

CHAPTER 129. NUCLEAR MEDICINE SERVICES

GENERAL PROVISIONS

- Sec.
129.1. Principle.
129.2. Organizational options.
129.3. Organization and staffing.
129.4. Director.
129.5. Consultation by physicist.
129.6. Education program for nuclear medicine personnel.

FACILITIES

- 129.11. Principle.
129.12. Space requirements.
129.13. Storage and disposal studies.
129.14. Equipment.

POLICIES

- 129.21. Policies and procedures.
129.22. Standardized diagnostic studies.
129.23. Radiation safety committee.
129.24. Written orders.

QUALITY CONTROL PROCEDURES

- 129.31. Principle.
129.32. Radioisotopes.
129.33. Instrument calibration procedures.
129.34. Radionuclides and radiopharmaceutical records.
129.35. Instrument log books.
129.36. Personnel monitoring.
129.37. Patient records.
129.38. Compliance with other law.

Cross References

This chapter cited in 55 Pa. Code § 6100.2 (relating to applicability).

GENERAL PROVISIONS

§ 129.1. Principle.

Nuclear medicine and consultation services should be conveniently available to meet the needs of the patients.

§ 129.2. Organizational options.

When these services are obtained outside the hospital for hospitalized patients, the providers of such services must be approved by the medical staff and must have a current permit from the Department of Environmental Protection.

Authority

The provisions of this § 129.2 issued under 67 Pa.C.S. §§ 6101—6104; and Reorganization Plan No. 2 of 1973 (71 P.S. § 755-2).

Source

The provisions of this § 129.2 amended September 19, 1980, effective September 20, 1980, 10 Pa.B. 3761. Immediately preceding text appears at serial pages (37876) and (37877).

§ 129.3. Organization and staffing.

The system for providing nuclear medicine services shall be clearly defined by the chief executive officer or the governing body.

Authority

The provisions of this § 129.3 issued under 67 Pa.C.S. §§ 6101—6104; and Reorganization Plan No. 2 of 1973 (71 P.S. § 755-2).

Source

The provisions of this § 129.3 amended September 19, 1980, effective September 20, 1980, 10 Pa.B. 3761. Immediately preceding text appears at serial page (37877).

§ 129.4. Director.

Direction of nuclear medicine services shall be provided by a member of the medical staff who is certified by the American Board of Nuclear Medicine or an equivalent Board who is eligible for Board certification, or who has successfully completed an approved residency in nuclear medicine or equivalent training. The director may be available full time or part time, depending on the size and complexity of the service. The director shall ensure that proper radiation safety principles and practices are observed.

§ 129.5. Consultation by physicist.

The services of a radiation physicist or other physical scientist shall be available, as needed.

§ 129.6. Education program for nuclear medicine personnel.

Nuclear medicine personnel should have the opportunity to further their knowledge and skills through on-the-job training, in-service education programs, and attendance at workshops and institutes held outside the hospital.

FACILITIES

§ 129.11. Principle.

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.

§ 129.12. Space requirements.

Space and facilities for the nuclear medicine service should include those necessary for the reception, examination, and diagnostic study of patients, as well as for related clerical work and conferences.

§ 129.13. Storage and disposal requirements.

Facilities shall be provided for the safe preparation, transportation, storage, and disposal of radioactive materials so that radiation levels meet the regulations of the Department of Environmental Protection and the United States Nuclear Regulatory Commission.

§ 129.14. Equipment.

The type, quantity and quality of equipment for the nuclear medicine service shall be adequate to conduct reliable diagnostic studies and therapy. Standards having equivalent energy radiations of the radionuclides used in patient studies shall be utilized for routine calibration and be readily available.

POLICIES

§ 129.21. Policies and procedures.

There shall be written policies and procedures for the nuclear medicine services. They shall be reviewed annually, revised as necessary, and dated to indicate the date of last review.

§ 129.22. Standardized diagnostic studies.

The director of nuclear services shall establish procedures to guide personnel in the standardized performance of diagnostic studies and to ensure that the identity, strength, and integrity of radio-pharmaceutical agents are maintained.

§ 129.23. Radiation safety committee.

(a) A radiation safety committee shall be established in hospitals providing nuclear medicine services. At least one member of this committee shall be a physician experienced in the safe handling of radioisotopes, in the measurement of radioactivity, and in determining radioisotope dosage for various patient studies

and treatments. Representatives of various fields of specialization should be included on the committee, as determined by the nature of the program conducted in the hospital.

(b) The radiation safety committee shall be responsible for all of the following:

- (1) Reviewing all proposals for diagnostic and therapeutic uses for radionuclides.
- (2) Recommending to the medical staff medical practitioners having suitable training and experience to perform nuclear medicine procedures.
- (3) Developing rules governing the use, removal, handling and storage of radioactive materials used in nuclear medicine procedures.
- (4) Recommending corrective and appropriate disciplinary action where there is a failure to observe safety rules and procedures.

§ 129.24. Written orders.

Nuclear medicine therapeutic and diagnostic services, when provided within the hospital, shall be performed only upon written request of the responsible physician or member of the house staff and shall be subject to the regulations otherwise governing written medical orders or exceptions thereto.

QUALITY CONTROL PROCEDURES

§ 129.31. Principle.

There shall be quality control procedures governing nuclear medicine services that ensure diagnostic reliability and patient safety.

§ 129.32. Radioisotopes.

All radioisotopes shall be prepared, stored, and periodically checked to ensure accuracy, patient safety and precision of results. All radioisotopes shall be labeled to indicate identity, date of preparation and concentration assay.

§ 129.33. Instrument calibration procedures.

Instrument calibration procedures designed to affirm proper performance shall be conducted periodically as required by the nature of the instrument. The results of these calibration procedures shall be recorded as provided in § 129.35 (relating to instrument log book).

§ 129.34. Radionuclides and radiopharmaceutical records.

The following records shall be maintained for radionuclides and radiopharmaceuticals:

- (1) Dates, amounts and methods of receipt and disposal.
- (2) Supplier and lot number.
- (3) The use, date, amount and identity of any recipient, where applicable.

§ 129.35. Instrument log books.

Instrument log books shall be maintained for the life of each instrument with at least the following information:

- (1) Calibration records of equipment and monitors showing dates, names of technologists and sources of reference standards.
- (2) Maintenance and repair records showing dates and source of service.

Cross References

This section cited in 28 Pa. Code § 129.33 (relating to instrument calibration procedures).

§ 129.36. Personnel monitoring.

The radiation exposure of nuclear medicine employes shall be monitored by means of film badges or other similar personnel monitoring devices. A record of the annual accumulation shall be maintained as part of the personnel file of the employe, and a copy given to the employe upon termination. The employe shall have access to these records during time of employment.

Authority

The provisions of this § 129.36 issued under section 2021(g) of The Administrative Code of 1929 (71 P. S. § 532(g)); and section 803 of the Health Care Facilities Act (35 P. S. § 448.803).

Source

The provisions of this § 129.36 amended through December 3, 1982, effective December 4, 1982, 12 Pa.B. 4129. Immediately preceding text appears at serial page (52850).

§ 129.37. Patient records.

Reports of nuclear medicine interpretations, consultations, and therapy shall be included in each patient's medical record. Duplicate reports shall be kept on file in the nuclear medicine department. The patient's medical record should show the identity, date and amount of radiopharmaceutical used, as well as any specific patient preparation performed. These records shall conform in other respects, with Chapter 115 (relating to medical records).

§ 129.38. Compliance with other law.

All applicable provisions of the Department of Environmental Protection and the United States Nuclear Regulatory Commission shall be complied with. A copy of the most recent inspection and approval letter by the Department of Environmental Protection shall be available for review by survey team members.

[Next page is 131-1.]

129-6

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