

"OFFICIAL RECORD COPY"

NOV 27 1985

Veterans Administration  
Medical Center  
ATTN: Mr. B. F. Brown, Director  
508 Fulton Street  
Durham, NC 27705

Gentlemen:

SUBJECT: CONFIRMATION OF SITE VISIT AND REQUEST FOR MORE INFORMATION ABOUT  
RENEWAL APPLICATION (Reference: 50730; 030-02630)

This refers to your application dated July 19, 1985, for renewal of License No. 32-01134-01 and confirms discussions during my visit to VA-Durham on November 12 and 13, 1985.

The purpose of my visit was to see your facilities and talk with key personnel involved in the radiation protection program.

Your application and radiation safety program have been reviewed and evaluated against the criteria contained in NRC Regulatory Guide 10.8 (October 1980) and Regulatory 10.5 (Revision 2 dated February 1985). These guides have been provided to Dr. Harris and Mr. Conrad Knight (persons designated as Chairman of VA-Durham Radiation Safety Committee and Radiation Safety Officer, respectively).

Outlined below are our findings and specific request for additional information and/or clarification about your radiation safety program.

1. ALARA Plan. Even though your Radioisotopes Safety manual makes a general commitment to the ALARA philosophy, a written plan signed by VA-Durham management was not provided in your application. We ask that you commit in writing to the model ALARA program in Appendix O of Regulatory Guide 10.8 (October 1980) or provide a written alternative plan for our review.
2. Total Possession Limit and Expected Throughput of Licensed Material. Item 8A of your license specifies a possession limit of 30 millicuries of each byproduct material with Atomic Nos. 3 through 83, inclusive. Please also specify the total possession limit for all materials 3-83, inclusive, and provide an estimate of your annual throughput for these isotopes.
3. Radiation Safety Program. It is our understanding that all radiation safety services are furnished to VA-Durham by Duke University under a contract arrangement. In order to document this for our files, we ask that you provide us a signed copy of the Memorandum of Understanding between VA-Durham and Duke University. The memorandum should specify factors such as:
  - a. Duties and responsibilities of key personnel;

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- b. Manhours which Duke University will devote to the VA-Durham program on a monthly basis;
  - c. Name of person(s) responsible for maintaining radiation protection program and Radiation Safety Committee records;
  - d. A specific commitment stating the type and frequency of survey to be performed by the radiation safety staff. Also, describe the type and frequency of surveys and records required by authorized users;
  - e. A description of the method used by Duke University personnel to brief the Director of VA-Durham concerning the radiation safety program status; and
  - f. A description of the specific working arrangement between VA Medical Center Durham and Duke University with respect to experimental Drug Committee review.
4. Administrative Procedures. It was not clear to us the method used for officially distributing the Radioisotope Safety Manual to users and requiring their compliance. Also, the manual was apparently last revised in January 1980. Since that time, NRC guides and regulations have been revised and thus, the manual may not now be current. Accordingly, we ask that you provide a description of, or a copy of the VA cover letter or memo that will be attached to the manual requiring user compliance. Also, indicate the frequency of routine revision of the manual and provide a commitment as to the expected date of next revision.
  5. Training of Personnel Who Work in or Frequent Restricted Areas. Even though your letter of July 24, 1980 commits you to training these personnel in accordance with 10 CFR 19.12, it is not clear how you confirm that the training has actually been given. Please describe your procedure for verifying that personnel working in or frequenting restricted areas have been trained in accordance with 10 CFR 19.12.
  6. Meeting Frequency and Record Maintenance for Radiation Safety Committee. Please confirm that the committee will meet quarterly and that records of committee meetings will be maintained for the duration of the license and that these provisions will be added to your Radioisotope Safety Manual at the next revision.
  7. Evaluation of Facilities and Equipment Utilized for Radioactive Gases and Potentially Volatile Materials Such As Iodine. At the time of my site visit, the Nuclear Medicine Radioisotope Authorization was not available for my review. Accordingly, I was unable to confirm that the xenon operations and other use of volatile materials had been independently evaluated by the Radiation Safety Officer in accordance with procedures such as those in the appendices of Regulatory Guide 10.8 (October 1980) and 10 CFR 20. Please describe your procedures for insuring that these evaluations are done and the records that will be maintained for documentation.

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8. Waste Disposal by Incineration. Please confirm that only waste generated by VA-Durham will be processed in the VA incinerator.

If you have questions about this letter or our licensing requirements, please call me. My telephone number is (404) 331-5554.

Unless we receive the requested information within one month from the receipt of this letter, we shall assume that you do not wish to continue the renewal process.

Sincerely,

Earl G. Wright  
Senior License Reviewer  
Nuclear Material Safety Section  
Division of Radiation Safety  
and Safeguards

Enclosures:

1. Regulatory Guide 10.5
2. Regulatory Guide 10.8

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11/ /85

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11/21/85

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