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U.S. DEPARTMENT OF ENERGY

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

OFFICE OF QUALITY ASSURANCE

AUDIT REPORT OF

MOBILE INSTRUMENTATION DATA ACQUISITION SYSTEM (MIDAS)

SANDIA NATIONAL LABORATORY (SNL), ALBUQUERQUE, NEW MEXICO

AUDIT NO. HQ-94-01-M

NOVEMBER 8-12, 1993

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102.7

MOBILE INSTRUMENTATION DATA ACQUISITION SYSTEM (MIDAS) ACTIVITIES

1.0 EXECUTIVE SUMMARY

This part of Quality Assurance Audit HQ-94-01 was performed to support General Atomics (GA) for the purpose of reviewing activities of the SNL MIDAS QA Program and identifying any deficiencies that may need to be corrected. This would facilitate the process of supplier qualification if and when it is required. The audit team attempted to verify compliance with the requirements of ASME NQA-1 (including all supplements) 1989 edition and the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements Document (QARD) RW-214, Revision 3 to the degree applicable. As a result, the audit team determined that SNL is ineffective in implementing its QA program in accordance with the MIDAS Quality Assurance Program Plan (QAPP) and the associated implementing procedures for QA Program Elements 1 through 19 (excluding Element 9).

The audit team concluded that the implementation of QA Element 2, *QA Program*, was unsatisfactory.

The audit team identified ten deficiencies. Four of these deficiencies, requiring only remedial actions, were corrected during the course of the audit. The balance of the deficiencies are presented relating directly to the applicable QA Program Element and are in the Corrective Action Reports (CARs) depicted in Attachment 4 of this report.

The audit team found that SNL demonstrated good practices in working as a team; resolving of identified deficiencies; and implementing software QA verification activities.

2.0 SCOPE

The audit team evaluated the SNL MIDAS QA Program as described in the MIDAS QAPP and the MIDAS Instructions for adequacy, and implementation. The QA Program for MIDAS is detailed in three QA Plans: the MIDAS QA Program Plan (QAPP), the Transportation System Development Department (TSDD) QAPP, and the Mobile and Remote Ranges Division (MRRD) QAPP. The MIDAS QAPP invokes the TSDD and MRRD QAPPs in paragraphs 1.2 and 3.2 for usage on the MIDAS Program. Similarly, the implementation documents (i.e., procedures and instructions) are presented in different formats and through different mediums. For example, the MIDAS QAPP ties into MIDAS Instructions, but the invoking of the TSDD QAPP mandates the usage of Quality Assurance Procedures (QAP), Sandia Laboratories Instructions (SLIs) and Engineering Procedures (EPs).

2.1 QA Program Elements

The QA program elements evaluated during the audit are in accordance with the published audit plan and are as follows:

1.0 - Organization
2.0 - Quality Assurance Program
3.0 - Design Control
4.0 - Procurement Document Control
5.0 - Instructions. Procedures. Plans. and Drawings
6.0 - Document Control
7.0 - Control of Purchased Items and Services
8.0 - Identification and Control of Items
10.0 - Inspection
11.0 - Test Control
12.0 - Control of Measuring and Test Equipment
13.0 - Handling, Storage, and Shipping
14.0 - Inspection. Test. and Operating Status
15.0 - Control of Nonconforming Items
16.0 - Corrective Action
17.0 - Quality Assurance Records
18.0 - Audits
19.0 - Computer Software

Requirements were drawn from NQA-1. the QARD. the MIDAS QAPP. The MIDAS Program Document. and the MIDAS instructions/procedures. as was appropriate.

2.2 Technical Activities

The utilization of a Technical Specialist was not required. The scope of this audit did not include technical activities.

3.0 AUDIT TEAM AND OBSERVERS

The following is a list of audit team members (with their assigned area of responsibility) and observers that were involved with the audit of MIDAS:

Title	Name	Organization	QA Program Element/Requirement
Audit Team Leader	Tom Swift	QATSS/HQAD	ALL
Audit Team Mgr	Bob Clark	HQAD	N/A
Auditor	Richard Peck	QATSS/HQAD	1-19 (Except 9)
Observer	Dennis Reid	NRC	N/A
Observer	Susan Zimmerman	State of NV	N/A

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The pre audit conference was held at SNL offices in Albuquerque. New Mexico on November 8, 1993. The audit team met daily to discuss audit activities. Daily debriefings were held with SNL management and the appropriate staff. The post audit meeting was held at SNL offices on November 12, 1993.

Personnel contacted during the audit for MIDAS are listed in Attachment 1. The list also indicates personnel who attended the pre audit and post audit meetings.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that in general the implementation of the QA program is ineffective. If adequate and timely corrective action is implemented in the deficient areas, then an 'effective' level can be achieved.

Eight QA Program Elements were determined to be implemented in a satisfactory manner. Three QA elements were determined to be marginal and seven were determined to be unsatisfactory. Although the Audit Plan indicated Element 9 (Control of Processes) as applicable, it was determined to be not applicable during the audit and therefore was not reviewed.

5.2 Stop Work or Immediate Corrective Actions or Additional Actions

No Stop Work Orders nor any immediate corrective actions were necessary during the audit.

5.3 QA Program Audit Activities

Details of the QA Program audit activities are provided in Attachment 2. A list of objective evidence reviewed during the audit is provided in Attachment 3.

5.4 Technical Activities

The scope of this audit did not include technical activities.

5.5 Summary of Deficiencies

The audit team identified ten deficiencies during the audit; four of these were corrected by SNL during the audit. A synopsis of identified deficiencies and those corrected during the audit are detailed below. The CARs are enclosed in Attachment 4.

5.5.1 Deficiencies

a) QA Program

The MIDAS QAPP, paragraph 3.2 currently references and invokes the Transportation System Development Department (TSDD) and Mobile and Remote Ranges Division (MRRD) QAPPs as mandatory for the MIDAS program.

It has been determined that neither the TSDD or MRRD QAPP meets the requirements of NQA-1 nor the QARD. Furthermore, the MIDAS QAPP alone does not meet NQA-1 nor the QARD. See CAR HQ-94-105-M.

b) QA Program (Training)

MIDAS QAPP, paragraph 3.2 requires that the QA Coordinator provide training covering the TSDD and MRRD QAPPs.

Contrary to the above requirement, the training was never provided by the QA Coordinator. See CAR HQ-94-105-M.

c) Design Control

MIDAS QAPP, paragraph 3.3 requires that drawings and changes be properly approved and controlled.

Contrary to the above, the actual as-built condition is reflected in a combination of drawings and Procedure Change Reports (PCRs) generated to supplement MIDAS procedures. The PCRs are not related to the drawings by any reference. See CAR HQ-94-101-M.

d) Inspection

NQA-1 and the QARD require that Quality Control (QC) inspection personnel be qualified. certified and independent from the work activities.

Contrary to the above requirements. there is no evidence that an independent QC inspection program has been developed for MIDAS for receiving, installation and test activities. It should be noted that a form of peer verification does occur in MIDAS installations and testing by trailer personnel. Also. for field experiments the QA Coordinator has delegated responsibility to technical personnel to perform the verification function. These personnel are technical personnel and not qualified and certified QC personnel. See CAR HQ-94-102-M.

e) Records

NQA-1 and the QARD require that QA records be maintained in an approved facility or fire proof cabinets or by duplicate file.

Contrary to the above requirements. no duplicate file exists for the calibration records for MIDAS at the Calibration Facility. Additionally, 30% of the remaining MIDAS records in the Records Library must still be duplicated. It should be noted that the MIDAS Program has chosen duplicate filing as the methodology for records storage. and the MIDAS Program Manager is actively moving to duplicate records outside of the Calibration Facility records.

The QARD requires that QA records be in a legible condition.

Contrary to the above requirement. it was found that the documentation for the calibration of four pieces of equipment from the MIDAS trailer was totally prepared using pencil. This documentation was the data taken during the calibration process and compared with the NIST standards to assure proper calibration within the appropriate parameters. Numerous erasure and cross-outs were present on the worksheets. The audit team has determined that although this practice is not specifically prohibited. it is not recommended when no duplicate file exists or the penciled documents have been photocopied for

establishment of original document purposes. See CAR HQ-94-104-M.

f) Audits

MIDAS QAPP. paragraph 3.18 requires that "planned and scheduled audits be performed to verify compliance with all aspects of the project Quality Assurance Program." Additionally, the QAPP requires that "these audits be performed by the Quality Assurance Coordinator in accordance with written procedures or checklists."

Contrary to the above requirements. there is no objective evidence to substantiate that the QA Coordinator planned. scheduled. or performed audits. Additionally, there is no evidence that surveillances were performed. See CAR HQ-94-103-M.

5.5.2 Deficiencies Corrected During the Audit

Deficiencies which are considered isolated or minor in nature and only require remedial action can be corrected during the audit. The following deficiencies were identified and corrected during the audit:

a) Training

MIDAS-14. paragraph 2.1 requires that the Program Manager assure that operators receive the required training prior to operating MIDAS.

Contrary to the above requirement. training was not completed for almost a two year period. Additionally, the documentation generated did not identify specifically the date the reading was conducted or when the capability demonstration took place. The documentation was a total tabulation with a final date sign-off only.

The Program Manager had already taken action by getting the required training completed by 4/15/92. The Program Manager has also developed new forms for the purpose of documenting reading assignments and capability demonstrations that indicate when the training was actually conducted. If effectively

implemented. these actions should prevent recurrence of this condition.

b) Training

MIDAS-14. paragraph 2.3 requires that the QA Coordinator review training procedures. provide approval of trainers. submit training requests. and provide guidance on training activities affecting quality.

Contrary to the above requirements. except for the review of the Training Procedure (MIDAS-14). the QA Coordinator has not participated in the training process for MIDAS personnel.

During the audit. the Program Manager revised the procedure deleting the requirement. The QA Coordinator can effectively monitor the training process through audits and surveillances.

c) Document Control

The MIDAS QAPP. paragraph 3.3 requires that MIDAS drawings be approved by Project and Quality Assurance personnel and then released to the SNL drawing system. Contrary to the above requirements. the QA Coordinator has not approved the MIDAS drawings. The Program Manager revised the MIDAS QAPP during the audit. deleting the requirement for the QA Coordinator to approve drawings.

Additionally, it was found that the Drawing List. maintained by the SNL Document Control group, contained erroneous drawing numbers. This list is utilized by users to confirm the latest drawing and to request copies of drawings. The audit team had requested that four drawings be retrieved from the Document Control Center (DCC). The Drawing List was used as the controlling document for requesting the drawings. The response to the request from the DCC indicated that one of the four drawings did not exist. Further research found that the drawing number as indicated on the list was incorrect (i.e.. R11201-000 instead of CK-R11201-000). An immediate review by the MIDAS Program Manager indicated other errors. all dealing with the absence of the two letter prefix. The List was immediately

reviewed. corrected and re-issued by the MIDAS Team and the DCC during the audit.

The remedial action taken should be effective in controlling the condition if the Drawing List is reviewed periodically by the DCC. SNL Management provided enough commitments and attention during the audit to provide the audit team with the confidence that recurrence control would be assured.

d) Software QA Program

The MIDAS Software Quality Assurance Plan (SQAP). para. 2.3. requires that the QA Coordinator verify the implementation of all aspects of the Software QA Plan. Contrary to the above requirement. there is no objective evidence available to substantiate that the QA Coordinator has verified implementation of all aspects of the SQAP.

The Program Manager generated a procedure change to the SQAP requiring the QA Coordinator to verify that the documentation has been completed which the QA Coordinator had actually been doing. Other activities can be covered through the normal audit/surveillance process. This remedial action suffices for correction of the condition.

6.0 RECOMMENDATIONS

The following recommendations are offered by the audit team. They do not reflect deficiencies and are intended to provide SNL management with possible opportunities for improving QA program implementation.

6.1 The use of multiple QA Programs and implementing documents that must meet the requirements of NQA-1 and the QARD lead to user confusion. inhibits proper maintenance and up-dating, and generally is impractical from the implementation stand point. It is recommended that SNL develop and implement one QA Program and utilize the appropriate procedures and instructions directly linked to that QAPP. This will enable the users of the Program to focus on the basic requirements easily and hopefully avoid implementation errors.

6.2 During the audit it was noted that some specific errors were present in the certification of Level II Non Destructive Examination (NDE) personnel for Helium Leak Rate Detection. It appeared that minimal requirements in the areas of experience and training were not satisfied. This area was determined to be outside the scope of the audit. but it is still recommended as an area that SNL should review in order to assure that all NDE personnel are properly qualified and certified.

6.3 The audit team recommends that the QA organization provide a more pro-active support of MIDAS activities. A QA Coordinator should be assigned to the Project and perform only QA activities.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit
Attachment 2: Audit Details
Attachment 3: List of Objective Evidence Reviewed During the Audit
Attachment 4: CARs

ATTACHMENT 1

Personnel Contacted During the Audit

NAME	ORGAN.	TITLE	PRE	CONTACT	POST
M. Arviso	SNL	Senior Technical Associate		X	
D. Baehr	SNL	QA Coordinator	X	X	X
P. Bennett	SNL	Senior Tech. Staff	X		
M. Brady	SNL	Dept. Manager (Acting)	X		X
R. Clark	DOE	Director. HQAD	X	X	
W. Coutier	QATSS	Audit Team Member	X		X
H. Dameron	M&O	Audit Team Member	X	X	X
M. Hankinson	SNL	Programmer Analyst		X	
W. Lake	DOE	Mechanical Engineer	X		
W. Leisher	SNL	Senior Tech. Staff	X	X	X
B. Luna	SNL	Program Manager	X	X	X
P. Malone	SNL	Programmer Analyst		X	
P. McConnell	SNL	Task Manager	X		X
K. McFall	QATSS	Audit Team Member	X	X	X
D. Miles	SNL	QA Coordinator		X	
T. Mills	SNL	Admin. Program Manager	X	X	X
R. Peck	QATSS	Audit Team Member	X	X	X
H. Pike	SNL	Cal Lab/Project Leader		X	
P. Reardon	SNL	Consultant	X		
D. Reid	NRC	Audit Team Observer	X	X	X
P. Sanchez	SNL	Senior Clerk/Warehouse		X	
T. Sanders	SNL	Program Manager	X		X
K. Seager	SNL	Program Manager	X		X
T. Swift	QATSS	Audit Team Leader	X	X	X
J. Thornton	SNL	Audit Team Member	X		X
W. Uncapher	SNL	Program Manager	X	X	X
J. Woodard	SNL	Program Director		X	X
S. Zimmerman	State of Nevada	Audit Team Observer		X	

ATTACHMENT 2

Audit Details

The following is a summary of the QA Program activities covered during the audit. A list of objective evidence reviewed by program element is given in Attachment 3.

1.0 ORGANIZATION

The audit team reviewed the SNL MIDAS organizational interfaces and responsibilities. The organization identified in the MIDAS QAPP and the MIDAS Program Document is current except for the use of MIDAS personnel individual names and the fact that some of the personnel identified are no longer on the MIDAS Program. The responsibilities identified for the Program Manager, System Coordinator, and operators are adequate and are being fulfilled.

Implementation of QA Program Element 1 was determined to be satisfactory.

2.0 QUALITY ASSURANCE PROGRAM

The QA Program for MIDAS is detailed in three QA Plans: the MIDAS QA Program Plan (QAPP), the Transportation System Development Department (TSDD) QAPP, and the Mobile and Remote Ranges Division (MRRD) QAPP. The MIDAS QAPP invokes the TSDD and MRRD QAPPs in paragraphs 1.2 and 3.2 for usage on the MIDAS Program. Similarly, the implementation documents (i.e., procedures and instructions) are presented in different formats and through different mediums. For example, the MIDAS QAPP ties into MIDAS Instructions, but the invoking of the TSDD QAPP mandates the usage of Quality Assurance Procedures (QAP), Sandia Laboratories Instructions (SLIs) and Engineering Procedures (EPs). Regardless, it was determined by the audit team that these existing Programs do not comply with NQA-1 and the QARD. See Section 5.5.1(b) and CAR HQ-94-105-M for the deficiencies.

SNL Management should consider that the use of multiple QA Programs and implementing documents that must meet the requirements of NQA-1 and the QARD may lead to user confusion. See Recommendation 6.1 of this report.

The audit team reviewed the area of training for MIDAS personnel which is detailed in MIDAS instruction #14. Three deficiencies were discovered two of these were corrected during the audit. See Sections 5.5.1(b) and 5.5.2(a) of this audit report for details and CAR HQ-94-105-M.

Implementation of QA Program Element 2 was determined to be unsatisfactory.

ATTACHMENT 2

Audit Details

3.0 DESIGN CONTROL

QA Program Element 3 was reviewed because it was committed to in the MIDAS QAPP and the associated documents. The design of MIDAS was established by the SNL MIDAS Project Team. This design is detailed in the drawings developed, the MIDAS Procedures, and the Procedure Change Requests (PCR) relevant to MIDAS. The MIDAS Drawings had all of the necessary reviews and approvals preceding their issuance for usage. However, during the review of the design control process, it was discovered that the design had been modified utilizing the PCRs. It appeared that 4 PCRs had been generated, approved and issued at the time of the audit. The PCRs do not receive the same level of review and approval (i.e., no design verification) and are not linked to the MIDAS Drawings by any reference or system. As a result, it was determined that the MIDAS Drawings did not reflect an accurate as-built configuration and that the process for reviewing, approving and controlling changes to the design is flawed. See deficiency 5.5.1(c) of this report and CAR HQ-94-101-M.

Implementation of QA Program Element 3 was determined to be unsatisfactory.

4.0 PROCUREMENT DOCUMENT CONTROL

The audit team reviewed purchase orders for Ectron, Tektronics, Dynamics and a Personnel Contract. The purchase orders addressed the necessary technical requirements such as drawings, specifications, and QA requirements. The purchase orders were properly approved.

All items purchased for the MIDAS Program appear to be "commercial grade off-the-shelf" components. Exception to various supplier oriented requirements is documented within the MIDAS QAPP.

Implementation of QA Program Element 4 was determined to be satisfactory.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

The audit team verified that instructions, procedures and drawings were available to personnel performing activities affecting quality. The MIDAS QAPP, Program Document, Instructions, and drawings were verified to be properly prepared, approved, and distributed. Complete historical files and documentation were available in the Records Library.

Implementation of QA Program Element 5 was determined to be satisfactory.

ATTACHMENT 2

Audit Details

6.0 DOCUMENT CONTROL

The audit team verified the adequacy of the document review and control process by evaluating the comment/resolution cycle for MIDAS Instructions, the MIDAS Drawing list, distribution lists, and the related records packages. The Quality Assurance Records Library maintains all records except for the control of MIDAS drawings which are maintained by the SNL Document Control Center. The use of document control numbers, lists and stamps adequately control the issue of QA program documents.

One problem area was discovered and corrected during the audit that dealt with errors contained on the Drawing List. See Deficiencies Corrected During the Audit Section 5.5.2(C) of this report.

Implementation of QA Program Element 6 was determined to be satisfactory.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

The audit team reviewed the records of two primary suppliers (Hewlett-Packard and Ectron) and two minor suppliers (Tektronics and Dynamics). The Purchase Orders were available and the appropriate application of quality had been applied as delineated by the MIDAS QAPP and the MIDAS Instructions.

The audit team attempted to review the receiving inspection program and found that the only inspection performed was for damage. No review of accompanying paperwork had been performed. The damage inspection was performed by warehouse personnel and only documented if damage was found. Item damage is documented on a Disposition Report for Carrier Damage Material (DRCDM). The item is appropriately segregated to await disposition by the MIDAS Project Team. No other documentation was available to substantiate the receiving inspection of the items. Some level of assurance is gained by the fact that the MIDAS Project tests all components in place and any found to not function properly are removed and returned to the vendor. Regardless, some apparent weaknesses exist because of the lack of formalized receiving inspection, the coinciding reviews of documentation, and the overall documentation of the process. See deficiency Section 5.5.1(d) of this audit report and CAR HQ-94-102-M.

Implementation of QA Program Element 7 was determined to be marginal.

ATTACHMENT 2

Audit Details

8.0 IDENTIFICATION AND CONTROL OF ITEMS

The audit team reviewed the hardware directly associated with the composition of the MIDAS trailer. Universal sources, waveform recorders, thermocouples and network analyzers were the items reviewed for identification, storage, keeping and tracking. The SNL Controlled Property List was presented as the Equipment List that effectively tracked all MIDAS Equipment.

Implementation of QA Program Element 8 was determined to be satisfactory.

9.0 CONTROL OF SPECIAL PROCESSES

This QA Program Element was not reviewed by the audit team because GA will be performing all NDE activities and welding is not applicable. However, during review of Element 10 activities it was noted by the audit team that an apparent problem in the qualification/certification of NDE personnel existed. See the recommendation in section 6.2 for further details. Action is being taken by SNL Management to address this issue.

10.0 INSPECTION

The audit team was unable to find any evidence of an independent Quality Control inspection program. Inspection exists only in the form of those performed by peers, with the peers being from the same group that performed the installation. Field testing and MIDAS trailer installations were both reviewed in an attempt to find out the breadth of the problem. It was determined that the field testing activities were only different in their inspection methodologies by the fact that the QA Coordinator had delegated his verification responsibilities to technical personnel via memorandum. See section 5.5.1(d) for additional details and CAR HQ-94-102-M.

Implementation of QA Program Element 10 was determined to be unsatisfactory.

11.0 TEST CONTROL

The audit team verified test activities concerning the MIDAS trailer installations and field testing activities. Test activities concerning the installed components in the MIDAS trailer are controlled utilizing test procedures and checklists to sign off each aspect of the system test. Field activities are tests that also utilize procedures and checklists, but are strictly data acquisition scenarios utilizing the MIDAS trailer. Regardless, as limited as it is, it appears that control of tests is adequate.

Implementation of QA Program Element 11 was determined to be satisfactory.

ATTACHMENT 2

Audit Details

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT (M&TE)

The audit team evaluated the M&TE lab for the adequacy of M&TE calibration controls. M&TE due for calibration is recalled to the lab and calibrated using traceable standards and qualified personnel under controlled conditions. Calibration stickers are used to identify equipment calibration status and dates. Data is recorded and maintained in a manual records system with no "backup" files. Recall and calibration of equipment was verified to be completed in a timely manner. The audit team reviewed five pieces of equipment to verify calibration, type, and the adequacy of the calibration. Inconsistencies were found in the area of records which are discussed in section 5.5.2 and Element 17 of this attachment.

Implementation of QA Program Element 12 was determined to be satisfactory.

13.0 HANDLING, STORAGE, AND SHIPPING

The audit team was unable to determine the scope of receipt inspection (see Element 7 discussion) and the documentation available. The audit team visited the warehouse. All MIDAS equipment is "off the shelf" and boxed in standard protective packaging with the required desiccant. All MIDAS equipment is immediately shipped to the MIDAS trailer and then kept in a controlled environment. Regardless, there is no receiving inspection function or other inspection function that documents this entire process.

Implementation of QA Program Element 13 was determined to be satisfactory.

14.0 INSPECTION, TEST, AND OPERATING STATUS

The audit team verified that inspection plans (non-peer), travelers, and tags are not utilized by the MIDAS Program to track the relevant processes. The use of tags is not being implemented. Appropriate inspection or status stamps are not used. Essentially, the requirements of NQA-1 are not detailed in the SNL documents and therefore not implemented. For corrective action purposes this Element will be tied to the corrective actions under Element 10.

Implementation of QA Program Element 14 was determined to be unsatisfactory.

ATTACHMENT 2

Audit Details

15.0 CONTROL OF NONCONFORMING ITEMS

The audit team reviewed four "Deviation from Requirements/Return of Warranted Material Reports" (DFR/RWMR). This document has primarily been used by the MIDAS Team to return equipment that has failed in the testing process or did not function properly. All DFR/RWMRs reviewed appeared to be properly dispositioned and controlled. however, because there is no status control. a potential for problems exists. Further discussion concerning corrective action is contained in Element 16.

Implementation of QA Program Element 15 was determined to be satisfactory.

16.0 CORRECTIVE ACTION

The audit team could not confirm if a corrective action program has been implemented for the MIDAS Program. Outside of the deficiency documents discussed in Elements 7 and 15, no corrective action documents could be produced. This is probably a result of the lack of activity in the audit/surveillance area by SNL QA.

Evidence was exhibited to the audit team of long standing deficiencies that would not have been documented if they were not discovered during the course of this audit. Specific examples exist in the area of records. inspections. QA program. and audits.

Implementation of QA Program Element 16 was determined to be unsatisfactory.

17.0 QUALITY ASSURANCE RECORDS

Records packages have been developed for MIDAS in the Records Library and at the Calibration Lab. See Section 5.5.1(e) of this report and CAR HQ-94-104-M.

Implementation of QA Program Element 17 was determined to be unsatisfactory.

18.0 AUDITS

The audit team was unable to verify the audit process. The SNL QA Coordinator never developed an audit schedule nor were any internal audits performed relating to the MIDAS Program. The audit team did review two audit reports that were presented by SNL during the audit. Both of these audits were conducted by organizations external to SNL. The first audit reviewed was conducted by DOE Albuquerque (July 27-31. 1992). It touched upon the MIDAS Program by pointing out that the Software QA Program was not being fully implemented. This appears to be the only aspect of

ATTACHMENT 2

Audit Details

the MIDAS Program that was covered. The second audit was conducted by Knolls as a qualification (limited scope) audit of MIDAS in the area of the testing of tubular products. This audit was conducted on March 10. 1993. The audit team determined that neither of the audits met the specific criteria contained in the MIDAS QAPP (para. 3.18) concerning the planning and scheduling of audits by the QA Coordinator. See Section 5.5.1(f) of this report and CAR HQ-94-103-M.

Implementation of QA Program Element 18 was determined to be unsatisfactory.

19.0 COMPUTER SOFTWARE

The audit team reviewed the requirements as detailed in the MIDAS Software Quality Assurance Plan (SQAP). It was confirmed that the raw information or data and the variables used in processing the information is documented in a record unique to the particular experiment or data set. The MIDAS personnel were able to present the proper documentation verifying that all software was correctly developed and that the user documentation included the proper information. Documentation was also presented (and found acceptable) to display the preliminary design review. the design review. and the proper validation and verification of the software. One discrepancy was corrected during the course of the audit. See Deficiencies Corrected During the Audit Section 5.5.2(d) of this audit report.

Implementation of QA Program Element 19 was determined to be satisfactory.

ATTACHMENT 3

List of Objective Evidence Reviewed During the Audit

1.0 ORGANIZATION

Procedures/Plans

- Transportation System Development (TSD) Quality Assurance Program Plan (QAPP), Revision A, 6/10/88
- MIDAS Quality Assurance Program Document
- Program Directive (PD) 1.4, Revision C, 9/24/90

Correspondence/Miscellaneous

Organization Chart, SNL Transportation Systems Chart, 7/30/92

2.0 PROGRAM

Procedures/Plans

- TSD QAPP, Rev. A, 6/10/88
- MIDAS QAPP, Rev. A, 4/19/90
- Mobile and Remote Ranges Division, QAPP, Rev. A, 2/15/86
- MIDAS Program Document, Rev. A, 4/19/90
- MIDAS System Description, Rev. A, 4/19/90
- CSDP QAPP, Rev. E, 9/30/91

Correspondence/Miscellaneous

- Teleconference Memorandum, QA Program Questions, R.G. Peck to W. Uncapher/T. Mills, 10/29/93
- Procedure Change Report (PCR) #42, dated 11/10/93

Training Documentation

- MIDAS Specific
  - W. Uncapher
  - M. Arviso
  - M. Hankinson
- NDE Training\Qualification Package for:
  - M. Arviso

ATTACHMENT 3

List of Objective Evidence Reviewed During the Audit

3.0 DESIGN CONTROL

Procedures/Plans

- MIDAS QAPP, Rev. A, 4/19/90
- TSD QAPP, Rev. A, 6/10/88
- MIDAS PCR Form

Design Documents

- Drawing CK-R11201, Rev. A, Flow Diagram
- Drawing R11208, Rev. A, Thermocouple Panel Assembly (Rack 1)
- Drawing R11232, Rev. A, Electrical System B-96
- Drawing R11243, Rev. A, Front Panel Timing Input - Output
- Procedure Change Requests:
  - 38, Tape Machine Procedure
  - 39, System Description - Tape Machine Multiplexer
  - 40, System Description - Installation of Secondary Transient Recorder System
  - 41, System Description - Installation of Secondary Transient Recorder System

4.0 PROCUREMENT DOCUMENT CONTROL

Procedures/Plans

- PD 3.2, Preparation and Control of Procurement Documents, Rev. D, 1/18/91
- MIDAS QAPP, Rev. A, 4/19/90

Purchase Orders

- 75-0093
- 78-9816
- 75-0587
- 75-7142

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Procedures/Plans

- MIDAS QAPP, Rev. A, 4/19/90
- MIDAS Program Document, Rev. A, 4/19/90

ATTACHMENT 3

List of Objective Evidence Reviewed During the Audit

Correspondence/Miscellaneous

- Letter, Review and Comment of MIDAS Plans and Procedures, dated 2/16/90

Comment/Resolution Documentation

- MIDAS-13, Calibration Procedure, Rev. A
- MIDAS-9, Central System Processor Procedure, Rev. A
- MIDAS Software QA Plan (SQAP), Rev. A

Drawings

CK-R11201
R11208
R11232
R11243

6.0 DOCUMENT CONTROL

Procedures/Plans

- PD3.3, Document Control, Rev. C, 9/24/90
- MIDAS QAPP, Rev. A, 4/19/90
- MIDAS 1 Cable Testing and Verification Procedure, Rev. A, 4/19/90
- MIDAS 2 Signal Conditioner/Amplifier Procedure, Rev. A, 4/19/90
- MIDAS 3 Matrix Switch Procedure, Rev. A, 4/19/90

Correspondence/Miscellaneous

- Produce Records Request for Drawings CK-R11201, R11208, R11232, R11243, dated 11/9/93 requested by W. Uncapher
- Document Control Drawing List

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

Procedures/Plans

MIDAS QAPP, Rev. A, 4/19/90

ATTACHMENT 3

List of Objective Evidence Reviewed During the Audit

Purchase Orders

75-0093, Ectron Thermocouple Simulator/Calibrator
78-9816, Personnel Contract
75-0587, Tektronics Scope (Oscilloscope)
75-7142, Dynamics Bridge Completion Cards

8.0 IDENTIFICATION AND CONTROL OF ITEMS

Procedures/Plans

- MIDAS QAPP. Rev. A. 4/19/90
- PD 2.9, Handling, Storage and Shipping. Rev. B. 6/29/90

MIDAS Equipment

- Hewlett-Packard (HP) Universal Source Function Generator. HP3245A
- HP Waveform Recorder. HP5183
- Ectron Thermocouple. 1120
- HP Network Analyzer. HP3577A

10.0 INSPECTION

Procedures/Plans

MIDAS QAPP. Rev. A. 4/19.90

Inspection Checklists

- Interface Panel (IP) #2. Cable IP2-TBI-NO-23. 7/16/90
- IP2. Cable IP2-TBI-NO-61. 7/20/90
- Rack 5, Spectrum Analyzer. HP-3585B. 8/2/90
- Rack 3. Function Generator. HP-3245A. 8/2/90

11.0 TEST CONTROL

Procedures/Plans

- MIDAS QAPP. Rev. A. 4/19/90
- PD 2.7. Test Control. Rev. E. 9/23/91
- MIDAS 1. Cable Testing and Verification Procedure. Rev. A. 4/19/90

ATTACHMENT 3

List of Objective Evidence Reviewed During the Audit

Test Checklists

- Rack 4 Amplifier Cable No. 04-05-08-J7. 8. 1. 2, 7/19/90
- Bridge Card 1-39 tested by Digital Multimeter HP 3478A. 7/12/90
- Bridge Card 1-15 tested by Digital Multimeter HP 3478A. 7/12/90
- Bridge Card 1-47 tested by Digital Multimeter HP 3478A. 7/12/90

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

Procedures/Plans

- MIDAS QAAP. Rev. A, 4/19/90
- MIDAS 13. Calibration Procedure. Rev. A. 4/19/90

MIDAS Equipment Checked

- HP Universal Source, calibration identification (ID) 2831A00589
- HP Multimeter, calibration ID 2926006884
- HP Waveform Recorder, calibration ID 2806A00498
- HP Network Analyzer. calibration ID 3001A14400

13.0 HANDLING, STORAGE, AND SHIPPING

Procedures/Plans

- MIDAS QAPP. Rev. A. 4/19/90
- PD 2.9. Handling, Storage, and Shipping, Rev. B. 6/9/90

Documentation Reviewed

- Waybill No. 064-654 7/22/92
- Waybill No. 9995230095 4/21/92
- Waybill No. 027429945 4/10/92
- Waybill No. 005202872 3/18/92

14.0 INSPECTION, TEST, AND OPERATING STATUS

See documentation for Elements 10 and 11

ATTACHMENT 3

List of Objective Evidence Reviewed During the Audit

15.0 CONTROL OF NONCONFORMING ITEMS

Procedures/Plans

- MIDAS QAPP, Rev. A, 4/19/90
- PD 5.8, Control of Nonconforming Items. Rev D. 9/23/91

Deficiency Documentation

- Deviation from Requirements/Return of Warranted (DFR/RWMR)
- DSP Technology 2/25/91
- HP Multimeter HP345A 4/27/89
- HP Universal Source HP3245A 4/27/89
- Time Code Processor (18-3111) 11/21/91

16.0 CORRECTIVE ACTION

See documentation for Element 15

17.0 QUALITY ASSURANCE RECORDS

Procedures/Plans

- MIDAS QAPP. Rev. A. 4/19/90
- MIDAS Program Document. Rev. A. 4/19/90

Documentation Reviewed

Document No.	Subject	Date
211	Bettis Honeycomb Crush Test #1	6/24/93
219	Longitudinal Low Velocity Test	6/30/93
H1224A Impact	Hold Point Checklist (Bettis Test)	6/29/93
SER U-3	Hold Point Checklist	1/20/93

Note: See other documentation for Elements 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, 13, 15, 19 for total reviewed

ATTACHMENT 3

List of Objective Evidence Reviewed During the Audit

18.0 AUDITS

Procedures/Plans

- MIDAS QAPP. Rev. A 4/19/90
- PD 5.3, Quality Audit. Rev. C. 9/24/90

Note: No other objective evidence was available for MIDAS

19.0 COMPUTER SOFTWARE

Procedure/Plans

- MIDAS QAPP. Rev. A. 4/19/90
- MIDAS SQAP. Rev. A. 4/19/90
- PD 2.1, Software Quality Assurance. Rev. B. 1.18/91
- MIDAS-21 Source Code Files. Rev. A. 9/29/93
- MIDAS-22 Standards, Practice and Conventions. Rev. A. 9/29/93
- MIDAS-24, Rev. A. User Manual. 4/19/90

Test Data

- Bettis Honeycomb Crush Test #7
- Sequence Number 211
- Hardware Self-test
- Database Integrity Check
- Diagnostic Test #10
- System Integrity Test

Miscellaneous/Correspondence

Publication. Sam Stearns and Ruth David. Algorithms

Design Reports, Specifications and Technical Reviews

- MIDAS Preliminary Design Review. 8/18/92
- MIDAS Critical Design Review. 8/25/93
- Independent Design Review. 8/25/93
- Software Design Requirements. 9/29/93
- Software Interface Specification. 9/29/93
- Software Verification and Validation. 9/29 93

ATTACHMENT 4

CARs

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

[1] CAR NO HQ-94-001-M
DATE 2/15/93
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QA

CORRECTIVE ACTION REQUEST

[2] Controlling Document	[2] Related Report No.
MIDAS QAPP, Rev. A, NQA-1 OCRWM QARD-214, Rev. 3 Basic Reqs.	HQ-94-01-M
[3] Responsible Organization: SNL MIDAS	[4] Discussed With: W. Uncapher

[5] Requirement:

NQA-1, Basic Requirement 3 and the QARD require that the design be defined, controlled, and verified. Also, design changes shall be governed by control measures commensurate with those applied to the original design.

MIDAS QAPP, paragraph 3.3 (Design Control) requires that drawings and changes be properly approved and controlled.

[6] Adverse Condition:

Contrary to the above, the actual as-built condition is reflected in a combination of drawings and Procedure Change Reports (PCRs) generated to supplement MIDAS procedures. The PCRs are not related to the drawings by any reference, nor are they approved utilizing the same methodology of development, design verification and final approval. The PCRs reviewed modified the MIDAS design and therefore modified the as built configuration. Examples: PCRs 38, 39, 40 and 41.

[7] Does a significant condition adverse to quality exist? Yes x No__ If Yes, Circle One: A B (C)	[9] Does a stop work condition exist? Yes__ No x If Yes - Attach copy of SWO If Yes, Circle One: A B C D	[11] Response Due Date: 2/14/94

[12] Required Actions: [X] Remedial [X] Extent of Deficiency [X] Preclude Recurrence [X] Root Cause Determination

[13] Recommended Actions:

1. Reconsider the applicability of Program Element 3 (Design Control) since the MIDAS test facility is not an item of a nuclear facility and provide alternative controls to assure facility operates for its intended purpose.
2. Review all PCRs to determine if other modifications exist.
3. Incorporate PCRs and drawings into one traceable package.

[14] Initiator R. G. Peck Date	[14] Issuance Approved by: QADD Date
[15] Response Accepted QAR Date	[15] Response Accepted QADD Date
[16] Amended Response Accepted QAR Date	[16] Amended Response Accepted QADD Date
[17] Corrective Actions Verified QAR Date	[18] Closure Approved by: QADD Date

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WASHINGTON, D.C.

[3] CAR NO. -Q-94-001-M
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QA

CORRECTIVE ACTION REQUEST (Continuation Page)

[13] Recommended Actions:

4. Assure that all PCRs found that modify the design receive the appropriate design verification.
5. Revise the Program to assure that the proper design document is used to modify the design.
6. Provide training to assure that all personnel are cognizant of the requirements related to Program Element 3.

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[9] CAR NO. HQ-94-002-M
DATE: 12/15/93
PAGE: 1 OF 1
QA

CORRECTIVE ACTION REQUEST

[1] Controlling Document	[2] Related Report No.
NQA-1 (Basic Requirements 2 and 10) and OCRWM QARD-214, Rev. 3	HQ-94-01-M
[3] Responsible Organization	**[4] Discussed With**
SNL MIDAS	W. Uncapher

[5] Requirement:

NQA-1 and the QARD require that Quality Control (QC) inspection personnel be qualified, certified, and independent from the work activities. Inspection for acceptance shall be performed by persons other than those who performed or directly supervised the work being inspected.

[6] Adverse Condition:

Contrary to the above requirements, there is no objective evidence that an independent QC inspection program has been developed for MIDAS for receiving, installation and test (field) activities.

[9] Does a significant condition adverse to quality exist? Yes x No__ If Yes, Circle One: A B (C)	[10] Does a stop work condition exist? Yes__ No x ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	[11] Response Due Date: 2/14/94

[12] Required Actions: [X] Remedial [X] Extent of Deficiency [X] Preclude Recurrence [X] Root Cause Determination

[13] Recommended Actions:

1. Reconsider the applicability of Program Element 10 (Inspection) since the MIDAS test facility is not an item of a nuclear facility and provide alternative controls to assure facility operates for its intended purpose ;
2. Develop a QC inspection program for MIDAS.
3. Generate Nonconformance Reports for installed hardware not inspected under a QC program.
4. Train all responsible personnel to assure that they are knowledgeable concerning the QC inspection Program.

[7] Initiator	[14] Issuance Approved by:
R. G. Peck Date 12/15/93	QADD Date 12/21/93
[15] Response Accepted	[16] Response Accepted
QAR Date	QADD Date
[17] Amended Response Accepted	[18] Amended Response Accepted
QAR Date	QADD Date
[19] Corrective Actions Verified	[20] Closure Approved by:
QAR Date	QADD Date

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[8] CAR NO. HQ-94-003-M
DATE: 12/15/93
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QA

CORRECTIVE ACTION REQUEST

[1] Controlling Document	[2] Related Report No.
MIDAS QAPP, Rev. A	HQ-94-01-M
[3] Responsible Organization: SNL MIDAS	[4] Discussed With: W. Uncapher

[5] Requirement:

MIDAS QAPP, paragraph 3.18 requires that "planned and scheduled audits be performed to verify compliance with all aspects of the project Quality Assurance Program." Additionally, the QAPP requires that "these audits be performed by the Quality Assurance Coordinator in accordance with written procedures or checklists."

[6] Adverse Condition:

Contrary to the above requirements, there is no objective evidence to substantiate that the QA Coordinator ever planned, scheduled, or performed audits. Additionally, there is no evidence that surveillances were performed. This covers the entire term since the MIDAS Program was approved (4/19/90).

[9] Does a significant condition adverse to quality exist? Yes x No__ If Yes, Circle One: A B (C)	[10] Does a stop work condition exist? Yes__ No x ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	[11] Response Due Date: 2/14/94

rec 12/21/93

[12] Required Actions: [X] Remedial [X] Extent of Deficiency [X] Preclude Recurrence [X] Root Cause Determination

[13] Recommended Actions:

1. Comply with QAPP requirements for planning, scheduling, and performing audits.
2. Evaluate the impact of not having implemented an audit program.
3. Provide training to applicable personnel in Program requirements.

[7] Initiator	[14] Issuance Approved by:
R. G. Peck Date 12/15/93	QADD Date 12/15/93
[15] Response Accepted	[16] Response Accepted
QAR Date	QADD Date
[17] Amended Response Accepted	[18] Amended Response Accepted
QAR Date	QADD Date
[19] Corrective Actions Verified	[20] Closure Approved by:
QAR Date	QADD Date

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[5] CAR NO. -Q-94-004-M
DATE: 2/15/93
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CORRECTIVE ACTION REQUEST

[1] Controlling Document	[2] Related Report No.
NQA-1	HQ-94-01-M
[3] Responsible Organization: SNL MIDAS	[4] Discussed With: W. Uncapher

[5] Requirement:

1. NQA-1, supplement 17S-1 requires that basic provisions be incorporated in the records management system. This includes specific requirements that records must be legible.

2. NQA-1, Supplement 17S-1, Section 4.4 requires that QA records be stored to prevent damage or destruction from natural disasters, environmental conditions, and biological agents.

[6] Adverse Condition:

1. Calibration records are not currently stored as QA Records in any one of the NQA-1 methods.

2. MIDAS records located in the Records Library are not being maintained in dual storage (approximately 50%) or another NQA-1 method.

3. Calibration records were found to have numerous erasures and improper corrections (cross-outs). These records are in pencil and are not duplicated.

[9] Does a significant condition adverse to quality exist? Yes__ No x If Yes, Circle One: A B C	[10] Does a stop work condition exist? Yes__ No__ ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	[11] Response Due Date: 2/14/94

[12] Required Actions: [X] Remedial [X] Extent of Deficiency [X] Preclude Recurrence [X] Root Cause Determination

[13] Recommended Actions:

1. Establish duplicate files for all records or another NQA-1 method.
2. Provide training to assure that all applicable personnel are aware of NQA-1 and QARD requirements for the maintenance and storage of records.

[7] Initiator R. G. Peck Date 12/11/93	[14] Issuance Approved by: QADD Date
[15] Response Accepted QAR Date	[16] Response Accepted QADD Date
[17] Amended Response Accepted QAR Date	[18] Amended Response Accepted QADD Date
[19] Corrective Actions Verified QAR Date	[20] Closure Approved by: QADD Date

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[5] CAR NO. -Q-94-005-M
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CORRECTIVE ACTION REQUEST

[1] Controlling Document	[2] Related Report No.
NQA-1 and OCRWM QARD RW-214, Rev. 3	HQ-94-01-M
[3] Responsible Organization: SNL MIDAS	[4] Discussed With: W. Uncapher

[5] Requirement:

1. OCRWM QARD Section 2 requires that program participants develop quality assurance program documents that reflect the requirements of the QARD and NQA-1.
2. MIDAS QAPP, paragraph 3.2 requires that the QA Coordinator provide training covering the Transportation System Development Department (TSDD) and Mobile and Remote Range Department (MRRD) QAPPs.

[6] Adverse Condition:

1. The MIDAS Program is committed to the TSDD and MRRD QAPPs. Review of these documents indicates that they do not meet QARD and NQA-1 requirements. Examples of problem areas are as follows:
   a. TSDD QAPP Rev. A (6/1/88) was never upgraded to QARD requirements (4/13/90)
   b. TSDD QAPP does not commit to NQA-1 Basic Requirement 2 Supplement 2S-1 and Appendix 2A-1 nor provide any instructions for compliance.
   c. The TSDD QAPP does not commit to NQA-1 Basic requirement 2 supplement 2S-3 (QA Program Audit Personnel) nor does it provide any instructions for compliance.
   d. The TSDD QAPP does not provide any of the details spelled out in NQA-1 Basic Requirement 3.0 and supplement 3S-1 for design control.

[9] Does a significant condition adverse to quality exist? Yes x No__ If Yes, Circle One: A B (C)	[10] Does a stop work condition exist? Yes__ No x ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	[11] Response Due Date: 3/14/94 Revised 4/24/93

[12] Required Actions: [X] Remedial [X] Extent of Deficiency [X] Preclude Recurrence [X] Root Cause Determination

[13] Recommended Actions:

Based on intended function of MIDAS, revaluate the QA requirements that are applicable and develop revised QA Program that meets applicable criteria of the OCRWM QARD, DOE RW-0333P and submit to OCRWM M&O for acceptance

[7] Initiator R. G. Peck Date 2/15/93	[14] Issuance Approved by: QADD Date 2/15/93
[15] Response Accepted QAR Date	[16] Response Accepted QADD Date
[17] Amended Response Accepted QAR Date	[18] Amended Response Accepted QADD Date
[19] Corrective Actions Verified QAR Date	[20] Closure Approved by: QADD Date

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CORRECTIVE ACTION REQUEST (Continuation Page)

[6] Adverse Condition (continued):

e. The MRRD QAPP is a document that is not formatted or apparently even intended to comply with the current requirements of NQA-1 or the QARD.
f. The TSDD QAPP does not contain a section of Software Quality Assurance or computer software.
g. The MIDAS QAPP (by itself) does not meet the requirements of NQA-1 and the QARD.

2. The QA Coordinator has never provided any training in the TSDD and MRRD QAPPs.

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WASHINGTON, D.C.

CAR NO. _____
DATE: _____
PAGE: _____ OF _____
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CORRECTIVE ACTION REQUEST (Continuation Page)

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Format for Corrective Action Response

The CAR response shall include the following information:

1. Corrective Action Response for CAR # _____

   A. Remedial Action - Actions taken to correct specific deficiencies noted.

      (Required for all CARs)

   B. Investigative Action - Actions taken to determine the extent of the condition.

      (Required for all significant conditions adverse to quality or any Condition Adverse to Quality if requested by CQA)

   C. Root Cause Determination - Identification of the root cause of the condition.

      (Required for all significant conditions adverse to quality or any Condition Adverse to Quality if requested by CQA)

   D. Corrective Action to Preclude Recurrence - Actions taken to address the root cause and preclude recurrence of the condition.

      (Required for all significant conditions adverse to quality or any Condition Adverse to Quality if requested by CQA)

2. For each action above, identify the name of the individual assigned responsibility for completion and the anticipated (or actual, if complete) completion date.

3. Response Approved: _____ Date: _____
   Responsible Manager