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

April 13, 2026

EAF-NMSS-2025-0102

Ms. Jean Fleming  
Vice President of Licensing, Regulatory  
and Probabilistic Safety Analysis  
Holtec International  
Krishna P. Singh Technology Campus  
1 Holtec Boulevard  
Camden, NJ 08104

SUBJECT: HOLTEC INTERNATIONAL, INC. – NRC RESPONSE TO DISPUTED  
VIOLATIONS IN NRC INSPECTION REPORT NO. 07201014/2025201

Dear Ms. Jean Fleming:

On December 19, 2025, the U.S. Nuclear Regulatory Commission (NRC) documented (ADAMS ML25342A103) two notices of violations (NOVs) (NOV 07201014/2024201-01 and NOV 07201014/2024201-02) and one non-cited violation (NCV 07201014/2024201-04). The first NOV involved a failure to obtain a Certificate of Compliance (CoC) amendment, pursuant to 10 CFR 72.244, prior to implementing a design change that created a possibility for a malfunction of the HI-STORM Flood/Wind (FW) version E1 and multi-purpose canister with a different result than any malfunction previously evaluated in the Final Safety Analysis Report (FSAR), as updated. The second NOV involved a violation of 10 CFR 72.146 for failure to subject design changes made on the HI-STORM FW overpack to design control measures commensurate with those applied to the original design. The NCV involved a violation of 10 CFR 72.48 (d)(1) for failure of the certificate holder to maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and of tests and experiments that provided the bases for the determination that the change, test, or experiment did not require a license or CoC amendment.

On January 19, 2026, you provided a response (ADAMS ML26022A038) contesting the NOVs and NCV. On February 10, 2026, the NRC acknowledged receipt of your response (ADAMS ML26037A097) and informed you that we would evaluate your response and provide you with the results of our evaluation.

After careful consideration and deliberation, the NRC is withdrawing NOV 07201014/2024201-01 and NOV 07201014/2024201-02, and NCV 07201014/2024201-04. NRC staff will revise and reissue NRC Inspection Report 07201014/2025201 to reflect these decisions. This withdrawal does not diminish the importance of fully evaluating, and documenting, design changes to consider the performance of the cask and any impacts to safety.

To make this decision, we conducted a detailed review of your response and the applicable regulatory requirements, in accordance with Section 2.8 of the NRC Enforcement Manual. This

review included staff who were not involved in the original inspection effort and are qualified to independently perform these types of inspections. A detailed summary of the staff's review is in the enclosure.

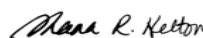
For NOV 07201014/2024201-01 and NOV 07201014/2024201-02, the NRC staff reviewed information provided in your response and information you provided following the September 3, 2025, pre-decisional enforcement conference (ADAMS ML25253A288). The Holtec response presented only qualitative information but did not include any quantitative assessment. Therefore, NRC staff conducted its own confirmatory analysis leveraging information from NRC staff's safety assessment of a Holtec license amendment to CoC 1032, currently under review. The NRC staff determined that it is feasible for water to enter the annulus of the cask during a rainfall event; however, the staff determined a substantial rainfall event would need to occur for a long period of time for water to accumulate to the degree that the vents are fully blocked. Additionally, the water would need to be retained in the vents, blocking the vents for a period greater than analyzed. The NRC staff concluded that given the low likelihood of a substantial rainfall event for a period long enough to fully block the vents, and considering evaporation, there is a very low risk of a blocked vent during a normal rainfall event. The NRC staff further that a blocked vent during a rainfall event would not result in a malfunction of a structure, system, or component (SSC) important to safety beyond what is evaluated in the FSAR. Given the very low likelihood of such an occurrence, the NRC determined that additional review was not warranted.

For NCV 07201014/2024201-04, the NRC staff reviewed the 10 CFR Part 72 rule; its statement of consideration in Federal Register 64 FR 53615; Regulatory Guide 3.72 "Guidance for Implementation of 10 CFR 72.48, Changes, Tests, And Experiments"; and the NRC-endorsed NEI 12-04, Revision 2, "Guidelines for 10 CFR 72.48 Implementation." Staff concluded that there is ambiguity in the NRC endorsed guidance regarding whether the evaluation performed by Holtec, must include appropriate benchmarking using an FSAR-described case. Consistent with IMC 0610, Appendix G, "Screening and Documentation of Very Low Safety Significance Issue Resolution Process," the NRC concluded that further deliberation on these issues would not effectively or efficiently serve the Agency's mission.

In accordance with 10 CFR 2.390, "Agency Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's ADAMS, accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions regarding this matter, please contact Gerond George of my staff at 301-415-3882 or via electronic mail at [Gerond.George@nrc.gov](mailto:Gerond.George@nrc.gov).

Sincerely,



Signed by Helton, Shana  
on 04/13/26

Shana Helton, Director  
Division of Fuel Management  
Office of Nuclear Material Safety  
and Safeguards

Docket No. 72-1014

Enclosures:

NRC Evaluation of Licensee Response to Violations in NRC Inspection Report  
07201014/2025201

SUBJECT: HOLTEC INTERNATIONAL, INC. – NRC RESPONSE TO DISPUTED VIOLATIONS IN NRC INSPECTION REPORT NO. 07201014/2025201

DATED: April 13, 2026

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**ADAMS Accession Number: PKG:ML26084A561, LTR: ML26084A554,  
eConcurrence: 20260325-70007**

## **NRC EVALUATION OF LICENSEE RESPONSE TO VIOLATIONS IN NRC INSPECTION REPORT 07201014/2025201**

### **Background**

On December 19, 2025, the U.S. NRC issued a final significance determination letter EAF-NMSS-2025-0102 (ADAMS Accession No. ML25342A103) that included two notices of violations (NOVs) of Severity Level IV significance and three non-cited violations (NCV) of Severity Level IV significance.

In a letter dated January 19, 2026 (ADAMS Accession No. ML26022A038), Holtec International, Inc. (Holtec) contested the two NOVs and one NCV. Holtec provided its position that Holtec complied with regulatory requirement for Title 10 of the *Code of Federal Regulations* (10 CFR) 72.48(c)(2)(vi), "Changes, tests, and experiments (CTEs)," 10 CFR 72.146, "Design control," and 10 CFR 72.48(d)(1).

The two contested NOVs included a violation of 10 CFR 72.48(c)(2)(vi) for a failure of the certificate holder to obtain a certificate of compliance ("CoC") amendment pursuant prior to implementing a design change that created a possibility for a malfunction of the HI-STORM Flood/Wind (FW) version E1 and multi-purpose canister with a different result than any malfunction previously evaluated; and, a violation of 10 CFR 72.146, for a failure to subject design changes made on the HI-STORM FW overpack to design control measures commensurate with those applied to the original design. The contested non-cited violation of 10 CFR 72.48(d)(1) was associated with the certificate holder's failure to maintain records including a written evaluation which provided the bases for the determination that a change in finite element analysis software did not require a license or CoC amendment.

### **Restatement of NOV 07201014/2024201-01**

Violation: 10 CFR 72.48(c)(2)(vi), "Changes, tests, and experiments," requires, in part, that a certificate holder shall obtain a CoC amendment pursuant to 10 CFR 72.244, prior to implementing a proposed change, test, or experiment if the change, test, or experiment would create a possibility for a malfunction of an SSC ITS with a different result than any previously evaluated in the FSAR (as updated).

Contrary to the above, from September 2021 to present, Holtec failed to obtain a CoC amendment pursuant to 10 CFR 72.244, prior to implementing a proposed change that created a possibility for a malfunction of an SSC ITS with a different result than any previously evaluated in the FSAR as updated. Specifically, Holtec failed to obtain a CoC amendment pursuant to 10 CFR 72.244, prior to implementing a design change that raised the air inlet vents from the bottom of the HI-STORM FW overpack to above ground positions, which created a low point for water to collect in the overpack after normal rainfall. When Holtec made this change and evaluated the design change with their design control change process, Holtec failed to recognize that this created a possibility for all air inlet vents to become blocked for a period greater than what was analyzed in the FSAR when rainwater entered the overpack. The HI-STORM FW FSAR sections 4.6.2.4 (100% Blockage of the Air Inlets), 12.2.13 (100% Blockage of Air inlets), and table 12.2.1, "Accident Events and Their Probability of Occurrence," had considered an extended period where all air inlet vents are blocked and that this was a non-credible event, respectively. However, this design change created a possibility for all air inlet vents to become blocked for a period greater than what was analyzed in the FSAR and made what was deemed as a non-credible event to a credible

event that would create a possibility for a malfunction of the HI-STORM FW overpack and MPC with a different result than any previously evaluated in the FSAR as updated. The malfunction of the HI-STORM FW overpack could result in fuel within the MPC exceeding temperature limits and the MPC exceeding pressure limits during normal operation.

### **Summary of Licensee Response – NOV 07201014/2024201-01**

The HI-STORM FW licensing basis, documented in the FSAR, distinguishes between normal and accident conditions, each with separate analyses and acceptance criteria. While FSAR Table 12.2.1 notes no mechanistic way for complete vent blockage, full vent blockage is already analyzed as an accident scenario (e.g., flood, debris, snow) in FSAR Section 12.2.13, with corrective actions outlined in Section 12.2.13.4.

The inspection report incorrectly conflates two scenarios: normal rainfall and accident conditions involving full vent blockage. Applying accident descriptions and time limits to normal rainfall events is inappropriate because the licensing basis for these scenarios is different. While the report suggests rainwater entering during normal conditions could lead to an off-normal or accident condition, this interpretation misrepresents the FSAR's established analyses. The HI-STORM FW FSAR states that water ingress during normal rainfall is not postulated. The upper vents are circumferential and positioned such that rain entry would require sideways flow, which is highly unlikely. The 10 CFR 72.48 Evaluation No. 1541 design change did not alter the upper vent design, so rainwater entry under normal conditions remains highly unlikely. Both the HI-STORM FW FSAR and NRC safety evaluations confirm that water ingress during normal conditions was not expected, nor were lower vents intended for drainage. Blocking ventilation would require over 20 gallons of water, making this scenario non-credible and not a new malfunction.

The NOV conflicts with prior NRC approvals for similar Holtec cask designs. The HI-STORM 100 system, including its "Version E" amendment (approved May 2021), featured elevated vents and revised heat load limits, similar to the HI-STORM FW system introduced under 10 CFR 72.48. Both systems share comparable licensing bases for normal rainfall and 100% vent blockage accidents. During review of HI-STORM 100 with elevated vents, NRC staff raised no concerns about water ingress under normal conditions and approved the design without requiring additional technical specifications for drain line clearance. The current NOV does not explain the change in NRC's position from the earlier approval, where water entry during normal rainfall was deemed not credible and vent blockage analysis was considered sufficient for nearly identical vent designs.

### **NRC Evaluation - NOV 07201014/2024201-01**

The NRC staff performed an independent review of the licensee's position, as described in its January 19, 2026, letter. Additionally, the staff discussed Holtec's response with subject matter experts familiar with technical analyses used in licensing of dry cask storage designs.

#### *Credibility of Vent Blockage due to Water Ingress*

The FSAR Table 12.2.1 identifies the event of 100% air blockage of air inlets as a "non-credible" event associated with its probability of occurrence. It also notes that, "Because the air openings are along the circumference of the cask, and surveillance is at very short intervals (see Technical Specification), the assumption of blockage of all openings has no mechanistic basis."

Technical Specification 3.1.2 Surveillance Requirement (SR) 3.1.2 does not provide assurance that water is not blocking the HI-STORM vent *if* rainwater were to ingress to the system and were to be retained. Specifically, due to the geometric configuration of the raised vent, and standard practice of performing this surveillance requirements by a simply walk-by of the vent to observe outside blockage, the NRC has little confidence that if rainwater were present, it would be identified.

In addition, the identification of the water through the SR 3.1.2 is an important operator action to ensure LCO 3.1.2.B is initiated to restore the SFSC heat removal system to operable status. This operator action is important to ensure that the certificate holder's transient thermal analysis in Section 4.6.2 is maintained, ensuring the blockage is no longer than 32 hours.

Under the assumption that rainwater ingress occurs and is retained, the change creates a possibility for a malfunction with a different result than previously evaluated. However, the staff considered whether it is credible for rainwater to ingress and be retained to such a level that a malfunction occurs.

The FSAR Section 8.12.1, Operating Environments, identifies that the overpack subject to rain, snow, ice, and wind. Specifically, Section 8.1.2.1 states that,

*During fuel loading, handling or storage the components of the HI-STORM FW System experience the following environments (see Tables 8.1.1, 8.1.2, and 8.1.3).*

...

- *External atmosphere – During long term storage the casks are exposed to outside atmosphere, air with temperature variations, solar radiation, rain, snow, ice, etc.*

*As discussed below, the components of the HI-STORM FW System has been engineered to ensure that the environmental conditions expected to exist at nuclear power plant installations do not prevent the cask components from rendering their respective intended functions.*

Thus, the HI-STORM is exposed to environment that could lead to water ingress and given the design of the FW system, it is feasible for some amount of water to ingress into the overpack. Specifically, water could enter through a combination of driving horizontal rain due to a sideways wind/rain combination. It could also feasibly enter due to rain or snowfall on the cask lid, which drains down the side of the overpack and runs into the vents. The feasibility of *some level* of water to ingress the cask is reinforced by both the licensee's and NRC's operating experience.

#### *Independent Confirmatory Analysis*

The staff conducted an independent assessment of inlet vent blockage because of rainwater accumulation. The staff evaluated the following:

- Maximum rainwater accumulation
- Water vaporization rate
- Heat transfer from the MPC to water in a flooded cask scenario

The NRC staff considered that a substantial rainfall event would need to occur for a long period of time for water to accumulate to the degree that the vents are fully blocked. Additionally, the

water would need to be retained in the vents, blocking the vents for a period greater than analyzed.

Staff concluded that blockage of the inlet vents from water accumulation due to rainfall is highly unlikely because (1) the height of water accumulation in a rainfall event would not reach the height of the inlet vents on the inside of the extended configuration casks, and (2) the rate of water loss by vaporization exceeds the maximum water accumulation rate in the cask. Therefore, the NRC staff's independent analysis concluded that the new malfunction will not create a different result than previously evaluated in the FSAR.

### *Operating Experience*

While Holtec did not provide a similar analysis, Holtec did provide NRC with limited operating experience (OE) for HI-STORM FW systems at three general licensees, with the overpack design implemented under 10 CFR 72.48 Evaluation No.1541. The NRC inspection report noted water presence in unloaded overpacks at several sites. Holtec clarified that only very small amounts of water were found in loaded casks, and asserted that the water would not accumulate sufficiently to block airflow given the evaporation that would occur. The OE for loaded systems with elevated vents supports Holtec's position that significant rainwater accumulation under normal conditions is not significant. Accident scenarios involving vent blockage are already addressed in the FSAR with operator actions and modified durations.

The staff notes that if there has been (or in the future there is) communication to Holtec from a general licensee about water retention and blockage following the CTE, this would be expected to be identified and documented as condition adverse to quality within the certificate holder's corrective actions program, and depending on the condition could be reportable under 10 CFR 72.242.

### *Prior NRC Approvals*

On March 30, 2019, the certificate holder submitted documentation in pursuit of a new Amendment to its storage Holtec HI-STORM 100 storage system, which is not the subject of the NOV's or NCV's contested by Holtec. However, there are several similarities in the design of the HI-STORM 100 and the HI-STORM FW. In its letter to the NRC on March 20, 2019 (ML19092A172), discussing the summary of proposed changes for the amendment the certificate holder states that,

*(HI-STORM 100S Version E is a variant of HI-STORM 100S Version B with the following improvements: increased number of inlet vents, **elevated inlet vents**, added bottom supports to elevate the MPC inside the enclosure vessel, improved top lid design to limit shear load on the closure bolts and provide increased outlet flow area.*

As the certificate holder indicates in their dispute, Amendment 15 was approved without additional technical specification, or modification to the normal or accident evaluations with the addition of the raised vent. Although the HI-STORM 100 and HI-STORM FW are separately certified cask systems, the NRC staff acknowledges that their design changes are similar.

### **NRC Conclusion NOV 07201014/2024201-01**

While the NRC staff determined that under the assumption that rainwater ingress and retention can occur, the change could create a possibility for a malfunction with a different result than

previously evaluated. However, as discussed above, the NRC staff's independent analysis concluded that retention would not occur to the extent that vents would be fully blocked; therefore, the new malfunction will not create a different result than previously evaluated. The staff also considered the relative safety significance of the design change, and concluded that it was very low. The NRC concluded that further deliberation on this issue would not effectively or efficiently serve the Agency's mission. As such, the NRC has decided to withdraw the violation.

### **Restatement of NOV 07201014/2024201-02**

Violation: 10 CFR 72.146(c), "Design Control," requires, in part, that the certificate holder shall subject design changes to design control measures commensurate with those applied to the original design.

Contrary to the above, from September 2021 to present, Holtec failed to subject a design change made to the HI-STORM FW overpack to design control measures commensurate with those applied to the original design. Specifically, Holtec made a change to the original HI-STORM FW overpack design using their design change control process to raise the air inlet vents from the bottom of the overpack to above ground positions. However, Holtec failed to identify that rainwater that enters the overpack can remain trapped inside of the overpack blocking the air inlets for an extended period. The trapped rainwater could result in the fuel exceeding peak cladding temperatures and increase the internal pressure limits in the MPC if there is no operator action taken to drain the water. This design change also does not allow operators to visually observe the trapped rainwater from the outside due to the configuration of this new design making this a more active versus a passive design function. Furthermore, this condition could create the possibility of an unanalyzed condition where an event considered non-credible in the FSAR is now a credible event.

### **Summary of Licensee Response to NOV 07201014/2024201-02**

Holtec contests that the NRC's two violations, one under 10 CFR 72.48 and one under 10 CFR 72.146, are redundant. Holtec stated that, even if the NRC believes the design change should have required prior approval under 72.48, it should not also be cited for a design control violation. Holtec states that it followed all required design control processes, completed all engineering change documents, and performed analyses consistent with the original HI-STORM FW design.

There is no discussion in the violation documentation provided as to what item in design control the staff believes Holtec did not apply appropriately.

### **NRC Evaluation of NOV 07201014/2024201-02**

NRC Enforcement Manual, Part 1, Section 1.3.5. "Documenting Related Violations," provides NRC staff guidance for documenting related violations. Specifically, the guidance states that violations should not be grouped in a way that artificially increases their significance. Grouping is appropriate only when violations are closely related, such as sharing a cause-and-effect relationship or arising from the same event, and is intended to show that the NRC recognizes they stem from a single problem rather than multiple unrelated failures. When violations are grouped, the combined "problem" is assigned the severity level of the most significant violation, and lower-level violations cannot be aggregated to create a higher severity level. The staff determined based on a review this guidance that citing of two requirements is not redundant, and is permissible within NRC enforcement guidance.

However, as identified by Holtec, that the violation itself lacked the details necessary when challenged. Specifically, the citation of 10 CFR 72.146(c) in itself only states that the certificate holder “shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license or CoC require prior NRC approval.” This citation in itself should normally be paired with an additional citation or reference to 10 CFR 72.146 (a) or (b) and specifically identify the requirements therein that were not followed. The “specifically” section of the “contrary to”, does provide potential details, but does not clearly delineate what aspect of “Design Control” was not followed. Accordingly, the staff determined that the violation does not contain sufficient clarity to be cited. Given the very low safety significance of the issue, the NRC concluded that further deliberation on this issue would not effectively or efficiently serve the Agency’s mission. As such, the NRC has decided to withdraw the violation.

#### **Restatement of NCV 07201014/2024201-04**

Violation: 10 CFR 72.48(d)(1) requires, in part, that the certificate holder shall maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test, or experiment does not require a license or CoC amendment pursuant to paragraph (c)(2) of this section.

Contrary to the above, as of May 2025, the certificate holder (Holtec) failed to maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. The records did not include a written evaluation which provided the bases for the determination that the introduction of an alternative storage overpack for the HI-STORM FW Version F and common lid using an updated MOE does not require a license or CoC amendment pursuant to paragraph (c)(2) of this section. Specifically, Holtec used a different version of the ANSYS finite element analysis (ANSYS 2020 R2 vs 11) for the new overpack and lid than what was previously approved for the standard HI-STORM FW (ANSYS 11). Holtec performed a verification & validation of the ANSYS 2020 R2 with favorable results. However, Holtec did not reanalyze one or more representative cases using the revised software (ANSYS 2020 R2) to compare those cases with those in the FSAR to determine if the current results produced results that are conservative, non-conservative, or essentially the same, as the previous values in the FSAR for the overpack and common lid. Since Holtec did not compare the results to those in the FSAR, the evaluation did not have an adequate written bases to determine if prior NRC review and approval was needed.

#### **Summary of Licensee Response to NCV 07201014/2024201-04**

Holtec disagreed with the violation asserting that it goes beyond the NRC-endorsed guidance document, NEI 12-04, “Guidelines for 10 CFR 72.48 Implementation,” and transformed the guidance document into a new regulatory requirement.

Holtec used an updated ANSYS version (2020 R2) instead of the older version (11) listed in the HI-STORM FW FSAR to analyze structural performance under 10 CFR 72.48 allowances. Holtec asserted that update was not a change the methodology because the new version underwent verification and validation process, which produced results “essentially the same” as the previous version.

The NRC staff cited a violation based on NEI 12-04 guidance, claiming Holtec did not compare cases identical to those in the FSAR. However, NEI 12-04 does not require identical FSAR cases, only representative cases. The staff's assertion that these representative cases must be compared to identical cases in the FSAR does not appear to have any basis in the guidance document, nor the regulatory guide that endorses that guidance.

Guidance documents like NEI 12-04 and Regulatory Guide 3.72 are not regulations, and strict adherence is not legally required. Regulatory Guides provide acceptable methods but allow alternatives if justified. Therefore, NRC's claim that Holtec violated 10 CFR 72.48 by not following the staff's interpretation of guidance is inconsistent with regulatory principles.

### **NRC Evaluation of NCV 07201014/2024201-04**

The NRC staff agrees that endorsed industry guidance, such as NEI 12-04, or Regulatory Guides, such as Regulatory Guide 3.72, are not regulatory requirements on their own. They provide methods that are acceptable to the NRC to meet certain regulatory requirements. However, certificate holders (and licensees) may commit to, or reference, industry guidance or Regulatory Guides within implementing procedures to ensure compliance with regulatory requirements.

The staff notes that the Holtec committed to using the endorsed industry guidance, NEI 12-04, in procedure HSP-321, "Screening and Evaluation of Changes, Tests, and Experiments under 10 CFR 72.48." The procedure is used as a subset of the licensee's design control program to ensure compliance with the requirements of 10 CFR 72.146, "Design Control." Therefore, Holtec established NEI 12-04 as their means for ensuring compliance with 10CFR 72.48.

The staff evaluated the certificate holder's claim that NEI 12-04 requires only representative, not identical, FSAR cases when changing software versions. NEI 12-04 Section 6.8 treats changes to software versions as changes to an MOE *element*, not a new MOE, which the staff agreed was the correct classification. Under Section 6.8.1 of the NEI 12-04 guidance, two steps are required: (1) software verification and validation under the QA program, and (2) benchmarking representative cases using both old and new software. These steps may be done together but must remain distinct.

NEI 12-04, Section 6.8.1, discusses that "Changes to elements of MOEs that yield conservative results or results that are essentially the same over the entire range of use for the method would not be departures from approved MOEs." To determine if the results are "essentially the same," the guidance from NEI 12-04, Section 6.8.1.2, would be applied.

NEI 12-04, Section 6.8.1.2, states that,

*The determination of whether a new analysis result would be considered "essentially the same" as the previous result **can be made through benchmarking the revised MOE to the existing one, or may be apparent from the nature of the differences between the MOEs.** When benchmarking a revised MOE to determine how it compares to the previous one, the analyses that are done must be for the same set of conditions to ensure that the results are comparable, and the revised MOE should only be used where the benchmarking has demonstrated it to be conservative or essentially the same.*

Therefore, to adequately evaluate the change utilizing the process defined in NEI 12-04 Section 6.8.1.2, “Essentially the Same Results, against the criteria defined in Section 2.8, a review of representative case should contain a case that can be compared against the previous results from the MOE without the modified elements.

The NRC staff notes that even in the absences of NEI 12-04 or Regulatory Guide 3.72, the statements of consideration in 64 FR 53615 associated with 10 CFR 72.48 provide adequate definitions and guidance for 10 CFR 72.48.

64 FR 53615 states in part that,

*For the purposes of this rule, a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses means (1) changing **any of the elements** of the method described in the FSAR (as updated) unless the **results of the analysis are conservative or essentially the same**; or (2) changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application. Results from a changed method are conservative relative to results from the previous method, if closer to the limits or values that must be satisfied to meet the design bases. **Results are “essentially the same” if they are within the margin of error needed for the type of analysis being performed, even if tending in the nonconservative direction. Results are essentially the same if the variation in results because of the change to the method is explainable as routine analysis sensitivities, and the differences in the results are not a factor in determining whether any limits or criteria are satisfied. The determination can be made through benchmarking (new vs. old method), or may be apparent from the nature of the changes between the methods. When benchmarking a method to determine how it compares to the previous one, the analyses that are done must be for the same set of plant conditions, otherwise, the results may not be comparable. Approval for intended application includes assuring that the approved method was approved for the type of analysis being conducted, generically approved for the type of facility using it, and that all terms and conditions for use of the method are satisfied.***

The NRC staff notes that the language in the statements of consideration in 64 FR 53615 is nearly identical to the language cited from NEI 12-04 Section 6.8.1.2, “Essentially the Same Results.” Accordingly, the reviewer found that the same conclusion can be drawn by referencing the statements of consideration. Specifically, to adequately evaluate the change, the method, not simply the element, should be benchmarked against the previous results from the MOE without the modified element(s). Typically, the previous results from the MOE is described in the FSAR and longstanding industry practice is to benchmark against the description in the FSAR.

#### **NRC Conclusion NCV 07201014/2024201-04**

The NRC staff identified that the description section of the inspection report incorrectly identified engineering change order (ECO) 5018-126, Revision 1, and 10 CFR 72.48 Evaluation No. 1516, Revision 1 rather than ECO 5018-130, Revision 1, and 10 CFR Evaluation No. 1541, Revision 1. The staff agrees this reference should be corrected.

The staff recognizes that industry practice historically has been to use FSAR-described MOE results to determine whether results remain conservative or essentially the same. Holtec did not do that in this case. Staff agrees that verification and validation may be performed in the same

step as the benchmarking of the MOE. Additionally, staff acknowledges that the NRC-endorsed guidance is silent on whether the FSAR described case must be used as the representative case. Further study would be needed to determine whether the representative cases, used by Holtec, must include the FSAR-described case. Staff concluded that there is ambiguity in the NRC endorsed guidance regarding whether the evaluation performed by Holtec, must include appropriate benchmarking using a FSAR-described case. Therefore, given the very low safety significance of the issue, the NRC concluded that further deliberation on this issue would not effectively or efficiently serve the Agency's mission.