UNITED STATES
NUCLEAR REGULATORY COMMISSION
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August 18, 2021

MEMORANDUM TO: William Kennedy, Acting Chief
Advanced Reactor Licensing Branch
Division of Advanced Reactors and Non-Power Production and
Utilization Facilities
Office of Nuclear Reactor Regulation

FROM: Kerri A. Kavanagh, Chief   *Signed by Kavanagh, Kerri on 08/18/21*
Quality Assurance Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

SUBJECT: REGULATORY AUDIT REPORT OF ARGONNE NATIONAL LABORATORY FOR PROVIDING LEGACY DATA IN SUPPORT OF ADVANCED REACTOR TECHNOLOGY LICENSE APPLICATIONS – (CAC NO. A17017)

The Department of Energy's (DOE) Advanced Reactor Technology (ART) program has supported efforts to recover and preserve metallic fuel data generated throughout the U.S. sodium cooled fast reactor program (SFR). Those efforts have been focused on establishing databases of the historical experimental data. The experimental data included fuel performance and safety-related data that are pertinent to future licensing activities of metallic fuel based advanced fast reactors. The data need to be sufficient in scope (geometrical design, chemical composition) and cover fuel performance areas that are likely to be considered as key issues/phenomena by the Nuclear Regulatory Commission (NRC) staff based on past experiences. In addition, the operating parameters under which those experimental data were gathered will need to encompass the operating conditions (duty cycles and off-normal conditions) of the metallic fuel used in specific reactor design. Thus, qualification of those experimental measurements data that are available is needed to demonstrate that the data are of high enough quality that can allow for its use in licensing related activities. This qualification process will determine the quality rigor that can be associated with the data.

From June 7-11, 2021, the U.S. NRC's Office of Nuclear Reactor Regulation staff conducted a virtual audit to support its review of future license applications. The NRC staff audited various documents and interviewed support staff. Specifically, the staff focus was to validate aspects of Argonne National Laboratory's (ANL) implementation of programmatic controls for the qualification of those experimental measurements data that may be needed to demonstrate that the data are of high enough quality that can allow for its use in licensing related activities.

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The regulatory audit report which describes the staff's observations and documents additional actions needed to resolve this effort is provided in the enclosure.

Enclosure: As stated

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REGULATORY AUDIT REPORT OF ARGONNE NATIONAL LABORATORY FOR PROVIDING LEGACY DATA IN SUPPORT OF ADVANCED REACTOR TECHNOLOGY LICENSE APPLICATIONS – (CAC NO. A17017)

Background

The U.S. DOE's ANL submitted for the NRC staff's review, a proposed Quality Assurance Program Plan (QAPP), ANL/NE-16/17, Revision 2 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19311C506) dated October 21, 2019. The purpose of ANL's QAPP is to provide adequate quality assurance (QA) controls to validate key legacy nuclear fuel developmental information and plant data for use by potential developers of advanced reactor design applications. The information was generated, characterized, and summarized at historic DOE research and development facilities. The ANL legacy metallic fuel data qualification program collected, maintained, and qualified metallic fuel data generated through the SFR program. ANL will manage and establish the pedigree of the data and information in accordance with the QAPP. The QAPP establishes a general process to determine the use of the historical information and legacy metallic fuel data for a future end user's licensing activities using as a foundation the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1-2008/2009 Standard which the NRC staff has found as an acceptable method of meeting Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50. The process will consist of evaluating the adequacy of the QA controls which initially developed the legacy metallic fuel data. This includes the methods used for collection, the input of the data, and the verification that data management systems QA requirements were met, per the specified quality standards. Specifically, the QAPP will be used to provide adequate programmatic controls to evaluate historic metallic fuel irradiation information in support of fuel qualification. The intended end users may then use the acceptable data to support licensing activities for advanced reactor designs that satisfy the NRC's nuclear plant licensing regulations.

The ANL QAPP validation process is based on the method provided in ASME's NQA-1-2008/2009, Part III, Subpart 3.3, Non-Mandatory Appendix 3.1, "Guidance on Qualification of Existing Data." The NRC does not evaluate Part III as part of its acceptance review of the NQA-1 Standard, as documented in Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction)." The ANL has stated the QAPP is the top-level policy document that establishes the method in which quality is achieved for evaluating and controlling the SFR legacy fuel data. In accordance with ANL's QAPP, ANL has prepared software under a Software Quality Assurance Plan (SQAP) in accordance with the requirements of NQA-1-2008, Part II, Subpart 2.7. The ANL requested a formal NRC review of the QAPP for the SFR Metallic Fuel Data Qualification evaluation.

By the letter dated June 10, 2020 (ADAMS Accession No. ML20147A468), the NRC indicated that ANL/NE-16/17, Revision 2 was acceptable for submittal of the "-A" version and the associated safety evaluation (SE) dated April 29, 2020 (ADAMS Accession No. ML20106F242).

Regulatory Audit Observations

ANL Methodology for Validation of Legacy Data

The purpose of the audit was for the NRC staff to verify adequate implementation of ANL's programmatic controls for validating key legacy nuclear fuel developmental information and plant data for use by potential applicants. The ANL QAPP validation process is based on a modified version of NQA-1-2008, Part III, Subpart 3.3 Non-Mandatory Appendix 3.1, "Guidance on Qualification of Existing Data," for qualification of existing data. The data qualification process includes data qualification planning, a controlled process for evaluating and establishing data quality, and documentation of the results of this process. Appendix 3.1 is comprised of four qualification methods including a) QA program equivalency, b) data corroboration c) confirmatory testing and d) peer review.

ANL took exception to confirmatory testing as a method available for data validation. Additionally, the NRC staff determined that the only method being currently implemented was peer review. ANL has prepared a Software QAPP (SQAPP) in accordance with the programmatic controls of NQA-1-2008, Part II, Subpart 2.7 and developed associated procedures. However, ANL has yet to implement this process.

ANL implemented NFD-PRO-5.3-01, "Data Qualification Methods," Revisions 0-1, for establishing the process for qualification of existing data, including data of indeterminate quality, for use in activities under the control of both the QAPP for SFR Metallic Fuel Data Qualification, ANL/NE-16/17, Revision 3 and the SQAPP for Nuclear Fuel Codes and Data (NFD), ANL/NE-17/7, Revision 1.

The overall process, as documented in NFD-PRO-5.3-01, had the Fuel Development and Qualification (FDQ) Manager direct qualification planning, preparation, scheduling, and designation of a subject matter expert (SME). In this role, the FDQ Manager directed the gathering of any previously applied quality programs, procedures, and documentation to consider for equivalency to NQA-1 standards. The FDQ Manager also directed the assembly and control data sets prior to beginning qualification. The SME leads the review. A Project Quality Assurance Representative (QAR) or a SME prepare a data qualification report. A Software Integration Manager (SIM) reviews the data qualification report for consistency with respect to NFD configuration management. Finally, the FDQ Manager reviews the report and designates acceptance of the data for qualification.

The ANL peer review methodology used to independently evaluate data to determine acceptability was reviewed. Administrative controls in the procedure included 1) confidence is warranted in the data acquisition or developmental results or 2) the data have been used in a similar range of applications. If the peer review evaluation indicates the uncertainties are unacceptable or the data interpretations are inappropriate, this result should be fully documented. The resulting data qualification report will provide for the inclusion of any dissenting conclusions and comments by individual peer reviewers. This method includes an evaluation of the data acquisition and development approach, including test plans, to determine: 1) the acceptability of the uncertainties associated with the employed data acquisition or development methodology, 2) the adequacy and appropriateness of the interpretations derived from the data, and 3) the extent to which the uncertainties affect the interpretations, conclusions, and overall validity of the data. The procedure also provided a methodology to inform end-users of any subsequent modifications or errors found in the data.

The NRC staff reviewed the following completed data packages:

<u>X441</u>

The data qualification report for X441 was for contact profilometry of 61 elements from the DP-1 test. ANL's Integral Fast Reactor (IFR) concept was under demonstration in the Experimental Breeder Reactor II (EBR-II) since February 1985. This was a 61-pin bundle steady-state irradiation experiment on IFR fuel elements in the EBR-II to determine the effects of fuel-element design parameters on integral fuel element behavior. The objectives of the DP-1 test were (1) to determine the design envelope of IFR fuel elements for satisfactory performance, (2) to provide input for optimization of IFR fuel designs, and (3) to generate data for validating fuel pin performance codes. Procedures describing the irradiation experiment and the loading diagram for Subassembly X441 was contained in the data qualification report.

The profilometer is an electronic gauge used to produce a diameter profile of an element or capsule continuously over the region of interest. The measurement is made by two horizontally opposed magnetic transducers connected to sapphire-tipped sensing probes which directly contact the element as it is pulled upward to obtain a profilometer trace. Procedures were available for operation and maintenance of the associated equipment.

ANL digitized the profilometry data. However, the data was not done under the SQAPP.

The NRC staff determined that the appropriate quality controls were implemented for the qualification of the legacy data and the associated documentation was adequate for X441.

<u>X419</u>

The data qualification report for X419 was for fuel fission gas release data for U-10Zr/D9 fuel elements irradiated in EBR-II. One of the first steps undertaken to demonstrate the technical feasibility of ANL's IFR concept was to irradiate three lead subassemblies of U-Pu-Zr fuel in EBR-II. In February of 1985 the 61-element subassembly X419, began operation in EBR-II with D9-clad fuel. The strategy for the irradiation included interim examination and reconstitution of X419 at low burnup (.8, 1.9, and 2.7 percent).

Subassembly X419 operated in a mid-flat core position (3C2) for EBR-II reactor runs 133 and 134 prior to the first interim examination at 1.9% burnup. Reconstitution of the subassembly (X419A) with 18 fresh elements was followed by one additional reactor run (136) in the same grid location. Elements examined from X419 after run 136 included originally loaded elements at 2.7% burnup as well as those at 0.8% burnup which had been loaded just prior to run 136. Steady-state operating conditions were calculated from post-run neutronics and hydraulic information supplied by the EBR-II Analysis Department. Temperatures were calculated with the heat transfer code, HECTIC. Beginning-of-life fuel properties were used for these calculations. The report summarized post-irradiation examinations (PIEs) of X419 fuel after two interim testing periods.

A test procedure provided the steps to initially breech the fuel element, take pressure readings, and recover gases. Characterization of the fuel and cladding microstructure by optical metallography was performed a description of the process was provided. Agas mass spectrometer was also used to analysis once the fuel had been adequately prepared.

The NRC staff identified that the appropriate quality controls were not implemented for the qualification of the legacy data and the associated documentation X419. The original data

qualification report was not signed by the SME, QAR, SIM, or FDQ Manager. Prior to completion of the audit, the ANL team members subsequently provided a revised signed copy of the data qualification report

X447

The data qualification report for X447 was for the fuel cladding chemical interaction (FCCI) data irradiated in EBR-II. Element DP-11 from subassembly X447 underwent non-destructive examination (NDE) at the Hot Fuels and Examination Facility (HFEF) and destructive examination (DE) at the Alpha Gamma Hot Cell Facility (AGHCF). Examinations included neutron radiography, axial gamma scanning, diameter measurements (profilometry), metallography (optical microscopy), scanning electron microscopy (SEM), and electron microprobe (EPM). The qualification report focused on the DP-11 element and FCCI in U-10Zr fuel elements clad in HT9 cladding. The specific data set examined for fuel element DP-11 was generated in 1992. Metallographic (MET) images evaluated material microstructure to determine the performance of the pins in high temperature and the FCCI.

The procedures were documented in the AGHCF operation manual and included procedures for metallographic preparation, mounting, and microphotography of specimens. The metallograph also contained settings for magnification and magnification checks. The settings were checked semi-annually by the metallographer using the magnification standards in the cell and eventually were routinely performed on an annual basis.

The NRC staff identified that the appropriate quality controls were not implemented for the X447 qualification report. The original data qualification report did not have signature spaces for QAR or SIM and was not signed by the FDQ Manager. Prior to completion of the audit, the ANL team members subsequently provided a revised signed copy of the data qualification report. The NRC staff determined that the appropriate quality controls were implemented for the qualification of the legacy data and the associated documentation was adequate for X447.

ANL used "Data Qualification Methods" NFD-PRO-5.3-01 to implement Section 4, "Validation Process" of the QAPP to qualify existing data. The NRC staff reviewed 3 examples of QAPP implementation (Contact Profilometry: X419, Fission Gas Release: X441 and Cladding: X447). In each of the examples, ANL used the peer review methodology to qualify existing data. The NRC staff identified ANL has not performed a qualification assurance program equivalency or data corroboration methods per Section 4.2.3 "Qualification Methods" of the QAPP. The NRC staff also identified ANL has not developed implementing procedures for a qualification assurance program equivalency or data corroboration method.

Software

The ANL QAPP is the top-level policy document that establishes the method in which programmatic quality controls are achieved for evaluating and controlling the SFR legacy fuel data. In accordance with ANL's QAPP, ANL would prepare software under a SQAPP in accordance with the programmatic controls of NQA-1-2008, Part II, Subpart 2.7. The NRC staff identified ANL has not implemented software under the SQAPP.

Corrective Action Program

The NRC staff reviewed ANL's policies and implementing procedures that govern the corrective action program to verify compliance with the requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. Section 3.2.16 of ANL's QAPP, Revision 2, states, in part, "ANL has established an issues management and tracking program and process that includes the necessary measures and laboratory wide procedures to promptly identify, control, document, classify, and correct conditions adverse to quality." Furthermore, Section 3.2.16 states, in part, "ANL implements an electronic Issues Management and Tracking System."

The NRC staff identified that the appropriate quality controls were not implemented for data qualification forms approval signatures per Data Qualification Procedure NFD-PRO-5.3-01, Revision 0. The NRC staff noted that ANL's data qualification procedure identified personnel responsibilities in Section 2.3, approvals in Section 7, and a data qualification form in Section 9.2. The measures for data qualification planning, evaluating and establishing data quality under controlled methods, and documenting the results included but was not limited to, the responsibilities and approvals of the SME, Project (QAR), SIM, Fuel Development and Qualification (FDQ) Manager.

ANL opened PRISM Form No. PERF0034028 to perform an extent of condition of past data qualification forms to ensure accuracy, completeness, and that all necessary approval signatures are obtained. ANL uses a "Performance Improvement" procedure which governs the use of PRISM. ANL also opened PRISM Form No. PERF003767 to revise the QAPP and Data Qualification Procedure to 1) correct the new PRISM corrective action tracking system, and 2) add signature approval lines to both the procedure itself and to the sample data qualification form template placed at the end of the procedure.

Prior to completion of the audit, the ANL team members subsequently provided a revised signed copy of the data qualification report. The NRC staff determined that the appropriate quality controls were implemented for the qualification of the legacy data and the associated documentation.

ATTACHMENT

1. Entrance/Exit Meeting Attendees and Persons Interviewed

Name	Affiliation	Interviewed	Entrance	Exit
Abdellatif M.Yacout, Ph.D.	ANL	X	X	X
Kun Mo	ANL	X	X	X
Aaron Oaks	ANL	X	X	X
Jeffrey Alicz	ANL	X	X	X
Paul Prescott	NRC		X	X
Nickolas Savwoir	NRC		X	X

2. INSPECTION PROCEDURES USED

- Inspection Procedure (IP) 35017, "Quality Assurance Implementation Inspection." dated December 10, 2020

- IP 43002, "Routine Inspections of Nuclear Vendors," dated January 27, 2017

Documents Reviewed

ANL Documents

NFD-PRO-5.3-01, Rev. 1, "Data Qualification Methods," dated June 1, 2021
NFD-PRO-5.3-01, Rev. 0, "Data Qualification Methods," dated June 30, 2017
LMS-MNL-5, Rev. 2, "Performance Improvement Manual," (PRISM), dated March 3, 2021
NFD-PRO-3.6-01, Rev. 0, "NFD [Nuclear Fuel Codes and Data] Document Control," dated June 30, 2017
NFD-PRO-3.6-01, Rev. 1, "NFD Document Control," dated June 30, 2021
ANL/NE-17/7, Rev. 0, "Software Quality Assurance Program Plan (SQAPP) for Nuclear Fuel Codes and Data," dated June 9, 2017
ANL/NE-16/17, Rev. 3, "Quality Assurance Program Plan for SFR Metallic Fuel Data Qualification," dated June 2, 2021
ANL/NE-16/17, Rev. 1, "Quality Assurance Program Plan for SFR Metallic Fuel Data Qualification," dated May 26, 2019
ANL/NE-16/17, Rev. 0, "Quality Assurance Program Plan for SFR Metallic Fuel Data Qualification," dated July 5, 2017
ANL/NE-16/17, Rev. 2, "Quality Assurance Program Plan for SFR Metallic Fuel Data Qualification," dated October 21, 2019

NRC Documents

U.S. Nuclear Regulatory Commission Safety Evaluation for Argonne National Laboratory Quality Assurance Program Plan ANL/NE-16/17, REVISION 2, dated April 29, 220

ANL Experiment Documents

NFD-DQR-5.3, Rev.1-13, Data Qualification Report, for "Qualify Hard-copy Contact Profilometry Data for X441," dated June 2, 2021
CP-HC-QA-V1.0, Rev 0, "Contact Profilometry Hard-Copy Data Qualification Assurance Record," dated January 14, 2021
Data Package for the Irradiation of the DP-1 Test (X441) in EBR-II, dated September 3, 1987
Final Loading Diagram for Subassembly X441, dated October 18, 1987
W0202-0007-SA-01, Rev. 1, "Element Contact Profilometer Operation and Maintenance," dated August 8, 1984
Specification of Contact Profilometry Data, V1.1 dated August 27, 2020
ANL/HFEF-0003, "A Fuel-Element Profilometer for the HFEF," dated September 17, 1973
Experimental Studies of U-Pu-Zr Fast Reactor Fuel Pins in the Experimental Breeder Reactor-II, dated July 1990
NFD-PRO-5.3-01, Rev. 0, "Quality HFEF Data Fuel Fission Gas Release Data for U10Zr/D9 Fuel Element Irradiated in EBR-II X419 and X419A," dated June 8, 2021
ANL-IFR-55, "Post irradiation of U-Pu-Zr Fuel Elements from Subassemblies X419 and X419A, dated December 15, 1986
W0018-0032-ES-00, Rev. 00, "Gas Assay, Sample and Recharge System (GASR) Operation and Maintenance Manual," dated May 20, 1986
ANL-OKLO-10, "PIE Data for U-10Zr/316SS Fuel Elements in the X423 Series," dated June 14, 2019
ANL-IFR-19, "Test Description for the Integral Fast Reactor Subassemblies X419, X420 and X421," dated August 6, 1985
Quality Assurance Requirements, Rev. 4, "Guide for Irradiation Experiments in EBR-II," dated November 20, 1986
W0630-0108, Analytical Laboratory Operating Procedure, Rev. 0, "Varian MAT CH7 Gas Mass Spectrometer," dated April 21, 1999
Cladding FCCI Data Qualification Form November 13, 2017
Cladding FCCI Data Qualification Form, Rev 1, June 10, 2021

Corrective Action Documents

PRISM form No. PERF0034028
PRISM form No. PERF003767