

file

FEB 07 1985

Nuclear Diagnostics, Inc.
ATTN: Mr. Charles G. Burchett
Secretary/Treasurer
29W281 Calumet
Warrenville, IL 60555

Gentlemen:

Reference: Your Application for an NRC License to Possess and Use Radioactive Materials as a Mobile Nuclear Medicine Service

In order to complete our review, we need additional information and/or clarification of the following items:

1. Authorized Users

In order to obtain authorization for Mins Chen, M.D. to use radio-pharmaceuticals in Groups I, II, and III, you will need to submit documentation of Dr. Chen's training/experience equivalent to that outlined in Sections II, III, IV and V of Appendix A as printed in the enclosed December 2, 1982 Federal Register.

2. Radiation Safety Officer

a. Your application lists two individuals designated as the Radiation Safety Officer (RSO). For clarity and continuity of your radiation safety program, however, only one individual should be designated to perform the functions of the RSO. Please resubmit the name of the one individual who will function as your RSO. If one of the individuals designated will serve as an assistant RSO, please specify this.

b. Specify the duties, authority, and availability of your RSO for your routine program and during emergencies.

3. Please clarify whether you are applying for an NRC license as an institution pursuant to Section 35.11 of 10 CFR Part 35 (enclosed) or a group of physicians pursuant to Section 35.12. If you are applying as an institution, you will need to submit the composition and duties of your Radiation Safety Committee. The composition should be equivalent to that specified in Section 35.11 and the duties and meeting frequency should be equivalent to those specified in Appendix B of the enclosed Regulatory Guide 10.8.

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4. Instrumentation

- a. Your proposed program includes the use of survey meters for several procedures (e.g., area surveys, wipe tests of incoming packages) at multiple sites; however, your application indicates that you have only one low-level survey meter available. Please modify your instrument list to include a sufficient number of low-level instruments so that one instrument will be available during use at each site.
- b. Please modify your area survey, vehicle survey, and package opening procedures to include instructions to use only a low-level survey meter (e.g., CDV-700) since the CDV-715 survey meter indicated in your application is not sufficiently sensitive to detect the levels of contamination for which these procedures are designed.
- c. If you desire to have your instruments calibrated by any NRC/State approved firm as indicated in Item 10 of your application, you will need to specify that these firms are approved by the NRC or Agreement States to perform services such as instrument calibration for other licensees.

5. Facilities

- a. For each place (hospital) where imaging studies are to be performed, please submit a description of how access will be controlled during times when radioactive materials are being used to minimize exposure to individuals other than your technologist or patients.
- b. We cannot authorize you to utilize an area in Cole Hospital, a medical institution, for your hot lab unless this area and its use is administratively separate from the medical institution. This means that your licensed material must be received, possessed, used, stored, and disposed of under your license and you cannot use Cole Hospital's equipment, facilities, procedures or personnel. It appears from your application that you are not administratively separate and are using hospital equipment, facilities and personnel. If we are correct in our assumption, you will need to modify your procedures to indicate a new location for receipt, storage, and preparation of materials. (Section 35.12(b) of 10 CFR Part 35 states, in part, "The Commission will not approve an application by an individual physician or group of physicians for a specific license to receive, possess, or use byproduct material on the premises of a medical institution unless...the physician brings the byproduct material with him and removes the byproduct material when he departs....")

- c. Submit a detailed diagram of the area where your hot lab will be located. Indicate the type, dimensions, position, and thickness of shielding that you will use for use and storage of Tc-99m generators, storage of radiopharmaceuticals, storage of radioactive waste, and preparation of Group III kit radiopharmaceuticals. Identify adjacent areas and show that adequate steps have been taken to ensure that radiation levels in unrestricted areas do not exceed the limits specified in Section 20.105 of 10 CFR Part 20 (enclosed). Indicate the steps you will take to ensure against unauthorized removal of radioactive materials from the area.

6. Intended Use of Material

We cannot authorize you, as a mobile nuclear medicine service, to prepare radiopharmaceuticals at each temporary job-site (i.e., hospital) where imaging studies will be performed as indicated in Section B of the supplementary information portion of your application. Mobile nuclear medicine services are licensed only for preparation of radiopharmaceuticals at a base location and the transport of unit or multi-unit doses to temporary job sites. Please modify your procedures to reflect preparation only at your base location (i.e., hot lab facility).

If any hospitals, listed as temporary job-sites in your applications, desire to continue to prepare radiopharmaceuticals on their premises, the hospital should keep its NRC license and you should delete the hospital from your application.

7. Ordering and Receipt of Material

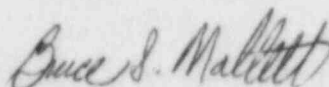
Please clarify who will be ordering materials and verifying possession limits for your license, since Item 13 of your application appears to indicate that a Nuclear Medicine Technologist will be ordering materials from your own company, Nuclear Diagnostics, Inc.

8. Please submit a statement from the administrator/president of Central Community Hospital granting approval for use of radioactive materials by Nuclear Diagnostics, Inc. at his or her facility.
9. Specify the name and qualifications of a physician that will be onsite at the time that radiopharmaceuticals are administered for each job-site. This physician must have at least thirty (30) hours of training in basic radiological handling techniques.
10. Please modify your procedures to include maintenance of all records at your base site.

If you have any questions or require clarification of any of the information stated above, you may contact us at (312) 790-5625.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 77914.

Sincerely,



Bruce S. Mallett, Ph.D., Chief
Materials Licensing Section

Enclosures:

1. 12/2/82 Federal Register
Notice
2. 10 CFR Parts 20 and 35
3. Regulatory Guide 10.8

cc w/o encls:

Ronald D. Edwards, Radiation
Protection Consultants

RIII

86-2/8/85

Mallett/jl
2/8/85

CONVERSATION RECORD

TIME

1:00 (P)

DATE

1/26/85

TYPE

☐ VISIT☐ CONFERENCE☒ TELEPHONE☒ INCOMING☐ OUTGOING

ROUTING

NAME/SYMBOL

INT

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT
WITH YOU

Chuck Burchett

ORGANIZATION (Office, dept., bureau,
etc.)

Nuclear Diagnostics

TELEPHONE NO.

SUBJECT

inquiry on the status of New License

Application CN 77914

SUMMARY

Mr. Burchett stated that he needed his license ASAP due to the fact that Nuclear Diagnostics was losing about \$2000 per week and the possibility of losing their contract with the particular hospital they would be servicing with nuclear medicine procedures. He also stated he didn't know what had happened to the application, since it was prepared in September, 1984. He stated that licensing told him it was received in December. He stated that Ron Edwards, consultant dropped it off.

ACTION REQUIRED

Conference passed on to assigned Reviewer

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

J. L. Made

DATE

1/28/84

ACTION TAKEN

SIGNATURE

TITLE

DATE