

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No. 94-02 Associated AR,SR,NCR NO. N/A

PART 1: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

See attached.

Initiated by: Donald W. Dunavant *DD* Date: 4-29-94

PART 2: PROPOSED ACTION Responsible Element Manager: *all-Sage*

a) Root Cause:

b) Corrective Action to Preclude Recurrence:

SEE ATTACHED. Target Date for Completion: _____

Response provided by: _____ Date: _____

PART 3: APPROVAL
Comments/Instructions:

Director of QA: *Shirley Mahabadi* Date: *5/30/94*

PART 4: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION

ON 12/16/94 The final surveillance report on the evaluation and completion of CNWRA Scientific Notebooks was signed (see rpt. 94-12). This concluded work since 6/17/94 related to Scientific Notebooks and included one-on-one training by the CNWRA QA Specialist. Remedial action to correct scientific notebooks was also accomplished.

Verified by: *Shirley Mahabadi* Date: *12/16/94*

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE SURVEILLANCE REPORT

PROJECT NO.: 20-5702-154 REPORT NO.: 94-12 PAGE 1 OF 1

SURVEILLANCE SCOPE: Scientific Notebooks were evaluated for compliance with QAP-001, Revision 2 in response to Corrective Action Request (CAR) 94-02. Due to the close relationship between QAP-001 and QAP-014, compliance to QAP-014, Revision 0 was also evaluated. The requirements of both QAP-001 and QAP-014 were reviewed with appropriate personnel during this evaluation.

REFERENCE DOCUMENTS:

QAP-001, Revision 2, "Scientific Notebook Control"
QAP-014, Revision 0, "Documentation and Verification of Routine Calculations"
Corrective Action Request 94-02

STARTING DATE: November 4, 1994 **ENDING DATE:** December 16, 1994

QA REPRESENTATIVE: R. W. Folck, SwRI Institute QA *Rw Folck*

PERSONS CONDUCTING TEST/EXAM/ACTIVITY:

H. Manaktala, R. Green, K. Meyer, E. Pearcy, N. Sridhar, R. Hofmann, P. Lichtner, R. Janetzke, P. Laplante, B. Hill, C. Connor, D. Dunn, Y. Pan, B. Henderson, R. Bagtzoglou, A. Nedungadi, G. Wittmeyer, S. Mohanty, S. Hsiung, A. Pickens, S. Svedeman.

SATISFACTORY FINDINGS:

A total of ninety-eight (98) scientific notebooks were identified for review. Results of the review is as follows:

- Seventy-seven (77) scientific notebooks were reviewed, corrected as appropriate and now comply with the applicable requirements of QAP-001 and QAP-014.
- Fifteen (15) scientific notebooks were reviewed and found to comply with the applicable requirements of QAP-001 and QAP-014 or, were noted as being empty.
- Four (4) scientific notebooks could not be located and have been dispositioned as lost. The data contained in these notebooks was not used in any CNWRA products. See attachments 2 - 5.
- Two (2) scientific notebooks were removed from controlled status.

UNSATISFACTORY FINDINGS: None

NONCONFORMANCE REPORT NO.: N/A, Refer to CAR 94-02

ATTACHMENTS: #1 CNWRA Notebook Review Summary
 #2 - #5 PI Disposition of Lost Notebooks

RECOMMENDATIONS/ACTIONS:

1. Continue periodic verification activities.
2. Develop plan for the archival of photographs and data sheets referenced in scientific notebooks.
3. Close CAR 94-02

APPROVED: *[Signature]*
 CENTER DIRECTOR OF QUALITY ASSURANCE

DATE: 12/16/94

DISTRIBUTION:

ORIGINAL - CENTER QA DIRECTOR
ORIGINATOR
PRINCIPAL INVESTIGATORS: N/A
ELEMENT MANAGERS: P. Nair, A. Chowdhury, L. McKague, R. Baca, P. Mackin
W. Patrick, B. Sagar (T.D.), A. Cortinas

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CNWRA Notebook Review Summary
November - December, 1994
SR #94-12, Attachment #1
Ref: CAR 94-02
Update: 12/16/94

Notebook No.	Notebook Owner/ User(s)	Date Reviewed	Comment	Date Resolved
048	Aaron DeWispelare	6/23/94	Yes	9/09/94
059	Renner Hofmann	6/15/94	Yes	12/01/94
022	Bill Murphy	6/17/94	Yes	7/12/94
037	"	6/17/94	No	N/A
094	"	6/17/94	Yes	7/12/94
049	"	7/12/94	Yes	7/12/94
095(Elec)	Peter Lichtner	6/23/94	Yes	12/15/94
102	"	LOST	NOT	USED
107	Hengameh Karimi	6/22/94	Empty	N/A
108	"	6/22/94	Empty	N/A
105	Goodluck Ofoegbu	6/21/94	Empty	N/A
089	Miklas/Janetzke/	6/22/94	Yes	12/01/94
096	Dertatevasion	6/22/94	Yes	12/09/94
099	Kathy Spivey	6/22/94	No	N/A
091	Patrick LaPlante	6/23/94	Yes	12/14/94
042	J. Prikryl	8/5/94	Yes	8/5/94
058	Prikryl/Bertetti	7/7/94	Yes	11/02/94
061	Pabalan/Bertetti	7/7/94	Yes	10/14/94
038	"	7/7/94	Yes	10/14/94
081	"	7/7/94	Yes	11/02/94
020	"	7/7/94	Yes	11/02/94
026	"	7/8/94	Yes	10/14/94
37-1	"	7/8/94	Yes	10/14/94
082	"	8/12/94	No	NA
060	"	8/12/94	Yes	10/14/94
015	Paul Bertetti	7/8/94	Yes	10/14/94
031	Leslie/Bertetti	7/8/94	Yes	11/02/94

Notebook No.	Notebook Owner/ User(s)	Date Reviewed	Comment	Date Resolved
035	Leslie/Bertetti	8/15/94	Yes	10/14/94
075	Pearcy/Bertetti	7/8/94	Yes	11/28/94
024	"	7/8/94	Yes	11/02/94
041	"	7/7/94	Yes	10/14/94
021	E. Pearcy	8/15/94	Yes	10/14/94
036	"	8/15/94	Yes	11/02/94
044	Pearcy/Nguyen	8/19/94	Yes	12/08/94
084	Pearcy/Pickette	8/16/94	Yes	11/28/94
050	Pearcy/Pan	8/16/94	Yes	10/14/94
046	D. Turner	7/12/94	Yes	8/16/94
057	"	7/12/94	Yes	9/02/94
056	B. Hill	9/2/94	Yes	12/12/94
088	"	9/2/94	Yes	12/12/94
090	Hill/Luhr	9/29/94	Yes	12/16/94
097	B. Hill	LOST	Not	USED
072	C. Connor	9/2/94	Empty	N/A
073	"	9/2/94	Yes	12/06/94
079	"	LOST	NOT	USED
115(Elec.)	C. Connor	9/2/94	Yes	12/12/94
100	D. Ferrill	7/29/94	Yes	7/29/94
101	"	7/29/94	No	N/A
027	Cragolino/Dunn	7/27/94	Yes	11/28/94
032	"	7/27/94	Yes	12/01/94
029	H. Manaktala	9/9/94	Yes	9/9/94
039	"	9/9/94	Empty	N/A
040	"	10/13/94	Yes	12/09/94
103	Manaktala/Dunn	8/5/94	Yes	12/07/94
025	Sridhar/Dunn	7/27/94	Yes	11/28/94
045	"	7/27/94	Yes	11/28/94
009	"	7/27/94	Yes	12/01/94
085	"	8/5/94	Yes	11/28/94
086	"	8/5/94	Yes	12/01/94
109	Sridhar/Pan	10/24/94	Yes	12/12/94

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Notebook No.	Notebook Owner/ User(s)	Date Reviewed	Comment	Date Resolved
112	Henderson/Stirewolt	9/9/94	Yes	12/02/94
113	Henderson/Ferrill	9/9/94	Yes	12/02/94
114	"	9/9/94	Yes	12/02/94
034	Ferrill	8/5/94	Empty	N/A
051	Ferrill/Morris	12/2/94	Yes	12/02/94
054	"	8/5/94	Yes	12/02/94
033	"	9/1/94	Yes	12/02/94
065	R. Bagtzoglou	9/16/94	Yes	12/09/94
066	"	LOST	NOT	USED
067	"	9/16/94	Yes	12/09/94
068	"	9/29/94	Yes	12/13/94
069	"	9/16/94	Yes	12/09/94
093	Baca/Nedungadi	9/23/94	Yes	12/07/94
076	G. Wittmeyer	9/9/94	Yes	12/09/94
077	"	9/9/94	Yes	12/09/94
074	Mohanty/Pickens(04)	9/16/94	Yes	12/16/94
106	Mohanty	9/29/94	Yes	12/16/94
070	B. Sagar	Remove	Control	N/A
071	"	Remove	Control	N/A
092	Manteufel/Castellaw	8/10/94	No	NA
063	S. Hsiung/ Pickens(04)/Kana(04)	6/21/94	Yes	11/04/94
017	S. Hsiung	9/22/94	No	N/A
018	"	9/22/94	No	N/A
064	Hsiung/Nagy(06)	9/22/94	Yes	9/22/94
111	R. Brient	7/29/94	No	N/A
078	Manteufel/Green	8/12/94	Yes	10/28/94
083	"	8/12/94	Yes	12/07/94
087	"	8/12/94	Yes	10/28/94
028	Green/Svedeman	8/12/94	Yes	12/13/94
052	"	8/10/94	Yes	12/13/94
003	"	8/12/94	Yes	12/13/94

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CNWRA Notebook Review

Notebook No.	Notebook Owner/ User(s)	Date Reviewed	Comment	Date Resolved
023	R. Green	8/12/94	Yes	11/02/94
047	"	8/12/94	Yes	11/28/94
062	"	8/12/94	Yes	12/07/94
098	"	8/12/94	Yes	12/12/94
104	Green/Rice	8/12/94	Yes	11/28/94
110	R. Green	8/12/94	Yes	12/16/94
116	R. Green	8/12/94	Empty	N/A

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

DATE: October 5, 1994
TO: Peter Lichtner
FROM: Alice Cortinas
SUBJECT: Scientific Notebook

Your scientific notebook #102 has apparently been misplaced and cannot be located. I have verified that you were indeed issued scientific notebook #102. If you cannot locate this notebook today, please send me an e-mail note for the record and I will make a note in the Scientific Notebook Log that it was lost and not used. Thankyou for your cooperation.

cc: P. Nair
B. Mabele

Alice:

My recollection is that the notebook in question was too small and so I traded it in for #095 which I do have — but which is ^{being} replaced by a computerized notebook. I do not have #102 in my possession.

Peter

Alice Cortinas 8/19

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CNWRA SR# 94-12
Attachment #3

DATE: October 5, 1994
TO: Chuck Connor
FROM: Alice Cortinas
SUBJECT: Scientific Notebook

Your scientific notebook #79 & #90 has apparently been misplaced and cannot be located. I have verified that you were indeed issued scientific notebook #79 & #90. If you cannot locate this notebook today, please send me an e-mail note for the record and I will make a note in the Scientific Notebook Log that it was lost and not used. Thankyou for your cooperation.

cc: L. McKague
B. Mabrito

As far as I can tell I have been issued notebooks 72, 73, and 115. I have checked w/ students just in case and they were not issued 79 and 90 either. Certainly, no data were entered in #79 or #90 by me.
Chuck Connor

Notebook #90 assigned to Lohr @ the Smithsonian.
R. Zolh 12/16/94

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[26] From: ~~A Sotiropoulos~~ at CNRA 10/4/94 6:52PM (590 bytes: 1 ln) ^{23, 2/16/94}
To: Alice Curtius at CNRA-082
cc: Robert Baca at CNRA-082, Bruce Nabrite at CNRA-082
Subject: SCIENTIFIC NOTEBOOK #66

----- Message Contents -----

Text item 1: Untitled

Alice:

As I have (at least twice in the past) told Randy (the QA auditor), scientific notebook #66 has not been misplaced. Vivek Kapoor was assigned to it and apparently took it with him to California.

As far as I know he had not used it while he was at CNRA. Therefore, for all practical purposes you can consider it as "lost and not used."

Ross

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MEMORANDUM

From: Brittain Hill

December 16, 1994

To: QA

Subject: Scientific Notebook #097

Scientific notebook #097 ostensibly was issued to me in November, 1993, for project 20-5704-142. I have no recollection of this notebook, and believe that a simultaneous request by Chuck Connor for a notebook for work at the Smithsonian Institution (#090) has resulted in this confusion. Notebook 097 has not been used in any capacity for work at the Center or the Smithsonian, and should be considered "lost" and removed from the list of controlled notebooks.

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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

Attachment to CORRECTIVE ACTION REQUEST No. 94-02

Part 1: During the course of the audit, a number of scientific notebooks were reviewed for compliance to CQAM 2.4.1(5) and QAP-001. Notebooks specifically examined were CNWRA #009, 085, 025, 045, 054, 033, 087, 078, 047 and 073. A number of deficiencies were noted. Typical examples of problems noted were:

- corrections not dated or initialed and dated,
- blank pages not lined out,
- computer generated printouts or graphs contained in scientific notebooks without reference to method of generation or location of files,
- backup data and information not included to allow re-creation of data or verification of calibrations or acceptability of data,
- no initial entry sufficient to allow experimental approach to be verified or to document planning of experiments and equipment and personnel requirements.

The notebooks generally contained daily logs of activities and specific test parameters and results but were not put in context or described sufficiently to allow a thorough review of project activities. Discussions with project personnel indicated a lack of complete understanding of intent and/or detail requirements for scientific notebooks.

Note: A surveillance conducted in October 1993 found similar errors in eleven of fourteen notebooks reviewed. The surveillance focused on computer/software related activities. Followup training and corrective action were primarily addressed to these areas and personnel. The results of this audit indicate that additional training and surveillance should be applied to all Center staff. In addition, remedial action to address present notebook status should be considered.

Initiated by: Donald W. Dunavant

Date: 4-29-94

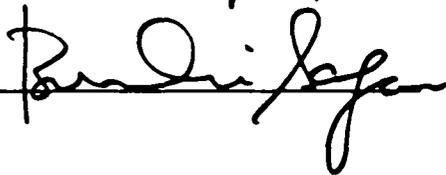
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Attachment to CAR-94-02

a) Root Cause: The CNWRA technical staff have all had experience with laboratory notebooks, but none had experience with applying the specific requirements needed for formal Scientific Notebook control. Although the technical staff have had training for QAP-001, the training was limited, and many of the staff's old habits continued. The training has not been sufficient to overcome these habits.

b) Corrective Action to Preclude Recurrence: For remedial action, Principal Investigators (P.I.s) shall be instructed by their respective Element Managers to bring their active Scientific notebooks for review for compliance with QAP-001 by QA staff. Nonconforming entries shall be identified to the Principal Investigator for correction. For corrective action to preclude recurrence, while identifying nonconforming entries, the QA staff will review with the P.I. the Scientific Notebook requirements as they pertain to the specific scope of work. QA staff shall also reinforce the need for QA reviews of initial entries and consultation during the early stages of a new activity (new experiment, field activity, or new phase of analysis or code development). In addition, a long range surveillance plan shall be developed with the objective of reviewing each active Scientific Notebook twice yearly.

Target date for completion: 7/29/94

Proposed by: 

Date: 5/30/94

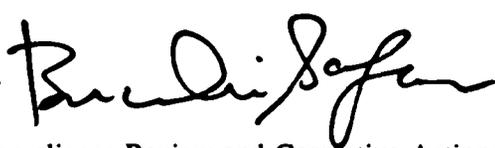
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CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

MEMORANDUM

June 2, 1994

TO: CNWRA Element Managers

FROM: Budhi Sagar, Technical Director 

SUBJECT: CNWRA Scientific Notebook Compliance Review and Corrective Actions

REFERENCE: Quality Assurance Procedure (QAP)-001,
Scientific Notebook Control, and
Corrective Action Request 94-02

A sample of Scientific Notebooks were reviewed for compliance with QAP-001 during the recent CNWRA Internal QA audit, and a number of deficiencies were noted which led to Corrective Action Request (CAR) 94-02. In response to the CAR, the CNWRA has committed to have the Principal Investigators review their Scientific Notebooks with QA Staff for compliance with the procedure and correction. This effort should also reinforce the Scientific Notebook requirements and the benefits of consultation with QA staff during the initial stages of a project activity to assure compliance with all applicable requirements.

The CNWRA Scientific Notebooks are listed according to Element, P.I., and notebook number on the pages attached to this memorandum.

Please have each of your P.I.s contact either Bob Brient (ext. 5537) or Bruce Mabrito (ext. 5149) to schedule compliance review sessions. This corrective action is targeted for completion (meaning all corrections will be made) by 7/29/94. Compliance review schedules should be set up by June 15, 1994.

BEM/fm
attachment

cc: W. Patrick
Directors
R. Brient

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CNWRA SCIENTIFIC NOTEBOOKS

<u>Element</u>	<u>Name</u>	<u>Notebook Nos</u>
EBS	P. Lichtner	095, 102
EBS	G. Cragnolino	027, 032
EBS	H. Manaktala	028, 039, 040, 103
EBS	N. Sridhar	025, 045, 085, 086, 109
GS	B. Murphy	022, 037, 049, 094
GS	B. Hill	056, 088, 097
GS	C. Connor	072, 073, 079, 090
GS	B. Leslie	031, 035
GS	D. Ferrill	100, 101
GS	R. Hofmann/J. Menchaca	059
GS	E. Percy	021, 024, 036, 041, 044, 075, 084
GS	E. Percy/Y. Pan	050
GS	J. Prikryl	042, 058
GS	S. Young/K. Spivey	099
GS	B. Pabalan	020, 026, 037-1, 060, 061, 081, 082
GS	B. Henderson/S. Young/G. Wittmeyer	112, 113, 114
GS	D. Turner	046, 057
GS	S. Young	033, 051, 054
PA	R. Bagtzoglou	065, 066, 067, 068, 069
PA	R. Green	023, 028, 047, 062, 098, 104, 110
PA	R. Baca/A. Nedungadi	093
PA	G. Wittmeyer	076, 077
PA	S. Mohanty	106
PA	R. Janetzke	074, 089, 096
PA	B. Sagar	070, 071

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CNWRA SCIENTIFIC NOTEBOOKS

<u>Element</u>	<u>Name</u>	<u>Notebook Nos</u>
PA	R. Manteufel	078, 083, 087, 092
RDCO	G. Ofoegbu/S. Hsiung	105
RDCO	H. Karimi	107, 108
RDCO	S. Hsiung	017, 018, 063, 064
SSI	M. Miklas/P. LaPlante	091
WSE&I	B. Brient	111
WSE&I	A. Dewispelare	048

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

16/19

DATE: July 28, 1994

TO: CAR 94-02 File

FROM: *for* Bruce Mabrito, Director QA *Mabrito*

In order to complete reviews of scientific notebooks, the due date for corrective action completion is extended to August 31, 1994. This extension is necessitated by the limited availability of SwRI QA personnel to conduct the reviews.

cc: CNWRA Directors/Element Managers

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

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MEMORANDUM

August 31, 1994

TO: Corrective Action Request Folder

FROM: Bruce Mabrito, Director of Quality Assurance 

SUBJECT: Extension of Time Required to Complete CAR No. 94-02

REFERENCE: CAR No. 94-02, Scientific Notebook Entries Did Not Comply Fully with QAP-001 Requirements

Due to the length of time it is taking for the complete review and correction of the CNWRA Scientific Notebooks, plus the parallel training of the Scientific Notebook users, the time to complete this Corrective Action Request is hereby extended to October 14, 1994.

Progress in this corrective action process has been consistent, monitored, and it is simply taking more time for the thorough review and training of each Scientific Notebook user than originally planned. One benefit has been that lessons learned from this corrective action process have been utilized to input to Revision 2 of the Quality Assurance Procedure-001, Scientific Notebook Control.

If there are questions about this action, please contact me at ext. 5149.

cc: CNWRA Directors
Element Managers
R. Brient

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

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MEMORANDUM

October 14, 1994

TO: CNWRA Corrective Action Request File 94-02
FROM: Bruce Mabrito, Director of Quality Assurance 
SUBJECT: Scientific Notebook Surveillance, Progress on Corrective Action, and Extension of Due Date

The purpose of this memorandum is to provide status on the corrective action process to CAR No. 94-02 and provide a new date for closure of the CAR.

As of this date, a total of 90 CNWRA Scientific Notebooks (SN) have been reviewed by the Quality Assurance Specialist. One SN is yet to be reviewed because it was at first determined to be "lost" and then the Principal Investigator realized that a university consultant had the SN. That one SN is scheduled to be reviewed the week of 10/16/94.

A total of 74 SNs had comments by the QA Specialist as needing corrective action to fully comply with QAP-001, the Scientific Notebook Control procedure. Twenty (20) of those SNs have been corrected by the PI or responsible person and have been verified by the QA Specialist and have been so noted. Fifty-four (54) SNs are currently in the process of being corrected by the PI or responsible person, after which they will be verified by the QA Specialist.

During the process of the QA surveillance, a number of SNs (up to four) were not readily available for inspection and the QA Specialist determined them "lost." Follow up action resulted in either locating the SNs or determining that they were never utilized or received by the PI.

Due to the time needed to perform the comprehensive surveillance and the related corrective action, the target date for completing this corrective action response is now November 11, 1994.

If you have any questions, please contact me at ext. 5149.

cc: W. Patrick
Directors
Element Managers
R. Brient
R. Folck/cc30

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

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MEMORANDUM

November 11, 1994

TO: CNWRA Corrective Action Request File 94-02
FROM: Bruce Mabrito, Director of Quality Assurance 
SUBJECT: Scientific Notebook Surveillance, Progress on Corrective Action, and Extension of Due Date

The purpose of this memorandum is to provide status on the corrective action process to CAR No. 94-02 and provide a new date for closure of the CAR.

As of this date, all issued CNWRA Scientific Notebooks (SNs) have been reviewed by the Quality Assurance Specialist and approximately 50-percent of them have been rechecked after corrections have been made and signed off by QA.

As part of the continuing QA surveillance process, all CNWRA SNs have been either located or the PI has ascertained and attested that no quality affecting or important-to-licensing data has been discarded or lost. Follow up action was instrumental in locating all SNs and also in determining that no critical data was lost or compromised. In the process of this surveillance activity, PIs are being reminded that they are responsible for the maintenance and upkeep of the CNWRA SNs, even though they may have other qualified individuals actually making entries in the SNs.

Due to internal auditing and out-of-state travel by the QA Specialist being utilized in this corrective action, plus the November holidays, the time needed to complete this comprehensive surveillance and the related actions is hereby extended to December 16, 1994. Based on the work to date and the methods being utilized to correct the identified deficiency, approximately 75-percent of the effort has been completed as of this date. Clear progress is being made, however it is taking more time than originally anticipated.

If you have any questions, please contact me at ext. 5149.

cc: W. Patrick
Directors
Element Managers
R. Brient
R. Folck/cc30