

Nuclear Medicine Associates, Inc.

August 26, 1983

William Walker, Jr.
U.S. Nuclear Regulatory Commission
Materials Licensing Branch
Office of Nuclear Material
Safety & Safeguard
Washington, D.C. 20555

Re: New License Application

Gentlemen:

Attached is an application for a new U.S. NRC license. In accordance with the instructions found on page two of Form NRC 313M, we are submitting the following supplementary information.

- (X) Item #10. The methods and frequency for dose calibrator calibration and survey meter calibration are attached.
- (X) Item #12. A detailed description of our personnel training program is attached.
- (X) Item #13. A detailed description of our procedures for ordering and receiving radioactive material is attached.
- (X) Item #14. The procedures for safely opening packages containing radioactive materials as outlined in Appendix F, Licensing Guide 10.8 will be followed with the following exceptions. The procedures shall not be applicable to prepackaged in vitro kits except that radiation labels will be obliterated. In addition, evaluation of final source container wipe smears will be performed with a survey meter listed in Item #9 of this application.
- (X) Item #15. General rules for the safe use of radioactive materials are attached. Additionally, in accordance with 10 CFR 20.501, authorization is requested to dispose of the following records subsequent to NRC inspection of these records:

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1. Dose calibrator accuracy, constancy and linearity checks.
 2. Survey meter calibration records.
 3. Instrument calibration and quality assurance records.
 4. Records of training for occupational and non-occupational personnel.
- (X) Item #16. Emergency procedures outlined in Appendix H will be posted and implemented when necessary. The individuals to be notified and their telephone numbers will also be posted and revised as necessary.
- (X) Item #17. A detailed description of the procedures for performing area surveys and analyzing wipe test smears is attached.
- (X) Item #19. The procedures and precautions for dispensing of therapeutic radiopharmaceuticals are described in this attached Item. In addition, for I-131 therapy preparations:
1. Liquid sources will be opened in a vented hood if available. Gloves, tongs, and lead shielding will be utilized by personnel handling I-131 sources.
 2. Liquid I-131 sources received for redistribution purposes in closed remote displacement containers designed for direct oral administration to a patient will be treated with the same radiation safety precautions as are employed in the use of capsules containing this radionuclide.
 3. The criteria and procedures for a personnel bioassay program will be as described in Regulatory Guide 8.20, September, 1979.
- (X) Item #21. A detailed description of the facilities, equipment and procedures involved in the use of radioactive gases (i.e., Xenon-133) is included.
- (X) ALARA program is attached.

If you have any questions regarding this application, please do not hesitate to call W. Christopher Wagner, from Nuclear Medicine Associates, Inc., Cleveland, Ohio at (216) 641-5799.

Application Reviewed and
Approved by:

Steven Ray Lefevre, RPh, BCNP

Centra-Pharm, Inc.

Date: 10-10-83

Application Prepared by:

W. Christopher Wagner

Consultant
Nuclear Medicine Assoc., Inc.