UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

TERRESTRIAL ENERGY USA, INC. – FINAL SAFETY EVALUATION OF TOPICAL REPORT TITLED: "POSTULATED INITIATING EVENTS FOR THE IMSR400," REVISION C (EPID NO.: L-2025-TOP-0000)

SPONSOR AND SUBMITTAL INFORMATION

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Project No.:	99902076
Submittal Date:	December 27, 2024

Submittal Agencywide Documents Access and Management System (ADAMS) Accession No.: ML25006A141

Brief Description of the Topical Report:

By letter dated December 27, 2024, Terrestrial Energy USA, Inc. (TEUSA or the applicant) submitted a Topical Report (TR) titled: "Postulated Initiating Events for the IMSR400," Revision A, (Agencywide Documents Access and Management System (ADAMS) Accession No. ML25006A141), for the U.S. Nuclear Regulatory Commission (NRC or the Commission) staff's review. By email dated March 31, 2025, the NRC staff informed TEUSA that the TR contained sufficient information for the NRC staff to initiate its detailed technical review (ML25083A115). TEUSA subsequently submitted Revisions B and C of the TR on October 1, 2025, and March 30, 2026, respectively (ML25274A145 and ML26092A409).

In support of the review, the NRC staff conducted a regulatory audit in accordance with the approved audit plan (ML25139A596) and documented the results in an audit report (ML26098A165). This safety evaluation (SE) is based on the information provided in Revision C of the TR. The TR describes TEUSA's methodology for developing a set of postulated initiating events (PIEs) for the Integral Molten Salt Reactor (IMSR) design and provides a preliminary set of PIEs consistent with the design's maturity.

TEUSA requested the NRC staff's review and approval of the methodology described in the TR. The methodology includes the process that will be used to establish a set of PIEs for the IMSR400 and the criteria for classifying an individual PIE for evaluation. TEUSA has not requested approval of the enclosed list of PIEs or the classification of individual PIEs in this TR. Approval of the final comprehensive list of PIEs and the final individual PIE classification will be requested as part of a future license application review. The development of these will be within the scope of an approved quality assurance program (QAP), a description of which TEUSA will submit to NRC for review and approval as part of future pre-application engagements.

REGULATORY EVALUATION

The identification of initiating events that form the basis for design basis accidents (DBAs) and associated consequence analyses is addressed through the regulatory framework governing nuclear facility licensing. Under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities,” internal and external hazards are encompassed within appendix A, “General Design Criteria (GDC) for Nuclear Power Plants,” which establish the minimum requirements for the principal design criteria (PDC) for water-cooled nuclear power plants similar in design and location to plants for which construction permits have been issued by the Commission. The GDC are considered to be generally applicable to other types of nuclear power units and are intended to provide guidance in establishing the PDC for such other units. Regulatory Guide 1.232, “Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors,” Revision 0 (ML17325A611) (Reference 1), provides guidance for non-light water reactor (LWR) designers, applicants and licensees to develop PDCs, as required by the applicable NRC regulations for nuclear power plants. These requirements also exist under 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” where applicants must address such hazards through the safety analysis report and site-specific information required by 10 CFR 52.47, “Application for renewal,” and 10 CFR 52.79, “Contents of applications; technical information in final safety analysis report.”

For its evaluation of TEUSA’s methodology, the NRC staff used the following applicable guidance. Conformance with NRC guidance is one way of demonstrating compliance with the regulations or demonstrating technical acceptability.

- **NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition” (ML052340514) (Reference 2)**

  NUREG-0800 (SRP) section 15.0, “Introduction – Transient and Accident Analyses,” provides guidance to review and ensure that the applicant’s selection and assembly of the plant transient and accident analyses represent a sufficiently broad spectrum of transients and accidents or initiating events for LWR technology. The NRC staff considers the guidance in section 15.0 regarding transient and accident analyses to generally provide insights for non-LWRs.

  SRP section 19.0, “Probabilistic Risk Assessment and Severe Accident Evaluation for New Reactors,” provides guidance pertaining to the NRC staff’s review of the design-specific and plant-specific probabilistic risk assessments (PRA) for design certification applications and combined license applications. The applicant’s PRA submittal should be consistent with prevailing PRA standards, guidance, and good practices as needed to identify and characterize PIEs. The NRC staff considers the guidance in section 19.0 regarding the identification hazards to generally provide insights for non-LWRs.

- **Trial regulatory guide (RG) 1.247, “Acceptability of Probabilistic Risk Assessment Results for Non-Light-Water Reactor Risk-Informed Activities” (ML21235A008) (Reference 3)**

  This document endorses PRA standard The American Society of Mechanical Engineers/American Nuclear Society (ASME/ANS) RA-S-1.4-2021, “Probabilistic Risk

Assessment Standard for Advanced Non-Light Water Reactor Nuclear Power Plants." The initiating event analysis element in the PRA standard provides guidance and PRA supporting requirements to identify and characterize events that challenge plant operation during any plant operating state and require successful mitigation by plant equipment and personnel to prevent or to mitigate a release of radioactive material.

- **NUREG-1513, "Integrated Safety Analysis Guidance Document" (ML011440260) (Reference 4)**

  This document provides general guidance to fuel cycle licensees/applicants on how to perform an integrated safety analysis and document the results, and specifies technology-inclusive guidance for identifying initiating events. Specifically, it identifies acceptable methods for conducting a comprehensive and systematic search for initiating events and accident sequences.

- **RG 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light Water Reactors" (ML20091L698) (Reference 5)**

  This document endorses the principles and methodology in Nuclear Energy Institute (NEI) 18-04, "Risk-Informed Performance-Based Guidance for Non-Light Water Reactor Licensing Basis Development," which provides an acceptable method to identify licensing basis events (LBEs). NEI 18-04 presents a systematic process for identifying and classifying events and the associated sequences as anticipated operational occurrences (AOOs), design basis events, or beyond design basis events for non-LWRs. The outcome of the selection and evaluation of LBEs can be used to identify design features of the plant that are necessary and sufficient to ensure that risk goals are achieved, and licensing requirements are met.

- **DG-1413, "Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants" (ML22257A173) (Reference 6)**

  This document provides the NRC staff's technology-inclusive guidance for identifying initiating events, delineating event sequences, and identifying licensing events that can be used to inform the design and licensing bases and the content of applications for commercial nuclear plants.

TECHNICAL EVALUATION

Introduction

Note: [[ ]] denotes proprietary information.

In October 2020, TEUSA and Terrestrial Energy, Inc. (TEI) (hereafter collectively referred to as Terrestrial) were engaged in pre-licensing activities with the NRC and the Canadian Nuclear Safety Commission (CNSC), respectively, related to the IMSR design. PIEs for the IMSR were identified as a collaboration topic under the memorandum of cooperation between the NRC and the CNSC (Reference 7). Consequently, in May 2022, the NRC and CNSC (hereafter referred to as the regulators) issued a joint report, "Joint Report on Terrestrial Energy's Methodology for Developing a Postulated Initiating Events List for the Integral Molten Salt Reactor" (ML22139A124) (Reference 9), documenting the results of this collaboration in response to a request by Terrestrial for regulatory feedback on a white paper, "TEUSA submittal of Postulated Initiating Events for the IMSR," Revision 2 (ML21357A015), describing the process used to develop a set of PIEs for the IMSR design.

A PIE is an occurrence that challenges plant control and safety systems and whose failure could result in an undesirable end state and/or a release of radioactive material. The development of PIEs is a fundamental element of an applicant's safety analysis, including the deterministic safety analysis (DSA), hazard analysis, and PRA.

Based on the high-level information available at that time and the additional actions identified by Terrestrial to complete the methodology, the regulators jointly concluded that the resulting methodology would likely be technically sound and capable of generating a comprehensive set of PIEs. Given the early stage of the design, the PIE identification methodology was determined to be systematic, logical, and of appropriate scope. The regulators also identified additional information that should be considered by Terrestrial in further enhancement of the methodology and to be addressed in future licensing actions. The grouping, classification, and mitigation approaches presented in the white paper were considered reasonable, with the recognition that they are expected to evolve as the design matures and the PRA is developed.

With respect to the PIE list presented in the white paper, the regulators did not make a determination on acceptability because the design was still evolving. The regulators indicated that additional detail would be required in a future submittal to determine whether the PIE list is comprehensive and acceptable for approval.

Following these pre-licensing activities and in response to the comments in the joint report, TEUSA submitted a TR to the NRC on December 27, 2024, requesting the NRC's approval of the methodology described in the TR. The methodology includes the process that will be used to establish the set of PIEs for the IMSR400 and the criteria for classifying individual PIEs for evaluation. The methodology addresses events affecting the systems, structures and components (SSCs) included in the IMSR facility; it is not limited to the IMSR core unit. The methodology includes an evaluation of potential off-normal conditions that could challenge one or more fundamental safety functions.

The TR also documents how the comments contained in the joint report were considered and incorporated into revisions to the methodology previously reviewed by the regulators. Both the jointly issued comments and those issued specifically by the NRC staff were addressed and are discussed in the TR.

TEUSA included in the TR, the existing PIE list and the individual PIE classification commensurate with the current maturity of the design to demonstrate the output of the methodology. TEUSA has not requested the NRC's approval of this information at this time. The NRC's approval of a final, comprehensive PIE list and final PIE classifications will be requested by TEUSA as part of a future license application.

TR section I summarizes the purpose of the TR. TR section II provides an introduction of the licensing strategy and objective, description of the IMSR400, scope, and quality assurance (QA) practices in place for the methodology. TR section III describes the process for identifying the

PIEs and their classification criteria and provides a preliminary list of PIEs and their classifications. TR section IV provides TEUSA's conclusions regarding implementation of the methodology. TR section V addresses the comments provided in the joint report from the NRC and the CNSC.

NRC Staff's Evaluation of TEUSA's PIE Methodology for the IMSR400

The NRC staff evaluated the approach described in this TR to determine the acceptability of the approach for developing a set of PIEs for the IMSR400 design and the criteria for classifying individual PIEs for evaluation. The NRC staff's evaluation is based on TR, Revision C, as summarized above. In the joint report on TEUSA's white paper describing the methodology for developing PIEs, the regulators identified the following five key attributes for evaluating the soundness of a PIE methodology: 1) quality control; 2) systematic process; 3) scoping of PIEs; 4) grouping of PIEs; and 5) classification of PIEs. The NRC staff's review of the TR was conducted using these attributes.

1. Attribute 1: Quality Control

This attribute focuses on ensuring that the PIE methodology is effectively integrated with the designer's QA and configuration control processes. As the design and the list of PIEs evolve, appropriate quality controls are necessary to provide confidence in the results of the methodology and to prevent errors from propagating into downstream analyses and decisions. Quality controls apply to multiple activities, including safety analysis and the development of the PIE list. The NRC staff's review under this attribute emphasizes those aspects of quality control relevant to the PIE methodology, including documentation and traceability, verification and validation of results, definition of roles and responsibilities, and confirmation of personnel qualifications.

Quality Assurance and Controls for PIE Methodology

TEUSA provided information pertaining to quality controls in TR section II.4, "Quality Assurance." In the TR, TEUSA stated that QA practices are established to ensure that the PIE methodology is accurate, complete, and current with respect to design information, regulatory documents, internal analyses, and external literature and research. TEUSA stated that these practices will be implemented in accordance with the processes described in the TR and supported by general controls described in the TEI Management System Manual, which is comparable to 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." TEUSA further stated that the regulatory process described in the TR will be performed under a QA plan that meets NRC requirements and will include the use of qualified personnel to identify PIEs and the review and verification of resulting documentation under applicable management and review controls.

The NRC staff finds that the described QA framework, including the use of qualified personnel and the application of management and review controls, is generally consistent with accepted QA principles for ensuring the technical adequacy, traceability, and reproducibility of analyses supporting PIE identification. These elements are important for ensuring that the methodology is applied in a systematic and controlled manner. However, the NRC staff notes that the TR does not provide details for the NRC staff to verify that the QAP fully complies with the requirements of 10 CFR Part 50, Appendix B.

Based on the information provided, the NRC staff concludes that TEUSA has described a QA approach that is generally consistent with the intent of establishing adequate controls over the PIE identification process. The NRC staff finds this approach acceptable for the purpose of supporting the methodology described in the TR.

Because the NRC staff's approval is limited to the PIE methodology, the adequacy and implementation of the QAP, including compliance with 10 CFR Part 50, Appendix B, will need to be demonstrated as part of a future application. Accordingly, the NRC staff will defer its detailed review of the QAP and its implementation to a later stage when QA information is submitted.

Expertise Requirements

In TR section II.4.1, "Expertise Requirements," TEUSA stated that personnel with substantial knowledge of the design and proposed operation of the IMSR will be selected to perform the PIE methodology. TEUSA stated that a task lead is responsible for developing and executing an update plan for the PIE document, and that additional qualified personnel will review the results. Managers for the relevant technical and engineering disciplines are responsible for identifying personnel with appropriate expertise to serve as reviewers. The safety team manager is responsible for ensuring that the selected personnel possess relevant and sufficient expertise to support a comprehensive evaluation.

The NRC staff finds that TEUSA has defined roles and responsibilities for implementing, updating, and reviewing the PIE methodology, including the use of personnel with relevant expertise, assignment of a task lead for maintaining the PIE document, and the involvement of qualified reviewers and discipline managers. The NRC staff also notes that TEUSA has designated the safety team manager as the individual responsible for ensuring that personnel possess appropriate expertise to support the evaluation. These elements establish clear accountability, incorporate qualified technical input, and provide for independent review and management oversight, which are consistent with accepted QA and engineering practices. Therefore, the NRC staff concludes that the expertise requirements and associated management and review controls are adequately defined to support consistent and technically sound implementation and updating of the PIE methodology and are acceptable.

Management and Review Controls

In TR section II.4.2, "Management and Review Controls," TEUSA described a process for collecting and evaluating information that may affect the PIE list. TEUSA stated that this process relies on discipline-specific "points of contact" responsible for collecting new information from interfacing disciplines and communicating that information within their own discipline. Information is collected primarily through discipline meetings and periodic team meetings, during which updates and supporting documentation are shared. In addition, the review and comment process for new documentation includes all interfacing disciplines, and reviewers communicate relevant information to the team to ensure consistency across disciplines. For the safety team, the safety team manager is responsible for collecting information that could result in changes to the PIE documentation.

TEUSA stated that, based on the evaluation of new information, external documentation, and internal safety documentation, the safety team manager, with support from the safety team, determines whether updates to the PIE identification methodology, PIE list, or PIE classification are necessary. If updates are needed, the safety team manager initiates the selection of qualified personnel to perform the work.

TEUSA also stated that the task lead develops an update plan aligned with engineering changes to the IMSR design since the previous update. The plan identifies affected design areas, specifies reference inputs (e.g., design documents, literature, regulatory guidance), assigns work to qualified personnel, identifies interfacing disciplines, and establishes review actions. The safety team manager, in coordination with other discipline managers and the task lead, identifies reviewers with appropriate skills. After the plan is approved, the task lead executes the plan and produces a draft update. The draft is to be reviewed by safety team members and interfacing disciplines using established document control procedures to verify completeness and accuracy with respect to design information and relevant references.

The NRC staff concludes that TEUSA has sufficiently described a structured process for the identification, collection, and evaluation of new information that may affect the PIE documentation, including the use of discipline-specific points of contact, periodic interdisciplinary interactions, and management oversight by the safety team manager. The process sufficiently defines controls for initiating and implementing updates, including the development of an update plan aligned with design changes, identification of affected systems and inputs, assignment of qualified personnel, and performance of interdisciplinary reviews. In addition, the use of established document control and review procedures provides a mechanism to verify the technical accuracy, completeness, and consistency of updates with design and supporting references. Collectively, these elements establish a systematic and controlled framework for maintaining the PIE documentation. Therefore, the NRC staff concludes that the process is reasonable and acceptable.

Update Frequency and Lifecycle Controls

TEUSA stated that during the IMSR400 design, engineering, and pre-licensing phases, updates are not performed on a fixed schedule but are triggered by the collection and evaluation of new information by the safety team manager and safety team. TEUSA further stated that, once the design approval is issued, design evolution and associated PIE changes would be reduced because the design is complete; however, under the PIE maintenance process, updates to the PIE list are expected to identify new events or revise existing ones. TEUSA stated that PIE information will be updated periodically over the life of the plant. TEUSA identified natural assessment points such as updates to the PRA or following each core-unit reload (7 years). TEUSA further stated that significant changes to plant design or risk profile would be addressed through the applicable licensing basis change process.

The NRC staff concludes that the described approach provides reasonable triggers for maintaining the currency of the PIE list. Although no specific update interval is defined, updates are initiated as needed by plant personnel under the maintenance and control program. In addition, updates are expected to occur periodically, such as following PRA updates required by 10 CFR 50.71, “Maintenance of records, making of reports,” or after each core reload. Collectively, these triggers provide a sound and reasonable basis for maintaining the PIE list.

Interdisciplinary Review

TEUSA stated that during the conceptual design and basic engineering stages, relevant disciplines, including DSA, PRA, licensing, physics, thermal-hydraulics, civil, instrumentation and controls (I&C), research and development, fire protection, and system design, were involved in reviewing the PIE methodology and PIE list. During detailed engineering, TEUSA plans to establish an internal PIE panel composed of experienced personnel from relevant disciplines to support the identification, categorization, and classification of PIEs. TEUSA stated that the internal PIE panel will include experienced expertise from relevant technical disciplines and will be responsible for performing completeness checks. The panel will confirm that all relevant disciplines have been involved in the development of, and provided feedback on, the updated PIE list. The panel will also verify that the most recent approved versions of technical design documents were used in the PIE development process and that the updated list reflects the current design. In addition, the panel will confirm that the updated PRA has been used to identify failure modes and estimate failure frequencies, ensuring that all PIEs are appropriately categorized as AOOs, DBAs, and beyond design basis accidents (BDBAs). Furthermore, as part of the PIE update for an application, the panel will confirm that the full spectrum of internal and external hazards specific to the selected site has been considered in the PIE list.

The NRC staff finds that TEUSA's process reasonably incorporates the involvement of relevant technical disciplines throughout the design stages and includes the establishment of an internal PIE panel to perform completeness and consistency checks during detailed engineering. The NRC staff also finds that these elements, interdisciplinary input, use of current design information, incorporation of PRA insights, and formal completeness checks, provide a systematic and technically grounded approach for ensuring that the PIE list is comprehensive, properly categorized, and consistent with the design. Therefore, the NRC staff concludes that the described process provides an adequate basis for ensuring the technical completeness and consistency of the PIE identification and classification and is acceptable.

The NRC Staff's Evaluation Findings for Attribute 1

Based on its review of the quality control information provided in the TR and confirmation obtained through the audit, the NRC staff finds that TEUSA has reasonably described how quality control aspects relevant to the PIE methodology will be implemented, including documentation control, verification of results, definition of roles and responsibilities, interdisciplinary review, and use of qualified personnel. The NRC staff finds that the expertise requirements and management and review controls are reasonably characterized and provide confidence that the PIE methodology can be implemented in a manner that supports technically sound and consistent results.

However, because TEUSA has not submitted its QAP documentation for the NRC staff's review, the NRC staff does not make findings on the adequacy of the QA and configuration management program as part of this SE. The NRC staff notes that a future QAP, when submitted for the NRC staff's review, must demonstrate compliance with the requirements of 10 CFR Part 50, Appendix B, and may do so by conforming to the guidance in RG 1.28, "Quality Assurance Program Criteria (Design and Construction)," (Reference 8) by providing detailed documentation of personnel qualifications and QA controls for future PIE updates.

2. Attribute 2: Systematic Process

This attribute focuses on the designer's overall process for developing PIEs. A systematic process is expected to provide confidence that the methodology identifies all reasonably foreseeable initiating events and produces a PIE list that is reflective of the design during the design phase and is comprehensive at initial fuel loading. The NRC staff's review considers whether the process steps are logical, structured, and integrated with the DSA and PRA. This includes evaluating whether the approaches and processes are technically sound and whether the process includes provisions to identify, characterize, and appropriately account for uncertainties.

In TR section III, "Process for Identifying PIEs," TEUSA stated that a comprehensive list of PIEs is developed for all permissible plant operating modes to ensure completeness in the analysis of plant behavior. TEUSA stated that each identified PIE is categorized into one of seven categories based on the associated primary plant response or similar initiating failures. After the comprehensive list of PIEs is generated, the events are classified based on estimated frequency of occurrence into AOOs, DBAs, and BDBAs.

In the sections below, the NRC staff evaluates the proposed systematic process for identifying PIEs to determine whether the process provides a structured and comprehensive basis for supporting subsequent analyses. The categorizing (grouping) and classifying of PIEs are addressed under Attributes 4 and 5, respectively.

Approach for PIE Identification

In TR section III.1, "Approach for PIEs Identification," TEUSA stated that the PIE identification process is intended to be systematic and as complete as practicable. TEUSA stated that the causes of initiating events include both internal and external hazards. Internal hazards originate within the plant and may be human-induced or caused by SSC failures or malfunctions. Internal events include SSC failures, operator errors, and hazards (human-induced or caused by SSC malfunction) that directly or indirectly challenge one or more plant safety functions. External hazards originate externally to the site and its processes and are hazards over which the operator has little or no control (e.g., earthquakes). External events include human-induced or naturally occurring events as well as events originating in the steam plant.

TEUSA stated that important Type B initiating events, which are caused by human actions such as mispositioning or incorrect operation of equipment that inadvertently trips components or generates false control signals, are evaluated and reviewed as part of the PIE identification process.

TEUSA stated that the identification of hazards is based on generic IMSR400 qualification requirements and parameters because the methodology is currently based on a generic (non-site-specific) site. TEUSA stated that these hazards are described at a high level and will be further refined into more specific PIEs once a detailed site hazard assessment is completed. In addition, since the methodology and PIE list is currently based on a generic site, PIEs initiated by external hazards will require reevaluation once a site is selected, using the site evaluation and environmental assessment processes.

TEUSA stated that a deductive, top-down approach similar to a master logic diagram (MLD) is used to identify PIEs. This approach considers all plant operating modes and evaluates plant-level challenges that could lead to undesirable consequences. TEUSA also indicated that future work will include conducting mode-specific top-down assessments. To complement the top-down approach, TEUSA used an inductive, bottom-up approach to identify new PIEs and refine previously identified events. The bottom-up approach evaluates how lower-level failures may affect system- and plant-level functions. TEUSA applies failure modes and effects analysis (FMEA) as the primary bottom-up technique. During the design stage, TEUSA developed an FMEA for passive systems to confirm that no active failures or dependencies on supporting systems would cause the passive system to fail and that system failures would not generate additional PIEs. TEUSA stated that during the detailed engineering stage, additional bottom-up analyses will be performed as more detailed system design information becomes available. The TR provides examples of the application of MLD and FMEA in the IMSR PIE identification process.

In addition, TEUSA stated that industry and research sources, including Oak Ridge National Laboratory (ORNL) reports (e.g., ORNL-TM-732 and ORNL/TM-2019/1246), are used as completeness checks for initiating event identification. TEUSA stated that the PIE identification approach is iterative because the plant design continues to evolve. As new information becomes available, including regulatory guidance, design updates, operating experience from other reactors, and internal safety analyses (e.g., PRA and DSA), this information will be incorporated into the PIE update process.

The NRC staff finds that TEUSA's approach of using deductive and inductive approaches to systematically identify PIEs across all plant operating modes is technically sound and adequate. The top-down approach ensures that plant-level challenges and mode-specific hazards are considered, while the bottom-up approach evaluates how lower-level system failures, including passive system interactions, could propagate to plant-level events. The NRC staff notes that TEUSA also considers important Type B human errors, external hazards, and uses industry and research references to verify the completeness of initiating event identification. This provides reasonable assurance that the PIE list is comprehensive and complete.

The NRC staff further notes that TEUSA's methodology is iterative, allowing the incorporation of new design information, regulatory guidance, operating experience, and internal safety analyses (e.g., PRA and DSA) as they become available. This ensures that the PIE identification process remains current and technically robust as the design matures.

Based on this evaluation, the NRC staff concludes that TEUSA's use of deductive and inductive approaches, consideration of internal and external hazards, inclusion of human-induced events, and iterative updates provide a technically sound, systematic, and comprehensive basis for identifying PIEs. Therefore, the proposed methodology for PIE identification is acceptable.

PIE Identification

TR section III.2, "PIEs Identification," describes the application of the top-down MLD assessment used to identify PIEs. TEUSA specifies a top event for the IMSR400 design that considers all radiological sources within the plant, including reactor and non-reactor sources. The assessment evaluates internal events, internal hazards, external events, external hazards, common-cause hazards, release pathway challenges, plant responses, and resulting PIEs.

TEUSA also describes the application of bottom-up FMEA to complement the MLD process and provides example extracts from the preliminary FMEA worksheets to illustrate the type of information evaluated during PIE identification in section III.1 of the TR, as described above.

The NRC staff concludes that the use of MLD and FMEA techniques for PIE identification is consistent with generally accepted engineering and risk assessment practices. Although TEUSA provided the preliminary MLD flowcharts and FMEA worksheets as illustrative examples of how these techniques are implemented and documented; per the scope of review requested by TEUSA, a detailed review of its content and deliverables is outside the scope of this TR. Accordingly, the NRC staff does not draw conclusions regarding the specific inputs or results of the MLD and FMEA.

The NRC Staff's Evaluation Findings for Attribute 2

Identification of PIEs is a fundamental starting point for nuclear power safety assessment and risk evaluation. Therefore, a reasonably complete set of initiating events is necessary to determine challenges to plant safety functions and to support the selection and evaluation of LBEs, including AOOs, DBAs, and BDBAs.

The NRC staff finds that TEUSA's systematic process uses multiple complementary perspectives and techniques, including a top-down MLD approach and a bottom-up FMEA approach, consideration of human-induced initiating events, and the incorporation of generic operating experience and relevant data. This blended approach provides reasonable assurance that risk-significant and foreseeable initiating events are identified and evaluated.

Accordingly, the NRC staff concludes that the PIE identification process proposed by TEUSA is systematic, logical, and technically sound, and provides a reasonable and acceptable basis for developing a comprehensive set of PIEs to support subsequent safety and risk analyses.

3. Attribute 3: Scoping of PIEs

This attribute focuses on the scope of PIE identification and safety assessment activities used to develop a comprehensive PIE list. The NRC staff's review considers whether the applicant has adequately accounted for all relevant events and occurrences (e.g., failures, malfunctions, accidents, human errors, and hazards) applicable to the entire facility and its operating and operational states. The objective is to establish confidence that the PIE list is comprehensive and appropriately scoped. The scope of relevant events and occurrences include, but are not limited to:

- all potential radioactive sources;
- site-specific and non-site-specific events or hazards;
- internal and external events (natural, common-cause failures, and human-induced events);
- common-cause events affecting multiple reactor units (if applicable);
- potential combinations or interactions between events and reactor units; and
- plant operating modes, states, conditions, and configurations (whether normal or abnormal), and transitions between them.

In addition to the above considerations, justification or rationale for excluding PIEs should be documented to demonstrate that the scope of the PIEs is reasonable and acceptable.

Scope of the PIE Methodology

As discussed in TR section II, the proposed methodology evaluates a single-unit nuclear power plant (NPP) configuration located at a generic site. The methodology considers the evaluation of the following plant operating modes:

- Fuel storage
- Initial fueling
- Shutdown
- Startup
- At-power
- Shutting down
- Defueling
- Core-swap

TEUSA stated that PIEs associated with I&C and plant electrical systems are also considered. The identified PIEs include, as potential causes, failures of supporting systems, subsystems, and components that could lead to the loss of a safety function (e.g., failure of heating, ventilation, air conditioning (HVAC) system).

Based on its review and the information presented in the TR, the NRC staff concludes that by incorporating and evaluating a broad range of operating modes and including potential failures of critical supporting SSCs, the methodology addresses variability in plant configuration and operational states, ensuring that PIE identification is comprehensive and not biased toward a single operating condition. Accordingly, the NRC staff concludes that the current scope is reasonable and acceptable for demonstrating the implementation of the methodology and for supporting the preliminary identification of initiating events.

Nuclear Island and Balance of Plant Scope

The TR states that the methodology considers events occurring within the nuclear island and events that originate outside the nuclear island but propagate to it, including external hazards. The balance of the plant is modeled generically as a steam plant. Only bounding steam plant events that result in increased or decreased heat removal are considered. Specific steam plant events (e.g., main steam line break, loss of feedwater, loss of condenser cooling, turbine trip) are treated as potential causes of these bounding events. Steam plant events that could affect the nuclear plant pressure boundary are also considered.

The NRC staff concludes that limiting the scope to bounding steam plant effects while focusing on impacts to nuclear island safety functions is reasonable for a generic PIE identification methodology and is consistent with the TEUSA licensing framework. The NRC staff finds that the applicant has reasonably described the events considered in the initial evaluation, which limits the scope to bounding steam plant effects while focusing on impacts to nuclear island safety functions. Because the TR mainly addresses the methodology for PIE identification rather than establishing a complete set of PIEs, the NRC staff finds that this scoped approach is acceptable for demonstrating a technically justified and systematic basis for PIE identification in a generic design context and is consistent with the TEUSA licensing approach, which includes TEUSA's ongoing pre-licensing activities with the NRC staff to establish the safety case, design criteria, and regulatory pathway for licensing the IMSR within the existing U.S. regulatory structure.

Plant-Wide and Hazard-Initiated PIEs

The TR states that certain PIEs affect the entire NPP, including safety-related and non-safety-related systems, for example, loss of offsite power. Other internal and external hazards that may affect the entire NPPs include environmental events (e.g., flooding, fire, earthquake) and internal system failures (e.g., explosions, missiles). In the TR, external hazards are addressed using generic site parameters consistent with the IMSR400 design basis. Combination events involving multiple internal and/or external hazards are not included within the current scope of the preliminary PIE list. Incorporating combinations of events does not impact the PIE methodology; however, TEUSA has stated that a future revision of the PIE TR will address credible combinations of events, including those that are consequential or correlated.

The NRC staff concludes that TEUSA's approach of considering internal and external hazards within a generic site framework reasonably provides a systematic basis for identifying PIEs at this stage of design development. By limiting the current evaluation to individual hazards, the methodology still captures key safety-significant events without introducing complexity in early design. The NRC staff notes that the assessment of credible hazard combinations, as described by TEUSA, is not necessary to evaluate the methodology for PIE identification, but will be needed to ensure completeness of the PIE list and consistency with licensing expectations.

Protection Against Malevolent Acts and Aging Effects

The TR states that protection against an intentional large aircraft crash is addressed in the IMSR400 design under the scope of protection against malevolent acts. The TR also states that slow-developing degradation mechanisms (e.g., aging effects) are addressed through plant design features, equipment qualification, monitoring, maintenance, in-service inspection, and testing programs.

The NRC staff concludes that the TR's treatment of malevolent acts and aging mechanisms through design and programmatic controls, outside of the PIE methodology is reasonable and consistent with established practices (e.g., the use RG 1.217, "Guidance for the Assessment of Beyond-Design-Basis Aircraft Impacts," to address regulations such as 10 CFR 50.150[1], "Aircraft impact assessment").

Hazard Scope and Operating States

TR section II defines the scope of the PIE methodology and provides guidance applicable to all plant operating modes, including unique operating conditions such as core-unit replacement, fuel salt defueling, and long-term fuel salt storage. The applicable operating states for postulated events are identified in TR section III.4.1 through section III.4.7. The methodology applies to the full range of identified internal and external hazards within the defined scope.

The NRC staff concludes that the TR defines the scope of hazards and operating states to which the PIE methodology applies in a manner consistent with the IMSR400 design. The TR reasonably establishes the boundaries within which internal and external hazards are evaluated

[1] Pursuant to the sunsetting provision in 10 CFR 50.150(d), "[10 CFR 50.150] shall cease to have effect on April 8, 2027, unless the NRC determines that the cessation deadline should be extended to a date not more than 5 years in the future after offering the public an opportunity to provide input on the costs and benefits of this section and considering that input. The NRC will publish a document in the *Federal Register* announcing its determination and revising or removing this section accordingly."

and identifies the operating conditions relevant to postulated events. Based on this information, the NRC staff finds that the defined scope is sufficiently comprehensive to support the systematic identification of potential initiating events and to ensure that the methodology is applied across all plant conditions.

Frequency Considerations

As described in TR section V, TEUSA stated that the methodology considers internal events with postulated frequencies greater than 10^{-7} per year, while frequencies of external events will be based on applicable guidance. The applicant also noted that this approach is consistent with the licensing modernization project process.

The NRC staff concludes that the proposed approach for addressing event frequencies is reasonable and consistent with accepted practices, as discussed in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition"; RG 1.233, which endorses the LMP; and RG 1.247, which endorses the non-LWR PRA standard.

Screening Criteria

The PIE identification methodology does not apply screening criteria to exclude PIEs from consideration in demonstrating the performance of the fundamental safety functions (control, cool, and contain). TEUSA stated that screening criteria are used in the development of the PRA, but such screening does not apply to the PIE identification methodology.

The NRC staff concludes that because TEUSA applies screening only within the PRA and not within the PIE identification process, the PIE identification methodology is acceptable and supports the development of a comprehensive set of initiating events in a conservative and technically sound manner.

The NRC Staff's Evaluation Findings for Attribute 3

Based on its review, the NRC staff finds that the scope of the proposed PIE methodology clearly defines the plant configuration, operating modes, hazard types, and system interfaces considered in the identification of PIEs. The methodology appropriately addresses internal and external hazards, plant-wide events, supporting SSC failures, and applicable operating states, and it establishes a clear relationship between the PIE identification process and PRA development.

Accordingly, the NRC staff concludes that the scope of the PIE identification methodology is systematic, sufficiently comprehensive for a generic site application, and provides a reasonable and acceptable basis for identifying initiating events to support subsequent safety and risk evaluations.

4. Attribute 4: Grouping of PIEs

This attribute focuses on how PIEs with similar characteristics are grouped for analysis. The objective of event grouping is to simplify the safety analysis process by identifying limiting (or bounding) events within each group, thereby reducing the number of analyses needed to demonstrate compliance with acceptance criteria. A limiting event bounds the scenarios that present the greatest challenges to the applicable acceptance criteria. The NRC staff's review considers how PIEs are categorized, how limiting events are selected, and how safety and mitigating functions are addressed in the grouping process.

PIE Categorization

TEUSA stated that the top-down approach described in TR section III.2, resulted in the preliminary identification of **[[** **]]** for the IMSR400 design. The applicant further stated that these events were categorized according to its associated primary plant response (e.g., increase or decrease in core-unit heat removal) or by similar initiating failures (e.g., loss of piping or vessel integrity). The applicant clarified that this categorization is intended solely to organize the identified PIEs and is not used directly for PRA or DSA modeling purposes. The categories used are the following:

1) Unwanted changes in reactivity
2) Increase of core-unit heat removal
3) Decrease of core-unit heat removal
4) Loss of integrity of piping or vessel
5) Internal hazards
6) External hazards
7) Additional events.

The applicant stated that grouping of the PIEs for analytical purposes involves **[[**

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TEUSA also stated that the categorization presented in the TR may include multiple bounding events within a single category and may not align with the event grouping structure used in the PRA.

The NRC Staff's Evaluation Findings for Attribute 4

The NRC staff reviewed the applicant's approach to categorizing PIEs and concluded that organizing a large number of identified initiating events by primary plant response or similar failure mechanisms is a reasonable and systematic method for managing the completeness and traceability of the PIE identification process. The NRC staff notes that the categorization is used as an organizational tool and is distinct from the grouping of events performed within the PRA and DSA models.

The NRC staff further determines that distinguishing between internal hazards, external hazards, and additional events provides a clear high-level structure for the identified event set and supports subsequent risk-informed and deterministic evaluations. The NRC staff notes that analytical grouping within the PRA and DSA based on similar safety function impacts, system availability, operator demands, and success criteria is consistent with accepted risk assessment practices. It should be noted that the NRC staff did not make any findings regarding the acceptability of the IMSR400 PIE list or the resulting groupings presented in the TR.

Based on its review, the NRC staff concludes that the applicant's PIE categorization approach provides a logical and traceable organizational framework for the identified initiating events and is acceptable for supporting subsequent safety and risk evaluations.

5. Attribute 5: Classification of PIEs

This attribute focuses on how PIEs are classified based on their associated frequencies and consequences. The objective is to establish confidence in the designer's classification approach and justification of PIE frequencies. Classification supports the application of appropriate acceptance criteria, including safety, design, and operational criteria, as well as the identification of mitigating measures. The NRC staff's review considers how event classifications and frequency ranges are justified and demonstrated, how probabilities of combined system failures are evaluated, and how uncertainties are characterized and treated.

Classification of PIEs

The applicant stated that, for each PIE, the safety analyses (e.g., PRA and DSA) will determine which mitigating systems and safety functions are credited, based on the safety classification of the systems involved and the classification of the PIEs (i.e., AOO, DBA, or BDBA). The applicant indicated that, unless specifically identified, the listed PIEs do not require reactor shutdown via the shutdown rods to achieve a safe state. The applicant further stated that preventive measures and monitoring capabilities are identified where applicable and that, for credible events identified through the PRA and DSA, monitoring is assumed to be available to detect event occurrence.

The applicant described the frequency-based classification framework as follows:

- **AOOs:** Events with frequencies greater than or equal to 10^{-2} per reactor year.
- **DBAs:** Events with frequencies greater than or equal to 10^{-5} per reactor year and less than 10^{-2} per reactor year.
- **BDBAs:** Events with frequencies less than 10^{-5} per reactor year.

The applicant stated that PIEs are classified based on frequency and consequences to support the selection of appropriate analytical approaches and the application of corresponding safety, design, and operational acceptance criteria. The applicant further stated that, because the NRC staff has not established specific frequency ranges for accident classification applicable to this design and because the methodology may also be applied internationally, the proposed frequency ranges are based on CNSC requirements. Events with frequencies near classification boundaries are conservatively assigned to the higher frequency category, particularly where uncertainty exists.

The applicant stated that: **[[**

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The applicant stated that, in the current revision of the methodology, PIE frequencies and classifications were initially derived from probabilistic studies. For events not included in those studies or screened from them, the classification was based on engineering judgment informed by operating experience from other reactors. Operator errors were considered in determining event frequencies and classifications. The applicant noted that the classification of external hazards is site-dependent and therefore subject to change based on future site and environmental evaluation.

The NRC Staff's Evaluation Findings for Attribute 5

The NRC staff reviewed the applicant's proposed methodology for establishing and classifying PIEs and finds it reasonable, with appropriate consideration of uncertainty. Final PIE identification and classification are design- and site-specific and will be subject to further NRC staff's review as part of a future license application. In addition, the specific PIE list and individual event classifications were not included within the scope of the NRC staff's review of this TR.

The NRC staff concludes that the use of defined frequency ranges and treatment of uncertainty described in TR section III.5, "Classification of the PIEs", including the use of the 5^{th} and 95^{th} percentiles, to classify events as AOOs, DBAs, or BDBAs and provides a structured and transparent framework for determining the level of analysis and applicable acceptance criteria. The NRC staff further concludes that conservatively assigning events near classification boundaries to the higher frequency category is reasonable and appropriately accounts for uncertainties.

The NRC staff notes that deriving event frequencies primarily from probabilistic analyses and supplementing those results with engineering judgment and operating experience, where necessary, is consistent with risk-informed regulatory practices. The NRC staff determines that it is appropriate that operator errors are identified and considered in frequency determinations and that external hazard classifications are recognized as site-dependent.

The NRC staff concludes that the proposed methodology for classifying PIEs, including the defined frequency ranges, treatment of uncertainty, and integration with PRA and DSA, provides a systematic and reasonable basis for classifying initiating events. The approval of the final PIE list and individual classifications will be addressed in a future application-specific review.

CONCLUSION

Based on its review of the TR and supporting documentation, the NRC staff concludes that the applicant has proposed a systematic, technically sound, and reasonable methodology for the identification, scoping, categorization, and classification of PIEs for the IMSR400 design.

Because the NRC staff's approval is limited to the methodology described in the TR, certain aspects relevant to finalizing the PIE list and classifying individual PIE have not yet been fully addressed and are outside the scope of this review. Accordingly, the user of the methodology described in the TR should address these aspects when finalizing the PIE list and performing classification. The NRC staff will defer its review and conclusions on these matters until the relevant information is submitted for review. These aspects, discussed in the technical evaluation section, are summarized below:

- A QA plan that meets NRC regulations should be developed and submitted for the NRC staff's review.
- The maintenance and update interval should be defined once plant operating and maintenance procedures are available.
- The internal PIE panel process for performing completeness checks should be established.
- Human-induced events should be identified consistently with plant operating and maintenance procedures when available.
- Inputs to the MLD and FMEA should be technically appropriate and adequately supported.
- The plant operating modes described in the TR should be confirmed when final design information becomes available.
- Evaluation of credible hazard combinations should be addressed in future updates based on final design and site-specific information.
- The treatment of malevolent acts and aging mechanisms is outside the scope of this PIE methodology but should be addressed in other programs.
- As stated in the TR, during the detailed design stage, event classification should be performed using the 5^{th} and 95^{th} percentile confidence levels for component failure data.

The NRC staff concludes that the methodology includes appropriate quality control elements, such as documentation control, verification of results, defined roles and responsibilities, interdisciplinary review, and use of qualified personnel, which provide confidence that the PIE process can be implemented consistently. The NRC staff notes that QA and configuration management documentation has not been submitted and will be reviewed in future PIE updates.

The NRC staff concludes that the systematic process, employing complementary top-down (MLD) and bottom-up (FMEA) techniques, consideration of human-induced initiating events, and incorporation of generic operating experience, provides reasonable assurance that risk-significant and foreseeable PIEs are identified and evaluated. The scope appropriately addresses internal and external hazards, plant-wide events, SSC failures, and relevant operating states, providing a sufficiently comprehensive basis for subsequent safety and risk analyses.

The NRC staff concludes that categorizing PIEs by primary plant response or similar failure mechanisms provides a clear, logical framework to manage completeness and traceability. The use of defined frequency ranges to classify PIEs as AOOs, DBAs, or BDBAs, including the treatment of uncertainty and site-dependent external hazards, provides a transparent and structured basis for applying acceptance criteria. Since the NRC staff's approval is sought only for the methodology and classification criteria the final PIE list and individual classification result will be addressed in future reviews once submitted to the NRC.

Overall, the NRC staff concludes that the applicant’s methodology provides a systematic, traceable, and technically robust framework for developing a comprehensive set of PIEs and supporting subsequent safety and risk evaluations for the IMSR400 design. The NRC staff further concludes that the proposed methodology provides reasonable assurance that, if implemented as described, foreseeable PIEs would be systematically identified and appropriately evaluated and classified as AOOs, DBA, and BDBAs to support plant safety and risk assessments.

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Date: April 27, 2026