"Positive pressure room" means a room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is out of the room.

"Primary engineering control" means a device or room that provides an ISO class 5 environment for the exposure of critical sites when compounding sterile preparations. Such devices include laminar airflow workbenches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators.

"Risk levels for compounded sterile preparations" means the established classification for compounded sterile preparations based on the potential for microbial, chemical, and physical contamination of the preparations and are defined as follows:

1. "Low-risk level compounded sterile preparations" means preparations compounded with aseptic manipulations entirely within ISO class 5 or better air quality using only sterile ingredients, products, components, and devices. The compounding process involves only assembling, transferring, measuring, and mixing, using no more than three commercially manufactured sterile products, and not more than two entries into one sterile container or package to make the compounded sterile preparations. The compounding process is limited to aseptically opening ampules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.

2. "Medium-risk level compounded sterile preparations" means preparations compounded under low-risk level conditions but which require multiple individual or small doses of sterile products to be combined or pooled to prepare compounded sterile preparations that will be administered either to multiple patients or to one patient on multiple occasions. The compounding process includes complex aseptic manipulations other than single volume transfer, and requires an unusually long duration, such as that required to complete dissolution or homogeneous mixing.

3. "High-risk level compounded sterile preparations" means preparations compounded from non-sterile ingredients or from ingredients that are incorporated using non-sterile equipment before terminal sterilization, or from commercially manufactured sterile products that lack effective antimicrobial preservatives and whose preparation, transfer, sterilization, and packaging is performed in air quality worse than ISO class 5 for more than one hour. Water-containing preparations that are stored for more than six hours before terminal sterilization are also classified as high-risk level compounded 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. 13:39-11.2, 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.
Amended by R.2013 d.084, effective June 3, 2013.
See: 45 N.J.R. 439(a), 45 N.J.R. 1400(b).
Added definitions "Ante area", "Biological safety cabinet", "Buffer area", "Cleanroom", "Compounding", "Compounding aseptic containment isolator", "Compounding aseptic isolator", "Immediate use compounded sterile preparations", "ISO class 8 air quality conditions", "Negative pressure room", "Positive pressure room", "Primary engineering control", and "Risk levels for compounded sterile preparations"; in definitions "ISO class 5 air quality conditions" and "ISO class 7 air quality conditions", inserted "that is supplied by high-efficiency particulate air (HEPA) or HEPA-filtered air"; and deleted definition "ISO class 6 air quality conditions".

13:39-11.3 Application and pre-approval requirements for compounding sterile preparations

(a) An applicant for a new pharmacy who wishes to compound sterile preparations shall satisfy all pharmacy permit application requirements set forth in N.J.A.C. 13:39-4.1. As part of the permit application, the applicant shall submit plans detailing the physical arrangements necessary to ensure compliance with the requirements in this subchapter. An applicant for a pharmacy permit shall not dispense sterile preparations compounded at the site until receiving written approval from the Board to engage in such activities. Prior to issuing the written approval, the Board shall conduct an inspection of the pharmacy to ensure compliance with the requirements in this subchapter.

(b) The holder of an existing pharmacy permit who wishes to compound sterile preparations shall submit an amended pharmacy permit application to the Board. The amended permit application shall contain plans detailing the physical arrangements necessary to ensure compliance with the requirements in this subchapter. The holder of an existing pharmacy permit shall not dispense sterile preparations compounded at the site until receiving written approval from the Board to engage in such activities. Prior to issuing the written approval, the Board shall conduct an inspection of the pharmacy to ensure compliance with the requirements in this subchapter.

(c) A pharmacy permit holder who is approved to compound sterile preparations shall notify the Board at least 60 days in advance of any remodeling, change of location, or change in size of the pharmacy cleanroom, consistent with the requirements of N.J.A.C. 13:39-4.7 and 4.8. Such notification shall include the pharmacy's remodeling or relocation plans, as appropriate, the pharmacy's interim plans for the continuation of sterile compounding operations, which the Board shall review and approve, and the anticipated date of completion. The pharmacy permit holder and the pharmacist-in-charge shall ensure compliance with all requirements set forth in this subchapter while compounding operations continue during the remodeling or relocation process. The pharmacy permit holder shall notify the Board upon completion of the remodeling or relocation process, at which time the Board shall inspect the premises.

(d) A pharmacy holding an institutional permit that is approved to compound sterile preparations and that intends to compound sterile preparations using a laminar air flow workbench not located in a buffer area, as provided in N.J.A.C. 13:39-11.10, shall notify the Board at least 60 days in advance of its intention and of all locations where such equipment will be installed. The pharmacy permit holder shall notify the Board upon completion of such installation, at which time the Board shall inspect the equipment. The pharmacy shall not utilize such equipment to compound sterile preparations until receiving Board approval.

(e) A pharmacy permit holder who is approved to compound sterile preparations and who intends to utilize compounding aseptic isolators or compounding aseptic containment isolators not located in a buffer area, as provided in N.J.A.C. 13:39-11.8, shall notify the Board at least 60 days in advance of its intention and of all locations where such equipment will be installed. The pharmacy permit holder shall notify the Board upon completion of such installation, at which time the Board shall inspect the equipment. The pharmacy shall not utilize such equipment to compound sterile preparations until receiving Board approval.

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.
Repeal and New Rule, R.2013 d.084, effective June 3, 2013.
See: 45 N.J.R. 439(a), 45 N.J.R. 1400(b).
Section was "Sterile and non-sterile preparation services; environment".

13:39-11.4 Cleanroom: use, access, location; temperature; air pressure

(a) The pharmacy shall have a designated area for sterile preparation compounding, known as the "cleanroom." A cleanroom shall be physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites. Critical sites are locations that include any component or fluid pathway surfaces (for example, vial septa, injection ports, beakers), openings (for example, opened ampules, needle hubs), exposed and at risk of direct contact with air (for example, ambient room or HEPA-filtered), moisture (for example, oral and mucosal secretions), or touch contamination. A cleanroom shall include a buffer area and an ante area. The buffer area shall contain an ISO class 5 or better primary engineering control, such as a laminar airflow workbench, biological safety cabinet, compounding aseptic isolator, and/or compounding aseptic containment isolator, unless the buffer area has ISO class 5 or better air quality.

(b) All sterile compounding shall take place within the confines of the buffer area, except for the following:

1. Compounding in a compounding aseptic isolator or a compounding aseptic containment isolator pursuant to N.J.A.C. 13:39-11.8;

2. Compounding in a laminar air flow workbench in an institutional pharmacy pursuant to N.J.A.C. 13:39-11.10; and

3. Compounding immediate use compounded sterile preparations in an institutional pharmacy pursuant to N.J.A.C. 13:39-11.11.

(c) A cleanroom shall be:

1. Accessible only to designated personnel;

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

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 with an ideal temperature of 66 degrees Fahrenheit.

(d) A pressure indicator or air velocity meter shall be installed that can be readily monitored for correct room pressurization or air velocity, respectively, consistent with the following:

1. For compounding of non-hazardous drugs, if the buffer area and the ante area are physically separated through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02 inch to 0.05 inch water column shall be required. For buffer areas not physically separated from the ante area, the principle of displacement airflow shall be employed. Using displacement airflow, an air velocity of 40 feet per minute or more from the buffer area across the line of demarcation into the ante area is required.

2. For compounding of antineoplastic agents and other hazardous substances in a cleanroom pursuant to N.J.A.C. 13:39-11.9, the primary engineering control shall be placed in an ISO class 7 buffer room that is physically separated from other preparation areas and has not less than 0.01 inch water column negative pressure to adjacent positive pressure ISO class 7 or better ante room, thus providing inward airflow to contain any airborne drug.

3. For compounding of antineoplastic agents and other hazardous substances outside of a cleanroom pursuant to N.J.A.C. 13:39-11.8, if a compounding aseptic containment isolator is used outside of a buffer area, the compounding area shall be physically separated from other areas and shall maintain a minimum negative pressure of 0.01 inch water column and have a minimum of 12 air exchanges per hour.

(e) No chewing gum, drinks, candy, or food items shall be brought into the cleanroom.

The following annotations apply to N.J.A.C. 13:39-11.4 prior to its repeal by R.2013 d.084:

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.

The following annotations apply to N.J.A.C. 13:39-11.4 subsequent to its recodification from N.J.A.C. 13:39-11.16 by R.2013 d.084:

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.
Recodified from N.J.A.C. 13:39-11.16 and amended by R.2013 d.084, effective June 3, 2013.
See: 45 N.J.R. 439(a), 45 N.J.R. 1400(b).
Section was "Controlled environment for compounded sterile preparations: use, access, location; temperature". Rewrote (a); added new (b); recodified former (b) as (c); in the introductory paragraph of (c), and in (c)2, substituted "cleanroom" for "controlled environment"; in (c)2, deleted a comma following "preparations"; in (c)4, inserted "with an ideal temperature of 66 degrees Fahrenheit"; and added (d) and (e). Former N.J.A.C. 13:39-11.4, General requirement for compounded sterile preparations; pre-approval, repealed.

13:39-11.5 Cleanroom requirements

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

(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. All work surfaces shall be resistant to damage from cleaning and sanitizing agents.

(c) Junctures where ceilings meet walls shall be covered, caulked, or sealed to avoid cracks and crevices in which microorganisms and other contaminates can accumulate. All areas in ceilings and walls where the surface has been penetrated shall be sealed.

(d) Ceilings that 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) Walls shall be constructed of flexible material (for example, heavy gauge polymer), panels locked together and sealed, or of epoxy-coated gypsum board.

(f) Floors shall have a covering that shall be seamless or have heat-welded seams and coving to the sidewall. There shall be no floor drains.

(g) There shall be no dust-collection overhangs (such as ceiling utility pipes) and ledges (such as window sills) should be avoided. 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) Carts shall be of stainless steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility.

(j) Refrigerators shall be within, or reasonably accessible to, the cleanroom in order to ensure the integrity of the compounded sterile preparations, consistent with the requirements of N.J.A.C. 13:39-11.12(b)3.

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.
Recodified from N.J.A.C. 13:39-11.17 and amended by R.2013 d.084, effective June 3, 2013.
See: 45 N.J.R. 439(a), 45 N.J.R. 1400(b).
Section was "Controlled environment for compounded sterile preparations: construction". Substituted "cleanroom" for "controlled environment" in (a); rewrote (b) and (c); in (d), substituted "that" for "which"; rewrote (e); in (f), inserted "There shall be no floor drains"; in (g), substituted "and ledges (such as window sills) should be avoided" for "or ledges (such as window sills)"; and rewrote (i) and (j). Former N.J.A.C. 13:39-11.5, Pharmacist in charge and permitholders' responsibilities, recodified to N.J.A.C. 13:39-11.12.

13:39-11.6 Ante area requirements

(a) The ante area shall have appropriate environmental control devices capable of maintaining ISO class 8 air quality conditions for non-hazardous drug compounding activities and ISO class 7 air quality conditions for hazardous drug compounding activities as provided in N.J.A.C. 13:39-11.4(d)2.

(b) The ante area shall contain the following equipment:

1. A sink with hot and cold running water with an integrated and closed plumbing system;

2. Waste containers for all personal protective equipment;

3. An eyewash station; and

4. A hazardous waste spill kit.

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.
Recodified from N.J.A.C. 13:39-11.20 and amended by R.2013 d.084, effective June 3, 2013.
See: 45 N.J.R. 439(a), 45 N.J.R. 1400(b).
Section was "Controlled environment for compounded sterile preparations: anteroom". Rewrote (a); in the introductory paragraph of (b), substituted "ante area" for "anteroom"; in (b)1, inserted "with an integrated and closed plumbing system"; and deleted (c). Former N.J.A.C. 13:39-11.6, Pharmacy technicians, interns and externs; required supervision, recodified to N.J.A.C. 13:39-11.13.

13:39-11.7 Buffer area requirements

(a) The buffer area shall have appropriate environmental control devices capable of maintaining ISO class 7 air quality conditions during normal activity consistent with the requirements of N.J.A.C. 13:39-11.4(d).

(b) The buffer area shall contain only the following:

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

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

3. Items that have been cleaned and disinfected immediately prior to their being placed in the buffer area.

(c) Equipment and other items used in the buffer area shall not be taken from these areas except for calibration, servicing, or other activities associated with the proper maintenance of the item.

(d) The buffer area shall be kept clean and arranged in an orderly fashion. All required equipment shall be maintained in good operating condition.

(e) The buffer area shall not be used for bulk storage, warehousing, or clerical and secretarial functions.

(f) The buffer area shall not contain any sinks.

(g) The buffer area shall be a minimum of 100 square feet in size and shall be compatible with the volume of compounding being conducted.

(h) The buffer area shall contain waste containers in compliance with Occupational Safety and Health Administration (OSHA) standards for disposal of used needles and syringes set forth in 29 CFR 1910.1030 and for disposal of chemotherapy waste set forth at 29 CFR 1910.1200, incorporated herein by reference, and available at www.osha.gov.

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.
Recodified from N.J.A.C. 13:39-11.18 and amended by R.2013 d.084, effective June 3, 2013.
See: 45 N.J.R. 439(a), 45 N.J.R. 1400(b).
Section was "Controlled environment for compounded sterile preparations: stocking, maintenance and supplies". Rewrote the section. Former N.J.A.C. 13:39-11.7, Training requirements for compounding sterile preparations, recodified to N.J.A.C. 13:39-11.16.

13:39-11.8 Use of compounding aseptic isolators and compounding aseptic containment isolators located outside of a cleanroom

A pharmacy may utilize compounding aseptic isolators and compounding aseptic containment isolators not located in a cleanroom to prepare compounded sterile preparations, provided the compounding aseptic isolators and compounding aseptic containment isolators can provide isolation from the room and maintain ISO class 5 air quality during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of compounded sterile preparations. A pharmacy utilizing a compounding aseptic containment isolator not located in a cleanroom to compound antineoplastic agents and other hazardous substances shall comply with the requirements of N.J.A.C. 13:39-11.4(d)3. Particle counts sampled approximately six to 12 inches upstream of the critical exposure site must maintain ISO class 5 air quality levels during compounding operations. Compounding personnel shall obtain documentation from the manufacturer that the compounding aseptic isolator or compounding aseptic containment isolator will meet this standard when located in worse than ISO class 7 environments. A compounding aseptic isolator and compounding aseptic containment isolator not located in a buffer area shall be located in an area that is maintained under sanitary conditions and such area shall only be traveled by persons engaging in the compounding of sterile preparations.

New Rule, R.2013 d.084, effective June 3, 2013.
See: 45 N.J.R. 439(a), 45 N.J.R. 1400(b).
Former N.J.A.C. 13:39-11.8, Batch preparation, recodified to N.J.A.C. 13:39-11.17.

Rewrote the section. Former N.J.A.C. 13:39-11.5, General requirement, recodified to N.J.A.C. 13:39-11.4.
Recodified from N.J.A.C. 13:39-11.5 and amended by R.2013 d.084, effective June 3, 2013.
See: 45 N.J.R. 439(a), 45 N.J.R. 1400(b).
Section was "Pharmacist in charge and permitholders' responsibilities". Rewrote the section. Former N.J.A.C. 13:39-11.12, Handling, packaging and delivery, recodified to N.J.A.C. 13:39-11.22.

13:39-11.13 Pharmacy technicians, pharmacy interns, and pharmacy externs; required supervision

(a) Pharmacists shall provide immediate personal supervision to pharmacy technicians, pharmacy interns, or pharmacy externs who are performing sterile compounding. The ratio of pharmacists to pharmacy technicians shall not exceed 1:2 at any given time unless all of the requirements of N.J.A.C. 13:39-6.15 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 pharmacist may delegate to pharmacy technicians, pharmacy interns, or pharmacy externs only the following tasks: recording of the prescription, selection of the drugs, container, and diluent, labeling, and compounding of preparations. The pharmacist shall ensure that each task has been performed correctly.

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.
Recodified from N.J.A.C. 13:39-11.6 and amended by R.2013 d.084, effective June 3, 2013.
See: 45 N.J.R. 439(a), 45 N.J.R. 1400(b).
Section was "Pharmacy technicians, interns and externs; required supervision". Rewrote the introductory paragraph of (a) and (b). Former N.J.A.C. 13:39-11.13, Policy and procedure manual for compounded sterile preparations, recodified to N.J.A.C. 13:39-11.23.

13:39-11.14 Personnel cleansing and garbing requirements

(a) All personnel who engage in compounding sterile preparations shall comply with the following requirements before entering the buffer area:

1. Personnel shall remove personal outer garments (for example, bandanas, coats, hats, jackets, scarves, sweaters, vests), all cosmetics, and hand, wrist, and other visible jewelry or piercings (for example, earrings, or lip or eyebrow piercings);

2. The wearing of artificial nails or extenders is prohibited while working in the compounding area. Natural nails shall be kept neat and trimmed;

3. Personnel protective equipment shall be donned in the following order:

i. Dedicated shoes or shoe covers;

ii. Head and facial hair covers (for example, beard covers in addition to face masks);

iii. Face masks; and

iv. Eye shields, if required;

4. A hand and forearm cleansing procedure shall be performed. Personnel shall remove debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing for at least 30 seconds. Hands and forearms to the elbows shall be completely dried using either lint-free disposable towels or an electric hand dryer; and

5. Personnel shall wear non-shedding gowns with sleeves that fit snugly around the wrists and enclosed at the neck, that are designed for buffer area use.

(b) Following the completion of all steps in (a) above, and once inside the buffer area, personnel shall perform antiseptic hand cleansing, using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations. Once hands are dried thoroughly, personnel shall don sterile gloves. Gloves shall be routinely inspected for holes, punctures, or tears, and shall be replaced immediately if any are detected.

1. Gloves become contaminated when they make contact with non-sterile surfaces during compounding activities. Disinfection of contaminated gloved hands may be accomplished by wiping or rubbing sterile 70 percent Isopropyl Alcohol (IPA) on all contact surface areas of the gloves and letting the gloved hands dry thoroughly. Routine application of sterile 70 percent IPA shall occur throughout the compounding process and whenever non-sterile surfaces (for example, vials, counter tops, chairs, and carts) are touched.

(c) When compounding personnel exit the cleanroom during a work shift, the exterior gown may be removed and retained in the cleanroom if not visibly soiled, and may be re-donned during that same work shift only. Shoe covers, hair and facial hair covers, face masks/eye shields, and gloves, however, shall be replaced with new ones before re-entering the buffer area, and proper hand hygiene shall be performed, consistent with (a) and (b) above.

New Rule, R.2013 d.084, effective June 3, 2013.
See: 45 N.J.R. 439(a), 45 N.J.R. 1400(b).
Former N.J.A.C. 13:39-11.14, Quality assurance program for compounded sterile preparations, recodified to N.J.A.C. 13:39-11.24.

13:39-11.15 Cleaning and disinfection requirements for cleanroom, buffer area, and ante area

(a) The cleanroom, buffer area, and ante are shall be cleaned and disinfected consistent with the following requirements:

1. All surfaces in laminar airflow workbenches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators shall be cleaned and disinfected at the beginning of each work shift, before each batch preparation is started, after spills, and when surface contamination is known or suspected;

2. All counters, work surfaces, and floors shall be cleaned and disinfected daily; and

3. All walls, ceilings, and storage shelving shall be cleaned monthly.

(b) All cleaning and disinfection shall be performed consistent with the standards established in USP 797 Appendix II, which is incorporated herein by reference, as amended and supplemented, and which is available for purchase at the United States Pharmacopeia website, www.usp.org.

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.
Repeal and New Rule, R.2013 d.084, effective June 3, 2013.
See: 45 N.J.R. 439(a), 45 N.J.R. 1400(b).
Section was "Patient profile records for compounded sterile preparations".

13:39-11.16 Training and evaluation requirements

(a) The pharmacist-in-charge and all pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs involved in compounding sterile preparations shall have didactic and practical training in sterile preparation compounding, including proper personnel cleansing and garbing, and cleaning and disinfecting the sterile compounding areas, cleanroom technology, laminar flow technology, isolator technology, if applicable, and quality assurance techniques. Such training shall be documented for each person before that individual begins to compound sterile preparations and annually thereafter for all pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs who compound sterile preparations. 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 and annually thereafter, all pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs shall have passed a written test that demonstrates competency in all areas set forth in (a) above, and in 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. 13:39-11.23.

(c) The pharmacist-in-charge shall be responsible for testing of the aseptic technique of all pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs involved in compounding sterile preparations, consistent with the methods set forth in USP 797 concerning "Aseptic Manipulation Competency Evaluation," incorporated herein by reference, as amended and supplemented, and which is available for purchase at the United States Pharmacopeia website, www.usp.org, prior to compounding sterile preparations. Aseptic technique retesting shall be conducted annually for all personnel engaged in compounding low- and medium-risk level preparations and semi-annually for all personnel engaged in compounding high-risk level preparations.

(d) All pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs engaging in the compounding of sterile preparations shall successfully complete an initial gloved fingertip/thumb sampling procedure prior to compounding sterile preparations. Gloved fingertip/thumb sampling shall be conducted annually for all personnel engaged in compounding low- and medium-risk level preparations and semi-annually for all personnel engaged in compounding high-risk level preparations.

(e) Individuals who fail the written test and/or the test of aseptic technique shall be prohibited from compounding sterile preparations until passing both tests.

(f) All test results shall be maintained by the permit holder for five years and shall be made available to the Board for inspection upon request.

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.
Recodified from N.J.A.C. 13:39-11.7 and amended by R.2013 d.084, effective June 3, 2013.
See: 45 N.J.R. 439(a), 45 N.J.R. 1400(b).
Section was "Training requirements for compounding sterile preparations". Rewrote the section. Former N.J.A.C. 13:39-11.16, Controlled environment for compounded sterile preparations: use, access, location; temperature, recodified to N.J.A.C. 13:39-11.4.

13:39-11.17 Batch preparation

(a) Pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs, consistent with N.J.A.C. 13:39-11.13, may compound sterile preparations in a quantity that is supported by prior valid prescriptions or medication orders before receiving a valid written prescription or medication order, provided the pharmacist: