Independent Assessment of Software Quality Assurance Program Implementation at the Oak Ridge National Laboratory

February 2024

Office of Enterprise Assessments
U.S. Department of Energy

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Acronyms

CFR	Code of Federal Regulations
CRAD	Criteria and Review Approach Document
DOE	U.S. Department of Energy
EA	Office of Enterprise Assessments
NQA	Nuclear Quality Assurance
OFI	Opportunity for Improvement
ORNL	Oak Ridge National Laboratory
OSO	ORNL Site Office
QAP	Quality Assurance Program
QAPD	Quality Assurance Program Description
SBMS	Standards-based Management System
SME	Subject Matter Expert
SQA	Software Quality Assurance
SRS	Software Registration System
UT-Battelle	UT-Battelle, LLC

INDEPENDENT ASSESSMENT OF SOFTWARE QUALITY ASSURANCE PROGRAM IMPLEMENTATION AT THE OAK RIDGE NATIONAL LABORATORY

Executive Summary

The U.S. Department of Energy (DOE) Office of Enterprise Assessments (EA) conducted an independent assessment of software quality assurance (SQA) program implementation at the Oak Ridge National Laboratory (ORNL) from October to November 2023. The purpose of this assessment was to evaluate the performance of the UT-Battelle, LLC (UT-Battelle) SQA program. This assessment also evaluated the effectiveness of the DOE Office of Science ORNL Site Office (OSO) in providing oversight of the SQA program.

EA identified the following strengths:

- UT-Battelle's divisions and directorates demonstrated a commitment to enhancing SQA program performance at ORNL by performing annual SQA self-assessments and by the recent merger of software quality and business requirements to enhance efficiency.
- UT-Battelle software application owners exhibited thorough knowledge of their respective applications and functionality.
- UT-Battelle subject matter experts provide useful SQA program training across ORNL.

EA also identified several weaknesses, as summarized below:

- UT-Battelle has not established processes and procedures for identifying major modifications and then appropriately applying additional SQA requirements from applicable consensus standards.
- UT-Battelle does not ensure that applicable quality requirements are applied to all software graded as Research Software.
- UT-Battelle has not specified and implemented the minimum training and qualification requirements needed for the use of all safety and non-safety software.
- UT-Battelle has not demonstrated implementation of all required SQA criteria for all non-safety software.
- UT-Battelle did not update the software inventory list to reflect a software grading level change.
- OSO has not evaluated the performance of the SQA program that is currently implemented at ORNL and does not maintain technical capability sufficient to evaluate contractor SQA program performance.

In summary, UT-Battelle has implemented a generally adequate SQA program at ORNL with some relatively minor observed weaknesses. Safety and non-safety software applications are managed through processes that provide reasonable assurance of software quality that supports nuclear safety and mission operations. However, several weaknesses associated with the SQA program were identified during this assessment. In addition, OSO has adequately reviewed and approved the UT-Battelle SQA program but has not evaluated and assessed the program in the last five years. Until the weaknesses identified in this report are addressed, or effective mitigations are put in place, software quality at ORNL will not be optimally managed consistent with DOE requirements and the UT-Battelle quality assurance program.

INDEPENDENT ASSESSMENT OF SOFTWARE QUALITY ASSURANCE PROGRAM IMPLEMENTATION AT THE OAK RIDGE NATIONAL LABORATORY

1.0 INTRODUCTION

The U.S. Department of Energy (DOE) Office of Nuclear Engineering and Safety Basis Assessments, within the independent Office of Enterprise Assessments (EA), conducted an assessment of software quality assurance (SQA) program implementation at the Oak Ridge National Laboratory (ORNL) from October to November 2023. The purpose of this assessment was to evaluate the SQA program implemented by the primary site contractor, UT-Battelle, LLC (UT-Battelle). This assessment also evaluated the effectiveness of the DOE Office of Science ORNL Site Office (OSO) in providing oversight of the SQA program.

This assessment was performed consistent with *EA Plan for Phase 2 of the Enterprise-wide Independent Assessment of Software Quality Assurance Process Implementation, January 2023*, which describes the second phase of a two-phase, enterprise-wide, targeted assessment of SQA processes. The first phase of this targeted assessment process examined and analyzed the design of SQA programs implemented throughout the DOE enterprise, helping to identify general, complex-wide strengths and weaknesses. The first phase also helped inform the development of an EA plan for conducting assessments of SQA program implementation at selected DOE sites. Accordingly, this second phase assessment evaluated SQA program implementation by examining UT-Battelle SQA processes. The assessment evaluated a sample of both safety and non-safety software, software that has been assigned varying grading levels, and software that is implemented for a variety of functions (e.g., nuclear and radiological safety analyses, administrative activities).

2.0 METHODOLOGY

The DOE independent oversight program is described in and governed by DOE Order 227.1A, *Independent Oversight Program*, which EA implements through a comprehensive set of internal protocols, operating practices, assessment guides, and process guides. This report uses the terms "best practices, deficiencies, findings, and opportunities for improvement (OFIs)" as defined in the order.

As identified in the assessment plan, this assessment considered requirements related to software, as presented in 10 CFR 830, *Nuclear Safety Management*, subpart A, *Quality Assurance Requirements*, and DOE Order 414.1D, *Quality Assurance*, and applicable consensus standards, including American Society of Mechanical Engineers Nuclear Quality Assurance (NQA)-1, *Quality Assurance Requirements for Nuclear Facility Applications*. EA used EA CRAD 30-10, Revision 0, *Software Quality Assurance Criteria and Review Approach Document*, to guide this assessment.

EA examined key documents, such as program plans and descriptions, implementing procedures, software lifecycle management documentation, assessment reports, and training and qualification records. EA also interviewed key personnel responsible for developing and executing the associated programs and observed meetings and activities that support SQA program implementation. The members of the assessment team, the Quality Review Board, and the management responsible for this assessment are listed in appendix A.

There were no previous findings for follow-up addressed during this assessment.

3.0 RESULTS

3.1 Quality Assurance Program

This portion of the assessment evaluated the UT-Battelle quality assurance program (QAP) for safety and non-safety software.

Safety Software

UT-Battelle has established a generally adequate ORNL QAP, as described in the DOE-approved document *Quality Assurance Program Description* (QAPD), dated January 20, 2023, and in general, it appropriately addresses safety software. The ORNL QAPD provides an overview of the quality program applicable to all ORNL work performed by UT-Battelle based on requirements from the International Organization for Standardization consensus standard ISO 9001:2015, *Quality Management System – Requirements*; 10 CFR 830, subpart A; and DOE Order 414.1D, attachment 1, *Contractor Requirements Document DOE O 414.1D Chg 2*, *Quality Assurance*, and attachment 2, *Quality Assurance Criteria.* The QAPD adequately describes additional quality assurance requirements or guidance documents to be applied on a project- or process-specific basis based on potential risk factors and customer requirements. The additional quality assurance requirements of interest to this assessment include NQA-1-2000 for existing nuclear facilities; NQA-1-2008 with the NQA-1a-2009 addenda for new nuclear facilities and major modifications of existing nuclear facilities; and DOE Order 414.1D, attachment 4, *Safety Software Quality Assurance Requirements for Nuclear Facilities*, for safety software.

The QAPD quality requirements crosswalk parses the following source requirements to the Software Quality Requirements topical area:

- DOE Order 414.1D, attachment 4
- NQA-1-2000
- NQA-1-2008 with the NQA-1a-2009 addenda.

The QAPD does not parse DOE Order 414.1D, attachment 2, in the requirements crosswalk for Software Quality Requirements implemented through the Quality Assurance (QA) and Information Technology (IT) management systems. (See **OFI-UT-Battelle-1**.)

UT-Battelle maintains institutional quality assurance implementing procedures through the web-based Standards-based Management System (SBMS) for work activities governed by the QAPD. The SBMS *Software Quality Assurance and Other Software Requirements* (SBMS SQA) subject area establishes SQA requirements for developing, modifying, upgrading, purchasing, acquiring, or using software that qualifies as Safety Software, Research Software, or General Software. The SBMS SQA subject area contains procedures for determining SQA program applicability and categorization, applying SQA to Safety Software, applying SQA to General Software, performing SQA assessments, and retiring software. Additional subject area content includes mandatory and recommended exhibits, guidelines, and links to the Software Registration System (SRS), the SQA assessment checklist form, and sources for assistance. During this assessment, the SBMS SQA subject area was revised to further assist software owners with accessing the appropriate SBMS information for managing their software. The revision added a link to the "ORNL Buy" system (used for purchasing software) and procedures (including associated exhibits, guidance, and forms) for the following five processes:

- Conducting software planning
- Determining IT investments and initiating funding
- Requesting cloud services

- Purchasing and registering software
- Using and reassigning software.

The QAPD, SBMS SQA subject area, and SRS ensure the assignment of grading levels A, B, or C to all safety software based on a defined graded approach for applying SQA program requirements. DOE Software Central Registry toolbox codes do not receive special treatment and are not exempt from SQA program requirements. Requirements for legacy software deployed prior to December 12, 2011, are adequately addressed within the SBMS SQA subject area. However, contrary to ORNL QAPD section *Applicability* and DOE Order 414.1D, attachment 2, section 4.a, neither the QAPD nor the SBMS SQA subject area define "major software modification" or specify additional requirements from NQA-1-2008, with the NQA-1a-2009 addenda, to be used for software supporting new nuclear facilities or major modifications to existing nuclear facilities, activities, or projects. (See **Deficiency D-UT-Battelle-1**.) Without established definitions, processes, and procedures, software owners may apply incorrect consensus standard requirements to new safety software and existing safety software under revision.

The SBMS SQA subject area also requires that all software owners periodically review software documentation to confirm that the SRS entry for their software is complete and accurate. Each ORNL organization is required to perform an annual assessment to ensure that SQA requirements have been considered for software owned by their organization (i.e., SQA self-assessments). As appropriate, 27 ORNL organizations performed these self-assessments in both 2022 and 2023. In addition to the SBMS SQA subject area, UT-Battelle appropriately maintains implementing documents and procedures at the division and directorate levels, customized based on program risk or customer requirements, such as procedures relating to business management software for nuclear facilities, safety basis and safety-related calculations, spreadsheets, instrumentation control software, and internal software review boards.

UT-Battelle employs two trained and qualified SQA subject matter experts (SMEs) to revise, maintain, and ensure an effective SQA program. These SMEs provide a 3-hour ORNL SQA program training and a 90-minute ORNL SQA program awareness training to individuals from across the laboratory. Additionally, one-hour sessions are held periodically on specific aspects of the SQA program. Although the quality organization maintains a spreadsheet for all three types of training, including the topics of the periodic one-hour sessions, only the 3-hour training completions are recorded in Success Factors, the laboratory-wide training system. The two SQA SMEs are also responsible for performing an annual analysis of all SQA self-assessments conducted annually by ORNL divisions and directorates. As designed, the ORNL SQA program places a significant breadth of responsibilities for oversight of the program on the two SQA SMEs. During interviews, staff indicated that this breadth of responsibilities presents an implementation challenge. In addition, deficiencies in SQA program implementation observed during this assessment, as documented herein, were not identified through program oversight by UT-Battelle. (See **OFI-UT-Battelle-2**.)

Non-safety Software

The QAP established by UT-Battelle also addresses non-safety software in a generally appropriate manner and meets the requirements of DOE Order 414.1D, attachment 2, through the QAPD and multiple SBMS subject areas. Non-safety software is categorized as Exempt Software , General Software, or Research Software using the SBMS SQA subject area and the SRS for online documentation. The procedure titled, *Determine SQA Applicability and Categorization*, dated November 22, 2021, points to the *Software Quality Assurance (SQA) Exemptions* exhibit, which includes seven categories of Exempt Software. As stated in the exhibit, "SQA requirements do not apply" to this Exempt Software. However, the five procedures listed above that were added to the SBMS SQA subject area contain quality assurance requirements that are not explicitly identified as SQA requirements, and which flow down from the DOE Order 414.1D, attachment 2, criteria. Because these added procedures fully apply to Exempt Software,

UT-Battelle is not grading Exempt Software to zero. Nevertheless, when software is determined through use of the *Software Quality Assurance (SQA) Exemptions* exhibit to be Exempt Software to which SQA requirements do not apply, a user of the exhibit may cease use of the procedures grouped in the SBMS SQA subject area without appropriately applying the five added procedures where applicable. (See **OFI-UT-Battelle-3**.)

Although not stated in the QAPD, General Software also follows applicable ISO 9001:2015 and NQA-1-2000 requirements as implemented through the SBMS SQA subject area using a defined graded approach. General Software grading levels include Minor Impact, Moderate Impact, Significant Impact, and Severe Impact. However, UT-Battelle did not include these grading levels in the QAPD most recently submitted to OSO for review and approval. (See **OFI-UT-Battelle-4**.)

The SBMS SQA subject area appropriately includes procedures titled, *Apply SQA to Safety Software* and *Apply SQA to General Software*. However, contrary to DOE Order 414.1D, attachment 1, section 1.b, the SBMS SQA subject area does not apply applicable quality requirements for Research Software. (See **Deficiency D-UT-Battelle-2**.) Specifically, once the procedure titled, *Determine SQA Applicability and Categorization*, identifies software as Research Software, no further steps are defined that require the implementation of applicable quality requirements. Instead, the software owner is "encouraged to consider all or part of recommended *Research Software Work Activities* guideline to ensure quality of software that is supporting research activities." Encouraging the consideration of recommended guidelines does not ensure that quality requirements are implemented. Confusion regarding the Research Software categorization process resulted in at least one ORNL division systematically categorizing some software as Research Software in the SRS and as General Software internally. (See **OFI-UT-Battelle-5**.)

Quality Assurance Program Conclusions

UT-Battelle has established a generally adequate QAP for safety and non-safety software. The implementing procedures that UT-Battelle maintains through the web-based SBMS, and the additional procedures maintained at the division and directorate levels for work activities governed by the QAPD, are adequate. However, UT-Battelle has not established procedures for the application of additional NQA-1 requirements for major modifications to safety software. Also, the SBMS SQA subject area does not ensure that applicable requirements are implemented for Research Software. Additionally, areas for improvement were found regarding application of DOE Order 414.1D, attachment 2, criteria to all software, the applicability of software exemptions given recent changes to the SBMS SQA subject area, and the inconsistency of SQA program implementing procedures across all ORNL divisions.

3.2 Software Quality Assurance Program Implementation

This portion of the assessment evaluated UT-Battelle implementation of, and adherence to, SQA program procedures for safety software and non-safety software.

Safety Software

EA reviewed SQA program implementation for the following 19 safety software applications:

- Ansys 19.2
- Building 3525 Fissile Material Inventory Control
- Building 7920 Vessel Off-Gas AJ-112 Fan Motor Controller
- DARWIN
- FireWorks
- High Flux Isotope Reactor Controller

- HotCellData_v4.1
- MACCS2 Version 1.13.1
- MACCS2 Version 1.13.1 (MACCS2 – HFIR)
- Monte Carlo N-Particle (MCNP) 5 Version 1.60
- Parker Zeta 61XX Controller/Drivers
- Phoenix Trisafe
- Plutonium-238 Target Fabrication Automated Metrology Station
- Postmax2
- Radioactive Material Inventory System
- RISKMAN Probabilistic Risk Analysis Software
- SCALE 6.2.3
- STAAD.Pro V8i Edition
- Waste Characterization Spreadsheets.

UT-Battelle has established an adequate QAP with a graded approach to appropriately identify safety software subject to quality controls in accordance with DOE Order 414.1D, attachments 2 and 4. UT-Battelle personnel adequately adhere to applicable SQA program requirements in the management and use of all sampled safety software applications. Safety software owners exhibited thorough functional knowledge of the software applications for which they are responsible. The software management plans were appropriately approved and distributed and include a roles and responsibilities matrix that clearly defines project assignments. The requirements specifications adequately address the software function and performance methodology. The software documentation adequately describes the overall architecture and workflow based on an approved process model. Software data collection was appropriately gathered, measured, and analyzed per SQA program requirements to research problems, answer questions, evaluate outcomes, and forecast trends and probabilities. The risk analysis documented by UT-Battelle for the reviewed software documentation demonstrates effective mitigation of potential loss of data or functionality. Reviewed documentation showed that testing was performed during each stage of the development workflow, and appropriately included peer reviews and audits. For 18 of the 19 sampled safety software applications, reviewed user training documentation demonstrated appropriate training of users aligned with their skill levels. However, contrary to DOE Order 414.1D, attachment 2, section 2, UT-Battelle has not specified training requirements for safety software application STAAD.Pro V8i, and as such, does not demonstrate implementation of training requirements. (See **Deficiency D-UT-Battelle-3**.) By not specifying and implementing training requirements, the proper use of software applications cannot be ensured.

Non-safety Software

EA reviewed SQA program implementation for the following 20 non-safety software applications:

- Advanced Plant Phenotyping Laboratory Programmable Logic Controller Software
- DNS Services at ORNL
- Dual Conductance Path
- EAGLE-I
- EasyHaz Laser Hazard Analysis Software
- Emergency Prediction Information Code (EPICode)
- EMIS Main System Control Software
- GENIE
- High Performance Storage System
- HotSpot Health Physics Codes
- IMBA – Professional Plus

- Instrument Personnel Protection System- PLC configuration software
- LabKey Server
- O365-SharePoint Online
- PlanetSense
- Ra-223 Dispensing Calculator Form
- Standards-Based Management System
- Screening for Work Acceptance in Non-Reactor Nuclear Facilities (SWANN)
- Site Access Control System
- Site Access Control System – RS2.

UT-Battelle has established an adequate QAP with a graded approach to appropriately identify non-safety software subject to quality controls in accordance with DOE Order 414.1D, attachment 2. UT-Battelle personnel adequately adhere to applicable SQA program requirements in the management and use of the sampled non-safety software applications, and non-safety software application owners exhibited thorough knowledge of their respective applications and functionality. However, contrary to DOE Order 414.1D, attachment 2, section 4, UT-Battelle did not implement all required SQA criteria or maintain an application-specific software management plan for the Site Access Control System – RS2 non-safety software application. (See **Deficiency D-UT-Battelle-4**.) By not maintaining an application-specific software management plan, no program management process is available to follow, and the software will be subject to inconsistent and unpredictable functional responsibility identification, application performance, and work processes.

For all sampled non-safety software applications, the reviewed risk analysis process demonstrated effective mitigation of potential loss of data or functionality. For 17 of the 20 sampled non-safety software applications, the reviewed training records demonstrated appropriate training and qualification of personnel acquiring, maintaining, using, and assessing non-safety software applications. However, contrary to DOE Order 414.1D, attachment 2, section 2, UT-Battelle has not maintained any records/documentation to demonstrate implementation of training requirements for non-safety software applications EPICode, EAGLE-I, and PlanetSense. (See **Deficiency D-UT-Battelle-3**.) By not implementing training requirements, the proper use of software applications cannot be ensured.

UT-Battelle maintains a generally adequate software inventory list. However, contrary to DOE Order 414.1D, attachment 4, section 2.a.(2), UT-Battelle has not updated the software inventory list to reflect that the EMIS Main System Control Software has been recategorized from Research Software to General Software with Significant Impact. (See **Deficiency D-UT-Battelle-5**.) Inaccuracies in the list of current and functioning software applications, which includes identification of their assigned grading level, could lead to the misuse of software.

Documentation maintained to implement SQA requirements was not always consistent, easily retrievable, easily identifiable, or well-understood by all with SQA responsibilities. Some software management plans covered multiple software applications without identifying them by name. For example, the software management plan titled, *SQA Plan for IOSD - NED Spreadsheets*, was observed to be applicable to eight different spreadsheet applications; however, none of those spreadsheet applications were explicitly identified by name. In some cases, software owners had inherited software ownership and were unaware of the existence or location of the requested records (e.g., EPICode, GENIE). Annual documentation reviews that are programmatically required to be performed by software owners did not in all cases identify inconsistent, inaccessible, or missing documentation or inadequate transfer of software responsibilities for existing safety and non-safety software, as identified in **Deficiency D-UT-Battelle-4**. (See **OFI-UT-Battelle-6**.)

Software Quality Assurance Program Implementation Conclusions

UT-Battelle's adherence to its SQA procedures is generally adequate, and its management of the reviewed safety and non-safety software applications is generally effective. However, UT-Battelle did not update the ORNL software inventory list to reflect a change in software grading level and has not implemented all required criteria or application-specific software management plans for all reviewed safety and non-safety software. Additionally, documentation maintained to implement SQA requirements was not always consistent, easily retrievable, easily identifiable, or well-understood by all with SQA responsibilities.

3.3 Software Security

This portion of the assessment evaluated the UT-Battelle processes used to ensure the security of safety and non-safety software managed under the implemented SQA program.

The UT-Battelle SQA program is adequately established and effective in ensuring the security of safety and non-safety software, in accordance with applicable requirements. The UT-Battelle SQA program adequately ensures that hardware, software, and electronic data are protected from cybersecurity and phishing attacks by using access credentials and anti-phishing controls. The software security procedures and documentation are comprehensive and adequately conveyed. The UT-Battelle QAP ensures that appropriate clearance is required for access to specific classified information and includes the documentation and approval of penetration and functionality testing. The SBMS SQA subject area defines an adequate risk analysis process to mitigate the risk of a total loss of data in the event of a data breach or application outage. The process directs that a contingency plan and a risk response strategy be developed and includes three templates to assist software owners in their implementation (i.e., templates titled, *Software Configuration Management*, Revision 1.0; *Software Quality Assurance Plan*, Revision 1.0, and *Software Failure Analysis*, Revision 0). The Software Quality Assurance Plans established for the reviewed software applications confirmed that the SBMS SQA subject area has been effectively implemented to help ensure software security.

Software Security Conclusions

UT-Battelle adequately ensures the security of safety and non-safety software. To accomplish this, the SQA program adequately implements comprehensive procedures that flow down applicable security requirements. The software security procedures and documentation are comprehensive and adequately convey the applicable requirements.

3.4 Federal Oversight

This portion of the assessment evaluated OSO oversight of the UT-Battelle SQA program.

OSO has established adequate SQA oversight processes through procedure OSOP 226, *Oversight*, and the associated work practice document WP 453, *Contractor Formal Assessment Program* (CFAP). These OSO procedures define appropriate processes for planning, performing, and documenting assessments, and following up on issues and corrective actions in accordance with documented procedures and work practices. However, the most recent SQA assessments are a February 2016 CFAP report evaluating UT-Battelle SQA practices and a September 2018 SQA independent assessment. Both assessments were performed by OSO Operations and Oversight Division personnel and UT-Battelle SMEs using the OSO/contractor partnered assessment model defined in OSOP 226. Since then, quality assurance functions were moved from the Operations and Oversight Division to the Business Division, and several revisions of the QAP have been approved by OSO and implemented by UT-Battelle, most recently in

January 2023. Contrary to DOE Order 226.1B, *Implementation of Department of Energy Oversight Policy*, sections 4.b.(1) and 4.a.(2), in the last five years, OSO has not documented the performance of any oversight activities to evaluate the currently implemented SQA program. Additionally, OSO does not currently have an SQA SME on staff to perform contractor oversight. (See **Deficiency D-OSO-1**.) The lack of independent assessments of the currently implemented ORNL SQA program limits OSO knowledge of contractor performance. In addition, not having a qualified SQA SME, or augmenting the Federal staff with such expertise (e.g., program office support staff), inhibits OSO's ability to plan and conduct evaluations of UT-Battelle SQA program performance.

OSO appropriately reviews and approves proposed changes to the ORNL QAPD prior to implementation. OSO does not, however, currently have any resources assigned to DOE-STD-1172, *Safety Software Quality Assurance Functional Area Qualification Standard*, and have not relied upon available DOE Office of Science, Office of Safety and Security, support for SQA-specific oversight of program performance. This lack of SQA subject matter expertise presents a vulnerability for OSO in its responsibility to perform oversight of the ORNL SQA program. (See **OFI-OSO-1**.)

Federal Oversight Conclusions

OSO has established generally adequate SQA oversight processes. Further, OSO appropriately reviewed and approved the current ORNL QAPD. However, OSO has not performed any assessments to evaluate the performance of the currently implemented SQA program, and OSO does not have staff with the necessary expertise to evaluate SQA program performance.

4.0 BEST PRACTICES

No best practices were identified during this assessment.

5.0 FINDINGS

No findings were identified during this assessment.

6.0 DEFICIENCIES

Deficiencies are inadequacies in the implementation of an applicable requirement or standard. Deficiencies that did not meet the criteria for findings are listed below, with the expectation from DOE Order 227.1A for site managers to apply their local issues management processes for resolution.

UT-Battelle, LLC

Deficiency D-UT-Battelle-1: UT-Battelle has not prescribed processes and procedures for identifying major modifications and applying additional applicable SQA requirements from NQA-1-2008, with the NQA-1a-2009 addenda, to such modifications and new facilities, activities, or projects, as procedurally required by the UT-Battelle QAPD. (ORNL QAPD, sec., *Applicability*, and DOE Order 414.1D, att. 2, sec. 4.a.)

Deficiency D-UT-Battelle-2: The UT-Battelle SBMS SQA subject area does not ensure that applicable quality requirements are applied to Research Software. (DOE Order 414.1D, att. 1, sec. 1.b.)

Deficiency D-UT-Battelle-3: UT-Battelle has not specified and implemented the minimum training and qualification requirements needed for the use of all safety and non-safety software. (DOE Order 414.1D, att. 2, sec. 2)

Deficiency D-UT-Battelle-4: UT-Battelle has not prepared, used, or maintained records and documentation that prescribes processes or specifies requirements to be applied to all non-safety software. (DOE Order 414.1D, att. 2, sec. 4)

Deficiency D-UT-Battelle-5: UT-Battelle did not update the software inventory list to reflect a software grading level change. (DOE Order 414.1D, att. 4, sec. 2.a.(2))

Oak Ridge National Laboratory Site Office

Deficiency D-OSO-1: OSO has not evaluated the performance of the SQA program at ORNL in the last five years and does not maintain technical capability sufficient to evaluate SQA program performance. (DOE Order 226.1B, secs. 4.b.(1) and 4.a.(2))

7.0 OPPORTUNITIES FOR IMPROVEMENT

EA identified the OFIs shown below to assist cognizant managers in improving programs and operations. While OFIs may identify potential solutions to findings and deficiencies identified in assessment reports, they may also address other conditions observed during the assessment process. These OFIs are offered only as recommendations for line management consideration; they do not require formal resolution by management through a corrective action process and are not intended to be prescriptive or mandatory. Rather, they are suggestions that may assist site management in implementing best practices or provide potential solutions to issues identified during the assessment.

UT-Battelle, LLC

OFI-UT-Battelle-1: Consider parsing the DOE Order 414.1D, attachment 2, criteria in the requirements crosswalk in the ORNL QAPD for the topical area *Software Quality Requirements* to clarify that those criteria apply to all software.

OFI-UT-Battelle-2: Consider reviewing SQA oversight staffing levels to determine whether they are adequate to achieve established quality objectives.

OFI-UT-Battelle-3: Consider reviewing the processes detailed in the procedure titled, *Determine SQA Applicability and Categorization*, and exhibit titled, *Software Quality Assurance (SQA) Exemptions*, to ensure that direction to apply all quality assurance criteria to all software grading levels is appropriately conveyed.

OFI-UT-Battelle-4: Consider including the grading levels for General Software in the QAPD that was recently submitted to OSO for review and approval.

OFI-UT-Battelle-5: Consider reviewing division and directorate SQA procedures for inconsistencies with laboratory-wide SQA requirements.

OFI-UT-Battelle-6: Consider reviewing the process used by software owners to plan required annual software information reviews in the software registration system to determine the need for explicit guidance that facilitates consistently thorough reviews such that they support effective self-assessments and analyses.

Oak Ridge National Laboratory Site Office

OFI-OSO-1: Consider utilizing internally developed or externally acquired SQA subject matter expertise to lead and/or support assessments of ORNL SQA program implementation.

Appendix A
Supplemental Information

Dates of Assessment

October – November 2023

Office of Enterprise Assessments (EA) Management

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