HOLTEC INTERNATIONAL

Holtec Center, One Holtec Drive, Marlton, NJ 08053
Telephone (856) 797-0900
Fax (856) 797-0909

January 30, 2014

USNRC Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-001
ATTN: Glenn M. Tracy, Director
Office of New Reactors

Holtec International
PROJ0798

Subject: Holtec International Voluntary Response to Regulatory Issue Summary (RIS) 2013-18, "Licensing Submittal Information and Design Development Activities for Small Modular Reactor Designs"

References: [1] RIS 2013-18, dated November 15, 2013

Dear Mr. Tracy:

This letter transmits Holtec International's voluntary response to the referenced Regulatory Issue Summary.

Enclosures 1 and 2 contain Holtec's non-proprietary version and proprietary version of this response, respectively. Enclosure 3 to this letter is an affidavit prepared in accordance with 10 CFR 2.390 requesting that Enclosure 2 be withheld from public disclosure due to its proprietary nature.

If you have any questions, please contact me at 856-797-0900, ext. 3924.

Sincerely,

Mark Beaumont

Mark Beaumont, Director
Small Modular Reactor Licensing
Holtec International

cc: Michael Mayfield, USNRC
Stewart Magruder
Jan Mazza, USNRC
Thomas Marcille, Holtec International

Enclosures:

Enclosure 1: Response to RIS 2013-18 (Non-proprietary)
Enclosure 2: Response to RIS 2013-18 (Proprietary)
Enclosure 3: Affidavit Pursuant to 10 CFR 2.390 to Withhold Information from Public Disclosure

TOID
NRD

AFFIDAVIT PURSUANT TO 10 CFR 2.390

I, Mark D. Beaumont, 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 information provided in Enclosure 2 to Holtec letter Document I.D. 2108010. This Enclosure 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).

(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.b and 4.c, above.

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(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 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.

(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.

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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.

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

Mark D. Beaumont, being duly sworn, deposes and says:

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

Executed at Marlton, New Jersey, this 30th day of January, 2014.

Mark D. Beaumont
Holtec International

Subscribed and sworn before me this 30th day of January, 2014.

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MARIA C. MASSI

MARIA C. MASSI
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires April 25, 2015

Response to RIS 2013-18, "Licensing Submittal Information and Design Development Activities for Small Modular Reactor Designs"

(Non-Proprietary)

Design and Licensing Submittal Information

- ***When (month and year) are applications planned for design-related applications and what NRC action will be requested (i.e., a CP, DC, DA, or ML, or a COL that does not cite a DC or DA)?***

  Response:

  The date for submittal of the Holtec Design Certification Application (DCA) for the SMR-160 design is currently being re-evaluated, and is a function of the design development program and the NRC's evolving DCA 'Acceptance Criteria. Consideration of evolving criteria is important to ensuring that the requisite level of design detail is available to ensure the application is accepted for docketing and accelerated NRC review.

- ***Will the applicants be organized into DCWGs? If known, what is the membership of the DCWG, and which party is the primary point-of-contact designated for each DCWG?***

  Response:

  Holtec is responsible for the design and licensing of the SMR-160. While it is premature to establish a DCWG, Holtec and our nuclear utility partners, PSEG and SCANA/SCE&G, support the DCWG concept and recognize its value to the efficiency of the licensing process. Further, we have established an Executive Advisory Board (EAB) comprised of Chief Operating Officers and/or Chief Nuclear Officers from US nuclear utilities to advise the SMR-160 design development and licensing programs.

  [

  ] 4(b.), 4(c.)

- ***Have protocols been developed to provide coordinated responses for requests for additional information with generic applicability to a design center?***

  Response:

  Not yet established.

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- ***Which applicant that cites the design will be designated as the reference COL applicant, or, alternatively, how will various applications (e.g., CP, DC, or COL applications) be coordinated to achieve the desired design-centered licensing review approach?***

  Response:

  Not yet established.

- ***When (month and year) will CP, COL, or ESP applications be submitted for review? In addition, what are the design, site location, and number of units at each site?***

  Response:

  Not yet established.

- ***Are vendors or consultants assisting in the preparation of the application(s)? If so, please describe their roles and responsibilities for the design and licensing activities.***

  Response:

  Current SMR-160 project work is focused on those engineering and analysis activities necessary to complete the plant design specification and underpinning engineering records, in advance of preparing a Design Certification Application. Holtec contracts with numerous vendors and consultants to support SMR-160 development. Our largest current contracted partner is URS, and their work scope includes design and analysis of numerous mechanical and fluidic plant systems.

Design, Testing, and Application Preparation

- ***What is the current status of the development of the plant design (i.e., conceptual, preliminary, or finalizing)? Has the applicant established a schedule for completing the design? If so, please describe the schedule.***

  Response:

  [

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(Non-Proprietary)

] 4(b.), 4(c.)

We have developed a complete and comprehensive Project Execution Plan (PEP), in addition to a Project Management Plan (PMP). The PEP reflects work, deliverables, milestones, submittals, schedules and budgets associated with a project baseline submitted to DOE with our 2013 SMR cost-sharing application. DOE denied our request, and as such, we are currently reworking our PEP (and associated schedule) to reflect lack of DOE program support.

- ***What is the applicant's current status (i.e., planning, in progress, or complete) for the qualification of fuel and other major systems and components? Has the applicant established a schedule for completing the qualification testing? If so, please describe the schedule.***

  Response:

  Planning/In-progress. [

  ] 4(b.), 4(c.)

  We have developed a major Test Program baseline plan that is coordinated around a fully developed Work breakdown Structure (WBS) and Division of Responsibility (DOR) that includes schedule and budgets. We are in the planning stage for a new physical facility slated for construction in Camden, NJ. The test facility will house those integral and separate effects tests and equipment and components associated with the SMR-160 scaled Integral System Test (IST) and Integrated Containment Test (ICT).

- ***What is the applicant's status (i.e., planning, in progress, or complete) in developing computer codes and models to perform design and licensing analyses? Has the applicant defined principal design criteria, licensing-basis events, and other fundamental design and licensing relationships? Has the applicant established a schedule for completing the design and licensing analyses? If so, please describe the schedule.***

  Response:

  Planning/In-progress. We have defined principal design criteria, Design Basis Events and fundamental licensing relationships. Primary work underway includes [

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(Non-Proprietary)

] 4(b.), 4(c.) The current schedule is being re-baselined, as per the questions above.

- ***What is the applicant's status in designing, constructing, and using thermal-fluidic testing facilities and in using such tests to validate computer models? Has the applicant established a schedule for the construction of testing facilities? If so, please describe the schedule. Has the applicant established a schedule for completing the thermal-fluidic testing? If so, please describe the schedule.***

  Response:

  [

  ] 4(b.), 4(c.)

  As previously stated, we are in the planning stage for a new physical facility slated for construction in Camden, NJ. The test facility will house those integral and separate effects tests and equipment and components associated with the SMR-160 scaled Integral System Test (IST) and Integrated Containment Test (ICT).

- ***What is the applicant's status in defining system and component suppliers (including fuel suppliers), manufacturing processes, and other major factors that could influence design decisions? Has the applicant established a schedule for identifying suppliers and key contractors? If so, please describe the schedule.***

  Response:

  Holtec has established committed relationships with vendors to augment our capabilities.

  A majority of the capital equipment required for the NSSS and ESF systems, as well as non-safety related systems, will be manufactured by Holtec (i.e., steam generators, reactor vessel, containment pressure vessel, air-cooled condensers, feed water heaters, etc.). Holtec currently holds an N-Stamp and has the capability to design and manufacture this equipment in its Manufacturing Division (HMD) facilities near Pittsburgh, PA.

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- ***What is the applicant's status in the development and implementation of a quality-assurance program?***

  Response:

  Holtec has a comprehensive QA Program that meets the requirements of 10 CFR Part 50 Appendix B and NQA-1 that is in use in our dry storage program and is the same QA Program that is implemented for our 1OCFR50 Appendix B work which includes the design and manufacturing of fuel storage racks and ancillary equipment. This program is being adapted as necessary to cover the development of the SMR-160.

  On December 16, 2013 Holtec submitted Revision 2 to Topical Report HI-2135649-NP, "Topical Report on the Quality Assurance Program for Holtec International's Small Modular Reactor Design Certification"; along with responses to the first round of Requests for Additional Information. This topical report is expected to receive NRC approval in early CY2014.

- ***What is the applicant's status in the development of probabilistic risk assessment (PRA) models needed to support applications (e.g., needed for Chapter 19 of safety analysis reports or needed to support risk-informed licensing approaches)? Does the applicant plan to use the PRA for any risk-informed applications (i.e., risk-informed technical specifications, risk-informed inservice inspection, risk-informed categorization and treatment, risk-informed inservice testing, etc.)? What are the applicant's plans for using the PRA models in the development of the design? At what level will the PRA be prepared, and when will it be submitted in the application process?***

  Response:

  The SMR-160 design process is risk-informed at the conceptual design level, and [ ] 4(b.), 4(c.)

- ***What is the applicant's status in the development, construction, and use of a control room simulator?***

  Response:

  [ ] 4(b.), 4(c.)

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(Non-Proprietary)

- ***What are the applicant's current staffing levels (e.g., full-time equivalent staff) for the design and testing of the reactor design? Does the applicant have plans to increase staffing? If so, please describe future staffing plans.***

  Response:

  Holtec International employs approximately 850 nuclear professionals. Approximately 150 work at the Marlton, NJ Technology Center; many of whom are engaged in the SMR-160 development program. Future staffing plans include real and certain growth with respect to applied nuclear engineering skill sets: nuclear physics, thermal hydraulics, civil and mechanical engineering.[ ] 4(b.), 4(c.)

What are the applicant's plans on the submittal of white papers or technical and topical reports related to the features of its design or the resolution of policy or technical issues?

Response:

White papers, technical reports and topical reports are being developed during the design and licensing process for NRC consideration during the Pre-Application licensing phase.

- ***Has the applicant established a schedule for submitting such reports? If so, please describe the schedule.***

  Response:

  During [ ] 4(b.), 4(c.)

  Holtec has a fully developed design and Pre-Application plan. During Pre-Application engagement we will provide further long range details and schedule.

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- ***Will ESP applicants seek approval of either proposed major features of the emergency plans in accordance with 10 CFR 52.17(b)(2)(i) or proposed complete and integrated emergency plans in accordance with 10 CFR 52.17(b)(2)(ii)?***

  Response:

  Not Applicable at this time.

- ***Describe possible interest in the use of the provisions in Subpart F, "Manufacturing Licenses," of 10 CFR Part 52, instead of, or in combination with, other licensing approaches (e.g., DC or DA).***

  Response:

  At this time Holtec fully anticipates submitting a Design Certification Application (DCA) consistent with the provisions of 10 CFR Part 52. We have no plans to pursue any other licensing approaches.

- ***Describe the desired scope of a possible ML and what design or licensing process would address the remainder of the proposed nuclear power plant. For example, would the ML address an essentially complete plant or would it be limited to the primary coolant system that basically comprises the integral reactor vessel and internals?***

  Response:

  Not Applicable.

- ***Describe the expected combination of manufacturing, fabrication, and site construction that results in a completed operational nuclear power plant. For example, what systems, structures, and components are being fabricated and delivered? Which of these are being assembled onsite? Which of these are being constructed onsite?***

  Response:

  [

  ] 4(b.), 4(c.)