U.S. Department of Energy

Consolidated Audit Program

Checklist 9

Data Quality for Non-Destructive Assay

Revision 2.2
Based on QSAS Revision 2.8

Audit ID:	**Date:**

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Areas of Review During Audit

__ NDA System Calibration
__MDA Determination
__ Infinite Thickness
_ _ NDA Measurement Uncertainty
__ NDA Measurement Traceability
__ NDA Software Quality Assurance

__ Acceptable Knowledge
__ NDA Data Review and Verification
__ NDA Measurement QC
__ Batch Quality Control
__Performance Evaluation (PE) Programs
__Document Control

__ NDA Measurement Support Equipment
__ Instrument Maintenance
__ Contamination Control
___Identification of Measurement Item (prior to performance of NDA measurements)
__ Measurements of material densities

A = Acceptable
F = Finding
U = Unsatisfactory
O = Observation
NA = Not Applicable

Referenced regulations are accessible at the following URLs:

- https://doecap.oro.doe.gov/

NOTE:

- When audit findings are written against *site-specific documents* (i.e., SOPs, QA Plans, licenses, permits, etc.), a *copy* of the *pertinent requirement text* from that document *must* be attached to this checklist for retention in DOECAP files.

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Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
1.0	**NDA System Calibration**		

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Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
1.1	Methods employed for initial calibration of an NDA measurement system: method manuals and/or procedures for initial calibration of NDA system developed, documented and implemented addressing NDA method, modeling techniques as applicable, data reduction, traceability, etc.; • NDA initial calibration(s) performed in accordance with established consensus standards, such as ANSI15.20, Reg Guide 5.53, ASTM C1316-08, etc., as applicable; • where consensus standards are not used for initial calibration, an applicable method is developed, implemented and fully documented; • initial calibrations are performed using representative working reference materials (WRMs) traceable to a nationally recognized reference base; • where traceable WRMs are not currently available, standards used for initial calibration are correlated to traceable WRMs; • where there are an insufficient number and denomination or traceable materials to support initial calibration, an alternate strategy is implemented and documented; • where surrogate matrices are used for calibration, the design, procurement and as-built documentation is sufficient to establish critical physical properties to demonstrate representativeness of waste items of interest.; • initial calibration spans the mass/activity range consistent with		

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Item Number	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed Audit Notes
	characterization project data quality objectives (DQOs), documentation clearly shows this;		

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	• initial calibration accounts for source/matrix configurations representative of the actual waste population as per measurement campaign goals and DQOs and is clearly documented; • initial calibration error components identified, and propagated into a total measurement uncertainty, method is technically defensible and clearly documented; • techniques in place to detect measurement items not within the capability of initial calibration; • documentation and records of the entire initial calibration process/results are maintained such that calibration can be reproduced; • fundamental physical constants used in calibration and data reduction, e.g., decay constants, branching ratios, material attenuation tables, neutron yields, master gamma libraries, etc. are documented and controlled.; • Procedure or document exists establishing conditions under which initial calibration must be evaluated and/or re-established. *QSAS Sections 5.4.1, 5.4.1.1, 5.4.1.2, 5.4.2.2, 5.4.2.1a; 5.4.2.1, 5.4.5.2, 5.4.6, D.4 DOE, QSAS Appendix E.1.1, E.1.1.1.*		

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1.2	Method employed for confirmation of initial calibration of NDA measurement system: • method manuals and/or procedures for NDA measurement system calibration confirmation developed, documented and implemented; • a technique for performing a calibration confirmation has been developed and documented; • the technique produces clear and objective evidence that independently confirms the validity of the initial calibration; • the WRM/matrix surrogate configuration(s) used for confirmation are representative of the waste forms of interest and are not the same as used for establishing the initial calibration; • the number of different confirmation WRM/matrix configurations reasonably validate the calibration realm of the NDA system and is documented; • WRMs used in the calibration confirmation process are not the same as used to establish the initial calibration, this is documented, and where necessary, temporary waivers of this requirement have been obtained; • calibration confirmation acceptance technique and criteria have been established and documented.;		

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	• Calibration confirmation measurement have been performed, evaluated and documented; • Where calibration confirmation results were unacceptable, a corrective action plan (CAP) was developed, implemented and documented; • For waste form configurations not meeting confirmation acceptance criteria, such configurations are clearly identified and excluded from characterization with that calibration; • a periodic requirement for and conditions under which a calibration confirmation is to be performed has been established and documented; • documentation, data files, and records of the calibration confirmation process are sufficient to reconstruct the confirmation. *QSAS Appendix E.1.1.2*.		

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1.3	Methods employed for periodic calibration verification of the NDA measurement system: • calibration verification procedure(s) developed and implemented; • procedures have provisions for production of WRM/matrix surrogates that are representative of the waste forms the calibration is valid for; • procedure has provisions to perform a calibration verification measurement every five rolling days of NDA operation; • where longer calibration verification periods are used, up to thirty rolling operational days, sufficient data and documentation has been established to technically justify the longer period; • sufficient data and documentation that point calibration verification data reasonably span the calibration realm in every twelve month period; • procedure provides for calibration verification test item to be assembled by an individual independent from NDA operations such that the measurement is performed in a manner blind to the NDA operator and analyst; • acceptance parameters and criteria have been established for acceptable calibration verification measurements; • corrective action measures and plans have been established to address unacceptable calibration verification results; • tracking and trending of calibration verification is evaluated to monitor long term performance stability. *QSAS Appendix E.1.1.3.*		

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2.0	**MDA Determination**		
2.1	A method for determining the measurement LLD and/or MDA is available for each isotope of interest. *QSAS, Section D.4, DOE-25 and Appendix E.1.1.5.*		

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3.0	**Infinite Thickness**		
3.1	• Techniques for determination of infinite thickness have been implemented as applicable *QSAS Appendix E, Section E.1.1.6*		

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4.0	**NDA Measurement Uncertainty** • A document, plan or procedure(s) is in place delineating the method of uncertainty determination, identification of error components and propagation into a TMU for each measurement item for waste forms of concern; • The expression of and units of TMU is clearly defined and understandable on measurement item reports, etc.; • Where off-the-shelf data acquisition and analysis programs are used, there is clear documentation of the TMU process and the manner in which it is expressed. *QSAS Appendix E, Section E.1.1.7*		

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5.0	**NDA Measurement Traceablity**		
5.1	A program and/or procedure is in place to ensure working reference materials (WRMs) and support equipment standards, e.g., weights, are traceable to nationally recognized reference base, e.g., NBL, NIST, for calibration, QC checking etc. Where traceable standards are not available, appropriate alternate strategy is in place. *QSAS Appendix E Section E.1.1.8 and E.1.1.8.a*		
5.2	• Traceable WRMs used for initial calibration and calibration confirmation are representative of elements, isotopic composition, physical and chemical form as per the waste items of interest, as applicable. *QSAS Appendix E Section E.1.1.8.b*		
5.3	• procedures governing the specification, procurement, acceptance, control and management of WRMs are in place. *QSAS Appendix E, Sections E.1.1.8.c and E.1.1.8.h*		
5.4	• WRM information and records including: content, manufacturer, date of purchase, certificate of traceability, expiration date, re-certification, etc., are maintained and available. *QSAS Appendix E, Section E.1.1.8.d and E.1.1.8.e*		
5.5	• Traceable WRMs are verified at least every five years using a standard traceable to a nationally recognized reference base;		

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	• Procedures and schedules are in place to maintain confidence in WRMs including contamination control and integrity as well as for safe handling, transport, and storage. *QSAS Appendix E, Section E.1.1.8.f, E.1.1.8.g and E.1.1.8.h*		

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6.0	**NDA Software Quality Assurance**		
6.1	Plans and/or procedures governing procured or in-house software used for NDA characterization, recording, reporting, storage, retrieval, etc., are in place. • Evidence of software quality control, verification and validation is available and maintained; • For in-house developed or modified, software development, planning and QA controls are in place; • Software configuration control and change procedures are in place; *QSAS Appendix E, Sections E.1.1.9, E.1.1.9.a, E.1.1.9.b, E.1.1.9.c*		
6.2	• NDA working configuration/data files, master gamma libraries, efficiency tables, etc. are controlled to prevent unauthorized access; • Spreadsheets used for NDA characterization are verified initially and after changes or software revisions and upgrades; • Procedures are in place to ensure data integrity • Spreadsheets are controlled, write-protected and content documented; • Procedures are in place for the control, transmission, protection and storage of generated NDA characterization data; • Computers and automated data equipment are maintained and provided a proper operating environment; • Procedures are in place for the security, assess control, and changes to computer records;		

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	• an inventory of software used to generate NDA characterization data as well as a file of historical software, software procedures, changes, etc. are in place. *QSAS Appendix E, Section E.1.1.9.d, E.1.1.9.e, E.1.1.9.f, E.1.1.9.g, E.1.1.9.h, E.1.1.9.i, E.1.1.9.j, E.1.1.9.k*		

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7.0	**Acceptable Knowledge**		
7.1	Where NDA methods do not provide a direct quantification of a characterization property, e.g., ^{234}U mass/activity, acceptable knowledge used to determine such quantity has been validated and is documented. *QSAS Appendix E, Section E.1.1.10*		

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8.0	**NDA Data Review and Verification** • An NDA report is provided for each measurement item; • NDA item reports contain and/or have reference to all input data, measurement configuration, acquisition parameters, analyses, software version, AK data, measurement procedure used, etc. to allow reproduction of the measurement result; • Reference to a technical document or procedure that contains equations for calculations used to obtain results; • name or initials of the person performing the analysis; • date and time that the NDA measurement was performed; • name or initials of the peer, supervisory, or QA reviewer; • Procedures are in place to ensure a complete review and approval of each measurement item report by an appropriately qualified person; • Procedures are in place to ensure data verification and that batch data reports are properly prepared, reviewed and approved. • Batch reports include or reference as appropriate all applicable measurement information and data, QC data, etc. *Appendix E, Section E.1.1.11 and E.1.1.11.1, E.1.1.11.2, QSAS, Section 5.10*		

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9.0	**NDA Measurement QC** • QC measurements are performed at the required frequency; • Analytical sets or batches are reasonably defined and properly bracketed by valid QC measurements; • At least one replicate measurement is performed per batch; • Regimen for evaluating QC measurement results is in place; • QC control limits, action levels and appropriate corrective action responses are defined and in place; • Efficiency check technique is acceptable; • Energy calibration check technique is acceptable; • Energy resolution check technique is acceptable; • Replicate measurement technique is acceptable; • Background measurement technique and frequency acceptable; • QC data are control charted and appropriately monitored through trending techniques as applicable. *Section 4.10, QSAS Appendix E, Section E.2.1, E.2.1.1, E.2.1.2, E.2.1.3, E.2.1.4, E.2.1.5, E., ANSI N42.14, Section 6.2*		

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10.0	**Batch Quality Control** • unique identification, tracking, and batch association of measurements and QC measurements; • identification and frequency of analyzing QC measurements; • analysis of positive controls (e.g., daily performance checks); • the use of other controls (e.g., replicates); • reference or control standards (e.g., check standards); • how data from QC measurements are assessed, reported, and reviewed; • how QC batch associations are maintained when reanalysis/recounting of measurements/QC measurements is necessary; • documentation of control data and control charts; • narrating all instances where QC criteria are not met; • who assesses, reports, reviews and makes decisions that relate to QC data. *QSAS, Sections 4.10, 5.9.2, Appendix E.2 Sections E.2.1, E.2.1, E.2.1.2, E.2.1.3, E.2.1.4, E.2.1.5, Appendix E.3*		

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11.0	Performance Evaluation (PE) Programs		
11.1	• Evidence of participation in applicable PE programs is available; • Where PE program results were unacceptable, corrective action measures are taken and resolution of such is available. *QSAS, Section 5.9, DOE-1, QSAS Appendix E, Section E.1.1.12*		

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12.0	**Document Control**		
12.1	• Controlled methods and/or procedures are accessible to the individual performing the analyses. Changes to records are signed or initialed by responsible staff. The reason for the signature or initials is clearly indicated, such as “sampled by,” “prepared by,” or “reviewed by”; *QSAS Sections 4.3.1 and 5.4.1*.		
12.2	• All corrections in record-keeping errors are made by one line marked through the error. Justification for the change is included if the reason is not self-explanatory. The individual making the correction signs (or initials) and dates the correction. *QSAS Sections 4.3.3 and 4.12.2*		

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13.0	**NDA Measurement Support Equipment**		
13.1	Daily check weighings are performed using NIST-traceable weights. Daily checks are documented in controlled logbooks. *QSAS, Section 5.5.2.1.d*		
13.2	Certified check weights shall be verified every five years. Alternatively, Class 1 check weights may be reverified using controlled check weight standards that are used exclusively for this purpose. *QSAS, Section 5.5 DOE-4*		
13.3	Scales are calibrated before initial use and annually thereafter and labeled to that affect by an independent professional technician not associated with the organization's daily operation. *QSAS, Sections 5.5.2.1, QSAS Appendix E.1.1.8, 5.5 DOE -4*		

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14.0	**Instrument Maintenance**		
14.1	Each item of equipment is labeled, marked, or otherwise identified to indicate its calibration status. Malfunctioning or out-of-calibration equipment is tagged or segregated and not used until it has been repaired or re-calibrated. *QSAS, Sections 5.5.7, 5.5.8, 5.5.9, 5.5 DOE-9*		
14.2	Instrument maintenance records are maintained (e.g., maintenance is recorded in a logbook) and the following is identified and documented: • instrument manufacturer, • model number, • serial number, • instrument configuration, • instrument settings, • detector identifications, • any instrument damage, malfunctions, repairs or modifications, and • details of maintenance performed to date and planned for the future. *QSAS, Sections 5.5.3, 5.5.5*		
14.3	Repair, reconfiguration or replacement of an instrument is followed by calibration confirmation of the system. When calibration confirmation parameters are not met, the effect in previous		

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	calibrations and tests is examined. *QSAS, Appendix E.1.1.2 and Section 5.5.7*		

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15.0	**Contamination Control**		
15.1	There is effective separation between neighboring areas when activities therein are incompatible, when possible. *QSAS, Section 5.3.3, QSAS Appendix E.2.1.5*		
15.2	Adequate measures are taken to ensure good housekeeping in the work area and to ensure that any contamination does not adversely affect data quality. *QSAS, Section 5.3.5*		

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16.0	Identification of Measurement Item (prior to performance of NDA measurements)		
16.1	NDA personnel are informed of the physical characteristics of the waste matrix. The process used to share this information with the NDA group is designed to ensure consistency and accuracy. Development of waste profiles is one means to achieve this requirement. • The physical characteristics that are pertinent to NDA methods are identified or listed as unknown Some examples are: • The average density of the waste matrix • The degree of homogeneity of the density within the waste matrix • Solid versus liquid • The gross and net weight of the waste container • The anticipated distribution of radioactive and non-radioactive isotopes • The presence of neutron absorbers such as boron, iron, chlorine, hydrogen, etc.		

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17.0	**Measurements of material densities**		
17.1	The process used to determine the attenuation characteristics of material being measured with NDA techniques is documented. The following methods are commonly accepted techniques:		
	• Transmission Corrected Technique The transmission corrected technique refers to a series of attenuation measurements of a matrix using a transmission source. Gamma rays are susceptible to the effects of shielding within the matrix material. If the amount of gamma ray attenuation is unknown, the calculation model cannot compensate for the gamma rays that do not escape the material that is being measured. The use of a transmission source ensures that the amount of attenuation is a known parameter, and is appropriately addressed.		
	• Differential Peak Absorption Technique Spectra are obtained, and an analysis is performed of the various gamma energy lines that relate to the isotope being measured. For example, ^{235}U has five primary gamma energy lines. Evaluation of the absorption characteristics for individual gamma-ray energies provides valuable information relative to the attenuation characteristics for the radioactive material and matrix. The evaluation is performed over a broad range of energies. This ensures that the attenuation correction factors for individual gamma-ray energies are appropriately addressed. The comparison of the energy spectra and the absorption characteristics or mass values calculated by the software provide assurance that the attenuation factors and the degree of homogeneity with respect to uranium concentration used within the calculation model are consistent with the data collected by the NDA instruments.		

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	Conservative Matrix Density Technique Conservative estimates for the attenuation characteristics of the matrix material can be calculated using process knowledge. The assumed density is compared to the net weight of the container to ensure that the assumed density exceeds the known weight for the item of interest. The use of a conservative density estimate ensures that the amount of attenuation is adequately accounted for and is conservatively addressed. This comparison provides assurance that the degree of homogeneity with respect to the distribution of fissile material and the remaining matrix material is known and adequately addressed. The degree of homogeneity has a significant impact on the determination of attenuation factors as well as the interpretation of the NDA data.		

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References cited in this checklist:

ANSI 15.20, Guide to Calibrating Nondestructive Assay Systems

ANSI N15.36 Nondestructive Assay Measurement Control and Assurance

ANSI N42.12-1994, American National Standard Calibration and Usage of Thallium-Activated Sodium Iodide Detector Systems for Assay of Radionuclides.

ANSI N42.14-1999, American National Standard for Calibration and Use of Germanium Spectrometers for the Measurement of Gamma-Ray Emission Rates of Radionuclides.

ANSI N42.23-1996, American National Standard Measurement and Associated Instrumentation Quality Assurance for Radioassay Laboratories.

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

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

U.S. Department of Energy, 2012, US DOE Quality Systems for Analytical Services (QSAS), Revision 2.8.

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