



Greater Community Hospital

Creston, Iowa 50801

May 29, 1979

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Secretary of the Commission  
U.S. Nuclear Regulatory Commission  
Washington, D. C. 20555  
ATTN: Docketing and Service Branch

Dear Sir:

In reference to the recent April 16, 1979, letter which I received last week concerning a proposed amendment to Section 35.11 of 10 CFR Part 35, I would like to make the following comments.

I feel the NRC should get together with the JCAH and decide which we should have; the current Medical Isotopes Committee or the Committee the NRC is proposing. We have at least 14 Committees at our Hospital. What we don't need is another Committee. If the NRC and the JCAH don't get together, that is what we will have.

There are over eight different state and federal agencies with jurisdiction over just the Department of Radiology of our Hospital. This does not count the HSA, PSRO, JCAH and other private organizations which take up a tremendous amount of Physician patient care time with meetings and reports. I cannot fault the reason for the existance of such Committees and organizations from an idealistic point of view, but realistically, the horrendous amount of reports and records required is forcing up the cost of medical care and I predict if it continues, one day I will be found missing and when found will be suffocated under a mountain of charts, reports and rules and regulations.

I sincerely hope the Nuclear Regulatory Commission will consult with the Joint Commission on Accreditation of Hospitals and decide on what type of Committee should govern the activities of facilities using Radionuclides for medical purposes.

Very truly yours,

JED PAUL, M.D.

Enclosure: Nuclear Medicine Service as required by the Joint Commission on Accreditation of Hospitals.

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# Nuclear Medicine Services

## *Principle*

*Nuclear medicine services and consultation shall be conveniently available to meet the needs of the patients as determined by the medical staff.*

**STANDARD I** The mechanism for providing diagnostic and therapeutic nuclear medicine procedures shall be clearly defined.

**INTERPRETATION** The hospital shall have a mechanism for providing nuclear medicine procedures that is adequate for the scope and complexity of the hospital programs offered. When there is an organized nuclear medicine department/service, it shall be directed by a physician qualified in nuclear medicine, and staffed appropriately. Where only limited procedures are performed in the facility, as in the case of in vitro testing in the clinical laboratory, an organized nuclear medicine service shall not be deemed to exist. When nuclear medicine procedures are performed outside the hospital for hospitalized patients, the outside sources must be approved by the medical staff and must meet the requirements of these standards.

The director of the organized nuclear medicine department/service shall be a member of the medical staff. The credentials files of the director and of all other physicians practicing diagnostic and/or therapeutic nuclear medicine in the facility shall reflect their training, experience, and current competence in the specialty. The director shall ensure that proper radiation safety principles and practices are observed and that all technical personnel are qualified for the duties performed. The formal training and on-the-job experience of each nuclear medicine technologist shall be documented. Appropriate credentials shall be required for any pharmacist involved in the preparation of radiopharmaceuticals. When limited nuclear medicine procedures are performed within the facility, supervision shall be provided by a physician who is qualified in nuclear medicine and who shall ensure personnel safety that is compatible with the degree of hazard and in keeping with the safety requirements outlined in this section of the *Manual*.

The services of a health or radiation physicist should be available, at least on a con-

sultant basis, for educational purposes and for safety evaluations of all equipment, and storage and handling practices.

All nuclear medicine personnel should participate in in-service education programs as well as outside workshops and professional society meetings. The extent of participation shall be documented and shall be realistically related to the size of the staff and the scope and complexity of the nuclear medicine services performed. The director shall contribute to the in-service education of nuclear medicine personnel.

The director shall document the evaluation of the services provided, to ensure the optimum degree of quality and safety, as well as to ensure their appropriateness.

All nuclear medicine procedures performed in the facility shall be in accordance with appropriate institutional or individual licensure requirements.

**STANDARD II Nuclear medicine services, when provided within the hospital, shall have adequate space and facilities to meet, with safety, the diagnostic and therapeutic needs of the patients.**

**INTERPRETATION** Space and facilities for the nuclear medicine department/service should include that necessary for the reception, examination, and diagnostic study of patients, as well as for related clerical work and for conferences. Adequate accommodations shall be provided for the clinical care of therapeutic patients. Facilities shall be provided for the safe preparation, storage, and disposal of radioactive materials so that radiation levels in all areas are as low as practicable and do not exceed accepted standards. The nuclear medicine service area shall be protected from sources of interfering radiation.

The type, quantity, and quality of equipment for the nuclear medicine procedures performed shall be adequate to conduct reliable diagnostic studies as determined by the director and the medical staff. Standards having energy radiations equivalent to those of the radionuclides used in patient studies should be utilized for routine calibration, and should be readily available.

**STANDARD III There shall be quality control policies and procedures governing nuclear medicine activities that ensure diagnostic and therapeutic reliability and safety of patients and personnel.**

**INTERPRETATION** All radioactive materials, reagents, and standards shall be prepared, stored, and checked at a defined interval to be determined by the director, to ensure accuracy, patient safety, and precision of results. All reagents must be labeled to indicate identity, date of preparation, and assay. Instrument calibration procedures sufficient to affirm proper performance shall be conducted each day the instrument is used, and the results recorded. All safety survey instruments in the facility should be calibrated at least annually. The recommendations of the National Council on Radiation Protection and Measurements should be known and applied.

Where required by federal, state, or local regulations, by licensure requirements, or by the medical staff, a radioisotope committee shall be established. At least one member of this committee must be a physician experienced in the safe handling of radioisotopes, in the measurement of radioactivity, and in determining radio-

isotope dosage for various patient studies or treatments. Representatives of various fields of specialization should be included on the committee, as determined by the nature of the program being conducted. In larger facilities, this committee may be absorbed into a radiation safety committee. When either of these committees exists, it shall work in cooperation with the hospital safety committee. The committee should meet as often as required, but not less than every six months, and shall maintain written minutes of each meeting. The committee concerned with nuclear medicine activities should have at least the following responsibilities:

- To review all proposals for diagnostic and therapeutic uses of unsealed radionuclides
- To recommend to the medical staff those practitioners having suitable training and experience to perform nuclear medicine procedures
- To develop regulations for the use, transport, storage, and disposal of radioactive materials used in nuclear medicine procedures
- To recommend remedial action when there is failure to observe protection recommendations, rules, and regulations
- To establish rules to guide nursing and other individuals who are in contact with patients receiving therapeutic amounts of unsealed radionuclides; rules relating to the discharge of such patients; and rules to protect personnel involved when such patients undergo surgical procedures or autopsy

Quality control procedures shall be developed to guide personnel in the standardized performance of diagnostic studies and therapeutic procedures, and to ensure that the identity, strength, and integrity of all radiopharmaceutical agents are maintained.

Policies and procedures relating to safety within the nuclear medicine services areas shall be developed and enforced. These shall include as a minimum:

- a requirement for wearing the appropriate exposure-monitoring devices at all times when in the area;
- guidelines to be followed in the event of radioactive contamination of personnel, equipment, or environment;
- a requirement that there be written authority for all nonphysicians who administer radioisotopes parenterally where legally permissible;
- a requirement for security of all "hot" and "decay" areas in order to protect all individuals in the hospital;
- rules prohibiting oral pipetting of radionuclides and eating or drinking in the work areas;
- establishment of an effective radiation protection survey program to be performed at least every six months; and
- protective shielding for syringes, injection vials, and stock sources of radioactivity.

For other than radiation safety requirements, see also the Functional Safety and Sanitation section.

STATEMENT

Communications from the field reveal instances wherein nonradiologist physician members of medical staffs have been granted privileges to practice diagnostic radiology, including the interpretation of certain radiologic studies and the authentication of the official radiologic report that is entered into the patient's medical record.

The standards do not require that all x-rays be read by a radiologist, but they do require that the exercise of radiology privileges be limited to practitioners whose qualifications therefor have been established through the credentialing process.

The specific language related to this function is contained in the interpretations of Standards I (page 155) and V (page 159) of the Radiology Services section of the Accreditation Manual for Hospitals:

"All physicians practicing diagnostic and/or therapeutic radiology in the facility shall be members of the medical staff. Their credentials files shall reflect the training, experience, and current competence required for all aspects of radiologic services in which they are engaged. When privileges to perform specific limited interpretive diagnostic and monitoring radiologic studies have been granted to staff physicians who are not radiologists, such studies should be those of a highly specialized nature, the performance of which requires special qualifications of training and/or experience in the use of the equipment and in the interpretation of results, as well as practice in a field of related diagnostic/therapeutic activities...."

A radiologist shall ordinarily provide an authenticated report for all examinations to enhance consistency and correctness in interpretations and reports of radiologic findings. Reports of specialized procedures performed by staff physicians who are not radiologists may be authenticated by such individuals when they have been granted such privileges through the normal medical staff credentialing mechanism, as provided for in the first paragraph of Standard I...."

It is the intent of the Board of Commissioners that only individuals qualified to render an overall interpretation of any radiologic study should do so, and that in the interest of good patient care, this interpretation be performed in a timely manner. It is not the intent of the Radiology Services standards, as written, to allow all physicians to assume the skills of a qualified radiologist, but rather to acknowledge certain properly credentialed physicians (nonradiologists) using radiologic equipment in the performance of specialized studies and in certain monitoring studies.

However, this official explanation of the intent of the Radiology Services standards does not preclude any member of the medical staff from entering into the medical record as a progress note, an opinion independent of the official interpretive report of any diagnostic radiologic study, particularly in cases where a definitive radiologic clinical interpretation is not possible.

**STANDARD IV** Records required by federal, state, and local authorities, as well as records consistent with competent practice of nuclear medicine, shall be maintained.

**INTERPRETATION** Nuclear medicine diagnostic and therapeutic procedures shall be performed only upon the written request of the responsible physician or a member of the house staff. Such procedures may also be provided for authorized physicians who are not members of the medical staff for their patients who are not being evaluated or treated in the hospital. Reports of nuclear medicine interpretations, consultations, and therapy shall be included in the patient's record; duplicate records should be kept on file in the nuclear medicine department/service. The patient's medical record shall also reflect the identity, date, and amount of radiopharmaceutical used, as well as any specific preparation of the patient. For further requirements relating to medical records, see the Medical Record Services section.

Records to be maintained on radionuclides and radiopharmaceuticals should include at least the following information:

- The dates, amounts, and methods of receipt and disposal
- The supplier and lot number
- The use, date, amount administered, and the identity of any recipient

Instrument log books to be maintained shall include at least the following:

- Calibration records of equipment and monitors showing dates, name of technologist, and sources of reference standards
- Maintenance and repair records, showing dates and sources of service
- The findings of federal, state, or local evaluations or those of a consultant radiation physicist, and the action taken to correct any deficiencies found

Records shall be maintained to show the radiation exposure of all nuclear medicine personnel, as well as the results of routine radiation safety surveys.