UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4352

MAR 3 0 2005

Martin W. Johnson, M.S.
Radiation Safety Officer
Edward W. Sparrow Hospital
1215 East Michigan Avenue
Lansing, MI 48909-7980

Dear Mr. Johnson:

Enclosed is Amendment No. 92 to your NRC Material License No. 21-01430-01 in accordance with your request. Your license has been issued for a ten year term and will not expire until March 31, 2015. Please note that the changes made to your license are printed in **bold** font.

Please review the enclosed document carefully, as many changes and reformatting have occurred, and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers. If you have any questions concerning this renewal please contact me at either (630) 829-9841 or (800) 522-3025.

A. During my review of your renewal application dated September 30, 2004, and the letters dated February 28, 2005, and March 30, 2005, I noted that the aggregate renewal request had not been fully prepared in accordance with NUREG 1556, Vols. 5 and 7, in that only NUREG 1556, Vol. 9 was apparently used. Full use of all of these documents would have greatly reduced your regulatory burden and enhanced safety by providing for more comprehensive, updated safety procedures and a complete renewal application.

NUREG 1556, Vols. 5, 7 and 9 are available by accessing our website at :

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/

If you need assistance locating these documents on our website please contact me as noted above.

As your application dated September 30, 2004, and the letters dated February 28, 2005, and March 30, 2005, were incomplete in several key respects I renewed your license by continuing your currently licensed documents in Condition No. 21.

If you wish to replace the old documents in Condition No. 21 that are dated prior to September 30, 2004, with current and complete commitments, please address the information described below in section B of this letter. To clarify and resolve the items in question, which will complete your license, a written response should be submitted. Your response should be addressed to my attention and refer to control number 313776 to facilitate proper handling.

Using the NUREG 1556 series documents will help ensure that your licensing correspondence is prepared more completely and in a less burdensome manner.

313776

In preparing your response and all future licensing correspondence please focus on providing the information requested in the Appendix to NUREG 1556, Volumes 5, 7 and 9, entitled "Suggested Format for providing the information requested in items 5 through 11 on NRC Form 313."

It is recommended that you use the suggested responses and model procedure/appendix references whenever possible, appending descriptive information as appropriate. It is advisable to read the corresponding text in the front of each NUREG to ensure a complete understanding of the commitments that you make.

Some general suggestions include not submitting resumes, curricula vitae, college transcripts, any personal, proprietary information, blueprint diagrams, and any extraneous, detailed information and procedures.

If you must deviate from a model procedure or suggested response, it may be possible to simply indicate what the deviation is and still use the model procedure/ suggested response as a "basic" commitment. Descriptive information may be "recycled" from previous documents only so long as it is current, complete information equivalent to the model procedure (as appropriate) and does not contain extraneous material.

It is in your best interests to only provide those commitments, statements, representations and procedures, in a clear and explicit manner, that we require to issue your license. These documents will form the basis for the license in the last condition of the license, called the "tie-down" condition.

You will realize the benefit of a reduced regulatory burden while enhancing safety and maintaining compliance and efficiency if you establish your license in this manner.

In fact, the easiest way to prepare your licensing correspondence is to take copies of each Appendix to NUREG 1556, Volumes 5, 7 and 9, entitled "Suggested Format for Providing the Information Requested in Items 5 through 11 on NRC Form 313" to your copy machine and copy each out directly (or the relevant sections therein).

Read the text in the front of the NUREG that corresponds to each section and simply fill in the checkmarks and blanks on the copied checklist, thereby making your license commitments. Please do not re-type the checklist as errors and omissions may be introduced. If you need to append certain information or provide an alternative procedure, please be sure to incorporate the information in the NUREG, at a minimum, to ensure completeness.

If you have further questions concerning these matters please contact me at (630) 829-9841 or (800) 522-3025.

B. Specific discrepancies concerning the application dated September 30, 2004, and the letters dated February 28, 2005, and March 30, 2005 ("renewal correspondence"), include the following:

1. Your renewal correspondence was silent with respect to continued authorization for materials in 10 CFR 35.500, strontium-90 in Novoste intravascular

brachytherapy (IVBT) devices and phosphorus-32 in Guidant Galileo IVBT devices.

As I assumed this was an oversight I continued all of these authorizations as they appeared on Amendment No. 91, prior to the renewal, including the authorized user authorizations.

If you wish to delete these authorizations please explicitly direct us to do so in your response and support your request accordingly. Support for such requests includes a historical retrospective of the most recent sealed sources procured under the license for each authorization and submitting a copy of an acknowledgment of receipt from the vendors involved or other authorized transferees, showing that each licensed party received your last active sources. 10 CFR 30.41 and 30.51 require this information and we must review it before we can amend your license to remove these authorizations from your license. The vendors or other authorized transferees involved should have sent this to you automatically when you returned the last source/device.

A copy of the last leak test result for each of the last sealed sources procured under each authorization of the license must also be submitted to demonstrate that no residual contamination is present.

2. Your letter dated February 28, 2005, requests deletion of your cesium-137 sealed source inventory, as permitted by 10 CFR 35.400. However, we did not receive a copy of an acknowledgment of receipt from you that the disposal company involved provided to you, showing that the disposal company was licensed and acknowledged receipt of your sources. 10 CFR 30.41 and 30.51 require this information and we must review it before we can amend your license to remove this authorization from your license. The disposal company should have sent this to you automatically when you shipped the sources.

   Therefore I continued authorization for the cesium-137 sealed source inventory on your license at this time under Item 6.D..

3. Your license requests continued authorization for depleted uranium in Item 6.G., in part for use as shielding in the high dose rate (HDR) remote afterloading brachytherapy device. In checking this device on the Sealed Source and Device Registry it appears that your vendor, Nucletron, does not use depleted uranium to shield its devices.

   Please clarify whether this authorization is appropriate and if it is not, please direct us to amend this authorization in your response.

4. Your renewal correspondence requested expanded authorization for Drs. Massin, Janick, Chung, Patrick, Ludema, Tai and Arrington to include sodium iodide I-131 for diagnostic studies. However, no supporting information concerning each physician's training and experience was submitted to complete my review of these requests.

Please submit appropriate information about each physician's training and experience to use sodium iodide I-131 for diagnostic studies, pursuant to 10 CFR 35.392, 35.930 or 10 CFR 35.930, and 10 CFR 35.59, as applicable.

For additional information in preparing your response, please note the enclosed excerpt of the "Statements of Consideration" for revised 10 CFR Part 35, published April 24, 2002, Issue 9 on page 20265. You may also wish to refer to section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Final, for assistance in preparing your response.

Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.790, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

5. Your renewal correspondence was silent with respect to continuing authorizations for Thomas Stefanakos, M.S. as an Authorized Medical Physicist and Subhash C. Sharma, Ph.D. as an authorized user (non-medical use) for the self-shielded irradiator. I assumed this to be an oversight and I continued authorizations for both individuals on the renewed license.

   If it is your intention to delete these individuals from your license please respond with an explicit statement for each directing us to delete them from the license.

6. I could not verify the iodine-125 source from Mentor, Model No. Prostaseed I125 SL requested for your authorization in 10 CFR 35.400.

   Please provide current certification numbers, manufacturers' names and model numbers for each sealed source you wish to possess under 10 CFR 35.400. However, you do not need to resubmit this information for sources already listed in Item 7.D.

7. Please specify the exact locations of use (addresses and room numbers) for the HDR room, the self-shielded irradiator room and the laboratories where chromium-51 and phosphorus-32 are used. We can then amend Condition No. 10 to accurately reflect these authorized locations of use.

8. The description and diagrams of your facilities and equipment in your renewal correspondence were incomplete.

   Please address all appropriate information in NUREG 1556, Vol. 7, Item 8.9.9 and Appendix K for the laboratories where chromium-51 and phosphorus-32 are used.

   Please state whether the room where the HDR device is used has changed with respect to its construction or shielding capability. If it has not, please simply state that the expected exposure levels and shielding calculations currently on file still apply. If any changes have occurred, please provide appropriate revised shielding calculations and supporting information and diagrams to enable us to

independently verify exposure levels.

On the diagram of your HDR room please identify what "H" and "I" refer to, as this information was not provided in your renewal correspondence.

Please describe your radiation monitoring instrumentation and address all appropriate information in NUREG 1556, Vol. 7, Item 8.10.2 and Appendix M.

9. Section 8.21 Item 10 in your renewal correspondence appears to imply that you will not post the information required by 10 CFR 35.610, as the following statement is made: "As this procedure manual is located at the unit's console, posting of the location seems redundant."

   Please be advised that, if you do not intend to post the documents required by 10 CFR 35.610 (c)(1), you must first apply for and be granted an exemption to this regulation. It did not appear to me that the above statement constituted an exemption request. Please contact me if you wish to discuss this item further.

10. For the continued authorization of your self-shielded irradiator program please complete your renewed license in accordance with NUREG 1556, Vol. 5, by addressing section 10.6, "Operating and Emergency Procedures" and section 10.8, "Routine and Non-Routine Maintenance" in your response.

11. For the continued authorization of your research and development program please complete your renewed license in accordance with NUREG 1556, Vol. 7, by addressing section 8.8, "Training For Individuals Working In or Frequenting Restricted Areas," section 8.10.6, "Safe Use of Radionuclides and Emergency Procedures," section 8.10.7, "Surveys" and section 8.11, "Waste Management,"in your response. Appendices J, P, Q and T in NUREG 1556, Vol. 7 may be of use to you in preparing your response.

12. Please clarify the spelling of Michelle Elsesser's name in Condition No. 12. Your letter dated February 28, 2005, spells her last name "Elesser" whereas her name appears on Amendment No. 91 of your license as "Elsesser," which is how I continued it.

C. You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter

will be available electronically in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. The enclosed license document is exempt from public disclosure in accordance with 10 CFR 2.390, because its disclosure to unauthorized individuals could present a security vulnerability.

Sincerely,

Colleen Carol Casey
Materials Licensing Branch

License No. 21-01430-01
Docket No. 030-02009

Enclosure:

Amendment No. 92