NRLSD BULLETIN 96-1: MEDICAL ISOTOPES COMMITTEE (MIC), ITS ROLE AND RESPONSIBILITIES IN A LICENSED INSTITUTION

A. ADDRESSEES

All licensees authorized to use radioactive materials for medical purposes.

B. PURPOSE

This bulletin is intended to remind all licensees concerned of their responsibilities to ensure that activities involving radioactive materials are performed in accordance with regulations and license conditions. Regulatory requirements must be met unless otherwise exempted by order or as specifically stated in the license. A specific provision in Parts 12, 13 and 14 of the CPR requires all licensed institutions to form a Medical Isotopes Committee (MIC) that will oversee the medical use of radioactive materials throughout the licensed institutions.

C. DESCRIPTION OF CIRCUMSTANCES

Records of a number of licensees and reports from regulatory inspection activities show that the Medical Isotopes Committee (MIC) has not been established or has failed to perform effectively in many licensed institutions. The MIC is expected to exercise a major role in the effective and safe use of radioactive material in any medical application within the licensed institution.

D. DISCUSSION

The requirement for the establishment of the MIC in all medical institutions licensed by PNRI to use radioactive material is specified in Section 13 of CPR Parts 12,13 and 14, which states that:

" Each medical institution licensee shall establish a Medical Isotopes Committee to oversee the medical use of radioactive materials".

The MIC requires a membership that is described in Section 13 of the CPR. The MIC should be a balanced representation from management, the operations staff and Safety Officers. The licensee will see to it that designated members are qualified and will be able to perform effectively according to the regulation. For new licenses, it is implied that the MIC may be formed during the term of the initial license. This period is deemed sufficient for the licensee to identify and designate the members and for the Committee to be able to establish a program in accordance with the regulatory provision. Thereafter, the MIC will perform accordingly. In addition, in accordance with Section 14 of Part 13 of the CPR, the licensee shall provide the MIC and the RHSO, where applicable, sufficient authority, organizational freedom, and management prerogative, to:

(1) Identify radiation safety problems;

- (2) Initiate, recommend, or provide corrective actions; and
- (3) Verify implementation of corrective actions.

When the licensee has established in writing the authorities, duties and responsibilities of the MIC and the RHSO, he must immediately inform the PNRI and submit copies of such information. The MIC then, will organize itself and develop its program for the conduct of business, meetings, and reporting activities, the licensee will likewise notify and inform the PNRI of the approved MIC program and schedule for the conduct of meetings. In exercising its role to oversee the medical use of radioactive materials throughout the licensed institution, the MIC shall review the licensee's operating and safety procedures, operational records, personnel qualifications, area surveys and personnel experience records, and inventories of radioactive materials. When necessary, the MIC assists in the investigation of incidents and resolution of problems. Any individual who is proposed to become an authorized user, Physicist or RHSO in the license, must secure an endorsement from the MIC before submitting to PNRI such proposal. Other specific functions of the MIC are described in the corresponding section in CPR Parts 12, 13 and 14.

E. REQUIRED LICENSEE ACTION

It is required that licensees review this bulletin and comply with the regulatory requirements of the Institute with regards to the organization and responsibilities of the Medical Isotopes Committee (MIC) to exercise control over the use of radioactive materials in medicine and to prevent any failure of the radiation safety program.

Each licensee is required to submit a written response or reaction to this bulletin and if you have any questions about the information in this bulletin please contact the person listed below.

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