COLLEGE OF ENGINEERING
THE UNIVERSITY OF TEXAS AT AUSTIN

Department of Mechanical Engineering • 1 University Station C2200 • Austin, Texas 78712-0292
Telephone (512) 471-1131 FAX (512) 471-8727

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ATTN: Document Control Desk
Nuclear Regulatory Commission
Washington, DC 20555-0001

Christian Araguas
Chief, Division of Spent Fuel Management
U. S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards

SUBJECT: Docket No. 50-602, Response to Request for Additional Information on (Transportation) Quality Assurance Plan

REFERENCE: Request for Additional information for Review and approval of the University of Texas at Austin Request for Part 71 Quality Assurance Program for Packaging and Transportation of Radioactive Material (September 26, 2018 – ADAMS accession number ML18270A082)

Sir:

Attached is a response to the referenced Request for Additional Information, with the response incorporated in an updated, proposed QAP.

If there are any questions, please feel free to contact P. M. Whaley at whaley@mail.utexas.edu or 512 232 5374.

Sincerely,

P. M. Whaley

I declare under penalty of perjury that the foregoing is true and correct.

W. S. Charlton

A020
Q004
NRR

Att: Attachment 1, Response to Additional Information of Sep 26 2018
Attachment 2, UT Austin Nuclear Engineering Teaching Laboratory Quality Assurance Program (Type B Packages)

RESPONSE TO ADDITIONAL INFORMATION OF SEP 26 1018

Section 3 Organization

1. **Provide a description of how the current organization provides assurance that the required authority and organizational freedom, including sufficient independence from cost and schedule, when opposed to safety considerations, are provided.**

Under the current organization chart and organization description it appears that the QAP and NETL daily operations will be performed within the operating organization. In addition, it appears that the staff performing the packaging, shipping and receiving inspections will also be responsible for implementing the QAP.

This information is needed to determine compliance with 10 CFR 71.103(d).

As is typical with university research reactor facilities, NETL has a small staff. As a result, the NETL staff members regularly perform multiple types of duties. Thus, during an operation involving packaging material that falls under this QAP, NETL operations staff would also perform QA activities. We do not feel this is a conflict of interest since when operating within a "nuclear safety culture," ALL members of the organization have authority and responsibility to report safety related issues. Certain NETL operations and supervisory staff are licensed by the US Nuclear Regulatory Commission and have legal responsibilities to "observe, all applicable rules, regulations, and orders of the Commission" (10CFR55.53(d)) with protection from potential retaliation (10CFR50.7) and all university staff have the authority to report suspected noncompliance or safety issues and are protected from potential retaliation (UT-System policy UTS 131). Furthermore, should a NETL staff member feel their concern is not being addressed within NETL, they can report via the Compliance & Ethics Hotline (https://compliance.utexas.edu/, https://www.utsystem.edu/offices/systemwide-compliance/hotline, 877-507-7321) to the University Compliance Services where the matter will be escalated to university upper management with protection from potential retaliation (UT Handbook of Operating Procedures 3-1022). In addition, the Reactor Oversight Committee reviews the QAP and the results of activities conducted under the QAP.

Section 5 Quality Assurance Program

1. **Please explain the activities that will be covered by the Quality Assurance Program.**

Your submittal states that this program will include activities that are important to safety for receiving, handling, loading and delivering to a carrier for transport. This submittal also states that specifically, this QAP will address the unloading of a package from a truck, receiving a loaded package and shipping an unloaded package from the NETL on a truck. This section does not mention that the QAP will address the loading of radioactive material into a package for later shipment. A 10 CFR Part 71 QAP is not required for unloading, receiving, or shipping unloaded packages.

The section has been revised to include loading and offering to a carrier a loaded package.

2. **Please explain how QAP procedures will be developed and who will be responsible for writing these procedures.**

Section 3, Organization, states that the Reactor Oversight Committee will review and approve all written procedures. Section 5, Quality Assurance Program, states, in part, that quality assurance will be accomplished through the use of written procedures incorporating regulatory requirements, applicable portions of the NETL Health Physics Procedures, specific procedures developed by the manufacturer of the package and other procedures. Section 11, Instructions,

Procedures, and Drawings, states that activities important to safety will be ensured by following manufacturer's instructions, procedures, and limitations as they related to the safe use of packages. This QAP does not explain how QAP procedures will be developed.

This information is needed to determine compliance with 10 CFR 71.105.

The section has been revised to include details of development of the QAP procedures.

Section 31 Nonconforming Materials, Parts, or Components

1. **Please describe the program to address nonconforming material. Will nonconformance reports be developed to document the nonconformance in addition to identifying the nonconformance in the inspection report? Who will disposition the nonconforming item?**

Section 31 states, in part, that any part that is damaged or unable to perform its intended function shall be identified in the inspection report. 10 CFR 71.131, Nonconforming Materials, Parts, or Components, states, in part, that procedures for identification, documentation, segregation, disposition, and notification to affected organizations must be included. Section 31 mentions the identification of the nonconformance in the inspection report for the receipt/shipping inspections but makes no mention of further documentation of the nonconformances.

The section has been revised to clarify documentation of the nonconformance and disposition of the nonconforming item.

2. **Who will perform replacement activities for the package if a nonconformance is identified?**

Section 31 states that replacement parts must be obtained from the package owner. However, Section 5, Quality Assurance Program, states that NETI does not intend to rework, repair maintain or modify the package. It is not clear if in the case of a nonconformance the package owner will provide the replacement part and NETI will be performing rework, repair or modification activities for the package.

This information is needed to determine compliance with 10 CFR 71.131.

The section has been revised to clarify who will perform replacement activities.

Section 33 Corrective Actions

1. **Please describe the process to correct any conditions adverse to quality identified by your QAP.**

Section 33 states that conditions that are detrimental to quality will be promptly identified and reported to the NETI Associate Director (or designee). 10 CFR 71.133, Corrective Actions, states, in part. that measures shall be established to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment. and nonconformances, are promptly identified and corrected. Section 33 does not address how any conditions adverse to quality will be corrected.

This information is needed to determine compliance with 10 CFR 71.133.

This section has been revised to describe the process to correct any conditions adverse to quality.

Section 37 Audits

1. **Please describe the training requirements for the individual chosen to perform audits.**

Section 37.3, Team Selection, states in part that an independent individual will be chosen that has an understanding of the program and the requirements for compliance. 10 CFR 71.137, Audits,

states that audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. This QAP does not address any training requirements or regulatory guidance to be used to assure that the audit leader and members (if necessary) are adequately trained.

This information is needed to determine compliance with 10 CFR 71.137

This section has been revised to describe the training requirements for the individual chosen to perform audits.

UT Austin Nuclear Engineering Teaching Laboratory

QUALITY ASSURANCE PROGRAM (TYPE B PACKAGES)

1 Quality Assurance Requirements

This Quality Assurance Program (QAP) applies to shipments of TRIGA® type reactor fuel and other radioactive material requiring a Type B package. This QA Program is submitted pursuant to 10 CFR Part 71 Subpart H and is appended to NETL procedure ADMN-2, Procedures for Design Features and Quality Assurance.

Transport will be performed by a licensed carrier. The shipping package will be a Type B package with an approved Certificate of Compliance (CoC). The package will usually be on loan from entities such as the Department of Energy or a prime contractor. When consignor of a shipment of licensed material, NETL is ultimately responsible for ensuring that the package conforms to the CoC.

The sections of this QAP and implementing procedures are numbered and named based on corresponding sections of 10 CFR 71 Subpart H. Non-continuous procedure numbers are intentional and are consistent with the numbering in Subpart H:

- Where numbering of Subpart H sections is not sequential, the unused number is noted in this QAP as "No current 10CFR71 Subpart H Section"
- Procedures are developed for Subpart H sections applicable to the QAP at NETL; sections of Subpart H not applicable to the NETL QAP are noted as "Not Applicable to NETL," with an explanation in the QAP.

2 No current 10CFR71 Subpart H Section

3 ORGANIZATION

Figure 1~~Figure 1~~ represents the organization chart for the operation of the reactor facility. The QAP will be the responsibility of the Associate Director at The University of Texas at Austin Nuclear Engineering Teaching Laboratory (NETL). The QAP will be performed within the Operating Organization. The Reactor Oversight Committee will review and approve all written procedures. NETL Reactor Operations and Health Physics personnel will have primary responsibility for monitoring all packaging, shipping and receiving activities.

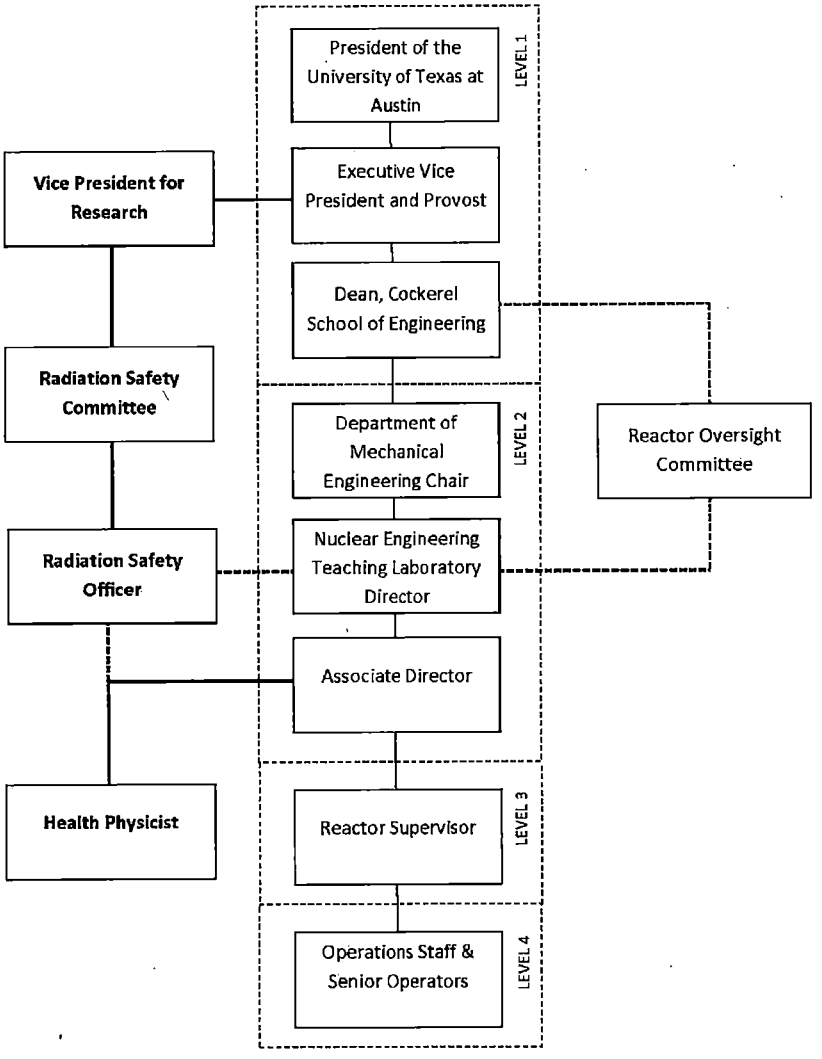

Figure 1

4 No current 10CFR71 Subpart H Section

5 QUALITY ASSURANCE PROGRAM

The scope of this program includes activities that are important to safety for receiving, handling, unloading, loading, and delivering to a carrier an approved and certified Type B package for the transport of TRIGA fuel or other radioactive material. ~~Specifically, this QAP addresses unloading a package from a truck, receiving a loaded package at the NETL, and shipping an unloaded package from the NETL on a truck.~~

NETL does not design, fabricate, assemble, or test packages, and does not intend to procure any package for ownership or lease to others. NETL does not intend to rework, repair (other than minor field repairs at the direction of the package owner and/or manufacturer), maintain or modify the package; repair (other than minor field repairs at the direction of the package owner and/or manufacturer) and maintenance of the package will remain the responsibility of the package owner.

Quality assurance will be accomplished through the use of written procedures incorporating regulatory requirements, applicable portions of the NETL Health Physics Procedures, specific procedures developed by the manufacturer of the package (e.g. package operating procedures specified in the package Safety Analysis Report), and other procedures developed during review of packaging and transportation planning. Procedure-based checklists (or equivalent) will be used by individuals (or their designees) who are responsible for quality assurance. During development of these procedures, consideration will be given to the complexity and proposed use of the package and its components including but not limited to the impact of malfunction or failure of the item to safety, the need for special controls and surveillance over processes and equipment, and the degree to which functional compliance can be demonstrated by inspection or test. These procedures will be developed and written by NETL staff.

6 Changes to QAP

Changes to this QAP will be performed in accordance with 10CFR70.106.

7 Package Design Control (Not Applicable to NETL)

Package design control is the responsibility of the package owner; design activities related to packages will not to be performed by the Facility.

8 No current 10CFR71 Subpart H Section

9 Procurement Document Control (Not Applicable to NETL)

Procurement document control is the responsibility of the package owner. No procurement documents are expected to be generated during this use of the package other than the procurement documents for the package itself. Procurement of the package is usually conducted via contract between the package user and the package owner.

Specific terms of use of the package will be stipulated in the contract or by memorandum between NETL and the package owner for use of the package. These contract terms will, at a minimum:

- Specify the scope of work intended for the package
- Require the package owner to demonstrate that the package conforms to the specifications contained within the CoC (i.e. by providing a valid and signed CoC, and a copy of the most recent package certification inspection).

- Require the package owner to provide a copy of their QAP approval letter to ensure that the quality control of the package owner is acceptable.
- Require the package owner to provide Copies of the quality control documents associated with spare or replacement parts of parts replaced during the contracted package use.

The contract or memorandum containing the terms of package use must be reviewed and signed by an authorized representative of NETL. This contract will be retained by NETL as a quality assurance document.

Any replacement parts will be procured by the package owner under their QAP. The package owner is responsible for furnishing NETL with copies of the reviewed and approved procurement documents for the replacement parts. These procurement documents will be retained by NETL as well as the package owner.

10 No current 10CFR71 Subpart H Section

11 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities important to safety will be ensured by following procedures as described in section 5 such as manufacturer's instructions, procedures, and limitations as they relate to the safe use of the packages.

12 No current 10CFR71 Subpart H Section

13 DOCUMENT CONTROL

Control shall be exercised over the documents that are used in this shipping activity. The documents include a master document check-list, inspection procedures, loading and unloading procedures, package certification documents, radiation survey records, and shipping papers. All procedures and check-lists and changes will be approved by the Reactor Oversight Committee, NETL Director, Reactor Manager, and/or Senior Reactor Operator as appropriate.

14 No current 10CFR71 Subpart H Section

15 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES (Not Applicable to NETL)

Control of purchased material, equipment, and services is the responsibility of the package owner. No equipment or services will be purchased that are applicable to this use of the package, other than procurement and use of the package itself.

In order to ensure that the package itself conforms to the procurement requirements specified in Section 9 of this plan, the package will be inspected upon receipt according to Section 21 of this plan with respect to the procurement requirements established in Section 9.

Control over services applicable to the use of the packages (~~eg.~~e.g. loading, unloading, opening, and closing the package) will be exercised via the contract scope of work, and will, in all respects, be performed in accordance with the operating procedures specified in the package Safety Analysis Report. Additionally, loading and shipping services must conform to the limits and specifications of the package CoC.

Proper loading of the cask will be demonstrated via inspections in accordance with Section 21 of this plan, and adherence to the operating procedures specified in the package SAR.

16 No current 10CFR71 Subpart H Section

17 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS (Not Applicable to NETL)

Identification and control of materials, parts, and components is the responsibility of the package owner. No materials, part or components are intended to be identified or controlled for this activity under the NETL QAP. Should conditions adverse to quality occur, they will be identified and communicated to the package owner through the QAP Section 33.

The package should arrive at NETL in a "ready to use" configuration, fully assembled. In the event that a package component is damaged during transit to NETL it will be identified by receipt inspection in Section 21. Should a package component be damaged during unloading or loading operations, it will be identified during exercise of activities conducted under Section 27. In the event a package component is damaged the package owner will be notified and will provide replacement or repair (as necessary) in accordance with Section 9.

Copies of the quality control documents required by the package owner's QAP for any spare or replacement parts should be furnished to NETL by the package owner in accordance with Section 9, and will be retained by NETL along with a complete summary of all parts that were replaced during the contracted package use. The documents will be reviewed by the NETL Associate Director prior to those parts being used in a shipment from NETL in accordance with Section 21.

18 No current 10CFR71 Subpart H Section

19 CONTROL OF SPECIAL PROCESSES

No special processes are to be undertaken for this activity.

20 No current 10CFR71 Subpart H Section

21 INTERNAL INSPECTION

The following inspection activities will be implemented for each package procured for shipping purposes:

21.1 Receiving Inspections

Checklists will be established to ensure receipt inspections are performed to verify:

1. Any unique identification of the package as received agrees with the package as shipped
2. The Proper package assembly
3. External dose rates are congruent with those listed on the radioactive shipping paperwork
4. Shipping papers are properly completed
5. Packages are conspicuously and durably marked in compliance with USDOT regulations
6. Measures are established to ensure that the consignee is present to accept receipt of the package

21.2 Shipping Inspections

Checklists will be established to ensure inspections are performed to verify:

1. The package is uniquely identified
2. Quality control documents for spare or replacement parts acquired after package receipt have been reviewed by the NETL Associate Director
3. Proper package assembly
4. Moderators and neutron absorbers are present (if applicable)
5. Valves are set to specification and to prevent tampering
6. Shipping papers are properly completed and signed by a university certified hazmat shipper
7. Packages are conspicuously and durably marked in compliance with USDOT regulations

21.3 Maintenance Inspections

These inspections will not be performed under this activity unless specifically designated by the package standard operating procedures.

21.4 Inspection Documentation

Inspection records will be maintained to document performance of inspection activities

22 No current 10CFR71 Subpart H Section

23 TEST CONTROL

23.1 Procedures

Procedures will be prepared to ensure that applicable tests, surveys, or other measurements are performed according to manufacturer's instructions. Properly calibrated equipment will be used and methods for documenting tests will be established.

23.2 Acceptance Tests

Measures will be established to ensure that acceptance tests (as applicable) are performed prior to offering a package for transport. Tests may include structural integrity, leak tightness, component performance, and shielding and thermal integrity.

23.3 Results

Test results will be documented, evaluated, and maintained as QA records. The NETL Associate Director (or designee) will determine acceptability of the records.

24 No current 10CFR71 Subpart H Section

25 CONTROL OF MEASURING AND TEST EQUIPMENT

25.1 Calibration Control

Gauges, reference standards, etc. are not expected to be used for this activity. Radiation measuring equipment will be used for this operation. This equipment will be the property of NETL. Calibration records for this equipment will be maintained by NETL in accordance with existing standard operating procedures.

A calibrated torque wrench ~~will~~ may be used for cask closure. This torque wrench will be calibrated with traceable standards, and the calibration records covering the duration of use ~~of~~ at NETL will be maintained by the NETL.

25.2 Out of Calibration Equipment

Equipment that is out of calibration will not be used.

26 No current 10CFR71 Subpart H Section

27 HANDLING, STORAGE, AND SHIPPING CONTROL

27.1 Preservation

Measures will be established to ensure that cleaning, handling, storage, and shipping are accomplished in accordance with the package design requirements to prevent damage or deterioration by environmental conditions. Provisions for use of special equipment such as cranes or lifting devices will adequately identify and protect package components. Conditions identified in the CoC will be adhered to when loading or unloading packaging.

27.2 Preparation, Release and Delivery to Purchaser

Measures will be established to ensure that the following requirements are completed prior to shipping:

1. Cavities have been adequately dried
2. All conditions have been completed prior to offering for transport
3. All USNRC and USDOT requirements have been satisfied prior to offering for transport
4. All shipping papers have been completed and reviewed for accuracy and completeness

28 No current 10CFR71 Subpart H Section

29 INSPECTION, TEST, AND OPERATING STATUS

A master check-list will be established to track the status of inspections, test, and operating conditions.

30 No current 10CFR71 Subpart H Section

31 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

Shipping and receiving inspections will be conducted according to Section 21 of this plan.

These inspections will include identification of parts that are unable to meet the specifications listed in the package CoC, and package Safety Analysis Report. Any part that is damaged or unable to perform its intended function as specified in the package CoC or SAR shall be identified in the inspection report and removed from service.

Nonconforming parts ~~must~~ will be clearly labeled and removed from the work area to prevent their inadvertent use. The package owner will be consulted to determine the appropriate course of action, to include possible repairs and disposition of nonconforming items, to return the package to useable condition. If it is determined that a minor field repair can be done by NETL personnel, any r~~R~~eplacement parts ~~must~~ will be obtained from the package owner. If a more substantial repair is needed, the package owner will make the necessary repair. Control over the replacement parts must be exercised by the package owner in accordance with Section 17 of this plan.

Additionally, an assessment must be made on whether or not the replacement part has impacted the validity of the CoC, or if the package must be recertified by the package owner. A copy of this assessment and the new package certification (if necessary) must be retained by NETL. An

addendum to the inspection report will be created detailing the actions taken including repairs and disposition of the nonconforming items.

32 No current 10CFR71 Subpart H Section

33 CORRECTIVE ACTION

~~33.1 Reporting~~

Causes of conditions that are detrimental to quality will be promptly identified and reported to the NETL Associate Director (or designee). As NETL is simply a user of the package, findings will be relayed to the owner and/or manufacturer of the package for evaluation. Corrective actions will be formulated in consultation with the package owner and/or manufacture as appropriate. Findings, corrective actions, and results of corrective actions will be documented to ensure ~~Measures will be established to identify any corrective action from suppliers are obtained and~~ that corrective actions were implemented and effective.

34 No current 10CFR71 Subpart H Section

35 QUALITY ASSURANCE RECORDS

35.1 General

QA records will be generated for each activity that is performed during the receipt, unloading, opening and closing, loading, preparation of shipping papers, and adherence to conditions specified by the manufacturer. The records will demonstrate delivery to a carrier and have evidence to show that USNRC and USDOT requirements have been satisfied.

Inspection and test records will identify: the test or observation performed, show that the tests or inspections were complete, record test or survey data, identify any conditions that are detrimental to quality, names of individuals performing the tests or inspections, and whether the results were acceptable.

35.2 Generating Records

Measures will be established to generate and store records. Paper copies of records generated will be stored in secure files. Additionally, documents may be formatted for electronic storage.

35.3 Indexing and Classification Records

Records generated for these activities will be designated as non-permanent and will be retained for a period of at least 3 years or as prescribed in the University of Texas Handbook of Operating Procedures 3-1410, Records Management, whichever is longer.

35.4 Receipt, Retrieval, and Disposition of Records

The records generated by these activities will be maintained by NETL. Procedures are in place for storage of records that relate to transportation and health physics activities that relate to the use of licensed material at the Facility.

35.5 Storage, Preservation, and Safekeeping

Measures will be established to maintain records for the required period. Measures to be established include:

1. Prevention of damage from fire, flood, or other environmental damage
2. Electronic records will be stored on a system which is backed up periodically or on media stored in a manner that prevents damage as indicated in item 1 above
3. Unauthorized personnel will not have access to records
4. Damaged records will be promptly replaced

36 No current 10CFR71 Subpart H Section

37 AUDITS

37.1 Elements of an Audit Program

Due to the small number of uses of any package an audit will be conducted after each use of a package. ~~An auditor will be appointed by the~~The Reactor Oversight Committee (ROC) will appoint an appropriately trained auditor (which may be a member of the ROC). In accordance with Technical Specifications Section 6.2.1, ROC members will be knowledgeable in fields which relate to nuclear safety. ~~The conditions of~~In accordance with Technical Specifications Section 6.2.4, the audit will be a select examination of records, logs, or other documents by a person not directly responsible for the documents. ~~will be met in establishing an audit program.~~ A checklist patterned after the sections of this QAP and corresponding sections of 10CFR71 Subpart H will be used to guide the audit process.

37.2 Scheduling of Audits

An audit will be performed after each ~~shipment~~ use of the package to ensure that elements of the program are in place and that appropriate documentation was generated and maintained.

37.3 Team Selection

Due to the small scope of this ~~activity~~activity, an independent individual will be chosen that has an understanding of the program and the requirements for compliance. Specific training concerning this audit for the chosen individual will be at the discretion of the ROC and will vary depending on the prior training and experience of the chosen individual. Due to the qualifications of the ROC members, the chosen individual will likely have extensive pertinent training and

experience and thus specific training for this audit will typically be a simple review of the audit checklist and this QAP.

37.4 Various Audit Actions

The auditor will meet prior to the audit to discuss scope and objectives and after the audit to discuss findings, clarify facts, and to ensure all appropriate information has been gathered. A report will be generated to identify deficiencies and a response is required to address deficiencies. The ~~auditor~~ ROC will ensure that a schedule for resolving the items identified is presented and that corrective action is implemented. The report and response(s) will be retained in accordance with Section 35.