**From:** Elliott, Robin
**To:** Sarah McKenney (smckenney@childrensnational.org); "knewman@childrensnational.org"
**Cc:** Lanzisera, Penny
**Subject:** Renewal of U.S. NRC License No. 08-03309-01, MCN 586845 Request for Additional Information
**Date:** Tuesday, September 22, 2015 4:04:00 PM

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Docket No. 03001323
License No. 08-03309-01
Control No. 586845

Kurt Newman, M.D.
CEO & President
Children's National Medical Center
111 Michigan Avenue, N.W.
Washington, DC 20010-2970

SUBJECT: CHILDREN'S NATIONAL MEDICAL CENTER, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 586845

Dear Dr. Newman:

Please acknowledge receipt of this communication.

This is in reference to your letter received in the Region 1 office May 4, 2015 requesting to renew Nuclear Regulatory Commission License No. 08-03309-01. In order to continue our review, we need the following additional information:

1. Thank you for providing the room diagrams your diagnostic PET, Hot lab and quiet room. Please provide the following additional information relative to these use facilities:
    a. Provide a description of adjacent locations including those located immediately above and below these areas.
    b. You indicated that your research use of F18 will occur in the same location as the diagnostic activities. Please indicate whether it will be limited to human use using F18 radiopharmaceuticals approved for use under an Investigational New Drug Application by the Food and Drug Administration. If so, it will fall under 35.6 and there is no need to list it separately. Confirm that human research protocols involving material licensed under 10 CFR 35.6 will receive Institutional Review Board approval and informed consent from human research subjects prior to use.
    c. Provide a description of your waste storage area used for research waste.

2. You stated that you, "will use forms found in 10 CFR 35.190, 290, 390 and 392 for review of medical users as authorized medical users." Please clarify that you intend to use NRC Forms 313A (AUD) and 313A (AUT) for reviewing training and experience for medical authorized users.

3. You provided an "Application For Authorization For Use of Radiation Source" and provided a list of the topics that the Radiation Safety Committee will review for non-medical users; however, the minimum criteria for approval for training and experience, and facility and

equipment considerations was not provided. Please forward this information.

4. In Item 9 and 14 you state that daily wipes are performed in Nuclear Medicine and recorded weekly. Please confirm if you intended to state that daily surveys and weekly wipes are performed and recorded. For clinical and research areas, describe surveys required while using radioactive materials. Also, describe any confirmatory surveys conducted by Radiation Safety in research and clinical areas.

5. Confirm that you use the manufacturer supplied calibration sources for use with the gamma counter and liquid scintillation counter.

6. You provided a very detailed and comprehensive Emergency Response Policy and Procedure and Emergency Operating Plan and Hospital Incident Command Roles. Please indicate who receives training relative to this plan and the frequency with which the training is provided. In addition, please note that your Hospital Code Purple (Attachment 2a1), Code Navy (Attachment 2a2), and Code Orange (Attachment 2a3) documents in your Emergency/Operating Plan were not required to be submitted and will not be tied to your license.

7. Your emergency response plan addressed safety considerations for handling contaminated patients; however, it did not appear to cover the routine day-to-day tasks that Nuclear Medicine staff and researchers will need to know for safe handling of radioactive material. Please provide your detailed procedures for safe use of licensed materials in both medical and non-medical uses. You may adopt Appendix T to NUREG 1556 Vol. 9 Rev 2 for medical uses and Appendix R to NUREG 1556 Vol. 11 for research uses.

8. In Attachment 3b you provided a document entitled "Radioactive Materials Management" Policy Number CH:FS:04b. Please provide the following:
    a. In Section I.B.1 it describes the procedure the Nuclear Medicine Department will use for acquisition, delivery, receipt and inventory of radioactive materials. Will the same procedure be used for research?
    b. In Sections I.B.4 (b), I.B.4 (f) and I.B.4 (h) activities are described which involve the transport of radioactive material off the Children's National Medical Center campus. Please indicate who will prepare the package/documentation for the shipment to be in compliance with the Department of Transportation requirements.
    c. In Section I.B.4(c) disposal by release to the air is referenced. Provide more information regarding anticipated releases to the environment and describe how these releases are estimated and compared to the limits in Appendix B to 10 CFR Part 20.
    d. In Section I.B.4(d) you referenced 10 CFR Part 20 with respect to the requirements for sanitary sewer disposal. Please be advised that these requirements are found in 10 CFR 20.2003 not 10 CFR 20.202 as you have quoted.
    e. In Section I.B.4(d) you state that you will dispose of animal waste in the sanitary sewer. This waste must meet the requirements of being readily soluble or readily dispersible in water. Please confirm.
    f. In Section I.B.4 (e) it lists "Disposal by release to normal trash." Please clarify the "or other dry media" that you have included in this section is limited to dry media used for liquid scintillation counting as described in 10 CFR 20.2005.
    g. In Section I.B.4 (g) you reference conducting a survey following decay for a period a ten half-lives. The survey states it is to verify something but does not state what it is verifying. Please clarify that the survey will verify that the material is at background dose rates prior to incineration.

h. Confirm that you will develop and document detailed Waste Management Procedures to include procedures for disposal by decay-in-storage, disposal of liquids into the sanitary sewerage, compaction (if applicable), and transfer to an authorized recipient. You may find procedures in Appendix V to NUREG-1556, Volume 11 useful in the development of your procedures. In addition, please confirm that you do not incinerate radioactive waste.

9. In your response to Item 9, you indicated that Appendix M of NUREG 1556, Vol. 11, will be used for audits. Confirm that the Radiation Safety staff will perform these audits, and describe the process for resolving audit findings.

10. Authorized User training and experience for Drs. Vyas and Tsai were not required to be submitted since the authorized users may be approved through your Radiation Safety Committee. A cursory review noted:
    a. no training was provided to show Dr. Vyas experience for 35.300 radioactive materials, so her use would be limited to 35.100 and 35.200 uses only unless other training (e.g. I-131) is documented.
    b. Dr. Tsai's recent experience and preceptor for 35.300 uses is limited to I-131 <33mCi.

    Please confirm that you will review this information with your Radiation Safety Committee.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Licensee Toolkits, see our toolkit index page.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 586845. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5076.

In order to continue our prompt review of your application, please respond within **15 calendar days** from the date of this letter.

Regards,

*Robin L. Elliott*

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