Restoration Services, Inc.

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June 23, 2011

Mr. Tom Hines
U.S. Department of Energy
Portsmouth/Paducah Project Office
Paducah Site Office
P. O. Box 1410
Paducah, KY 42002

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Dear Mr. Hines:

DOE Contract DE-AT30-08CC40018 – Transmittal of *United States Department of Energy Portsmouth/Paducah Office Quality System for Non-Destructive Assay Characterization,* DOE/PPPO/03-0235&D0

Per your request, enclosed is the *United States Department of Energy Portsmouth/Paducah Office Quality System for Non-Destructive Assay Characterization, DOE/PPPO/03-0235&D0.*

If you have any questions in reference to these documents, please contact Mr. Lane Paschal of my staff at 270-217-0548.

Sincerely,

Michael Logan
Program Director

ML:rhb

Enclosures: As Stated Above

c: Vince.Adams@lex.doe.gov, PPPO/PORTS
Joel.Bradburne@lex.doe.gov, PPPO/PORTS
Richard.Mayer@lex.doe.gov, PPPO/LEX
RFerguson@rsienv.com, RSI/Oak Ridge
Mark.Scott@lex.doe.gov, RSI/PORTS
Dan.Mosley@lex.doe.gov, HEI/PORTS
LPaschal@comcast.net, RSI/PORTS
File-Program Director
RMDC-File-RC

P.O. Box 448, Waverly, Ohio 45690
Telephone: 740-897-2414 ❖ Fax: 740-897-2982 ❖ www.rsienv.com

DOE/PPPO/03-0235&D0

U.S. Department of Energy
Portsmouth/Paducah Project Office

Quality System
for
Nondestructive Assay Characterization

Revision 0

This document has been approved for public release:

Henry H. Thomas (signature on file) 6/7/11
Classification & Information Control Officer Date

DOE/PPPO/03-0235&D0

U.S. Department of Energy
Portsmouth/Paducah Project Office

Quality System for Nondestructive Assay Characterization

Revision 0

Date Issued—May 2011

Restoration Services, Inc.
Waverly, Ohio
Task Order DE-AT30-08CC40018
GSA Contract GS-10F-0273S

APPROVAL

U.S. Department of Energy
Portsmouth/Paducah Project Office

Quality System
For
Nondestructive Assay Characterization

Revision 0

May 2011

DOE/PPPO/03-0235&D0

Approved by: _____ Date: _____

William Murphie
Manager
Portsmouth/Paducah Project Office

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ACRONYMS

%R	percent recovery
%RSD	percent relative standard deviation
α	alpha
β	beta
σ	sigma
μCi	microcurie
AK	acceptable knowledge
AmO_2	americium dioxide
ANSI	American National Standards Institute
ASQC	American Society for Quality Control
ASTM	American Society for Testing and Materials
Bq	becquerel
CAP	corrective action plan
CB	confidence bound
CCGPM	General Conference on Weights and Measures
CFR	Code of Federal Regulations
Ci	curie
CGI	commercial grade item
CRM	certified reference material
D&D	decontamination and decommissioning
DOE	U. S. Department of Energy
DOECAP	DOE Consolidated Audit Program
DQO	data quality objective
EPA	U. S. Environmental Protection Agency
FWHM	full width half maximum
H&S	health and safety
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
keV	kiloelectron volt
IMS	Information Management System
Lc	critical level
LLD	lower limit of detection
LLQ	lower limit of quantitation
MARLAP	Multi-Agency Radiological Laboratory Analytical Protocol
MCA	multi-channel analyzer
mCi	millicurie
MDA	minimum detectable activity
NBL	New Brunswick Laboratory
NCS	Nuclear Criticality Safety
NDA	nondestructive assay
NELAC	National Environmental Laboratory Accreditation Conference
NIST	National Institute of Standards and Technology
NMC&A	Nuclear Material Control and Accountability
NTP	National Transuranic Program
pCi	picocurie (1×10^{-12} Ci)
PDP	performance demonstration program
PE	performance evaluation
PPPO	Portsmouth/Paducah Project Office
PuO_2	plutonium dioxide

QA	Quality Assurance
QAD	Quality Assurance Division
QAMS	Quality Assurance Measurement System
QC	Quality Control
QSNDA	Quality Systems for Nondestructive Assay
RF	radio frequency
RPD	relative percent difference
SI	standard unit
SNM	special nuclear material
SOP	standard operating procedure
SOW	statement of work
SRM	standard reference material
$T_{1/2}$	half-life
TMU	total measurement uncertainty
UO_2F_2	uranyl fluoride
V&V	verification and validation
WRM	working reference material
wt%	weight percent

EXECUTIVE SUMMARY

The U.S. Department of Energy (DOE) Portsmouth/Paducah Project Office (PPPO) requires Nondestructive Assay (NDA) service providers to have an approved quality system for NDA characterization in place before the performance of work similar to the quality systems implemented at analytical laboratories. A quality system is a documented structure that assures a defined standard of quality in the planning, implementation, and verification/validation of a product or service compliant with the needs and requirements of the end-user.

This document addresses those elements necessary to establish, implement, and maintain an effective Quality System for Nondestructive Assay (QSNDA) compliant with applicable federal, state, and local regulations and DOE orders and requirements. This QSNDA characterization document defines Quality Assurance (QA) Program requirements that must be considered and implemented, as applicable, by the NDA service provider.

The requirements in this QSNDA document are based on the principle that work shall be planned, documented, performed under controlled conditions, verified and/or validated, and periodically assessed to establish work quality and process effectiveness and to promote improvement. This QSNDA document contains QA requirements that NDA service providers must comply with to demonstrate that they operate a quality system, are technically proficient, and are able to generate and maintain valid and defensible data.

This document addresses elements regarding the management and organization of the QA Program implemented by the NDA service provider, in addition to fundamentals to be applied in managing program activities. In addition, the technical requirements the NDA service provider must address in its quality system to assure data quality objectives are addressed.

Providers of NDA characterization services to the PPPO shall be committed to generating data of known, documented, and legally defensible quality that meets the requirements of DOE Order 414.1D and NQA-1 2004 with addenda through 2007. An NDA service provider intending to provide characterization services for containerized uranium-contaminated wastes and process components for the PPPO must effectively implement the requirements as delineated in this document. The NDA service provider may use alternate QA measures or plans provided they are equivalent to this document and concurred by the PPPO.

1. INTRODUCTION

A quality system is a documented structure that assures a defined standard of quality in the planning, implementation, and assessment of a product or service compliant with the needs and requirements of the end-user. Elements of a quality system include policies, objectives, principles, organizational authority, responsibilities, accountability, and an implementation plan to ensure data quality is controlled, known, and documented at a stated confidence level. Data generated under such a program is in turn used to demonstrate regulatory and contractual compliance and for decision-making purposes.

The U.S. Department of Energy (DOE) Portsmouth/Paducah Project Office (PPPO) requires Nondestructive Assay (NDA) service providers to have an approved Quality System for Nondestructive Assay (QSNDA) characterization in place before the performance of work. This QSNDA characterization document defines Quality Assurance (QA) program requirements that must be considered and implemented as applicable by the NDA service provider. The content of this document uses pertinent components of the DOE document, *Quality Systems for Analytical Service*, Revision 2.6, November 2011, which is based on the U. S. Environmental Protection Agency (EPA) National Environmental Laboratory Accreditation Conference (NELAC) Chapter 5, "Quality Systems" as implemented July 2005. Additionally, applicable NDA QA program requirements as currently implemented through the National Transuranic Program (NTP) and managed through the DOE Carlsbad Area Office are included in this document.

The requirements in this QSNDA document are based on the principle that work shall be planned, documented, performed under controlled conditions, and periodically assessed to establish work quality, process effectiveness, and to promote improvement. Management and line personnel are responsible for planning to achieve a defined level of quality and for promoting continuous improvement of such. QA organizations and personnel are responsible for verification and validation (V&V) of the required level of data quality. This quality system document delineates a process by which appropriate NDA methods are selected, their capability evaluated, implemented for operation, and their performance assessed and documented.

The NDA service provider is responsible for developing, documenting, and implementing a waste NDA characterization program QA plan that addresses the elements of this QSNDA. The NDA QA plan shall be submitted to the PPPO for approval. Recommended QA plan elements and requirements are contained in this QSNDA document. The NDA service provider may submit a QA plan that differs from that as recommended through the QSNDA, but must prove that any alternate method is equivalent to or better than elements as contained in the QSNDA. Wastes may not be characterized, certified, or shipped before PPPO approval of the NDA QA plan.

The PPPO will conduct surveillances and audits as applicable to ensure the NDA service provider is in compliance with its approved QA plan. NDA service providers seeking a PPPO contract award must ensure implementation of all QA policies and practices and essential standard operating procedures (SOPs) per the intent of this QSNDA. All items identified in this document shall be available for inspection and audit.

Any exceptions to the applicability of portions of this document based on the nature of the contract under consideration must be concurred by the PPPO.

2. SCOPE

This QSNDA document contains QA requirements that NDA service providers must comply with to demonstrate that they operate a quality system, are technically proficient, and are able to generate and maintain valid and defensible data. A NDA service provider is a legally accountable entity engaged in contractual arrangements to provide NDA characterization services and is ultimately responsible for generating data of known quality in compliance with the client requirements. This document applies to NDA characterization of containerized uranium-contaminated wastes and process components generated as a result of DOE decontamination and decommissioning (D&D) and waste management activities. In-situ NDA field measurements of process cells, equipment, and components are included in the scope of this document. This document addresses the following issues and requirements:

1. Program elements and requirements for use by NDA service providers in developing their quality, administrative, and technical systems, plans, and procedures governing their operations and data quality,
2. QA program organization structure and associated responsibilities,
3. Personnel training and qualification,
4. Data quality objectives (DQOs),
5. Control of work processes, including implementing procedures, nonconforming work, and corrective and preventative actions,
6. NDA methods and method confirmation,
7. NDA instrumentation and support equipment,
8. NDA measurement traceability, uncertainty, and use of acceptable knowledge (AK),
9. NDA quality control (QC) measures,
10. Requirements for demonstrating NDA capability and performance to support regulatory compliance assessment, qualification, and must have PPPO concurrence,
11. Requirements regarding the generation, storage, safekeeping, and disposition of QA records,
12. Procurement requirements including proposal/bid evaluation, procurement documentation, supplier performance evaluation (PE), nonconformance issues, etc.,
13. Software V&V requirements, configuration control, and documentation, and
14. Program assessment requirements including management reviews, independent surveillances, and audits.

Compliance with health and safety (H&S) regulations on NDA service provider operations are not specifically covered in this document. It is the responsibility of the NDA service provider to identify and comply with applicable H&S requirements.

3. MANAGEMENT REQUIREMENTS

This section addresses elements regarding the management and organization of the QA program implemented by the NDA service provider in addition to fundamentals to be applied in managing program activities.

3.1 ORGANIZATION

Effective implementation of a quality system or QA program is dependent on the efforts of personnel at all levels of the organization. The organizational structure and personnel assignments shall be such that those responsible for performing work are accountable for achieving, maintaining, and improving quality. Management is responsible for defining the required level of quality, developing plans and procedures to attain quality, and supporting the workers in the pursuit and improvement of quality. NDA service provider QA organizations are responsible for verifying the achievement of quality at a known level during implementation of the quality program.

3.1.1 NDA Service Provider

The NDA service provider is a business entity engaged in a contractual agreement to provide NDA characterization services and is ultimately responsible for generating data of known quality in compliance with applicable regulations and client and/or end-user requirements. The NDA service provider, or organization of which it is a part, shall be an entity that is bound to legal obligations.

The NDA service provider shall establish and implement policies, plans, and procedures that control NDA measurement and characterization activities. Those policies, plans, and procedures shall assure consideration of and compliance with requirements as delineated in this document.

The quality system shall cover work conducted in NDA service provider permanent facilities, at sites away from its permanent facilities, or in temporary or mobile facilities.

If the NDA service provider is part of an organization performing activities other than NDA measurements, the responsibilities of key personnel in the organization who have an involvement or influence on NDA characterization activities shall be defined in order to identify potential conflicts of interest. Where the NDA service provider is part of a larger organization, arrangements shall be such that departments having conflicting interests (e.g., production, commercial marketing, or financing) do not adversely influence NDA service provider compliance with the requirements of this document. The NDA service provider must be able to demonstrate that it is impartial and that its personnel are free from any undue commercial, financial, or other pressures that might influence their technical judgment. NDA service providers shall not engage in any activity that may endanger the trust in its competence, independence of judgment, impartiality, and integrity in relation to its NDA characterization activities.

The NDA service provider management shall:

1. Define the organization and management structure of the NDA service provider, its place in any parent organization, and the relationship between quality management, NDA technical operations, and support services.
2. Appoint backup personnel for key managerial positions, including the technical director and quality manager.
3. Have managerial and technical personnel with the authority and resources needed to perform their duties. Personnel shall have adequate training and experience to perform work activities subject to

this QSNDA. Personnel shall also be able to identify departures from quality system requirements contained herein and procedures governing the conduct of NDA characterization and to initiate actions to prevent or minimize such occurrences.

4. Ensure compliance with all applicable regulations, end-user DQOs and requirements, DOE orders and requirements, and applicable federal, state, and local laws.
5. Have processes to ensure its management and personnel are free from any undue internal and external commercial, financial, or other pressures and influences that may adversely affect the integrity of their data.
6. Have policies and procedures to ensure the protection of client and/or end-user confidential information and proprietary rights, including procedures for protecting the electronic storage of information and data and transmission of reports and results.
7. Specify the responsibility, authority, and interrelationships of all personnel who manage, perform, or verify work affecting the quality of NDA characterization process and resulting data. Documentation of such shall include a clear description of the lines of responsibility in the NDA service provider organization and shall be proportioned such that adequate supervision is assured.
8. Provide adequate supervision of the NDA measurement and characterization staff, including direct supervision of trainees by personnel familiar with implemented NDA measurement methods and procedures and the assessment of NDA QC data and measurement results.
9. Have NDA technical management staff who have overall responsibility for the technical operations and those resources needed to ensure the required level of quality is instituted into NDA characterization operations.
10. The NDA technical director (however named) shall ensure that personnel operating NDA equipment and/or analyzing the resultant data have the appropriate educational and/or technical experience to perform such duties. Documentation of qualifications is required.
11. Appoint a quality manager who, irrespective of other duties and responsibilities, shall have a defined responsibility and authority for ensuring the quality system as it relates to NDA characterization activities and is implemented and followed at all times.
12. Have direct access to the highest level of management at which NDA characterization policy and/or resource decisions are made. Where staffing is limited, the quality manager may also be the NDA technical director.
13. Serve as the focal point for NDA measurement QA/QC and be responsible for the oversight, review, and evaluation of such data and information.
14. Have functions independent from NDA measurement operations for which they have QA oversight.
15. Be able to evaluate NDA measurement data objectively and perform assessments without outside (e.g., managerial) influence.
16. Be empowered to stop unsatisfactory work or prevent the reporting of NDA results generated from an out-of-control measurement system.
17. Have documented training and/or experience in QA/QC procedures and be knowledgeable in the PPPO QSNDA quality system.
18. Be competent in the knowledge of NDA measurement methods for which data review is performed.
19. Perform timely review of QC data and control charts for out-of-control conditions and initiate preventative or corrective actions as appropriate. Data analysis software should be used for the statistical evaluation of data for trends and biases.
20. Arrange for or conduct internal audits, notify NDA characterization management of deficiencies in the quality system, and monitor corrective actions.
21. For purposes of maintaining DOE PPPO qualification, ensure participation in applicable performance demonstration or evaluation program(s) when they are scheduled.

3.2 QSNDA CHARACTERIZATION

Implementation of a quality system is an integral part of NDA measurement/analysis, operational activities, data generation, and reporting. This section defines QA program requirements necessary to establish confidence that NDA characterization activities will be satisfactorily performed by the NDA service provider.

1. The NDA service provider shall issue a quality statement of policies and objectives under the authority of the chief executive. The quality statement shall at a minimum include the following:

    a) NDA service provider management's commitment to the quality of its NDA characterization methods and resultant data in servicing its clients,
    b) Definition and documentation of its quality objectives, policies, systems, and plans and its commitment to good and professionally accepted NDA characterization practices and standard of service,
    c) Require that all personnel involved in NDA characterization activities have read and understand applicable quality documentation and shall implement such policies and procedures in their work, and
    d) The NDA service provider management's commitment to compliance with this QSNDA characterization document and other PPPO quality requirements and guidance documents as applicable.

2. The NDA service provider shall be responsible for developing and implementing a QA plan that addresses the elements of this QSNDA.
3. The NDA service provider's QA plan shall document its systems, programs, manuals, procedures, instruction, and training to the extent necessary to ensure and demonstrate that NDA measurement results are of known quality and valid.
4. The roles and responsibilities of NDA technical management and the quality manager, including their responsibility for ensuring compliance with this document, shall be defined in a quality manual or plan.
5. The quality manual or plan shall be submitted to PPPO for review and concurrence. NDA characterization activities may not be performed before such concurrence is obtained.
6. The PPPO will institute audits and surveillances to ensure the NDA service provider is in compliance with its own QA plan(s).
7. The QA plan shall list on the title page a document title, the NDA service provider's full name and address, the effective date of the version, and approval signature(s).
8. The quality plan and related quality documentation shall also include or reference the following:

    a) The name of the quality manager and name and contact information for individual(s) responsible for the NDA characterization facility(ies), mobile or otherwise.
    b) A table of contents list and applicable lists of references, terms, glossaries, and appendices.
    c) The organization and management structure of the NDA service provider, its place in any parent organization, and relevant organizational charts.
    d) The relationship between management, NDA technical operations, support services, and the quality system.
    e) Identification of the NDA service provider's approved signatories. (Note: The title page of the quality manual must have the signed and dated concurrence [with appropriate titles] of all responsible parties including the quality manager(s), technical director(s), and the individual who has overall responsibility of all NDA characterization activities, such as the NDA characterization director or manager).
    f) Job descriptions of key NDA staff and reference to the job descriptions of other staff.

g) A listing of qualifications and/or certifications and a list of all NDA measurement methods used to perform NDA measurements under PPPO contracts.
h) Processes for establishing that NDA and management personnel are knowledgeable and adequately experienced in the duties they are assigned to carry out and means to ensure they receive necessary training.
i) Mechanisms for ensuring the NDA service provider reviews all new work and associated QA objectives to ensure it has the appropriate methods, facilities, and resources before accepting and/or commencing such work.
j) Reference to NDA measurement method selection and application and method V&V procedures used.
k) Reference to procedures used for initial NDA system calibration, confirmation and verification, QC, and maintenance of NDA instrumentation and associated equipment.
l) Reference to methodology for NDA measurement uncertainty determination.
m) Reference to continuing NDA method confirmation and verification techniques, PE programs, use of reference materials, and internal QC practices.
n) Reference to procedures for ensuring NDA data review/validation are performed and that documentation is maintained and available.
o) Reference to NDA equipment, working reference materials (WRMs) used, the NDA service provider's procedures, and associated documentation for establishing NDA measurement traceability to nationally recognized reference bases.
p) Reference to procedures for selecting and procuring materials, equipment, and services used by the NDA service provider in the process of NDA measurement analysis and report generation.
q) Reference to procedures regarding procurement of NDA system parts; traceable WRMs, standards, or check sources; replacement/spare parts; and materials and services having the potential to affect data quality per end-user requirements.
r) Reference to procedures addressing spare parts and materials management.
s) Reference to procedures that identify records required to be retained as well as procedures for control and maintenance of documentation through a document control system that ensures all SOPs, manuals, or documents clearly indicate the time period the procedure or document was in force.
t) Reference to procedures governing the information management system (IMS); processing and maintenance of electronic data, data management, and software V&V; and version control.
u) Reference to procedures addressing changes to existing electronic data and specifying required retention times of electronic data, documentation, and records.
v) Procedures that establish a reasonable frequency for reviewing, updating, and distributing current revisions of controlled documents and procedures (e.g., SOPs).
w) Reference to procedures to be followed to implement preventative and/or corrective actions when NDA characterization deficiencies are detected or when departures from documented policies and procedures occur.
x) NDA service provider management arrangements for granting and documenting temporary exceptions to departures from documented policies and procedures.
y) Procedures for dealing with complaints and protecting confidentiality (including national security concerns) and proprietary rights.
z) Procedures for audits and surveillances, technical or otherwise.

9. The NDA service provider is responsible for implementing and documenting all necessary QA and QC measures and activities applicable to NDA waste characterization.
10. Data integrity shall be evaluated to determine the data can be reproduced and that the data reported was based on appropriate measurement procedures. Additionally, QA procedures are to determine if there was any fraudulent or improper practices being performed by scientists, technicians, engineers, analysts, and managers. The NDA service provider shall establish and maintain data integrity

procedures. These procedures shall be defined in detail. The four required elements of a data integrity system are:

a) Data integrity training,
b) Signed data integrity documentation for all NDA service provider employees,
c) In-depth periodic monitoring of data integrity, and
d) Data integrity procedure documentation.

11. Data integrity procedures shall be signed and dated by senior management. These procedures and the associated implementation records shall be maintained and made available for auditor review. The data integrity procedures shall be annually reviewed and updated by management.
12. The NDA service provider management shall provide a mechanism for confidential reporting of data integrity issues associated with their work. Employees shall be assured that confidentiality and a receptive environment exists for employees to privately discuss ethical issues or report items of ethical concern. In instances of ethical concern, a process shall be in place whereby the NDA service provider management is informed of the need for any further detailed investigation.
13. The QA manual or plan shall be maintained current under the responsibility of the quality manager.

3.3 DOCUMENT CONTROL

The NDA service provider shall establish and maintain procedures to control all documents of which the quality system is comprised (internally generated or from external sources). Quality documents may encompass, but not be limited to, policy statements, procedures, specifications, procurement records, calibration data, NDA measurement results and reports, national standards, textbooks, posters, notices, memoranda, software, drawings, and plans. These may be on various media, whether hard copy or electronic, and may be digital, analog, photographic or written. Operator aids shall also be included in the document control process. An operator aid is defined as a technical posting other than formal a procedure, rule, instruction, and so forth that assists workers in accomplishing specific tasks.

3.3.1 Document Approval and Issue

All documents for NDA characterization use shall, as part of the quality system, be reviewed and approved for use by authorized personnel before issuance. A master list, or equivalent document control procedure, identifying the current revision status as well as the distribution of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

The master list or document control procedure shall ensure that:

1. Authorized editions of appropriate documents are available at all locations where operations essential to the NDA service provider characterization activities are performed,
2. Documents are periodically reviewed and revised to ensure continued suitability and compliance with applicable requirements where necessary,
3. Invalid or obsolete documents are promptly removed from all points of issue/or otherwise assured against unintended use, and
4. Obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

Quality system documents generated by the NDA service provider shall be uniquely identified. Such identification shall include the issuing organization, date of issue, revision identification, page numbering, and the total number of pages or a mark to signify the end of the document.

3.3.2 Document Changes

Changes to documents shall be reviewed and approved by the personnel in the same position as the person who performed the original review unless specifically designated otherwise. The designated personnel shall have pertinent experience or access to background information upon which to base their review and approval.

If the NDA service provider's document control system allows for the amendment of documents by hand, pending the document re-issue, the procedures and authorizations for such amendments shall be defined. Amendments shall be clearly marked, initialed, and dated. A revised document shall be formally reissued as soon as practicable.

Procedures shall be established and implemented to describe how changes in documents maintained in computerized systems are made and controlled.

3.4 REVIEW OF REQUESTS, TENDERS, AND CONTROL

The NDA service provider shall establish and maintain procedures for the review of requests, tenders, and contracts. Any differences between the request or tender and the contract shall be resolved before any work commences. The qualification status of the NDA service provider must also be reviewed. The NDA service provider must inform the client and/or end-user of the results of this review if it indicates any potential conflict, deficiency, lack of appropriate qualification status, or inability on the NDA service provider's part to complete the specified work. Each contract shall be acceptable to the NDA service provider, the client, and/or end-user.

The NDA service provider shall ensure policies and procedures are in place to review the content of NDA characterization contracts. These policies and procedures shall at a minimum address the following:

1. Contract DQOs and other requirements are to be clearly defined, documented, and understood.
2. A determination as to whether the NDA service provider has the necessary NDA instrumentation, personnel and information resources, and that the personnel have the skills and expertise necessary for the performance of the NDA characterization measurements as required per the contract.
3. The appropriate NDA measurement method(s) is available and capable of meeting the client and/or end-user DQOs and requirements.
4. Consideration of data and results obtained from applicable sources that could be utilized to objectively establish that a capability exists to meet the client and/or end-user DQOs and requirements, including the following:

    a) Previous participation in NDA capability and PEs,
    b) Success in similar NDA characterization contracts, and
    c) Computational methods and/or internal testing and confirmation of NDA measurement methods using test items of known value yielding objective documentation for accuracy, measurement uncertainties, detection limits, etc.

Records of NDA characterization contract reviews shall be maintained in addition to pertinent discussions regarding the client and/or end-user requirements or work results during the period of execution of the contract. For review of routine and other simple tasks, the date and the identification (e.g., initials) of the person responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial inquiry stage or on granting of the contract for ongoing routine work performed under a general agreement with the client and/or end-user, provided the

requirements remain unchanged. For new, complex, or advanced NDA measurement tasks, a more comprehensive record should be maintained.

The review shall cover any work that is subcontracted by the NDA service provider.

If a contract needs to be amended after work has commenced, the same contract review process shall be repeated, and any amendments shall be communicated to all affected personnel. Suspension of qualification, revocation of qualification, or voluntary withdrawal of qualification must be reported to the client and/or end-user.

3.5 SUBCONTRACTING OF NDA SERVICES

NDA service provider subcontracts may be necessary due to unforeseen reasons (e.g., workload, need for further expertise, or temporary incapacity) or on a continuing basis (e.g., through permanent subcontracting, agency or franchising arrangements). Any work placed with a subcontractor shall be pre-approved through the PPPO and meet the requirements of this QSNDA for the NDA characterization work. The subcontractor performing the work shall be indicated in the final report to the client and/or end-user.

The NDA service provider shall advise the client and/or end-user of any subcontracting arrangements and shall not use any subtier NDA service providers or sub-clients (including those possessing the same or similar corporate name) for performance of work without written concurrence from the PPPO.

The NDA service provider using a subtier NDA service organization or sub-client shall document and is responsible for ensuring that such subclient meets all requirements of this QSNDA, including being available for inspections and audits. Some clients and/or end-users may not allow any subcontracting to third party (subtier) NDA service providers. If this is the case, then it is to be specifically noted in the contract.

The NDA service provider is responsible to the client and/or end-user for any subtier work performed except in the case where the client and/or end-user or a regulatory authority specifies which subclient is to be used.

The NDA service provider shall maintain a register of all subclients that it uses for NDA characterization work and maintain a record of the evidence of compliance with this QSNDA.

3.6 PURCHASING OF SERVICES AND SUPPLIES

An NDA service provider considering procurement of NDA instrumentation, software, supplies, and services having a potential to affect NDA data quality shall evaluate the supplier before procurement activities. NDA service providers shall ensure newly procured items and services meet established technical and QA requirements and perform as specified. For PPPO projects, existing NDA instrumentation, software, and supplies under the control of the NDA service provider are grandfathered under this requirement. Prospective suppliers shall be evaluated and selected on the basis of documented requirements and associated criteria. Records of supplier evaluations are to be maintained and an approved supplier list kept current. The responsible organization shall verify that approved suppliers continue to provide acceptable items and services.

Commercial grade items (CGI) intended for use in nuclear safety applications should be procured in accordance with documented processes using recognized consensus standards (DOE G 414.1-2A *Quality Management System Guide*).

The NDA service provider shall have a policy and associated procedure(s) for the selection and purchasing of instruments, services, and supplies it uses that have a potential to affect NDA measurements and characterization data quality. Procedures shall exist guiding the purchase, receipt, and storage of NDA equipment, certified reference sources, software, consumable materials, etc.

The NDA service provider policy for the selection and purchasing of quality-related NDA services and/or supplies shall include requirements for the training of personnel involved in the evaluation, procurement, and inspection process.

3.6.1 Source Evaluation

The proposal or bid evaluation process shall include a determination of conformance to applicable procurement requirements. The evaluation shall be performed by designated, technically qualified personnel including the QA organization and shall include, at a minimum, the following:

- Technical considerations,
- QA program requirements,
- Supplier personnel skills,
- Supplier production capabilities,
- Supplier past performance,
- Alternatives proposed by the supplier, and
- Exceptions taken by the supplier

3.6.4 Supplier Selection

1. Supplier selection shall be based on evaluation of the supplier’s capability to provide items or services in accordance with procurement requirements.
2. The NDA service provider organization or persons responsible for supplier source selection shall be identified and include QA personnel as appropriate.
3. Measures for selecting procurement sources should include one or more of the following elements:

    a) An evaluation of the supplier’s history for providing an identical or similar product that performs satisfactorily in actual use,
    b) Evaluation of the supplier's current QA documentation supported by any documented qualitative and quantitative information, and
    c) Evaluation of the supplier’s technical and QA capability based on an evaluation of the supplier’s facilities, personnel, and quality program implementation.

4. Results of the procurement source selection shall be documented and maintained.

Before a contract is awarded, the purchaser shall resolve or obtain commitments to resolve deficiencies identified during the proposal or bid evaluation.

Supplier QA provisions shall be accepted by the purchaser QA management before the supplier is authorized to start work.

The NDA service provider shall ensure purchased equipment and supplies that affect NDA measurement quality are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the NDA measurements concerned. These

services and supplies used shall comply with specified requirements. Records of actions taken to verify compliance shall be maintained.

3.6.5 Procurement Documentation

Procurement documentation for items affecting NDA measurement quality shall contain information describing the items, services, and supplies under consideration. Purchasing documents shall be reviewed and approved for technical content before use. Procurement documents shall include the following as applicable to the item or service being procured:

1. Statement of work (SOW),
2. Technical requirements including the following:

    a) Design bases shall be identified or referenced,
    b) Specific documents (e.g., drawings, codes, standards, regulations, DOE orders, procedures, or instructions) that describe the technical requirements of the items or services to be furnished shall be identified. The revision level or change status of these documents shall also be identified, and
    c) Applicable tests, inspections, hold points, or acceptance criteria that the purchaser employs to monitor and evaluate the performance of the supplier shall be specified.

3. QA provisions specified by the purchaser QA organization shall include:

    a) The requisite QA and associated documentation requirements depending on the control level of the item or service being procured,
    b) The pass-down requirements the supplier shall incorporate into any sub-tier procurement document. When deemed appropriate, the purchaser may permit some or all supplier work to be performed under the purchaser QA program provided that the requirements are adequately implemented. In these cases, procurement documents shall specify that the purchaser's QA implementing procedures are applicable to the supplier and that the purchaser shall provide these documents to the supplier,
    c) Right of access to supplier facilities and records for inspection and audit by the purchaser or other designee authorized by the purchaser,
    d) Requirements and provisions for procurement document disposition if the supplier is required to maintain QA records,
    e) Requirements for the supplier to report nonconformances and obtain purchaser approval of supplier-recommended dispositions, and
    f) Spare and replacement parts or assemblies and the appropriate technical and QA requirements for ordering.

3.6.9 Procurement Document Review and Approval

1. The NDA service provider is responsible for review of the procurement documents and any changes thereto shall be made to verify that the documents include appropriate provisions to ensure items or services meet the prescribed requirements. Procurement document changes shall be subject to the same degree of control as the original documents.
2. Procurement document reviews shall be performed and documented before the document being issued to the supplier.
3. Reviews shall be performed by personnel who have access to pertinent information and who have adequate understanding of the requirements and scope of the procurement.
4. Procurement document reviews shall include representatives from the technical and QA organizations and shall be approved by responsible management.

3.6.10 Supplier PE

The NDA service provider shall establish measures to interface with the supplier and to verify supplier performance as deemed necessary. The measures shall include:

1. Establishing an understanding between the purchaser and supplier of the requirements and specifications identified in the procurement documents,
2. Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements,
3. Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement requirements,
4. Identifying and processing necessary change information,
5. Establishing the method to be used to document information exchanges between purchaser and supplier, and
6. Establishing the extent of assessment activities and inspection.

When there are indications that subcontractors knowingly supplied items or services of substandard quality or not consistent with specified requirements, such information shall be forwarded to appropriate management for action and notification to affected client and/or end-user.

3.7 SERVICE TO THE CLIENT/END-USER

The NDA service provider shall afford clients or its representative's cooperation to clarify the client's request(s) and to monitor performance in relation to the work performed.

3.7.1 Complaints

1. The NDA service provider shall have a policy and procedure for the resolution of complaints received from clients, end-users, or other concerned parties. Records shall be maintained of all complaints, investigations, and corrective actions taken by the NDA service provider.
2. The NDA service provider shall immediately notify affected clients and/or end-users of potential data confidentiality or quality issues. Corrective actions taken to resolve the issue shall be submitted to the client in a timely and responsive manner.

3.8 CONTROL OF NONCONFORMING NDA CHARACTERIZATION WORK

1. The NDA service provider shall have a policy and procedures that are implemented when any aspect of its NDA characterization work, or the results of this work, do not conform to its own procedures or the requirements of the client and/or end-user. The policy and procedures shall ensure that:

    a) The responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of analytical reports, as necessary) are defined and taken when nonconforming work is identified,
    b) Evaluation of the significance of the nonconforming work is made,
    c) Corrective actions are taken as soon as practicable including decisions regarding the acceptability of the nonconforming work,
    d) Where data quality is or may be impacted, the client and/or end-user is to be notified,
    e) Define how the analyst shall treat data if the nonconformances or QC measurements are unacceptable, and
    f) The responsibility for authorizing the resumption of work is defined.

2. To the extent possible, NDA measurement results shall be reported only if all QC and verification measures are acceptable. If a data quality measure is found to be out-of-control, and the data is to be reported, all NDA measurements associated with the failed data quality measure shall be reported with the appropriate NDA service provider defined data qualifier(s) and noted in the case narrative included with the verification package.
3. Where an evaluation indicates the nonconforming work could recur or there is doubt about the compliance of the NDA service provider's operations with its own policies and procedures, corrective action measures shall be promptly implemented.

3.9 CORRECTIVE ACTION

The NDA service provider shall establish policies and procedures and designated personnel for implementing corrective actions for nonconforming work or when departures from client and/or end-user requirements have been identified.

3.9.1 Cause Analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the deficiency.

3.9.2 Selection and Implementation of Corrective Actions

Where corrective action is needed, the NDA service provider shall identify potential corrective action(s). Written SOPs shall be in place for the notification of affected clients and/or end-user regarding nonconformances. A corrective action plan (CAP) shall be developed to address the deficiency or nonconformance. The corrective action(s) shall include documentation of steps taken to eliminate problems and/or to prevent recurrence.

1. The NDA service provider shall develop and submit a proposed CAP to the PPPO for concurrence before implementation of corrective actions where client and/or end-user data quality is affected. The client and/or end-user is also to be notified that the corrective action process has been initiated. The NDA service provider shall have a system for tracking, trending, and implementing lessons learned to prevent nonconformance recurrence.
2. Upon completion of the corrective action(s), the NDA service provider shall provide the results of the corrective action to the PPPO. The NDA service provider shall review the results of the CAP to ensure the corrective actions taken have been documented and adequately addressed the issue. The PPPO must concur with the results of the CAP and provide written concurrence to the NDA service provider to continue characterization activities as applicable. The NDA service provider shall document any required changes resulting from a corrective action investigation. The client and/or end-user is to be notified of the results of the PPPO CAP review status.
3. Corrective actions that have received PPPO concurrence must be implemented. Changes to the CAP must receive PPPO concurrence. Willful avoidance of corrective actions and implementation of corrective actions may result in work stoppage until the corrective action has been implemented.

3.9.3 Additional Audits

Where the identification of nonconformances or deficiencies cast doubt on the NDA service provider’s compliance with its own policies and procedures or on its compliance with this document, the NDA service provider shall ensure the appropriate areas of activity are audited as soon as possible.

3.10 PREVENTIVE ACTION

Preventive action is a proactive process intended to identify opportunities for improvement as opposed to reacting to the occurrence of problems or complaints.

1. Needed improvements and potential sources of nonconformances, either technical or concerning the quality system, shall be identified. If preventive action is required, plans shall be developed, implemented, and monitored to reduce the likelihood of the occurrence of such nonconformances and to take advantage of opportunities for improvement.
2. Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure their effectiveness.
3. Documentation of preventive actions shall be maintained for review.

3.11 RECORD REQUIREMENTS AND CONTROL

The NDA service provider shall maintain a record system compliant with applicable standards and regulations. The system shall produce unequivocal, accurate records that document NDA service provider activities.

3.11.1 Requirements

1. The NDA service provider shall establish and maintain procedures for the identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions. Records may be in any media, such as hard copy or electronic media.
2. The NDA service provider shall have procedures for the independent review of records, logbooks, and the like to ensure quality records are legible, accurate, and complete.
3. All records shall be legible and be stored and retained in such a way that they are readily retrievable in locations that provide a suitable environment to prevent damage, deterioration, or loss.
4. The NDA service provider shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to, or amendment of, such records.
5. All generated data, except those generated by automated data collection systems, shall be recorded directly, promptly, and legibly in permanent ink.
6. Documentation of changes made to data (either hardcopy or electronic) shall include the identification of the person who authorized the change. When mistakes occur in records, each mistake shall be crossed out – not erased – made illegible, or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction. In the case of records stored electronically, changes to data or files shall include the identification of the authorizing person. When corrections are because of reasons other than transcription errors, the reason for the correction shall be documented. If not self-explanatory, corrections to quality records shall also include a justification for the change.
7. All quality and analytical records shall be retained per DOE requirements from generation of the last entry in any given record. The PPPO shall be notified before the planned disposal of records. The method of disposal/destruction shall be specified. Written approval/concurrence must be received from all affected clients and/or end-users before disposal of any records associated with PPPO analytical data.
8. All records shall be held secure and in confidence unless specifically exempted.
9. The NDA service provider shall have a plan to ensure the records are maintained or transferred according to client and/or end-user instructions in the event the NDA service provider transfers

ownership or goes out of business. In addition, in cases of bankruptcy, appropriate regulatory and state legal requirements concerning records must be followed.

3.11.2 Records Management and Storage

The record keeping system must allow historical reconstruction of all NDA service provider activities, both administrative and technical, that contributed to the production of client and/or end-user information and data.

1. All records (including those pertaining to NDA instrumentation), certificates, and reports shall be safely stored, held secure, and in confidence to the client and/or end-user.
2. The record keeping system shall facilitate the retrieval of all working files and archived records for inspection and verification purposes (e.g., set format for naming electronic files).
3. Records control system SOPs shall address the requirements for access to and control of the files, including accountability of records removed from the storage location.
4. Access to archived data and information shall be documented with an access log. These records shall be protected against fire, theft, loss, environmental deterioration, vermin, and, in the case of electronic records, electronic or magnetic sources.
5. The NDA service provider shall establish a record management system for control of laboratory notebooks, instrument logbooks, NDA field worksheets, standards logbooks, instrument calibration, analytical methods, validation, storage, and reporting.
6. Records stored only on electronic media must be supported by the hardware and software necessary for their retrieval.
7. Records stored or generated by computers or personal computers shall have hard copy or write-protected backup copies.
8. Dual storage at a separate location is considered an acceptable option for protecting records from loss because of fire, theft, and/or other forms of record loss.

3.11.2.1 Administrative records

The following administrative records shall be maintained:

1. Personnel qualifications, experience, and training records,
2. Records of demonstration of capability,
3. Log of names, initials, and signatures for all individuals responsible for signing or initialing any NDA characterization record,
4. Procurement records,
5. Program documentation, including but not limited to the QA plan and SOPs,
6. Audits and surveillances,
7. Management reviews, and
8. Pertinent correspondence with PPPO, client, regulatory agencies, and other entities regarding the NDA characterization project.

3.11.2.2 Technical records

The NDA service provider shall retain records of original NDA measurement data, derived data, calibration records, technical manuals and procedures, staff records (including training and proficiency), a copy of each NDA measurement report issued, and related quality records. NDA measurement records shall contain sufficient information to reproduce the measurement configuration and analysis process to allow the NDA measurement and data results to be repeated. The NDA measurement configurations, data reduction, reports, technical reviews, validation, and so on must be readily understood per the

documentation. Records shall be complete to the extent that an audit trail can be readily constructed. Technical information and data to be retained includes but is not limited to:

1. All information and data concerning but not limited to NDA instrumentation, analytical methods, calibrations, measurement configurations, raw data, reduced data, software name and version, and data V&V associated with the project at hand shall be documented.
2. Measurement item description, identification code, volume, net/gross weight, and instrument printouts. Volume and/or gross/net weight are exempted where they are not applicable to the end result (e.g., enrichment measurements).
3. Description or reference to the NDA method used, including a reference to computational steps used to reduce acquired data and information into a reportable analytical value.
4. All original raw data, whether hardcopy or electronic, for calibrations, NDA measurements, and associated QC measures, validations, NDA field worksheets, analysts' worksheets, log books, manual calculations, and data output records.
5. NDA measurement data and supporting analyses shall be recorded as of the date and time they are made and shall be identifiable and related to an identifiable task. Records shall include the identity of personnel involved in NDA measurement acquisition, analyses, reviews, and so on, as applicable.
6. Results of data review, V&V, and cross-checking procedures.
7. Copies of final NDA data reports, batch QC reports and data verification packages.
8. Technical correspondence relating to NDA characterization activities for a specific project.
9. All corrective action reports, audits, and audit responses.
10. Independent PE participation and results.

NDA service providers shall establish a review frequency for all laboratory notebooks, instrument and radioactive standard logbooks, procedures for data acquisition/reduction, validation, verification, and record archival. The review frequency shall be determined and documented. Documentation of the reviews shall be maintained and available for review. Where hand-written logbooks are used, permanent, bound laboratory notebooks (logbooks) are required and loose leaf binders shall not be used. Each logbook shall have a unique serial number clearly displayed. Logbooks shall have sequentially numbered pages, have entries that are signed by the person responsible for performing the activity at the time the activity is performed, and have entries in chronological order. All logbook pages must be closed when the activities documented are completed or carried over to another logbook page. The person responsible for performing the closure shall be the one who performed the last activity documented. Closure shall occur at the end of the last activity performed or as soon as practicable thereafter.

3.11.3 NDA Service Provider Measurement Item Tracking

The NDA service provider shall develop and implement a measurement item identification and tracking system. Measurement items are individual containerized waste packages or process components. Records of all procedures the measurement item is subjected to while in the possession of the NDA service provider shall be maintained. These records include item identification, date of measurement, measurement result report, and other pertinent data.

3.12 INTERNAL AUDITS

1. The NDA service provider shall annually conduct internal audits of its activities to verify that its operations continue to comply with the quality system requirements of its own QA plan and this document. The internal audit program shall address all elements of the quality system, including NDA measurement and characterization activities. It is the responsibility of the quality manager to plan and organize audits on a frequency as specified in the QA plan and as requested by management.

Such audits shall be carried out by trained and qualified personnel who are independent of the activity to be audited.

2. Management shall ensure sufficient resources are available so that all internal audits are conducted by personnel independent of the activity under audit. Personnel conducting independent assessments shall have sufficient authority, access to work areas, a clear understanding of the observed activities, and organizational freedom necessary to observe all activities affecting quality and to report the results of such assessments to management.
3. When audit findings cast doubt on the operational effectiveness or on the correctness and validity of the NDA measurement results, the NDA service provider shall take timely corrective action and notify PPPO, client and/or end-users in writing if investigations show the NDA results may have been affected. The NDA service provider must specify in the QA plan the time frame for notifying the PPPO, client and/or end-user of events that cast doubt on the result validity.
4. The NDA service provider shall immediately notify PPPO, client and/or end-user in writing of potential data quality issues. A CAP shall be devised and be submitted to PPPO in a timely manner, identifying corrective actions taken to resolve the issue. The results of the CAP shall be documented and provided to PPPO for concurrence.
5. The area of activity audited, audit findings, and corrective actions that arise from findings shall be recorded. The NDA service provider management shall ensure these actions are discharged within the agreed time frame as indicated in the quality manual and/or SOPs.
6. Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

3.13 MANAGEMENT REVIEW

The Management Review shall not be performed in lieu of an internal audit. The management review is an independent executive review.

1. In accordance with a predetermined schedule and procedure, the NDA service provider's executive management shall periodically, and at least annually, conduct a review of the NDA service provider's quality system and NDA characterization activities to ensure their continuing suitability and effectiveness and to introduce necessary changes or improvements. The review shall take account of:

    a) The effectiveness and implementation of policies and procedures,
    b) Reports from managerial and supervisory personnel,
    c) The outcome of recent internal audits,
    d) Corrective and preventive actions,
    e) Audits and assessments by external agencies,
    f) The results of all PE and proficiency tests,
    g) Changes in the volume and type of the work,
    h) PPPO, client, and/or end-user feedback,
    i) Complaints, and
    j) Other relevant factors such as QC activities, resources, and staff training.

2. Management review shall also include facility H&S, hazardous, and radioactive material management functions.
3. Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure those actions are carried out within an appropriate timescale. The NDA service provider shall have a procedure for review by management and maintain records of review findings and actions.
4. The NDA service provider, as part of its overall internal auditing program, shall ensure a review is conducted with respect to any evidence of inappropriate actions or vulnerabilities related to data

integrity. Discovery of potential issues shall be handled in a confidential manner until such time as a follow-up evaluation, full investigation, or other appropriate actions have been completed and the issues clarified. All investigations that result in finding of inappropriate activity shall be documented and shall include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients. All documentation of these investigations and any actions taken shall be maintained for at least five years.

4. TECHNICAL REQUIREMENTS

4.1 GENERAL

NDA methods as applied to waste containers and process components can be complex measurements depending on the number of instrument response variables associated with the item of interest. It is therefore critical to the assurance of data quality that all components affecting an NDA measurement be considered and appropriately addressed. Factors affecting NDA measurement accuracy and uncertainty range from the waste form or process component composition and configuration to the competency of NDA personnel.

The extent to which waste form and process component matrix/source configurations affect NDA measurement accuracy and uncertainty differs among NDA methods, gamma and neutron, and the manner in which that method is implemented. Regardless of the measurement technique employed, the NDA service provider shall take account of all significant bias and precision uncertainty components. It is expected this will be performed by developing a thorough understanding of the waste form and process component configurations of interest, development and implementation of NDA measurement techniques and procedures, the traceable calibration of NDA instrumentation, QC measures, data validation, and the training/qualification of NDA personnel. This section addresses technical requirements the NDA service provider must address as in its quality system to assure data quality.

4.2 NDA PERSONNAL TRAINING AND QUALIFICATION

Personnel involved in the NDA characterization process shall be trained and qualified to ensure they are capable of performing their assigned tasks and that their job proficiency is maintained.

1. The NDA service provider shall evaluate and establish personnel qualification requirements for project positions or job functions as necessary to execute NDA characterization activities. These positions include managers, technique developers, scientists, engineers, analysts, operators, maintenance personnel, technicians, independent assessment personnel, and inspectors. The evaluation and resulting personnel qualification requirements for identified job positions shall be documented. To this end the NDA service provider shall:

    a) Analyze each job position to define the degree of qualification in terms of education, experience, skills, training prerequisites, and responsibilities for all NDA characterization functions. Job specific qualifications shall be commensurate with the scope, complexity, and nature of the NDA characterization work.
    b) Ensure personnel selected to fill NDA job positions have the necessary education, experience, and training per established requirements. The qualification of an individual shall be based upon an evaluation of education level, training, type and duration of experience, and demonstrated skills. The results of this evaluation are to be compared to the established requirements for the job position to determine and document qualification.

2. The NDA service provider shall maintain current job descriptions for all personnel who manage, perform, or verify work affecting the quality of NDA measurements, analysis, and reporting.
3. The NDA service provider shall have sufficient personnel to support the NDA characterization task as defined in the contract. Each staff member must have the necessary combination of education, experience, training, technical knowledge, and demonstrated skills applicable to their particular function.

4. The NDA service provider shall ensure all personnel including part-time, temporary, contracted, and administrative personnel are trained in applicable QA and H&S programs. Training shall emphasize the correct performance of work, describe why the applicable quality and safety requirements exist, and describe the fundamentals of the work and the context.
5. The training program shall be subject to ongoing review to determine instruction and training program effectiveness and shall be upgraded whenever needed improvements or enhancements are identified. The NDA service provider shall:

    a) Ensure personnel receive indoctrination and training, including on-the-job and hands-on training as needed to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, job responsibilities and authority, and QA implementing procedures before performing any NDA characterization tasks.
    b) Ensure the competence of all staff that develop techniques, data reduction methods, calibration regimens, perform NDA measurements, analyze acquired data, perform QC checks, QA assessment and oversight, operate equipment, manage records, and so on.
    c) Authorize specific personnel to develop data acquisition and reduction techniques, NDA calibrations, perform NDA measurements, analyze data, issue data reports, perform data validation, perform data verification, provide expert interpretations, and so forth. Only appropriately trained and qualified personnel shall be allowed to perform NDA measurements. Standardized training requirements for NDA personnel should be based upon existing industry standardized training requirements (e.g., American Society for Testing and Materials [ASTM] C1490, *Standard Guide for Selection, Training and Qualification of Nondestructive Assay [NDA] Personne*l). Requalification of NDA personnel shall be based upon evidence of continued satisfactory performance and must be performed at a frequency as determined and documented by the NDA service provider.
    d) Ensure the production and maintenance of records generated during general indoctrination, training, and qualification are collected and maintained as QA records. The NDA service provider shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills, and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.
    e) Besides personnel education, training, skill, and experience records, the NDA service provider shall maintain records on demonstrated proficiency for each NDA measurement technique. Qualification records should include up-to-date documentation of the following:

        i. Evidence demonstrating each employee has read, understood, and is using the latest version of the NDA service provider's in-house quality documentation which relates to his/her job responsibilities.
        ii. Training courses or workshops on specific equipment, analytical techniques, or procedures.
        iii. General knowledge of NDA characterization operations, NDA techniques, NDA QA/QC procedures, QA measures, and records management.
        iv. Detailed analyst training records. Analyst training shall be considered current if an employee training file contains certification that such personnel have read, understood, and agreed to perform NDA measurements per the current approved method(s) or SOP(s). Analyst proficiency shall be demonstrated initially and annually thereafter. Analyst training shall be adjusted as appropriate if significant changes to NDA methods and procedures occur. The method the NDA service provider uses to determine proficiency and associated performance criteria shall be documented.

6. When staff members are undergoing training, appropriate supervision shall be provided.

7. Data integrity shall be evaluated to determine the data can be reproduced and that the data reported was based on approved measurement procedures. Additionally, QA procedures are to determine if any fraudulent or improper practices were being performed by scientists, technicians, engineers, analysts, and managers.
8. Data integrity training shall be provided as a formal part of new employee orientation and on an annual basis for all current employees. Key topics covered during training must include organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting, how and when to report data integrity issues, and record keeping. The training shall include discussion regarding all data integrity procedures, data integrity training documentation, in-depth data monitoring, and data integrity procedure documentation. Employees are required to understand that any infractions of data integrity procedures will result in an investigation that could lead to consequences, including immediate termination or civil/criminal prosecution. The initial data integrity training and the annual refresher training shall have a signature attendance sheet or other form of documentation demonstrating that all staff have participated and understand their obligations related to data integrity. Senior managers acknowledge their support of these procedures by:

   a) Upholding the spirit and intent of the organization's data integrity procedures and
   b) Effectively implementing the specific requirements of the procedures.

   Specific examples of breaches of ethical behavior should be discussed, including improper data manipulations, adjustments of instrument, time clocks, and inappropriate changes to calibrations. Data integrity training requires emphasis on the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful but are in one sense or another partially deficient. The data integrity procedures may also include written ethics agreements, examples of improper practices, and examples of improper data manipulations, requirements for external ethics program training, and any external resources available to employees.

9. The NDA service provider shall use personnel employed by or under contract to the NDA service provider. Where contracted and additional technical and support personnel are used, the NDA service provider shall ensure that such personnel are supervised and competent and that they work in accordance with the NDA service provider's quality system.

4.3 NDA MEASUREMENT SYSTEM ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

The staging of an NDA measurement system must consider the logistic requirements related to movement of NDA measurement items to and from the instrument as well as environmental factors such as sources of radio frequency (RF) and temperature variations. Every reasonable effort shall be invested to eliminate or control these variable environmental factors. Methods to control or monitor these factors shall be implemented in SOPs to ensure data quality. These methods include but are not limited to:

1. Effective separation between neighboring areas in which there are incompatible activities. This includes keeping the NDA measurement area removed to the extent practicable from waste storage areas or lanes where wastes are transported to prevent unwanted background or fluctuations thereof.
2. Real-time or portable radiography activities shall be well removed from areas where NDA measurements are conducted or controlled so as not to interfere with ongoing NDA measurements.
3. The location of fixed NDA measurement systems should be climate controlled to minimize or eliminate the impact of environmental variation on the response of the NDA system.
4. Sources of RF should be evaluated before staging of a fixed NDA measurement system. Typical sources include two-way radios, variable speed electric motor controllers, and other sources.

5. Measures shall be taken to ensure the NDA measurement area is not contaminated over time, thereby introducing additional complications to data acquisition and analysis. If contamination is accumulating to the point of becoming an interference problem to NDA measurements and analysis, the NDA service provider shall have a plan in place to identify and eliminate the source and implement measures to prevent recurrence.
6. The NDA facility shall have a safety inspection program in place that includes routine walk-downs of NDA measurement areas for safety-related concerns.
7. Measures shall be taken to ensure good housekeeping in the NDA measurement area.
8. Work spaces must be available to ensure an unencumbered work area. Work areas include access and entryways to the NDA measurement area and office areas and data handling and storage area(s).

4.4 DQOs

DQOs are determined by and derived from the defined needs of the client and/or end-user. The NDA service provider is to understand the DQOs and requirements and select or develop measurement methods that will ensure compliance. The DQOs are determined from the requirement and need statements as contained in the client and/or end-user contract documentation. It is the responsibility of the NDA service provider to evaluate the client and/or end-user requirements, needs, and DQOs in terms relevant to its current NDA capability. Assistance regarding the determination of DQOs can be found in the EPA document, "*Guidance for the Data Quality Objectives Process*," EPA-QA/G-4 or equivalent document. DQOs may require adjustment through time as regulatory, client and/or end-user requirements change. The DQO process shall address internal regulatory driven needs of organizations such as NMC&A, NCS, and security. Documentation of changes or adjustments to established DQOs shall be clearly documented. Concurrence between the NDA service provider, client, and/or end-user and other affected parties shall be documented.

1. DQOs for management of radioactive materials are typically specified in terms of a set of radionuclides and other characteristics (e.g., enrichment) for which quantification and reporting is required. The client and/or end-user DQOs are commonly expressed in terms of an allowable measurement uncertainty and minimum detectable quantities at a stated confidence level. A client and/or end-user DQO may specify the allowable uncertainty on a per measurement item or waste container population basis (as a function of activity concentration) as a specified confidence that a given limit is not exceeded.
2. The NDA service provider shall understand and document the client and/or end-user DQOs associated with the NDA characterization task. The client and/or end-user shall receive written confirmation of the NDA service providers' interpretation and understanding of the DQOs. The statement of DQO understanding may be either in client and/or end-user correspondence or included in the NDA service provider's quality plan or related documentation. The client and/or end-user must concur in writing with the DQOs as interpreted, understood, data reporting units and format, and documented by the NDA service provider.
3. Based on an agreement among the client and/or end user and the NDA service provider regarding the content and meaning of the established DQOs, the NDA service provider is to propose a format and content for the NDA data report (see Section 4.13.1). The end user shall evaluate the proposed reporting format and content ensuring that it supplies information and data necessary to comply with and meet its data needs. The NDA characterization report format and content shall be agreed upon among the client and/or end user and NDA service provider and documented.

4.5 NDA MEASUREMENT METHODS AND METHOD VALIDATION

The NDA service provider shall use appropriate NDA methods for characterization of waste form and process component measurement item configurations addressed in the scope of work. This includes

staging of measurement items for data acquisition, analysis of acquired data, estimation of measurement uncertainty, QC checks, use of statistical techniques for analysis of QC data, data validation, and other methods. All relevant instructions, standards, manuals, operator aids, and reference data shall be kept current and be readily available to NDA personnel. The NDA service provider shall develop SOPs for each measurement method used. When available, these SOPs shall comply with nationally or internationally recognized standards for the measurement method (e.g., ASTM or American National Standards Institute [ANSI] standards). Deviation from established NDA measurement methods is permitted only if documented, technically justified, authorized, and accepted by the PPPO.

4.5.1 Method Selection

The NDA service provider shall use NDA measurement methods which are commensurate with the NDA characterization task at hand, project DQOs, and other client and/or end-user requirements. Sources of NDA methods include but are not limited to the following:

1. Methods published in international or national standards (ANSI, ASTM) by reputable technical organizations in relevant scientific texts or journals as specified by the manufacturer of the NDA instrumentation. If using a technical standard, the NDA service provider shall ensure it uses the latest valid edition of the standard when developing a SOP. When technical standards change, an evaluation of the changes shall be made with respect to impact on implemented NDA measurement practices. If the standard or guidance document is modified for use, such shall be noted and documented.
2. Methods developed by the NDA service provider or other adopted methods may be used if appropriate for the intended use and concurred by the PPPO. If one or more NDA measurement methods are developed by the NDA service provider, it shall be a planned activity and shall be assigned to and managed by qualified personnel who are supported and equipped with adequate resources.
3. When the client does not specify an NDA method or where there is no national standard or guidance document, method(s) to be employed shall be fully documented and validated and be available to the PPPO.
4. When specific NDA methods for characterization are mandated or requested by the PPPO or client, only those methods shall be used.

4.5.2 NDA Method Manual(s)

The NDA service provider shall have and maintain in-house method manual(s) or equivalent document for each NDA measurement method used to generate data for the client and/or end-user. Manuals shall be derived from published NDA measurement methods or internally developed methods properly documented. In cases where modifications to the published method have been made by the NDA service provider, where portions of the published method are not applicable for the planned measurements, or where the referenced NDA method is ambiguous or insufficient in detail, changes or clarifications shall be clearly described and documented. The method manual may also be incorporated into a SOP provided adequate detail to fully describe the method is included. Each NDA method shall include or reference the following as applicable:

1. Identification of the NDA measurement method,
2. Summary of the NDA method,
3. Method scope and application,
4. Compatible containerized waste and process component geometries and matrices,
5. Methods of determination for detection limits and minimum detectable values,
6. Sources of interference for the expected application and radionuclide(s),

7. Calibration techniques and standards needed to perform calibrations,
8. Description of data acquisition and reduction techniques used,
9. Measurement uncertainty determination technique,
10. Calibration confirmation method and performance information and data for source/matrix configurations nominally representative of the actual measurement item population,
11. QC techniques, data assessment and acceptance criteria for QC measures,
12. Description of verification process,
13. Description of data reporting and approval process
14. Corrective actions for out-of-control data,
15. Contingencies for handling out-of-control or unacceptable data,
16. Safety considerations,
17. Applicable tables, diagrams, flowcharts, and confirmation data,
18. Data validation method, and
19. References.

Method manuals/SOPs shall be approved, maintained current, available, and controlled documents.

4.5.3 SOPs

1. The NDA service provider shall develop and maintain NDA measurement method implementing SOPs governing NDA characterization activities within it scope of work. SOPs shall be written and approved and issued for the conduct of NDA measurements, NDA instrument calibration and maintenance, NDA measurement QC, data reduction, verification, reporting, and validation.
2. SOPs shall be internally written documents that implement instructions provided in NDA manufacturer manuals accepted national standards or techniques developed in-house. Regardless of the source of the technical method, if it serves as an NDA acquisition and analysis procedure contributing to the generation of end user data, it must be clearly labeled as a SOP and incorporated into the document control system.
3. Each SOP shall clearly indicate the effective date of the document, the revision number, and the signature(s) of the approving authority.
4. SOPs shall be organized and kept current and accessible to all personnel involved in the NDA characterization work.
5. All SOPs shall be reviewed on a frequency or as-needed basis determined by management to ensure applicability with the current regulatory environment, technical applicability, and consistency with other QSNDA documentation (e.g., quality plan).

4.6 NDA SYSTEM INSTRUMENTATION AND SUPPORT EQUIPMENT

The NDA measurement facility shall have NDA instrumentation and support equipment necessary to carry out the NDA characterization activities associated with the contract SOW. In those cases where the NDA service provider needs to use equipment outside its permanent control, it shall ensure the requirements of this QSNDA are met relative to equipment and/or services.

NDA measurement instrumentation and associated software shall be capable of achieving the client and/or end-user requirements and needs per the scope of work. Before being placed into service, NDA instrumentation shall be initially calibrated or the previously determined calibration confirmed to ensure applicable client and/or end-user requirements are met. Calibration requirements are divided into two parts:

1. Requirements for the NDA measurement system calibration, which are divided into an "initial" NDA measurement system calibration, a calibration confirmation performed on an annual basis at a minimum, and a periodic operational "verification" of the NDA measurement system calibration.
2. Requirements for analytical support equipment.

4.6.1 NDA Measurement System Calibration

This section concerns traceable NDA measurement system "initial calibration" for measurement of radioactive material in containerized wastes and process components and the continuing confirmation of such. Procedures shall be developed and implemented for NDA measurement system calibration methods and processes. For the purposes of this QSNDA, the term calibration is referred to and defined in three separate ways: 1) initial calibration, 2) calibration confirmation, and 3) calibration verification.

The "initial calibration" is that fundamental calibration that addresses and accounts for the response of an NDA measurement system to radioactive materials present in the waste containers or process components of interest (measurement items). The "calibration confirmation" is a thorough corroboration of the "initial calibration" using traceable WRMs and representative waste matrix/process component configurations. The "calibration verification" is a periodic verification of the "initial calibration" to ensure on-going long-term data quality compliance through the period of NDA operations.

Detailed procedural steps for calibration are not specified here. However, those elements that must be considered during the "initial calibration," "calibration confirmation," and periodic "calibration verification" are enumerated. This allows the NDA service provider autonomy in devising and implementing techniques and analytical procedures for these three calibration definitions. Through these three mechanisms, the NDA service provider shall demonstrate the calibration and associated uncertainty is compliant with applicable client and/or end-user requirements and objectives initially and throughout the contract period.

4.6.1.1 Initial NDA system calibration

An NDA measurement system "initial calibration" shall be performed to ensure the measurement system response provides valid data of known quality. Calibrations shall be performed using traceable WRMs obtained from suppliers maintaining a nationally recognized reference base and an accredited measurement program. Full documentation of the calibration technique, process, and results is required. For cases where there is an insufficient number and denomination of traceable radioactive material standards to support the "initial calibration," the NDA service provider can develop alternate calibration strategies based on available resources. This strategy must have the documented PPPO concurrence.

The development and establishment of an "initial calibration" shall address the following as applicable:

1. SOPs shall be in place to specify steps/activities necessary to develop and determine the "initial calibration," including but not limited to specification of traceable radioactive sources or their alternates, geometrical positioning of sources, traceable source/matrix media configurations, acquisition of NDA system response data, computational methods, analysis of response data to determine a robust calibration, calibration acceptance criteria, calibration applicability and qualifiers, and calibration uncertainty.
2. The "initial calibration" shall be performed through the use of traceable WRMs unless exceptions are granted. For mass calibrations (i.e., calibrations that use a direct measurement of the same isotopes, matrices, and containers that will subsequently be measured in unknown items), the radioactive material mass and matrix characteristics must span and bracket the range of anticipated values for measurement items. For calibrations based on instrument response modeling, sufficient information

shall be provided in the method description and calibration regimen to assure that the calibration measurements and model appropriately spans and brackets the anticipated analysis space (e.g., provide mechanisms to account for anticipated geometries, radioactive material mass, chemical composition, and matrix characteristics). For enrichment determinations using the enrichment meter technique, the initial calibration must span the range of enrichments in anticipated unknown item measurements.

3. The measurement uncertainty associated with the application of the "initial calibration" shall be established and documented using a sound and technically defensible technique. Methods for the estimation of total measurement uncertainty (TMU) shall be developed and documented. Where applicable, the calibration uncertainty shall include terms for mass, matrix characteristics, and configurations. These methods shall consider at a minimum uncertainty components, the calibration uncertainty model (method of uncertainty component propagation), estimates of uncertainty introduced by differences between item characteristics, and calibration modeling assumptions. For example, if the model assumes homogeneous distribution of the isotope of interest, the uncertainty introduced if items are not homogeneous using a worst-case distribution determined by a documented engineering judgment with supporting data must be determined.
4. The NDA measurement method capability related to each initial calibration must be defined and documented. As applicable, this capability includes waste matrix types, process equipment types, geometries, configurations, radioactive material types, matrix density range, hydrogenous material range, radioactive material mass range, radioactive material compound, and other parameters affecting instrument response. The intent of defining the capability is to delineate where the calibration is applicable and where it is not.
5. Where surrogate materials are used to simulate waste matrices, their configuration(s) must be nominally representative of the actual waste item population. The design of surrogate matrix configurations must be documented. Surrogate materials used to produce a given matrix configuration shall be carefully specified, procured, and the resultant physical properties and configuration documented.
6. If NDA method manuals, national standards, or a mandated NDA calibration method do not specify the number of traceable WRMs to span the mass/activity and radioactive material compound(s) characteristics of the waste/process component, a minimum number must be determined and technically justified. This requirement does not apply to NDA methods that rely on modeling to address mass/activity and other radioactive material and waste matrix or process component characteristics. The NDA service provider must document this number and the denominations in a calibration SOP or other applicable document.
7. For NDA methods that do not necessarily require calibration with source material similar in nature to the waste or process items (e.g., neutron counting), those source(s) used are still required to be traceable and not the same as used for the "initial calibration." However, accounting of the efficiency variation because of the composition of the actual waste radioactive material shall be assessed and corrected for (e.g. californium (Cf)-252) fission neutron spectrum counter efficiency versus uranyl fluoride (UO_2F_2) neutron spectrum efficiency.
8. The "initial calibration" process shall be clearly documented, including the calibration measurement configurations, data acquisition parameters, acquired data, data reduction methods, resultant calibration factors or expressions, and statistical analysis. Records containing information pertinent to the calibration process shall be retained including but not limited to WRM and/or surrogate waste matrix configurations used to acquire instrument response data, calibration determination techniques, SOP(s) used, data acquisition parameters, NDA system identification, analytical software used, traceable standard identifications, analytical support equipment information, and electronic file storage locations. Records shall be sufficient to allow reproduction of the "initial calibration."
9. The initial calibration shall be re-established when repairs or changes are made to the measurement system that is likely to affect one or more calibration parameters. Examples that may require repeating the initial calibration include but are not limited to the following:

a) Major NDA system repairs or modifications,
b) Replacement of vital NDA measurement system components (e.g., collimator, multi-channel analyzer [MCA], and neutron generator),
c) Change in collimator depth and/or aperture not accounted for in a model, and
d) Significant software modifications and/or changes.

4.6.1.2 Calibration confirmation

A confirmation of the "initial" NDA measurement system calibration shall be performed. In this context, confirmation means the "initial calibration" shall be assessed and determined to be correct and true by the objective collection of evidence supporting the calibration was correctly established.

1. The "calibration confirmation" process is to produce objective evidence demonstrating the applicability and correctness of the "initial" calibration relative to the waste forms and process components of interest. The recommended method is to assemble test item(s) consisting of source/matrix configuration(s) nominally representative of the waste form and process components to be characterized. They cannot be the same configurations used to establish the "initial calibration." They must contain a known and traceable radioactive element/isotope mass/activity and/or enrichment in a known and representative configuration. The confirmation test item(s) are then measured using the "initial calibration" of the NDA system. The number of differing test item configurations used to confirm the calibration is to be determined by the NDA service provider and documented. The reported "calibration confirmation" measurement result must agree (with criteria as established by the NDA service provider) with the known element/isotope mass/activity and/or enrichment of the confirmation test item(s). The NDA service provider acceptance criteria shall not exceed the bias and precision criteria as presented in Section 4.6.1.3.
2. The radioactive sources used for "calibration confirmation" purposes shall to the extent practicable be representative of the actual radioactive material compositions and chemical compounds as found in the waste item inventory of interest.
3. Radioactive material standards used for "calibration confirmation" are to be traceable to a nationally recognized reference base (e.g., National Institute of Standards and Technology [NIST] or New Brunswick Laboratory [NBL]). The traceable standards used for "calibration confirmation" shall not be related to (from the same feedstock or lineage) those used to perform the "initial calibration." Should there be a lack of traceable standards to comply with this requirement, the NDA service provider can submit a request for a waiver to the PPPO. The PPPO can set the expiration period of the waiver not to exceed three years. After expiration of the waiver, if the noncompliance issue still exists, the NDA service provided will have to resubmit for a PPPO waiver.
4. Calibration confirmation acceptance is assessed through the degree of agreement between the known "calibration confirmation" test item value and that as determined in the NDA confirmation measurement result. The NDA service provider is to determine the "calibration confirmation" source/matrix surrogate configuration(s). The NDA service provider should also consider developing bias and precision acceptance criteria specific to the NDA system and the measurement items under consideration. Upper limit PPPO imposed "calibration confirmation" measurement regimen and acceptance criteria are delineated in Section 4.6.1.3.
5. Calibration confirmation results outside the NDA service provider defined criteria found in Section 4.6.1.3 require implementation of corrective actions as applicable. Under no circumstance are "calibration confirmation" results to exceed the maximum allowable acceptance criteria unless a specific exception is provided by the PPPO. Where the NDA service provider proposes confirmation acceptance limits greater than the Section 4.6.1.3 limits, there must be a clearly documented technical justification that has PPPO concurrence.

6. For the case where a corrective action was required and subsequently implemented, the "calibration confirmation" process is to be repeated. Acceptable results must be obtained and documented before the NDA system is put back into operation. Where a "calibration confirmation" failure was determined to be because of a minor issue (e.g., wrong constant, wrong efficiency file used, or an inappropriate test item), the entire "calibration confirmation" measurement regimen may not need to be repeated. This is acceptable provided it is documented and the corrective action is documented and has PPPO concurrence. All corrective actions and their effects, supporting data, results, approvals/concurrences, and the like shall be documented and retained.
7. In the case where the "calibration confirmation" was acceptable for certain types or categories of radioactive material/matrix configurations but unacceptable for other categories having differing source/matrix properties, conditional acceptance of the "calibration confirmation" can be made. The NDA service provider; however, must clearly identify which categories of source/matrix configurations are approved for NDA measurement and which are not. The technical basis for accepting certain source/matrix categories shall be documented and available for review. The client and/or end-user shall be notified of those source/matrix categories having conditional approval. Recalibration or corrective action efforts shall be implemented and documented for source/matrix categories not meeting acceptance criteria for "calibration confirmation."
8. The "calibration confirmation" process shall be performed on a periodic basis, at least annually, as determined by the NDA service provider or when there are indications warranting a re-assessment of the "initial calibration," e.g., the source/matrix configuration of measurement items varies from the source/matrix configurations used to develop the "initial calibration." Additional causes for performing a "calibration confirmation" include:

    a) Major NDA system repairs or modifications,
    b) Replacement of NDA measurement system components (e.g., detector, neutron generator, or supporting electronic components that have the potential to affect data quality),
    c) Re-calibration,
    d) Significant changes to the NDA system software, and,
    e) Relocation of the system (applies to fixed stationary systems).

9. Records must be retained to permit reconstruction of any NDA measurement system "calibration confirmation," (e.g., NDA method, measurement system configuration, confirmation date, primary radioactive isotope(s), mass or concentration and response, calibration factor(s), or equations/coefficients used to convert NDA instrument response to mass/concentration). Documentation must explicitly connect the "calibration confirmation" data/records to the "initial calibration."

4.6.1.3 Calibration confirmation acceptance criteria

Bias and precision limits are used to determine the acceptability of "calibration confirmation" measurements. The limits specified in this QSNDA are PPPO upper limits intended to be applied to all NDA measurement techniques over all waste matrix and process component configurations. The PPPO "calibration confirmation" limits are not specifically tied to a client or end-user DQO or requirement, but rather they are nominal performance levels expected of NDA systems used in the PPPO program. Failure to comply with these bias and precision limits is used as an indicator to the PPPO and NDA service provider that more capable measurement techniques need to be developed.

NDA measurement system bias and precision should be determined through the acquisition of replicate measurements using waste matrix container and/or process component mock-ups combined with traceable WRMs. The source/matrix configurations are to be representative of the actual measurement item

population. The number of different source/matrix test configurations and replicate measurements of each shall be determined by the NDA service provider and documented.

The calibration confirmation bias is to be determined in any manner deemed suitable by the NDA service provider, e.g., %Bias [(mean measured value - known value)/known value]*100, percent recovery (%R) (mean measured value/known value)*100, etc. The bias shall not be outside the limits as described in Table 1.

Precision is reported as percent relative standard deviation (% RSD). The %RSD shall not exceed the value tabulated in Table 1. The NDA service provider can use a lesser number of replicates. The %RSD limit for a number of difference replicates are tabulated in Table 2.

Table 1. PPPO Bias and Precision Limits

Confirmation Range	%Bias	%R
bias (lower limit)	-30	70
bias (upper limit)	30	130
precision	20% RSD at the 95% confidence level for 15 replicates	

Table 2. Upper Limits for %RSD versus Number of Replicates

Number of Replicates	2	4	6	8	10	12	14	15
Max %RSD[a]	1.8	10.0	14.0	16.2	17.7	18.8	19.7	20.0

a – the values listed are derived from the measured standard deviation of the replicate measurements using

$$\frac{s}{\mu} \bullet 100\% < \sqrt{\frac{(0.292)^2 \bullet \chi^2_{0.05,n-1}}{n-1}} \bullet 100\%$$

where s is the measured standard deviation, n is the number of replicates, μ is the known or true value, $\chi^2_{0.05,n-1}$ is the critical value for the upper 5% tail of a one sided chi-squared distribution, with n-1 degrees of freedom, and the 0.292 constant corresponds to a 95% upper confidence bound (CB) on the true system precision limit of 29.2%.

NDA service providers may develop alternate methods and limits for bias and precision. Such alternate methods and limits must be technically justifiable, clearly documented, and are subject to PPPO concurrence before use.

Failure to comply with the bias and precision requirements for calibration confirmation requires development of a CAP. The CAP shall include detail on the nature of the failure, its suspected causes, methods to evaluate potential causes, and activities proposed to identify and rectify the deficiency. The CAP results shall be documented and show why the failure occurred and what actions were taken to prevent a recurrence. The calibration confirmation shall be performed again after the corrective actions have been implemented and the results documented.

4.6.1.4 Calibration verification

A "calibration verification" is a measure designed to provide long-term information on the stability of the "initial calibration" while minimizing the impact on operational schedules and resources. The "calibration verification" test item(s) must meet the criteria described in Section 4.6.1.2 (1) – (3). A "calibration verification" shall be performed at least once every five operational days for each measurement system and calibration. A five-day operational period is defined as a rolling tally of five days where NDA operations were in effect that used the affected measurement system and calibration, but not necessarily consecutive. The start point for the five-day operational period is from the start of PPPO approved operations or the first operational day after the previous rolling five-day tally was completed. The five-day operational "calibration verification" requirement may be extended to a maximum of 30 operational days provided the NDA service provider can demonstrate and technically justify the long-term stability of the NDA system per established acceptance criteria.

Calibration verification test items are typically selected from or assembled from the traceable standards and matrix containers or process component mock-ups used in the "calibration confirmation" process. The "calibration verification" test item is to be submitted to NDA operations in a "blind" manner where applicable and processed through the measurement routine as though it were an actual measurement item. The verification test items are to be selected and/or configured and submitted such that during a 12-month period the operational space of the NDA system as per the initial calibration. The "calibration verification" is a point check in the calibration realm. It is not required that each waste matrix type be tested over the entire operational space. However, it is expected that the calibration verification configurations vary over the operational space. The NDA service provider can utilize other methods of "calibration verification" provided they are documented and have received PPPO concurrence. The NDA service provider is responsible for specification, assembly and selection of "calibration verification" test items, and meeting the applicable rolling operational day period (i.e., minimum of five days with a maximum of 30 days).

Acceptable performance for a "calibration verification" item measurement result in terms of bias, precision, trending measures, and so forth shall be determined and documented by the NDA service provider. It is recommended that the PPPO "calibration confirmation" acceptability requirements of Section 4.6.1.3 be considered in this process. A CAP for out-of-control "calibration verification" results is to be prepared by the NDA service provider. The CAP shall include a provision requiring the evaluation of measurement item data potentially affected by the failed "calibration verification" measure. The "calibration verification" protocol, monitoring, acceptance criteria, and action levels must receive PPPO concurrence.

To re-iterate, the "calibration verification" routine is summarized below:

1. The "calibration verification" test item(s) is to be submitted to the NDA system operator in a blind fashion when applicable and processed through the same routine actual waste items are subject to.
2. The "calibration verification" shall be performed at least once per rolling five days of NDA operations (not necessarily consecutive) or a longer period up to 30 days as justified.
3. The "calibration verification" item is to be assigned a measurement item name or number that does not reveal the content to the operator and analyst, but is known to and tracked by the person responsible for submitting, evaluating, and tabulating the verification data.
4. The "calibration verification" parameter evaluated shall be one or more of the primary radioactive element(s)/isotope(s) as specified/expressed in the DQOs or client requirements (e.g., ^{235}U and ^{238}U mass).
5. The individual responsible for configuring or selecting the "calibration verification" item should not be associated with NDA measurement personnel if possible. Such individual should also retrieve the

analytical data report for the verification item and monitor the results relative to established acceptance criteria. Trending analyses of the accumulated data are to be performed as applicable and documented. It is preferable an individual in the quality organization manage the selection, delivery/retrieval, acceptance status, and so forth of the "calibration verification" process.

6. Unacceptable "calibration verification" results shall require notification of NDA measurement personnel and subsequent implementation of an appropriate corrective action. Based on technical evaluation of unacceptable "calibration verification" result(s), a variety of actions may be taken including recalibration. The CAP shall include a provision to evaluate data that may have been affected by the failure. The corrective action shall be documented, reported as applicable, and retained.
7. Criteria for an acceptable "calibration verification" must be determined by the NDA service provider, technically justified, and documented. The calibration verification protocol and acceptance criteria must receive PPPO concurrence.

4.6.1.5 NDA method detection limit

A methodology shall be in place to determine NDA measurement system detection limit for those radionuclides specified in the DQOs or other client requirements. It shall be re-determined each time there is a significant change in the measurement method or waste form configuration. Instruments performing low-level waste discrimination measurements must have a minimum detectable activity (MDA)/lower limit of detection (LLD) sufficient to meet the applicable segregation value. The methodology for determination of the MDA/LLD is to be documented by the NDA service provider.

The LLD is that level of radioactivity which, if present, yields a measured value greater than the critical level (Lc) with a 95% probability, where the Lc is defined as that value which measurements of the background will exceed with 5% probability (the LLD may be defined in a different manner to comply with client and/or end-user needs). Because the LLD is a measurement-based parameter, it is not feasible to calculate LLDs for radionuclides that are not determined primarily by measurement, (e.g., ^{99}Tc in such cases), the NDA service provider shall derive the equivalent of an LLD, (i.e., a reporting threshold for a radionuclide(s) when it is technically justified). This value may be based on decay kinetics, scaling factors, or other scientifically-based relationships and must be adequately documented in site records.

4.6.1.6 Infinite thickness

For a given radioactive material deposit, a thickness may be reached beyond which there is no increase in counts for an increase in thickness. This phenomenon is typically only observed in gamma-ray counting. At this point, infinite thickness has been reached. The NDA service provider shall have a documented process for identifying infinite thickness when performing measurements. Some common techniques include the following:

1. Transmission Factor - ASTM C1133-89, "Standard Test Method for NDA of Special Nuclear Material in Low Density Scrap and Waste by Segmented Passive Gamma-Ray Scanning," ASTM 1989.
2. Peak ratio - Software such as Multi-Group Analysis for Uranium.

When infinite thickness is approached or exceeded for the highest gamma ray energy observed for an isotope, mass measurements for that isotope shall not be reported. It is acceptable in such cases to measure an isotope with higher energy peaks and report a mass of the other isotope based on a known isotopic ratio. When this is done, the uncertainty must include the uncertainty for the measured isotope and the uncertainty in the isotopic ratio. An example is if infinite thickness is exceeded for the 185.7 kiloelectron volt (keV) peak from ^{235}U, the mass of ^{238}U can be measured provided infinite thickness for

the 1001 keV peak has not been reached and total attenuation at this energy can be accurately estimated. The enrichment of the deposit can then be used to report the ^{235}U mass, but the uncertainty must include the ^{238}U uncertainty and the uncertainty in the enrichment estimate.

4.6.2 Analytical Support Equipment

Analytical support equipment are measurement devices not part of the actual NDA measurement system instrumentation, but ancillary to and in support of NDA measurements and analyses. These include but are not limited to weight scales, WRMs, independent background measurement equipment, radiography systems, and temperature measurement devices. In short, any device that is used to provide data required for the NDA data analysis routine used to produce a quantitative NDA measurement result, including QC instrumentation.

1. All support equipment shall be maintained in proper working order. Support equipment shall as practicable be uniquely identified by a documented identification protocol.
2. NDA measurement system and support equipment shall be operated by authorized personnel.
3. Current instructions on the use and maintenance of support equipment (including any relevant manuals provided by the equipment manufacturer) shall be readily available for use. All equipment shall be properly maintained, inspected, and cleaned. Maintenance procedures shall be documented.
4. All support equipment shall be calibrated or calibration confirmed at least annually using reference standards that are traceable to the International System of Units bracketing the range of use. When a reference standard is not available or the range of use cannot be bracketed, written concurrence for use of substitute standards or standards that do not bracket the range must be obtained from the PPPO. The results of such calibrations or verifications shall be within applicable instrument specifications. Support equipment that has a static calibration such as tape measures and squares does not fall under this requirement. It is recommended that when this type of equipment is initially purchased that a check is made to ensure the demarcations, distance interval, or angles are correct. Such support devices should be replaced when damaged or defaced.
5. Annual support equipment calibration confirmations or more frequent periodic verifications yielding results out-of-compliance with acceptance criteria/instrument specifications shall be removed from service until repaired. After return to service, the instrument shall be calibrated or calibration verified. The NDA service provider shall maintain records of instrument repair.
6. Support equipment performance acceptability (e.g., scale weight), shall be checked in the expected use range with applicable traceable WRMs. Raw data records and logs of support equipment calibrations, calibration verifications, and checks shall be documented and retained. Instrument checks and results shall be documented in a log.
7. NDA analysts shall ensure data obtained from support equipment used for NDA characterization purposes has been checked per the specified frequency and is within the applicable acceptance criteria.
8. QC acceptance criteria shall be commensurate with the analysis or application for which the equipment is being used. The NDA service provider shall determine acceptability criteria and document it.
9. Corrective actions shall be performed in the event support equipment does not fall within the QC acceptance criterion.

4.6.3 NDA System and Support Equipment Maintenance and Records

1. The NDA service provider shall maintain records of each major item of NDA instrumentation and support equipment and its software as applicable. These records must include a current list of available major equipment, date of purchase, repair history, calibration history, and current status. The records should include but not be limited to the following:

a) The identity of the equipment item and its software if applicable,
b) Manufacturer's name, serial number, or other unique identification,
c) Functional check data sheets or logs tabulating compliance with the acceptance criteria,
d) The current location of identified equipment,
e) Manufacturer's operating, calibration, and maintenance instructions,
f) SOPs or other document specifying instrument configuration and settings,
g) Dates, results, and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration,
h) Any damage, malfunction, modification, or repair to the equipment, and
i) Date received and date placed in service.

2. The NDA service provider shall have procedures for the safe handling, transport, storage, use, and planned maintenance of NDA measurement and support equipment to ensure proper functioning and in order to prevent contamination or deterioration.
3. NDA system instrumentation and support equipment that has been subjected to mishandling, gives suspect results, or has been shown to be defective or outside specified limits shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out-of- service until it has been repaired and shown by calibration or testing to perform correctly. The NDA service provider shall examine the effect of the defect or departure from specified limits on previous NDA measurements and shall institute a "Control of Nonconforming Work" procedure.
4. Whenever practicable, all NDA instrumentation and related support equipment under the control of the NDA service provider requiring calibration shall be labeled, coded, or otherwise identified to indicate the status of calibration including the date when last calibrated and the date or expiration criteria when recalibration is due. When the hardware itself cannot be labeled, the calibration status, expiration date, and other pertinent information shall be contained in a log or other document and retained.
5. When NDA instrumentation and/or support equipment goes outside the direct control of the NDA service provider, it shall be, at a minimum, ensured that the function and calibration status of the equipment are correct through a "calibration verification" assessment. The equipment is to not to be returned to service until acceptable "calibration verification" results are obtained.
6. NDA measurement equipment, including hardware and software, shall be safeguarded from unauthorized adjustments that would invalidate the NDA measurement results.

4.7 NDA MEASUREMENT SYSTEM SOFTWARE

Software QA requirements must be implemented by PPPO NDA contractors that utilize software as part of NDA waste characterization either developed in-house or acquired.

When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage, or retrieval of NDA measurement data, the NDA service provider shall have documentation or SOPs for software activities, including but not limited to the following:

1. For software acquired from a commercial vendor or other third party, evidence of software QC, V&V, and other pertinent data shall be acquired and maintained by the NDA service provider. Software verification is the process of evaluating software to determine whether the products of a given development phase satisfy the conditions imposed at the start of that phase (IEEE-STD-610). Software validation is the process of evaluating software during or at the end of the development process to determine whether it satisfies specified requirements (IEEE-STD-610).
2. For software developed or modified by the NDA service provider, software development planning and QA controls shall be identified in documented plans. The plans shall be formally reviewed and approved. The following activities shall be addressed in such plans/procedures:

a) Software development and testing,
b) Software V&V,
c) Software configuration control, and
d) Software operation and maintenance.

3. Computer software developed by the NDA service provider shall be documented as per applicable software development quality standards. Such standards usually require documentation, including:

   a) Software specification document,
   b) Software design document,
   c) Software test plan, and
   d) Software V&V document (Note: Commercial off-the-shelf software [e.g., word processing, database, and statistical programs in general] used within its designed application range are usually considered to be sufficiently validated). However, NDA service provider developed software and/or modifications to commercial software must be validated.

4. The NDA service provider shall implement V&V and QA methods to ensure all in-house developed software accurately performs intended functions, including:

   a) Software testing,
   b) Acceptance criteria,
   c) Documentation of test results,
   d) Test review and approval, and
   e) Frequency of verification of the software.

5. Software change procedures shall include instructions for requesting, authorizing, software change requirements, testing, QA, approving, and implementing changes.
6. Data such as but not limited to decay constants, branching ratios, material attenuation values, neutron yields, and master gamma libraries used in the reduction or processing of NDA measurement data to a reportable quantity, whether electronic or hardcopy, shall be placed under a control system so only authorized individuals have access.
7. Working data files or source files (e.g., nuclear data libraries, master gamma libraries, geometry files, efficiency files) shall be controlled by the NDA service provider to prevent unauthorized access or inadvertent changes.
8. When commercial software is used that has the capability of performing user-defined calculations or macros (e.g., spreadsheet), all user-defined components shall be verified before initial use and after changes. Documentation of such shall be readily available for review. Appropriate protections must be included to preclude inadvertent changes to user-defined equations or macros. Printouts from such software should include all information used to calculate results.
9. Software version control methods must be in place to document the software version currently used as well as data reports with the date and time of generation and the software version used to generate the data report. Software that includes user-defined calculations or macros shall also track revisions to the user-defined customization using version information.
10. Procedures shall be established and implemented for protecting data generated for waste characterization purposes, including but not limited to integrity and confidentiality of data entry or collection, data storage, data transmission and data processing.
11. Computers and automated equipment are to be maintained to ensure proper function and must have appropriate environmental and operating conditions necessary to maintain the integrity of NDA measurement data and information.

12. Procedures are to be established and implemented for the maintenance of security of data, including the prevention of unauthorized access to and the unauthorized amendment of computer records.
13. An inventory of all applicable software shall be maintained that identifies the software name, version, classification and exemption status (DOE 0 414.C or latest version), operating environment, and the person and organization responsible for the software.
14. Maintain a historical file of software, software operating procedures, software changes, and software version numbers.

4.8 NDA MEASUREMENT TRACEABILITY

The calibration of NDA instrumentation and support measurement devices (e.g., weight scale) used for NDA characterization shall have traceable calibrations established and documented before being put into service. Traceability is the ability to relate individual measurement results through an unbroken chain of calibrations to a nationally recognized reference base (e.g., NIST or NBL). For NDA measurements, traceable materials include but are not limited to radioactive WRMs and certified weights for scale calibrations.

1. The NDA service provider shall have a program and procedures for establishing a traceable "initial calibration," "calibration confirmation," and "calibration verification" as well as QC checking of its NDA instrumentation and support equipment. This program shall include a system for selecting, using, and controlling traceable reference standards for the NDA measurement instrumentation and support equipment. For cases where traceable WRMs are not yet available, the NDA service provider can propose alternate methods. The PPPO will have to concur with such alternate methods.
2. Traceable sources used for "initial calibration" shall be traceable for all attributes used in the calibration (e.g., a ^{252}Cf source shall be certified in its neutron yield and isotopic composition used to calculate the decay rate, and a mixed nuclide source used to perform an efficiency calibration of a gamma ray detector shall be certified for the yield of each gamma ray energy used in the calibration and the decay properties of the contributing nuclides). Traceable sources used for "calibration confirmation" and "calibration verification" shall to the extent practicable be representative of the elements, isotopic composition, physical form, chemical compound, and other properties. as contained in actual waste items.
3. The NDA service provider shall have a procedure(s) for the specification, procurement, and acceptance of WRMs. The WRM certifications shall be acquired, maintained, and traceable to a nationally recognized reference base (e.g., NIST or NBL).
4. The NDA service provider shall retain records for all WRMs, including the manufacturer/vendor, the manufacturer's Certificate of Traceability, the date of receipt, and a certificate expiration date. Existing standards that do not have certificates or assigned expiration dates are exempt from this requirement. However, standards that do not have certificates and/or expiration dates must still comply with the five-year re-verification requirement.
5. Traceable standards shall be verified at a minimum every five years. Standards with an expiration date less than five years shall be verified at a period equal to the expiration time interval. Verification of a standard is accomplished through an assessment of its usable attribute for the NDA application (e.g., ^{235}U 185.7 keV gamma-ray emission rate and neutron emission rate). There are a number of means by which a standard can be deemed verified as acceptable for use. The standard can be sent to a qualified facility maintaining measurement systems traceable to a certified reference material (CRM) for a determination of the standard attribute of interest. In this case the standard is simply given an updated attribute value and returned to the NDA service provider. Another method is to cross compare the standard with another traceable standard possessing the same attribute in a calibrated and operational measurement system. An evaluation of the results can lead to verification of the standard that is about to or has expired. The NDA service provider must determine the acceptable uncertainty in the verified value relative to the NDA characterization process at hand.

The verification method used and standard verification acceptability criteria shall be documented. The results of the verification are to be documented and maintained as a QA record.

6. WRM Certificates of Traceability shall contain information and data that clearly detail traceability to a CRM. See Appendix C for a radioactive WRM certificate of traceability that contains necessary and sufficient information and data to establish traceability.
7. Checks needed to maintain confidence in the status of WRMs shall be carried out according to defined procedures and schedules.
8. The NDA service provider shall have procedures for the safe handling, transport, storage, and use of WRMs in order to prevent contamination or deterioration and protect their integrity.

4.9 ACCEPTABLE KNOWLEDGE

NDA methods typically directly quantify one or more of the prevalent radionuclides known to be present in the waste and process component items. Other radionuclides may be present, some of which are not readily quantifiable through the NDA method being employed. Radionuclides common to gaseous diffusion plant operation under the purview of the PPPO include: ^{40}K, ^{60}Co, ^{137}Cs, ^{90}Sr, ^{99}Tc, ^{230}Th, ^{232}Th, ^{234}Th, ^{237}Np, ^{238}Pu, ^{239}Pu, ^{240}Pu, ^{241}Am, ^{234}U, ^{235}U, and ^{238}U. The ^{235}U, and ^{238}U. These isotopes are the prevalent radionuclides and are typically directly measureable through common NDA methods. Of these radionuclides, ^{90}Sr and ^{99}Tc do not produce useful signals for NDA measurement. Other radionuclides such as ^{238}Pu, ^{239}Pu, ^{240}Pu, and ^{241}Am are typically present in trace quantities. ^{238}U is not directly measureable by gamma-ray methods, but can be accurately quantified when in secular equilibrium with its progeny ^{234}Th and ^{234m}Pa. NDA measurement campaigns will nonetheless often require that the balance of radionuclides be quantified or the MDA determined and reported.

In addition, passive neutron measurements cannot discern between neutrons produced by different isotopes. ^{234}U produces the largest fraction of neutrons in enriched uranium with almost all of the balance of the neutrons produced by ^{238}U. For such measurements, the mass of ^{235}U must be estimated based on an isotopic composition derived by other means.

For radionuclides to be reported per contractual requirements but not quantifiable through existing NDA techniques, isotopic ratios or radionuclide scaling factors based on AK of the facility process are commonly employed. The radionuclides and isotopes that are quantifiable through the NDA methods are used in conjunction with AK derived ratios and scaling factors to quantify the radionuclides not directly quantifiable. To use AK to determine such ratios and scaling factors, the NDA service provider must technically justify the AK data and its use with NDA measurement information. The AK ratios or scaling factors must be appropriate to the generation point of the waste, process component, and other generation points.

Uncertainties reported when scaling factors are used must include the uncertainty in the scaling factor. For example, the TMU for neutron based ^{235}U mass estimates must include uncertainty in the estimate of enrichment and in the estimate of ^{234}U concentration. Where the measured material is $UO_2F_2 \bullet nH_2O$, the uncertainty in the neutron yield per unit mass of uranium must include uncertainty arising from the estimate of n, the number of waters of hydration.

4.9.1 Methods for Confirmation of Radionuclidic/Isotopic Ratio AK

To use AK regarding isotopic ratios and scaling factors, they must be confirmed in one manner or another to be used to quantify radionuclides known to be in the waste/process item population. Such AK can be confirmed by sampling followed by data analysis on PPPO-certified measurement systems which may include radiochemistry. Other methods include computational techniques. For example, ^{234}U can be difficult to quantify using NDA methods, but isotopic ratios for ^{234}U may be calculated from knowledge

of the ^{235}U enrichment. Similarly, a waste container's concentration of ^{137}Cs can be used to derive a ^{90}Sr value through the application of the appropriate scaling factor(s).

All scaling factors used must be technically sound and based on known, documented relationships or correlations. Documentation must be sufficient to enable independent calculation of the scaling factor or ratio of interest. When radiochemistry is used for confirmation, less reliance on calculated ratios/factors is required. However, valid estimates of uncertainty introduced by sampling must be included in the correlations and not simply the uncertainty of the analytical method(s) employed. Each NDA service provider must technically justify that techniques used to confirm the ratio/scaling factor of nonmeasurable radionuclides and uncertainties are valid.

4.9.2 AK Documentation

The use of AK information concerning the radiological composition of a waste type or large process component must be documented either in an AK summary report for that waste type/component or other controlled document. Should this information be contained in AK package(s) prepared to meet other general waste characterization requirements, it need not be duplicated in other controlled documents that address the radiological properties of the waste stream. However, all relevant information must be included in the AK record.

The type and quantity of supporting documentation may vary by waste stream and shall be compiled in a written record that includes a summary identifying all sources of information used to delineate the waste stream's isotopic distribution or radionuclide scaling factors. The basis and rationale for the delineation shall be clearly summarized in an AK report and traceable to referenced documents. Assumptions made in this rationale shall be identified. The following information should be included as part of the AK written record:

1. Map of the site with the areas and facilities involved in waste generation and process equipment identified,
2. Facility mission description as related to radionuclide-bearing materials and their management (e.g., routine production, fuel research and development, and experimental processes),
3. Description of the specific site locations (such as the area or building) and operations relative to the isotopic composition of the uranium bearing wastes and process components they generated,
4. Waste identification or categorization schemes used at the facility relevant to the waste material's isotopic distribution (e.g., the use of codes that correlate to a specific isotopic distribution and a description of the isotopic/radionuclidic composition of each waste stream),
5. Information regarding the waste's physical and chemical composition that could affect the isotopic distribution (e.g., processes used to remove ingrown daughters or alter its expected contribution based solely on radioactive decay kinetics), and
6. Statement of all numerical adjustments applied to derive the material's isotopic distribution (e.g., scaling factors, decay/in-growth corrections and secular equilibrium considerations).

4.9.3 Supplemental AK Information

Supplemental AK information should be obtained dependent on availability. The amount and type of this information cannot be mandated, but information should be collected as appropriate to support contentions regarding the waste's isotopic distribution. This information is used to compile the waste's AK written record. Supplemental AK documentation that may be used includes but is not limited to information from the following sources:

1. Safeguards and security, materials control and accountability, and other nuclear materials control systems or programs and the data they generated,
2. Reports of nuclear safety or criticality, accidents/excursions involving the use of special nuclear material (SNM), or nuclear material,
3. Waste packaging procedures, waste disposal, building or nuclear material management area logs or inventory records, and site databases that provide information on SNM or nuclear materials,
4. Test plans, research project reports, or laboratory notebooks that describe the radionuclide content of materials used in experiments,
5. Information from site personnel (e.g., documented interviews), and
6. Historical analytical data relevant to the isotopic distribution of the waste stream.

4.9.4 AK Discrepancy Resolution

If there is any form of discrepancy between AK information related to isotopic ratios or composition, the NDA service provider will evaluate the sources of the discrepancy to determine information credibility. Information that is not credible or information that is limited in its applicability to the NDA characterization effort will be identified as such, and the reasons for dismissing it will be justified in writing. Limitations concerning the information will be documented in the AK record and summarized in the AK report. In the event the discrepancy cannot be resolved, the site will perform direct measurements for the impacted population of containers or process items. If discrepancies result in a change to the original determinations, the AK summary will be updated.

4.10 NDA QC

The purpose of a measurement control program is to test and ensure the stability of the measurement process and to gain additional information on measurement uncertainties where practicable. The measurement control program provides for the administration, evaluation, and control of measurement processes. The design of the measurement control program is to ensure the NDA measurement process provides data of sufficient quality (i.e., the measurement system is in control per defined criteria). The NDA service provider can then make and document qualifying statements about the suitability and validity of measurement data as generated for the end-user.

QC measurements are to be performed in conjunction with and related to a batch of NDA measurement items. A batch is a grouping of similar measurement items to which a set of QC criteria is applied to demonstrate acceptability of the results. The batch size is specified to be 20 items such that when one replicate is performed per batch, a 5% check of the data is achieved. Besides the replicate requirement are pre- and post-batch QC checks (e.g., background and energy calibration checks). A batch can be fewer than 20 items as for the case where there are fewer than 20 similar measurement items available for analysis or other driving circumstances, such as throughput requirements.

For each measurement item batch, QC measures are to be performed before commencement of a batch and at the end of the batch. An analytical batch may span a period of more than one day, but the requirement to perform QC checks per day is not superseded. The replicate QC measure does not have to be performed twice per batch, but rather once. Performance checks shall bracket the NDA measurements which comprise the batch. Out of control performance checks for a given NDA instrument shall cause the batch data to be considered suspect. Corrective actions shall be in place to evaluate the measurement item results for the affected batch.

4.10.1 QC Procedures

The NDA service provider shall have procedures implementing applicable QCs for monitoring the validity of NDA measurements and the analytical results. The NDA QA program shall specify qualitative and quantitative acceptance criteria for the QC checks. The NDA QC measures and acquired information/data shall be documented or logged in such a way that trends are detectable. Statistical techniques shall be applied to the evaluation of acquired QC data and action levels specified. Procedures shall also be in place to activate corrective actions when QC criteria are not satisfied. The QC program shall be periodically reviewed. In addition, the NDA service provider shall address the following:

1. Development of a QC plan with clearly defined roles and responsibilities. The QC program should assure objectivity and independence of action. The person assigned responsibility for the QC program shall be knowledgeable of the measurement system being controlled, statistical QC, and the process being monitored. The organization should provide sufficient separation of functions to avoid any conflict of interest.
2. Acquisition and maintenance of suitable WRMs and check sources to monitor measurement system performance during NDA characterization operations. Records concerning specification and acquisition of standards and sources, including an assessment of their uncertainties and procurement shall be documented and retained.
3. QC checks shall include a means to evaluate the variability and/or repeatability of NDA measurement results.
4. Determination of measurement parameters and acceptance criteria necessary to ensure the accuracy of the NDA method using daily performance checks and analysis of performance check data (e.g., control charts, trending analysis, and replicate measurements).
5. QC protocols as specified in the NDA service provider's method manual and/or procedure(s) shall be followed.
6. QC measurement parameter action levels shall be established and documented. Details concerning QC requirements, acceptance criteria, and action levels are addressed in Appendix D.
7. Written procedures shall be developed and documented to address out-of-control conditions and the subsequent re-qualification of the instrument.

4.10.2 NDA QC Requirements

Procedures cited in various ASTM, ANSI standards, NRC standard practices, and guidelines as referenced in Appendix A are recommended for use at all NDA measurement facilities. For the PPPO QSNDA, QC requirements must at a minimum include the following:

1. **Background Measurements** must be performed and recorded for fixed facility neutron and gamma systems for each system in use at least once per day and twice for each batch. The once per day background measurement can serve as the beginning or ending background measurement required for the batch. The two background measurements for each batch shall bracket the start and end of the batch, one at the beginning of the batch and one at the end of the batch, unless PPPO concurrence is obtained otherwise. The count time for neutron and gamma background checks shall be at least as long as the measurement count time unless otherwise specified and documented by the NDA subject matter expert (SME). The background measurement shall be evaluated before daily NDA measurements. Depending on environmental conditions, the background frequency may need to be increased to ensure data quality. Increases in the frequency of background measurements shall be determined as appropriate by the cognizant SME (Note: Enrichment measurement systems that employ an infinite-thickness analysis technique do not require a background performance check). The recorded background data is to be monitored using control charts or tolerance charts to ensure the background environment is within statistical control. Contributions to background because of radiation from nearby radiation producing equipment, standards, or wastes must be controlled to the extent practicable or more frequent background checks must be performed.

2. **Instrument Performance Measurement** checks must be acquired for each NDA measurement system in use at least once per day and twice for each data set or batch. For each performance check two measurements shall be used to bracket the batch, one before and one after the batch measurements are complete. Performance checks include detection efficiency checks, matrix correction checks, and for spectrometric instruments, energy calibration and energy resolution checks. An out-of control energy calibration check may cause measurement item results to be suspect since the last successful energy calibration check. Energy calibration checks can be performed at a greater frequency than once per day. Performance checks, as applicable, shall also be acquired on support equipment.
3. **Replicate Measurements** are used to determine the repeatability of a measurement system that represents the intrinsic instrument variability. Repeatability variance is a short-term variance usually dominated by counting statistics. The replicate measurement is acquired by randomly selecting one measurement item that has been processed through the NDA system for the batch. This measurement item is then to be re-measured using the same NDA system, software, and acquisition/reduction parameters. Data analysis is to be performed independently for the two measurements. The second measurement of the item is to be performed any time before the start of the next data set or batch. This repeat measurement is then the replicate for that batch. A minimum of one replicate measurement is required for each batch. For a randomly selected replicate measurement item that corresponds to a measurement below the lower limit of quantitation (LLQ), the 95% uncertainty ranges of the pair of measurements must overlap. Appendix D contains additional information and recommendations on the evaluation of replicate data.

4.11 NDA MEASUREMENT UNCERTAINTY

NDA service providers shall have and apply methods and procedures for estimating TMU for all reported values. Before contract approval, the NDA service provider shall perform a preliminary identification of source of uncertainty and produce measurement uncertainty estimates for the waste population to be characterized. A reasonable estimate of the magnitude of uncertainty expected is to be documented. Reasonable estimation shall be based on knowledge of the performance of the method and shall make use of previous experience and when available validation data from similar measurement apparatus and configurations. The estimated measurement uncertainties must be evaluated per client and end-user needs and requirements. Specific attention shall be paid to communicating the expected uncertainty so as to not exaggerate or mislead interested persons and agencies as to the reality of the uncertainty magnitude.

The method used to calculate TMU for the purpose of demonstrating compliance with the DQOs must be documented and technically justified. Compliance with this requirement will be evaluated in technical audits and review of the TMU documentation package for each assay system by the PPPO. References providing general guidance for determining the TMU are provided in Appendix A.

The NDA service provider shall have a method to determine TMU for each NDA system employed including:

1. Develop a document or plan that delineates the approach to TMU determination, defines significant measurement uncertainty components, and determines a method for acquiring data/information on components of variance and processing acquired data and information to arrive at technically defensible TMU for the measurement item population of interest.
2. Produce a procedure or applicable document that provides specific direction on the acquisition of NDA system measurement data for use in deriving the TMU.
3. Produce documentation that clearly describes the processing of acquired data, accounting for all significant variables, and the application of statistical techniques to determine the TMU.
4. Clearly define how the TMU is expressed (e.g., 95% confidence level, percent one-sigma [σ]).

5. The TMU determination method must be clearly documented for audit purposes and review by the PPPO.
6. NDA service providers that utilize commercial off-the-shelf data analysis and uncertainty software are still accountable to produce clear documentation of the TMU approach, components of variance, and technique for arriving at the TMU value. Claims of propriety by the vendor will not be permitted although confidentiality agreements to prevent unnecessary spread of this information will be allowed.

The PPPO shall concur with NDA service provider TMU methods and application before the generation of data.

4.12 CAPABILITY DEMONSTRATION

The NDA service provider shall demonstrate that its NDA methods, calibrations, and uncertainty estimates are applicable to the waste forms under consideration and are commensurate with DQOs and client requirements. Part of this demonstration of proficiency is the participation in applicable capability demonstration evaluations as conducted by PPPO-sanctioned approving and qualification agencies. Elements of the PE process include:

1. NDA service provider shall demonstrate successful participation in applicable PE program(s) as part of a contract award under this QSNDA. The NDA service provider shall demonstrate continued proficiency throughout the term of the contract award. The testing will be single-blind and representative of the waste matrix types and configurations and analytes (e.g., ^{235}U, ^{238}U) to be characterized over the contract.
2. The PPPO reserves the right to submit blind PE test items at any time during the contract. The NDA service provider shall continue to participate in all applicable rounds of external PE programs. The results of all PE programs will be compiled in reports for use by the DOE and the PPPO.
3. Unacceptable NDA results for PE test item(s) as determined per PE program criteria will require the NDA service provider to implement corrective action procedures and submit a CAP to the client and/or end-user. Until the corrective action is implemented and the results PPPO concurrence, the NDA service provider may not submit characterization reports for the matrix/radionuclide class related to the failed test item configuration. PE program acceptance criteria are found in the *PPPO Performance Demonstration Program Plan for Nondestructive Assay of Uranium Contaminated Wastes*.
4. Documentation of successful capability demonstration such as a Certification Statement or letter of concurrence from the PPPO or other approved qualifying agency must be acquired and retained by the NDA service provider and made available upon request. All associated supporting data necessary to reproduce the PE measurement results as contained in the Certification Statement or equivalent document must be retained by the NDA service provider.
5. Once the initial capability demonstration is successfully completed, continuing demonstration of method performance is required by implementing periodic “calibration verification” measurements as well as all applicable QC requirements.

4.13 NDA DATA REPORTING, REVIEW, AND VERIFICATION

4.13.1 NDA Measurement Data Reporting

The NDA service provider is to document individual NDA measurement item results in a standard report format agreeable to and concurred with by the client. For each NDA measurement item there shall be a separate report. The NDA measurement item reports shall contain or reference the location of information sufficient to fully describe all input data, NDA configuration information, acquisition

parameters, analysis technique, software version, QC data, and so forth to allow reconstruction of the reported results. The NDA measurement item report should contain the following distinct sections but can be modified as appropriate.

1. Title and contact information, including:

    a) Report title (e.g., "NDA Measurement Item Report"),
    b) Name of NDA service provider,
    c) Client contact name for which report is to be delivered and NDA service provider point of contact responsible for ensuring the submittal of the report in the approved manner, and
    d) Identification of project name, site, or facility NDA measurement items are associated with.

2. Measurement item identification and QC information:

    a) Measurement item identification/designator and other identifiers/designations as applicable (e.g., the clients own identifier),
    b) Date(s) of NDA data acquisition,
    c) Analysis, background, and QC file names,
    d) Measurement item description,
    e) NDA field worksheet file name, log name, or other identifier,
    f) Gross/net weight, if applicable,
    g) NDA measurement live time, and
    h) Location of NDA measurement system, site name, facility name, building name, and other identifying information.

3. Primary radionuclide measurement results:

    a) Primary NDA measurement quantitation method (e.g., gamma, neutron),
    b) Primary radio-elements/radioisotopes and their associated TMUs in appropriate units, (for example, gram, activity, activity concentration, MDA, and % uncertainty),
    c) Total uranium mass, activity, concentration, and associated TMU,
    d) ^{235}U fissile gram equivalent and associated TMU (gram), and
    e) Other primary quantities such as uranium enrichment weight percent (wt%) and associated wt% TMU.

    Primary radionuclides are those that are most significant to DQO compliance.

4. NDA acquisition and analysis information:

    a) NDA detector or system identification,
    b) Name of ancillary data and/or information sheets associated with the NDA measurement item. These are often called NDA Field Worksheets and contain information pertinent to the analysis of the acquired data such as container fill height and measurement configuration (e.g., detector to item distance and operator signature/date),
    c) Identification of real time radiography examination files, if applicable,
    d) The acquisition software identification and version, and
    e) Analysis software identification and version.

5. Comment/Narrative section:

a) Name or reference to procedures used to acquire the NDA measurement data, analyze the data, and acquire supporting data/information used in analysis,
b) Name or reference to QC procedures utilized in the acquisition and processing of the data,
c) Identification or reference to WRM and check source(s) used for calibration and/or QC activities,
d) Identification of or reference to calibration procedures and records and/or location, and
e) If not specified elsewhere, definition of the quoted uncertainties (i.e., one σ, two σ). When TMU is reported differently on the batch cover sheet of the IMS, the method of expressing TMU shall be specified on the NDA measurement item report sheet or the applicable procedures referenced.

The NDA measurement item report is to have the analyst signature and date and the independent technical reviewer signature and date.

4.13.2 Data Verification

Data verification is a systematic confirmation by examination and provision of evidence that specified requirements have been met to ensure the required data quality characteristics have been obtained. The verification process ensures applicable QCs have been properly implemented and data validity per program requirements have been met. Verification activities are usually performed at the batch level where all QA elements ranging from NDA measurement reports to compliance with applicable regulations and DQOs are collected, collated, and prepared for submittal. NDA measurement data reports are to be provided to the client on a batch basis as determined with and agreed to by the client.

1. Batch data reports are to be submitted to the client for each measurement batch on standard form (hard copy or electronic equivalent). Batch data reports shall at a minimum include the following:

   a) NDA service provider name, batch number, NDA measurement item identifications included in the batch, and date and signature release by authorized personnel,
   b) Table of contents,
   c) QC data, backgrounds, replicate data, control charts, and the like for the relevant batch time period, and
   d) Data verification per the NDA service provider QA Plan and as per applicable procedures.

2. Batch reports must be reviewed and approved by qualified personnel before being submitted. The project manager or designee shall ensure a Batch Verification Summary is prepared for each Batch Data Report. These two reports may be combined and shall consist of a detailed checklist documenting that the batch has been adequately reviewed and comply with program objectives. Only appropriately trained and qualified personnel shall be allowed to perform data verification/review. Verification reviews shall ensure:

   a) The QC documentation for the batch report is complete and includes as applicable a list of containers in the set or batch and applicable set or batch QC results.
   b) Data were collected as described in the planning documents and are complete and correct. All batch data reports must be approved by the project manager or designee. The project manager shall verify at a minimum the following information:

      i. Data generation-level verification have been performed by a second qualified person and appropriate signature release,
      ii. Batch review checklists are complete,
      iii. Batch reports are complete and data are properly reported (e.g., data are reported in the correct units and with the correct number of significant figures), and
      iv. Data comply with program objectives.

c) Results of the review may require that qualifiers be placed on the use of the data. Verification methods shall be planned and documented. The documentation shall include the acceptance criteria used to determine if the data are valid.

4.13.3 NDA Data Validation

All NDA measurement data must be validated (reviewed and approved) by qualified personnel before being reported. At a minimum, the data and analysis must be reviewed by an independent technical reviewer (a second qualified person). This reviewer shall be an individual other than the data generator (analyst) who is qualified to have performed the initial work. The independent technical reviewer shall verify at a minimum the following information:

1. NDA measurement system QC results are within established control limits, and if not, the data have been appropriately dispositioned using the nonconformance process. This shall include complete summarized qualitative and quantitative data for all waste containers with data flags or qualifiers.
2. "Calibration verification" measurements were performed and reviewed as acceptable.
3. NDA system data acquisition and reduction were conducted in a technically correct manner in accordance with current approved methods (verification of procedure and revision).
4. Calculations performed outside of software that is in the software QA program have been verified by a valid calculation program, a periodic spot check of verified calculation programs (not required with every report), and/or 100% check of all hand calculations.
5. Proper constants such as half lives, branching ratios, attenuation values, neutron yields, and gamma libraries were used.
6. Data were reported in the proper units and correct number of significant figures.
7. Values that are not verifiable to within rounding or significant difference discrepancies must be rectified before completion of independent technical review.
8. The data have been reviewed for transcription errors.
9. The data meets client/end-users requesting MDAs.
10. Calibrations were documented.
11. Standards were traceable to national recognized certificates.

4.14 DATA MANAGEMENT AND CONTROL

4.14.1 Data and Records Retention

The following nonpermanent records shall be maintained at the NDA service provider facility or shall be forwarded to a PPPO approved repository. The records shall be documented and retrievable by batch number or other scheme as concurred with by the client. The records include but are not limited to the following:

1. NDA measurement batch reports,
2. All raw data, including instrument printouts, calculation records, and NDA QC results, and
3. All NDA system and support equipment calibration data and reports, as applicable.

4.14.2 IMS

The NDA service provider shall have an IMS for the control and maintenance of documents and records. The program shall include such elements as:

1. Definition of acceptance criteria, testing, documentation, and approval required for changes to the IMS hardware and communication equipment. Documents that should be available to demonstrate the validity of NDA service provider generated software include:

    - IMS software acceptance criteria,
    - Software description and functional requirements,
    - Listing of algorithms and formulas,
    - Testing and QA documentation, and
    - Installation, operation, and maintenance records.

2. NDA service provider employees shall have initial training in computer security awareness upon employment and shall have ongoing refresher training on an annual basis. Documentation of the training shall be maintained and available for review.
3. Periodic inspections of electronic operations shall be performed by the QA organization to ensure the integrity of electronic data. The QA organization shall maintain records of inspections and submit reports to management, noting any problems identified with electronic data processing, and stating the corrective actions taken.
4. Individual user names and passwords for all IMS users. IMS passwords shall be changed on a regular basis at a minimum of once per year.

4.14.3 IMS Safeguards

Fire extinguishers designed to avoid damage to computer equipment must be available and mounted in visible accessible areas.

4.14.4 IMS Electronic Data Security

The NDA service provider shall ensure the following electronic data security items have been addressed:

1. Individual user names and passwords have been implemented,
2. Operating system privileges and file access safeguards are implemented to restrict the use of the IMS data to users with unauthorized access,
3. All IMS users are trained in computer awareness security on an annual basis,
4. System events such as log-on failures or break-in attempts are monitored,
5. The electronic data management system is protected from the introduction of computer viruses,
6. System backups occur on a regular and published schedule and can be performed by more than one person within an organization,
7. Testing of the system backups must be performed and documented to demonstrate the electronic backups contain all required data, and
8. Physical access to the servers is limited by security measures such as locating the system within a secured facility or room and/or utilizing cipher locks or key cards,

The NDA service provider shall notify the client and/or end-user before major changes in software or hardware configuration of the electronic data management system.

APPENDIX A: REFERENCES

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Society for Testing and Materials.

ANSI N15.36-1994, American National Standard for Nuclear Materials – Nondestructive Assay Measurement control and Assurance

Regulatory Guide 5.53, Qualification, Calibration, and Error Estimation Methods For Nondestructive Assay

ASTM C1316 -08 Standard Test Method for Nondestructive Assay of Nuclear Material in Scrap and Waste by Passive-Active Neutron Counting Using a 252Cf Shuffler

ASTM C1592-04 Standard Guide for Making Quality Nondestructive Assay Measurements

ASTM C1493-01 Standard Test Method for Non-Destructive Assay of Nuclear Material in Waste by Passive and Active Neutron Counting Using a Differential Die-Away System

U.S. Department of Energy. *Performance Demonstration Program Plan for Nondestructive Assay of Drummed Wastes for the TRU Waste Characterization Program*. DOE/CBFO-01-1005. Carlsbad, New Mexico, Carlsbad Field Office

American National Standards Institute. *Nondestructive Assay Measurement Control and Assurance*, ANSI N15.36. American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018

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APPENDIX B: TERMS AND DEFINITIONS

TERMS AND DEFINITIONS

Note: The following is a compilation of DOE definitions as well as applicable NELAC, Multi-Agency Radiological Laboratory Analytical Protocol (MARLAP) and NTP definitions.

Acceptance Criteria: Specified limits placed on characteristics of an item, process, or service defined in requirement documents.

Acceptable Knowledge (AK): Any information about the process used to generate waste, material inputs to the process, and the time period during which the waste was generated as well as data resulting from the analysis of waste.

Accuracy: The degree of agreement between an observed value and true value of an attribute of a measurement item. Accuracy includes a combination of random uncertainty (precision) and bias. The characteristics of an analysis or determination that ensures that both the bias and precision of the resulting quantity will remain within specified limits. (ANSI)

Activity, of radionuclides: The expected number of spontaneous nuclear decays (transformations) in unit time from a specified energy state (excluding prompt decays from a lower nuclear level) for a given amount of a radionuclide. Its standard unit (SI) is the becquerel (Bq), where one Bq equals one decay per second. Activity has often been expressed in curies (Ci), where 3.7×10^{10} Bq equals 1 Ci exactly. (ANSI)

Analyst: The designated individual who performs the "hands-on" analysis of acquired NDA data and information and is responsible for ensuring required QC controls and assurance practices to meet the required level of quality.

Assessment: The evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria.

Assessor: One who performs on-site assessments of qualification authorities and a NDA service providers' capability and capacity for meeting PPPO requirements. Among other assessment methods, an assessor may examine records and other physical evidence for each method or instrument for which qualification has been requested.

Audit: A systematic evaluation to determine the conformance to quantitative and qualitative specification of some operational function or activity.

Background: An extraneous signal superimposed on the signal of interest. (C1673-10a Standard Terminology of C26.10 Nondestructive Assay Methods – ASTM)

Batch (Set): A measurement set or batch is a group of NDA measurements that is analyzed with the same instrument, instrument calibration, and analytical software composed of 20 measurements. Batch size may vary depending on the throughput of the NDA system for the measurement items at hand but may not be greater than 20.

Becquerel (Bq): The SI for reporting activity is the Bq, where one Bq equals one decay per second. Activity has often been expressed in Ci, where 3.7 X 1010 Bq equals 1 Ci, exactly. (ANSI)

Bias: The deviation of a single measured value or mean value of a random variable from a corresponding known value divided by the known value.

Blind Test Item: A test for analysis with a composition known to the submitter. The analyst may know the identity of the test item but not its analyte mass/activity content. It is used to test the analyst's or NDA service provider's proficiency in the execution of the measurement process.

Calibration: Set of operations that establish under specified condition, the relationship between values indicated by a measuring instrument or measuring system and the corresponding values of standards measured.

1) In calibration of support equipment, the values are established through the measurement of Reference Standards that are traceable to a reference base such as the NIST.
2) In calibration of NDA instrumentation, the standards used for calibration are typically WRMs that are specified and purchased or fabricated with a certificate of traceability from a reference base such as NIST.

Capability Demonstration: An activity used to establish the ability of the analyst to generate measurement results acceptable bias and precision.

Certified Reference Material (CRM): A reference material, one or more of whose property values are certified by a technically valid procedure and accompanied by or traceable to a certificate or other documentation that is issued by a certifying body. (ISO Guide 30-2.2)

Characterization: Measurement analysis - whether by review of AK, nondestructive examination, NDA, or radiochemical analysis of the radioactive material constituents of interest in a waste item.

Check source: A radioactive source not necessarily traceable to a national standards body such as NIST in the USA that is used to confirm the continuing satisfactory operation of certain instrument parameters (e.g., energy resolution, detector efficiency).

Commercial Grade Item (CGI): A structure, system, component, or part thereof that affects its safety function that was not procured from a supplier on the approved suppliers list. The quality of a CGI is assured using the requirements of a commercial grade dedication program.

Configuration Control: The process of identifying and defining the configuration items in a system, controlling the release and change of these items throughout the system life cycle, and the recording and reporting of the status of configuration items and change requests.

Confirmation: Verification of the identity of a component or instrument response through the use of an approach differing from the original method.

Conformance: An affirmative indication or judgment that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements. (ANSI/ASQC E4-1994)

Control Chart: A graphical representation of data taken from a repetitive measurement or process. Control charts may be developed for various characteristics (e.g., mean, standard deviation, and range) of the data. A control chart has two basic uses:

1. As a tool to judge if a process is in control and

2. As an aid in achieving and maintaining statistical control. For applications related to radiation detection instrumentation or radiochemical processes, the mean (center line) value of a historical characteristic (e.g., mean detector response which may be corrected to a common date for radioactive decay), subsequent data values, and control limits placed symmetrically above and below the center line are displayed on a control chart.

Control limit: Predetermined values usually plotted on a control chart which define the acceptable range of the monitored variable. There can be both upper and lower limits; however, when changes in only one direction are of concern, only limits to one side are necessary. It is common to include both warning and action limits. When a measured value exceeds the warning limit, an evaluation is typically made to determine if measurements should proceed or if corrective action is needed. When n action limits are exceeded, the measurement process must be stopped, the problem investigated, and corrective action(s) taken.

Correction factor: A numerical factor by which the result of an uncorrected result of a measurement is multiplied to compensate for a systematic effect. Most NDA measurement methods require one or more correction factors to be calculated and applied to each measured item.

Corrective Action: Measures that are taken to rectify conditions adverse to quality and, where necessary, to preclude recurrence.

Count rate: The rate at which detector pulses are being registered in a selected voltage interval. The unit is reciprocal seconds (i.e., s-1). Generally the count rate is uncorrected for detector efficiency. The count rate divided by the detector efficiency for a specific particle and energy will yield the source activity.

Count time: The time interval for the counting of a sample or source by a radiation detector. Depending upon the context used, this can be either the "clock" time (the entire period required to count the sample) or "live" time (the period during which the detector is actually counting). Live time is always less than or equal to clock time.

Counting efficiency: The ratio of the count rate to the disintegration rate usually expressed as a percentage (*E=(R/A) X 100)*. The counting efficiency may be a function of many variables, such as radiation energy, source composition, and source or detector geometry.

Counting uncertainty: Component of measurement uncertainty caused by the random nature of radioactive decay and radiation counting.

Critical Level (Lc): See Decision Level.

Curie (Ci): The traditional unit used to express the activity (amount) of radioactive material. The international system of unit for activity is the Bq.

1 Ci = 2.22 x 1012 disintegrations/minute
1 millicurie (mCi) = 2.22 x 109 disintegrations/minute
1 microcurie (μCi) = 2.22 x 106 disintegrations/minute
1 picocurie (pCi) = 2.22 disintegrations/minute
1 Bq = 1 disintegrations/second

Data Accuracy: Per 40 CFR §194.22(c)(1), is defined as "the degree to which data agree with an acceptable reference or true value."

Data Audit: A qualitative and quantitative evaluation of the documentation and procedures associated with NDA measurements to verify that the resulting data are of acceptable quality (i.e., that they meet specified acceptance criteria).

Data Quality Objective (DQO): DQOs are qualitative and quantitative statements specified to ensure that data of known and appropriate quality are obtained. The DQO process is a series of planning steps typically conducted during the assessment and investigation and designed to ensure the type, quantity, and quality of environmental data used in decision making are appropriate. The DQO process involves a logical step-by-step procedure for determining which of the complex issues affecting a site are the most relevant to planning a site investigation before any data are collected.

Data Reduction: The process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, and collation into a more useable form. [EPA- Quality Assurance Division (QAD)]

Decision Level: In the context of analyte detection, the minimum measured value (e.g., of the instrument signal or the analyte concentration) required to give confidence that a positive (nonzero) amount of analyte is present in the material analyzed. The decision level is sometimes called the Lc or critical value (MARLAP). It is the quantity of analyte at or above which an *a posteriori* decision is made that a positive quantity of the analyte is present. For this document, the probability of a Type I error (probability of erroneously reporting a detectable nuclide in an appropriate blank or sample) is assumed to be set at 0.05; however, other confidence levels may be dictated by the end user.

Detection Limit: The smallest amount (activity or mass) of an analyte in a sample that will be detected with a probability beta (β) of nondetection (Type II error) while accepting a probability alpha (α) of erroneously deciding that a positive (nonzero) quantity of analyte is present in an appropriate blank sample (Type I error). For the purposes of this document, the α and β probabilities are both set at 0.05 unless otherwise specified. MDA is not comparable to method detection limit since both Type I and Type II errors are considered.

DOECAP: DOE Consolidated Audit Program

Do**cument Control**: The act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly, and controlled to ensure use of the correct version at the location where the prescribed activity is performed. (ASQC)

Energy Calibration: The correlation of the MCA channel number to decay photon energy obtained from the location of peaks from known radioactive standards.

Error: An estimation of the analytical measurement uncertainty expressed as an error term with a specific analytical result or as a typical value for a specific analytical technique.

Fissile material: Any material consisting of or containing one or more radionuclides that can undergo neutron-induced fission with neutrons of essentially zero kinetic energy (e.g., thermal neutrons), such as ^{233}U, ^{235}U, and ^{239}Pu.

Half-life ($T_{1/2}$): The time required for one-half of the atoms of a particular radionuclide to disintegrate or undergo nuclear transformation.

Inspection: An activity such as measuring, examining, testing, or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformance is achieved for each characteristic. (ANSI/ASQC E4- 1994)

International Standard of Units: The coherent system of units adopted and recommended by the General Conference of Weights and Measures. [General Conference on Weights and Measures (CGPM)]

Isotope: One of two or more forms of a single element. The atoms of each isotope have the same number of protons but different numbers of neutrons in their nuclei. Thus, isotopes have the same atomic number but differ in atomic mass. Isotopes may be stable (not spontaneously decaying) or unstable (spontaneously decaying, emitting ionizing radiation).

Information Management System (IMS): The automated information system used by a NDA service provider to collect and track data including but not limited to analysis, QC, operability, final result calculation, and report generation.

Lower Limit of Detection (LLD): The level of radioactivity which if present will yield a measured value greater than the critical limit with a 95% probability. The critical limit is defined as that value which measurements of the background will exceed with a 5% probability.

Matrix: The substrate of a measurement item.

Measurement: A technical operation that consists of the determination of one or more characteristics of the radioactive material of interest.

Measurement Method: A scientific technique for performing a specific measurement as documented in a SOP or as published by a recognized authority.

Measurement System: An implemented test method that includes the operator(s) and the equipment used to perform the measurement.

NDA Service Provider: A business entity that has engaged in a contractual agreement to provide NDA characterization services and is ultimately responsible for generating data of known quality in compliance with the client and/or end-user requirements.

Nuclide: A species of atom characterized by its mass number, atomic number, and nuclear energy state providing that the mean $T_{1/2}$ in that state is long enough to be observable. [International Union of Pure and Applied Chemistry (IUPAC) 1995]

Operator Aid: A technical posting, other than formal procedures, rules, instructions, etc., that assists workers in accomplishing specific tasks and are not required to be posted or displayed by any organization or procedure. All operator aids must be controlled by the facility.

Performance Demonstration Program (PDP): A rigorously controlled program of providing test items to NDA service providers for analysis, reporting of results, statistical evaluation of the results, and scoring of such as well as producing a performance summary for the PPPO.

Test Item: An item for which the radioactive material content is unknown to the analyst. The test item measured by the analyst in a blind fashion and measurement results are provided to the testing agency.

Precision: The degree to which a set of measurements of the same property obtained under similar conditions. Precision is usually expressed as standard deviation relative to the mean or known value.

Quality Assurance (QA): An integrated system of activities involving planning, QC, quality assessment, reporting, and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence. [Quality Assurance Measurement System (QAMS)]

Quality Assurance [Project] Plan : A formal document describing the detailed QC procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved. (EPA-QAD)

Quality Control (QC): The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. (QAMS)

Quality Manual: A document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory to ensure the quality of its product and the utility of its product to its users. (NELAC)

Quality System: A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items) and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC. (ANSI/ASQC E-4 1994)

Radioactive Decay: Process by which a spontaneous change in nuclear state takes place. This process is accompanied by the emission of energy and subatomic particles.

Radioactive Waste: Solid, liquid, or gaseous materials containing radionuclides regulated under the Atomic Energy Act of 1954 as amended and of negligible economic value considering recovery costs.

Radioactivity: Spontaneous emission of radiation either directly from unstable atomic nuclei or as a consequence of a nuclear reaction.

Radionuclide: A nuclide that is radioactive (capable of undergoing radioactive decay).

Radiation Yield: The amount of radiation of the type being measured that is produced per each disintegration that occurs. For gamma spectrometry, this is commonly called “gamma abundance.”

Random Error: A result of a measurement minus the mean that would result from an infinite number of measurements of the same measure and carried out under repeatability conditions (ISO 1993a) (MARLAP)

Raw Data: Any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets, records, memoranda, notes, or exact copies thereof that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, microfilm or microfiche copies, computer printouts, magnetic media including dictated observations, and recorded data from automated instruments. If exact copies of raw data have been prepared (e.g., tapes that have been transcribed verbatim, data, and verified accurate by signature), the exact copy of exact transcript may be submitted. (EPA-QAD)

Percent Recovery (%R): The ratio of the amount of analyte measured in a sample to the amount of analyte known to be in the sample expressed as a percentage.

Percent Relative Standard Deviation (%RSD): The ratio of the standard uncertainty of a measurement result or mean measurement result over the result itself times 100.

Reference Standard: A standard generally of the highest metrological quality available at a given location from which measurements made at that location are derived.

Region of Interest: In radiochemical analysis, the MCA region defining the isotope or analysis parameter of interest displayed in terms of energy or channels.

Relative Bias: The quotient of the bias divided by the expected value.

Relative Standard Deviation: The ratio of the standard uncertainty of a measurement result to the result itself.

Replicate: The measurement of the variable of interest performed on an actual waste measurement item using the same NDA system, software version, calibration factors, and so on. The replicate is the set of two NDA measurements of a single actual waste item identified to serve as the replicate for the given batch. The replicate waste item is to be associated with a defined measurement item batch and is a required QC measurement for that batch. The replicate is performed as a measure of short term reproducibility.

Reproducibility (of results of measurement): The closeness of the agreement between the results of measurements of the same measure and carried out under changed conditions of measurement. A valid statement of reproducibility requires specification of the conditions changed. The changed conditions may include principle of measurement, method of measurement, observer (or analyst), measuring instrument, reference standard, location, conditions of use, and time. Reproducibility may be expressed quantitatively in terms of the dispersion characteristics of the results. Results are usually understood to be corrected results. (Adapted from ISO, 1993a)

Required Detection Limit: A contractually specified detection limit that under typical analytical circumstances shall be achieved.

Requirement: Denotes a mandatory specification often designated by the term “shall.”

Sensitivity: The capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) or a variable of interest. (NELAC)

Shall: Denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled. (ANSI)

Should: Denotes a guideline or recommendation whenever noncompliance with the specification is permissible. (ANSI)

Sigma (σ): The symbol σ and the term “sigma” are properly used to denote a true standard deviation.

Standard Deviation: The square root of a variance of a random variable. The variance is a measure of the variation of the observations within a measurement set. The standard deviation is often estimated

using a set of measurements of the random variable. The standard deviation has the same units as the measured quantity and therefore, is particularly convenient when describing the variability of the measured quantity. (ANSI)

Standard Operating Procedure (SOP): A written document that details the method of an operation, analysis, or action whose techniques and procedures are thoroughly prescribed and that is accepted as the method for performing certain routine or repetitive tasks. (QAMS)

Standard Reference Material (SRM): A CRM produced by the NIST or other equivalent organization and characterized for absolute content independent of analytical method. (QAMS)

Supervisor (however named): The individual(s) designated as being responsible for a particular area or category of scientific analysis. This responsibility includes direct day-to-day supervision of technical employees, supply and instrument adequacy and upkeep, QA/QC duties, and ascertaining that technical employees have the required balance of education, training, and experience to perform the required analyses.

Surrogate: A combination of traceable radioactive materials and a known configuration of matrix materials used to replicate the characteristics of actual waste forms and process components.

Systematic error: An error component that produces a fixed bias in the underlying expected value of a determination from measurement to measurement. (ANSI)

Total Measurement Uncertainty (TMU): An estimate or approximation of the error associated with a measured value by propagation of individual uncertainties. The TMU shall include both systematic and random error.

Traceability: The property of a result of a measurement whereby it can be related to appropriate standards generally international or national standards through an unbroken chain of comparisons.

Validation: The confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

Verification: Confirmation by examination and provision of evidence that specified requirements have been met. Note: In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation, or specification peculiar to the management of the measuring equipment. The result of verification leads to a decision either to restore in service, to perform adjustment, to repair, to downgrade, or to declare obsolete. In all cases, it is required that a written trace of the verification performed shall be kept on the measuring instrument's individual record.

Waste characterization: The process of determining that waste characteristics comply with applicable requirements and demonstrates acceptable performance of the activities defined by PPPO-approved site-specific plans.

Working Reference Material (WRM): A material or substance, one or more properties of which are traceable to a nationally recognized reference base and used for the calibration of a measurement system, the assessment of a measurement method, or for assigning values to materials.

APPENDIX C: CERTIFICATE OF TRACEABILITY FOR RADIOACTIVE WRM

Los Alamos National Laboratory
Certificate of Content and Traceability

U. S. Department of Energy
PuO_2/AmO_2-Diatomaceous Earth Working Reference Material # NTP000X

This Working Reference Material (WRM) Source contains high purity plutonium dioxide (PuO_2) and americium dioxide (AmO_2) dispersed uniformly in diatomaceous earth, doubly encapsulated in welded zirconium cylinders.

NUCLEAR MATERIAL CONTENT

The nuclear material contents and total alpha activity for this WRM are listed below. Also listed are overall uncertainty estimates at 95% confidence bounds (CB) for each quantity.

Component†	Quantity or Value*	95 % CB
Total PuO_2 in WRM	0.14990 grams	± 0.00051 grams [a]
Assay of Pu in PuO_2	0.8788 g Pu/g PuO_2	± 0.0009 g Pu/g PuO_2 [b]
Total Pu in WRM	0.13173 grams	± 0.00043 grams [c]
Assay of ^{241}Am in PuO_2	1243 µg/g PuO_2	± 3 µg/g PuO_2 [d]
^{241}Am in PuO_2	0.00019 grams	± 0.0000005 grams [e]
Added AmO_2	0.01255 grams	0.00002 grams
Assay of ^{241}Am in added AmO_2	0.785 g ^{241}Am/g AmO_2	±0.006 g Am/g AmO_2
Added ^{241}Am from AmO_2	0.00985 grams	0.00007 grams
Total ^{241}Am in WRM	0.01003 grams	0.00007 grams
Pu Isotopic Weight Fraction* (Pu from PuO_2 only)		
^{238}Pu	0.000149	± 0.000005 [f]
^{239}Pu	0.929956	± 0.000015 [f]
^{240}Pu	0.067209	± 0.000007 [f]
^{241}Pu	0.002022	± 0.000008 [f]
^{242}Pu	0.000659	± 0.000003 [f]
Total Alpha Activity in WRM	44.38 mCi 1.64E+09 Bq	± 0.27 mCi [g] ± 1.0E+07 Bq [g]

***All values decay corrected to 9/01/99** **† see notes on reverse**

This Source was manufactured in August-September, 1999, by the Analytical Chemistry Group of Los Alamos National Laboratory, MS G740, Los Alamos, NM, 87545. The Source Expiration date is 9/1/2074.

Sealed Source Certification

This statement certifies that this source, NTP0001, meets the requirements for classification as a sealed radioactive source as defined in ANSI/HPS N43.6-1997 Classification 97C43323.

_____	_____	_____	_____
Group Leader	**Date**	**Project Manager**	**Date**

Actinide Analytical Chemistry Group NDA PDP WRM Production

Quantitative information and uncertainties on the nuclear content of this WRM are listed on this Certificate. Complete information regarding the Pu and Am content, Pu isotopic ratios, chemical composition, elemental impurities, containment, and WRM fabrication procedure is described in the *NDA PDP WRM Phase IIIA Production Plan* and in files retained by the Los Alamos National Laboratory Actinide Analytical Chemistry Group.

MEASUREMENT METHODS AND TRACEABILITY

The nuclear contents of this WRM were characterized and quantified using the following methods with traceability to the National Institute of Standards and Technology (NIST) or New Brunswick Laboratory (NBL) standards.

Measurement	Measurement Method	Reference Material
Weighing	5 place analytical balance	NIST traceable certified weights
Pu Assay	Controlled Potential Coulometry	NBS SRM 949f
Am Assay	Isotope Dilution Mass Spectrometry	NBS SRM 948
Pu Isotopic	Total Evaporation Mass Spectrometry	NBS SRM 948
Alpha Activity	Calculated using Pu and Am mass, and isotope half lives listed below.	Pu $T_{1/2}$ as stated for NBS SRM 948 Am $T_{1/2}$ as stated for NIST SRM4322B

The stated Alpha Activity was calculated using the following isotope half lives (in years): ^{238}Pu: 87.74; ^{239}Pu: 24,119; ^{240}Pu: 6,560; ^{241}Pu: 14.34; ^{242}Pu: 387,000; and ^{241}Am: 432.2.

NOTES

†Due to the complexity of combining separate feedstock's of PuO_2 (which contains AmO_2) and AmO_2 (which contains PuO_2 that has different assay and isotopic characteristics) and in accounting for holdup losses, calculation of Total Pu and ^{241}Am from PuO_2 in each WRM is not straightforward and cannot be reproduced exactly from the data provided on the certificate.

Random and systematic error terms were combined and reported as 95% confidence intervals. Error terms include estimates of the following:

(a) Balance precision, buoyancy, standard weight bias.
(b) Long and short term precision, instrument control check bias, weighing precision and bias.
(c) Pu weights and assay terms, and holdup corrections.
(d) Long and short term precision and bias.
(e) Am weights, Am assay terms, and holdup corrections.

(f) Long and short term precision and bias.

(g) Based on propagated uncertainties on the Pu mass, ^{241}Am mass and Pu isotopic uncertainties listed above. It is recommended that all facilities use the half-lives listed above for decay corrections to preclude facility-to-facility differences introduced through use of different half life values.

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APPENDIX D: NDA QC CONTROLS AND ACCEPTANCE CRITERIA

NDA QC CONTROLS AND ACCEPTANCE CRITERIA

The NDA measurement QC program consists of measurement regimens to obtain data and use such data to demonstrate the NDA measurement method produces measured quantities of the required quality over a defined measurement item batch. QC parameters and associated acceptance criteria are presented in this section.

D-1. QC MEASUREMENTS

NDA system performance checks shall be performed each day of NDA operations and at the beginning and end of each batch, however defined. A batch may span a period of more than one day, but the requirement to perform QC checks per day is not superseded. At the start of a batch, QC measurements shall be acquired and evaluated per their respective limits. The beginning of the performance check for the next sequential batch can be the ending performance check for the previous batch. An out-of-control performance check at the end of the defined batch period shall cause all NDA measurements acquired since the last successful performance check to be considered suspect. Corrective actions shall be in place to evaluate the measurement item results for the affected measurements.

Check sources used for QC checks should be traceable and provide adequate counting statistics for a relatively short count time. If the check source is not traceable, it should be correlated with a traceable source or well known, characterized, and documented.

All performance data shall be monitored on an as-recorded basis and over time using control chart and trending techniques. If source decay correction is necessary (e.g., for ^{252}Cf sources used for neutron counting systems), degradation of precision for a fixed counting time may need to be taken into account. Most monitoring techniques assume that measurement data are distributed normally and that observations are independent. The assumption of normality should be assessed before implementation of a control regimen. The NDA service provider is responsible for determining acceptance criteria for as-recorded and long term data trending. Recommended control chart limits and actions levels are contained in Table D-1. CAPs or procedures shall be in place to manage out-of-control results and the associated measurement item data.

D-1.2 Efficiency, Energy Calibration, and Energy Resolution

D-1.2.1 Efficiency

Efficiency checks for neutron and gamma measurement systems shall be performed at least once per day for each measurement system in use. For gamma-ray systems that use multiple gamma-ray energy peaks for analysis, the efficiency check shall include a peak at the upper end and a second peak toward the lower end of the spectral regions typically analyzed (e.g., 1001 keV and 185.7 keV). The efficiency check shall be acquired and evaluated at the beginning and end of each analytical batch. The once per day requirement can serve as either the beginning or ending batch check. An out-of control efficiency check will cause measurement item data to be suspect since the last successful efficiency check. Efficiency checks can be performed at a greater frequency than once per day.

D-1.2.2 Energy Calibration

An energy calibration check for gamma measurement systems shall be performed at least once per day for each measurement system in use. For systems that use peak fitting software with expert technical review of each spectrum and employ the capability of energy re-calibration on a per spectrum basis, a daily check is all that is required.

For other gamma ray measurement systems (e.g., systems that use channel based regions of interest), additional checks, as described below, are necessary. The energy calibration check shall be acquired and evaluated at the beginning and end of each analytical batch. The once per day requirement can serve as either the beginning or ending batch check. An out-of-control energy calibration check will cause measurement item data to be suspect since the last successful energy calibration check. Energy calibration checks can be performed at a greater frequency than once per day.

D-1.2.3 Energy Resolution

A full width half maximum (FWHM), or equivalent, resolution check for gamma measurement systems shall be performed on each spectrum for which sufficient peak areas to obtain accurate FWHM estimates are observed. If gamma ray peaks at multiple energies are used for analysis, the resolution check must include a peak at the high end of the range and a second peak toward the lower end of the range (e.g., 1001 keV and 185.7 keV). An out-of control FWHM check will cause measurement item data to be suspect since the last successful energy calibration check. Administrative limits can be used for evaluation of the resolution check. If administrative limits are used, they shall be supported by appropriate initial evaluation of each system's capability.

D-1.3 Replicate Measurements

Repeatability is assessed through the acquisition and analysis of a replicate measurement on a randomly selected measurement item from each batch. The selected measurement item is then re-measured using the same NDA system and software. Analyses shall be independently performed (i.e., if differential peak analysis is used to estimate item self attenuation, the differential peak analysis shall be performed independently on both sets of spectra). The second measurement of the item is to be performed any time before the start of the next batch. This repeat measurement in conjunction with the initial item measurement produces the replicate for that batch. When replicate data do not meet the corresponding acceptance criteria, corrective action as per applicable procedures shall be initiated.

When two replicates are utilized to assess repeatability, the data should be evaluated as follows:

$$\frac{|D-S|}{S} \times 100 \leq 25\%$$

where D is the duplicate results and S is the first value obtained for the measurement item.

An acceptable relative percent difference (RPD) shall be less than 25% or other criteria specifically requested by the client.

For a randomly selected replicate measurement item that corresponds to a measurement below the LLQ, the 95% uncertainty ranges of the pair of measurements must overlap.

A control chart of the RPD shall be maintained for trending analysis. Procedures shall be established for the collection, processing, and periodic evaluation of replicate data. Alternate methods for determining repeatability and assessing its acceptability may be implemented by the NDA service provider provided they are documented and approved by the PPPO.

D-1.4 Background Measurements

Background measurements must be performed for fixed facility neutron and gamma systems at least once per day and at the beginning and end of each batch. The once per day background measurement can serve as the beginning or ending background measurement required for the set or batch. The count time for neutron and gamma background checks shall be at least as long as the measurement count time unless otherwise specified and documented by the NDA SME. The background measurement shall be evaluated before daily NDA measurements.

Depending on environmental conditions, the background frequency may have to be increased to ensure data quality. Increases in the frequency of background measurements shall be determined as appropriate made by the cognizant SME (Note: Enrichment measurement systems do not require a background performance check). The recorded background data is to be monitored using control charts or tolerance charts to ensure that the background environment is within statistical control.

D-2. RECOMMENDED QC ACTION LEVELS AND RESPONSE

Qc measurements shall be performed on a periodic basis as prescribed above and evaluated relative to established acceptance criteria. Qc measurements shall also be reviewed and evaluated over time to determine continued acceptability of the assay system and to monitor trends. If daily QC checks yield results that are outside the acceptable range(s), the required responses in Table D-1 must be followed. The NDA service provider may implement more restrictive control limits and other administrative limits as applicable. All control limits and associated actions are to be documented and maintained.

Trending analysis that indicate yielding eight QC points in a row either above or below the mean QC indicates a the presence of a potential bias. This condition will require that an evaluation be performed for practical significance. It does not mean the measurement system is out of control (see criteria in Table D-1). The evaluator is to determine whether or not to remove the bias or correct for the bias.

Table D-1. Range of Applicability

Category	Acceptability Range[a]	Required Response
Acceptable Range	$\lvert Data \rvert$ [b] $\leq 2\sigma$[c]	No action required
Warning Range	2σ[c] $< \lvert Data \rvert \leq 3\sigma$[c]	The performance check shall be rerun no more than two times. If the rerun performance result is within 2σ, then the additional performance checks shall be documented and work may continue. If the system does not fall within the $\pm 2\sigma$ after two rerun performance checks, then the required response for Action Range shall be followed.
Action Range	$\lvert Data \rvert > 3\sigma$[c]	Work shall stop and the occurrence shall be documented and appropriately dispositioned (e.g., initiating a nonconformance report). The NDA system shall be removed from service pending successful resolution of the failure cause. All assays performed since the last acceptable performance check are suspect pending satisfactory resolution. At a minimum, calibration verification is required before returning the system back to service.

[a] - American National Standards Institute. *Nondestructive Assay Measurement Control and Assurance,* ANSI N15.36.
[b] – Absolute value
[c] - The standard deviation is only based on the reproducibility of the data check measurements themselves. This is not TMU.