



September 2, 2009

US Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

Reference: NRC Letter to Holtec dated August 6, 2009- Exercise of Enforcement Discretion

Subject: Reply to EA-09-190

Dear Sir or Madam:

Holtec International has completed its review and evaluation of the non-cited violation as addressed in the above referenced letter. Our responses are provided below:

Summary of Violation:

Part 72.48(c)(2)(vii) and (viii) of 10CFR, requires, in part, that the certificate holder request an amendment prior to implementing a change that would alter a design basis limit for a fission product barrier or result in a departure from a method of evaluation as described the FSAR. The method for evaluating the integrity and performance of the confinement boundary after fabrication was the explicit specification of a set of tests and examinations to confirm MPC design criteria, including the helium leak rate test in Revision 3 of the FSAR. In the HI-STORM 100 System FSAR, Revision 3, Holtec specified that helium leak rate testing of the MPC shell seams and shell-to-baseplate welds was a MPC design criteria and also added that leakage of the MPC was not credible based on the materials, and methods of fabrication and inspection. In Chapter 9 of the FSAR, Holtec identified helium leak rate testing as one of the tests performed to demonstrate integrity of the MPC confinement boundary. The NRC accepted this approach and the original safety evaluation report acknowledged the leak rate testing requirement; performance of this testing formed part of the basis for the staff's determination that confinement and thermal safety limits could be met for the HI-STORM 100 MPCs. This level of assurance was considered necessary for the maximum heat load and source term limits permitted in the HI-STORM 100 certificate of compliance. Based on the above, NRC determined that Holtec was not permitted to eliminate (or alter) the method for demonstrating leaktightness of the MPC confinement boundary without NRC approval.

Length of Time Violation Lasted:

The violation existed from February, 2006 to June 30, 2009. The 72.48 was originally processed in February of 2006. From this time until formal identification of the violation, 107 MPCs were manufactured and loaded without fabrication leakage testing being performed. An additional 95 MPCs were manufactured without a fabrication leakage test and have either been shipped to the

LIMS501

LIMS5



site but were not loaded or have been in storage at Holtec's Manufacturing Division. The fabrication leakage testing was incorporated back into the manufacturing process for MPCs beginning manufacturing on July 1, 2009.

Root Cause:

The root cause of the violation is an inadequate 72.48 procedure which was developed based on Holtec's interpretation of the applicable documents. Holtec's interpretation was due in part to some ambiguity in the regulations and corresponding guidance documents. Holtec's interpretation of the requirements specified in 10CFR72.48, 10CFR72.236(l) and the NEI guidance documents for 72.48 led to Holtec's determination that a 72.48 was the appropriate process for the change. Additional discussion on Holtec's interpretation of each of the two specific 72.48 sections as they relate to the identified change are provided below:

- 1) 10CFR72.48(c)(2)(viii) requires a license amendment if the proposed change or test results in a departure from a *method of evaluation* described in the FSAR used in establishing the design bases or in the safety analyses. 10CFR72.48(a)(2) provides a clear definition for a *departure from a method of evaluation*. The NEI guidance document addresses *method of evaluation* as those strictly dealing with analysis. Based on this, as the removal of the leakage test did not impact any analysis, Holtec believed that a departure from a method of evaluation had not occurred.
- 2) 10CFR72.48(c)(vii) requires a license amendment prior to implementing a proposed change, test or experiment if the change, test or experiment would result in a design basis limit for a fission product barrier as described in the FSAR being exceeded or altered. Based on the fact that Holtec was not modifying the defined leakage rate in the FSAR in conjunction with the technical evaluation on leak tightness as addressed in the above referenced NRC letter, Holtec did not consider that the failure to complete the test would invalidate a design basis limit.

Holtec also considered the following when determining the application of 10CFR72.48(c)(vii): Amendment 2 of the HI-STORM approved the removal of the confinement dose calculations from the FSAR (See FSAR Revision 3) because the MPC was considered to have no credible leakage. Holtec was still performing the leakage testing on the MPC fabrication welds because the MPC was relied on as the secondary containment boundary under Part 71 transportation license. The welds needed to be tested prior to loading into storage because there would not be an opportunity for the welds to be tested again in order to fulfill the requirements of the transportation certificate. When the regulations changed for transportation the test was no longer required. The removal of the test did not change the way the MPC was designed or



manufactured and did not affect the ability of the MPC to perform its function of confining the radioactive contents. The example given in the NEI Guidance in regards to helium leak testing specifically addresses "after closure" and since testing of the closure welds were required per the CoC/TS an amendment would have been required to remove it. Leakage testing of the fabrication welds was not required in the CoC/TS or per ASME code.

Corrective Actions Taken In Response to the Violation and Corrective Steps to Reinstate Helium Leak Rate Testing:

- 1) Leakage testing has been reinstated at the manufacturing facility for all MPCs currently being fabricated or in storage. Leakage tested on newly fabricated MPCs was reinstated on July 1, 2009.
- 2) On site leakage testing of all unloaded MPCs is being scheduled with customers and will be performed prior to loading of the MPC. Completion dates will be dependent on availability of site personnel to provide support, loading schedules etc..
- 3) The 72.48 process is being upgraded by the following actions:
 - a) The checklists used for the 72.48 screening/evaluations has been updated to provide improved clarity and additional questions which will provide better guidance to the preparer.
 - b) The 72.48 procedure will be modified to provide additional cautions/clarifications. Expected completion date: September 25, 2009.
 - c) Classroom training for 72.48 preparers will be provided to address the revised procedure and summarize the issues from this violation. Expected completion date: September 30, 2009.
- 4) The FSAR has been updated to re-establish the helium leakage test of the MPC shell and shell to baseplate welds with acceptance criterion of "leaktight" in accordance with ANSI N14.5. (1×10^{-7} atm-cc/s air)
- 5) Holtec will discuss with NEI the areas where additional detail or clarifications in the guidance documents may be necessary to provide better guidance to users. Expected completion date: October 2, 2009.



Extent of Conditions

An extent of conditions evaluation has been performed in order to determine whether any other previous 72.48s issued by Holtec may have eliminated tests from the FSAR that would not be allowed per 72.48. There were two other 72.48s (numbers 751 and 863) issued in the past that have deleted tests from the FSAR. In both cases, the 72.48 went to the evaluation phase and were determined to meet the criteria to be processed under a 72.48. As part of the actions taken as a result of the violation, both of these 72.48s were reviewed using the new guidance provided by the modified 72.48 checklists. The results of the review concluded that the use of the 72.48 process for the change was still appropriate.

Justification for Continued Use of Loaded MPCs

The function of the loaded MPCs is not affected by the failure to complete a fabrication leakage test and as such is not reportable under either 10CFR21 or 10CFR72.242. A higher leakage rate could affect the heat transfer function of the MPC and add to site boundary dose. Holtec has performed evaluations to show that the MPCs will continue to meet their required functions. A summary of the evaluations performed for each is provided below.

Holtec report HI-2094407 (Thermal Compliance of the HI-STORM 100 System for 40 Year on-Pad Storage with a Postulated Helium Leakage Rate) was issued using a leakage rate of 1×10^{-5} atm-cc/sec. The intent of the report was to evaluate whether the excess helium in the MPCs is greater than the helium that will leak out, assuming a leak of this magnitude for 40 years of storage. The CoC/TS requires a minimum backfill of helium in the MPC. The thermal analysis in the FSAR does not take credit for this full amount and uses a lower value. The difference in the minimum backfill and the amount of helium credited in the thermal analysis is termed the "excess" helium H_i . If H_i is greater than the helium that will leak out ("escaped" helium H_e), the thermal analysis in the FSAR would remain applicable without limitation on initial heat load in the canister. Computations documented in the report showed that the quantity of excess helium (H_i) is greater than the amount of helium which will leak (H_e) by at least one order of magnitude. This is applicable for every CoC amendment and for all affected MPC types. Results are summarized below:



Comparison of Minimum "Excess Helium" at Time = 0 and "Escaped Helium" After 40 Years of Storage						
	CoC #1014-1, 2, 3, or 4			CoC #1014-5		
	MPC-68	MPC-32	MPC-24	MPC-68	MPC-32	MPC-24
Minimum Excess Helium at t = 0 (liters), H_i	1114	815.4	835	842.4	1340.2	1393.3
Total amount of "escaped" helium using upper bound postulated leak rate (liters), H_e	12.6	12.6	12.6	12.6	12.6	12.6
H_i/H_e = Factor of Safety	88	64	66	66	106	110

Based on the above, it was determined that a new thermal analysis was not required, that the fuel cladding temperatures will remain below the ISG-11 Revision 3 limits, and that the fuel will always remain in an inert atmosphere.

A report on the state of the art methodology for computing the effluents' contribution to the site boundary dose was prepared using a significantly higher leak rate of 1×10^{-5} . This report computes the dose using sensibly conservative yet realistic assumptions and results in the limits specific in 72.104 not being exceeded.

The state-of-the-art confinement methodology is based on the USNRC document SMSAB-00-03, "Best Estimate Offsite Dose from Dry Storage Cask Leakage." This method takes into account aerosol deposition inside the confinement boundary (the MPC) so that it is not released. No credit is taken for aerosol deposition outside the confinement boundary subsequent to release; therefore this aerosol remains suspended in the air, which is still a significant conservatism. The users of the loaded MPCs will use this methodology when preparing their 72.104 reports, however the following factors must be considered:

- Atmospheric dispersion factors are calculated for 500 meters using the meteorological conditions specified in ISG-5, Rev 1 for normal/off-normal and accident conditions. Each site should verify that their site-specific atmospheric dispersion factors are bounded by this value. Additional reduction in the dose rate can be achieved by considering site-specific dispersion factors.
- Burnup and cooling time of the stored fuel is chosen to produce a bounding source term comparable to what can actually be stored in the



MPC in accordance with the burnup, cooling time, and decay heat limits of the CoC. No verification of individual fuel assembly burnup and cooling time is necessary.

- A leak rate of 1×10^{-5} atm-cc/sec is used. This is bounding considering that of the 194 MPCs helium leakage tested; the maximum leakage rate detected was 7.78×10^{-7} atm-cc/sec.

The following are postulated bounding doses from effluent release compared to regulatory limits to an individual as a result of the assumed leak rate by MPC type:

	MPC-32 ¹	MPC-68	Regulatory Limit
10CFR72.104(a) - Normal (1 Cask)			
Whole body ADE	4.07E-04 mrem/year	5.05E-04 mrem/year	25 mrem/yr
Thyroid ADE	8.47E-05 mrem/year	1.12E-04 mrem/year	75 mrem/yr
Critical Organ ADE (Max)	2.67E-03 mrem/year	3.25E-03 mrem/year	25 mrem/yr
10CFR72.104(a) - Off-normal (1 Cask)			
Whole body ADE	4.63E-03 mrem/year	4.51E-03 mrem/year	25 mrem/yr
Thyroid ADE	9.46E-04 mrem/year	9.21E-04 mrem/year	75 mrem/yr
Critical Organ ADE (Max)	3.05E-02 mrem/year	3.01E-02 mrem/year	25 mrem/yr
10CFR72.106(b) - Accident (1 cask)			
TEDE	1.02E-01 mrem/30 days	9.95E-02 mrem/30 days	5 rem/30 days
TODE=DDE+CDE (Max)	1.36E+00 mrem/30 days	1.18E+00 mrem/30 days	50 rem/30 days
LDE	7.15E-02 mrem/30 days	6.56E-02 mrem/30 days	15 rem/30 days
SDE	1.71E-02 mrem/30 days	1.59E-02 mrem/30 days	50 rem/30 days

¹MPC-24 doses are bounded by MPC-32

ADE: Annual Dose Equivalent; TEDE: Total Effective Dose Equivalent; TODE: Total Organ Dose Equivalent; DDE: Deep Dose Equivalent; CDE: Committed Dose Equivalent; LDE: Lens Dose Equivalent; SDE: Shallow Dose Equivalent



(Note: The leakage rate of 1×10^{-5} atm-cc/sec used in the above calculations was determined based on it being two orders of magnitude greater than leak tight. This is considered to be significantly conservative based on results of all previous and current fabrication leakage tests performed on MPCs supplied by Holtec. The leakage rate used was agreed upon between Holtec and the NRC on August 6, 2009 (reference Holtec letter to the NRC dated August 6, 2009 (Interim Corrective Action) and NRC response letter dated August 6, 2009)).

In addition to the analysis provided above, leakage tests performed before, during and after the timeframe of the violation provide statistical support of the leakage rate acceptability of the loaded MPCs that did not receive a fabrication leakage test. Specifically no repairs were required to meet the leakage rate acceptance criteria specified by the FSAR for any MPCs manufactured by Holtec. This includes:

- a) 26 MPCs on site or at the fabrication facility leakage tested after identification of violation.
- b) 9 MPCs for site specific licenses tested during the time period when MPCs under Holtec's generic license were not being fabrication leakage tested
- c) Over 180 MPCs leakage tested prior to Holtec eliminating the fabrication leakage test

Reportability Evaluation Under 10CFR21 and 10CFR72.242

Based on the analysis discussed in the previous section, Holtec has determined that no defect exists and that the function of the MPC has not been affected by the failure to complete a fabrication leakage test. As such, this issue is not reportable under either 10CFR21 or 10CFR72.242.

At this time we have started a campaign to complete leakage testing of those unloaded MPCs already delivered to the site as well as those currently in storage at our manufacturing facility. As of September 1st, we have completed leakage testing of 17 on-site MPCs and 9 MPCs in storage or in process of manufacturing at the fabrication facility. The results of these tests showed each of the MPCs was verified to be leaktight in accordance with ANSI N14.5 without any rework required on the welds.

Attached to this letter are two Holtec reports and an affidavit pursuant to 10CFR 2.390 requesting the withholding of the reports from the public.

The two Holtec reports provide a basis for the continued justification of the MPCs loaded without the helium leakage test performed on the fabrication welds.



Holtec Center, 555 Lincoln Drive West, Marlton, NJ 08053

Telephone (856) 797-0900

Fax (856) 797-0909

The thermal report shows that sufficient helium will exist in the canister to ensure fuel cladding remains below ISG-11 rev. 3 limits and in an inert atmosphere. The effluent dose report provides bounding dose rates for normal, off-normal, and accident conditions of storage.

Holtec requests the NRC's review of these documents as part of the determination of continued use so that users of HI-STORM 100 systems containing these MPC may either use the bounding effluent dose rates in the report or the methodology with their site specific parameters to update their 72.212 report.

Please feel free to contact us with any questions or clarifications you may have regarding our response to the non-cited violation.

Sincerely,

Ms. Tammy Morin
Licensing Manager
Holtec International

emcc: Mr. David W. Pstrak, Chief, Rules, Inspection and Operations Branch, SFST, NMSS
Mr. Raymond Lorson, Deputy Director, Technical Review Directorate, SFST, NMSS
Mr. Nader Mamish, Deputy Director, Licensing and Inspection Directorate, SFST, NMSS
Mr. John Goshen, Project Manager, Licensing and Inspection Directorate, SFST, NMSS
HUG
Holtec (Group 1)

Attachment 1: Holtec Proprietary Report HI-2094407R0

Attachment 2: Holtec Proprietary Report HI-2094420R0

Attachment 3: Affidavit Pursuant to 10CFR 2.390

AFFIDAVIT PURSUANT TO 10 CFR 2.390

I, Tammy S. Morin, being duly sworn, depose and state as follows:

- (1) I have reviewed the information described in paragraph (2) which is sought to be withheld, and am authorized to apply for its withholding.
- (2) The information sought to be withheld is Holtec Reports provided in Attachments 1 and 2 to Holtec letter Document ID 5014690, which contains Holtec Proprietary information.
- (3) In making this application for withholding of proprietary information of which it is the owner, Holtec International relies upon the exemption from disclosure set forth in the Freedom of Information Act ("FOIA"), 5 USC Sec. 552(b)(4) and the Trade Secrets Act, 18 USC Sec. 1905, and NRC regulations 10CFR Part 9.17(a)(4), 2.390(a)(4), and 2.390(b)(1) for "trade secrets and commercial or financial information obtained from a person and privileged or confidential" (Exemption 4). The material for which exemption from disclosure is here sought is all "confidential commercial information", and some portions also qualify under the narrower definition of "trade secret", within the meanings assigned to those terms for purposes of FOIA Exemption 4 in, respectively, Critical Mass Energy Project v. Nuclear Regulatory Commission, 975F2d871 (DC Cir. 1992), and Public Citizen Health Research Group v. FDA, 704F2d1280 (DC Cir. 1983).

AFFIDAVIT PURSUANT TO 10 CFR 2.390

- (4) Some examples of categories of information which fit into the definition of proprietary information are:
- a. Information that discloses a process, method, or apparatus, including supporting data and analyses, where prevention of its use by Holtec's competitors without license from Holtec International constitutes a competitive economic advantage over other companies;
 - b. Information which, if used by a competitor, would reduce his expenditure of resources or improve his competitive position in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product.
 - c. Information which reveals cost or price information, production, capacities, budget levels, or commercial strategies of Holtec International, its customers, or its suppliers;
 - d. Information which reveals aspects of past, present, or future Holtec International customer-funded development plans and programs of potential commercial value to Holtec International;
 - e. Information which discloses patentable subject matter for which it may be desirable to obtain patent protection.

The information sought to be withheld is considered to be proprietary for the reasons set forth in paragraphs 4.a and 4.b, above.

- (5) The information sought to be withheld is being submitted to the NRC in confidence. The information (including that compiled from many sources) is of a sort customarily held in confidence by Holtec International, and is in fact so held. The information sought to be withheld has, to the best of my knowledge and belief, consistently been held in confidence by Holtec International. No public disclosure has been made, and it is not available in public sources. All

AFFIDAVIT PURSUANT TO 10 CFR 2.390

disclosures to third parties, including any required transmittals to the NRC, have been made, or must be made, pursuant to regulatory provisions or proprietary agreements which provide for maintenance of the information in confidence. Its initial designation as proprietary information, and the subsequent steps taken to prevent its unauthorized disclosure, are as set forth in paragraphs (6) and (7) following.

- (6) Initial approval of proprietary treatment of a document is made by the manager of the originating component, the person most likely to be acquainted with the value and sensitivity of the information in relation to industry knowledge. Access to such documents within Holtec International is limited on a "need to know" basis.
- (7) The procedure for approval of external release of such a document typically requires review by the staff manager, project manager, principal scientist or other equivalent authority, by the manager of the cognizant marketing function (or his designee), and by the Legal Operation, for technical content, competitive effect, and determination of the accuracy of the proprietary designation. Disclosures outside Holtec International are limited to regulatory bodies, customers, and potential customers, and their agents, suppliers, and licensees, and others with a legitimate need for the information, and then only in accordance with appropriate regulatory provisions or proprietary agreements.
- (8) The information classified as proprietary was developed and compiled by Holtec International at a significant cost to Holtec International. This information is classified as proprietary because it contains detailed descriptions of analytical approaches and methodologies not available elsewhere. This information would provide other parties, including competitors, with information from Holtec International's technical database and the results of evaluations performed by Holtec International. A substantial effort has been expended by Holtec International to develop this information. Release of this information would improve a competitor's position because it would enable Holtec's competitor to copy our technology and offer it for sale in competition with our company, causing us financial injury.

AFFIDAVIT PURSUANT TO 10 CFR 2.390

- (9) Public disclosure of the information sought to be withheld is likely to cause substantial harm to Holtec International's competitive position and foreclose or reduce the availability of profit-making opportunities. The information is part of Holtec International's comprehensive spent fuel storage technology base, and its commercial value extends beyond the original development cost. The value of the technology base goes beyond the extensive physical database and analytical methodology, and includes development of the expertise to determine and apply the appropriate evaluation process.

The research, development, engineering, and analytical costs comprise a substantial investment of time and money by Holtec International.

The precise value of the expertise to devise an evaluation process and apply the correct analytical methodology is difficult to quantify, but it clearly is substantial.

Holtec International's competitive advantage will be lost if its competitors are able to use the results of the Holtec International experience to normalize or verify their own process or if they are able to claim an equivalent understanding by demonstrating that they can arrive at the same or similar conclusions.

The value of this information to Holtec International would be lost if the information were disclosed to the public. Making such information available to competitors without their having been required to undertake a similar expenditure of resources would unfairly provide competitors with a windfall, and deprive Holtec International of the opportunity to exercise its competitive advantage to seek an adequate return on its large investment in developing these very valuable analytical tools.

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Document ID 5014690
Non-Proprietary Attachment 3

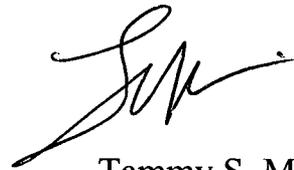
AFFIDAVIT PURSUANT TO 10 CFR 2.390

STATE OF NEW JERSEY)
) ss:
COUNTY OF BURLINGTON)

Ms. Tammy S. Morin, being duly sworn, deposes and says:

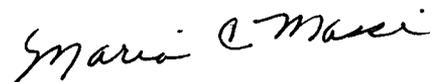
That she has read the foregoing affidavit and the matters stated therein are true and correct to the best of her knowledge, information, and belief.

Executed at Marlton, New Jersey, this 31st day of August, 2009.



Tammy S. Morin
Holtec International

Subscribed and sworn before me this 31st day of August, 2009.



MARIA C. MASSI
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires April 25, 2010