HOLTEC

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January 19, 2026

U.S. Nuclear Regulatory Commission
Attn: Director, Office of Enforcement
Washington, DC 20555-0001

Holtec International
Corporate Inspection
Docket No. 72-1014, 72-1032, and 72-1040

Subject: Reply to a Notice of Violation; EAF-NMSS-2025-0102

Holtec International (Holtec) is submitting to the Nuclear Regulatory Commission (NRC) this response letter to the Notice of Violation EAF-NMSS-2025-0102 to contest three violations of Severity Level IV significance; two notices of violations (NOVs) and one non-cited violation (NCV). The two contested cited violations involved: (1) Violation of 10 CFR 72.48(c)(2)(vi), "Changes, tests, and experiments (CTEs)," for 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); and, (2) Violation of 10 CFR 72.146, "Design control," 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. As a part of the final enforcement determination, the NRC made the decision to combine violations (1) and (2) as the violations were closely related. The contested Severity Level IV non-cited violation of 10 CFR 72.48(d)(1) required that the certificate holder maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and of tests and experiments. These records 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.

Holtec respectfully requests NRC to review Holtec's basis for contestation and re-evaluate the three violations for accuracy and consider withdrawing the violations. As described in Attachment 1 to this letter, the determination for the two cited violations does not accurately represent the licensing basis for the system and is a contrary position to previous NRC staff approvals. For the contested NCV, the NRC determination applies a guidance document as though it is a regulation and imposes requirements beyond what the guidance document provides.

IE09
OE01
NMSS26
NMSS
OE

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Should there be any questions regarding this matter, please contact me at (856) 797-0900 x 3578.

Respectfully,

Jean A. Fleming

Digitally signed by Jean A. Fleming
DN: cn=Jean A. Fleming, c=US, o=Holtec Decommissioning International, LLC, ou=Regulatory and Environmental Affairs, email=J.Fleming@Holtec.com
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Jean A. Fleming
Vice President, Licensing and Regulatory Affairs
Holtec International

Attachment 1: Reply to a Notice of Violation; EAF-NMSS-2025-0102

Attachment 2: Slides from Holtec PEC Meeting (ML25240B644)

Attachment 3: Supplemental Information Submitted After PEC (Holtec Letters 5014989 and 5014990)

cc:

Shana Helton
Gerond George

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ATTACHMENT 1

Reply to a Notice of Violation; EAF-NMSS-2025-0102

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1.0 NOV Summary Statement:

In Notice of Violation (EAF-NMSS-2025-0102), the Nuclear Regulatory Commission (NRC) issued Holtec International (Holtec) two cited violations of Severity Level IV significance in the "Notice of Violation" (NOV) enclosure. These violations are as follows:

(1) 10 CFR 72.48(c)(2)(vi), "Changes, tests, and experiments (CTEs)," requires, in part, that a certificate holder shall obtain a certificate of compliance (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 a structure, system, or component (SSC) important to safety (ITS) with a different result than any previously evaluated in the final safety analysis report (FSAR) (as updated).

Contrary to the above, from September 2021 to present, Holtec International, Inc. (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 Flood/Wind (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, a credible event that would create a possibility for a malfunction of the HI-STORM FW overpack and multi-purpose canister (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.

(2) 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.

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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 modern design making this a more active versus a passive design function. Furthermore, this condition could create the possibility of an unanalyzed condition where an even considered non-credible in the FSAR is now a credible event.

2.0 Executive Summary of Response:

Holtec asserts that these two NOVs are based on a misinterpretation of the HI-STORM FW licensing basis, a change in position from previous NRC approvals, and an incorrect application of operating experience.

2.1 Misinterpretation of Existing HI-STORM FW Licensing Basis

The HI-STORM FW licensing basis, as documented in the HI-STORM FW FSAR (ML25136A284), evaluates different scenarios for the HI-STORM FW cask system. Some scenarios consider "normal conditions" that the cask is subjected to, and other scenarios consider "accident conditions" with different acceptance criteria established for each of the scenarios. Each of the "normal conditions" and "accident conditions have *different* licensing basis and analyses.

A full blockage of the cask vents is considered an accident condition, as described in FSAR Section 12.2.13. This scenario, although unlikely, is included in FSAR section 12.2.13.1, which states, "a flood, blizzard snow accumulation, tornado debris, or volcanic activity, where applicable, can cause a significant blockage." Because these scenarios, including flood, could cause blockage, the FSAR provides a full analysis of 100% vent blockage.

The possibility that the vents could be blocked (by water or another substance) is already an analyzed condition in the FSAR and is not a new malfunction, regardless of the vent style of the overpack. Therefore, it is not a new malfunction. FSAR Table 12.2.1 indicates that there is no mechanistic way for the vents to become fully blocked, but as the FSAR text indicates, this is still a fully analyzed condition.

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To the extent the NRC staff has concerns about the possibility for air inlet vents to be blocked by water in the overpack for a longer duration, the FSAR already addressed that scenario prior to the design change. FSAR section 12.2.13.4 identifies the corrective actions required after an accident condition where the cask vents become fully blocked, which includes additional operator actions after a complete blockage. FSAR section 12.2.13.4 also permits site specific analysis and actions if the duration of a vent blockage due to an accident exceeds the currently analyzed duration. This section applies to both the existing HI-STORM FW systems and those introduced through the 72.48 process. This information is applicable to both the accident scenario and off-normal conditions.

Inspection report 072001014/2025-201 states that "changing the height of the inlet vents created a potential for water to remain trapped in the lower portion of the overpack after a normal rainfall occurrence while in storage. If enough water enters the overpack, it could block airflow to the air inlet vents and result in an adverse thermal effect on the fuel assemblies and the MPC." This statement confuses two scenarios in which water might enter an overpack. More specifically, a normal rainfall event, such as that discussed in the inspection report, is a different scenario than the accident scenario that would cause 100% vent blockage, and therefore the licensing basis is different. It is not appropriate for the accident description and accident time limits to be applied to a normal rainfall event. The inspection report indicates, if rainwater entered the overpack during normal conditions, "then for normal storage conditions this would lead to an off-normal and accident condition."

The HI-STORM FW FSAR licensing basis during the normal condition rainfall event, states that water is not postulated to enter the cask system. The upper vents are physically located on the side of the cask and arranged around the entire circumference of the cask. This design configuration would require rain to enter sideways, which is highly unlikely under normal conditions, and would not be of sufficient quantity during the normal rainfall event to block the airflow passages. It would require approximately 20 gallons of rainwater to enter the vents to fully block the passages. The system is already designed such that even a 50% blockage keeps all temperatures below normal limits, so it would take a significant inflow of water to have any adverse thermal impact. The design change implemented under 72.48 #1541, did not change the design of these upper vents and therefore the ability for normal condition rainwater to enter the vents remains equally unlikely. The HI-STORM FW FSAR and the NRC safety evaluation reports (SERs) issued to approve the HI-STORM FW system, do not indicate that water was expected in the overpack during normal conditions and that the lower vents were relied upon to provide a drainage pathway for the water to exit the overpack. The possibility of more than 20 gallons of rainwater entering the overpack during a normal rainfall event to block the ventilation passages remains a non-credible event, and therefore it is not a new malfunction that would occur during normal operation of the system. This conclusion is supported by the operating experience discussed below.

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2.2. Operating Experience Applicability

On September 3, 2025, the NRC and Holtec convened for a PEC (ML25240B644, included as Attachment 2 to this letter) at the NRC Headquarters to discuss the apparent violations. During that meeting and in follow-up documentation, Holtec provided the staff with operating experience (included as Attachment 3 to this letter) for the HI-STORM FW systems that were implemented under the design change in 72.48 #1541. The inspection report states, "The team noted that operating experience showed the presence of water in the overpacks at several different sites related to this design change." That statement is made without appropriate context. While Holtec agrees that some sites did find very small quantities of water in some overpacks (on the order of 2-3 tablespoons or approximately 1 ounce), it must be emphasized that the volume of water was several orders of magnitude below any amount that could cause the blockage of airflow.

Additionally, and more importantly, the systems that observed any measurable quantity of water were unloaded systems that did not contain spent fuel and are not subject to the normal or accident conditions in the HI-STORM FW FSAR. While sites do store unloaded systems in similar fashion to loaded systems, they are not subject to the same level of control as the loaded systems, and therefore operating experience on unloaded casks should not be considered directly applicable. For example, a site would not be required to perform daily checks for vent blockage on unloaded casks nor would the site implement the post-accident operations that are expected in the FSAR if a flood accident impacted unloaded casks, meaning that FSAR Section 12.2.13.4 would not be required to be implemented.

In summary, OE determined that the presence of water in the loaded casks was minimal, on the order of 2-3 tablespoons or approximately 1 ounce of volume, and any water accumulation in unloaded casks stored onsite is irrelevant since the FSAR requirements of a loaded cask do not apply until the cask is loaded with spent fuel.

The operating experience on a large number of loaded systems with the elevated vents is consistent with Holtec's assertion that under normal conditions, it is not credible that significant rainwater could accumulate and block airflow. As described in Section 2.1, an accident condition of vent blockage is considered in the FSAR, including provisions for operator actions and modified accident durations.

2.3. Change in Position from Previous Regulatory Approvals

The NOVs are inconsistent with approvals received by Holtec for similar cask designs. The HI-STORM 100 system has a version of the cask called "Version E." This system was submitted to the NRC as an amendment due to technical specification changes, including revised heat load limits. The Version E cask also incorporates elevated vents very similar to the HI-STORM FW versions introduced under 72.48. The HI-STORM 100 licensing basis on normal condition rainfall and 100% blockage accident is also similar to that of the HI-STORM FW system. During

review of the HI-STORM 100 system with elevated vents, staff raised no concerns about any change to that licensing basis to address the possibility of water entering the system during normal conditions. Additionally, the design was approved with no additional technical specification changes needed related to the need to ensure the drain line was clear. This NOV does not address staff's changed position from when the HI-STORM 100 Version E amendment was approved (Amendment 15, May 2021) where the staff did not find water entering the overpack during normal rainfall to be credible and found the vent blockage accident analysis to be sufficient duration for an almost identical vent design.

2.4 Redundant Violations

In issuing the two NOVs to Holtec related to the elevated vents, the NRC staff issued both a violation of 10 CFR 72.48 and a violation of 10 CFR 72.146, which appear to be redundant violations. Although Holtec contests that the change violated 10 CFR 72.48, even if the staff disagrees, the change should not also be considered a design control violation. Holtec subjected the new design to every step in the design control process as outlined in Holtec procedures. All necessary engineering change documents were completed and analyses performed commensurate with those applied to the original design of the HI-STORM FW. The NRC staff documentation of the violation of 10 CFR 72.146 indicates that, "The team determined that Holtec needed to seek prior NRC review and approval for this design change to the HI-STORM FW overpack because this change would create a possibility for a malfunction of a SSC ITS with a different result than any previously evaluated in the FSAR (as updated)." The requirement to submit amendments for new malfunction, however, falls under 10 CFR 72.48, not the design control regulation. There is no discussion in the violation documentation provided as to what item in design control the staff believes Holtec did not apply appropriately. The violation discussion focuses on the guidance in NEI 12-04 which is guidance on how to apply the requirements of 10 CFR 72.48 and does not provide any guidance on the design control regulations in 72.146. Accordingly, Holtec believes the referenced guidance document does not provide a basis for concluding that design control measures were violated.

2.5 Corrections to Documented Violations

Holtec also disagrees with the statement in the inspection report that "Holtec implemented compensatory measures in revision 1 of the ECO and 10 CFR 72.48 evaluation to remove the plugs from the drain lines if the overpack has a separate drain line near the baseplate of the overpack." This statement is not accurate. Neither the original revision nor the revision 1 to those documents discusses the existence of plugs on drain lines nor suggests that operators remove those drain plugs. In summary, those revisions indicate that they were made to provide detail regarding the relationship of the drain line to the thermal analysis. The only place the word "plug" appears in either of those referenced documents is related to a shielding analysis of the thimble plug devices, which is unrelated to the drain line discussion.

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3.0 NCV Summary Statement

The NRC issued Holtec an NCV which states:

"The team identified a Severity Level IV non-cited violation of 10 CFR 72.48(d)(1) which 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."

4.0 Executive Summary of Response

Holtec disagrees with the violation because it goes beyond the endorsed guidance document, NEI 12-04, "Guidelines for 10 CFR 72.48 Implementation," and transforms what is described in the violation, but not the guidance document, into a new regulatory requirement that was violated.

4.1 Additional Requirements Imposed by Violation

Holtec used an updated version of ANSYS (ANSYS Version 2020 R2) from the software version listed in the HI-STORM FW FSAR (ANSYS Version 11) to analyze the structural performance of the HI-STORM FW system under the allowances of 72.48. This newer revision of the ANSYS code was not a change in methodology because the code underwent both verification and validation and was demonstrated to give "essentially the same result" as the previous code years.

The description of the violation provided by the NRC staff references the NEI 12-04 guidance document in support of the violation and states, "Holtec did not complete all the steps described in the guidance document to compare those cases with those in the FSAR."

But NEI 12-04 (6.8.1 and the associated subsections) does not establish any expectation that the cases utilized for comparison of code versions must be identical to those cases run for the FSAR. The NEI 12-04 descriptions state that the code must be verified and validated, which the NRC staff appears to agree Holtec performed. NEI 12-04 then states in Section 6.8.1, "the revised software must be used to re-analyze one or more representative cases that were analyzed using the previous version of the software. The results of the old and new sets of representative cases are then compared to determine if the revised software produces results that are conservative, non-conservative, or essentially the same." As Holtec described during the PEC and in the supplemental information provided after the meeting, a number of cases were run that were representative of how the software is used in the licensing basis evaluations. The results from those cases were shown to be essentially the same. Section 6.8.1.2 of NEI 12-04 discusses how to determine if the results are essentially the same, including the results being within rounding error

and that the analysis run in each version of the code must be for the same set of conditions for benchmarking of the revised MOE. But Section 6.8.1.2 does not indicate that those analyses must be identical to FSAR documented analyses. 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.

4.2 Application of Guidance as Regulatory Position

As described in Section 4.1, Holtec asserts that the cases run to demonstrate the new ANSYS version is acceptable follow the referenced guidance document; however, even if the staff disagrees, the guidance document should not be applied as a regulation that can be violated. The violation description states that "Section 6.8.1, 'Guidance for Changing One or More Elements of a MOE,' provides a similar example of a code version change and provides the steps necessary to determine whether prior NRC review and approval is required." But strict adherence to a guidance document is unnecessary to comply with applicable regulations. RG 3.72, which endorses the NEI 12-04 document, expressly states that "regulatory guides are not NRC regulations and compliance with them is not required. Methods and solutions that differ from those set forth in RGs are acceptable if supported by a basis for the issuance or continuance of a permit or license by the Commission." Therefore, an RG is an acceptable approach for meeting the regulatory requirement but is not a legally binding requirement. Stating that Holtec violated 10 CFR 72.48 because the documentation did not follow the staff's interpretation of a guidance document is inconsistent with this principle.

5.0 Holtec Conclusion

Holtec respectfully requests that the NRC reconsider the issuance of the NOV for violating 10 CFR 72.48(c)(2)(vi) and 10 CFR 72.146 and the NCV for violating10 CFR 72.48(d)(1) in inspection report 072001014/2025-201 based on the information presented above. Holtec believes that the 72.48 evaluation is consistent with the HI-STORM FW approved licensing basis, NRC endorsed guidance, and staff positions previously documented. As a result, Holtec seeks a resolution that acknowledges compliance with the established regulatory framework and avoids unnecessary and unjustified burdens on our users.

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ATTACHMENT 2

Slides from Holtec PEC Meeting (ML25240B644)

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Pre-Decisional Enforcement Conference
Inspection Report 07201014/2024-201

Agenda

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- Background
- Additional Information on Apparent Violations
- Safety Significance of Apparent Violations

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Apparent Violations

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- NRC performed inspection in October 2024
- NRC Inspection Report No. 72-1014/2024-201, Reference number EAF-NMSS-2025-0102, received on July 17, 2025
  - ✓5 Apparent Violations
  - ✓Apparent Violation A and B are being considered for escalated enforcement
  - ✓Apparent Violations C, D, and E are currently considered SL-IV, however Holtec will provide additional information, as applicable.

Additional Information on Apparent Violations

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Apparent Violation A:

- NRC claims, "**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."

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Additional Information on Apparent Violation A

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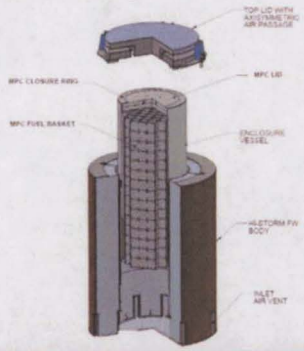
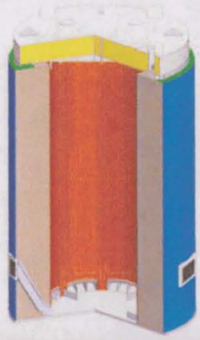
- Apparent violation claims that Holtec had created a new possibility that air inlet vents to be blocked from rainwater in the Version E and E1 design of the HI-STORM FW
  - Previous Design:



  - Version E Design



Additional Information on Apparent Violation A

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- Holtec FSAR clearly indicates that: "A blockage of all of the circumferentially arrayed vents cannot be realistically postulated to occur at most sites. However, a flood, blizzard snow accumulation, tornado debris, or volcanic activity, where applicable, can cause a significant blockage." (Section 12.2.13)
  - There is no credit in the existing licensing basis taken for the fact that water would exit the previous design ground level vents – neither FSAR nor SER have any documentation that this was relied on
  - There is no pathway for rainwater to enter the upper vents and collect at the bottom of the system - vents are on the side of the lid, and covered with perforated screens, rain would have to go fully sideways to enter
  - FSAR says this is because of the circumferential vents - upper vents are essentially the same circumferential design in both variants
  - Although vent blockage is considered non-credible, an accident analysis is still performed and documented in the FSAR

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Additional Information on Apparent Violation A

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- Holtec disagrees that this is a new malfunction
  - ✓ Blockage of vents from rainwater remains non-credible as stated in the FSAR
  - ✓ NEI 12-04 defines malfunction as the failure of the SSC to perform intended design function
    - Overpack maintains its structural integrity
    - Cooling passages are not credibly blocked and maintain airflow to keep heat transfer function as designed
  - ✓ Notwithstanding, a vent blockage analysis is performed in the FSAR, so the scenario is an analyzed accident condition

Additional Information on Apparent Violation A

HOLTEC INTERNATIONAL

- During the design process for the new versions, Holtec did consider the possibility of an accident condition, like a flood, where water would credibly enter the vents (not from normal rainwater)
  - ✓ A drain line was included to recover from such an accident
  - ✓ Not needed for normal operation, where rainwater entrance is not credible, but for post-accident recovery
  - ✓ Some loaded casks had plugs closing those drain lines
    - When those plugs were removed from loaded casks, no water was found
      - ➢ This operating experience supports the existing licensing basis that during normal conditions rainwater does not block the vents
    - Unloaded casks do not apply to this scenario
      - ➢ May not be stored in same manner
      - ➢ Not subject to license

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Additional Information on Apparent Violation A

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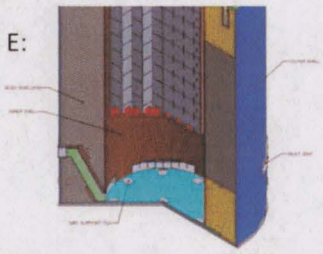
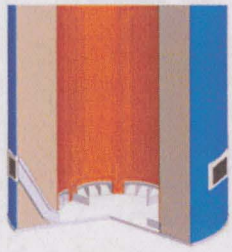
- Precedent exists on similar designs
  - ✓HI-STORM 100 Version E was submitted to the NRC under amendment, due to new canister types and new heat loads
  - ✓System has very similar vent styles to HI-STORM FW Version E
  - ✓System has a similar licensing basis where no credit is taken for rainwater exiting from the bottom vents, because no significant amount of water can credibly enter the system
  - ✓NRC review and approval of that design does not identify rainwater intrusion as a malfunction, nor was there any need to change the analysis of the vent blockage event, and no change to LCOs

HI-STORM 100 Version E:



HI-STORM FW Version E:



Apparent Violation B

HOLTEC INTERNATIONAL

- NRC claims, "**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 due to the elevated position of the air inlet vents.** This trapped rainwater could result in a condition where air inlet vents are blocked longer than previously analyzed in the FSAR, thereby causing a potential for the fuel to exceed peak cladding temperatures and to exceed the internal pressure limits in the MPC."

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Additional Information on Apparent Violation B

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- This violation is essentially the same as Apparent Violation A
- Holtec disagrees with the violation, it remains non-credible for rainwater to enter the vents since the design maintains essentially the same top vents
- The new design was evaluated under design control measures commensurate with those applied to the original design
  - ✓ All impacted disciplines were evaluated
  - ✓ New analyses performed where needed
  - ✓ Changes were documented and evaluated using Holtec's design control procedures, engineering change documentation, and 72.48 process
  - ✓ Unclear which design control measure was violated

Safety Significance of Apparent Violations A and B

HOLTEC INTERNATIONAL

- NRC Enforcement Policy 6.1 (c)(6) - Severity Level III includes (for 50.59s) "the licensee fails to obtain prior Commission approval for an activity or change that has a consequence evaluated by the SDP as having low-to-moderate or greater safety significance"
- **No safety significance associated with this design change**
  - ✓ Rainwater intrusion is non-credible in the FSAR in normal operations
  - ✓ For accident scenarios, 100% vent blockage is evaluated in the FSAR (PCT limit 570 °C)
- At full design basis heat load (46.36 kW), 32 hours of blockage still remains within accident pressure and temperature limits (PCT less than 570°C)
  - ✓ At this heat load, any water in the system would evaporate (water boils at 100°C)
  - ✓ At lower heat loads, time of blockage is longer, but water still evaporates
  - ✓ At low enough heat loads where water does not evaporate, vent cooling is no longer required for system to remain below pressure and temperature limits

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Apparent Violation C

NRC claims, "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 moving of the HI-STORM 100 overpack version E and E1 without a lid outside the fuel building does not require a license or CoC amendment pursuant to paragraph (c)(2) of this section."

"Specifically**, Holtec stopped at their procedural 10 CFR 72.48 screening process step and did not perform a full evaluation**. The inspectors determined that Holtec should have screened this design change for a full evaluation under Holtec's screening questions a. and c. since (1) the proposed activity could adversely affect the design function of the MPC and (2) there was no method of evaluation used in supporting an updated FSAR analysis that demonstrates the intended design function will be accomplished under design basis conditions such as natural phenomena. "

Additional Information on Apparent Violation C

- Holtec disagrees with this violation - the violation indicates that screening questions (a) and (c) should have been answered 'YES'
- Question (a) relates to adversely impacting a design function of the MPC
  - ✓ The screening in 72.48 #1591 states that no design function of the MPC is adversely affected
  - ✓ The site-specific tornado missiles at the impacted site are bounded by those in the FSAR, therefore there is no adverse impact from the existing FSAR analysis
  - ✓ All impacts to the MPC are bounded by the existing analyses
- Question (c) relates to a change in MOE
  - ✓ There was no new evaluation performed in support of this proposed activity, because the missiles remain bounded by the FSAR, therefore no MOE is impacted
    - The violation statement seems to acknowledge this – "there was no method of evaluation used in supporting the updated FSAR analysis"
  - ✓ The FSAR has an analysis of a direct impact on the MPC lid from tornado missiles that bound those at the site, therefore no new evaluation is performed

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Safety Significance of Apparent Violation C

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- **No safety significance associated with this apparent violation**
- The MPC is already evaluated in the FSAR for a direct missile impact to the lid
- The site-specific missiles are bounded by those in the FSAR
- While the scenario is fully evaluated and shown to have no safety consequences, the probability of a tornado missile occurring during the short period of time where the HI-STORMs are being moved is extremely low
- All fuel at the impacted site (IPEC) has already been moved to dry storage and no further lidless HI-STORM movement is expected, so the scenario is now non-credible

Apparent Violation D

HOLTEC INTERNATIONAL

- NRC claims, "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 failed to 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 method of evaluation 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) for the new overpack and lid than what was previously approved for the standard HI-STORM FW (ANSYS 11**). Holtec performed a verification and 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."

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Additional Information on Apparent Violation D

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- While the use of ANSYS Version 2020 R2 is considered a change to an element of an MOE, Holtec disagrees that it requires prior NRC approval based on the following:
  - Holtec has verified and validated ANSYS 2020 R2 in accordance with the company's approved QA program. Specifically, ANSYS 2020 R2 was validated per the requirements in Holtec procedure HSP-101101, and the results are documented in Holtec report HI-2012627 rev. 16. [Note: Section 3.6 of the HI-STORM FW FSAR includes a compliance matrix that summarizes the steps taken by Holtec to validate ANSYS and ensure the numerical accuracy of all solutions.]
  - A total of 39 representative cases were analyzed using both the previous version of ANSYS (Version 11) and the revised version (Version 2020 R2).
  - The results from the representative cases using both the previous version and the revised version of ANSYS were found to be "essentially the same", as the results agreed within roughly 1% of each other.

Additional Information on Apparent Violation D

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- The 39 representative cases analyzed by Holtec considered a wide range of ANSYS element types, material behaviors, boundary conditions, etc., which are commonly used by Holtec in dry storage applications.
  - For example, one of the cases analyzed (VM7) uses 3D structural solid elements (SOLID185) and a bi-linear stress-strain curve to simulate the plastic behavior of a steel pipe under compression. This same element type and a similar nonlinear material model are used to simulate the behavior of the HI-STORM FW Common Lid during the tipover event.
  - Another case (VM66) uses 3D solid shell elements (SOLSH190), which are also employed in the analysis of the HI-STORM FW Common Lid, to analyze the vibration modes of a cantilevered steel plate.
- Holtec deliberately selected these 39 cases analyzed using both ANSYS Version 11 and ANSYS Version 2020 R2 because they collectively represent the finite element (FE) attributes and features that are used in the FSAR

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Additional Information on Apparent Violation D

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- This approach is fully supported by the guidance in Section 6.8.1 of NEI 12-04, which calls for the revised software (i.e., ANSYS 2020 R2) to be used to re-analyze "one or more representative cases".
  - While the exact case from the HI-STORM FW FSAR would qualify as a "representative" case, NEI 12-04 does not mandate that a specific FSAR case be re-analyzed using the revised software.
- While the guidance implies V&V and representative cases as being a 2 step process, Holtec chose V&V cases that were also representative cases for the licensing basis usage of the software – this is not prohibited
- Holtec maintains that the change from ANSYS Version 11 to ANSYS Version 2020 R2 is not a departure from the approved MOE established in the HI-STORM FW FSAR, and the change in software version is acceptable under 10 CFR 72.48 per the guidelines established in NEI 12-04.

Safety Significance of Apparent Violation D

HOLTEC INTERNATIONAL

- **No safety significance associated with this apparent violation**
- The change in code year for a well validated code that has been run with cases representative of those in the FSAR has no impact on the safety of the system
- Version 11 was released in February 2007, Version 2020 was released in 2020
  - Version 11 is not current industry standard for operating systems
  - Version 11 is no longer supported by ANSYS
- The results demonstrate that the system is within all existing limits
- No safety concerns were raised during the inspection or in the inspection report

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Apparent Violation E

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- NRC claims,"**(Holtec) failed to establish measures to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected.** Specifically, **Holtec failed to promptly identify and correct a quality issue (QI) for the Holtec position paper (DS-331) credited in the storage and transportation system design basis of the FSARs for the development of stress and strain curves**. Holtec used the wrong value, which would place the systems in an unanalyzed state or outside their storage and transportation systems licensing basis. However, when identified during the EA-23-044 cited violation issue and HI-STORM FW amendment review in December 2023, Holtec failed to initiate a QI and correct the deficiencies and nonconformances. "

Additional Information and Safety Significance of Apparent Violation E

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- Holtec revised the position paper identified in Apparent Violation E several times to address staff questions during HI-STORM FW Amd 7 review
  - Position paper is a reference in Amd 7
  - Methodology is fully documented in the FSAR independent of the position paper
- In response to EA-23-044, full root cause was performed and reviewed by NRC
  - The position paper is not identified in the EA-23-044 documentation
  - However, the issue has been added to Holtec's QI process in response to NRC inspection report
- There is no safety significance to this issue
  - The FSAR is the licensing basis regardless of any supporting references or position papers
  - All related analyses use the updated methodology as approved by the staff

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Summary

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- No Safety Significance associated with ANY apparent violations
- The designs under question in Apparent Violations A and B are consistent with the existing licensing basis and were documented under 72.48 evaluations
- The proposed activity in Apparent Violation C is not adverse to the MPC and does not use a new MOE
- The proposed activity in Apparent Violation D uses representative cases to demonstrate the acceptability of a new code year in accordance with NEI 12-04 guidance
- Apparent Violation E has no regulatory or safety significance, position papers are not licensing basis documents

Thank You

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ATTACHMENT 3

Supplemental Information Submitted After PEC (Holtec Letters 5014989 and 5014990)

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Attachment 1 to Holtec Letter 5014989

NRC Pre-Decisional Enforcement Conference Information Requests

Apparent Violations A and B

NRC Request – Provide details on operating experience on water found in unloaded casks (and loaded if any exists) including how the unloaded cask storage configuration might differ from a loaded cask configuration

Holtec has requested this information from users and expects to be able to provide additional information to the NRC staff by September 16

NRC Request – Provide FSAR sections that direct general licenses on recovery actions to take after a flood and any drawings that show the drain line. Include any recovery procedures provided to users. Also include communications to users about potential violations.

HI-STORM FW FSAR Section 12.2.7.4 contains the recovery actions to be taken after a flood, and says:

> "At the completion of the flood, exposed surfaces may need debris and adherent foreign matter removal. For the HI-STORM FW Version E, Version F, and Version E 1 a drain connection may be included to assist with removal of any additional water that remains after the flood."

HI-STORM FW FSAR Section 12.2.13.4 contains the corrective actions to be taken after a 100% blockage of air vents (by any material)"

> "For an accident event that completely blocks the inlet or outlet air openings for greater than the analyzed duration, a site-specific evaluation or analysis may be performed to whether adequate heat removal for the duration of the even would occur. Adequate heat removal is defined as the minimum rate of heat dissipation that ensures cladding temperatures limits are met and structural integrity of the MPC and overpack is not compromised. For those events where an evaluation or analysis is not performed or is not successful in showing that cladding temperatures remain below their short term temperature limits, the site's emergency plan shall include provisions to address removal of the material blocking the air inlet openings and to provide alternate means of cooling prior to exceeding the time when the fuel cladding temperature reaches its short-term temperature limit.

The FSAR clearly indicates that users must have provisions to remove debris, foreign material, water, or any other material as recovery from both the flood and vent blockage events. These post-accident recovery actions apply to all versions of HI-STORM FW. No

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specific recovery procedures are provided to users, as the FSAR indicates it is referred to the site's emergency plan.

A drawing showing the drain line is included as a proprietary attachment to this letter.

Meeting minutes from meetings held with users related to the potential violations are also included as a proprietary attachment to this letter. Note that these are just summary meeting minutes, these meetings are not transcribed in their entirety.

Apparent Violation C

NRC Request – Provide the FSAR section and any supporting analysis related to the tornado missile impact on the MPC lid in the HI-STORM overpack

The direct missile impact on the MPC lid is discussed in Section 3.4.4.1.3 (b) of the HI-STORM FW FSAR. As stated in that section:

> "The MPC upper lid is analyzed for a direct missile impact because, when the MPC is placed inside the HI-TRAC VW, the MPC lid is theoretically accessible to a vertically downward directed small or intermediate missile."

The text indicates that the analysis was performed because the design of the HI-TRAC exposes the MPC lid to a potential missile. The actual evaluation is contained in the supporting calculation package (HI-2094392, Appendix D, included as a proprietary attachment to this letter). The analysis contained in that calculation package clearly indicates that the evaluation takes no consideration for the surrounding overpack. The evaluation is a direct impact to the steel plate of the MPC lid only. Therefore, the analysis is unchanged for an MPC in a HI-STORM FW overpack (with no lid) or in a HI-TRAC VW transfer cask, as documented in the existing 72.48 screening.

Apparent Violation D

NRC Request – Are there any additional direct comparison to FSAR results for the specific cases in the applicable 72.48? NRC staff wants to understand how Holtec came to the "essentially the same" conclusion.

As stated during the conference, Holtec did not run the exact same FSAR lid analysis in both ANSYS Version 11 and ANSYS Version 2020. Prior to the introduction of the Version F in 72.48 # 1516, the common lid was analyzed using ANSYS Version 11. In accordance with the guidance in NEI 12-04, Holtec performed a validation and verification of ANSYS Version 2020 and documented it in accordance with Holtec's QA program requirements. NEI 12-04, Section 6.8.1 states that, "the revised software must be used to re-analyze one or more representative cases that were analyzed using the previous version of the software. The

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results of the old and new sets of representative cases are then compared to determine if the revised software produces results that are conservative, non-conservative, or essentially the same."

Holtec ran the same cases in Version 11 and Version 2020 and documented them in HI-2012627. Specifically, for the lid evaluation, case VM7 uses the same element type and nonlinear material model that are used to model the common lid during the tipover event. As documented in HI-2012627, the results for case VM7 (and all other cases) for Version 11 and Version 2020 are different by less than 1%. Based on the comparison of results from the two versions, Holtec determined that the modified MOE gives "essentially the same" results.

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."

Case VM7 (and all other cases) were done using the exact same set of conditions, the results were shown to be comparable, thus completing the benchmarking as expected by the guidance document. ANSYS Version 2020 is only used because the cases that show essentially the same results are appropriately representative of the scenarios for which it is used in this proposed activity.

Apparent Violation E

NRC Request – Please provide the QI that was written to document the position paper concern.

Holtec QI-3620 is included as a proprietary attachment to this letter.

Potential Corrective Actions

During the conference it was discussed that Holtec disagrees with the apparent violations as currently documented. Holtec has entered the apparent violations into our corrective action program for tracking, but has not performed a full review and determined final corrective actions. However, if at the conclusion of the full NRC enforcement process the

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violations remain as currently stated, Holtec has considered corrective actions that may be implemented.

For Apparent Violations A and B, if the NRC determines that these changes should have been submitted for an amendment, Holtec will submit amendments as required to bring systems back into compliance. Holtec would also work with general licensees to support the exemption requests that may be needed to continue loading campaigns. Holtec would also perform a full extent of condition review to ensure similar issues do not exist with other 72.48 evaluations, and include any updated training or procedures necessary.

For Apparent Violation C, if the NRC determines that a full evaluation was required, Holtec would update the 72.48 to document a full evaluation. Holtec would also do an extent of condition review to identify any other similar 72.48 screenings and update those documents as necessary.

For Apparent Violation D, if the NRC determines that the representative cases performed were not sufficient to provide reasonable assurance that the new ANSYS code version provides essentially the same results as the previous version, Holtec would run the exact FSAR analysis with ANSYS Version 2020 and document that the results are essentially the same as provided in the FSAR. The 72.48 documentation would be updated to reference the additional FSAR case. Holtec would review other 72.48s for the extent of condition and update any evaluations which contain the same conclusions. Holtec would also update the 72.48 training and procedural guidance to make it clear that the representative and benchmarking cases described in the NEI guidance must match exact FSAR scenarios to prevent recurrence of the issue.

For Apparent Violation E, the issue has been fully evaluated in the QI process, and corrective actions have been completed as identified in the proprietary QI attached to this letter.

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Attachment 1 to Holtec Letter 5014990

Summary of Operating Experience Provided by HI-STORM FW Users

Below is a summary of what Holtec received as operating experience for water intrusion into HI-STORM FW Overpacks, specifically focused on the designs that have elevated vents. This information summarizes what was voluntarily provided by users of the HI-STORM FW system. Holtec believes the provided information is representative of industry wide experience.

Utility A: This utility "has no experiences where HI-STORM 100 or HI-STORM FW Overpacks were found with water inside them." Note that this utility does not have any elevated vent designs currently installed.

Utility B: "There have been no observations, or evidence found, of water accumulating or draining from any of the FW HI-STORMs (with or without the lid) in use." This utility has overpacks with the elevated vent design, and has stored the systems with either no plugs or mesh covered plugs on the drain lines since 2022.

Utility C: "Following information from Holtec and questions from the NRC regarding FW raised vent design and drain lines with plugs, [Utility] has monitored empty and loaded HI-STORMs on a periodic basis for water trapped in the annular region for those overpacks with elevated vents and a drain line.

"Site 1 has loaded FW E1 overpacks and has periodically checked the loaded units by removing the solid plug originally provided for the 5 casks loaded in 2023. No water has been observed exiting the drain on loaded casks, these were checked when unloaded casks were checked. The 2023 cask order was for 5 casks and only 3 were loaded with fuel, 2 empties remained on the ISFSI until Feb of 2025 when they were loaded with fuel. During the time period of Dec 2023 to 2024 the overpacks were checked in June 2024 and water was found in one (0406) of the two empty units, no water was noted in the second empty unit. No differences were noted regarding the 0406 unit when compared to the other one.

Overpacks were checked in November of 2024 and a small amount of water was found in one empty unit (0405) and more water in the other empty unit (0406). The solid plugs were removed from all casks in December of 2024. The empty overpacks at Site 1 were stored on the ISFSI without MPC's installed, but the overpack lid and all screens were installed.

[Site 2] received a delivery of 6 HI-STORM FW casks in May of 2023. These empty overpacks were stored on the ISFSI without MPC's installed, but the overpack lid and all screens were installed. The solid plug was installed on these empty units. On December 7, 2023 three of the six units were checked, and no water was present. In April 2024 one (serial number 0418) of the six empties had water exit the drain line when the plugs were removed from each unit. In June of 2024 two weeks in a row June 4 and June 10 all six units were checked. Water was observed to exit the drain line from the same empty unit

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(0418) that water was observed exiting the drain line in April. The other 5 units showed no water when checked. The solid plugs were removed in June 2024.

HI-STORM 0418 was located in the center of the empty units. Site 2 personnel inspected the unit including looking at the top and lid and no abnormalities or differences were noted with this unit. In addition, [Utility C] requested that Holtec review the fabrication records and package to determine if this unit had any differences from the other 5 units and no differences were noted.

[Site 3] loaded the initial 7 FW E1 overpacks in the first quarter 2023. Periodically the solid plug was removed from each unit to verify no water present at a minimum in April and June, no water has been observed exiting the drain during these checks. In February of 2025 the solid plug was permanently removed. "

Utility D: "[Utility D] has 33 fully loaded HI-STORM FW Version E Storage Systems on the ISFSI pad (loaded between 1/8/2021 to 5/21/2021). While performing WR-03958 (Remove Hi-Storm drain plugs and check for standing water) a small amount of water drained from two of the 33 Hi-Storms. Approximately two tablespoons of water drained from the south plug on Hi-Storm 10, which was loaded with a cask on March 7, 2021 . No water drained from the north side plug. Approximately one tablespoon of water drained from the south plug on Hi-Storm 18, which was loaded with a cask on April 2, 2021 . No water drained from the north side plug. The small amount of water which was drained from Hi-Storms 10 and 18 would be too small to impact air circulation through the Hi-Storm."

Utility E: This utility utilizes the HI-STORM 100 system with the similar vent style, so the operating experience is included as it is relevant to the HI-STORM FW overpack design. "In February 2025, [Utility E] verified that there is no water in any of the 73 HI-STORM 100S Version E or Version E1 drain lines. The drain plugs were reinstalled following the inspection. The current plan is to install mesh plugs later this year or early next year."

All of the operating experience provided by sites supports the FSAR statements that blockage of the vents on loaded casks by any normal rainwater intrusion is non-credible, regardless of the lower vent style. Only one utility had evidence of any water in loaded casks, and the amount was well below any level that would block airflow through the system. One utility did note small amounts of water in certain unloaded casks, however, these were not loaded. While the unloaded casks are stored in similar fashion to the loaded casks, they are not subject to the same rules as the loaded casks and the operating experience is not directly applicable.