

## QUALITY MANAGEMENT PROGRAM

**Purpose:** The Nuclear Medicine will follow these established guidelines to ensure safe and effective testing is provided.

**Policy:**

This program commits the Nuclear Medicine Service to a policy of good practice in the administration of radioactive materials to patients. The elements of this program are based upon:

1. The establishment of clear and concise communication between the technologist and the physician.
2. To provide a system for review of the effectiveness of the communication between the technologist and the physician.
3. To establish a record keeping system to maintain records of instructions, written directives or other written communications, along with reviews and evaluations of their effectiveness.
4. Programs to assure that radioactive materials will be administered as directed by the authorized user: (may also be a physician under the supervision of an authorized user).
5. Written directives are required prior to administration for the following procedures:
  - any teletherapy radiation dose
  - any gamma stereotactic radiosurgery radiation dose
  - any brachytherapy radiation dose
  - any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131
  - any therapeutic administration of a radiopharmaceutical.
6. All workers involved in the medical use of radioactive materials will request clarification from an authorized user if any element of the written directive is unclear, ambiguous, or apparently erroneous.
7. All workers will stop the medical use on a patient and seek guidance if there is an apparent discrepancy in records, observations, or physical measurements that may result in a therapy misadministration or a recordable event (except in emergency situations threatening the patient's well being).

8. Before medical use, the person administering the radioactive material will verify that the medical use is in accordance with the written directive.
9. Before medical use, the person administering the radioactive material will verify that the medical use is in accordance with the written directive.
10. Additional requirements for these precautions requiring written directive.
  - Before writing a directive, the authorized user will personally review the patient's case to establish that the medical use is indicated for the patient.
  - Before administering a radiopharmaceutical, the authorized user will personally make, date and sign a written directive.
11. Any change in the written directive will be made by the authorized user, will be recorded in writing in an appropriate record, and will be dated and signed. NOTE: In an extreme emergency oral revision to a written directive may be accepted provided that it is documented in the patient's chart within 48 hours.
12. After administering a radiopharmaceutical an authorized user will date and sign a written record which certifies the dosage administered, and the agreement, or lack thereof, between the radiopharmaceutical administration and the written directive.
13. Review to evaluate patient administrations, recordable events and misadministration.
  - A review of representative sample of patient's administrations will be conducted at least annually.
  - These reviews will verify compliance with all aspects of the quality management program; 100% compliance with written directives, 100% of recordable events corrective action.
14. The effectiveness of the program is evaluated.
  - Review the frequency and cases of all unsatisfactory administrations for trends and to suggest possible corrective action.
  - Recommend modification in procedures to assure that radioactive materials are administered as directed by the authorized users.

15. Records of these reviews, evaluations and findings will be maintained in Auditable form for 3 years.

16. Response to a recordable event

- Each recordable event will be evaluated within 30 days of the discovery.
- The relevant facts will be assembled, including the cause – if known.
- Identify what, if any, corrective action is required to prevent recurrence.
- Retain a record of relevant facts and any corrective action for 3 years.

17. Records of each administered dose and each written directive (where a written directive is required) will be maintained for 3 years.

18. As needed, modifications will be made to increase the efficiency of the quality management program without reducing the programs effectiveness. Modifications will be approved by the radiation safety committee and a copy of the modifications will be furnished to the Radiation Protection Division within 30 days.

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Director of Nuclear Medicine

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Date

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RSO

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Date

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Hospital Administrator

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Date

Reviewed: 11/06, 3/22/10