

TERRESTRIAL ENERGY

December 16, 2021

Letter #: L211216

Ms. Sarah Eaton, Director
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Canadian Nuclear Safety Commission
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U.S. Nuclear Regulatory Commission
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Subject: Revision 2 of TEUSA IMSR® Postulated Initiating Events (PIE) White Paper and Terrestrial Energy Responses to the Second Round of CNSC/NRC Feedback

In September 2021, the Canadian Nuclear Safety Commission (CNSC) and the United States Nuclear Regulatory Commission (NRC) jointly provided a second round of feedback on the methodology and selection of Postulated Initiating Events (PIE) for the Integral Molten Salt Reactor (IMSR®) design. The references for this methodology were provided in:

- Documentation supporting the TEI IMSR® Phase 2 Vendor Design Review process; and
- Revision 1 of the TEUSA White Paper related to PIE for the IMSR®

This TEI/TEUSA joint letter and its Enclosures provide 1) a consolidated response to the second round of joint regulatory feedback and questions provided to Terrestrial Energy in September 2021, and 2) Revision 2 of the TEUSA white paper on IMSR® PIE. Enclosure 1 to this letter provides clarity on those sections of the white paper that were revised in response to the feedback.

Enclosure 1 contains the responses to the series of questions/feedback provided by the CNSC/NRC. Enclosures 2 and 3 contain the proprietary and non-proprietary versions of Revision 2 to the TEUSA white paper on IMSR® PIE. Portions of Enclosure 2 are proprietary, and we request that this document be withheld from public disclosure in accordance with the provisions of 10 CFR 2.390. An affidavit supporting the withholding request is provided in Enclosure 4.

TEI and TEUSA are available to discuss the responses, the updated white paper, the timeline for completing the joint regulatory report, and any additional information needed after the CNSC and the NRC have completed their review of the provided materials. If you have questions relating to this information, please contact either Robert Ion or Robin Rickman whose contact information is listed below:

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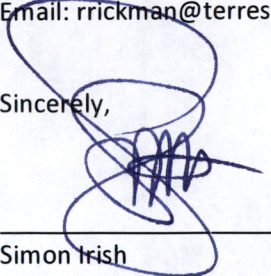
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Sincerely,



Simon Irish
CEO - Terrestrial Energy Inc.
CEO - Terrestrial Energy USA, Inc.

Enclosures:

1. Terrestrial Energy Responses to 2nd Round of CNSC/NRC Feedback on IMSR® Postulated Initiating Events
2. Postulated Initiating Events for IMSR® (Revision 2) – Proprietary
3. Postulated Initiating Events for IMSR® (Revision 2) – non-Proprietary
4. Affidavit

Cc:

Mohammed Shams (NRC)
Adrian Muniz (NRC)
Christopher Van Wert (NRC)
Marcel de Vos (CNSC)
D. Duchesne (CNSC)
M. Rickard (CNSC)

Enclosure 4 to TEUSA Letter L211216

Terrestrial Energy USA Affidavit and Request for Withholding from Public Disclosure
(10 CFR 2.390)

TERRESTRIAL ENERGY USA

AFFIDAVIT

I, **Simon Irish**, state as follows:

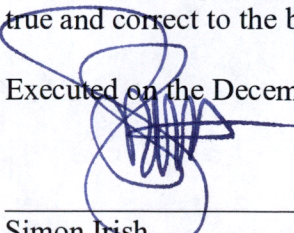
- (1) I am the Chief Executive Officer of Terrestrial Energy USA ("TEUSA") and have reviewed the information described in paragraph (2) which is sought to be withheld, and I am the authorizing official for TEUSA to apply for its withholding.
- (2) The information sought to be withheld, in its entirety, is contained in Enclosure 2 of TEUSA Letter L211216, "*Postulated Initiating Events for IMSR® (Revision 2)*."
- (3) I am making this request for withholding, and executing this affidavit in support thereof, pursuant to the provisions of 10 CFR 2.390(b)(1).
- (4) In making this application for withholding of proprietary and commercially sensitive information of which it is the owner or licensee, TEUSA relies upon the exemption from disclosure set forth in the *Freedom of Information Act* ("FOIA"), 5 U.S.C. Sec. 552(b)(4), and the *Trade Secrets Act*, 18 U.S.C. Sec. 1905, and NRC regulations 10 CFR 9.17(a)(4), and 2.390(a)(4) for trade secrets (Exemption 4). The material for which exemption from disclosure is here sought also qualifies under the narrower definition of trade secret, within the meanings assigned to those terms for purposes of FOIA Exemption 4 in, respectively, *Critical Mass Energy Project v. Nuclear Regulatory Commission*, 975 F.2d 871 (D.C. Cir. 1992), and *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280 (D.C. Cir. 1983).
- (5) The information sought to be withheld is considered proprietary and/or commercially sensitive for the reasons set forth in paragraphs (4)b and (4)c shown below. Some examples of categories of information that fit into the definition of commercially sensitive information are:
 - a. Information that discloses a process, method, or apparatus, including supporting data and analyses, where prevention of its use by TEUSA's competitors without license from TEUSA constitutes a competitive economic advantage over other companies;
 - b. Information that, if used by a competitor, would reduce their expenditure of resources or improve their competitive position in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product;
 - c. Information that reveals aspects of past, present, or future TEUSA development plans and programs, resulting in potential products to TEUSA;
 - d. Information that discloses trade secrets or potentially patentable subject matter, or both, for which it may be desirable to obtain patent protection.
- (6) To address 10 CFR 2.390(b)(4), the information sought to be withheld is being submitted to NRC in confidence. The information is of a sort customarily held in confidence by TEUSA, and is in fact so held. The information sought to be withheld has, to the best of my knowledge and belief, consistently been held in confidence by TEUSA, not been disclosed publicly, and not been made available in public sources. All disclosures to third parties, including any required transmittals to the NRC, have been made, or must be made, pursuant to regulatory provisions, or to proprietary or confidentiality agreements that provide for maintaining the information in confidence. The initial designation of this

information as proprietary and/or commercially sensitive, and the subsequent steps taken to prevent its unauthorized disclosure, are as set forth in the following paragraphs 6 & 7.

- (7) Initial approval of proprietary and commercially sensitive treatment of a document is made by the manager of the originating component, who is the person most likely to be acquainted with the value and sensitivity of the information in relation to industry knowledge, or who is the person most likely to be subject to the terms under which it was licensed to TEUSA. Access to such documents within TEUSA is limited to a "need to know" basis.
- (8) The procedure for approval of external release of such a document typically requires review by a vice president for technical content, competitive effect, and determination of the accuracy of the proprietary and/or commercially sensitive designation. Disclosures outside TEUSA are limited to regulatory bodies, customers, and potential customers, and their agents, suppliers, and licensees, and others with a legitimate need for the information, and then only in accordance with appropriate regulatory provisions or proprietary or confidentiality agreements, or both.
- (9) The information identified in paragraph (2), above, is classified as proprietary and/or commercially sensitive because it contains detailed information regarding TEUSA's licensing plans and technical details about the Integral Molten Salt Reactor (IMSR®) which TEUSA is developing for US deployment.
- (10) Public disclosure of the information sought to be withheld is likely to cause substantial harm to TEUSA's competitive position and foreclose or reduce the availability of profitmaking opportunities. The information contains proprietary technical details of the IMSR® design and details regarding TEUSA's licensing strategy. The development of TEUSA's chosen licensing path comprises a substantial investment of time and money by TEUSA. The precise value of the expertise to use in devising this licensing path is difficult to quantify, but it clearly is substantial. TEUSA's competitive advantage will be lost if its competitors are able to use the results of the TEUSA's experience to normalize or verify their own process or if they are able to claim an equivalent understanding by demonstrating that they can arrive at the same or similar conclusions. The value of this information to TEUSA would be lost if the information were disclosed to the public. Making such information available to competitors without them having been required to undertake a similar expenditure of resources would unfairly provide competitors with a windfall, and deprive TEUSA of the opportunity to exercise its competitive advantage to seek an adequate return on its large investment in developing its licensing strategy.

I declare under penalty of perjury that the foregoing affidavit and the matters stated therein are true and correct to the best of my knowledge, information, and belief.

Executed on the December 16, 2021



Simon Irish
Chief Executive Officer, Terrestrial Energy USA, Inc.

Enclosure 1: Terrestrial Energy Responses to 2nd Round of CNSC/NRC Feedback on IMSR[®] Postulated Initiating Events

The content of this enclosure provides responses to the joint feedback provided by the Canadian Nuclear Safety Commission (CNSC) and U.S. Nuclear Regulatory Commission (NRC) staff regarding the Terrestrial Energy USA (TEUSA) Postulated Initiating Events (PIE) identification methodology as described in TEUSA's updated Integral Molten Salt Reactor (IMSR[®]) PIE White Paper (ADAMS Package Accession No. ML21211A518) and Terrestrial Energy, Inc./TEUSA Response to CNSC/NRC Feedback and Questions on IMSR[®] PIE White Paper to Support Joint Regulatory Review (ADAMS Package Accession No. ML21209A989). The format will be to list the specific feedback received from the regulators and a proposed response. When responses propose modifications to the methodology, those changes will appear in either the revised design documentation developed by TEI and adopted for use by TEUSA or in specific revisions to the TEUSA white paper.

1. General Feedback:

- a. Terrestrial should ensure that both TEI and TEUSA use appropriate terms as necessary for each regulator.

Response: To the extent possible, the TEUSA white paper will use terms that are specific to the U.S. domestic regulatory process. When TEUSA references technical documents that are developed for use by TEI in their regulatory activities with the CNSC, TEUSA will retain the TEI language with an explanation.

- b. By the term methodology, we understand Terrestrial to mean the steps and processes used within the vendor's management system to conduct, for example, safety analyses and safety classification activities. Terrestrial presented preliminary work to establish the methodology to support the conceptual design and stated that further refinements are necessary going forward. However, at this point in time it is not clear what work needs to be done to support further refinement of the methodology to support detailed design activities. Terrestrial should present the details of the methodology going forward, including processes to support confidence in the methodology. To provide feedback regarding the methodology, both regulators need to see the detailed steps and processes that make up the methodology or, if the details are not currently available, a description of expected steps and processes. This will demonstrate how the vendor's activities are converging towards a high degree of confidence in the results if the methodology is used to identify and classify PIEs. We expect that the steps and processes are described in sufficient detail before the regulatory staffs can provide detailed feedback on the methodology. Any areas that are not fully developed at this stage should be identified and an expected timeline for completion should be presented.

Response: The TEUSA white paper has incorporated additional information in Section IV that speaks to the specific steps and processes that will be used within the PIE development process. Specific references to the detailed TEI procedures are also included in the revised white paper.

- c. The NRC staff notes that a number of commitments have been made by the vendor that are focused on CNSC Vendor Design Review (VDR) activities. Responses regarding the VDR process need to clarify if (or how) these commitments would also apply to activities in the USA. Some examples are noted in the question-specific feedback provided below.

Response: TEI acknowledges this comment. TEI has made it clear that the processes used by TEI will be identical to the processes employed by TEUSA. Any changes made by TEI to the PIE methodology will also be implemented by TEUSA.

2. Feedback/Questions on Responses to Joint Questions:

a. Response # 1(a)

- i. The revised white paper appears to remove the “bottom-up” portion of the PIE identification methodology because the design isn’t developed to the component level necessary to complete a “bottom-up” approach. If Terrestrial wishes to receive feedback from CNSC and NRC regarding the methodology for identifying PIEs, the methodology of performing the “bottom-up” approach should be described in sufficient detail for us to perform an assessment. The application of the methodology itself can wait until the design has matured to the component level.

Response: TEI will propose a bottom-up methodology to the CNSC/NRC by end March 2022.

- ii. The response commits TEI to submitting the “bottom-up” approach to the CNSC as part of the PSA [probabilistic safety assessment] but does not mention the NRC. Will TEUSA follow the same approach as TEI or will there be a different methodology for the NRC to review?

Response: As mentioned above, TEUSA will follow the same approach as TEI.

- iii. Response to Question 1a states, “The main reason for the choice of top-down methodology was that the design details were still developing at the time of the PIE, making a bottom-up assessment rather difficult, as the level of design resolution did not go down to the component level”

Based on the response and the statements in the white paper (e.g., “[a]t the current stage, the probabilistic studies are not yet completed and so the classification shown in this document is based on engineering judgement and previous similarity with other potential events.”), it is noted that the PIE list presented in Section VII of the white paper is not based on the complete methodology as described. Therefore, we cannot make any conclusions regarding the comprehensiveness, completeness, and fidelity of the IMSR® design and PIE list.

Response: The TEUSA request to make conclusions about the completeness of the PIE list has been modified in the cover letter forwarding these feedback responses. The cover letter now requests feedback on the methodology to the extent that the details of the design and methodology permit.

- iv. The response to Question 1a states, “TEI has committed to the CNSC that a fault-tree analysis and an FMEA [Failure Modes and Effects Analysis] will be part of the PSA for the License to Construct.”

There are no commitments (or discussions) made by TEUSA in the white paper, Rev. 1, to perform and integrate FTA, FMEA, and/or any other approaches to finalizing the PIE list.

This gives the impression that there is a divergence between the TEI and TEUSA methodologies to identify PIEs. The white paper should make clear if there are differences between the TEI and TEUSA methodologies or if the commitments are intended to apply to TEUSA’s interactions with the NRC as well. The NRC staff notes that two or more approaches in combination with the insights from the human reliability analysis (HRA) would provide a more comprehensive and justifiable PIE list.

Response: TEUSA will employ the same methodology as employed by TEI with no exceptions. The white paper has been modified to make it clear that there will be no deviations from the TEI methodology.

- v. Response to Question 1a states, "Fault trees provide a similar perspective to a bottom-up analysis."

This statement is correct but not always true. A "qualitative" fault-tree analysis can be used to identify the additional failures but not the initiators nor pre-accident human-induced initiating events.

Response: This comment does not require a response.

b. Response #1(b)

- i. The response to Question 1b states, "With each PIE iteration, the number of events becomes larger: not so much because completely different events have been added, but more because detailed events are added under each overall category."

It is unclear why the detailed events are added to the PIE list. Later in the process, should all detailed events be grouped or combined for the event sequence analysis? Normally, the systematically identified individual initiating events (IEs) are grouped using a systematic process for a more manageable list and for input to the event sequence analysis.

Response: To this point, the PIE list has not combined events, although they are grouped under appropriate headings. However, the PRA thus far has (and will continue to) combined events where it can be shown that one event bounds a number of similar events. Likewise, the deterministic safety analysis will assess a bounding event among events of a similar nature.

- ii. Response to Question 1b states, "The safety analysis will choose bounding events for each PIE or group of PIEs to reduce the impact of design detail."

Define the term "bounding events," e.g., frequency-based, consequence-based, site-specific based, etc.

Response: In the current context of the TEI design documents, the term "bounding event" is chosen based on the most severe radiological consequences for a category of events.

- iii. Response to Question 1b states, "The two methods will result in a consolidated list of PIEs by the time of application for a License to Construct."

The process to consolidating the two methods is not provided. TEUSA should include the integration step in the white paper as part of the methodology.

Response: TEUSA is not prepared to provide the details of the integration step in this revision of the white paper. Details of the integration process will need to be determined pending the completion of the PRA in 2022.

c. Response #1(c)

- i. Response to Question 1c states, "There was no screening of events performed during the PIE. The focus of the PIE was on internal events and on a "standard" list of external events relative to a Canadian generic site. However, extremely rare severe external events (e.g., large meteorite strike) were not included." In addition, the white paper states, "Events with a frequency likelihood less than 5E-7 are considered so rare that they would not need to be considered when assessing the capabilities of the plant to respond to those postulated events."

Response: This comment does not require any additional response.

- ii. During the meeting, the NRC suggested that TEUSA review ASME/ANS [American Society of Mechanical Engineers/ American Nuclear Society] RA-S-1.4-2021, Section 4.3.11, "Hazards Screening Analysis" to determine if it is applicable for the IMSR design.

Response: During the next evolution of the PIE methodology, TEUSA/TEI will review the

referenced ASME/ANS document for applicability.

- iii. Response to Question 1c states, "TEI is currently preparing a case on the frequency of failure of passive components and systems, which will factor in such failure mechanisms and their prevention." We are interested in viewing these cases when they are developed and used to support future licensing activities. There are currently no NRC endorsed techniques for assessing passive structures, systems, and components (SSCs) reliability/frequency (except piping, heat exchangers, etc.).

Response: There is no plan to include additional discussion of the treatment of passive components or system failures in the revised white paper. Additional work is still underway in this topic area.

- iv. Response to Question 1c states, "In the report, we did classify events as AOO [anticipated operational occurrence], DBA [design basis accident], BDBA [beyond design-basis accident] based on experience with other reactors, and engineering judgement."

We understand from the white paper that the engineering judgement used to classify the events is presented as a starting point and not the results of following the complete methodology. The overall methodology used to classify events (including the use of engineering judgement, research and development results, etc.) needs to be further clarified.

Response: Additional discussion of the methodology is provided in the updated white paper. No additional discussion with respect to uses of engineering judgement or research and development is available at this time.

d. Response #1(d)

- i. We understand that FMEA is not used at this preliminary stage of design development, but if it is part of the methodology, it should be explained in enough detail for the reviewers to understand how TEI and TEUSA use it and provide an assessment. The response also only seems to refer to future use of FMEA in the PSA (for CNSC). Does this indicate that there is a difference between the TEI and TEUSA methodologies?

Response: As previously stated, TEUSA will employ the TEI methodology in its licensing applications without exception.

- ii. Response to Question 1d states, "Also as previously noted, a fault-tree analysis [FTA] will be part of the PSA for the License to Construct. Fault trees provide a similar perspective to a bottom-up analysis."

Fault tree analysis (performed in PRA) is a graphical tool to model the causes of system failures. It uses Boolean logic to combine a series of basic events to generate cutsets and quantify top event probability. It is basically a top-down approach initiated with a top event. The use of FTA in the PIE identification methodology as a bottom-up analysis should be presented in enough detail to permit CNSC/NRC assessment, if our feedback is desired.

Response: Per our response to 1(a) (i), TEI will describe its methodology for bottom-up analysis by end March 2022.

e. Response #1(e)

- i. The response doesn't commit to a specific requirement regarding the makeup or skillset of an analyst (or team of analysts), but instead simply states what was done at this preliminary stage. Our original question was related to any panel or skillset requirements per the methodology. Provide the requirements per the methodology that drive the makeup of analysts (or team of analysts) and the processes that support them. The NRC staff notes that diverse expertise and experience brought by a team or panel is preferred (see guidance for maintenance rule, Title 10 of the Code of Federal Regulations (10 CFR) Section 50.69, LMP, etc.). For example, Nuclear Energy Institute (NEI) 00-04 (as endorsed by RG 1.201) provides guidance pertaining to the decision regarding the categorization of components be presented to an expert panel, known as the Integrated Decision-making Panel (IDP). The IDP is composed of a group of experienced plant personnel representing diverse plant functions and responsibilities.

Response: Additional discussion on the procedural steps was provided in Section IV of the white paper and the documents outlining the specific TEI procedures has been added to the list of References.

f. Response #1(f)

- i. We have no additional feedback related to this topic.

g. Response #1(g)

- i. Response to Question 1g states, "The PIE assumes fairly coarse failures in the SSCs: e.g., pump failure, rather than failure of specific components in the pump; generic fueling error (taken in the supporting safety analysis as the maximum physically permitted by the fueling mechanisms, rather than a realistic value)."

Response: The comment is correct. At this stage of design maturity, the list of PIE is developed using a coarse evaluation process to assess challenges to the design. As stated in an earlier response, as the detail of the design matures, the list of PIE will evolve and reflect the specific individual SSC failures or the combination of SSC failures as the initiating events. Such evolution is evident in the PIE list contained in the Tables of the most recent version of the TEI document.

- ii. The response to Question 1g does not fully address the issues of concern, i.e., it is unclear whether the assumptions made relevant to the frequency estimates, recovery, performance, etc., will be refined once more design/detailed specifications and information become available. If so, reevaluation of the first-of-a-kind SSCs and associated assumptions should be specified as a future step in the PIE methodology.

Response: As the detailed design matures, plant performance analysis develops, research & testing programs deliver, and the PRA is refined, we would expect to revisit and update the PIE document to remove assumptions, confirm that PIEs are unaffected by detailed PIE causes (or update those that are) and that plant response is as described. PIE classification would also be informed and refined by initiating event frequency assessment, drawing on the results of the PRA.

h. Response #1(h)

- i. Similar to some other responses, this response states what was done as opposed to what is required to be done by the methodology. We understand that simplified analyses are made during the design phase, but to provide an assessment of the methodology that will be used in the licensing phase, we need to understand the requirements of the methodology.

Response: Additional information was provided in Section IV of the white paper to provide additional discussion of the methodology.

- ii. Response to Question 1h states, "The PIE analysis followed the same procedure used for all safety analysis in IMSR400: Safety Analysis Procedure IMSR400-30711-PRO-004. We also followed the relevant portions of the company QA [quality assurance] manual: IMSR400-30710-MAN-001."

Was the QA manual IMSR400-30710-MAN-001 developed based on the principal elements of 10 CFR 50 Appendix B?

Response: Additional information was provided in the white paper to respond to this comment. In general terms, the TEI Management System manual, in many respects, mirror the overarching requirements contained in 10 CFR 50 Appendix B and ASME NQA-1. The content and acceptability of the TEUSA quality assurance program will be the topic of a future Topical Report and NRC review.

- i. Response #2(a)
 - i. We have no additional feedback related to this topic.
- j. Response #2(b)
 - i. We have no additional feedback related to this topic.
- k. Response #3
 - i. We have no additional feedback related to this topic.
- l. Response #4
 - i. Terrestrial's definition of "Power Operating States" is unclear to us and whether Terrestrial is committing to look at all Power Operating States or not. Terrestrial indicates that they will look at more than simply "At-Power", but it's not clear if they are committing to a thorough systematic approach. For example, Low Power, Shut Down (guaranteed), and Startup states/stages are not assessed in the report. Provide additional details regarding the methodology's approach for these states.

Response: TEI will look at all operating states.

Model currently addresses three steady states (power, shutdown, fuel storage). However, it will need extending to cover transitions (e.g., core-unit filling, start-up, shutdown, defuel, core-swap etc.). Extension of the model to consider transitions between nominal steady states requires development and documentation of PRA methodology for intermediate operating states. For example, the table will be expanded to include an additional column to identify applicable POS's.

- m. Response #5
 - i. Response to Question 5 states "There was no screening done in the PIE." White paper, Page 7 states, "At this stage of the IMSR® design maturity, TEUSA has projected that most of the PIEs will have minimal or no consequences because of the fundamental nature of design and passive/inherent safety features of the IMSR400 facility. A more detailed radiological consequence assessment will be performed after the PSA is completed, which will occur prior to TEUSA submitting an SDA application."
 - TEUSA should confirm whether any PIE will be screened based on the radiological consequences as part of the process. If so, describe the radiological consequence criteria to be used for PIE screening.

Response: At the present time, the methodology does not exclude the identification of events for which there are no radiological consequences. While no determination has been made at this time, it is possible that those events that have no radiological release or pose no health effects to workers or the public will be excluded from discussion in a future license application. For licensing purposes, only those events that pose potential health effects to plant workers or result

in releases of radionuclides to the environment will be presented.

n. Response #6

- i. Terrestrial should explain how uncertainties are handled as part of the methodology even if the uncertainties themselves are unknown at this point.

Response: How uncertainties are handled as part of the methodology will be described in the updated PRA methodology when the PRA assessment is complete. As such, this is not discussed in the current version of white paper.

- ii. Response to Question 6 states, "The PSA submitted for the License to Construct will address uncertainties in event frequency using sensitivity and uncertainty analysis."

The PSA uncertainty analysis examines the uncertainty spread in the results arising from the uncertainty in SSC failure probabilities and is not normally used to examine the uncertainty associated with the IE frequencies. TEUSA should explain in more detail how the PSA uncertainty analysis is intended to be applied.

Response: The results of best estimate fault tree analysis in the PRA will be used to inform the classification of PIEs by frequency. Where initiating events are influential and their initiating event frequency (IEFs) have large uncertainties (e.g., RV failure frequency), the PRA program will also consider including them in uncertainty analysis. The same is also true of influential failures on demand with high uncertainties (e.g., RV failure during an accident transient). This will involve defining the associated probability distribution in each case in the risk model, followed by its evaluation by Monte Carlo simulation. The PRA results will show both numerically and graphically the uncertainty in both IEF and overall risk results (via upper and lower bound values and plots of probability density function). With respect to PIE classification, where the IEF is close to a classification boundary and the uncertainty is high, one factor that will be taken into consideration in deciding the final PIE classification is the upper bound frequency (e.g., 95% confidence level).

o. Response #7

- i. Provide where and when design details for systems included in the PIE methodology will be provided along with identification of system dependencies, if any.

Response: The project is currently transitioning from basic engineering to detailed design. A preliminary PRA has been done to support basic engineering and has identified system dependencies at a level consistent with the design. This will be refined once the detailed design is closer to completion. The identification of system dependencies is an output of the PRA, not the PIE.

p. Response #8(a)

- i. Response to Question 8a states, "The plant is also computer- controlled, which reduces the chances of human error. A fueling error is a human induced event, probably the most significant, and is in the PIE. More details on human-initiated events will arise from the human factors review and the PSA as the design develops."

Human Factors (HF) review is mentioned for the first time in the response to Question 8a. It is noted that the software and hardware failures are not in the PIE list. It is difficult to draw the boundaries of PIE without referring to all other project activities.

Response: A Human Factors Engineering Program has been part of the design for several years. As the details develop, we will consult with the HF team to ensure we have not missed credible human errors that would result in worse consequences than the system failures already defined. At the moment, the control system is not defined to the level of detail to determine if software and hardware failures are worse than the system-wide failures already included.

q. Response #8(b)

- i. Response to Question 8b states, "Loss of DC power would be a subset of PIE 3-8 (Loss of Offsite Power)."

Our current understanding is that the plant responses are different for these two initiators, but we also recognize that we do not have final plant details at this point. Therefore, additional clarification is needed. Otherwise, DC power should be treated separately.

Response: Details of the electrical design are still evolving, and we agree that loss of DC power may need to be treated as a separate initiator once the design is finalized.

- ii. Response to Question 8b states "Loss of HVAC will be included later as the HVAC safety functions are defined. We agree that some events need to be expanded in the next revision."

How does the safety function influence the PIE selection?

Response: PIEs are selected based on their potential impact on nuclear safety per the top-down approach. Loss of HVAC could impact the functioning of instrumentation and control in the affected rooms, as well as rendering them uninhabitable. This may impact the safety functions that the instruments and people perform. The impact is probably covered by the assumption of system-wide failures in the PIE, but the issue would be a failure in HVAC affecting controls for more than one system.

r. Response #8(c)

- i. Response to Question 8c states, "For a specific site, a more detailed list will be developed as part of the License to Construct."

TEUSA should clarify the design certification/standard design approval/combined license/operating license applicants' responsibilities to confirm and complete the PIE list.

Response: We agree. For the site in Canada that was being evaluated for a possible license to construct application, TEI started from a generic hazards list and was given access to the specific hazards assessment for the nuclear power plants already existing on the site. We then adapted the generic hazards list to the specific site. Had that particular project proceeded, the licensee would be required to review and approve the hazards assessment and submit it to the regulator as a "knowledgeable customer." We would expect a similar process for any other specific site.

In the US, it is the responsibility of the future license applicant to assure that the list of PIE is both accurate and comprehensive. Determination that the PIE list is both accurate and comprehensive is part of the established license application review process. If a topical report was previously reviewed and approved on this topic, it is the responsibility of the license applicant to notify the regulator of any changes (design or site related) that would alter any previous conclusions made on the topical report.

s. Response #8(d)

- i. The requested table appears to be incorporated into the wrong section. Please edit the document as necessary to put this table in the correct section.

Response: Editorial changes have been made to the white paper in response to this comment.

t. Response #9

- i. Response to Question 9 states, "We agree. The events would be very site-specific – e.g., if there are already other reactors on site. Should a commitment be made for a multi-unit site, a multi-unit PIE (and /or PSA) would be performed. There are techniques being developed world-wide for the latter."

TEUSA should include this response in its white paper.

Response: TEUSA has included this information in the white paper as requested.

3. Feedback/Questions on Responses to NRC-specific questions:

a. Question #1

- i. The NRC staff agrees with the revised approach to approach this report as a white paper with staff feedback rather than approval as stated in the response. However, the NRC staff does wish to comment that the cover letter for the revised PIE White Paper is not in alignment with this response and indicates that TEUSA is still requesting staff approval. Based on the response to the question, the staff will proceed with a staff assessment.

Response: After considering the staff comment, TEUSA will make it clear in its cover letter that it is not requesting a staff assessment of the white paper at this time. TEUSA will take any feedback provided as part of the joint CNSC/NRC review summary document and factor that into its topical report on PIE that will be submitted at a later date.

b. Question #2

- i. The NRC staff can include an assessment of the PIE list within the context of white paper feedback. This feedback will likely rely heavily on audited information, and it should be recognized that if TEUSA later wishes to obtain NRC staff approval in a future licensing action, some of this information might be necessary on the docket. It's also worth noting that the PIE list provided in the white paper did not fully follow the methodology provided in the initial white paper due to the incomplete design so the staff's feedback will be limited to the information provided along with identification of information we would need to see in the future. The NRC staff requests that TEUSA clarify the level of detail that the NRC staff should apply to the PIE list assessment.
- ii. The NRC staff recognizes the sensitivity to the phrase "essentially complete design". The staff's use of the phrase was not intended within the context of a Part 52 application but instead within the context of generically requesting NRC staff approval of a white paper. Perhaps a better explanation is that a fully developed methodology which is associated with a mature design will have far fewer limitations and conditions which will therefore increase the usefulness of the NRC's approval. However, since the response also indicates that we are to review this as a white paper now the NRC staff can simply point out areas that should be addressed at a later date. Does this approach align with TEUSA's request from the NRC staff?

The response states, "TEUSA would find it valuable if the staff can perform a detailed assessment of the PIE list information and document any potential concerns with the provided list (or conclude that the list appears to be reasonable given the maturity of the design and the information provided) in its assessment report. "The NRC staff cannot perform the preferred detailed assessment based on the limited information, but the NRC staff can provide a general assessment. Also, the NRC staff notes that the PIE list was not generated following the complete methodology and instead relied solely on engineering judgement at this stage. Therefore, the NRC staff cannot assess TEUSA's application of the methodology.

Response: TEUSA acknowledges that the assessment of the PIE methodology and the PIE list is limited by the fact that the design is still undergoing design finalization, and that the PRA is not completed. For those reasons, TEUSA acknowledges that additional information will be needed to fully support the detailed review required by the NRC before it can prepare its safety evaluation on this topic. The opportunity for that more detailed review will occur when TEUSA submits its topical report on IMSR[®] PIE methodology at a later date.

c. Question #3

- i. Based on the response, the NRC staff would like to offer the following text taken directly from RG 1.233 in case there was ambiguity regarding basis for the staff's question:

C.1 Staff Position: NEI 18-04 provides an acceptable method for identifying and categorizing events, with the following clarifications:

- a. *The staff emphasizes the cautions in NEI 18-04 that the F-C target figure does not depict acceptance criteria or actual regulatory limits. The anchor points used for the F-C target figure are expressed in different units, timescales, and distances than those used in NRC regulations to provide common measures for the evaluations included in the methodology. The F-C target provides a reasonable approach for use within a broader, integrated approach to determine risk significance, support SSC classification, and confirm the adequacy of DID.*
- b. *The F-C target and related discussions in NEI 18-04 include an upper bound event sequence frequency (i.e., 95th percentile) of 5×10^{-7} /plant-year to define the lower range of BDBEs. Applicants should not consider this demarcation of lowest-event frequencies on the F-C target and category definitions a hard-and-fast cutoff but instead should consider it in the context of other parts of the methodology described in NEI 18-04. These other considerations include the role of the integrated decision-making panel described in Section 5 of NEI 18-04, DID assessments, accounting for uncertainties, and assessing for potential "cliff-edge effects," which involve a dramatic change in plant behavior caused by a small change in a plant parameter.*

- ii. The NRC staff notes that the F-C target has been removed from the paper and therefore this question is no longer directly applicable. However, the revised wording still does not directly provide justification for the chosen cut-off points but instead simply states what they are. The NRC staff expects that future licensing action requests will include some level of justification.

Response: TEUSA notes that the frequency criteria for categorization of PIE as AOOs, DBAs, and BDBEs is consistent with the guidelines presented in international and domestic references and have broadly been accepted as reasonable cut-off points for categorization of events. TEUSA believes that use of international and domestic accepted values for accident categorization is a sufficient basis for use in U.S. licensing activities. If additional discussion is needed, it will be provided in a subsequent license application or topical report.

4. Feedback/Questions on revisions to PIE white paper:

- a. Section X of the revised report refers to DBDAs but then mentions that as of the revision there are 38 "beyond design basis events". We assume the acronym is supposed to be BDBAs and that there are 38 "beyond design basis accidents". Is this assumption correct?

Response: Events that are more severe than a design basis accident will be referred to as a beyond design basis event. The terminology will be clear in the planned topical report that will be submitted at a later date.

- b. Are Figures 1-7 supposed to be in Section IV instead of Section V?

Response: The figures have been moved to the appropriate location.

5. Additional Feedback:

a. The white paper (Rev. 1) should consistently use the terms design basis event, beyond design basis event, design basis accident, and beyond design basis accident. It should be noted that DBAs are a subset of DBEs.

i. The white paper (Rev. 1) should consistently use the terms classification, classify, classes, categorization, and categories. For example:

- Page 4 states, "The main objective of this report is to identify all foreseeable PIEs, group them into categories, and classify the PIEs at this stage based on engineering judgement into AOOs, DBAs, and BDBAs."
- Page 4 states, "The PIEs are further grouped into categories, based on similarity of the initiating failures, key phenomena, or system and operator response."
- Page 6 states, "...the events are grouped into different categories i.e., AOO, DBA and BDBA."

b. A white paper sent to the NRC for review should use NRC terminology. For example, "PRA" as mentioned in 10 CFR 52.47(a)(27) and 10 CFR 52.79(a)(46), should be used instead of "PSA." Both are tools to quantify plant risk but they are performed based on different standards. Otherwise, include a description of PSA in the white paper and describe how it relates to "PRA".

[Response: Edits have been made to the paper in response to these and other similar comments.](#)