UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

July 26, 2013

Robert B. Boyd, D.V.M.
CEO/Director of Life Sciences
Radiation Safety Officer
Northern Biomedical Research, Inc.
1210 Pontaluna Road
Spring Lake, MI 49456

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING NORTHERN BIOMEDICAL RESEARCH, INC. NRC LICENSE NO. 21-26687-01 TERMINATION REQUEST (MAIL CONTROL NO. 580320)

Dear Dr. Boyd:

This refers to your letter dated March 28, 2013 (ML13092A267) regarding Northern Biomedical Research, Inc. U.S. Nuclear Regulatory Commission (NRC) License No. 21-26687-01. In that letter, you requested the NRC to terminate your license because radioactive materials were no longer being used at the facility listed on the license. On May 7, 2013 the NRC contacted you via a telephone call and requested that you provide additional information to support the license termination request, which is documented in a telephone conversation record (ML13203A155). Letter dated May 7, 2013 (ML13133A187) provided your responses to the NRC request for additional information which support your license termination request.

Based on a review of the documents you submitted on March 28, 2013 (ML13092A267) and May 7, 2013 (ML13133A187), the NRC staff has determined that additional information is required to complete the license termination. In particular, the NRC staff needs additional information relating to the facility's current status, the decommissioning surveys performed to demonstrate the facility's suitability for unrestricted use, and the decommissioning records maintained for the facility. The enclosure to this letter contains a detailed list of the requests for additional information necessary to evaluate the license termination request.

The NRC staff requests that Northern Biomedical Research, Inc. provide a response to this request for additional information within 30 days of the date of this letter, so that the license termination request can be completed in a timely manner.

In accordance with Title 10 Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy or proprietary, information so that it can be made available to the Public without redaction.

If you have any questions concerning the enclosed information, please contact Lionel Rodriguez at (630) 829-9609.

Sincerely,

Michael LaFranzo, Senior Health Physicist
Materials Control, ISFSI, and Decommissioning Branch
Division of Nuclear Materials Safety

Docket No. 030-34005
License No. 21-26687-01
Mail Control No. 580320

Enclosure:
As stated

REQUEST FOR ADDITIONAL INFORMATION FOR REVIEW OF LICENSE TERMINATION REQUEST FOR NORTHERN BIOMEDICAL RESEARCH, INC. LICENSE NO. 21-26687-01

Current Status of the Facility

1. Through a review of the cover letter provided on May 7, 2013 (ML13133A187), the NRC reviewer noticed that you had moved to a new facility in September 2012, and had vacated the facility located at 930 W. Sherman Boulevard, Muskegon, MI. In addition, through telephone conversations with members of your staff on July 18 and 19, 2013, the reviewer was informed that you no longer owned the 930 W. Sherman Boulevard, Muskegon, MI facility.

   License Condition Number 10 of your NRC license names the 930 W. Sherman Boulevard, Muskegon, Michigan facility as your location of use.

   Since the 930 W. Sherman Boulevard facility remains on your license, and the NRC is still gathering additional information to support approval of the facility's release for unrestricted use as part of the license termination, please provide the following information regarding the facility's current status:

   - When was ownership of the facility transferred?
   - Who currently owns the facility? Please provide the business contact information for the current owner of the facility including (i.e. name, phone number, email, address, etc.).
   - Is the facility currently occupied? Has the facility been occupied since ownership was transferred? If so, by whom?
   - Could you gain access to the facility?
   - How would you regain control of the facility and control access to it to ensure public health and safety if the facility is found not to be suitable for unrestricted use?

Decommissioning Surveys

2. Through a review of the radiation survey results attached to the NRC Form 314 provided on May 7, 2013 (ML13133A187), the NRC reviewer noted that only H-3 swipe surveys for the Preparation Room, Cage Wash Room, and what appears to be the Necropsy Room were provided to demonstrate compliance with the NRC's decommissioning criteria. License Condition Number 6 authorized use of Hydrogen-3 (H-3), Carbon-14 (C-14), Phosphorus-32, Sulfur-35, and Iodine-125 in unsealed form. Through a review of the license application dated August 22, 2011 (ML112351219), in the "Facility and Proposed Areas of Use Diagrams," the reviewer noted that there were about 20 different planned areas of radioactive material use at the facility.

   10 CFR 30.36(j) requires licensees to conduct radiation surveys where licensed activities were carried out and submit a report of the results of the surveys, or to demonstrate in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E. If radiation surveys are conducted, 10 CFR 20.1501(a)(2) requires, in part, that they be reasonable under the circumstances to evaluate the concentrations or quantities of

residual radioactivity. In addition, if decommissioning surveys are performed, 10 CFR 30.36(j)(2)(ii) requires licensees to specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested when performing radiation surveys to demonstrate compliance with the NRC decommissioning criteria. Finally, 10 CFR 30.36(i) has requirements for how the survey results should be reported.

Therefore, for each location where radioactive material was used at the facility, and for which you chose or choose to perform a decommissioning radiation survey to meet the requirements of 10 CFR 30.36(j), please provide the following:

- A list of the individual radionuclides used and/or stored at each location (each laboratory or room) at the facility
- A discussion on how each radionuclide with a half-life of greater than 120 days used and/or stored at each location is accounted for in the decommissioning surveys for that location
- A justification for excluding radionuclides authorized on your license from decommissioning surveys (i.e. short half-life combined with the time since it was last used, etc.)
- A justification for not performing decommissioning surveys in areas where radioactive material was proposed to be used (locations discussed in the August 22, 2011 license application)
- A justification for the number of samples taken at each location
- A justification for the sample locations chosen and why they are representative of the potential contamination in the locations
- An evaluation of any inaccessible areas that may contain residual radioactivity for which decommissioning surveys cannot be performed (i.e. pipes, air vents, under tiles, behind counters, etc.). (Can also be provided as part of the response to Item Number 3 of this enclosure.)

Also, please provide the following information related to the performance of the decommissioning radiation surveys:

- A copy of the procedure(s) used to perform the decommissioning radiation surveys
- A description of how the survey techniques (i.e. swipes, scan surveys, etc.) implemented for the decommissioning radiation surveys were adequate to detect they types of radiation emitted by the radionuclides used at each location
- A description of the process used to ensure that both fixed and removable contamination were accounted for in the decommissioning surveys
- The threshold you utilized for declaring the locations suitable for unrestricted use
- A description of the instrument(s) used for the surveys
- Certification demonstrating that each instrument used for the surveys was properly calibrated and tested (i.e. for swipe samples counted in a liquid scintillation counter, provide the raw analytical results for the measurements).

Note: Chapters 8 and 9 of NUREG 1757 Volume 1, specifically Figure 8.1, provide an acceptable method for performing surveys to demonstrate compliance with the NRC's decommissioning criteria.

3. Through a review of the documents attached to the NRC Form 314 provided on May 7, 2013 (ML13133A187), the NRC reviewer noted that, in the past, you disposed of radioactive materials through the sanitary sewer in accordance with 10 CFR 20.2003. The NRC reviewer also noted that you used a fume hood at the facility.

   As discussed in Request for Additional Information (RAI) Number 2 above, 10 CFR 30.36(j)(2) requires licensee's to conduct a radiation survey of the premises where licensed activities were carried out or to demonstrate in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E. 10 CFR 20.1402 provides the decommissioning criteria for unrestricted use. It states that a site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a Total Effective Dose Equivalent (TEDE) to an average member of the critical group that does not exceed 25 mrem per year, including that from groundwater sources of drinking water, and that the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA).

   The survey results provided did not include or discuss the dose contribution from any potential residual radioactivity remaining in any drains and associated piping at the facility where radioactive materials were disposed of to the sanitary sewer. In addition, if the fume hood surveyed at the facility was used for radioactive material effluents, the survey results provided did not address residual radioactivity remaining in the ventilation system connected to the fume hood.

   Therefore, please provide additional information on how any remaining residual radioactivity is accounted for in your demonstration that the site is suitable for unrestricted use in accordance the NRC's decommissioning criteria for (1) drains and associated piping used for sewer releases, (2) any fume hoods and associated ventilation systems (if used for effluents), (3) any other inaccessible areas which may contain residual radioactivity.

Decommissioning Records

4. As discussed in RAI Number 3 above, you disposed of radioactive materials through the sanitary sewer and used a fume hood at the facility.

   10 CFR 30.51(d) requires licensees, prior to license termination, to forward to the NRC waste disposal and environmental effluent records required to be maintained by 10 CFR 20.2108 and 20.2103(b)(4), respectively. 10 CFR 20.2108 requires, in part, that licensees maintain records of the disposal of licensed materials made under 10 CFR 20.2002, 20.2003, 20.2004, and 20.2005. 10 CFR 20.2103(b)(4) requires, in part, that licensees maintain records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

   Therefore, please provide all the waste disposal and environmental effluent records maintained in accordance with 10 CFR 20.2108 and 20.2103(b)(4), respectively, as required by 10 CFR 30.51(d). The records shall include all the records maintained since the original license was issued.

5. Through a review of the documents attached to the NRC Form 314 provided on May 7, 2013 (ML13133A187), the NRC reviewer noted that not all the records required to be forwarded to the NRC per 10 CFR 30.51(f) were included.

   10 CFR 30.51(f) requires licensees, prior to license termination, to forward the records required by 10 CFR 30.35(g) to the appropriate NRC Regional Office. 10 CFR 30.35(g) requires, in part, that licensee's keep records of information important to the decommissioning of a facility until the site is released for unrestricted use. 10 CFR 30.35(g)(1) through (4) provide the information the NRC considers important to decommissioning.

   Therefore, please provide the records required to be maintained by 10 CFR 30.35(g) and required to be forwarded to the NRC by 10 CFR 30.51(f). Records that fall under the scope of 10 CFR 30.35(g) that have been previously transmitted to the NRC in other submittals need not be forwarded, but references to these records should be made when replying to this request.