CHAPTER 39

STATE BOARD OF PHARMACY

Authority

N.J.S.A. 45:1-15.1, 45:14-47, 45:14-48a.(4), 45:14-61, and 45:14-62.

Source and Effective Date

R.2010 d.090, effective May 17, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1b, Chapter 39, State Board of Pharmacy, expires on May 17, 2017. See: 43 N.J.R. 1203(a).

Chapter Historical Note

Chapter 39, State Board of Pharmacy, was adopted and became effective prior to September 1, 1969.

Chapter 39, State Board of Pharmacy, was repealed and adopted as new rules by R.1989 d.314, effective June 19, 1989.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, State Board of Pharmacy, was readopted as 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).

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).

Pursuant to Executive Order No. 66(1978), Chapter 39, State Board of Pharmacy, was readopted as R.1999 d.214, effective June 16, 1999. See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Subchapter 10, Automated Medication Systems, was adopted as R.2000 d.28, effective January 18, 2000. See: 31 N.J.R. 2293(b), 32 N.J.R. 317(a).

Subchapter 3A, Continuing Education, was adopted as R.2003 d.130, effective March 17, 2003. See: 34 N.J.R. 1089(a), 35 N.J.R. 1433(a).

Chapter 39, State Board of Pharmacy, was readopted as R.2005 d.25, effective December 10, 2004. See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Subchapter 2, Licensure Requirements, was renamed Requirements for Initial Licensure; Subchapter 2A, Requirements for Reciprocal Licensure, was adopted in part as new rules and recodified in part from Subchapter 3, Licensure by Reciprocity; Subchapter 3, Licensure by Reciprocity, was renamed Registered Pharmacist Requirements; and Subchapter 8, Pharmacy Training Sites, was repealed by R.2009 d.247, effective August 3, 2009. See: 41 N.J.R. 371(a), 41 N.J.R. 2969(b).

Chapter 39, State Board of Pharmacy, was readopted as R.2010 d.090, effective May 17, 2010. As a part of R.2010 d.090, Subchapter 3, Registered Pharmacist Requirements, was renamed Pharmacist Requirements; and Subchapter 6, Registered Pharmacist-in-Charge; Pharmacy Personnel, was renamed Pharmacist-in-Charge; Pharmacy Personnel, effective June 21, 2010. See: Source and Effective Date. See, also, section annotations.

Subchapter 13, Collaborative Practice, was adopted as new rules by R.2013 d.017, effective February 4, 2013. See: 44 N.J.R. 655(a), 45 N.J.R. 214(b).

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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 New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq., and regulate the practice of pharmacy within the State of New Jersey.

(b) This chapter shall apply to all pharmacies; pharmacists; applicants for permits, licensure or registration; interns; externs; pharmacy technicians; 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).
Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (b), substituted "pharmacy technicians" for "supportive personnel" preceding "and anyone within the jurisdiction".
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Rewrote the section.

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.

"Address of record" means an address designated by a licensee or registrant. "Address of record" may be a licensee's or registrant's home, business or mailing address, but shall not be a post office box unless the licensee or registrant also provides another address which includes a street, city, state and zip code.

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

"Compounding" means the preparation, mixing, assembling, packaging and labeling of a drug or device as the result of a practitioner's prescription or initiative based on the relationship of the practitioner or patient with the pharmacist in the course of professional practice or for the purpose of, or incident to, research, teaching or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

"Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, which is required under Federal or State law to be prescribed by an authorized prescriber and dispensed by a pharmacist, in the usual scope of pharmacy practice.

"Dispense or dispensing" means the procedure entailing the interpretation of a practitioner's prescription or medication order for a drug, biological or device, and, pursuant to that order, the proper selection, measuring, compounding, labeling and packaging in a proper container for the subsequent administration to, or use by, a patient. The act of dispensing shall include all necessary consultation by the pharmacist.

"Drug or medication" means:

1. Articles recognized in the official United States Pharmacopoeia/National Formulary, official Homeopathic Pharmacopoeia of the United States, or any official supplement to any of them;

2. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals;

3. Articles (other than food) intended to affect the structure of any function of the body of human beings or animals; and

4. Articles intended for use as components of any article specified in 1, 2 or 3 above, but not including devices or their components, parts or accessories.

"Immediate personal supervision" means that the pharmacist is physically present in the compounding/dispensing area when interns, externs and pharmacy technicians are performing delegated duties, and the pharmacist conducts any necessary in-process checks and the final check in preparation and compounding of medications, including the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, the finished label and the accuracy and appropriateness of the actions of pharmacy technicians, interns and externs.

"Legend drug or device" means any drug or device that:

1. Bears, at a minimum, the symbol "Rx only" or words of similar import; and/or

2. Requires a prescription or order by a practitioner.

"Pharmaceutical services" means all services provided by a pharmacist. These services shall be concerned with, but not limited to: interpreting the prescription or medication order; selecting, preparing, compounding, packaging, labeling, distributing and dispensing prescribed drugs; the proper and safe storage of drugs; the monitoring of drug therapy; the reporting and recording of adverse drug reactions and the provision of appropriate drug information; teaching and counseling on the proper and safe use of drugs and medications.

"Pharmacist" means an individual holding an active license to engage in the practice of pharmacy in this State.

"Pharmacy" means a location permitted by the Board to engage in the practice of pharmacy in this State.

"Pharmacy technician" means an individual registered with the Board and who works under the immediate personal supervision of a pharmacist in compliance with N.J.A.C. 13:39-6.15. For purposes of this definition, interns, externs, cashiers, stocking and clerical help are not pharmacy technicians.

"Practitioner" means an individual currently licensed, registered or otherwise authorized by the jurisdiction in which the individual practices to administer or prescribe drugs and/or devices in the course of professional practice.

"Prescription" means a lawful order of a practitioner for a drug, device or diagnostic agent for a specific patient.

"Professional judgment" means judiciousness and discretion based upon thorough knowledge and sound application of the specialized body of knowledge peculiar to the practice of pharmacy, and an understanding of the relationship of this knowledge and its application to the well-being of the patient and to the judgment of the practitioner.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
Inserted "Address of record"; in "Legend drug or device", rewrote 1; rewrote "Licensed practitioner"; and in "Registered pharmacist" or "pharmacist", substituted a reference to licenses for a reference to certificates, and substituted a reference to the current license renewal period for a reference to the current registration period.
Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote "Address of record", added "Immediate personal supervision" and "Pharmacy technician", deleted "Direct supervision" and "Supportive personnel".
Amended by R.2007 d.283, effective September 4, 2007.
See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).
In definition "Address of record", inserted "or registrant" twice and inserted "or registrant's"; and in definition "Pharmacy technician", updated the N.J.A.C. reference.
Amended by R.2009 d.305, effective October 5, 2009.
See: 40 N.J.R. 5170(a), 41 N.J.R. 3840(a).
Rewrote definition "Prescription".
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Deleted definitions "Authorized prescriber", "Licensed practitioner" and " 'Registered pharmacist' or 'pharmacist' "; rewrote definitions "Compounding", "Dispense or dispensing", "Immediate personal supervision" and "Pharmacy technician"; substituted definition "Drug or medication" for definition "Drug or medicine"; added definitions "Pharmacist", "Pharmacy" and "Practitioner"; in paragraph 2 of definition "Legend drug or service" substituted "a practitioner" for "an authorized prescriber"; in definition "Pharmaceutical services", deleted "registered" preceding "pharmacist", and substituted "labeling" for "labelling" and "counseling" for "counselling"; and in definition "Professional judgment", substituted "practitioner" for "prescriber".

13:39-1.3 Fee schedule

(a) The following fees shall be charged by the Board:

1. For pharmacists as follows:

i.	Application for licensure	125.00.
ii.	Verification of licensure	25.00.
iii.	Application for reciprocity	125.00.
iv.	Application for reinstatement	
	(1) Disciplinary suspension	225.00.
	(2) Administrative suspension	225.00.
v.	Initial licensure fee	
	(1) If paid during the first year of a biennial renewal period	140.00.
	(2) If paid during the second year of a biennial renewal period	70.00.
vi.	Biennial license renewal	140.00.
vii.	Replacement biennial license	25.00.
viii.	Inactive license renewal	(To be determined by future rulemaking)
ix.	Late renewal fee	100.00.
x.	Replacement of initial wall license	40.00.
xi.	Continuing education review fee	10.00.
xii.	Continuing education program or course: sponsor review fee	50.00.

2. For in-State pharmacies as follows:

i.	Pharmacy permits	
	(1) Application for permit	275.00.
	(2) Annual permit renewal	175.00.
	(3) Change of ownership/name	275.00.
	(4) Change of location	275.00.
ii.	Replacement of annual permit	25.00.
iii.	Late renewal fee	100.00.
iv.	Verification of permit	25.00.

annually, review its written policies and procedures of operation and revise them if necessary.

(c) A copy of the written policies and procedures of operation adopted pursuant to this section shall be retained at the pharmacy and at the healthcare facility where the automated medication system is utilized. Upon request, the pharmacy shall provide to the Board a copy of the written policies and procedures of operation for inspection and review.

Amended by R.2009 d.305, effective October 5, 2009.
See: 40 N.J.R. 5170(a), 41 N.J.R. 3840(a).
In (a)5, substituted "N.J.A.C. 13:39-7.19" for "N.J.A.C. 13:39-7.14(h)".
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In (a)3, substituted "pharmacist-in-charge" for "registered pharmacist in charge" twice; added new (a)5; recodified former (a)5 through (a)7 as (a)6 through (a)8; in (a)7 and (a)8, deleted "registered" preceding "pharmacist"; and in (a)7, substituted "pharmacy technicians, interns and externs" for "support personnel acting" and inserted a comma following "record".

13:39-10.5 Personnel training requirements

The pharmacist-in-charge shall be responsible for ensuring that, prior to performing any services in connection with an automated medication system, all pharmacists and pharmacy technicians, interns and externs are trained in the pharmacy's standard operating procedures with regard to automated medication systems as set forth in the written policies and procedures of operation maintained pursuant to N.J.A.C. 13:39-10.4.

Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Substituted "pharmacy technicians, interns and externs" for "supportive personnel".
Amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Substituted "pharmacist-in-charge" for "registered pharmacist in charge" and "pharmacists" for "licensed practitioners".

13:39-10.6 Written program for quality assurance

(a) A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall operate according to a written program for quality assurance of the automated medication system which:

1. Requires continuous monitoring of the automated medication system;

2. Establishes mechanisms and procedures to test the accuracy of the automated medication system at least every six months and whenever any upgrade or change is made to the system;

3. Establishes a protocol for measuring the effectiveness of the automated medication system;

4. Requires the pharmacy to report to the Board each recurring error of the automated medication system. A "recurring error," for purposes of this section, means any specific type of inaccuracy within the automated medication system that occurs more than twice within a 14 day period; and

5. Requires the pharmacy to maintain all documentation relating to the written program for quality assurance for at least two years.

13:39-10.7 Written plan for recovery

(a) A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall maintain a written plan for recovery from a disaster which interrupts the ability of the pharmacy to provide services. The written plan for recovery shall include:

1. Planning and preparation for a disaster;

2. Procedures for response to a disaster;

3. Procedures for the maintenance and testing of the written plan for recovery; and

4. A procedure to notify the Board, each organization which has contracted with the pharmacy, each patient of the pharmacy, and other appropriate agencies, of a disaster and the date on which the pharmacy expects to recommence the provision of service.

13:39-10.8 Written program for preventative maintenance of automated medication system

A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall maintain a written program for preventative maintenance of the system.

SUBCHAPTER 11. COMPOUNDING IN RETAIL AND INSTITUTIONAL PHARMACIES FOR STERILE AND/OR NON-STERILE PREPARATIONS

13:39-11.1 Purpose and scope

This subchapter shall apply to all retail and institutional pharmacies which compound and dispense sterile and/or non-sterile preparations.

Amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Rewrote the section.
Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section.

13:39–11.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings:

"ISO class 5 air quality conditions" means conditions in which the air particle count is no greater than a total of 3,520 particles of 0.5 micrometers and larger per cubic meter of air (100 particles per cubic foot).

"ISO class 6 air quality conditions" means conditions in which the air particle count is no greater than a total of 35,200 particles of 0.5 micrometers and larger per cubic meter of air (1,000 particles per cubic foot).

"ISO class 7 air quality conditions" means conditions in which the air particle count is no greater than a total of 352,000 particles of 0.5 micrometers and larger per cubic meter of air (10,000 particles per cubic foot).

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Former N.J.A.C. 13:39–11.2, Training requirements, was recodified to N.J.A.C. 13:39–11.7.
Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section.

13:39–11.3 Sterile and non-sterile preparation services; environment

(a) A sterile preparation service is one specializing in the compounding and dispensing of sterile preparations upon receipt of a valid prescription or medication order. Such compounding shall take place in the confines of a controlled environment as required by N.J.A.C. 13:39–11.16; or when circumstances permit as set forth in N.J.A.C. 13:39–11.11(c), in a laminar hood, as provided by N.J.A.C. 13:39–11.22, or in a glove box, as provided by N.J.A.C. 13:39–11.23.

(b) Compounding of non-sterile preparations shall take place in a compounding environment designated specifically for that purpose.

Amended by R.1995 d.269, effective June 5, 1995.
See: 27 N.J.R. 43(a), 27 N.J.R. 2239(a).
New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Former N.J.A.C. 13:39–11.3, Supportive personnel; required supervision, was recodified to N.J.A.C. 13:39–11.8.
Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section.

13:39–11.4 General requirement for compounded sterile preparations; pre-approval

An applicant or permitholder who wishes to compound sterile preparations shall notify the Board at least 60 days prior to commencement and shall receive approval from the Board before commencing compounding of sterile preparations.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Former N.J.A.C. 13:39–11.5, Information required to appear on prescription label, was recodified to N.J.A.C. 13:39–11.11.
Recodified from N.J.A.C. 13:39–11.5 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 11:39–11.4, Compliance, repealed.

13:39–11.5 Pharmacist in charge and permitholders' responsibilities

(a) The pharmacist-in-charge shall supervise all sterile and/or non-sterile compounding. For purposes of supervising sterile compounding, the pharmacist-in-charge shall be trained in aseptic manipulation skills.

(b) The pharmacist in charge shall have the responsibility, in that section of the pharmacy where sterile and/or non-sterile preparations are compounded, for, at a minimum, the following:

1. Compounding of all preparations within the pharmacy or pharmacy satellite, including compounding of individual medication orders or prescriptions, the formulation of products in response to special drug needs and batch compounding;

2. Storage of all materials pertinent to the compounding of preparations, including drugs, chemicals and biologicals, and the establishment of specifications for procurement of the materials in accordance with State and Federal laws and regulations;

3. Ensuring that all packaging and labeling of all drugs compounded with the pharmacy are performed under the immediate personal supervision of a pharmacist;

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;

5. Ensuring that preparation and compounding of sterile preparations is performed only by licensed pharmacists who have been trained in aseptic manipulation skills, or by pharmacy technicians, interns or externs who have been trained in aseptic manipulation skills working under the immediate personal supervision of a licensed pharmacist trained in aseptic manipulation skills;

6. Ensuring that preparation and compounding of non-sterile preparations is performed only by licensed pharmacists or by pharmacy technicians, intern or externs working under the immediate personal supervision of a licensed pharmacist; and

7. Establishing procedures for maintaining the integrity and manufacturer's control identity of packaged material. The packaging records shall be initialed by the supervising pharmacist.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Former N.J.A.C. 13:39–11.6, Expiration date of sterile preparation, was recodified to N.J.A.C. 13:39–11.12.
Recodified from N.J.A.C. 13:39–11.6 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39–11.5, General requirement, recodified to N.J.A.C. 13:39–11.4.

13:39–11.6 Pharmacy technicians, interns and externs; required supervision

(a) Dispensing pharmacists shall provide immediate personal supervision to pharmacy technicians, interns or externs who are performing delegated sterile and non-sterile preparation compounding. The ratio of dispensing pharmacists to pharmacy technicians shall not exceed 1:2 at any given time unless all of the requirements of N.J.A.C. 13:39–6.6(d) and (e) are met.

1. 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 pharmacy technicians, interns or externs only the following tasks: recording of the prescription, selection of the drugs, container and diluent, typing of labels and compounding of preparations. The dispensing pharmacist shall ensure that each task has been performed correctly in the dispensing process.

Recodified from N.J.A.C. 13:39–11.3 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Rewrote the section. Former N.J.A.C. 13:39–11.8, Policy and procedure manual, was recodified to N.J.A.C. 13:39–11.14.
Recodified from N.J.A.C. 11:39–11.8 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 11:39–11.6, Pharmacist in charge and permitholders' responsibilities, recodified to N.J.A.C. 11:39–11.5.

13:39–11.7 Training requirements for compounding sterile preparations

(a) The pharmacist in charge and all personnel involved in compounding sterile preparations shall have practical or academic training in sterile preparation compounding, clean room technology, laminar flow technology, and quality assurance techniques. Such training shall be documented for each person before that individual begins to compound sterile preparations and annually thereafter. That documentation shall be maintained by the permitholder for five years and made available to the Board upon request.

(b) The pharmacist in charge shall be responsible for ensuring that, prior to compounding sterile preparations, all personnel are trained and can successfully demonstrate:

1. Comprehensive knowledge of the pharmacy's standard operating procedures with regard to compounding sterile preparations as set forth in the policy and procedure manual required to be maintained pursuant to N.J.A.C. 13:39–11.13;

2. Familiarity with the necessary compounding techniques; and

3. Appropriate aseptic technique, which shall be proven by means of a test batch of culture media, media fill or the equivalent.

(c) At least annually, the pharmacist in charge shall be responsible for testing the aseptic technique of all personnel involved in compounding sterile preparations by means of a test batch of culture media, media fill or the equivalent. Test results shall be maintained for five years, and shall be made available for the Board's inspection upon request. Individuals who fail to demonstrate acceptable aseptic technique shall be prohibited from engaging in sterile preparation compounding until demonstrating acceptable technique by means of a test batch of culture media, media fill or the equivalent.

Recodified from N.J.A.C. 13:39–11.2 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Rewrote the section. Former N.J.A.C. 13:39–11.7, Handling, packaging and delivery, was recodified to N.J.A.C. 13:39–11.13.
Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section.

13:39–11.8 Batch preparation

Pharmacists and pharmacy technicians, interns and externs may compound sterile and non-sterile preparations consistent with the provisions of N.J.A.C. 13:39–11.6 in a quantity that is supported by prior valid prescription or medication orders before receiving a valid written prescription or medication order, provided the pharmacist can document a history of valid prescriptions subsequently received shortly thereafter or medication orders that have been generated solely within an established professional prescriber-patient-pharmacist relationship, and provided they maintain the prescription on file for all such products dispensed at the pharmacy as required by state law. The pharmacist shall document the batch preparation process in accordance with N.J.A.C. 13:39–11.9(d).

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Former N.J.A.C. 13:39–11.9, Quality assurance program, was recodified to N.J.A.C. 13:39–11.15.
Recodified from N.J.A.C. 13:39–11.9 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39–11.8, Supportive personnel; required supervision, recodified to N.J.A.C. 11:39–11.6.

13:39-11.9 Documentation

(a) Consistent with the provisions of N.J.A.C. 13:39-11.5, the dispensing pharmacist shall ensure that compounded preparations have been properly prepared, labeled, controlled, stored, dispensed and distributed in accordance with the provisions of this subchapter.

(b) The pharmacist in charge shall be responsible for ensuring that policies and procedures exist so that all aspects of the dispensing process set out in (d) below are documented and that the pharmacist responsible for each preparation can be identified.

(c) On or after April 5, 2011, a pharmacy shall maintain an audit trail that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), intern(s) or extern(s) involved, consistent with the requirements of this chapter, in the steps of the compounding process set out in (d) below. All steps performed by a pharmacy technician, intern or extern shall be documented in the audit trail. All entries to the audit trail made by a pharmacy technician, intern or extern shall be reviewed and approved by the pharmacist. When more than one pharmacist is involved in the steps of the compounding process, the unique and secure user identifier(s) of the pharmacist(s) responsible for the accuracy and appropriateness of each step shall be recorded in the audit trail. Audit trail documentation shall be generated at the time each step is performed.

(d) Compounding steps which shall be documented are as follows:

1. Receipt of prescription or medication order;

2. Recording of prescription or medication order in the patient record profile system, pursuant to N.J.A.C. 13:39-11.15;

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

4. Verification that all pharmacy sterile preparation compounding is performed within a ISO class 5 laminar air flow hood or ISO class 5 clean room and that proper aseptic procedures are being used at all times to prevent bacterial contamination of this product;

5. Verification that ingredients comply with the prescription or medication order;

6. Verification that the prescription or medication order label complies with the requirements of N.J.A.C. 13:39-11.10; and

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

(e) The audit trail information shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be maintained for not less than five years from the date of the last entry in the record. The oldest four years of record information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of a record shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but off-site facilities used to store such records shall be secure. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations.

Recodified from N.J.A.C. 13:39-11.4 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Rewrote the section. Former N.J.A.C. 13:39-11.10, Patient profile records, was recodified to N.J.A.C. 13:39-11.16.
Recodified from N.J.A.C. 13:39-11.10 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39-11.9, Batch preparation, recodified to N.J.A.C. 13:39-11.8.
Amended by R.2009 d.305, effective October 5, 2009.
See: 40 N.J.R. 5170(a), 41 N.J.R. 3840(a).
Rewrote (c) and (e).

13:39-11.10 Information required to appear on prescription label

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

1. The date and, for sterile preparations, the time prepared;

2. In the retail pharmacy only, the name of the prescriber;

3. The name of the patient;

4. Directions for use;

5. The name and quantity of all active ingredients;

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

7. The use by date and, for sterile preparations, the use by time (If no time is stated, it is presumed to be 11:59 P.M. of the stated use by date).

8. Any ancillary and cautionary instructions as needed;

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

10. As pertinent, the requirements for proper storage.

Recodified from N.J.A.C. 13:39-11.5 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
In (a), inserted a reference to time in 1, and rewrote 2 and 10. Former N.J.A.C. 13:39-11.11, Controlled environment: entry, was recodified to N.J.A.C. 13:39-11.17.
Recodified from N.J.A.C. 13:39-11. and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote (a). Former N.J.A.C. 13:39-11.10, Documentation, recodified to N.J.A.C. 13:39-11.9.
Amended by R.2009 d.305, effective October 5, 2009.
See: 40 N.J.R. 5170(a), 41 N.J.R. 3840(a).
Deleted former (a)6; and recodified former (a)7 through (a)11 as (a)6 through (a)10.

13:39-11.11 Use by date of sterile preparation

(a) The use by date of a sterile compounded preparation shall be 24 hours or as otherwise stated by the manufacturer or current literature at the time of preparation, but shall not exceed 30 days after preparation.

(b) Any use by date that extends beyond 24 hours or the manufacturer's expiration date shall be substantiated by documentation satisfactory to the Board. Satisfactory documentation shall include, but not be limited to:

1. Manufacturer's criteria on extending beyond use dates;

2. Appropriate literature; and

3. Direct testing.

(c) In an institutional pharmacy, any sterile compounded preparation which is prepared under the pharmacy's control in a ISO class 5 laminar air flow hood which is not in a clean room and which meets the requirements of N.J.A.C. 13:39-11.22, shall be labeled to indicate that administration to a patient shall be initiated and completed within 28 hours of the beginning of the preparation time. If such a compounded preparation is prepared by closed-system aseptic transfer of a single, sterile, nonpyrogenic, finished medication obtained from licensed manufacturers into sterile final containers (for example, syringes, minibags, portable infusion-device cassettes), then the compounded preparation shall be labeled to indicate that administration to a patient shall be completed within the time recommended by the manufacturer but not exceeding 30 days after preparation. A closed system aseptic transfer is one which does not permit exposure of the pharmaceutical components to the environment, and shall be prepared in a ISO class 5 laminar air flow hood.

Recodified from N.J.A.C. 13:39-11.6 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
In (a), added "or current literature at the time of preparation" at the end of the sentence; and inserted a new (c). Former N.J.A.C. 13:39-11.12, Controlled environment: construction, was recodified to N.J.A.C. 13:39-11.18.
Recodified from N.J.A.C. 13:39-11.12 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39-11.11, Information required to appear on prescription label, recodified to N.J.A.C. 13:39-11.10.

13:39-11.12 Handling, packaging and delivery

(a) The pharmacy shall be responsible for the proper handling and packaging of compounded preparations for delivery from the pharmacy to the patient in order to assure and maintain integrity, efficacy, stability, and, where applicable, sterility, of these preparations. The pharmacist in charge shall ensure that:

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

2. Retail 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.

Recodified from N.J.A.C. 13:39-11.7 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
In (a), inserted a new first sentence in the introductory paragraph and changed "Delivery" to "Retail delivery" in 2. Former N.J.A.C. 13:39-11.13, Controlled environment: stocking, was recodified to N.J.A.C. 13:39-11.19.
Recodified from N.J.A.C. 13:39-11.13 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39-11.12, Expiration date of sterile preparation, recodified to N.J.A.C. 13:39-11.11.

13:39-11.13 Policy and procedure manual for compounded sterile preparations

(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 compounded sterile preparations.

(b) The policy and procedure manual shall include policies and procedures governing the following:

1. A risk-management program (including, but not limited to, incident report procedures, an adverse drug reaction system, and a product contamination system);

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

3. Equipment;

i. Procedures for use; and

ii. Documentation of appropriate certifications;

4. Sanitation standards and procedures;

5. Reference materials as set out in N.J.A.C. 13:39-5.8 and 11.24;

6. Information concerning drug:

i. Preparation;

ii. Storage and handling;

iii. Dispensing;

iv. Labeling;

v. Delivery; and

vi. Destruction, recalls and returns;

7. Patient recordkeeping as set forth in N.J.A.C. 13:39-11.15;

8. Handling, dispensing and documentation of investigational new drugs;

9. A quality assurance program as set forth in N.J.A.C. 13:39-11.14;

10. Verification of training and competency guidelines as set forth in N.J.A.C. 13:39-11.7;

11. Compounding process validation;

12. Documentation as set forth in N.J.A.C. 13:39-11.9;

13. Description of appropriate garb;

14. Conduct guidelines for personnel in the controlled areas;

15. Personnel responsibilities;

16. Patient education (retail patients);

17. Protocol and procedures to maintain the integrity of the interior work area of the laminar air flow hoods; and

18. Written procedures in compliance with the Occupational Safety and Health Administration standards for handling small and large spills of antineoplastic agents and other hazardous substances.

(c) The pharmacist in charge shall review at least every two years and, if necessary, amend the policy and procedure manual as needed. Documentation of the review shall be made available to the Board upon request.

Recodified from N.J.A.C. 13:39–11.8 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Rewrote (b). Former N.J.A.C. 13:39–11.14, Controlled environment: maintenance and supplies, was recodified to N.J.A.C. 13:39–11.19(c) through (e).
Amended by R.1999 d.196 effective June 21, 1999.
See: 30 N.J.R. 4113(a), 31 N.J.R. 253(a), 31 N.J.R. 1618(a).
In (b), added 18.
Recodified from N.J.A.C. 13:39–11.14 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a). 37 N.J.R. 295(a).
In (a), substituted "with regard to compounded sterile preparations" for "with regard to sterile admixture services"; in (b), substituted "where compounded sterile drugs are present" for "where sterile admixture drugs are present" following "that the premises" in 2 and amended the N.J.A.C. references in 5, 7, 9 and 12; in (c), inserted "at least every two years" following "in charge shall review", substituted "as needed" for "on at least an annual basis" following "policy and procedure manual" and deleted "annual" following "Documentation of the". Former N.J.A.C. 13:39–11.13, Handling, packaging and delivery, recodified to N.J.A.C. 13:39–11.12.

13:39–11.14 Quality assurance program for compounded sterile preparations

(a) This section shall apply both to commercially available sterile drug products that are dispensed to patients without compounding or other manipulation, and to sterile preparations which, 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 compounded sterile preparation retains its quality attributes within acceptable limits through a written quality assurance program. The quality assurance program shall require at least that:

1. A reasonable effort shall be made by the dispensing pharmacist to assure that compounded sterile preparations shall be kept under appropriate controlled conditions at the location of use by providing adequate labeling and verbal or written instructions regarding proper storage and administration as set forth by the product manufacturer, with each compounded sterile preparation dispensed;

2. The quality assurance program encompasses all phases of sterile compounding, including preparation, distribution, storage, administration, and directions for use for each type of product dispensed;

3. All compounding processes representative of all types of manipulations, products and batches must be sterile tested and validated at least every 12 months.

4. Air and surface sampling for microbial organisms in ISO class 5 laminar air flow hoods and ISO class 6 clean rooms is done twice annually and at any time when microbial contamination is suspected pursuant to United States Pharmacopoeia/National Formulary guidelines;

5. Laminar air flow hoods shall be certified every six months, and every time they are moved, by an independent certification company;

6. The ISO class 6 clean room and ISO class 7 anteroom shall be certified every six months by an independent certification company; and

7. All unused drugs and materials used in the compounding of sterile preparations, 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).

Recodified from N.J.A.C. 13:39–11.9 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
In (a), substituted "sterile" for "injectable" following "available"; and rewrote (b). Former N.J.A.C. 13:39–11.15, Clean room, was recodified to N.J.A.C. 13:39–11.20.
Recodified from N.J.A.C. 13:39–11.15 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39–11.14, Policy and procedure manual, recodified to N.J.A.C. 13:39–11.13.

13:39–11.15 Patient profile records for compounded sterile preparations

(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. 13:39–7.19; and

2. All medication orders for institutional patients.

(b) The pharmacist in charge shall ensure that a reasonable, documented attempt is made to include in the record over-the-counter and home remedies used by noninstitutional patients.

(c) The pharmacist in charge shall ensure that initial and ongoing multidisciplinary clinical monitoring and comprehensive care plans are maintained and readily available.

Recodified from N.J.A.C. 13:39–11.10 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

Rewrote (a) and (b) and inserted a new (c). Former N.J.A.C. 13:39–11.16, Anteroom, was recodified to N.J.A.C. 13:39–11.21.
Recodified from N.J.A.C. 13:39–11.16 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a), amended the N.J.A.C. reference in 1. Former N.J.A.C. 13:3911.15, Quality assurance program, recodified to N.J.A.C. 13:39–11.14.

13:39–11.16 Controlled environment for compounded sterile preparations: use, access, location; temperature

(a) The pharmacy shall have a designated area for sterile preparation compounding, known as the "controlled environment," consisting of a clean room and an anteroom unless the pharmacy meets the requirements of N.J.A.C. 13:39–11.22 or 11.23.

(b) A controlled environment shall be:

1. Accessible only to designated personnel;

2. Used only for the compounding of sterile preparations, or such other tasks that require a controlled environment;

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

4. Air conditioned to maintain a temperature of 59 to 77 degrees Fahrenheit.

Recodified from N.J.A.C. 13:39–11.11 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Rewrote (a); and in (b), substituted "sterile" for "parenteral" in 2 and added a new 4.
Recodified from N.J.A.C. 13:39–11.17 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a), substituted "sterile preparation compounding, known" for "sterile product preparation, known" and amended the N.J.A.C. references in the introductory paragraph, and substituted "for the compounding of sterile preparations" for "for the preparation of sterile products" in 2. Former N.J.A.C. 13:39–11.16, Patient profile records, recodified to N.J.A.C. 13:39–11.15.

13:39–11.17 Controlled environment for compounded sterile preparations: 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 damage from sanitizing agents.

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

(d) Ceilings which consist of inlaid panels shall be impregnated with a polymer to render them impervious and hydrophobic and shall either be caulked or weighted and clipped.

(e) Solid 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) There shall be no dust-collection overhangs (such as ceiling utility pipes) or ledges (such as window sills). All sprinkler heads shall be flush with the ceiling.

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

(i) All areas in ceilings and walls where the surface has been penetrated shall be sealed.

(j) Any clean room construction other than that specified in (a) through (i) above (for example, softwall, prefabricated, modular, portable clean rooms) shall be approved by the Board prior to installation and use.

Recodified from N.J.A.C. 13:39–11.12 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
In (b), inserted "damage from"; in (e), substituted "Solid walls" for "Walls"; rewrote (g) and (i); and added a new (j).
Amended by R.1999 d.196 effective June 21, 1999.
See: 30 N.J.R. 4113(a), 31 N.J.R. 253(a), 31 N.J.R. 1618(a).
In (d), substituted "either be caulked or weighted and clipped" for "also be caulked around each perimeter to seal them to the support frame" at the end.
Recodified from N.J.A.C. 13:39–11.18 by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Former N.J.A.C. 13:39–11.17, Controlled environment: use, access, location; temperature, recodified to N.J.A.C. 13:39–11.16.

13:39–11.18 Controlled environment for compounded sterile preparations: stocking, maintenance and supplies

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

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

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

3. Items which have been cleaned and sanitized immediately prior to their being placed in the clean room.

(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.

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

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

(e) 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 compounding of sterile preparations.

Recodified from N.J.A.C. 13:39-11.13 and 13:39-11.14 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Rewrote (a)3.
Recodified from N.J.A.C. 13:39-11.19 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (e), substituted "asceptic compounding of sterile preparations" for "asceptic preparation of sterile admixture products" in 6. Former N.J.A.C. 13:39-11.18, Controlled environment: construction, recodified to N.J.A.C. 13:39-11.17.

13:39-11.19 Controlled environment for compounded sterile preparations: 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 ISO class 6 air-quality conditions during normal activity shall be in place.

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

1. An ISO class 5 or better laminar airflow hood or a suitable ISO class 5 or better HEPA filter system;

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

3. Ancillary supplies required for proper compounding.

Recodified from N.J.A.C. 13:39-11.15 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Rewrote (d); and in (e), deleted former 2 and recodified former 3 and 4 as 2 and 3.
Recodified from N.J.A.C. 13:39-11.20 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (d), substituted "ISO class 6" for "class 1,000"; in (e), rewrote 1. Former N.J.A.C. 13:39-11.19, Controlled environment: stocking, maintenance and supplies, recodified to N.J.A.C. 13:39-11.18.

13:39-11.20 Controlled environment for compounded sterile preparations: anteroom

(a) The anteroom shall have an air quality of ISO class 7 or better.

(b) The anteroom shall contain the following equipment:

1. A sink with hot and cold running water;

2. Waste containers for all personal protective equipment;

3. An eyewash station; and

4. A hazardous waste spill kit.

(c) A refrigerator, as required by United States Pharmacopoeia Standards, shall be reasonably accessible to the anteroom to ensure the integrity of the compounded sterile preparations, but shall not be located within the controlled environment.

Recodified from N.J.A.C. 13:39-11.16 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
In (b), deleted former 2 and recodified former 3 through 5 as 2 through 4; and deleted (d).
Recodified from N.J.A.C. 13:39-11.21 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a), substituted "ISO class 7" for "Class 10,000"; in (c), substituted "integrity of the compounded sterile preparations, but shall" for "integrity of the sterile admixture product, but shall". Former N.J.A.C. 13:39-11.20, Controlled environment: clean room, recodified to N.J.A.C. 13:39-11.19.

13:39-11.21 Vertical air laminar flow hoods for compounded sterile preparations

(a) Pharmacies shall compound antineoplastic agents and other hazardous substances in an ISO class 5 vertical air laminar flow hood.

(b) Personnel who compound and dispense antineoplastic agents and other hazardous substances shall adhere to OSHA Work Practice Guidelines, as set forth in CPL 2-2.20B CH-4, Chapter 21, incorporated herein by reference, as amended and supplemented.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Recodified from N.J.A.C. 13:39-11.22 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

In (a), substituted "an ISO class 5" for "a class 100". Former N.J.A.C. 13:39-11.21, Controlled environment: anteroom, recodified to N.J.A.C. 13:39-11.20.

13:39-11.22 Laminar air flow hoods not in a clean room for compounded sterile preparations

Institutional pharmacy ISO class 5 laminar air flow hoods not located in a clean room may only be located in an area which is maintained under sanitary conditions and traveled by persons engaging in the compounding of sterile preparations. Such hoods shall be certified by an independent certification company prior to use when first installed or after being moved and at six-month intervals.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Recodified from N.J.A.C. 13:39-11.23 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Substituted "ISO class 5" for "class 100" and "engaging in the compounding of sterile preparations" for "engaging in sterile product preparation". Former N.J.A.C. 13:39-11.22, Vertical air laminar flow hoods, recodified to N.J.A.C. 13:39-11.21.

13:39-11.23 Controlled environment for compounded sterile preparations: self-contained sterile glove boxes

Self-contained ISO class 5 glove boxes, barrier isolation technology or the equivalent not located in a clean room may only be located in an area which is maintained under sanitary conditions and traveled by persons engaging in the compounding of sterile preparations. Such boxes shall be certified by an independent certification company prior to use when first installed or after being moved and at six-month intervals.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Recodified from N.J.A.C. 13:39-11.24 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Substituted "ISO class 5" for "class 10 to class 100" following "Self contained" and "engaging in the compounding of sterile preparations" for "engaging in sterile product preparation". Former N.J.A.C. 13:39-11.23, Laminar air flow hoods not in a clean room, recodified to N.J.A.C. 13:39-11.22.

13:39-11.24 Library references

In addition to the minimum reference library mandated in N.J.A.C. 13:39-5.8, each pharmacy engaged in compounding shall contain recognized references pertinent to specialized compounding preparations.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Recodified from N.J.A.C. 13:39-11.25 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39-11.24, Controlled environment: self-contained sterile glove boxes, recodified to N.J.A.C. 13:39-11.23.

13:39-11.25 Disposal of drugs and materials

All unused drugs and materials used in the compounding of preparations, including antineoplastic agents, shall be 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), so as not to endanger the public health.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Recodified from N.J.A.C. 13:39-11.26 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Substituted "compounding of preparations" for "preparation of sterile admixture products" preceding "including antineoplastic agents". Former N.J.A.C. 13:39-11.25, Library references, recodified to N.J.A.C. 13:39-11.24.

13:39-11.26 Security

The compounding area and its contents and other areas where compounded preparations are present shall be secured, so as to prevent access by unauthorized personnel.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Recodified from N.J.A.C. 13:39-11.27 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Substituted "compounding" for "sterile admixture" following "The" and "compounded preparations" for "sterile admixture drugs" following "area and its contents and other areas where". Former N.J.A.C. 13:39-11.26, Disposal of drugs and materials, recodified to N.J.A.C. 13:39-11.25.

13:39-11.27 Reserved

Recodified to N.J.A.C. 13:39-11.26 by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Section was "Security".

SUBCHAPTER 12. NUCLEAR PHARMACIES

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.