NOV 1 6 1989

12-00689-07

Docket Number 030-01215

Veterans Administration Medical Center 5901 E. Seventh Street Long Beach, California 90822

Attention: Dean R. Stordahl Medical Center Director

Gentlemen:

٩.

Thank you for your letter of November 7, 1989, in response to our Notice of Violation and Inspection Report Number 89-01, dated August 2, 1989, informing us of the steps you have taken to correct the items which we brought to your attention. Your corrective actions will be verified during a future inspection.

Your cooperation with us is appreciated.

Sincerely,

Original Signed

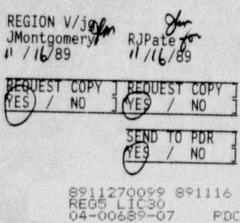
Robert J. Pate, Chief Nuclear Materials Safety and Safeguards Branch

bcc w/copy of ltr dated 11/7/89: Docket File G. Cook A. Johnson B. Faulkenberry J. Martin

J. Zollicoffer

State of California

bcc w/o copy of ltr dated 11/7/89: M. Smith



Medical Center

5901 East Seventh Street Long Beach CA 90822

002

Administration

November 7, 1989

In Reply Refer To: 600/115

U.S. Nuclear Regulatory Commission Document Control Desk Washington, D.C. 20555

Gentlemen:

This is in response to your letter of October 6, 1989 regarding your concerns about administrative support of the Radiation Safety Committee (RSC);

a. The RSC's authority to discipline users who fail to follow your radiation safety procedures or NRC regulations.

The Radiation Safety Committee, as are all committees of the Medical Center, is an advisory committee to the Medical Center Director. The Director has the final authority in granting approval for the use of radioactive materials as well as the disciplining of those who fail to follow NRC regulations or the specifics of our NRC license. The authority of the Director to discipline VA employees is detailed in VA Manual MP-5. With justification, the Medical Center Director may deny any medical employee or official the privilege of using or possessing radioisotopes. He may further subject the individual to formal dismissal as appropriate and defined in VA regulation.

b. Specifically, who in management is responsible for ensuring that the Committee possesses and, if necessary, uses this authority.

Both the Committee and the Radiation Safety Officer are accountable directly to the Medical Center Director. According to VA regulation, the Medical Center Director is the ultimate authority and in this case has delegated the Radiation Safety Committee the power to act in matters of Nuclear Regulatory Commission regulations and the implementations of the Medical Center broad form license.

c. The type of action the RSC is authorized to take when users fail to follow your radiation safety procedures or NRC regulations.

If a user is in violation of NRC regulations or the specifics of our NRC broad form license, the Committee will

Vate

8911270103 891116 REG5 LIC30 04-00689-07 PDC first advise the user of the infraction and will insist and assist, primarily through education and supervision, in bringing the user into conformity. If the user refuses or cannot comply, then the Committee, with the approval of the Medical Center Director, will withdraw the approval for the individual to use or possess radioisotopes. All radioactive materials within the user's possession will be confiscated and the radiation area appropriately decommissioned.

In those cases where users may be in compliance and operating at radiation levels that are below NRC action level, but levels which the Committee deems to be greater than necessary, then the Committee exercising standard ALARA principles, will work with the user to reduce the radiation burden.

This will be accomplished primarily through education and supervision with auditing of the users techniques and practices. Recommendations will be made in order to reduce the radiation burden to a level which the Committee believes is as low as can reasonably be achieved in that setting.

We have increased the radiation safety manpower by 0.5 FTEE. Hopefully these responses satisfy your concerns and answer your questions. If any further clarification or information is felt necessary, we will be happy to comply.

Sincerely yours,

Dean R. Stordanl Medical Center Director

cc: NRC Region V

.

4

004

VETERANS ADMINISTRATION MEDICAL CENTER Long Beach, California May 10, 1988

Medical Center Memorandum No. 00-16

RADIATION SAFETY CONNITTEE AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

1. PURPOSE.

.

To outline the policies and procedures of the Radiation Safety Committee with regard to the management of sealed and unsealed radioactive sources and electrically generated ionizing radiation.

2. INTRODUCTION.

In recent years, rapid developments in Nuclear Medicine have led to an unprecedented expansion in the use of radioactive materials for diagnosis, therapy, and research. As a licensee of the Nuclear Regulatory Commission (NRC) the Veterans Administration — Medical Center, Long Beach has legal as well as moral obligations to provide for the safety of personnel, patients and the public from the potential hazards accompanying the use and handling of radioactive materials.

3. POLICY.

In order to fulfill such obligations it is required that a Radiation Safety Committee be established at the VAMC Long Beach. It is the responsibility of this Committee to evaluate and act upon all proposals for the diagnostic and therapeutic use of radioactive materials within the VAMC, including all radionuclide research proposals. Radioactive materials shall not be used anywhere in the facility without prior approval of the VAMC Radiation Safety Committee (RSC). It is the further responsibility of this Committee to formulate a Radiation Safety Program which monitors the safety aspect of all ionizing radiation applications and to appoint a Radiation Safety Officer (RSO) who will be specifically responsible for effecting this program. The RSO is concerned with the safety aspects of all sources of radionuclide and machine-generated ionizing radiation, and all proposals for usage of radionuclides must have his/her approval, along with the Committee's action. In the absence of the RSO, backup responsibility is delegated to the physicists of Nuclear Medicine Service and Radiation Therapy Service.

4. DEFINITIONS.

Radiations: Those forms of electromagnetic and particulate energy produced by radioactive materials (radiomuclides), x-ray machines, and linear accelerators, which can penetrate tissue and cause ionization which may affect the physiology, anotomy, and genetics of the tissue.

6. RESPONSIBILITIES.

3.

a. The Radiation Safety Officer (RSO) is responsible for the monitoring of radiation usage in all areas of the Medical Center, submitting a report to the Radiation Safety Committee. In the Medical Research Programs, he/she is assisted by the QA Radiation Safety Technician. In the Radiation Therapy Program, he/she is assisted by the physicist of that Service for compliance with NRC Regulations regarding sealed sources. In the Nuclear Medicine Program he/she is assisted by the physicist of that Service regarding clinical applications of unsealed radioactive materials.

The RSO shall have the emergency authority to take immediate and prudent action in his/her best judgement in the alleviation of any situation involving an apparent radiation hazard to patients, personnel, or the general public; the RSO shall remain the controlling official until the emergency ceases, or until relieved by competent higher authority.

Specific responsibilities of the Radiation Safety Officer include the following:

(1) having precise knowledge of the location, inventory, and distribution of all radioactive materials present within the Medical Center and its related structures at all times;

(2) controlling acquisition, uses, and disposition of all such radioactive materials;

(3) assuring compliance of the users with the requirements of regulating and accrediting agencies, as well as local policies and bylaws;

(4) applying Quality Assurance principles to the conduct of the program;

(5) developing, recommending, and implementing policies and procedures in accord with current knowledge;

(6) disseminating radiation safety information to Medical Center personnel by providing both didactic and on-the-job training to users;

(7) reviewing and acting upon all stipulations of the Broad license;

(8) assessing the credentials of potential radionuclide users and advising the Radiation Safety Committee of findings and recommendations; and

(9) monitoring the safety performance and radiation exposure of all radionuclide users.

007

1.

.

.

b. The RSO will call a meeting of the Subcommittee as expeditiously as possible. At a minimum, the RSO, Senior Researcher, and QA Radiation Safety Technician must be present for action to ensue.

c. Credentials of the proposed user and his/her technical staff will be examined. In the absence of sufficient documentation to enable a privileges recommendation in the case of any individual, that person will be interviewed by the Subcommittee.

(1) If no significant knowledge deficiencies are found, radionuclide privileges will be recommended to the Radiation Safety Committee.

(2) In the case of deficient knowledge on the part of the professional applicant, where the proposed user is highly motivated to pursue privileges. he/she will be referred to the Chief. Nuclear Medicine Service, for consideration for training. Training will be documented for the Personnel record and the Office of Education.

(3) In the case of technician knowledge deficiencies, ne/she will be considered for training by the RSO and QA Radiation Safety Technician. Training will be documented for the Personnel Record and the Office of Education.

(4) Re-application for radionuclide privileges will be submitted

to the Subcommittee when training requirements are satisfied. Credentials will be reassessed and recommendations made, as in c.(1) above, as appropriate.

(5) Where recurring generic gaps in knowledge are identified, the ACOS/E will be consulted for the development and implementation of training on a programmatic scale.

5. REFERENCES: VA Manual, MP-5, Supplement Part II, Chapter 2, Change 28 and 31

Bylaws, Rules and Regulations of the Medical Staff, rev. 1988

JCAHO Accreditation Manual for Hospitals, 1988 Edition

10 CFR 30 and 10CFR 35, April, 1987

006

5.

(11) appointing a Credentialing and Privileging Subcommittee, which will review the background, training and experience of clinicians, investigators, and technicians who propose to use radioactive materials. The Subcommittee will make recommendations to the parent Committee concerning approval/disapproval of radionuclide privileges, needs for training, nature and scope of curricula, and conditions under which such privileges may be granted. (See Attachment I.)

7. REFERENCES:

VA Manual M-2, Part XX, Chapter 2, para.2.02

DMAS Circular 10-87-26, dated 4-3-87

Federal Register, Title 10, Chapter 1, Part 33, para, 33.14 and Part 35, para. 35.11 (Code of Federal Regulations - CFR); 4-1-87

10 CFR 35 paragraphs 21 and 22; 4-1-87

8. RESCISSIONS: MCM 00-16, dated January 7, 1985

9. ANNUAL REVIEW DATE: January

10. REVIEW AND REISSUE DATE: April 1991

11. FOLLOW-UP RESPONSIBILITY: Chairman, Radiation Safety Committee

ordahl

DEAN R. STORDAHL Medical Center Director

DIST: A, F (5 to 152)

Attachment I