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

January 4, 2022

Mr. Chris Vanderpool
Safety, Research, and Quality Manager
Hopewell Designs, Inc.
5940 Gateway Drive
Alpharetta, GA 30004

SUBJECT: HOPEWELL DESIGNS, INCORPORATED REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Vanderpool:

This letter is in response to your application dated November 8, 2021, requesting an amendment to your Sealed Source and Device Registration Certificate NR-1138-D-101-S to authorize the use of the C1610 source.

We do not have sufficient information to complete the review of your application. In the enclosure to this letter, you will find the list of questions and items not addressed in your application.

Please be aware that upon your request, proprietary information submitted to the U.S. Nuclear Regulatory Commission (NRC) may be withheld from public disclosure. To do this, you must follow the procedures in Title 10 of the *Code of Federal Regulations* (10 CFR) Paragraph 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390(b)(1).

We will continue our review upon receipt of this information. If we do not receive your reply within 30 calendar days from the date of this letter, we will consider your application as having been abandoned by you. This action would be without prejudice to the resubmission of another application with the required information.

In accordance with 10 CFR Section 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

If you have any questions, please contact me at (301) 415-4059, or by e-mail at Joseph.Rolland@nrc.gov.

Sincerely,

1/4/2022

X

Joseph Rolland
Mechanical Engineer
Signed by: NRC-PIV

Joseph Rolland, Mechanical Engineer
Materials Safety Tribal and Liaison Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Request for Additional Information

SUBJECT: HOPEWELL DESIGNS, INCORPORATED REQUEST FOR ADDITIONAL INFORMATION

DATED: January 4, 2022

ADAMS ACCESSION NO.: ML21350A446 ***Concurrence Via email**

OFFICE	MSST/MSTB	MSST/MSTB	MSST/MSTB	MSST/MSTB	MSST/MSTB
NAME	JRolland	TBrockington	LSepulveda	THerrera	JRolland
DATE	12/16/2021	12/16/2021	1/4/2022	1/4/2022	1/4/2022

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HOPEWELL DESIGNS, INC.
APPLICATION DATED NOVEMBER 8, 2021
REQUEST FOR ADDITIONAL INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Hopewell Designs, Inc. (Hopewell) application dated November 8, 2021, and determined that additional information is needed. In order to continue with our review, please address the issues listed below. This information is required by Title 10 of the *Code of Federal Regulations* (10 CFR) Section 32.210 and described in the relevant guidance document NUREG-1556, Volume 3, Revision 2, titled "Applications for Sealed Source and Device Evaluation and Registration."

Description/Construction

1. Please confirm that there have been no changes made to G10-1-2600-2SR or G10-2-2600-2SR devices to accommodate the C1610 sealed source, this includes how the sealed source is secured into the device source holders.

2. In your application request you indicated that the reference to the MDS Nordion source model C-161 needs to be corrected. We reviewed Hopewell's application dated November 16, 2015 and Hopewell's response dated April 10, 2016 to our request for additional information. Both documents included multiple references to the MDS Nordion source model C-161. Specifically, in response to question 1 it states that "The SSD (NR-8003-S-830-S) for the C-161 capsule does not specify a recommended working life. Hopewell Designs will have Southwest Research Institute or other comparable laboratory leak check each C-161 capsule per ISO 9978:1992, E2 (6.2.3) and (5.3.1)."

   However, we do note that the application included an engineering drawing for the source manufactured by Best Theratronics model C-161, Type 8 in the November 16, 2015 submission.

   Please address the following questions:
   - Indicate the make and model that is currently being used in the devices.
   - Indicate if Hopewell is still reusing the sources manufactured by MDS Nordion as documented in the registration certificate and supporting documentation.
   - If the correct model currently in use is Best Theratronics C-161, Type 8, please provide the history of use and provide a comparison to the MDS Nordion model C-161.
   - Confirm that the ANSI or ISO classification of the MDS Nordion and Best Theratronics source are the same or provide the source classification for the C-161, Type 8.
   - Confirm that both sources, the MDS Nordion and Best Theratronics, are identical.
   - Confirm how the source should be listed in the registration certificate.
   - Provide supporting documentation for the Best Theratronics source model C-161, Type 8, if different from the one submitted on November 16, 2015. This includes the prototype testing results for the model C-161, Type 8.
   - Please confirm that Hopewell will continue to have either the Southwest Research Institute or other comparable laboratory leak check each C-161, Type 8 sealed source as previously committed.

3. Please provide the results and procedures for the prototype testing of source model C1610 manufactured by Best Theratronics.

4. Please provide the differences, if any, between model C-161, Type 8 currently in use and Best Theratronics C1610.

5. Please provide the maximum activity for G10-1-2600-2SR and G10-2-2600-2SR with the addition of the new Best Theratronics source model C1610.

Quality Assurance (QA)

6. Please discuss any changes that have been made to Hopewell's QA program.