RECORD #145

TITLE: Authorized Users' Supervision of Medical Programs

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NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

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MEMORANDUM FOR: J. H. Joyner, Chief, TI Branch, Region I
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FROM: Leo B. Higginbotham, Chief, Radiological Safety Branch, IE

SUBJECT: AUTHORIZED USERS' SUPERVISION OF MEDICAL PROGRAMS

Enclosed is a copy of a recent response by NMSS to our earlier request for a review of the "authorized user" provisions of license conditions of VA hospitals and an apparent conflict therein with our related Interpretive Guide of October 1, 1979. A question on that matter had been raised by Region IV. In our subsequent discussions with NMSS, they agreed to try to clarify their overall philosophy on "authorized users." As indicated in their letter, however, they are currently reexamining their position on the VA Hospital license condition, which clearly has been an exception to their general philosophy. We shall keep you informed of their final conclusions on that matter.

In their "general discussion," NMSS does shed some further light on how they apply the terms "licensed material shall be used by _____" and "licensed material shall be used by, or under the supervision of _____." It is fairly clear that in the latter case, they make a distinction that the person being supervised must be a physician, whereas in the former case, he is not.

We feel that the discussion by NMSS is generally helpful, but certainly does not solve our overall problems in distinguishing between compliance and non-compliance situations on matters relating to authorized users and their supervision in medical programs.

We have considered issuing a revision of our Interpretive Guide, but have decided to hold off until after the completion of the current work by the NMSS Task Force on the Part 35 revision, which, as indicated by NMSS, will address and clarify the authorized user license conditions.

In the interim, if you have any comments on this matter, particularly the NMSS letter, please send them to us.

Leo B. Higginbotham, Chief
Radiological Safety Branch, IE

Enclosure: As stated

cc: FCMSS Staff

CONTACT: A. W. Grella
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NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

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MEMORANDUM FOR: Leo B. Higginbotham, Chief
Radiological Safety Branch
Division of Safeguards & Radiological Safety, IE

FROM: Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and Material Safety, NMSS

SUBJECT: AUTHORIZED USERS' SUPERVISION OF MEDICAL PROGRAMS

In accordance with my October 26, 1981 telephone conversation with Mr. Grella and other members of your staff, we agreed to answer your October 20, 1981 memorandum by considering two questions:

1. The specific question regarding the Veterans Administration's (VA) "nuclear network" involving their facilities at St. Louis, Missouri, Cheyenne, Wyoming and Grand Junction, Colorado.

2. The general question of our Branch's understanding of the two authorized user conditions (i.e., "Licensed material shall be used by _____" and "Licensed material shall be used by, or under the supervision of, _____") as they are used in medical licenses. Please note that our discussion of the more general question should be viewed as an interim response. We believe that the correct way to clarify NRC's position on this matter and to notify licensees of NRC's position is to define the meaning of these two license conditions in 10 CFR Part 35. Dr. William Walker, Leader of the Task Force working on the revision of 10 CFR Part 35, intends to include these definitions in the revised regulations.

Veterans Administration's "Nuclear Network"

To determine the extent of the VA's so-called "nuclear network", we contacted the VA Central Office in Washington, D.C. We learned that the "nuclear network" includes the following VA facilities: Amarillo, Texas; Grand Junction, Colorado; Cheyenne, Wyoming and those listed on the license issued to the St. Louis VA. We have found that as of November 10, 1981, only one specific license of limited scope (Cheyenne, Wyoming VA) differs from the normal nuclear medicine license.

In the case of the Cheyenne, Wyoming VA license, we approved Dr. Donati to act as authorized user (even though he is located in St. Louis) with the understanding that the facility has a qualified on-site radiation safety officer (Mr. Glueck) and that certain procedures will be followed. Condition 16. of the license approves Mr. Glueck and requires that the licensee follow the procedures set forth in his correspondence with us.

We believe that the licensee's correspondence clearly describes such matters as how patients will be selected, how doses will be prescribed, how test data will be evaluated and how the staff at the Cheyenne, Wyoming VA will interact with physicians at St. Louis VA. We recognize that this situation is different from other nuclear medicine facilities; however, we believe that the license contains sufficient commitments for proper inspection.

In the case of the VA hospital at Grand Junction, Colorado the existing license does not have special provisions similar to those contained in the license for the VA at Cheyenne. We have an amendment request from the licensee at Grand Junction that seeks to "clarify" the licensee's participation in the "nuclear network". We have not acted on the licensee's request. As result of your memorandum we are reexamining our position in this matter and plan to confer with VA staff before proceeding. We will keep you informed of our decision in this matter.

The license for the VA Hospital at Amarillo seems to be similar to other nuclear medicine licenses. We have no reason to believe that the authorized physicians are not physically located at the Amarillo facility. From NRC's standpoint there does not appear to be any need for Amarillo to be connected to the "nuclear network". The connection may be for consultation on unusual cases.

The Type A License of Broad Scope for the VA Hospital at St. Louis was renewed in June 1981 based on an application dated December 23, 1980 and a letter dated April 9, 1981. From the information contained in these documents it appears that the Jefferson Barracks, Poplar Bluff (MO) and Marion (IL) facilities are additional places of use that are staffed with authorized users, paramedical personnel, etc. and that operate in the same manner as the main St. Louis facility (i.e., in the same manner as any other nuclear medicine licensee).

It should be noted, though, that attachments to the licensee's 1975 correspondence did provide information pertaining to the "nuclear network" and procedures to be followed. The most recent inspection of this license in 1979 revealed items of non-compliance associated with the licensee's activities at these satellite facilities.

General Discussion of Authorized User Conditions as Used on Medical Licenses

A person named as an authorized user on an NRC license is responsible for ensuring that radioactive materials are handled and used safely and in accordance with NRC regulations and the terms and conditions of the NRC license. For activities involving human use of licensed material, the person must be a physician (see 10 CFR 35.3).

As stated in Enclosure 1, the Commission recognizes the uniqueness of the medical licensee, specifies certain duties (see the proposed 10 CFR 35.32(b)) that the authorized physician-user must either perform himself or may delegate only to another physician and lists other activities (see the proposed 10 CFR 35.32 (c)) that the authorized physician-user may delegate to properly trained paramedical personnel. Note that, in the information preceding the proposed rule in Enclosure 1, the Commission states that it still considers the authorized physician-user to be the "user of radioisotopes" even though he may have delegated certain activities to paramedical personnel. We believe in the continued validity of the position expressed in Enclosure 1.

If we were to take the position that paramedical personnel should be considered as authorized users (i.e., for those activities listed in the proposed 10 CFR 35.32 (c)), then we would have to review the training and experience of these personnel. However, in the medical policy statement published in February 1979 (Enclosure 3) the Commission decided not to become involved in determining the adequacy of training of paramedical personnel.

A. "Licensed material shall be used by _____".

This condition is used on private practice licenses (i.e., those issued pursuant to 10 CFR 35.12). The authorized physician-user has all of the responsibilities of an authorized user on any NRC license. In addition, in his special position as a physician he has the responsibilities listed in the proposed 10 CFR 35.32(b). Also, as indicated in Enclosure 1, he may delegate certain activities to properly trained paramedical personnel. (In Regulatory Guide 10.8 (Revision 1) and the draft teletherapy guide being prepared by M. Wangler, RES, we have used the word "directs" to describe how the authorized user interacts with technologists or other paramedical personnel.)

B. "Licensed material shall be used by, or under the supervision of,_____"

This condition is used primarily on institutional licenses (i.e., licenses issued pursuant to 10 CFR 35.11). As explained in Enclosure 1, this condition provides a means whereby nonapproved physicians under the supervision of an authorized physician-user can obtain training (primarily clinical training) that may enable them to qualify as authorized users.

On licenses with this condition, the authorized physician-user has all of the duties and responsibilities outlined in A. above. In addition he may provide clinical training for nonapproved physicians and may delegate to them the activities listed in the proposed 10 CFR 35.32(B).

In general, we believe that physicians working "under the supervision of" an authorized physician-user should be physicians-in-training. However, for relatively short periods of time a physician may work "under the supervision of" an authorized user while the license is being amended to add his name as an authorized user. We believe that any other physicians involved with the use of radioactive materials should be added to the license.

What constitutes direction of technologists and/or supervision of nonapproved physicians?

We agree with your Interpretive Guide that the wide variety of circumstances found in medical programs makes it impractical to define supervision or direction in terms of numerical times and distances, frequency of written or oral orders, performance of audits, etc. We also agree that inspectors must excercise considerable judgment in implementing guidelines on this matter. Some factors that should be considered are as follows:

1. The authorized physician-user has the same responsibilities as an authorized user on a non-medical license, e.g., ensuring that radioactive materials are handled and used safely and in accordance with NRC regulations and terms of the NRC license; ensuring that personnel such as technologists and physician-trainees have appropriate training and instruction.

2. The authorized physician-user is expected to manage the medical program authorized by the license, to set up the clinical parameters to be used by the nonapproved physicians he supervises with regard to patient selection, dose selection, clinical interpretation and, at a minimum, to review closely the radiation safety procedures used by, and the diagnostic and/or therapeutic procedures performed by, the supervised physician trainee.

3. One of the authorized physician-users should be present on the licensee's premises for on-going and reasonable periods of time. For example, it is not acceptable for the physician-user simply to come in alone at night and read scans; he must have more involvement with the program.

4. If none of the authorized users is physically present on the premises where radioactive materials are used, then one of the users should be available by telephone and should be able to get to the licensee's facility within a short time to handle any emergency.

5. Authorized physician-users who are ill, on vacation, or otherwise unable to fulfill the responsibilities outlined in Item 1 above and in the proposed 10 CFR 35.32(b) should not be considered as supervising or directing other personnel. The "visiting physician" condition (Enclosure 2) has been added to institutional licenses to assist in these situations. Licensees who do not have this condition or whose proposed "visiting physician" does not meet all of the requirements specified in Enclosure 2 should have their licenses amended to add the new user(s).

6. We have recommended to licensees that a physician (not necessarily one of the authorized users) be readily accessible when radioisotopes are administered (e.g., to treat anaphylactic shock). This recommendation is in accordance with the proposed 10 CFR 35.32 (g); see Enclosure 1.

We hope that these comments will be helpful to you. We will keep you informed of our future decisions regarding the VA's "nuclear network" and expect that one or more IE staff working with the Part 35 Revision Task Force will be involved in clarifying these license conditions in the revised regulation.

Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and
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Enclosures:
1. 1973 Proposed Rule Change
2. "Visiting Physician" Condition
3. 1979 Medical Policy Statement

cc: John Cook
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John Glenn, Ph.D.
Bruce Mallett Ph.D.