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**Nuclear Regulatory Commission**  
**Regulatory Conference**

**EA-23-044**

**Holtec International**

**USNRC Headquarters**  
**Thursday, October 26, 2023**

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# Meeting Logistics

This Microsoft Teams meeting will be **RECORDED** and **TRANSCRIBED**. Please be mindful.

Operation of Microsoft Teams Meeting call

Ensure all phones and background noises are **MUTED**

Scheduled break (15-minute)

NRC caucus (Teams Meeting)

Public Question Session (if you called in, please Press **\*1** on phone to “raise hand,” then wait for the Operator to acknowledge you.



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# Public Meeting Disclaimer

The public is invited to observe the meeting and will have one or more opportunities to communicate with the NRC *after* the business portion, but before the meeting is adjourned.



| Topic                                    | Participants  |
|--|---|
| NRC Opening Remarks and Introductions    | Shana Helton,<br>Director, NMSS/DFM   |
| Holtec Opening Remarks and Introductions | Holtec  |
| Enforcement Process                      | Michele Burgess, Sr. Regional Coordinator,<br>NMSS                          |
| Summary of Apparent Violations           | Earl Love, Sr. Transportation and Storage<br>Safety Inspector, NMSS/DFM/IOB |
| Holtec Presentation                      | Holtec  |
| Break and NRC Caucus                     | NRC   |
| Questions and Discussion                 | NRC and Holtec  |
| Holtec Closing Remarks                   | Holtec  |
| NRC Closing Remarks                      | Shana Helton,<br>Director, NMSS/DFM   |
| Public Question and Answer Session       | Public Attendees  |

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# Today's Meeting

- No Final Decision on safety significance or enforcement action will be made today.
- Our NRC Inspection Report (IR07201014/2022-201) provided our *current* understanding and perspective on the issue.
- We Want **Your, Holtec's, Perspective**
  - Any additional details NRC should consider
  - Whether findings/violations occurred
  - Perceived significance of the findings/violations
  - Corrective actions implemented and/or Planned Timeline



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# NRC Enforcement Program

- Inspection and/or Investigation
- NRC Review of Issues
- Exit Meeting with licensee
- Letter to Licensee with w/apparent violations
- Licensee submit written response or participate in a Pre-decisional Enforcement Conference (PEC) 
- NRC Review of ALL Information We are here
- Final Agency Decision, and communication of final decision to Holtec

# Possible Outcomes

- No Enforcement Action Taken
- A Notice of Violation (NOV). An NOV is a written notice that a violation has occurred and how the requirement was violated. A written response from the licensee or CoC may be required for a Notice of Violation.
- A Notice of Violation with a Civil Penalty. The purpose of a civil penalty is to emphasize compliance in a way that prevents future violations and that focuses attention on significant violations.
- And finally, in rare cases, the NRC can issue Orders – which can be used to Modify, Suspend, or Revoke a license.

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# Determine Significance = Severity Level

**SEVERITY LEVEL – I**  
(most significant regulatory concern)

**SEVERITY LEVEL – II**  
(very significant regulatory concern)

**SEVERITY LEVEL – III**  
(significant regulatory concern)

(Escalated Enforcement)

(Non-Escalated Enforcement)

**SEVERITY LEVEL – IV**  
(less significant concern, but more than minor)

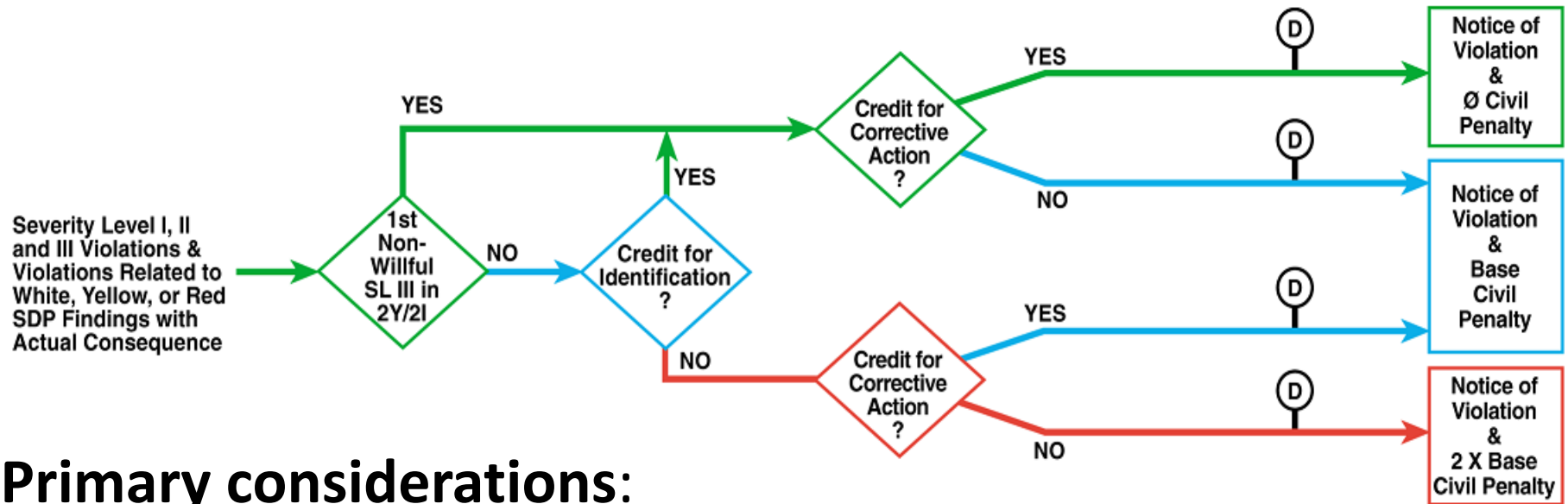


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## Four factors in assigning Severity Level

- Actual Safety Consequences
- Potential Safety Consequences
- Impact on Regulatory Process - Whether the NRC was prevented from carrying out its regulatory responsibilities
- Associated willfulness

# Civil Penalty



## Primary considerations:

1. How the violation was identified
2. The promptness and completeness of any corrective actions taken

If a licensee has not had escalated enforcement in the past 2 years or 2 inspections, the only factor in determining if a civil penalty is assessed is the licensee's corrective actions.

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# Appeal Rights

- Holtec has the right to challenge any NRC determination or action that may be presented.
- Instructions for challenging an NRC enforcement action are included in our transmittal letter and the action itself.

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# Enforcement Outcomes are Public Available

- If NRC takes enforcement action, it will normally be **publicly available** in ADAMS and on NRC's web site.
- In the event that a civil penalty or an order is issued, normally, a **press release** will be issued as well.

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## Background Information

- NRC DFM/IOB inspectors performed a routine fabrication inspection of Holtec International's Advanced Manufacturing Division in Camden, New Jersey December 12-15, 2022.
- The inspection assessed the adequacy of Holtec's fabrication activities for spent fuel storage casks with regard to the applicable requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-level Radioactive Waste, and Reactor related Greater Than Class C Waste."
- During the inspection, the team identified that Holtec implemented a design change from the standard welded basket design to a completely non-welded basket design designated as the Continuous Basket Shim (CBS) variant.
- The NRC inquired about the design change and was informed by Holtec that the design changes to the CBS basket were made through the 72.48 design change process.
- Based on the results of this inspection, the NRC determined that three (3) apparent violations of NRC requirements occurred.
- The details of the inspection are documented in Choice Letter (EA-23-044) and Inspection Report (Accession No. ML23145A175)

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# Apparent Violation No. 1

As required by 10 CFR 72.48(c)(2)(viii), “Changes, tests, and experiments,” Holtec failed to obtain CoC amendments pursuant to 10 CFR 72.244 prior to implementing proposed design changes that resulted in a departure from the method of evaluations described in the HI-STORM 100 and HI-STORM FW Final Safety Analysis Reports (updated) used in establishing the design bases;

Holtec made design changes to four multi-purpose canister (MPC) fuel baskets from the standard MPC 68M, 32M, 89, and 37 baskets to the MPC 68M-continuous basket shims (CBS), MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS basket variants that resulted in a departure from methods of evaluation (MOEs) described in the FSARs (as updated) used in establishing the design bases and failed to submit CoC amendment applications prior to implementing the changes.

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# Apparent Violation No. 1

## Regulatory Guidance for 10 CFR 72.48

The staff used the guidance described in NRC inspection manual chapter 0335, “Changes, Tests, and Experiments,” effective date January 29, 2021; Regulatory Guide (RG) 3.72, revision 1; and Nuclear Energy Institute (NEI) 12-04, “Guidelines for 10 CFR 72.48 Implementation,” revision 2 (endorsed by RG 3.72).

The staff used criteria from these documents (presented below) to assess whether the changes resulted in a departure from an MOE described in the Holtec FSARs:

- If the changes to one or more elements of the MOE yielded results that were not conservative or not essentially the same using the results from the analysis of record,  
  
or
- Whether Holtec’s use of a new or different MOE had been approved by the NRC for the intended application.

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# Details for Apparent Violation No. 1

## For the HI-STORM 100 (FSAR No. HI-2002444), Basket MPC 68M-CBS

1. A change occurred in the way the connections between the fuel basket and the shims were modeled in the Finite Element Analysis (FEA) model for the tipover by not explicitly modeling the CBS bolts.
  - In the original welded basket design, welds between the standard basket and shims were modeled by bonding the corner elements and assigning them the elastic material properties of the weld, effectively modeling the welds in the FEA.
  - The staff considered this an element change because it was a change to the overall FEA model of the tip-over analysis.
2. A change occurred in the strength evaluation of the connection between the basket and the shims by considering a bounding deceleration load of 60 g for the evaluation of the CBS bolts.
  - In the original welded basket design, welds between the basket and shims were evaluated using loads taken from FEA results.
  - The staff considered this a new or different MOE because Holtec changed the calculational framework for evaluating the bolts to one the staff has not reviewed or approved for this purpose.



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# Details for Apparent Violation No. 1

For the HI-STORM 100 (FSAR No. HI-2002444), Basket MPC 68M-CBS (Continued)

3. A change occurred in the way material property models were developed for the basket shims in the tipover FEA by using a bilinear material model and calculating a tangent modulus to account for plastic deformation.
  - In the original welded basket design, the material model for the basket shims was described as elastic with no plastic deformation in the shims.
  - The staff considered this an element change because it was a change to the mathematical model associated with the material performance of the shims.

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# Details for Apparent Violation No. 1

For the HI-STORM 100 (FSAR No. HI-2002444), Basket MPC 68M-CBS (Continued)

4. A change occurred in the tip-over/side drop analysis for the CBS basket shims by comparing the stress in the shims to the ultimate stress of the shim material.
  - In the original welded basket design, basket shims were designed to remain below the yield limit of the shim material.
  - The staff considered this a different MOE because it was a change to the acceptance criteria that was previously approved by the NRC.
  
5. A change occurred to the structural analysis of the CBS basket design by using FEA code engineering simulation software ANSYS, version 17 without comparing the results to the original version to determine if the revised software produced comparable results.
  - In the original welded basket design, ANSYS version 11.0, was used to analyze the standard basket design.
  - The team considered this an element change because a later version of the ANSYS code was adopted.

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# Details for Apparent Violation No. 1

**For the HI-STORM 100 (FSAR No. HI-2002444), Basket MPC 32M-CBS**

6. The lateral impact was assumed to directly transfer load between the shims and the basket without inducing stresses in the bolts.
  - For the standard welded basket design, the welds were evaluated using an applied bounding deceleration load of 100 g.
  - The staff considered this a different MOE because the strength evaluation of the connections between the fuel basket and the shims relied on a different assumption, which was inconsistent with the previous licensing basis assumptions.

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# Details for Apparent Violation No. 1

## For the HI-STORM FW (FSAR No. HI-2114830), Basket MPC 89-CBS and 37-CBS

7. A change occurred in the way the connections between the fuel basket and the shims were modeled in the tipover FEA model by not explicitly modeling the CBS bolts.
  - In the original welded basket design, welds between the standard basket and shims were modeled by bonding the corner elements and assigning them the elastic material properties of the weld, effectively modeling the welds in the FEA.
  - The team considered this an element change because it was a change to the overall FEA model associated with the tip-over analysis.

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# Details for Apparent Violation No. 1

## For the HI-STORM FW (FSAR No. HI-2114830), Basket MPC 89-CBS and 37-CBS (Continued)

8. A change occurred by not evaluating the lateral deflection results from the tip-over analysis against the fuel basket design criteria and concluding that the fuel baskets did not experience any permanent deformation in the active fuel region.
  - Holtec documented maximum local plastic strains reached the rupture strain of the 89-CBS basket and depicted small plastic deformation in the active fuel region of the 89-CBS basket and the MPC 37-CBS basket.
  - The staff considers this a new assumption in the MOE because this change was outside the conditions and limitations of NRC approval.

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# Details for Apparent Violation No. 1

For the HI-STORM FW (FSAR No. HI-2114830), Basket MPC 89-CBS  
and 37-CBS (Continued)

9. A change occurred to the evaluation of differential thermal expansion (DTE) by allowing the combined radial gap between the CBS basket, shims, and enclosure vessel to close.
- In the original basket design, the combined radial gap was maintained to prevent interference stresses from developing.
  - The staff considers this a new assumption in the MOE because this change was outside the conditions and limitations of NRC approval.

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# Summary of Apparent Violation No. 1

- Changes 2, 4, 6, 8 and 9 were different MOEs while 1, 3, 5 and 7 were changes in elements of the MOE.
- Guidance provided in NEI 12-04 considers mixing attributes of a different and existing MOE to be an overall change to an element of an MOE.
- Cumulative impacts from all the changes and changes to more than one element of MOEs were not consistent with the constraints and limitations of the fuel basket's design licensing basis.
- Different aspects of different approved MOEs were adopted and changes were not applied in the same manner as the original MOE.
- Changes were made to elements of MOEs that were not conservative or not essentially the same as the results of the analysis of record and therefore departed from the original MOEs.
- Original MOEs were not adopted in their entirety and were not applied consistently with the applicable terms, conditions, and limitations as the original MOEs approved by the NRC.

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# Apparent Violation No. 2

As required by 10 CFR 72.48(d)(1), “Changes, tests, and experiments,” Holtec failed to maintain records of changes that included written evaluations that provided an adequate bases for the determination that changing to the MPC CBS basket variants did not require CoC amendments pursuant to 10 CFR 72.48(c)(2).

Holtec’s written evaluations failed to provide an adequate bases for the determination that incorporation of the CBS design fuel basket variants did not require a CoC amendment. Holtec did not clearly and thoroughly discuss the impacts on departures from elements of the methods of evaluation (MOEs) described in the FSARs for the original design that were affected by the changes to the CBS design fuel basket variants (MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS). The impacted elements included the mathematical model associated with material performance and tip-over analysis; calculational framework for connections between fuel basket and shims; use of revised version of software; new assumptions; etc.



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# 72.48 Evaluation(s) Conclusion

By not submitting the CBS variant design changes for NRC review and approval, the changes to the existing methods of evaluation impacted the NRC's ability to perform appropriate evaluations to confirm that design changes met safety requirements.

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# Apparent Violation No. 3

As required by 10 CFR 72.146(c), “Design control,” Holtec failed to subject design changes for the MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS basket variants to design control measures commensurate with those applied to the original design.

Holtec failed to subject design changes from the MPC 68M, 32M, 89, and 37 standard basket designs to the MPC 68M-CBS, 32M-CBS, 89-CBS, and 37-CBS basket variants to design control measures commensurate with those applied to the original design and made changes in the conditions specified in the license that required prior NRC approval. Holtec failed to perform adequate tip-over analyses and to model the basket shim bolts for the four CBS basket variants. In addition, material strength comparisons were different and the thermal expansion gap was not maintained in the CBS baskets.

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# Immediate Safety Determination

- Licensees have already loaded and staged some of the casks affected by these apparent violations, and some are planning future loadings.
- NRC staff performed a preliminary safety evaluation to determine the safety impacts associated with continued short-term loading and staging of these casks.
- As a result of this preliminary evaluation, the staff concluded that there are no immediate safety concerns.
- The NRC will make its final safety determination when it receives additional information from Holtec.
- Until a final determination is made regarding whether there is a violation, users who load fuel in canisters using the Holtec CBS basket variant may be at risk of being in violation of regulatory requirements pending the outcome of the NRC enforcement determination.

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# Holtec International Presentation



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# NRC and Holtec International Discussions and Q&A Session

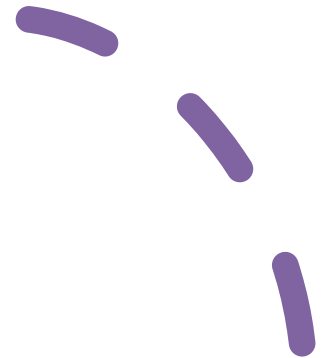
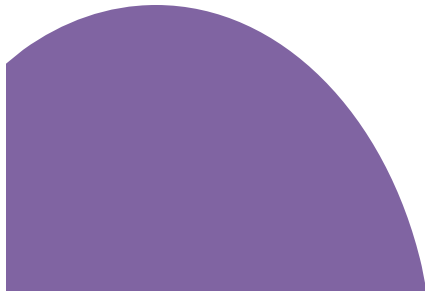


**NRC Regulatory Conference**  
*with*  
**Holtec International**



**NRC Caucus in Session**

*.....Returning shortly*



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# NRC and Holtec International Discussions and Q&A Session



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# Pre-decisional Enforcement Conference

## Closing Remarks

Dr. Kris Singh, Holtec International  
Shana Helton, NRC



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# Opportunity for Public Comments

- NRC has allotted 20 minutes for public comments
- To ask a question or provide a comment **to the NRC about the information discussed today**, please use the raise hand feature in TEAMS or for those on the bridgeline press **\*1** on your phone when prompted by the operator.
- Please clearly state your name and affiliation before you speak

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Thank  
you !

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# REFERENCES

- NRC Publicly Available Information
  - Choice Letter (Accession No. ML23145A175)
  - NRC Presentation Slides (Accession No. ML23297A232)
  - Holtec Presentation Slides (Accession No. ML23297A261)
  - Meeting Feedback form (Accession No. ML011160173)

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## Media Representatives

Please contact:

Mr. David McIntyre, NRC's Public Affairs  
Officer at [David.McIntyre@nrc.gov](mailto:David.McIntyre@nrc.gov)