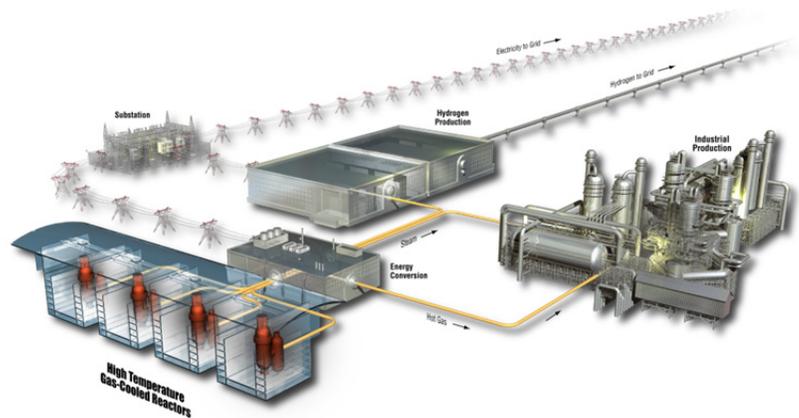


Guidance on Evaluating Historic Technology Information for Use in Advanced Reactor Licensing

October 2015



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Guidance on Evaluating Historic Technology Information for Use in Advanced Reactor Licensing

October 2015

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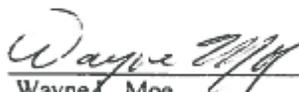


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SUMMARY

The establishment of a systematic process for the evaluation of historic technology information for use in advanced reactor licensing addresses a recommendation that is described in Idaho National Laboratory PLN-4910, “Advanced Reactor Technology-Regulatory Development Plan (RTDP).” In this plan, a licensing priority recommendation [Recommendation 1(D)] was made which states, “Evaluate, qualify, and control the configuration of historic SFR [sodium-cooled fast reactor] operations and test data. Two important demonstration plants were decommissioned over two decades ago and recovery of plant information is currently underway. Systematic efforts should be initiated to determine what informational gaps may still exist relative to the current technology safety case, the quality rigor that can be associated with these historic data, and a configuration management system established to ensure data integrity is not compromised going forward.”

Efforts are underway to recover and preserve Experimental Breeder Reactor II and Fast Flux Test Facility historical data under the U.S. Department of Energy, Office of Nuclear Energy, Advanced Reactor Technologies, fast reactor research-and-development program. To date, these efforts have generally emphasized preserving information from data-acquisition systems and hard-copy reports and entering it into modern electronic formats suitable for data retrieval and examination.

The guidance contained in this document has been developed to facilitate consistent and systematic evaluation processes relating to quality attributes of historic technical information (with focus on SFR technology) that will be used to eventually support licensing of advanced reactor designs. The historical information may include, but is not limited to, design documents for SFRs, research-and-development (R&D) data and associated documents, test plans and associated protocols, operations and test data, international research data, technical reports, and information associated with past U.S. Nuclear Regulatory Commission (NRC) reviews of SFR designs. The evaluation process is prescribed in terms of SFR technology, but the process can be used to evaluate historical information for any type of advanced reactor technology.

A summary depiction of the general quality evaluation process is provided in Appendix A. The process starts with an evaluation to determine whether the information could indeed be a candidate for use in a future licensing activity. Future licensing activities may consist of, (but is not limited to):

- Development of technical papers that address the advanced reactor safety basis and approach to ensure public safety
- Development of an analytical model to verify fuel performance and fission product release
- Development of fuel acceptance criteria and determination of fuel performance and fission product release for parameters that are important to the fuel safety margins, such as fuel operating temperature, maximum fuel accident temperature, fuel oxidizing environment, fuel burnup, energy deposition, and deposition rate in the fuel (due to reactivity accidents)
- Development and validation of analytical models and methods for safety and risk assessments
- Development of pre-application licensing submittals (e.g., white papers, technical reports, position papers, preliminary safety analysis reports, etc.)
- Development of final safety analysis reports that support design and/or combined license applications.

Additionally, Appendix B provides a discussion of typical issues that should be considered when evaluating and qualifying historical information for advanced reactor technology fuel and source terms, based on current light water reactor (LWR) requirements and recent experience gained from Next Generation Nuclear Plant (NGNP).

Systematic and ongoing regulatory interactions with NRC staff will be necessary for new advanced reactor technology. Interactions may begin in early pre-application development phases and continue

through submittal of a complete license application. Early interactions can greatly enhance efficiencies in the independent safety review and overall licensing processes. Additionally, NRC policy strongly encourages early interactions on key licensing topics, particularly those important to safety. NRC has a vested interest in the methods and approaches used in a fuel test program. SFR fuel qualification activities are seen as likely candidates for early regulatory interaction. Since essential SFR metallic fuel information could be generated by demonstration and qualification test programs sponsored by DOE, it is essential that all planned regulatory interactions with NRC staff that involve DOE-sponsored R&D (including, but not necessarily limited to, fuel testing) be coordinated with prospective applicants to ensure subsequent discussions accurately portray the strategies, approaches, and interests of the regulated community and coming fleet.

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ACRONYMS

AOO	anticipated operational occurrence
ALMR	advanced liquid-metal reactors
ANL	Argonne National Laboratory
ANSI	American National Standards Institute
ART	Advanced Reactor Technologies
ASME	American Society of Mechanical Engineers
CFR	Code of Federal Regulations
COL	combined license
CRBR	Clinch River Breeder Reactor
DBA	design basis accident
DOE	U.S. Department of Energy
DOE-NE	DOE Office of Nuclear Energy
EBR	Experimental Breeder Reactor
FFTF	Fast Flux Test Facility
FSAR	final safety analysis report
HTGR	high-temperature gas-cooled reactor
IAEA	International Atomic Energy Agency
LBE	licensing basis event
LMR	liquid-metal cooled reactor
LWR	light water reactor
LWR	light water reactor
MST	mechanistic source term
NEA	Nuclear Energy Agency
NGNP	Next Generation Nuclear Plant
NQA	Nuclear Quality Assurance
NRC	U.S. Nuclear Regulatory Commission
OECD	Organization for Economic Cooperation and Development
PRISM	Power Reactor Innovative Small Module
QA	quality assurance
R&D	research and development
RG	Regulatory Guide
RTDP	Reactor Regulatory Technology Development Plan
SAFDL	specified acceptable fuel design limit

SAFR	Sodium Advanced Fast Reactor
SECY	Office of Secretary (Commission Paper)
SER	safety evaluation report
SFR	sodium-cooled fast reactor
SMR	small modular reactor
SSC	system, structure, and component
TDO	Technology Development Office

Guidance on Evaluating Historic Technology Information for Use in Advanced Reactor Licensing

1. INTRODUCTION

1.1 Background

The United States (U.S.) had an active research and development (R&D) program focused on commercial demonstration and development of a liquid-metal cooled reactor from 1950 to 1989. The Atomic Energy Commission and its successor, the U.S. Department of Energy (DOE), principally funded this program. It involved collaboration among the national laboratories, reactor vendors, utilities, and the Nuclear Regulatory Commission (NRC). The program resulted in (1) the design, operation, and decommissioning of three test reactors (the Experimental Breeder Reactor-I [EBR-I], the Experimental Breeder Reactor-II [EBR-II], and the Fast Flux Test Facility [FFTF]) and (2) the design and issuance of a construction permit for a commercial demonstration plant, the Clinch River Breeder Reactor Project (CRBRP). The U.S. Government canceled construction of this plant in 1983.

The commercial joint government and industry development program ended in 1989 with the preliminary design of two advanced liquid-metal reactors (ALMRs); the sodium-cooled fast reactor (SFR) and the Power Reactor Innovative Small Module (PRISM), which were given preliminary safety evaluation reviews by the NRC. Because of a subsequent decline in interest in construction of new reactors in the U.S, the DOE continued the SFR program as a research and technology-development effort without focusing on a commercial-development program. However, recent increases in interest concerning advanced (non-LWR) reactors in the U.S. and the international Organization for Economic Cooperation and Development/Nuclear Energy Agency (OECD/NEA) in Generation IV reactors has inspired renewed focus in developing and licensing SFR for domestic energy production.

1.2 Purpose

The guidance contained in this document is to facilitate consistent and systematic evaluation processes concerning the quality attributes of historic technical information (with focus on SFR technology) that will be used to eventually support licensing of advanced reactor designs. The historical information may include, but is not limited to, design documents for SFRs, R&D data and associated documents, test plans and associated protocols, operations and test data, international research data, technical reports, and information associated with past U.S. NRC reviews of SFR designs..

The establishment of a systematic process for the evaluation of historical information for use in advanced reactor licensing addresses a recommendation that is described in Idaho National Laboratory, PLN-4910, “Advanced Reactor Technology-Regulatory Development Plan (RTDP)” In this plan, a licensing priority recommendation [Recommendation 1(D)] was made which states, “Evaluate, qualify, and control the configuration of historic SFR operations and test data. Two important demonstration plants were decommissioned over two decades ago and recovery of plant information is currently underway. Systematic efforts should be initiated to determine what informational gaps may still exist relative to the current technology safety case, the quality rigor that can be associated with these historic data, and a configuration management system established to ensure data integrity is not compromised going forward.” Efforts are currently underway to recover and preserve EBR-II and FFTF historical data under the DOE Office of Nuclear Energy (DOE-NE), Advanced Reactor Technologies fast reactor R&D program. To date, these efforts generally emphasized recovery and preserving information from data-acquisition systems and hard-copy reports and entering it into modern electronic formats suitable for data retrieval and examination.

1.3 Application

This document describes issues and requirements relative to an evaluation process of historical information and suggests a process that can be used to ascertain the requisite quality elements of experimental data that are recovered and preserved for future use in licensing. This document also offers options that can be considered and employed to “upgrade” information with respect to certain attributes of quality assurance (QA). The proposed evaluation process is prescribed for the SFR; however, the process can be used for evaluation of historical information that has been recovered and preserved for other types of advanced reactors.

Appendix A provides a description of the general process for evaluating the historical information. The process starts with an understanding of how the historical information contributes to the advanced reactor technology safety case and determining whether that information may be used for future licensing activities. If the information is expected to be of use, then the next step will be to determine the actual quality standard required of the historical information and determine whether further measures are required with respect to the quality level standing of the information. Lastly, a regulatory interface process is discussed that encourages early information exchange with the NRC staff to support future license application development and confirm the usability, comprehensiveness, and quality status of the historical information.

Additionally, Appendix B provides a discussion of typical issues that should be considered when evaluating and qualifying historical information for advanced reactor technology fuel and source terms, based on current light water reactor (LWR) requirements and recent experience gained from Next Generation Nuclear Plant (NGNP).

It should be noted that the guidance provided herein provides general information and a process template for evaluating historical information of use in licensing. The process is actually implemented by developing specific plans pertaining to the characteristics of the historical data and may require a supplemental design-specific licensing plan for that technology. This guidance can also assist research planners by drawing greater attention to the needs of future applicants and the NRC independent safety review process.

2. REGULATORY EXPERIENCE IN ADVANCED REACTOR TECHNOLOGY

2.1 Past Experience

Advanced reactors (i.e., non-light water reactors [non-LWRs]) have an extensive regulatory history, but there has been relatively little precedent-setting policy for their regulation (other than case-by-case reviews). These reviews included confirming the extent of their conformance with light water reactor (LWR) criteria. Accordingly the NRC has developed a Statement of Policy for Regulation of Advanced Nuclear Power Plants (Final Statement), published on July 8, 1986 (51 FR 24643), which encourages early interaction between the NRC and advanced reactor designers to establish licensing guidance applicable to these designs.

In June 1988, NRC issued NRC Regulatory Guide NUREG-1226, “Development and Utilization of the NRC Policy Statement on the Regulation of Advanced Nuclear Power Plants.” This NUREG provides NRC-endorsed guidelines and expectations for specific determination of which new designs fall within the Final Policy Statement (e.g., high-temperature gas-cooled reactor [HTGR], SFR). The NUREG also establishes a charter for an Advanced Reactors Group for performing technical reviews, and establishes and develops a defense-in-depth philosophy, standardization, the NRC’s safety goal and severe accident policy, applicable industry codes and standards of advanced reactor designs.

On October 14, 2008, the Commission issued its current policy statement regarding advanced reactors. The statement included items to be considered during the design of such reactors. The Commission's 2008 Policy Statement on the Regulation of Advanced Reactors reinforced and updated the policy statements regarding advanced reactors previously published. In part, the 2008 update to the policy states:

“Regarding advanced reactors, the Commission expects, as a minimum, at least the same degree of protection of the environment and public health and safety and the common defense and security that is required for current generation light-water reactors [i.e., those licensed before 1997]. Furthermore, the Commission expects that advanced reactors will provide enhanced margins of safety and/or use simplified, inherent, passive, or other innovative means to accomplish their safety and security functions.”

The Advanced Reactor Policy Statement summarizes previous experience with the regulation of HTGRs and SFRs. Construction permits and operating licenses were granted to the helium-cooled Peach Bottom-1 and Fort St. Vrain reactors, the sodium-cooled Fermi-1 reactor, and the Southwest Experimental Fast Oxide Reactor. The design of the DOE's FFTF was given a safety review by the NRC, but a license was not required or issued for its operation. Reviews were also performed on other reactor designs that were not subsequently built. For gas-cooled reactors, these were the Summit and Fulton applications for large HTGRs, the General Atomic Company's standard large HTGR plant (General Atomic Standard Safety Analysis Report), and a conceptual design for a gas-cooled fast breeder reactor (gas-cooled fast breeder reactor). With regard to SFRs, the Clinch River Breeder Reactor (CRBR) was reviewed, and a public hearing was held, but the project was terminated by Congress in 1983 before a construction permit was issued. It should be noted that because the CRBR was to be a power reactor prototype, it was subject to the same regulatory process as current commercial nuclear power projects.

In August 2012, in response to the congressional request and follow-on NRC discussions with congressional staff, the NRC prepared a comprehensive report, i.e., *Report to Congress: Advanced Reactor Licensing* (NRC 2012). This document addressed the NRC's overall strategy for, and approach to, licensing of advanced reactors. The report addresses license applications anticipated over the next one to two decades as well as potential licensing needs beyond 20 years. The report focused on commercial application of advanced reactors (i.e., NRC licensing of nuclear reactor facilities for commercial and industrial use).

Additionally, the NRC issued a pre-application safety evaluation report, NUREG-1369, “Sodium Advance Fast Reactor (SAFR) Liquid-Metal Reactor,” and NUREG-1368, “Power Reactor Innovative Small Module (PRISM) Liquid-Metal Reactor.” Other recent significant NRC assessments include review of the Next Generation Nuclear Plant (NGNP) key licensing issues documented in letter dated July 17, 2014, from the NRC's Office of New Reactors, to DOE.

2.2 General NRC Guidance and Requirements

The NRC has developed a large body of regulations on the basis of experience gained through operation of large commercial LWR facilities. However, many aspects of these regulations cannot be easily translated to non-LWR designs. To help facilitate this, the NRC will work with prospective applicants to address the regulatory framework needed for non-LWR designs.

Figure 1 depicts the key areas of the regulatory analyses conducted by the NRC to support future licensing process for advanced reactor technologies. Broad-scope research efforts are needed to develop the analysis methods and supporting data the NRC requires to formulate its safety findings for certifying an advanced reactor design and licensing a facility that references a certified design based on an advanced reactor technology. This process is further discussed in the NRC's *Report to Congress: Advanced Reactor Licensing* (NRC 2012).

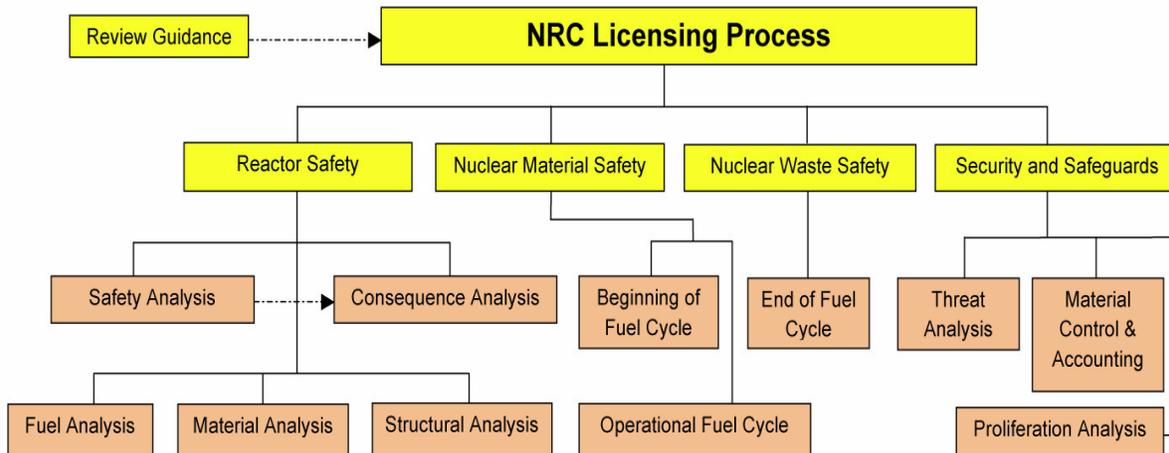


Figure 1. NRC licensing process.

Discussed below are some key licensing issues that will require detailed analysis by the NRC in advanced reactor designs and is expected to be addressed (at least in part) by DOE legacy reactor technology R&D information.

2.2.1 Reactor Safety

For any reactor design, analytical tools, data, and associated R&D are needed for confirmatory safety analysis to address challenges to three basic safety functions: (1) adequate heat removal, (2) reactivity control, and (3) confinement of radioactivity. The challenge to ensuring adequate heat removal centers on timely and sufficient cooling of the fuel element, core, reactor vessel, and reactor building, which are all critical to preventing failures of fission product barriers. The challenge to maintaining sufficient reactivity control includes the ability to maintain the reactor in a stable condition. The challenge to prevent the release of radioactivity outside the facility calls for maintaining the integrity of the fuel, core structures, primary pressure boundary, and reactor containment structures. Analytical tools must be able to verify the adequacy of the safety features of a given design to address these challenges.

2.2.2 Nuclear Material Safety

Generally, for any reactor technology, the outcome of materials research provides the technical bases for developing NRC staff positions pertaining to the evaluation of the designed integrity of components that protect the pressure boundary and maintain core geometry. A sound technical basis is necessary for evaluating, verifying, and confirming the applicant's data on the integrity and failure modes of components. Time-dependent failure criteria for materials need to be developed for ensuring safety and adequate operational life. Further development of the applicability of the current American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code for advanced reactors, and a greater understanding of the current state of design methodology for structural materials are both necessary.

2.3 Licensing Activities

The ART RTDP (PLN-4910) links advanced non-LWR technology development activities sponsored by the DOE-NE ART Program to key regulatory requirements and licensing issues likely to affect new reactor deployments in the domestic commercial energy market. The licensing-oriented discussions and recommendations documented in the plan are not constrained to any particular category, class, or type of advanced non-LWR technology, but rather are open to address an array of issues as dictated by contemporary ART R&D opportunities. However, because ART research is currently focused on two specific types of non-LWR reactor concepts (i.e., HTGR and SFR), the RTDP is scoped to reflect a similar emphasis.

Within the U.S., nuclear reactors are licensed after successfully completing an independent safety assessment conducted by the NRC. This assessment must result in findings that the information contained in the license application is comprehensive, representative, and characterizes systems and operations that adequately protect public safety. As a regulatory agency, the NRC does not conduct developmental research on new reactor designs, but rather focuses on evaluating the information and safety conclusions submitted by an applicant to secure a construction permit, operating license, early site permits, limited work authorization, design certification, and/or combined license.

Information required to complete a reactor license application is often generated from sources other than the applicant. As a government agency tasked with performing R&D to assist new reactor technology deployment, DOE-NE sponsors a wide range of studies and technical investigations that provide essential information to the reactor design community. This information may be foundational in understanding system performance, nuclear safety, and component reliability. Accordingly, many of the R&D activities sponsored by DOE-NE must consider NRC policies and regulatory requirements as those activities are initially planned and later performed.

To facilitate the NRC licensing of plants that significantly differ from the large LWR fleet, NRC works to address regulatory framework topics as they are identified by prospective applicants and presented to NRC staff. The staff and external stakeholders have already identified significant policy and technical issues associated with small LWR and non-LWR licensing evaluations; these issues, along with their status, can be found in numerous NRC and stakeholder position papers posted on the NRC website. Additionally, the NRC's Office of Research supports an extensive program that addresses critical areas of anticipatory and confirmatory research in support of the NRC license application review process.

3. GENERAL APPROACH FOR DETERMINING ACCEPTABILITY OF HISTORICAL TEST DATA, ANALYSIS, AND/OR OTHER TECHNICAL INFORMATION

3.1 Characterization of Historical Information

As discussed in PLN-4910, "Advanced Reactor Technology – Regulatory Technology Development Plan (RTDP)," efforts are underway to recover and preserve EBR-II and FFTF historical data under DOE-NE's ART fast reactor R&D program. To date, these efforts generally emphasized preserving historical information (e.g., data acquisition tapes and hard-copy reports) and entering it into modern electronic formats suitable for data retrieval and examination. It is desirable that data and information are entered and managed according to applicable quality assurance and NRC regulatory requirements as they are placed in a new electronic format. Test data and operational information generated by past technology development projects although assumed to have been generated using good scientific principles and research practices (i.e., industry best practice) in effect at that time must be qualified before it can be used.

Certain experimental SFRs have been constructed and operated in the U.S. that are expected to be the source of essential safety-related information. Perhaps the most relevant sources of plant heritage information come from experiences at EBR-II (located at Idaho National Laboratory and operated from 1964 to 1994 using metallic core fuel) and the FFTF (located at the Hanford Site in Washington and operated from 1980 to 1993 using mixed-oxide core fuel). Both facilities were built by DOE and its predecessor, the Atomic Energy Commission, to demonstrate the viability of a sodium-metal cooled fast reactor. However, the 62.5-MW(t) EBR-II design appears to share the greatest similarity with SFR concepts now being proposed for deployment.

Therefore, historical information gathered through the effort described above may include, but is not limited to, design documents for SFRs, R&D data and associated documents, test plans and associated protocols, operations and test data, international research data, technical reports, and information associated with past NRC reviews of SFR designs.

Additionally, it is important to recognize that historical information gathered from analytical modeling using historical codes and standards (including computer codes) can potentially be relied upon as qualified information for future use. For example, to support the fuel qualification program for PRISM design during the pre-application review, NRC acknowledged that the LIFE-METAL computer code is the analytical tool developed at Argonne National Laboratory (ANL) to model the response of the metal fuel and blanket elements to steady-state and operational transient conditions. Although the NRC staff had not formally reviewed the LIFE-METAL code thus far, they recognized an analysis done with this modeling technique provided good agreement with experimental data. They also recognized that confirmatory investigation dealing with relevant mechanisms involved in predicting fuel failure within the bounds was in progress. This discussion is provided in Section 4 of *NUREG-1368, Preapplication Safety Evaluation Report for the PRISM Liquid-Metal Reactor (NRC 1994)*. Therefore, results obtained from computer models that include LIFE-METAL computer code, can potentially be a component used in future fuel qualification programs. (NOTE: If the LIFE-METAL computer code has been updated since the earlier NRC staff review, changes to the code should be discussed with the NRC during early prelicensing discussions).

3.2 Evaluating Historical Information

The objective of evaluating the historical information is to determine whether the information provides a sufficient technical basis for use in future SFR licensing activity.

Historical information that may be essential to successful licensing includes (but is not limited to):

- Technical papers concerning the advance reactor safety basis and approach to ensure public safety
- Data that can be used to develop analytical methods and model and verify fuel performance and fission product release
- Determinations concerning fuel performance and fission product release for parameters which are important to the fuel safety margins, such as fuel operating temperature, maximum fuel accident temperature, fuel oxidizing environment, fuel burnup, energy deposition, and deposition rate in the fuel (due to reactivity accidents)
- Development of safety approach information and pre-application licensing submittals (e.g., white papers, technical reports, position papers, preliminary safety analysis reports, etc.)
- Development of final safety analysis reports (FSARs) that supports design COL applications.

Appendix A provides a general process flow diagram for evaluating historical information for licensing use. The process starts with an evaluation of the historical information to determine whether the information may be used for future licensing activities. If the information appears necessary for licensing, then the next step will be to determine the quality standard of the historical information. Lastly, a

regulatory interface process is included that encourages early information exchange with the NRC staff and leads to confirmation of the quality assessment and clarifies what “gaps” may still exist in the information.

Provide below is an expanded view of key attributes discussed in Appendix A to support the evaluation process.

3.3 Quality Standards

The scope of QA concerns in advanced reactor deployment begins with technology development and high-level design activities and continues through final design, construction, and operation of the facility. Since future applicants will utilize R&D test data (and associated safety conclusions) when preparing a license application, it is important to establish a sound QA program early in the technology development and high-level design phases of the project; this includes research that may have been done or is currently being done within the ART Program. A QA program description document is warranted for development activities relating to advanced reactor safety. A QA program description (based on 10 CFR 50, Appendix B) will provide and establish applicable QA requirements that meet the needs of the NRC licensing process.

The QA requirements must describe methods and establish applicable quality and administrative control requirements that meet 10 CFR 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants. This ensures that activities supporting the regulatory safety review process provide adequate confidence that safety-related systems, structures, and components (SSCs) will perform their required safety functions. These requirements may also be applied to certain equipment tests and research activities that affect non-safety-related SSCs yet support safe plant operations.

The ASME Standard NQA-1 2008/1a-2009, “Quality Assurance Program for Nuclear Facility Applications” (with applicable addenda), as endorsed by NRC Regulatory Guide (RG) 1.28, “Quality Assurance Program Criteria (Design and Construction),” provide fundamental QA requirements for satisfying 10 CFR 50, Appendix B. Additionally, the following documents describe methods that the NRC staff considers acceptable for complying with the provisions of 10 CFR 50, Appendix B:

- RG 1.8, “Qualification and Training of Personnel for Nuclear Power Plants”
- RG 1.33, “Quality Assurance Program Requirements (Operation).”

Additionally, the NRC regulation stipulated in 10 CFR 50, Appendix A, General Design Criteria for Nuclear Power Plants, GDC 1, “Quality Standards and Records,” requires that the structures, systems, and components important to safety shall be designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions to be performed. Where generally recognized codes and standards are used, they shall be identified and evaluated to determine their applicability, adequacy, and sufficiency and shall be supplemented or modified as necessary to ensure a quality product in keeping with the required safety function. A QA program shall be established and implemented in order to provide adequate assurance that these SSCs will satisfactorily perform their safety functions.

Technical information should have direct traceability to quality standards. For historic information, a record of the quality standards that were applied at that time should be maintained with historical information, if available. This includes items such as design control, control of instructions, procedures, drawings, test control, measuring and test equipment control, and records.

Also, it should be noted that implementing requirements prescribed in DOE Orders for meeting QA requirements may be nominally considered as meeting the industry best practice. However, it may not necessarily demonstrate that the quality standards endorsed by the NRC have been met. Therefore, it is important to assess each of the quality standards that were applied in historic DOE information against NRC-endorsed standards. For example, the current NRC-endorsed ASME NQA-1 is the 2008 version with NQA-1a-2009, addendum. Prior NQA-1 endorsements by the NRC included ASME NQA-1-1994

and ASME NQA-1-1984. Therefore, not all of the updates and addendums to the ASME NQA-1 were endorsed by the NRC staff in the past.

3.4 Qualification of Existing Data

If quality standard of the historical information is not available, is unknown, or cannot be confirmed, ASME NQA-1, Nonmandatory Appendix 3.1, "Guidance on Qualification of Existing Data," provides a suite of various qualification approaches that can be considered for use. The use of ASME NQA-1, Appendix 3.1, is a recognized approach to qualify historical data.

One or more of the following methods can be considered for use in qualifying historical data that are understood to be otherwise deficient in this area:

QA Program Equivalency: The QA Program Equivalency may be used to determine if the acquisition, development, or processing of data have been performed in accordance with sound technical, administrative practices or procedures that can be demonstrated to generally meet the applicable requirements and guidance of NQA-1. The employed practices or procedures must demonstrate industry-acceptable scientific, engineering, or administrative practices or processes with appropriate compliance documentation, as defined in data qualification planning. Examples of conditions for which the QA Program Equivalency Method may be useful include the following:

- A. Data acquisition, collection, or development records, including equipment calibration documentation, and personnel qualification records are available
- B. Documentation of the technical or administrative practices or procedures used to process the data are available.

Data Corroboration: The Data Corroboration method may be used to determine if subject matter data comparisons can be shown to substantiate or confirm parameter values. This method may include comparisons of the data to both other sources of qualified data, as well as to sources of other existing data, as defined in data qualification planning. Examples of conditions for which the Data Corroboration Method may be useful include the following:

- A. A sufficient quantity of corroborating data is available to permit valid statistical comparison with the unqualified data set(s)
- B. Inferences drawn to corroborate the existing data can be clearly identified, justified, and documented.

Confirmatory Testing: The Confirmatory Testing method may be used where tests can be designed and performed to establish the quality of existing or indeterminate data. Confirmatory testing also may be used when previous test results are not verifiable as a result of questionable testing methodology or a lack of applicable documentation. Confirmatory test results should demonstrate direct correlation to previous test results, if feasible. However, data extrapolation is acceptable within the limits defined in data qualification planning. Examples of conditions for which the Confirmatory Testing Method may be useful include the following:

- A. Similar test conditions are prescribed
- B. Test result correlation or extrapolations are applicable.

Peer Review: The Peer Review Method is used to independently evaluate data to determine if the employed methodology is acceptable; confidence is warranted in the data acquisition or developmental results; or the data have been used in a similar range of applications. Use of the Peer Review Method for this purpose should include an evaluation of the data-acquisition and development approach, including

test plans, to determine the acceptability of the uncertainties associated with the employed data-acquisition or development methodology, the adequacy and appropriateness of the interpretations derived from the data, and the extent to which the uncertainties affect the interpretations, conclusions, and overall validity of the data. If the evaluation indicates, the uncertainties are unacceptable or the data interpretations are inappropriate, this result should be fully documented. A report documenting the peer review activity should be prepared, as defined during data qualification planning, and should provide for the inclusion of any dissenting conclusions and comments by individual peer reviewers.

3.5 Previously Reviewed Information

If information was previously reviewed by NRC staff members, the result of that review should be clearly documented in a NRC document. The NRC document could be (but may not be limited to):

- NRC safety evaluation report
- NRC meeting minutes
- NRC NUREG
- NRC SECY papers
- Other forms of NRC correspondence and dialog in which a formal regulatory determination has been made.

In the past, NRC has published NUREGs to document NRC reviews of advance reactor technologies. These documents may provide excellent sources of information regarding the results of their review and include past comments and summary results. The following provides some key examples of past NRC reviews that have been documented in NUREGs:

- NUREG- 0358, “Fast Flux Test Facility Safety Evaluation Report,” U.S. Nuclear Regulatory Commission, August 1978.
- NUREG-0968, “Safety Evaluation Report Related to the Construction of the Clinch River Breeder Reactor Plant,” U.S. Nuclear Regulatory Commission, March 1983.
- NUREG-1368, “Pre-application Safety Evaluation Report for Power Reactor Innovative Small Module (PRISM) Liquid-Metal Reactor,” U.S. Nuclear Regulatory Commission, February 1994.
- NUREG-1369, “Pre-application Safety Evaluation Report for Sodium Advanced Fast Reactor (SAFR) Liquid-Metal Reactor,” U.S. Nuclear Regulatory Commission, December 1991.

Previously published industry documents may also provide important insight to licensing and operating activities associated with advanced reactor technology. These documents may have been reviewed by the NRC and resulted in a preliminary regulatory determination or similar staff commentary. With respect to SFR technology (e.g., FFTF, EBR-I, EBR-II, Fermi-1, CRBR, and PRISM), considerable liquid-metal-cooled reactors information has been compiled and collected by the NRC’s Knowledge Center, which is one of the agency’s key information technology applications for capturing and sharing knowledge (NRC 2014).

Additionally, international information may be relied upon concerning whether tests and/or data similar to the historic data have been reviewed and accepted by foreign agencies. For example, the International Atomic Energy Agency (IAEA) has a vast knowledge and a large collection of information on SFRs. The IAEA collection of information includes operational experience data, design information, R&D information, and safety.

Foreign programs can provide valuable design information, operating experience, and basic data about advanced reactors. However, reliance on foreign sources will require applicants to engage NRC staff for review and acceptance of applicable foreign data. This should include a discussion of major

design differences and similarities, performance-related experience, applicable R&D, and the associated QA standards. How this information is to be factored into the U.S., advanced design should be discussed early on with the NRC staff. It is noted that, as discussed in the NUREG/KM-007, *NRC Program on Knowledge Management for Liquid-Metal-Cooled Reactors* (NRC 2014), some international information has been collected in the NRC's Knowledge Center.

3.6 Open Issues

Open issues (items) are design and licensing issues that the NRC staff has determined will need further information or require action prior to closure. Open issues are typically captured in NRC documents, such as NRC Safety Evaluation Reports (SERs), correspondence from the NRC based on its review of a document or observation of tests, and other NRC documents that capture past interactions (e.g., meeting minutes). Therefore, it is important to assess the historical information to determine whether an open issue exists. This can be principally accomplished by reviewing past NRC documents, as discussed above. For example, the NRC's pre-application review of the SAFR Liquid-Metal Reactor is documented in NUREG-1369, "Pre-application Safety Evaluation Report (SER) for the SAFR Liquid-Metal Reactor." The SER represents the NRC staff's preliminary technical evaluation of the safety features in the SAFR design, including the projected R&D programs required to support the design, and the proposed testing needs. Although the NRC has conceptually accepted design and licensing information for SAFR, the NRC staff concluded that further research and design information and testing is needed to confirm many attributes of SAFR design (i.e., open items).

It is important to capture unresolved issues as they are found and catalog them for future closure. Once the open items are captured and cataloged, a closure plan should be developed for future resolution. The implementation of the closure plan will mostly likely occur at a later date when a license applicant is available and the closure plan is formally prepared for NRC staff review and input.

The resolution of the open item may involve (but is not limited to):

- Collection of data and information from a research, prototype or a demonstration plant
- Additional R&D testing and/or analysis, and/or confirmatory testing
- Development of a safety case that describes the integrated safety features of the specific plant design
- Issuance of new regulatory requirements, policies, and guidance
- Development, verification, and validation of new codes and models
- Further cooperative information exchange with the international community's (e.g., data exchange)
- Further interactions with the NRC staff that concludes with agency acceptance for licensing review.

Understanding and integrating the actions required to address remaining open issues will be an important task in the future NRC interaction. Capturing open issues and development of the closure plan for those issues is also critical to a successful NRC license application review. Timely resolution of open issues may require submission of technical/topical reports, supplemental information (including confirmatory tests that support historical information), and submittal of additional design data.

3.7 Regulatory Interface

Systematic and ongoing regulatory interactions with NRC staff will be necessary for new advanced reactor technology. Interactions may begin in early pre-application development phases and continue through submittal of a complete license application. Early interactions can greatly enhance efficiencies in the independent safety review and overall licensing processes. Additionally, NRC policy strongly encourages early interactions on key licensing topics, particularly those important to safety.

NRC has a vested interest in the methods and approaches used in a fuel test program. SFR fuel qualification activities are seen as likely candidates for early regulatory interaction. Essential SFR metallic fuel information could be generated by demonstration and qualification test programs sponsored by DOE. Consequently, it is recommended that all planned regulatory interactions with NRC staff that involve DOE-sponsored R&D (including, but not necessarily limited to, fuel testing) be coordinated with prospective applicants to ensure subsequent discussions accurately portray the strategies, approaches, and interests of the regulated community and coming fleet.

Interactions will likely be required to address remaining open issues for preparation and submittals of technical/topical reports, potential development of new regulatory policy that supports advanced reactor design and licensing, and, ultimately, the development and submittal of licensing applications for construction permit, design certification, and/or combined license applications. Although these tasks may be postponed until later in the pre-licensing schedule, knowing and understanding the tasks remaining for the licensing process will be key to successful NRC review and approval of the license application. Because a great deal of historic U.S. and international R&D and testing has already occurred, it is important to determine and categorize the information that has already been accepted by the U.S. and international regulatory organizations. Qualified historical information can be an important source of key information for future licensing activities.

Prior to preparation of new licensing submittals for NRC review, it is important to communicate early on regarding what design and licensing information will be submitted for NRC formal review. Information exchange with the NRC staff may be in the form of formal or informal (drop-in) meetings, presentations, telecommunications, and submittal of design and licensing information that supports pre-application activities. In most cases, preparation and submittal of licensing correspondence is required for a formal review and approval of design and licensing information by the NRC.

Typically, formal acceptance of information by NRC (as submitted by an applicant) is expected to support issuance of an NRC SER. In the past, SERs have been written for pre-application reviews and topical reports, with each FSAR Chapter reviewed and approved by the NRC during the design and COL certification process.

4. REFERENCES

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17. NUREG-1368, Pre-application Safety Evaluation Report for Power Reactor Innovative Small Module (PRISM) Liquid-Metal Reactor, dated February 1994.
18. NUREG-1369, Pre-application Safety Evaluation Report for Sodium Advanced Fast Reactor (SAFR) Liquid-Metal Reactor, December 1991.
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Appendix A

General Approach for Evaluation of Historical Information

Appendix A

General Approach for Evaluating Historical Information

The following offers a relational description of key steps necessary to qualify historic technical information for use in advanced reactor technology licensing. It should be noted that the process described herein is a generalized process for evaluating historical information. The process starts with an understanding of how the historical information contributes to the advanced reactor technology safety case and moves on to determining whether that information may be used for future licensing activities. If the information is expected to be of use in that capacity, then the next step is to determine the actual quality standard associated with the historical information and determine if further measures are required with respect to establishing the quality level standing of the information. Lastly, a regulatory interface process is discussed that encourages early information exchange with the U.S. Nuclear Regulatory Commission (NRC) staff to confirm usability, comprehensiveness, and quality status.

It should be noted that the following process was formulated from existing general guidance and should be used as a process template for evaluating historical information of value in licensing. The process should be implemented by developing specific plans and procedures pertaining to the characteristics of the historical data and may require a supplemental design specific licensing plan for that technology. This guidance also assists research planners by drawing greater attention to the needs of future applicants and the NRC independent safety review process.

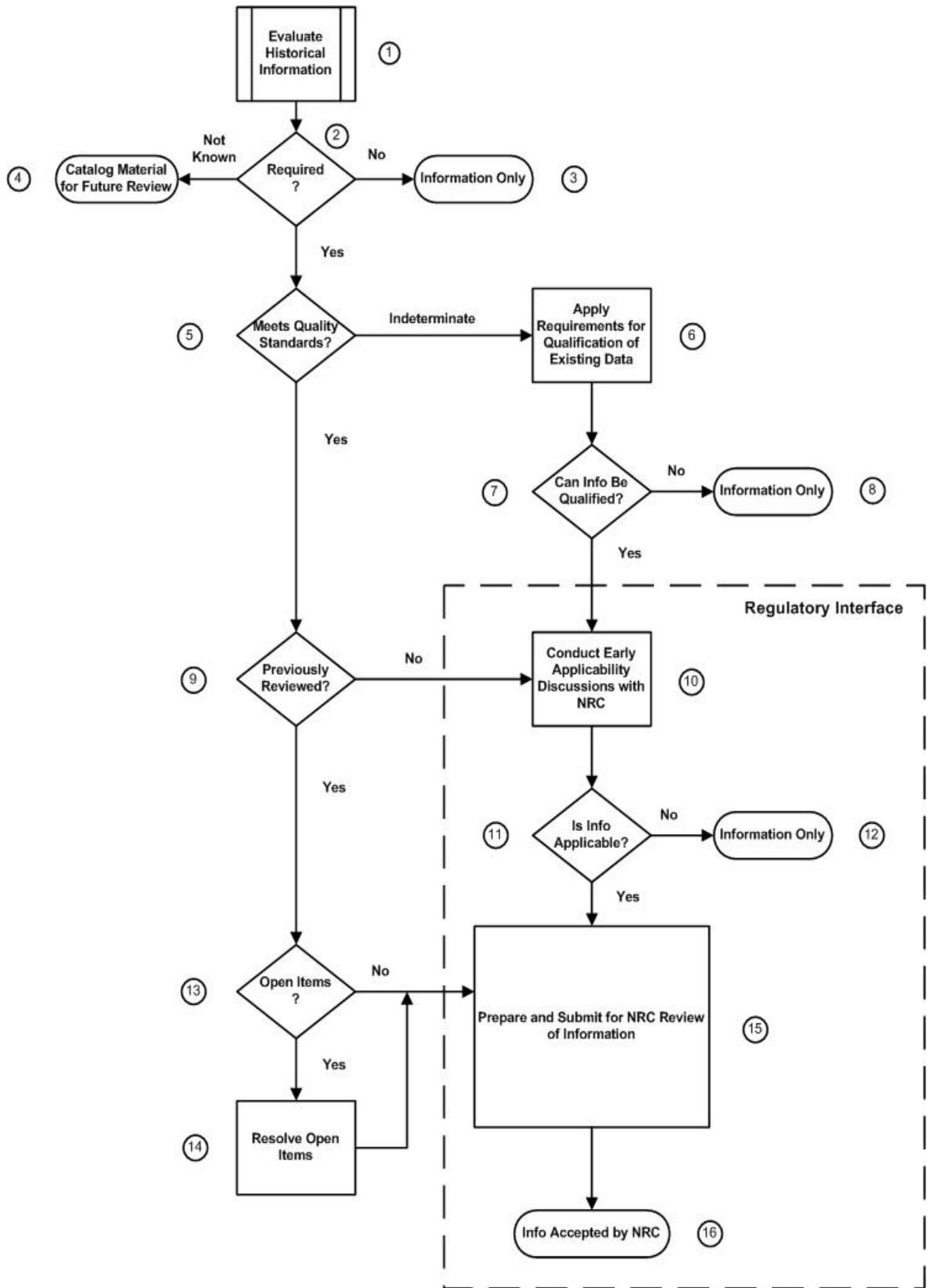


Figure A-1. Flow chart that depicts the general process determination of the historical information for future use in licensing activities.

1. Evaluating Historical Information

Evaluating historic advanced reactor technology information will be necessary to determine whether that information can be used for future licensing activity and, if so, what level of reliability can be assigned that information. The historical information may include (but is not limited to) design documents, research-and-development (R&D) data and associated documents, test plans and associated protocols, operations and test data, international research data, technical reports, and information associated with past U.S. Nuclear Regulatory Commission (NRC) reviews of SFR designs.

Additionally, it is important to recognize that historical information that has been gathered from analytical modeling using historical codes and standards (including computer codes) can potentially be used as qualified information for future use. For example, to support the fuel qualification program for PRISM design during the pre-application review, NRC acknowledged the LIFE-METAL computer code, developed at Argonne National Laboratory (ANL), as the analytical tool to model the response of the metal fuel and blanket elements to steady-state and operational transient conditions. Although the NRC staff had not formally reviewed the LIFE-METAL code, they recognized analysis done with this modeling technique provided good agreement with experimental data. They also recognized that confirmatory investigation that deals with relevant mechanisms involved in predicting fuel failure within the bounds was in progress. This discussion is further provided in Section 4 of *NUREG-1368, Preapplication Safety Evaluation Report for the PRISM Liquid-Metal Reactor (NRC 1994)*.

Therefore, results obtained from the LIFE-METAL computer code can potentially be used for future fuel qualification program. (NOTE: If the LIFE-METAL computer code has been updated since their earlier review, changes to the code should be discussed with the NRC.)

Historical information may be essential to provide a sufficient technical basis that supports future licensing activity. For example, historical advanced reactor information may be used for:

- Development of the advanced reactor safety basis and approach to ensure public safety
- Development of an analytical model to verify fuel performance and fission product release
- Development of fuel acceptance criteria and determination of fuel performance and fission product release for parameters that are important to the fuel safety margins, such as fuel operating temperature, maximum fuel accident temperature, fuel oxidizing environment, fuel burnup, and energy deposition and deposition rate in the fuel (due to reactivity accidents)
- Development/validation of analytical models and methods for safety and risk assessments
- Development of pre-application licensing submittals (white papers, technical reports, position papers, preliminary safety analysis reports, etc.,)
- Development of final safety analysis reports that support design and/or combined license (COL) applications.

Additional activity may consist of development of a safety case that describes the safety features of the plant design and development of regulatory white papers, technical/topical reports, and safety analyses reports that support not only future design and license application submittals in accordance with 10 CFR Part 50 or Part 52 for NRC review but also provide technical support for adaptations of the existing regulatory framework.

Early NRC interactions are strongly encouraged to benefit both the applicant and regulator and likely will be required to qualify historical advanced reactor information for regulatory use. These interactions can address data set uncertainties, comprehensiveness and what future actions are required to address remaining open issues. Additionally, discussion should take place to determine

whether new regulatory policies and/or regulatory guidance documents are needed to support future development and submittal of licensing applications for design and COL applications by the license applicant. Because regulatory interactions play a key role in determining information acceptance with respect to licensing, regulatory interface activities are depicted inside the phantom line of a process flow diagram depicted in Figure A-1.

2. **Required?**

This step is an initial screening of whether the historical information is required for future licensing activities.

Evaluate historical information to determine if the information will be used (or could be used) for future licensing activities. For example:

- If the information is test data collected for determining fuel performance, this will likely be relevant technical information required to support future licensing submittals.
- If the information is an environmental site characterization study performed for a specific site, then that information is likely not relevant to future licensing and can be considered as “for information only.” A new application in accordance with 10 CFR 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,” will be required for selection of the new site.

NOTE: The following documents can be used as a resource for determining whether information undergoing review will be required for future licensing submittals:

- NUREG-0358, “Fast Flux Test Facility Safety Evaluation Report,” U.S. Nuclear Regulatory Commission, August 1978.
- NUREG-0968, “Safety Evaluation Report Related to the Construction of the Clinch River Breeder Reactor Plant,” U.S. Nuclear Regulatory Commission, March 1983.
- NUREG-1368, “Pre-application Safety Evaluation Report for Power Reactor Innovative Small Module (PRISM) Liquid-Metal Reactor,” U.S. Nuclear Regulatory Commission, February 1994.
- NUREG-1369, “Pre-application Safety Evaluation Report for Sodium Advanced Fast Reactor (SAFR) Liquid-Metal Reactor,” U.S. Nuclear Regulatory Commission, December 1991.
- NRC Nuclear Regulatory Guide (NUREG)-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition.”*
- NRC Regulatory Guide 1.206, “Combined License Applications for Nuclear Power Plants.”*

* Although these documents were written for LWRs, they provide general guidance for determination of whether the information will be required for preparation of the future licensing application for NRC review.

If the evaluation determined that the information is not required for future licensing activity, proceed to Step 3.

If the evaluation determined that it is not known whether the information is required for future licensing activity, proceed to Step 4.

If the evaluation determined that the information is likely required for future licensing activity, proceed to Step 5.

3. **Information Only**

If the initial screening has determined that the historical information is not required for future licensing activities, then no further quality-related evaluation action is normally required.

The information should be considered “for information only” and archived as such.

4. **Not Known – Catalog Material for Future Review**

If the initial assessment cannot yet determine whether the information will likely be required for future licensing activities, then the information and all supporting information should be cataloged and archived for additional assessment should evolving future needs indicate that to be necessary. It is not recommended that significant effort be expended on qualifying historic data until a need for doing so is established with reasonable certainty.

5. **Meets Quality Standards?**

The historical information being reviewed should have clear traceability to the quality criteria and standards that were applied during the time the activity was performed. This applies not only to the data but various quality standard elements that affect the data. Quality elements of interest include (but is not limited to) quality assurance (QA) program descriptions; design control; procurement; control of instructions, procedures, and drawings; test control and control of measuring and test equipment; inspections; verifications; audits; and other similar records.

The following are common examples of NRC-acceptable quality standards:

- NRC-endorsed American Society of Mechanical Engineers NQA-1 standards
- 10 CFR 50, Appendix B, QA Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
- NRC-approved codes and modeling methods
- NRC-reviewed QA Plan for SAFR (149QPP00001, dated April 1, 1987)
- NRC-reviewed QA Plan for PRISM (NEDO-11209-04A, Rev. 5, dated March 1985)
- NRC staff Assessment of NNGP QA Program Description, dated September 12, 2012
- Applicable U.S. Department of Energy (DOE) Orders for meeting QA requirements.

NOTE: Although implementing the DOE Orders for meeting QA requirements may be considered the nominal equivalent of following best industry practices, DOE orders may not necessarily satisfy quality standards endorsed by the NRC. Therefore, it is important to assess each of the quality standards that may have been applied through DOE QA requirements against approved NRC NQA-1 standards. For example, the current NRC-endorsed standard is NQA-1-2008 with the NQA-1a-2009 addendum. Prior NRC endorsements were NQA-1-1994 and NQA-1-1984. Not all of the updates and addendums can be considered approved by the NRC staff.

If the quality standard of historical information is indeterminate (or cannot be demonstrated as meeting a particular quality standard), proceed to Step 6 to determine if guidance provided in NQA-1 can be applied to qualify existing information.

If historical information can be demonstrated to meet an NRC-recognized quality standard, proceed to Step 9.

6. **Apply Requirements for Qualification of Existing Data**

If applicability of historical information to the quality standard is indeterminate (or not known) or deficient in some underlying attribute, American Society of Mechanical Engineers NQA-1, Non-mandatory Appendix 3.1, Guidance on Qualification of Existing Data, provides a summary of various qualification approaches that may be used to address shortcomings. One or more of the following methods can be considered, as necessary and appropriate, for use to address deficiencies in a key quality attribute:

- **QA Program Equivalency:** QA Program Equivalency may be used to determine if the acquisition, development, or processing of data have been performed in accordance with sound technical, administrative practices or procedures that can be demonstrated to generally meet the applicable requirements and guidance intent of NQA-1. The employed practices or procedures must demonstrate industry-acceptable scientific, engineering, or administrative practices or processes with appropriate compliance documentation, as defined in data qualification planning.
- **Data Corroboration:** The Data Corroboration Method may be used to determine if subject matter data comparisons can be shown to substantiate or confirm parameter values. This method may include comparisons of the data to other sources of qualified data as well as other existing data as defined in data qualification planning.
- **Confirmatory Testing:** The Confirmatory Testing Method may be used when tests can be designed and performed to establish the quality of existing or indeterminate data. Confirmatory testing also may be used when previous test results are not verifiable as a result of questionable testing methodology or a lack of applicable documentation. Confirmatory test results should demonstrate direct correlation to previous test results where feasible. However, data extrapolation is acceptable within limits defined in data qualification planning.
- **Peer Review:** The Peer Review Method is used to independently evaluate data to determine if the employed methodology is acceptable, establish confidence in the data acquisition or developmental results, or if the data has been used in a similar range of applications. Use of the Peer Review Method for this purpose should include an evaluation of the data-acquisition and development approach, including test plans, to determine the acceptability of the uncertainties associated with the employed data-acquisition or development methodology, the adequacy and appropriateness of the interpretations derived from the data, and the extent to which uncertainties affect interpretations, conclusions, and overall validity of the data. If the evaluation indicates, uncertainties are unacceptable or the data interpretations are inappropriate, this result should be fully documented. A report documenting the peer review activity should be prepared as defined during data qualification planning and provide for the inclusion of any dissenting conclusions and comments by individual peer reviewers.

NOTE: New test regimes and analyses methods may be required to support future advanced reactor design and licensing. Therefore, qualification of certain historic information may not be warranted if those historic data are to be superseded by the results of new test plans. For example, if an additional fuel performance test is planned to collect data in the near term, the full qualification of historical information may not be required and should possibly be considered “for information only.”

7. Can Info Be Qualified?

If it is assumed that the historical information can be qualified to meet the quality standards using techniques as indicated in Step 6, proceed to Step 10.

If the historical information cannot be qualified to meet the quality standards, proceed to Step 8.

8. Information Only

If the historical information cannot be qualified to meet the quality standards, then the information should be considered “for information only” and cataloged as such. Confirmation of this determination with NRC staff may be warranted for certain types of historic data.

9. Previously Reviewed:

This step determines whether historic information of acceptable quality was previously reviewed by the NRC. If the information was previously reviewed by the NRC, the result of the review should be

clearly documented. NRC documents that commonly result from these reviews include (but are not limited to):

- NRC safety evaluation report
- NRC meeting minutes
- NRC NUREGs
- NRC SECY papers
- Other forms of NRC correspondence and dialog in which a formal regulatory determination has been made.

In the past, NRC has published NUREGs to document its reviews of advanced reactor technologies. These documents provide excellent sources of information regarding review results and generally include past comments and summary findings. The following are noteworthy examples of past NRC reviews documented in NUREGs:

- NUREG-0358, “Fast Flux Test Facility Safety Evaluation Report,” U.S. Nuclear Regulatory Commission, August 1978.
- NUREG-0968, “Safety Evaluation Report Related to the Construction of the Clinch River Breeder Reactor Plant,” U.S. Nuclear Regulatory Commission, March 1983.
- NUREG-1368, “Pre-application Safety Evaluation Report for Power Reactor Innovative Small Module (PRISM) Liquid-Metal Reactor,” U.S. Nuclear Regulatory Commission, February 1994.
- NUREG-1369, “Pre-application Safety Evaluation Report for Sodium Advanced Fast Reactor (SAFR) Liquid-Metal Reactor,” U.S. Nuclear Regulatory Commission, December 1991.
- NUREG/CR-1405, “NACOM Code for Analysis of Postulated Sodium Spray Fires in Liquid Metal Breeder Reactor (LMFBRs),” U.S. Nuclear Regulatory Commission, March 1980.

Published industry documents may also provide insight to licensing approaches and operating activities associated with advanced reactors. These may include information relating to the Fast Flux Test Facility, Experimental Breeder Reactor-I and -II, Fermi-1, Clinch River Breeder Reactor, PRISM, etc. Considerable liquid-metal-cooled reactors information, particularly on sodium-cooled fast reactors, has been compiled and collected at the NRC’s Knowledge Center, which is one of the agency’s key information technology applications for capturing and sharing knowledge (Reference: NUREG/KM-0007, “NRC Program on Knowledge Manage for Liquid-Metal-Cooled Reactors,” dated April 2014). Examples include:

- “Thermal Analysis of Liquid Metal Fast Breeder Reactors,” American Nuclear Society, LaGrange Park, Illinois, 1978.
- “Thermal Hydraulic Analysis,” GEFR-00833, General Electric, October 1988.
- “Integral Fast Reactor Program Plan,” General Electric, April 1991.

Additionally, international information may provide insight to determine whether similar tests and/or data have been reviewed and accepted in the past. International Atomic Energy Agency (IAEA) has a knowledge-management base with a large collection of information on liquid-metal cooled reactors (SFRs). Much of the design and operational information is captured for SFRs in IAEA-TECDOC-1569, “Liquid Metal Cooled Reactors: Experience in Design and Operation.” The NRC has been collaborating with the IAEA regarding international SFR experience to gain experience and knowledge for U.S. SFR programs.

If the evaluation determined that the information was not previously reviewed or is not known, proceed to Step 10.

If the evaluation determined that the information was previously reviewed, proceed to Step 13.

10. Conduct Early Applicability Discussion with NRC

An early dialog is encouraged with the NRC staff concerning activities that support the pre-application phase of design and/or COL license applications. This includes sharing of data collected and results achieved during the R&D phase. Past operating experience with test reactors, and the licensability of information collected during those activities may also be discussed. The purpose of these meetings is to receive a preliminary assessment (by the NRC staff) of the applicability of the historical data for licensing purposes. As a result, these early interaction with the NRC staff may determine that historical data is not appropriate or suitable for licensing use. If so, a new gap will have been identified that would have a direct effect on the project's R&D program schedule/costs and would have a negative impact on the project licensing schedule.

As part of this activity, a licensing plan should be developed. The plan should include (but is not limited to): licensing strategies, method for adapting LWR regulations, R&D activities, pre-application review activities, list of technical and topical reports (or white papers) for NRC staff review, and schedule overview that provides future licensing and design activities.

11. Is the Information Applicable?

Sharing of design and licensing information early in interaction stage is encouraged and should address the interests of prospective applicants, as well as the technology development researcher. To be effective, certain interactions may require the communication of proprietary design information, which must be protected from public release. Despite this, the interactions will aid in determination of which historical data will be applicable for future design and licensing activities (e.g., input for future development of analysis, data point for future confirmatory tests, etc.).

If historical information is determined to be not applicable for future licensing activity, proceed to Step 12.

If historical information will be used for future licensing activity, proceed to Step 15.

12. Information Only

If historical information was determined not applicable in future licensing, catalog the information and archive as "for information only."

13. Open Items?

This step is to determine whether historical information was previously accepted with or without open items when reviewed by the NRC. Review of past NRC documents will be necessary to determine whether any open NRC issues exist with the historical information. Open items are design and licensing issues that the NRC staff considers requiring further information or action prior to acceptance for review. For example, the NRC has documented its pre-application review of the SAFR Liquid-Metal Reactor in NUREG-1369, "Pre-application Safety Evaluation Report (SER) for the SAFR Liquid-Metal Reactor." The SER presents the NRC staff's preliminary technical evaluation of the safety features in the SAFR design, including the projected R&D programs required to support the design and testing needs. This means that although the NRC has conceptually accepted design and licensing information for SAFR, the NRC staff also concluded that further research and design information and testing is needed to confirm certain SAFR design attributes (i.e., open item). In some cases, these subsequent actions may not be clear and further NRC interaction will be required.

If the historical information was accepted with no open items, proceed to Step 15.

NOTE: Although certain historical information may have been previously accepted by NRC with no open items, it is important to exchange this information with the NRC and confirm the contemporary standing of the information. Since NRC reviews may have been done

many years ago and in a safety context different than exists today, a new NRC acceptance review may be required.

If open item is identified during the review, proceed to Step 14.

14. **Resolve Open Items**

If historic information contains open items, the gap in that information should be thoroughly characterized, captured, and cataloged for resolution planning in the future.

Once the open items are captured and cataloged, a closure plan can be developed for resolution of the open items for future licensing activities. The implementation of the closure plan will mostly likely occur at a later date with involvement from a license applicant. However, as part of the closure plan, it is important to develop a preliminary “roadmap” that describes and coordinates what actions are expected to be necessary for resolution of the issue.

The resolution of the open item may involve (but is not limited to) the following:

- Construction of a prototype or a demonstration plant
- Additional R&D program, including additional test and/or analysis, and/or confirmatory test
- Development of a safety case that describes safety features of the plant design
- Issuance of new regulatory policies
- Development of new codes and models
- Further cooperative information exchange with the international community (e.g., data exchange)
- Further interactions with the NRC staff.

When action has been taken to resolve the open item, proceed to Step 15.

15. **Prepare and Submit for NRC Review of Information**

Prior to preparation of licensing submittals for NRC review, it is expected that early communications with the NRC will be performed to obtain their prospective regarding what design and licensing information will actually be necessary for a comprehensive regulatory safety review. If the regulatory interaction takes place during the R&D phase (i.e., prior to having a declared licensee or an applicant involved in the interaction), the information exchanges may be in a form of white papers, meetings, presentations, telecommunications, and submittals of design and licensing information that support pre-application activities. In most cases, preparation and submittal of licensing correspondence is required to trigger a formal review and approval of design and licensing information by the NRC. Typically, licensing correspondence will be required for NRC review of those actions taken for resolution of past open items, new information that has not been previously reviewed and approved (e.g., past R&D data), and other design and licensing information that supports licensing application.

Also, dialog with the NRC staff for resolution of the remaining open issues is a potentially important R&D task. Capturing open issues and development of closure plans are critical to obtaining commitment and acceptance for closure of open issues. Resolution of open issues may require submittals of the following types of information:

- Technical reports
- Supplemental information that supports the historical information that was previously provided
- Additional design information.

NOTE: If an open item is focused on obtaining confirmatory results to validate tests/analyses, use of the current regulatory process/guidance depicted in 10 CFR Part 50 or Part 52 may be appropriate. For example, a commitment can be made during licensing in the form of inspection, testing, analysis, and acceptance criteria (ITAAC,) a pre-operation

requirement, or a license condition to address the issue. This action should be discussed in detail with the NRC staff and results documented in the license application.

Systematic and ongoing regulatory interactions with NRC staff will be necessary for new advanced reactor technology. Interactions may begin in early pre-application development phases and continue through submittal of a complete license application. Early interactions can greatly enhance efficiencies in the independent safety review and overall licensing processes. Additionally, NRC policy strongly encourages early interactions on key licensing topics, particularly those important to safety.

NRC has a vested interest in the methods and approaches used in a fuel test program. SFR fuel qualification activities are seen as likely candidates for early regulatory interaction. Essential SFR metallic fuel information could be generated by demonstration and qualification test programs sponsored by DOE. It is recommended that all planned regulatory interactions with NRC staff that involve DOE-sponsored R&D (including but not necessarily limited to fuel testing) be coordinated with prospective applicants to ensure subsequent discussions accurately portray the strategies, approaches, and interests of the regulated community and coming fleet.

16. Information Accepted by NRC

Legally binding acceptance of information is done through submittals by an applicant and documented in a form like an NRC SER. In the past, an SER has been written for pre-application reviews, topical reports submitted by a licensee, and each FSAR chapter reviewed and approved during the design certification process.

It should be noted that prior to an applicant submittal that is accepted and reviewed by NRC and documented in a format like an SER, current NRC review policy may limit pre-licensing determinations by NRC staff to “advisory-level” feedback in that a proposed approach may appear “reasonable” or a test plan seems “appropriately complete.”

Appendix B

Considerations for Evaluation Fuel Qualification and Source Terms

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Considerations for Evaluating Fuel Qualification and Source Terms

The following subsection provides general insights concerning typical approaches in evaluating and qualifying historical data for advanced reactor technology fuel and source terms. These insights are not restricted to any particular technology but can be applied to historical data and information for all types of advanced reactor technologies. Use of qualified historical information can be considered essential for fuel qualification and source terms in future licensing activities.

A wide variety of information will be necessary to establish the safety basis of a new reactor design. Analytical safety tools can become a significant licensing obstacle if not considered and appropriately addressed during early R&D planning. If appropriate codes are unavailable or if their validity cannot be confirmed to a degree that supports conservative conclusions regarding plant safety, a license may not be granted. At a minimum, analytical tools must always be able to verify the adequacy of specific design features that ensure adequate heat removal from the core, maintain reactivity control, and provide for radionuclide retention.

A regulatory safety analysis encompasses the areas of accident analysis and reactor and plant analysis. Reactor and plant analysis measures reactor and plant performance under normal operating conditions, whereas accident analysis verifies reactor and plant performance under design-basis conditions. Both areas of analysis rely on thermal-hydraulic (or in the case of non-water technologies, thermal-fluid) and neutronic (reactor physics) aspects of a technology. Major topics include:

- Accident progression modeling
- Primary system and containment performance
- Fission product behavior modeling
- Core heat removal
- Thermal-fluid dynamics
- Nuclear analysis
- Fission product transport
- Initiating event frequency.

Every licensed reactor is required to have appropriate methodologies, analytical tools, and high-quality support data available for use when addressing plausible questions about plant safety challenges. These challenges are also generally organized according to the three basic functions of:

1. Adequate core heat removal

Challenges to heat removal involve timely and sufficient cooling of fuel elements, the core, the reactor vessel, and design elements used for radionuclide retention. These elements are presumed to be critical to preventing fission product barrier failures. Ensuring fission product barrier integrity is a critical safety priority. Backup systems may be necessary to provide adequate defense in depth to ensure that required safety functions are performed during anticipated conditions.

2. Reactivity control

Challenges to reactivity control involve maintaining the reactor in a stable condition. A design may employ passive physics (e.g., negative temperature coefficient) to back up active control elements to handle a challenge. It must be demonstrated that reactivity control features will perform as intended in all circumstances where the function is essential to maintain safety.

3. Control of radionuclide release

Challenges to retention of radionuclides involve maintaining fuel integrity, core structures, and other barriers relied upon to limit releases of radioactivity to the environment.

It should be noted that any reactor technology that uses a highly innovative fuel (e.g., reactor fuels containing thorium) and/or new methods to ensure reactor core cooling (e.g., molten salt as a heat transfer fluid) in combination with other new active or passive safety features must still address the basic elements of the existing safety analysis process (i.e., thermal-fluids behavior, neutronics, fission product behavior).

A diagram of major research areas important to the plant safety review process and licensing is provided in Figure 2.

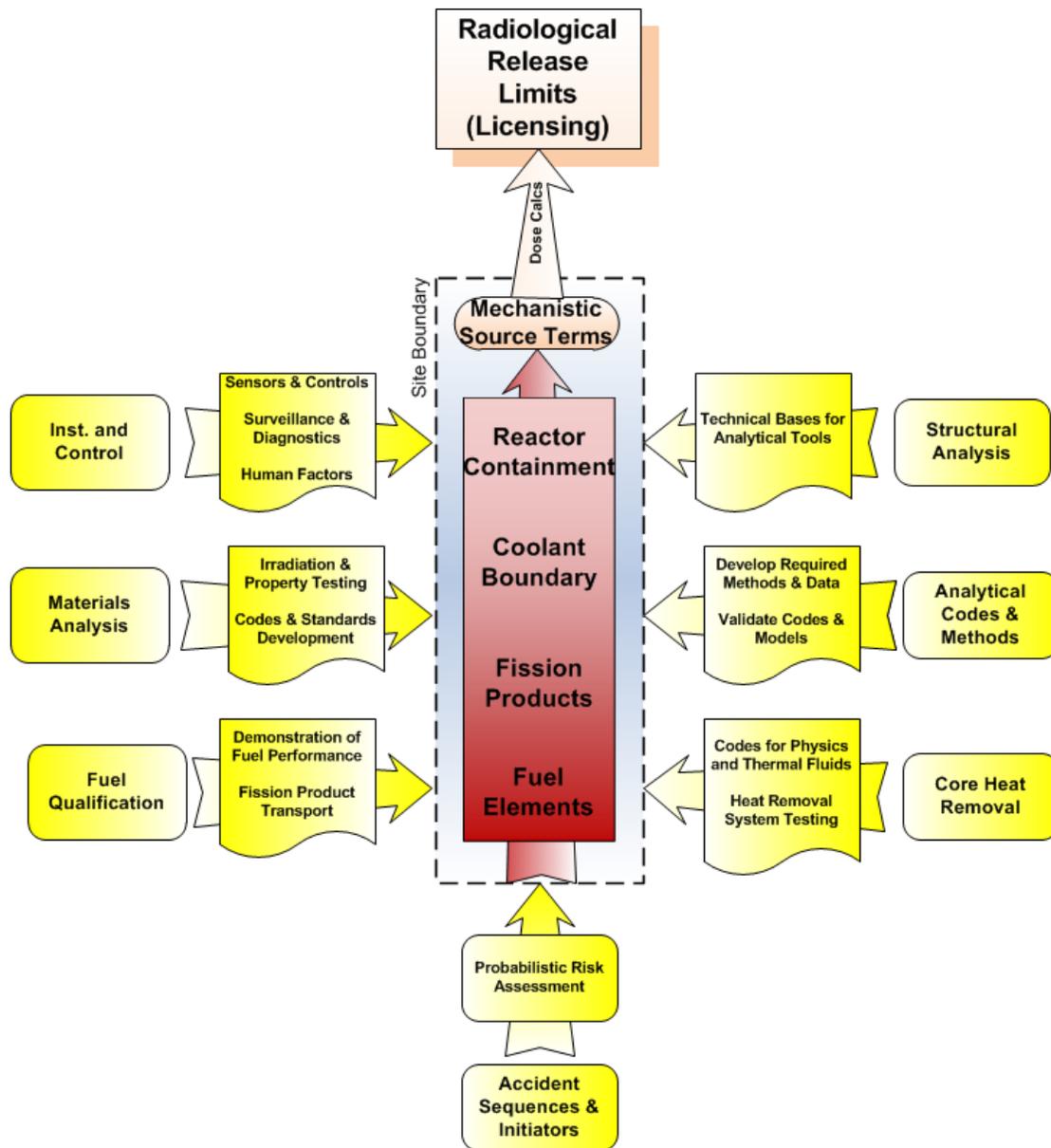


Figure 2. R&D elements that contribute to the plant safety and licensing review.

Realistic, yet conservative, radionuclide release analyses of all factors affecting dose calculations are essential to a positive safety review outcome. This analysis must be based on objective test information concerning fuel behavior during normal and off-normal conditions. Fission product release and transport characteristics must be understood for bounding design conditions and meet applicable radiological release limits for those conditions.

Discussed below are some of the key points that should be considered when developing a qualification program for fuel and source terms. Currently, the available industry and regulatory guidance for qualification of fuel and source terms is based on those developed for LWRs. No clear regulatory guidance and acceptance criteria exist for advanced reactor technologies at this time. However, as advanced reactor technologies continue to evolve and mature, additional industry and regulatory guidance will be developed to provide an improved regulatory framework for advanced reactor technologies.

It should also be noted that use of qualified historical information will be essential to the development of fuel qualification programs and safety analyses (including source term assessments). For example, historical information can be used support design and licensing-basis information and to help minimize the need for future confirmatory tests and/or analyses. Early dialog with the NRC is encouraged for these activities. This includes sharing of data collected during all phases of R&D, past operating experience of test reactors, and licensing-related information collected during those activities. Early interactions with the NRC staff may also indicate that certain historical data may not be applicable for a given licensing activity. As part of a response to this concern, a licensing plan should be developed that supports a coordinated and coherent regulatory dialogue. It should be tailored to design details of the specific technology and commercial offering under development that promotes technology objectives shared by applicants, NRC staff, and other affected stakeholders.

Fuel Qualification

The design, manufacture, and use of nuclear fuel are foundational to plant safety. Extensive fuel test knowledge and characterization data are required to meet established regulatory criteria. However, the infrastructure required to collect key fuels-related data is often highly specialized, costly to construct and operate, and relatively scarce. Because of this, DOE is a leading resource in nuclear fuels-related research. A fuel qualification program that includes long-term irradiation tests will generally be necessary to fully evaluate new and modified fuels. These factors, along with the long lead times needed to support certain types of in-core fuel tests, typically causes fuel research to be a significant licensing concern.

A robust experimental database is necessary to understand fuel system responses to a range of design and burnup conditions. Simulating fuel performance and fission product transport, retention, and releases under accident conditions also relate to this topic.

The following subsections outline key areas that must be considered when qualifying fuel for advanced reactor technology. Historical information that has been collected from past R&D efforts may be a valuable component in meeting the needs for fuel qualification but, as previously mentioned, the data must satisfy proper quality standard before they can be relied upon for use in safety-related decisions. An example of a particle fuel qualification approach for HTGR designs is provided in the *NGNP Fuel Qualification White Paper* (INL 2010).

Fuel Design Basis

Fuel system safety reviews for LWRs are performed under NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants,” Section 4.2. This plan ensures that the fuel design meets requirements of General Design Criteria (GDC) 10, GDC 35, and the core coolability requirements of 10 CFR 50.46. Section 4.2 of NUREG-800 also contains LWR-oriented guidance on specified acceptable fuel design limits (SAFDLs) that ensure (1) fuel is not damaged as a result of normal operation and anticipated operational occurrences, (2) fuel damage is never so severe as to prevent control-rod insertion when it is required, (3) the number of fuel-rod failures is not underestimated for postulated accidents, and (4) coolability is always maintained.

It is emphasized that SAFDL objectives were developed for water-cooled reactors; no clear acceptance criteria exist for advanced reactor fuel technology in the current regulatory framework. However, similar objectives for fuel design basis must be established and met for advanced reactor fuel technology. It should be anticipated that the following characteristics of advanced reactor fuel technology will be reviewed by the NRC during the design and licensing reviews:

- Design bases for the fuel
- Description and design drawings for the fuel
- Evaluation of the fuel design

- Plans for fuel testing, inspection, and surveillance.

Fuel Damage

To meet the requirements such as those prescribed in GDC 10 for normal operation, including anticipated operational occurrences (AOO), the fuel damage criteria should be given for all known damage mechanisms. Those requirements may include:

- Stress, strain, or loading limits for spacer grids, guide tubes, thimbles, fuel rods, control rods, channel boxes, and other fuel-system structural members should be provided. Stress limits obtained by methods other than those specified in Section III of the ASME Code should be justified.
- The cumulative number of strain fatigue cycles on the structural members should be significantly less than the design fatigue lifetime, which should be based on appropriate data and include a safety factor of 2 on stress amplitude or a safety factor of 20 on the number of cycles.
- Fretting wear at contact points to structural members should be limited, and allowable fretting wear should be stated in the safety analysis.
- Oxidation, hydriding, and the buildup of corrosion products (crud) should be limited. Allowable oxidation, hydriding, and crud levels should be discussed in the safety analysis and shown to be acceptable.
- Dimensional changes, such as rod bowing or irradiation growth of fuel rods, control rods, and guide tubes, should be included in the analysis to establish operational tolerances.
- Fuel and burnable-poison-rod internal gas pressures should remain below the nominal system pressure during normal operation unless otherwise justified.
- Worst-case hydraulic loads for normal operation should not exceed the hold-down capability of the fuel assembly (either gravity or hold-down springs).
- Control-rod reactivity should be maintained.

Fuel Failure

To meet requirements such as those prescribed in GDC 10 for normal operations, including AOO SAFDLs (as well as 10 CFR 100 as it relates to fission-product releases for postulated accidents), the fuel failure criteria should be given for all known fuel-failure mechanisms. For LWRs, NUREG-0800 provides eight failure modes, which may be applicable for advanced reactor technology. They are:

- Internal hydriding
- Cladding collapse
- Fretting of cladding
- Overheating of cladding
- Overheating of fuel pellets
- Excessive fuel enthalpy
- Bursting
- Mechanical fracturing.

These failure modes may or may not be of concern to an innovative advanced reactor design and should be evaluated using the most current information available on the emerging design. Additionally, different failure modes that are not discussed above for LWRs may exist, may need to be considered, and may be applicable for advanced reactor technology.

Fuel Coolability

Section 4.2 of NUREG-0800 states that for LWRs, fuel assemblies should retain coolability, including retaining-rod-bundle geometry with adequate coolant channels to permit removal of residual heat. Reduction of coolability can result from cladding embrittlement, violent expulsion of fuel, generalized cladding melting, gross structural deformation, and extreme coplanar fuel-rod ballooning. An assessment will be required concerning these issues with respect to advanced reactor design fuel coolability.

Fuel Design Requirements and Description

Section 4.2 of NUREG-0800 states that a description and design drawings that are sufficiently complete to provide an accurate representation of the fuel should be provided to the NRC. This includes comprehensive dimensional and metallurgical information regarding:

- Cladding
- Fuel pellet data, including dimensions, roughness, density, resintering, burnable-poison content, internal void volume, and fill gas type and pressure
- Enrichment data
- Hydraulic diameter
- Coolant design pressure
- Burnup limit.

The NUREG-0800 also states that the NRC will review the methods of demonstrating that the design bases are met. To ensure this, the NRC will examine:

- Operating experience with the fuel and other similar designs
- Prototype testing
- Analytical predictions.

Operating Experience

The NRC will review operating experience with fuel systems of the same or similar design. The operating experience should be described in detail, including the maximum burnup achieved, with the actual operating experience versus prototype testing or analytical predictions.

Prototype Testing

The NRC may expect prototype testing and supporting data to demonstrate adherence to the fuel design bases. Prototype testing typically includes both out-of-reactor and in-reactor testing. Out-of-reactor tests should be performed in a manner that determines and confirms the characteristics of the new design. Section 4.2 of NUREG-0800 does not set forth definitive requirements regarding design features that should be tested prior to irradiation. However, it does state that out-of-reactor tests have been performed for prior LWR designs of fuel assembly structural components and hydraulic characteristics. NUREG-0800 also states that NRC will review in-reactor testing of design features and lead-assembly irradiation of whole assemblies of a new fuel design. Of particular interest is the maximum burnup experience achieved in in-reactor prototype testing in relation to the specified maximum burnup limit for the new design.

Analytical Predictions

Section 4.2 of NUREG-0800 recognizes that some design bases and related parameters can only be evaluated analytically. With respect to LWR technology, NUREG-0800 provides a list of parameters that the NRC will review, including analytical models for fuel temperatures (stored energy), densification

effects, fuel-rod bowing, structural deformation, rupture and flow blockage, fuel-rod pressure, metal/water reaction rate, and fission product inventory. Adjusting and confirming this list of parameters must be confirmed with the NRC as a function of the advanced reactor design safety approach.

Fuel Testing, Inspection, and Surveillance

Section 4.2 of NUREG-0800 states that for a fuel design that introduces new features, a more detailed surveillance program, commensurate with the nature of the fuel, is warranted. The program should include appropriate qualitative and quantitative inspections to be carried out at interim and end-of-life refueling outages. This surveillance program should be coordinated with prototype testing and be built upon available data that may be available through historic activities. When prototype testing cannot be performed, a special detailed surveillance program may be required for the first irradiation of a new design.

Fuel Development and Qualification Program

If sufficient qualified historical data are not available to support qualification of the advanced reactor fuel type, it may be necessary to develop a new fuel-development and qualification program for advanced reactor technology. This type of program was established for modular HTGR technology under the Advanced Gas Reactor (AGR) Fuel Program (Ref: Technical Program Plan for INL Advanced Reactor Technologies Technology Development Office/Advanced Gas Reactor Fuel Development and Qualification Program”, PLN-3636, Rev 4, May 7, 2015).

Source Terms

A source term refers to the release of radionuclides from the fuel to the plant and beyond to the environment. With respect to advanced reactors, NRC recognizes that a “mechanistic source terms” (MST) approach should be employed. Use of an MST approach focuses on best estimate modeling the release and transport of radionuclides from the source to the environment for specific scenarios while accounting for retention and/or transmutation phenomena and uncertainties associated with the process. Determining an MST for radionuclide transport during all design basis conditions (including anticipated operational occurrences) may involve complex phenomena that require extensive test-based knowledge and a well-developed modeling capability for all involved processes of significance. While development of a detailed and technically sound MST will be design specific and the ultimate responsibility of an applicant, the approaches, tools, and methods used to perform safety assessments of MST related processes may be useful over a range of different design concepts.

Radionuclide releases must be initially defined at the source (i.e., the fuel) and quantified with respect to transport behaviors and attenuation factors as paths are established to the environment. Concentrations of radionuclides retained behind radiological release barriers (as a function of time) are crucial in defining a realistic and acceptable MST. Release and transport of key fission products during licensing basis events (LBEs) should be addressed at least in part through fuel testing. The goal underlying all such tests is to obtain a quantitative understanding of the relevant phenomenology and enable consequence predictions concerning released fission products.

Additionally, source terms and the radionuclide inventories that are developed with MST approach can be applied toward equipment environmental qualification, control room habitability analyses, and severe accident risk assessments in environmental impact statements. The mechanistic approach takes into account the inherent characteristics of the technology that provides multiple barriers to fission product transport to the environment in developing the source terms.

The following subsections describe key areas that are important when considering MST development. An example of MST approach development with respect to modular HTGR technology is provided in the *NGNP Mechanistic Source Terms White Paper* (INL 2010). This approach was reviewed by the NRC and found to constitute a reasonable approach in establishing a technical basis for the identification and

evaluation of key HTGR fission product transport phenomena (*NGNP – Assessment of Key Licensing Issues, (NRC July 17, 2014)*).

Radiological Design Basis

Certain regulatory guidance currently exists which communicate NRC expectations regarding the development of LWR-centric source terms and, as such, provide insight on the potential applicability of existing data to MST development for advanced reactor technologies.

Radiological design basis accidents (DBAs) for LWRs are currently analyzed based on pre-established deterministic source term releases into the containment. This DBA source term is described in the *Calculation of Distance Factors for Power and Test Reactor Sites* (DiNunno et al. 1962) and in NUREG-1465, “Accident Source Terms for Light-Water Nuclear Power Plants.” DiNunno et al. (1962) specified a non-MST, which that was based on experiments in the late 1950s involving heated, irradiated UO₂ fuel, pellets.

NUREG-1465, issued in 1995, is a more mechanistic portrayal of fission product release to the containment and was based on the understanding of severe accidents that evolved after the Three-Mile Island 2 accident.

NUREG-1465 indicates that the release fractions in the report are intended to be representative, or typical, of those associated with low-pressure core damage events. In its preface, NUREG-1465 states:

“Source terms for future reactors may differ from those presented in this report, which are based upon insights derived from current generation light-water reactors. An applicant may propose changes in source term parameters (timing, release magnitude, and chemical form) from those contained in this report, based upon and justified by design specific features.”

Guidance related to DiNunno et al. (1962) compliance for holders of operating licenses issued prior to January 10, 1997, is set forth in RGs 1.3 (boiling water reactors) and 1.4 (pressurized water reactors), while RG 1.183 applies to LWR applicants or license holders issued thereafter.

Key Factors

Several additional factors should be considered in a mechanistic definition of event-specific source terms for the advanced reactor technology. As these are defined and characterized, the influence of each on the calculated receptor dose is established. This permits development of a target for each element in the source term calculation to meet applicable safety goals. The development of these targets and the degree to which each element of the source term calculation can be characterized are addressed in several steps:

- Establish the top-level radionuclide control requirements to ensure the health and safety of the public and plant workers and to protect the environment.
- Identify LBEs for which plant conditions and source terms are to be calculated and compared with the goals.
- Identify and characterize the factors affecting radionuclide generation and transport for this reactor technology.
- Scope the influence of each factor on the magnitude of the source terms, and establish the principal parameters needed to characterize the effect of these factors on the generation and transport of radionuclides for the LBEs.
- Establish a target for each factor to achieve the goal for each event.
- Calculate source terms and dose rates based on the current understanding of generation and transport phenomena for the LBEs, and compare the calculated source terms and dose rates with top-level radionuclide control requirements.

- As needed to support meeting the top-level radionuclide control requirements, identify how well each factor is currently characterized to validate its target in establishing the source terms, and, where the current characterization is deficient, define the gaps between what is needed and what is known.
- Develop and complete analytic and testing programs to fill those gaps, if needed.
- Calculate source terms and dose rates again based on the more fully characterized and validated generation and transport phenomena for the LBEs, and compare the calculated source terms and dose rates with top-level radionuclide control requirements.

Fission Product Transport Codes and Models

Analytical tools are used to model and calculate fission product generation, transport, and release to the environment. To a large extent, these tools require computer codes specific to the reactor design. Generally speaking, separate sets of codes are used to calculate the distribution of fission products in the core and in the primary cooling system during normal operation (the initial conditions for accident analysis) and the behavior of the fission products during accident sequences, including any incremental, additional fuel failure and fission product transport and release. Fission product transport behavior in the reactor core and around the primary cooling system varies by species and with temperature and is affected by the materials used in the core and the primary cooling system. Consequently, full core computer codes and models of the entire primary cooling system are typically needed to track these effects. Therefore, demonstrated capability to predict with sufficient accuracy full core fuel performance and fission product transport and release under normal operating conditions and accident conditions is important to fuel qualification, MST qualification, and determination of required design margins.

Additionally, the best indicator of validity in design methods used to predict radionuclide source terms is the comparison of code predictions with actual measurement data from an operating reactor. Therefore, qualified historical data obtained from past prototype (or research) reactors can provide essential core performance and fission product transport data needed for fuel and mechanistic source terms qualification.

The goal of the fission product transport and source term activity is to produce a sound and conservative technical basis for source terms under normal operation and design accident conditions. The technical basis will be codified in design methods (computer models) and then validated by experimental data.