

Cardinal Health
Nuclear Pharmacy Services
7000 Cardinal Place
Dublin, OH 43017
614.757.5000 tel



www.cardinalhealth.com

Br. 2

July 31, 2006

U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Re: Cardinal Health Nuclear Pharmacy Services, NRC Radioactive Materials License
Number 34-31064-01MD.

03036977

Attention Licensing:

Please amend the above referenced license(s) to revise the frequency required for required bioassay for handlers of I-131. This change only affects the frequency of bioassay for I-131, and not I-123, and more accurately mirrors the guidelines in NRC Regulatory Guide 8.20. Please see the attached Bioassay Program Proposed Revision.

If you have any questions, please contact me at 614.757.3116.

Sincerely,

A handwritten signature in black ink, appearing to read "Dave Breuning".

Dave Breuning
Health Physicist
Nuclear Pharmacy Services

CC: PRSO, Loc 222, 223
License File Loc 222, 223 (3)

Encl: Bioassay Program Proposed Revision

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REGION 1
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NMSS/RGNI MATERIALS-002

Bioassay Program Proposed Revision

Our current bioassay program states that the following individuals must perform a bioassay:

- a) All individuals that handle an open form of quantities of radioactive iodine greater than or equal to those quantities shown in Table 1 of NRC Regulatory Guide 8.20 (see Appendix C for a copy)
- b) Any employee sufficiently close to the handling process (within a few meters, and in the same room as the worker handling the material).

The bioassays should be performed at this frequency:

- a) Individuals compounding I-131 capsules must perform bioassays weekly and individuals compounding I-123 must perform bioassays between 6 and 24 hours post-handling.
- b) Individuals who are not on a regular bioassay program, but have assisted in decontamination, for example after a spill, shall complete a bioassay between 6 and 24 hours post-exposure.

Upon review of NRC Regulatory Guide 8.20 we have determined that the bioassay frequency schedule can be modified. The proposed changes are as follows:

Individuals whom handle I-131 will be divided into two categories, **frequent and infrequent** handlers. A frequent handler is defined as an individual whom handles I-131 or is sufficiently close to the handling process once every two (2) weeks or more often. An infrequent handler handles I-131 less frequently than, once every two (2) weeks.

Frequent handlers must follow the following bioassay schedule:

- a) Between 6-72 hours after initial handling of I-131, a bioassay must be performed.
- b) After the initial bioassay, a biweekly bioassay schedule will be maintained. A bioassay must be performed once every 2 weeks.
- c) After 3 months of the biweekly bioassay schedule an individual can change their bioassay schedule to monthly if they meet the following condition.
 - During the three month biweekly period, they do not exceed thyroid burden action level one for I-131 (0.04 μ Ci).
- d) If at some point during the monthly bioassay schedule an individual exceeds the thyroid burden action level one. They will revert to the biweekly schedule until three consecutive months have passed with a thyroid burden less than action level one.

Infrequent handlers must perform one bioassay within 6-72 hours following handling I-131.

This is to acknowledge the receipt of your letter/application dated

7/31/2006, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment 34-31064-01MD There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 139232.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.