CHAPTER 39

STATE BOARD OF PHARMACY

Authority

N.J.S.A. 45:14–1 et seq.

Source and Effective Date

R.1994 d.351, effective June 16, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b), 26 N.J.R. 3878(a).

Executive Order No. 66(1978) Expiration Date

Chapter 39, State Board of Pharmacy, expires on June 16, 1999.

Chapter Historical Note

Chapter 39, State Board of Pharmacy, was filed and became effective prior to September 1, 1969. Chapter 39 was repealed and replaced with new rules by R.1989 d.314, effective June 19, 1989. See: 20 N.J.R. 1648(a), 21 N.J.R. 1712(a).

Pursuant to Executive Order No. 66(1978), Chapter 39 was readopted as R.1994 d.351. See: Source and Effective Date. See also, section annotations.

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SUBCHAPTER 1. GENERAL PROVISIONS

13:39–1.1 Purpose and scope

(a) This chapter is promulgated by the New Jersey State Board of Pharmacy. The rules contained in this chapter implement the provisions of the Pharmacy Act, N.J.S.A. 45:14–1 et seq. and regulate the practice of pharmacy within the State of New Jersey.

(b) This chapter shall apply to all registered pharmacies, pharmacists, pharmacist applicants, interns, externs, supportive personnel and anyone within the jurisdiction of the Board of Pharmacy.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

Case Notes

Violations of N.J.A.C. 13:39–8.14(b)2, 10 and 13 found as controlled substances records were improperly kept, misbranded drugs were in pharmacy and drugs were improperly stored, respectively; penalties (also cited as N.J.A.C. 13:39–8.12). New Jersey State Bd. of Pharmacy v. Yanuzzi, 4 N.J.A.R. 489 (1981).

13:39–1.2 Definitions

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise.

"Authorized prescriber" means a licensed practitioner who is authorized by law to write prescriptions and/or medication orders.

"Board" means the New Jersey State Board of Pharmacy.

2. A single dose of a drug from the original container for a specific patient.

(d) The pharmacist in charge shall obtain from the registered nurse on a suitable form a record of any drugs removed showing the following:

1. The name of the drug;
2. The dosage size;
3. The amount taken;
4. The date;
5. The patient's name and location; and
6. The signature of the nurse.

(e) The pharmacist in charge shall obtain with the record in (d) above the container from which the single dose was taken for drug administration purposes in order that it may be properly checked by a pharmacist.

(f) All records in (d) above shall be kept by the pharmacy for one year.

Recodified from 13:39–9.9 and amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39–9.19 Advisory committees

The pharmacist-in-charge, or designee, shall be an actively participating member on any committees of the facility that may be concerned with drugs and their utilization.

Recodified from 13:39–9.10 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39–9.20 Pharmacy and Therapeutics Committee

In all health care facilities providing pharmaceutical services to patients, an active standing committee of the institution entitled the Pharmacy and Therapeutics Committee or other appropriate name shall be established. A Pharmacy and Therapeutics Committee shall be multidisciplinary and include a pharmacist.

Recodified from 13:39–9.11 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39–9.21 Institutional pharmacy staff

The institutional pharmacy shall be staffed by sufficient, competent personnel in keeping with the size, scope and complexity of the pharmaceutical services provided.

Recodified from 13:39–9.12 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39–9.22 Pharmacist staff

(a) The institutional pharmacist staff shall include the following:

1. A pharmacist-in-charge, who shall direct the institutional pharmacy service and be responsible to the Administration of the facility.

2. Pharmacists who shall assist the pharmacist-in-charge as required depending on the size, scope and complexity of the service.

3. Any pharmacy interns, externs, and students, who shall function in accordance with the Board's rules and under qualified preceptor(s).

Recodified from 13:39–9.13 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39–9.23 Supportive personnel staffing

Supportive personnel in the institutional pharmacy shall work under the direct supervision and control of a registered pharmacist as provided in N.J.A.C. 13:39–6.4 and 6.7.

Recodified from 13:39–9.14 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39–9.24 Pharmacy facilities; space

(a) Adequate facilities (space, lighting, equipment, temperature control and supplies) shall be provided for the control of the professional, technical and administrative functions of the institutional pharmacy as needed for the effective and efficient assurance of patient safety through proper purchasing, receipt, storage, dispensing, administration and control of drugs.

(b) The facilities shall include, but are not limited to, those requirements provided in N.J.A.C. 13:39–7.3 through 7.7.

(c) The space provided for the institutional pharmacy shall be in accord with the size of the facility and the scope and complexity of the pharmaceutical services.

Recodified from 13:39–9.15 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39–9.25 Storage and security

(a) Provisions shall be made for adequate safe storage of drugs and biologicals wherever they are stored in the health care facility.

1. All drugs shall be secured for safe use and protected against illicit diversion. Controlled dangerous substances in the institutional pharmacy and throughout the facility shall be stored and protected in conformance with State and Federal laws and regulations.

2. Supplies of external preparations stored in patient care areas shall be kept separate from internal medications.

3. The pharmacist-in-charge shall be responsible for all the medications in the facility, that is, the drugs in the

pharmacy service area, drugs in transit, and the drugs in the patient care areas.

4. The drugs throughout the facility shall be maintained under adequate storage conditions including proper lighting, ventilation and temperature control as required by the United States Pharmacopoeia/National Formulary.

5. Adequate storage for pharmacy records shall be provided. Records not currently in use need not be stored in the pharmacy, but the storage facilities must be secure, and the records shall be readily retrievable by the pharmacy staff and authorized inspectors. Patient records shall be kept confidential.

Recodified from 13:39–9.16 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39–9.26 Equipment

Adequate equipment shall be provided for the compounding, packaging, labeling, refrigeration, sterilization, testing and safe distribution of drugs and biologicals, and other functions. The equipment shall be sufficient to process drugs required by the facility.

Recodified from 13:39–9.17 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39–9.27 Institutional decentralized pharmacies

(a) Institutional decentralized pharmacies, that is, "satellite pharmacies", means areas within the health care institution other than the original institutional permit location, where the preparation, dispensing, and compounding of medications are performed. Medication shall not be dispensed without a pharmacist present.

(b) Institutions utilizing or desiring to utilize institutional decentralized pharmacies shall file a remodeling application to the Board to conduct a decentralized pharmacy.

(c) Institutional decentralized pharmacies will be subject to normal Board inspections.

(d) The minimum equipment requirement for an institutional decentralized pharmacy shall be the following:

1. The current USP DI and supplements and suitable reference texts;

2. Patient profile record system;

3. Properly safeguarded storage place if necessary for Schedule II controlled dangerous substances if not dispersed;

4. A refrigerator if necessary for the exclusive storage of biologicals and other medicinal products requiring refrigeration;

5. Labels; and

6. A sink with hot and cold running water exclusive of restroom facilities shall be easily accessible to institutional decentralized pharmacy personnel.

Recodified from 13:39–9.18 by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

SUBCHAPTER 10. STERILE ADMIXTURE SERVICES IN RETAIL AND INSTITUTIONAL PHARMACIES

13:39–10.1 Sterile admixture services defined

A sterile admixture service is one involving the dispensing and specializing in the compounding and distribution of sterile parenteral products.

13:39–10.2 Compliance

(a) An institutional pharmacy which compounds and dispenses sterile admixture medications, parenteral nutrition and/or parenteral drug therapy shall meet the requirements of this subchapter.

(b) A retail pharmacy which, on or prior to September 19, 1994, compounded and dispensed sterile admixture medications, parenteral nutrition and/or parenteral drug therapy shall meet the requirements of this subchapter.

(c) A retail pharmacy which, on or prior to September 19, 1994 compounds and dispenses sterile admixture medications, parenteral nutrition and/or parenteral drug therapy shall meet the requirements of N.J.A.C. 13:39–11.

Amended by R.1994 d.476, effective September 19, 1994.
See: 26 N.J.R. 1303(a), 26 N.J.R. 3878(b).

13:39–10.3 General requirement

A pharmacy presently supplying or intending to supply a sterile admixture service shall notify the Board.

13:39–10.4 Pharmacist's responsibilities

(a) That section of a pharmacy which provides a sterile admixture service shall be under the direct supervision of a pharmacist licensed to practice in this State who should have practical or academic training in sterile product compounding, clean room technology, laminar flow technology, and quality assurance techniques. The registered pharmacist should have an adequate pharmacy background in clinical application of intravenous drug therapy either through experience or academic training.

(b) This pharmacist shall have the responsibility, in that section of the pharmacy which provides this special service for the following at a minimum:

1. Preparation of sterile admixtures compounded within the pharmacy;

2. Storage of all materials pertinent to the preparation of sterile admixtures, including drugs, chemicals and biologicals, and the establishment of specifications for procurement of the materials;

3. Labeling of all containers of sterile admixture preparations;

4. Recording all transactions of the pharmacy as may be applicable to State, Federal and local laws and rules, as may be necessary to maintain accurate control over, and accountability for, all pharmaceutical materials; and

5. Assuring that only licensed pharmacists meeting the requirements of (a) above or supportive personnel under direct supervision of a pharmacist prepare, compound, and dispense the sterile admixture preparations.

13:39–10.5 Handling, packaging and delivery

(a) The pharmacy shall provide special handling and packaging of compounded parenteral preparations for delivery from the pharmacy to the patient in order to assure and maintain sterility and stability of these preparations. The dispensed container shall bear a permanently affixed label with at least the following information:

1. Date prepared;

2. Name of physician, except for institutional inpatients;

3. Name of the patient;

4. Directions for use;

5. Name and amount of drug(s) added;

6. Name of the basic solution;

7. Name or identifying code of the pharmacist who checked or prepared the admixture;

8. The expiration date of the sterile preparation, which shall be the manufacturer's recommended expiration date or 24 hours, unless otherwise stated by the manufacturer, or an extended time may be substantiated with adequate documentation. This date shall appear on the label;

9. Name, address and telephone number of the pharmacy, except for institutional inpatients; and

10. Any ancillary and cautionary instructions as needed.

(b) Delivery of compounded parenteral preparations from the pharmacy to the patient shall be made within a reasonable time in order to ensure integrity and efficacy.

13:39–10.6 Patient records

A patient profile record shall be maintained and monitored for each patient. The patient profile record must contain available medical information consistent with prevailing pharmacy standards, and the complete record of the formulations of the sterile products which were dispensed.

13:39–10.7 Policy and procedure manual

(a) A policy and procedure manual shall be maintained at each pharmacy and be available for inspection by authorized agents of the Board. The policy and procedure manual shall set forth, in detail, the objectives and operational guidelines of the permit holder. The policy and procedure manual shall be maintained in current status. The Manual shall contain written documentation of such objectives and operational guidelines, including:

1. Microbiological evaluation, consistent with current standards for preparation of total parenteral nutrition, antineoplastic agents, antibiotics, large and small volume parenterals or other parenteral therapy;

2. Security;

3. Equipment;

4. Sanitation;

5. Reference materials;

6. Drug storage;

7. Drug dispensing;

8. Drug labeling;

9. Drug destruction and returns;

10. Delivery of drugs;

11. Recordkeeping;

12. Investigational new drugs; and

13. A quality assurance program which monitors personnel qualifications, training, performance, equipment, facilities, and such others as may be specified by the Board.

13:39–10.8 Pharmacy environment

(a) The compounding and dispensing of sterile admixture preparations shall be conducted in a pharmacy environment subject to the pharmacy permit laws of this State and in accordance with those requirements for the safe handling of drugs.

(b) The environment for this practice shall be set apart and designed and equipped to provide controlled aseptic conditions. Aseptic technique shall prevail in this environment to minimize the possibility of microbial contamination.

13:39–10.9 Minimum requirements for space

(a) The area for preparing sterile admixtures as provided for in these rules shall be referred to as the sterile admixture area and shall be set apart from general work and storage areas. This area shall be adequately air conditioned to maintain a temperature of 59 to 86 degrees Fahrenheit.

This separated area is to be used solely for the aseptic compounding of sterile admixture products.

(b) The sterile admixture area shall provide space for a minimum of one laminar air flow hood. The area shall be of adequate size to accommodate other equipment as provided in these rules and sufficient space to allow the pharmacist and other personnel in the sterile admixture area to adequately, safely, and accurately fulfill their duties related to sterile compounding.

(c) For the compounding and dispensing of antineoplastic agents, there shall be sufficient additional space to accommodate a vertical air laminar flow hood.

(d) The sterile admixture area shall have adequate space necessary for the storage, compounding, labeling, dispensing, and sterile preparation of drugs, and additional space as needed, depending on the size and scope of pharmaceutical services.

(e) The sterile admixture area shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition.

13:39–10.10 Minimum requirements for equipment

(a) The sterile admixture area shall contain the following equipment:

1. A suitable laminar air flow hood;

2. A sink with hot and cold running water exclusive of restroom facilities, shall be easily accessible to the personnel preparing sterile admixtures. This sink shall be maintained in a sanitary condition at all times.

3. A refrigerator as required by U.S.P. standards exclusively for storing of IV admixtures shall be easily accessible to personnel preparing the sterile admixtures; and

4. Appropriate waste containers for:

i. Used needles and syringes; and

ii. All waste including disposal of apparel used in preparation of antineoplastics.

13:39–10.11 Supplies

(a) The sterile admixture area shall maintain the following supplies:

1. Gloves, masks, and gowns;

2. Needles and syringes of various sizes;

3. Disinfectant cleaning agents;

4. Clean towels;

5. Handwashing materials, including antimicrobial skin cleaner; and

6. Any and all supplies necessary for the aseptic preparation of sterile admixture products.

13:39–10.12 Library references

In addition to the minimum reference library mandated in N.J.A.C. 13:39–7.7, each sterile admixture service shall contain references pertinent to this specialized practice.

13:39–10.13 Compounding requirements

(a) All sterile admixture compounding shall be performed within a certified air flow environment. Laminar air flow hoods or environments shall be certified and so documented at least semiannually.

(b) Proper aseptic procedures must be used at all times to prevent bacterial contamination of the product.

13:39–10.14 Disposal of drugs and materials

All unused drugs and materials used in the preparation of sterile admixture solutions, including antineoplastic agents, must be disposed of properly in accordance with accepted professional standards and applicable laws. Unused drugs and materials shall be disposed of in a manner so as not to endanger the public health.

13:39–10.15 Security

The sterile admixture area and its contents and other areas where drugs are stored shall be secured, so as to prevent access by unauthorized personnel.

SUBCHAPTER 11. STERILE ADMIXTURE SERVICES IN RETAIL PHARMACIES

13:39–11.1 Purpose and scope

This subchapter shall apply to all retail pharmacies which, on or after September 19, 1994, compound and dispense sterile admixture products, parenteral nutrition and/or parenteral drug therapy.

13:39–11.2 Training requirements

(a) The pharmacist in charge and the dispensing pharmacist shall have practical or academic training in sterile product compounding, clean room technology, laminar flow technology, and quality assurance techniques and shall be required to document such training if required by the Board.

(b) The pharmacist in charge shall be responsible for ensuring that, prior to performing delegated sterile admixture services, all supportive personnel are trained and can successfully demonstrate:

1. Comprehensive knowledge of the pharmacy's standard operating procedures with regard to sterile admixture services as set forth in the policy and procedure manual required to be maintained pursuant to N.J.A.C. 13:39–11.8;

2. Familiarity with the necessary compounding techniques; and

3. Appropriate aseptic technique, which shall be proven by means of a test batch of growth-media.

(c) At least every six months, the pharmacist-in-charge shall test the aseptic technique of supportive personnel by means of a test batch of growth-media. Test results shall be recorded in a log which shall be available for the Board's inspection.

13:39–11.3 Supportive personnel; required supervision

(a) The dispensing pharmacist shall provide direct supervision to supportive personnel who are working within the controlled environment, as defined in N.J.A.C. 13:39–11.11. The dispensing pharmacist shall supervise, at any given time, no more than two supportive personnel performing delegated sterile admixture tasks.

1. For the purposes of this subchapter, "direct supervision" means that the dispensing pharmacist shall be present in the dispensing area whenever supportive personnel are compounding sterile admixture products, and shall conduct in-process and final checks of all steps in preparation, compounding and dispensing of sterile admixture products.

2. Supervision shall include, but is not limited to, the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, and the finished label.

(b) The dispensing pharmacist may delegate to supportive personnel only the tasks set forth below in N.J.A.C. 13:39–11.4(b)2 (recording of the prescription), (b)3 (selection of the drugs, container and diluent), and (b)4 (compounding of sterile admixture). The dispensing pharmacist shall check that each task has been performed correctly prior to any further task being performed in the dispensing process.

Amended by R.1995 d.269, effective June 5, 1995.
See: 27 N.J.R. 43(a), 27 N.J.R. 2239(a).

13:39–11.4 Tracking document

(a) The pharmacist-in-charge and the dispensing pharmacist shall ensure that the sterile admixture product has been properly prepared, labeled, controlled, stored, dispensed and distributed in accordance with the provisions of this subchapter.

(b) The dispensing pharmacist shall prepare a document to track completion of the following steps of the compounding process. The tracking document(s) shall be initialed by the individual(s) who completed each step:

1. Receipt of prescription;

2. Recording of prescription in the patient record profile system, pursuant to N.J.A.C. 13:39–11.10;

3. Correct selection of the drugs, container, and diluent prior to their being compounded in the clean room;

4. Verification that all sterile admixture compounding is performed within the clean room and that proper aseptic procedures are being used at all times to prevent bacterial contamination of this product;

5. Verification that residual components comply with the order;

6. Verification that the prescription label complies with the requirements of N.J.A.C. 13:39–11.5; and

7. Verification that the prescription order is complete and ready to be dispensed, including any necessary ancillary supplies.

(c) The completed tracking document(s) shall be kept in a separate file.

13:39–11.5 Information required to appear on prescription label

(a) The dispensed container for any sterile admixture product shall bear a permanently affixed label with at least the following information:

1. The date prepared;

2. The name of the physician;

3. The name of the patient;

4. Directions for use;

5. The name of the basic solution;

6. The name and amount of drug(s) added;

7. The name or identifying code of the pharmacist who checked or prepared the sterile admixture product;

8. The name, address, and telephone number of the pharmacy;

9. The pharmacy's Drug Enforcement Administration (DEA) number, should the sterile admixture product contain any controlled dangerous substances;

10. The expiration date of the sterile admixture product;

11. Any ancillary and cautionary instructions as needed;

12. As pertinent, a warning consistent with applicable Federal and State law that cytotoxic products are biohazardous; and

13. As pertinent, the requirements for proper storage.

13:39–11.6 Expiration date of sterile preparation

(a) The expiration date of a sterile admixture product shall be 24 hours or as otherwise stated by the manufacturer.

(b) Any expiration date that extends beyond 24 hours or the manufacturer's expiration date shall be substantiated by documentation satisfactory to the Board.

13:39–11.7 Handling, packing and delivery

(a) To ensure the integrity and efficacy of compounded sterile admixture products, the pharmacist in charge shall ensure that:

1. A reasonable effort is made to provide tamper-evident packing;

2. Delivery is made from the pharmacy to the patient within a reasonable time; and

3. Proper in-transit storage is provided consistent with product labeling.

13:39–11.8 Policy and procedure manual

(a) The pharmacist in charge shall maintain a policy and procedure manual which shall set forth in detail the licensee's standard operating procedures with regard to sterile admixture services.

(b) The policy and procedure manual shall include at least the following:

1. A risk-management program (including, but not limited to, incident reports, adverse drug reactions, and product contamination);

2. Security measures (ensuring that the premises where sterile admixture drugs are present are secured, so as to prevent access by unauthorized personnel);

3. Equipment;

4. Sanitation;

5. Reference materials;

6. Drug storage;

7. Drug dispensing;

8. Drug labeling;

9. Drug destruction and returns;

10. Delivery of drugs;

11. Patient recordkeeping;

12. Investigational new drugs; and

13. A quality assurance program.

(c) The pharmacist in charge shall review and, if necessary, amend the policy and procedure manual on at least an annual basis. Documentation of the annual review shall be made available to the Board upon request.

13:39–11.9 Quality assurance program

(a) This section shall apply both to commercially available injectable drug products that are dispensed to patients without compounding or other manipulation, and to sterile admixture products that prior to dispensing have been in any way repackaged, reconstituted, diluted, admixed, blended, or otherwise manipulated (collectively referred to as "compounded").

(b) The dispensing pharmacist shall ensure that the sterile admixture product retains its quality attributes within acceptable limits through a written quality assurance program. The quality assurance program shall require at least that:

1. The sterile admixture product is kept under appropriate controlled conditions at the location of use, and is administered through adequate labeling and verbal or written instructions;

2. The potency, pH, sterility, freedom from pyrogen, particulate limits, container integrity, appearance, and other qualities or characteristics that the sterile admixture product is expected to have do exist for the entire labeled life of the sterile admixture product, or until the sterile admixture product is manipulated by the patient or caregiver;

3. The quality assurance program encompasses every sterile admixture product under the pharmacy's control and includes all phases of its preparation, distribution, storage, administration, and directions for use;

4. The proper analytical testing is performed at regular intervals of time in order to verify the microbiological, chemical, and physical quality of all sterile admixture products;

5. Air and surface sampling takes place monthly;

6. Laminar air flow hoods are certified semi-annually;

7. The Class 1,000 Clean Room is certified semi-annually; and

8. All unused drugs and materials used in the preparation of sterile admixture products, including antineoplastic agents, are disposed of properly in accordance with accepted professional standards and applicable laws, including the Medical Waste Act (N.J.S.A. 13:1E–48.1 et seq., P.L. 1989, c.34).

13:39–11.10 Patient profile records

(a) The pharmacist in charge shall ensure that a patient profile record is maintained and monitored for each patient. The patient profile record shall include, but is not limited to, the following:

1. Available medical information consistent with N.J.A.C. 13:39–7.14;

2. A complete record of the formulations of the sterile admixture products dispensed; and

3. Initial and ongoing clinical pharmacy monitoring plans.

(b) A reasonable, documented attempt shall be made to ensure that a patient profile record includes over-the-counter and home remedies.

13:39–11.11 Controlled environment: entry

(a) The pharmacy shall have designated areas, namely a clean room and an anteroom, which shall collectively be known as the controlled environment.

(b) The controlled environment shall be:

1. Accessible only to designated personnel;

2. Used only for the preparation of parenteral products, or such other tasks that require a controlled environment; and

3. Structurally isolated from other areas within the pharmacy by means of restricted entry or access.

13:39–11.12 Controlled environment: construction

(a) The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the controlled environment shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby minimizing spaces in which microorganisms and other contaminants may accumulate.

(b) All surfaces shall be resistant to sanitizing agents.

(c) Junctures of ceilings to walls shall be covered, caulked or sealed to avoid cracks and crevices where dirt can accumulate.

(d) Ceilings that consist of inlaid panels shall be impregnated with a polymer to render them impervious and hydrophobic, and shall also be caulked around each perimeter to seal them to the support frame.

(e) Walls shall consist either of panels locked together and sealed, or of epoxy-coated gypsum board.

(f) Floors shall have vinyl floor covering and shall be seamless or have heat-welded seams and coving to the sidewall.

(g) Dust-collection overhangs (such as ceiling utility pipes) or ledges (such as window sills) shall be either avoided or sealed.

(h) Ceiling lighting fixtures shall have exterior lens surfaces that are smooth, mounted flush, and air tight.

(i) Ceilings and walls shall have every penetration sealed.

13:39–11.13 Controlled environment: stocking

(a) The controlled environment shall contain only the following:

1. Items such as furniture, equipment, supplies, and other goods that are required for the tasks to be performed there;

2. Items that are nonpermeable, nonshedding, and resistant to disinfectants; and

3. Items that have been cleaned and sanitized just prior to their being enclosed.

(b) Whenever possible, equipment and other items used in the controlled environment should not be taken from these rooms except for calibration, servicing, or other activity associated with the proper maintenance of the item.

13:39–11.14 Controlled environment: maintenance and supplies

(a) The controlled environment shall be kept clean and arranged in an orderly fashion. All required equipment shall be maintained in good operating condition.

(b) The controlled environment shall not be used for bulk storage, warehousing, or clerical and secretarial functions.

(c) The controlled environment area shall contain the following supplies:

1. Gloves, masks, gowns, and other personal protective equipment;

2. Needles and syringes of various sizes;

3. Disinfectant cleaning agents;

4. Clean towels;

5. Hand-washing materials, including antimicrobial skin cleaner; and

6. Any and all supplies necessary for the aseptic preparation of sterile admixture products.

13:39–11.15 Clean room

(a) The clean room shall contain no sinks or floor drains.

(b) Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that the work surfaces may be readily cleaned and sanitized.

(c) The clean room shall be a minimum of 100 square feet in size and shall be compatible with the volume of compounding being conducted.

(d) Appropriate environmental control devices capable of maintaining Class 1,000 conditions during normal activity shall be in place, such as laminar airflow hoods or the zonal

laminar flow of high efficiency particulate air (HEPA) filtered air.

(e) The clean room shall contain the following equipment:

1. A laminar airflow hood or suitable HEPA filter system;

2. For the compounding and dispensing of antineoplastic agents, sufficient additional space to accommodate a vertical air laminar flow hood;

3. Waste containers in compliance with Occupational Safety and Health Administration (OSHA) standards for used needles and syringes, and for chemotherapy waste; and

4. Ancillary supplies required for proper compounding.

13:39–11.16 Anteroom

(a) The anteroom shall have an air quality of Class 10,000 or better.

(b) The anteroom shall contain the following equipment:

1. A sink with hot and cold running water;

2. Label and packaging equipment and supplies;

3. Waste containers for all personal protective equipment;

4. An eyewash station; and

5. A hazardous waste spill kit.

(c) A refrigerator, as required by USP Standards, shall be reasonably accessible to the anteroom to ensure the integrity of the sterile admixture product, but shall not be located within the controlled environment.

(d) In addition to the minimum reference library mandated in N.J.A.C. 13:39–7.7, each sterile admixture service shall also contain the most current edition of the American Hospital Formulary Service and other reference materials pertinent to this specialized service.

Amended by R.1995 d.269, effective June 5, 1995.
See: 27 N.J.R. 43(a), 27 N.J.R. 2239(a).

SUBCHAPTER 12. NUCLEAR PHARMACIES

Subchapter Historical Note

Subchapter 12, Nuclear Pharmacies, was recodified from Subchapter 11 by R.1994 d.476, effective September 19, 1994. See: 26 N.J.R. 1303(a), 26 N.J.R. 3878(b).

13:39–12.1 Definitions

The following words and terms when used in this subchapter shall have the following meanings, unless the context clearly indicates otherwise.

"Authentication of product history" includes, but is not limited to, identifying the purchase source, the ultimate use or disposition and any intermediate handling of any components of a radiopharmaceutical.

"Authorized practitioner" means a practitioner duly authorized by applicable Federal and State law to possess, use and administer radiopharmaceuticals.

"Designated agent" means an individual under the direct supervision of a practitioner authorized to communicate the practitioner's instructions to the nuclear pharmacy.

"Direct supervision" means that a qualified nuclear pharmacist shall be physically present in the compounding/dispensing area where the supportive personnel are performing delegated duties, and shall conduct in-process and final checks of all steps in preparation, compounding, and dispensing of drugs. This supervision shall include, but is not limited to, the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, and the finished label.

"Internal test assessment" includes, but is not limited to, conducting those tests necessary to insure the integrity of the test.

"Radiopharmaceutical" means any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act or in the FDA's Nuclear Pharmacy Guidelines and which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

"Radiopharmaceutical quality assurance" includes, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.

"Radiopharmaceutical service" includes, but is not limited to, the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; and the offering of those acts, services, operations or transactions necessary in the conduct, operation, management and control of a nuclear pharmacy.