENSING)

Date/Time Received: 5/18/90 2PM

Potentially Reportable Under:		Yes	No			Yes	No			Yes	No
	10CFR20		X	10CFR50			X	10CFR73			X
	10CFR21		X	10CFR71			X	L.E.R.		X	

Evaluated by: John C Sokalewicz (Name) — QQA Mgr. (Title) — 5/18/90 ~2:30 PM (Date/Time)

Unit Management Notified: N/A (Name) — (Title) — (Date/Time)

Licensing Notified: ☒YES ☐NO JOHN ROGERS (Name) — Licensing Engr. (Title) — 5/18/9 ~ 3:00 PM (Date/Time)

Corrective Action Response Date: 6/5/90 (10 working days or less) Confirmed Action Party: WARREN Simon (Name)

John C Sokalewicz — 5/20/90
QQA Manager — Date

N1209 (02-90)

3. CORRECTIVE ACTION RESPONSE

QDR No.: 90-025

Cause of Deficiency: Specimen A303-762 (RBL accession #127-706-0068) was a blind QC sample targeted to be positive for THC. Our lab reported a negative result (<100ng/ml). After being contacted by Dr. Maraldo, the sample was retested. Again, a negative result was obtained. Review of data showed that both tests gave results near our cut-off. GCMS confirmation gave a quantitative value of 95ng/ml for carboxy-THC, which confirms the screening result of <100ng/ml.

Actions to Correct Deficient Condition(s): None indicated at this time.

Actions to Prevent Recurrence: Dr. Ben Flora, Director of Toxicology RBL Burlington, contacted Dr. Elsohly, the supplier of this QC material, and discussed the possibility of sample deterioration or absorbance by the container during shipment. Dr. Elsohly felt this could be a possibility. There is sufficient sample left to return an aliquot to Dr. Elsohly for assay and to also send an aliquot to our Raritan facility for analysis.

Interim Corrective Action (if applicable): Dr. Elsohly has agreed to send more of the QC pool from which sample A303-762 was extracted, to Dr. Ben Flora for reassay. This will also be assayed at our Raritan Forensic facility and by Dr. Elsohly to either confirm or rule out a deterioration problem. Upon review of our most recent proficiency testing results, there appears to be no problem with our interlaboratory quantitation comparisons for this assay. Results of our follow-up testing with Dr. Elsohly will be forwarded to John Solakiewicz, GPU's QA Manager.

Received 6/22/90 JCS

Target Date for Completion of Corrective Action: June 30, 1990

Approved By: Mary R. Bircsak
Mary R. Bircsak, Q.A. Manager, North Region

Date: 6/1/90

FORWARD TO OQA MANAGER FOR CONCURRENCE

4. QA CONCURRENCE

6/25/90

Concurred: ☒ Yes ☒ No Reason (if No): ☒ JCS — Concurred - Based on the recently completed 11/6/90 audit at Elsohly Laboratories and the [illegible] appears to have adequate procedures and equipment in

Date: 11/16/90

Resolution: A second check and recheck by Elsohly indicate that sample (targeted positive) was found degraded, therefore no deviation existed.

Copy of response reviewed by auditor, Judy Venet - Rejected 30 days, dated 6/25/90 JCS 12/5/90

Date: / /

Concurred by: John Solakiewicz

Date: 12/20/90

5. VERIFICATION/CLOSEOUT

Corrective Action Verified by: Reid Brown

Date: 10/29/90

Verification Method: Audit No. - O-COM-90-16. Based upon the data examined and procedures observed during the audit, the false negative could not be attributed to Roche Labs. See attached Excerpts from the Audit.
Audit No. O-COM-90-13 - False Readings reported by biomedical labs cannot be attributed to blind samples supplied by ELI.
See excerpt from audit report attached.

Closed: [signature] OQA Manager acting

Date: 10/30/90

N1209B (02-90)

C. Council
Rev 10CFR Appendix B 2.8(2)(4)

Date