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DANIELLE SHEEN, INTERIM EXECUTIVE DIRECTOR

March 30, 2018

Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

RE: **Request for Exemption from Public Dose Limits for Certain Caregivers of Hospital Patients**
Materials License No. 21-00215-04 (University of Michigan)

Materials Licensing:

The University of Michigan (U-M) is requesting an exemption from the public dose limit in 10 CFR 20.1301(c), increasing the dose limit for certain caregivers of hospital patients from 500 mrem to 2 rem per therapy. In accordance with NRC Regulatory Issue Summary (RIS) 2006-18, the following information is provided to support this request:

1. Licensee: University of Michigan
   Materials License No. 21-00215-04

2. Authorized User: Kirk A. Frey, M.D. (Chief, Division of Nuclear Medicine)

3. Prescribing Physician: Gregory A. Yanik, M.D.

4. Contact: Mark L. Driscoll (RSO), 734-764-6200

5. Description of the situation necessitating the request:

U-M has administered iodine-131 metaiodobenzylguanidine (MIBG) to patients since 1987, for treatment of neuroblastoma and other conditions. MIBG is administered intravenously in liquid form. The administered activity is based on the weight of the patient, but typically ranges 200-500 mCi for pediatric patients.

Until 2016, U-M restricted the participation of caregivers, allowing them only to visit with the patient for mental health support reasons. In contrast, other medical centers require or allow caregivers to participate in basic care of MIBG patients, in part to maintain occupational doses as low as reasonably achievable (ALARA).

Due to changes with the MIBG program at U-M (including the use of a new isolation room and nursing staff), as well as how patients are referred nationally for treatment, caregivers will now be more involved in the basic care of MIBG patients. Each patient typically has 1-2 caregivers, although it's possible that additional family could be involved, depending on availability. U-M restricts the participation of caregivers; only one caregiver at a time is allowed in the isolation room.

6. Expected duration and needed starting date of exemption:

   Indefinitely, and effective immediately.

7. Expected dose that may be incurred by family caregivers:

   As noted in RIS 2006-18, experience with caregiver situations has demonstrated that virtually all such cases can be accommodated within the initial/default 2-rem dose limit exemption. This is consistent with our previous experience with caregiver doses, as well as various published articles on the topic. However, family caregivers at U-M were not previously involved in the care of MIBG patients. We fully expect caregiver doses to be well below 2 rem, and likely below 500 mrem per therapy.

8. Description of the control program and additional measures that will be implemented to monitor and control family caregiver exposures:

   U-M already maintains an effective program to control occupational and caregiver doses during MIBG therapies. The following additional measures will be implemented to ensure that the 2-rem dose limit is observed:

   a. Caregivers formerly received verbal instruction at the time of administration on radiation safety restrictions (room entry, contamination control, etc.) and maintaining doses ALARA. With their expanded role in basic care of the MIBG patient, caregivers will 1) receive information about their role and responsibilities during the informed consent process, in advance of patient admission, and 2) receive written and verbal instruction at the time of administration on radiation safety restrictions and maintaining doses ALARA. This instruction will include radiation safety restrictions (e.g., only one caregiver in the room, no eating/drinking in the room, etc.), use of personal protective equipment (PPE), ALARA (time, distance, and shielding), time logging, contamination control and monitoring, use of dosimetry, and emergency procedures. Caregivers will also be required to sign a written acknowledgment, attesting to their understanding of their responsibilities, the radiation safety restrictions associated with their role, and their pregnancy status. A listing of trained caregivers will be maintained on the isolation room door, for surveillance by medical staff.

      Caregivers are typically parents, but it's possible that extended family could be involved, depending on family availability (this is rare). Caregivers must be 18 or older; visitors under age 18 are not allowed for MIBG patients. Pregnant family members are discouraged from being caregivers for MIBG patients.

   b. Consent forms signed by caregivers are maintained on file by the licensee. As noted above, the written acknowledgment of radiation safety instruction will include a declaration that female caregivers are not pregnant, or are aware of the risks of fetal radiation exposure.

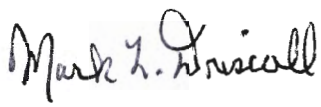
   c. Radiation protection measures intended to control caregiver doses include limitation of basic care activities (feeding, administering oral medications, entertaining); restricting time in the isolation room to necessary basic care activities, including recommended stay times and signing in/out of the room; maximizing of distance from the patient, including no sitting at bedside or in the isolation room, and interacting with the patient by video, when possible; administering care activities and visiting with the patient behind bedside shields; using of PPE in the isolation room, including proper donning and doffing; prohibiting eating/drinking in the isolation room; managing waste and potentially contaminated items; and post-entry contamination surveys and hand washing. In the event of "pressing

emergency conditions," caregivers will be asked to vacate the area or observe from the door of the isolation room, but this cannot be assured.

Both passive and real-time dosimetry will be issued to caregivers, with the real-time dosimeters evaluated at least once per day to monitor the caregiver's accumulated dose during the therapy; this will allow for any corrective actions, should a caregiver's dose accumulate faster than anticipated. Passive dosimetry will function as formal verification that the caregiver's total dose for the duration of the therapy complied with the 2-rem dose limit.

Thank you for your time, effort, and consideration in this amendment request. Please do not hesitate to contact me at (734) 764-6200 or drisc@umich.edu should you have any questions or comments regarding this correspondence.

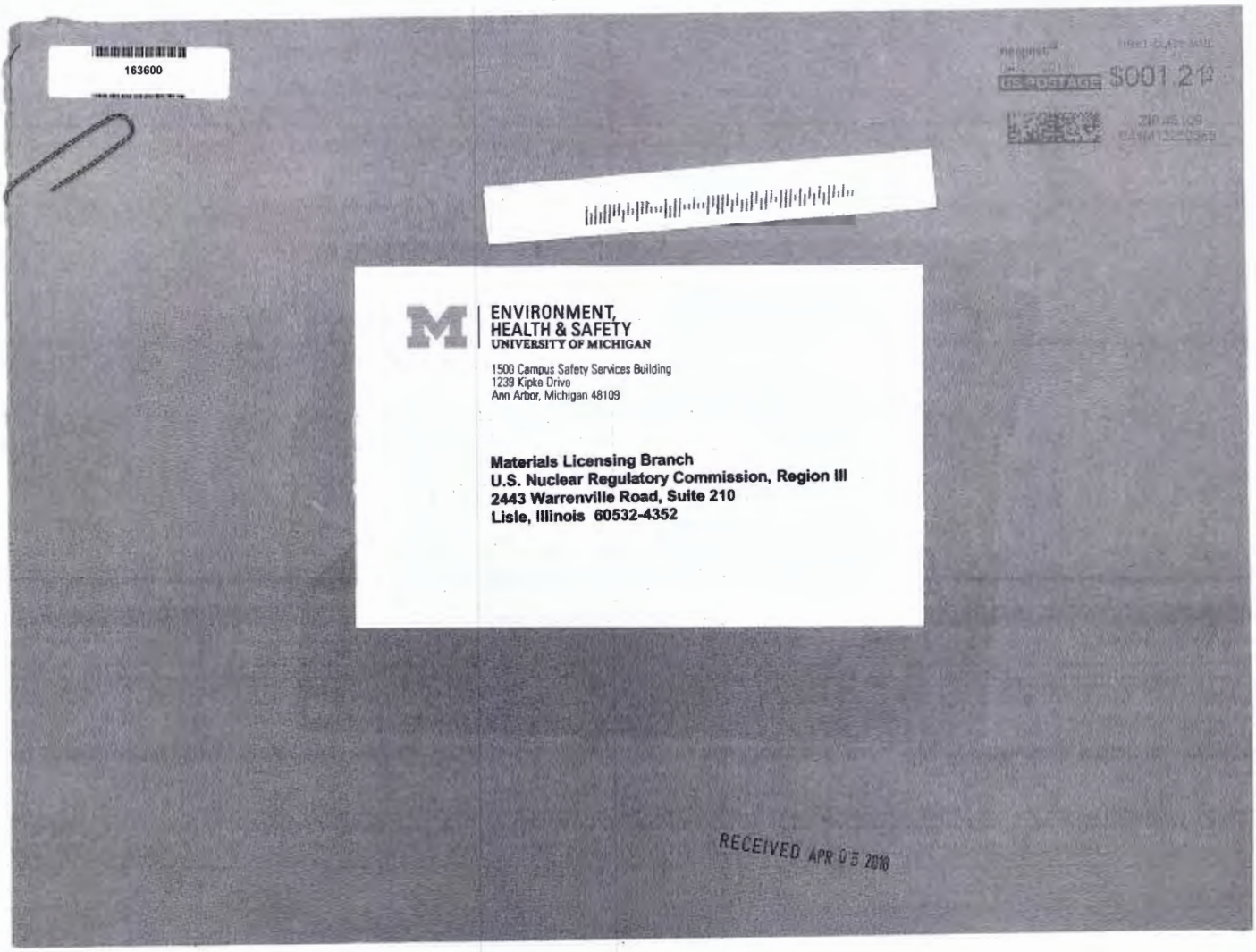
Sincerely,



Mark L. Driscoll
Director / Radiation Safety Officer
Radiation Safety Service / EHS

MLD/kwf

cc: Kirk A. Frey, M.D.
Gregory A. Yanik, M.D.
Ruthann Nichols, Ph.D., Chair, Radiation Policy Committee
Materials License (Broad Scope) No. 21-00215-04 Files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