VOLUME 45, ISSUE 11

ISSUE DATE: JUNE 3, 2013

RULE ADOPTIONS

LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

Adopted Amendments: N.J.A.C. 13:39-11.1, 11.2, and 11.5 through 11.14

Adopted Repeals and New Rules: N.J.A.C. 13:39-11.3, 11.11, 11.15, and 11.19

Adopted New Rules: N.J.A.C. 13:39-11.8, 11.9, 11.14, 11.18, and 11A

Adopted Repeals: N.J.A.C. 13:39-11.4, 11.21, 11.23, 11.24, 11.25, and 11.26

Adopted Recodifications with Amendments: N.J.A.C. 13:39-11.16, 11.17, 11.18, 11.20, and 11.22 as 13:39-11.4, 11.5, 11.7, 11.6, and 11.10, respectively

Compounding Sterile and Non-Sterile Preparations in Retail and Institutional Pharmacies

Proposed: March 4, 2013 at 45 N.J.R. 439(a).

Adopted: April 24, 2013 by the State Board of Pharmacy, Thomas F.X. Bender, R.Ph, Vice President.

Filed: May 9, 2013 as R.2013 d.084, **with a substantial and technical change** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:14-47 and 48.

Effective Date: June 3, 2013.

Expiration Date: May 17, 2017.

Summary of Public Comments and Agency Responses:

The official comment period ended April 3, 2013. The Board of Pharmacy (Board) received comments from the following:

1. Robert Fusco, President, NJ Association of Long-Term Care Pharmacy Providers;

2. Anthony J. Grzib, Pharamcist-in-Charge, Wedgewood Pharmacy;

3. Anne Nolan Fellows, State Director, National Association of Chain Drug Stores;

4. John Scott Karolchyk, Pharmacy Creations;

5. Elise M. Barry, CEO, New Jersey Pharmacists Association;

6. John Covello, Executive Director of Government and Public Affairs, Independent Pharmacy Alliance; and

7. Daniel Buchner, Central Admixture Pharmacy Services.

1. COMMENT: Three commenters expressed overall support for the Board's proposed changes, specifically as to the reorganization of the compounding rules into two distinct subchapters for sterile and non-sterile compounding. One commenter noted that this reorganization will help ensure clarity. Another commenter noted that this separate regulatory approach will make "regulating compounding administratively better" and will make it easier for independent pharmacies to understand the regulatory requirements for preparing compounded medications. Two commenters also expressed support for the Board's extensive changes to be consistent with industry best practices and industry developed and nationally recognized standards. One commenter stated that "these substantive and organizational changes will go a long way toward safeguarding the public and preventing patient harm."

RESPONSE: The Board thanks the commenters for their support.

2. COMMENT: Two commenters expressed concern about the regulation of out-of-State pharmacies. One commenter suggested adding language to ensure that out-of-State pharmacies are regulated in the same manner as in-State pharmacies. The commenter also suggested that a representative of the Board conduct an equivalent inspection and that the applicant pay the inspection costs incurred for the out-of-State inspection before granting a permit. Another commenter suggested that the regulations expressly state that the proposed regulatory compliance and enforcement procedures will be imposed on any sterile compounding

[page=1401] pharmacy that provides sterile compounded preparations to any New Jersey-based health care facility and patients, regardless of where the sterile compounding pharmacy is located. The commenter also asked the Board to clarify how it will enforce the proposed sterile compounding regulations as to the out-of-State entities for their quality control, procedures, and processes, and other key regulatory proposals.

RESPONSE: The Board relies on its authority under N.J.S.A. 45:14-73 to obtain information, including inspection reports, from out-of-State pharmacies. The out-of-State pharmacies are subject to the rules of the regulatory or licensing agency of the state in which it is located.

3. COMMENT: One commenter asked for a definitive definition of a buffer area.

RESPONSE: The Board believes the definition of a buffer area in proposed new N.J.A.C. 13:39-11.1 is clear. In proposed new N.J.A.C. 13:39-11.1, the Board defines "buffer area" to mean an ISO class 7 area where the primary engineering control is physically located and where the preparation and staging of components and supplies used in compounding sterile preparations occur.

4. COMMENT: One commenter suggested not specifying a vinyl floor because vinyl can get scuffed, cut, and torn, and is not easy to repair without cracks. The commenter suggested that there are better alternatives, such as other harder surfaces without any seams and can be caulked to the side walls making them seamless to the walls.

RESPONSE: The Board agrees with the commenter and is deleting the requirement in N.J.A.C. 13:39-11.5(f) that floors be covered with vinyl. Additional public notice of this change is not required because the change does not increase the burden on pharmacy permitholders or decrease the protections for the public. The effect of the deletion is to leave the requirements for floor coverings in clean rooms generic. A permitholder has the option to use vinyl or other floor covering, as long as it is seamless or has heat-welded seams and coving to the sidewall, and satisfies the requirements of N.J.A.C. 13:39-11.5(a), such that it is smooth, impervious, free from cracks and crevices, and nonshedding.

5. COMMENT: One commenter asked for clarification about the type of area needed for actual compounding of sterile preparations before they are placed into compounding aseptic isolators or a clean room.

RESPONSE: In accordance with proposed new N.J.A.C. 13:9-11.8, the area should be maintained under sanitary conditions and such area is to be traveled only by persons engaging in the compounding of sterile preparations. The Board also notes that, as a staging area, the area must be able to maintain the sterility of the compounding ingredients and equipment.

6. COMMENT: One commenter asked whether the garbing and seamless tiles requirements apply to the use of cais (compounding aseptic isolators) and cacis (compounding aseptic containment isolators) outside of an ISO 7 buffer area.

RESPONSE: In proposed new N.J.A.C. 13:39-11.10, the Board requires compliance with the garbing requirements of N.J.A.C. 13:39-11.14 when using compounding aseptic isolators and compounding aseptic containment isolators outside of an ISO 7 buffer area. The Board does not prescribe any flooring requirements when using compounding aseptic isolators and compounding aseptic containment isolators outside of an ISO 7 buffer area.

7. COMMENT: One commenter requested clarification of the term "supervise" in proposed new N.J.A.C. 13:39-11.12(a) in order to be consistent with proposed new N.J.A.C. 13:39-11.12(b)6. The commenter noted that the term "supervise" can be interpreted to mean "direct" supervision. The commenter further noted that many facilities and retail pharmacies operate on a 24-hour basis and believes it is important to consider that the pharmacist-in-charge will not be present at all times.

RESPONSE: N.J.A.C. 13:39-11.12(a) and (b) require that the pharmacist-in-charge, who is trained in aseptic manipulation skills, ensure that the preparation and compounding of sterile preparations is performed by pharmacists or pharmacy personnel under the immediate personal supervision of a pharmacist trained in aseptic manipulation skills. In N.J.A.C. 13:39-1.1, the Board defines "immediate personal supervision" to mean that the pharmacist is physically present in the compounding/dispensing area. In accordance with the new rules and amendments, the pharmacist-in-charge does not need to be physically present, but must ensure a pharmacist trained in aseptic manipulation skills is physically present to supervise pharmacy personnel engaged in sterile compounding. The Board also expects the pharmacist-in-charge to comply with the requirements of N.J.A.C. 13:39-6.2(f), which list his or her responsibilities and requires the pharmacist-in-charge to be present in the pharmacy for the amount of time, at least 35 hours per week, necessary to discharge those responsibilities.

8. COMMENT: One commenter asked for clarification of proposed new N.J.A.C. 13:39-11.16(b) as to the minimum passing grade for the written test without requiring the test to be retaken.

RESPONSE: The pharmacist-in-charge is responsibile to establish the training protocol, including establishing a minimum passing grade, that satisfies the requirements of N.J.A.C. 13:39-11.16(b); the Board does not prescribe the specific testing requirements. The Board notes that it believes it is a recognized standard in education for a minimum passing grade to be 70 percent.

9. COMMENT: One commenter expressed concern with the language in proposed new N.J.A.C. 13:39-11.18 and 11A.6 referring to the pharmacist's duty to know the "State and Federal laws pertinent to the prescriber's health care practice." The commenter believes that this language implies that a pharmacist should know every state and Federal law with respect to any prescriber's practice. The commenter recommends that the Board modify the proposed language to mirror the current regulatory requirements in N.J.A.C. 13:39-7.1.

RESPONSE: Consistent with regulatory construction and interpretation of "State" (capitalized), the reference in N.J.A.C. 13:39-11.18 and 11A.6 is solely to the State of New Jersey. Therefore, the language in N.J.A.C. 13:39-11.18 and 11A.6 means New Jersey and Federal laws pertinent to the prescriber's health care practice. The Board, however, believes it behooves all pharmacists who ship compounded preparations into another state to be aware of that state's laws and regulations.

10. COMMENT: One commenter requested clarification of the reporting requirements of proposed new N.J.A.C. 13:39-11.23(b)1i and 11A.10(b). The commenter asks if it is the Board's intention for pharmacists to report confirmed incidents of product contamination in only products that have been dispensed, or is the Board requiring the reporting of confirmed incidents of product contamination for all products, even those that have not been dispensed. The commenter further notes that he is not aware of any similar reporting requirements in the USP or within other states' pharmacy rules.

RESPONSE: It is the Board's intention that pharmacists report all confirmed incidents of product contamination, even as to those products that have not been dispensed. Whenever confirmed contamination is detected at any point in the compounding process it is to be reported to the Board within 48 hours of becoming aware of any such incidents. To ensure the protection of patients, the Board recognizes that it is imposing a reporting requirement that is more expansive than other states may require. The Board notes that USP 797 and 795 do not include requirements for reporting to state regulators, reporting requirements are determined by the respective state boards of pharmacy. The Board believes, in view of recent events in a number of states involving product contamination, that a more expansive reporting requirement to include the reporting of all confirmed incidents of product contamination, even those that have not been dispensed, is necessary to protect the health and safety of the public.

11. COMMENT: One commenter objected to proposed new N.J.A.C. 13:39-11.24 requiring that all high risk compounds, except those for inhalation and ophthalmic administration, must be tested for excessive bacterial endotoxins. The commenter notes that this requirement is not consistent with USP 797, which only requires testing when "25 identical packages are prepared or six hours at more than eight degrees Celsius or 12 hours at two to eight degrees Celsius has

been exceeded." The commenter believes that the proposed testing requirement will create an excessive financial burden.

RESPONSE: The Board confirms its intent that the sterility testing described in proposed new N.J.A.C. 13:39-11.24(a)5ii be consistent with the requirements of USP 797. The Board clarifies that in the rule as proposed, all testing specifications of N.J.A.C. 13:39-11.24(a)5 apply to all sterility testing, including the testing for excessive bacterial [page=1402] endotoxins, except that testing for excessive bacterial endotoxins does not apply to preparations for inhalation and ophthalmic administration.

12. COMMENT: One commenter suggested that the Board expand the language in proposed new N.J.A.C. 13:39-11A.3 "beyond referencing the banned drugs listed in the FDA's regulations to specific that includes drugs on this list that are used for veterinary purposes, such as Cisapride."

RESPONSE: The Board does not understand what the commenter is suggesting. If the commenter is suggesting that the language in N.J.A.C. 13:39-11A.3 be expanded to specifically include drugs that are used for veterinary purposes, the commenter did not offer any reasons for it suggestion, but the Board believes that the Federal Food and Drug Administration's list of Drug Products Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness applies to drug products for use by both humans and animals. With respect to the commenter's suggestion to add Cisapride, the Board believes that the Federal Food and Drug Administration is more qualified to determine which drug products many not be compounded. Accordingly, the Board declines to change the language as the comment suggests.

13. COMMENT: One commenter expressed concern with the requirement in proposed new N.J.A.C. 13:39-11A.4 for pharmacists who compound a commercially available product to maintain documentation of the reason for making the compound. The commenter noted that currently the pharmacy obtains the recipe for a commercially available product and provides an explanation, by email, as to why the patient needs the medication compounded versus using the commercially available product. The commenter suggests that the Board remove the proposed requirements and allow for email records that are currently being maintained to serve as adequate documentation of the reason for compounding these commercially available products.

RESPONSE: The Board notes that it does not specify the format or manner in which the documentation required in proposed new N.J.A.C. 13:39-11A.4 is to be maintained. The Board will accept any documentation that provides a rationale for compounding a commercially available product. Consistent with other documentation requirements set forth in the Board's rules, the Board expects the records to be readily retrievable and printable.

14. COMMENT: One commenter expressed concerns with new N.J.A.C. 13:39-11A.6

permitting, without a prescription, the preparation of compounded non-sterile preparations for a licensed prescriber for use in the prescriber's practice. The commenter similarly expressed concern with new N.J.A.C. 13:39-11A.7 permitting, without a prescription, the preparation of pharmacy generated products for over-the-counter sale. The commenter noted that this practice is prohibited in the majority of all retail community pharmacy settings. The commenter also believes that the language in these rules conflicts with N.J.A.C. 13:39-1.2 in which compounding is defined to mean "the preparation, mixing, assembling, packaging, and labeling of a drug or device as a result of a practitioner's prescription or medication order." The commenter also believes that, as a safety measure to protect the patients, prescribers, and the pharmacy and, in an effort to maintain compliance with existing Board requirements for dispensing prescription drugs, all compounded prescriptions are to be dispensed pursuant to a valid prescription, regardless if they are for use by the individual patient or licensed prescriber. The commenter stated that, as with all other medications, the prescription and medication order, written or oral and reduced to hardcopy, serves as a record of the drugs being ordered and dispensed. The commenter suggests that the Board remove the language from the proposed rules to keep protections in place and maintain consistency with existing regulations for dispensing prescription drugs.

RESPONSE: The Board notes that the proposed rule changes to N.J.A.C. 13:39-11A.6 and 11A.7 do not alter the Board's long-standing authorization, consistent with State and Federal laws, for pharmacists without a prescription to compound non-sterile preparations for prescriber practice use and pharmacy generated products for over-the-counter sale; the proposed rule changes provide specific requirements for the preparation of medications under these circumstances. The Board also notes that a prescription is not required for medications prepared for pharmacy generated products for over-the-counter sale, as long as the product does not contain an ingredient that exceeds allowable strengths and doses for over-the-counter drugs. The Board further notes that N.J.A.C. 13:39-11A.7 specifically prohibits the pharmacist from compounding a pharmacy generated product to be sold over-the-counter without a prescription or medication order if the finished product is one for which a prescription or medication order is required. The Board believes that proposed new N.J.A.C. 13:39-11A.6 and 11A.7 are consistent with the definitions of compounding in N.J.A.C. 13:39-11.2 and 1.2. The Board notes that the commenter misquotes the definition of compounding in N.J.A.C. 13:39-1.2, which defines compounding to mean "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** (emphasis added) with the pharmacist in the course of professional practice . . . Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns." The Board similarly defines "compounding" in proposed new N.J.A.C. 13:39-11.2 to include preparations based on a practitioner's prescription or medication order or initiative based on the relationship of the practitioner or the patient with the pharmacist, which is consistent with N.J.S.A. 45:14-41.

The Board declines to amend the rules as suggested by the commenter.

15. COMMENT: One commenter asked the Board to clarify what is meant in proposed new N.J.A.C. 13:39-11A.8 by the respective terms "regularly" and "occasional" compounding. The commenter suggested defining the term "occasional" by adding immediately afterwards the term "simple" to be consistent with the term as used in USP 1075. The commenter believes additional specificity with respect to these terms will better enable pharmacies to comply with the non-sterile compounding preparation standards in order to protect patient's health and safety. The commenter also noted its support for the Board's approach in this rule to provide flexibility to independent pharmacies that do very little non-sterile compounding versus those stores that do this type of preparation more frequently and recognizes that this section will provide appropriate preparation and operational standards for any pharmacy conducting non-sterile compounding preparations.

RESPONSE: The Board thanks the commenter for its support. The Board believes that the terms "regularly" and "occasional" as used in proposed new N.J.A.C. 13:39-11A.8 are clear. As defined in Webster's II, New Riverside University Dictionary, "regularly" is intended to convey customary, usual, or normal or recurring at regular intervals, and "occasional" is infrequent. The Board believes that a pharmacist in his or her professional judgment can differentiate between regularly engaging and engaging in occasional compounding and, therefore, declines to modify the language as the commenter suggests.

16. COMMENT: One commenter noted that the requirement in proposed new N.J.A.C. 13:39-11A.10(b) for the pharmacist-in-charge to report to the Board any incidents of confirmed product contamination of non-sterile compounded products within 48 hours of becoming aware of any such incidents "is not a function that community retail pharmacies practice." The commenter noted that, in an effort to fully comply, pharmacies would need to implement procedures to satisfy this requirement, as well as add language to existing programs that would instruct the pharmacists to notify the Board within 48 hours of being notified of out-of range assay results. The commenter requests the Board to allow additional time for pharmacies to fully implement these changes in order to comply with these new requirements.

RESPONSE: The Board notes that proposed new N.J.A.C. 13:39-11A.10(b) does not require the pharmacist-in-charge to report out-of range assay results; the proposed new rule only requires the reporting of any incidents of confirmed product contamination of non-sterile compounded products. The Board does not believe pharmacies require additional time to implement the reporting requirements and, therefore, denies the commenter's request for additional time to implement these reporting requirements.

17. COMMENT: One commenter raised concerns with proposed new N.J.A.C. 13:39-11A.11 in

which, in those instances where the manufactured drug product is the source of the active ingredient, the beyond-use date should not be later than 25 percent of the time remaining until the product's expiration date or six months, whichever is earlier. The commenter noted that the most current version of the USP 795 [page=1403] changed the "25% criterion" to include the "duration of therapy," which recommends that the product is used within the duration of therapy and does not expire during the beyond-use-date. The commenter also noted that, currently in New Jersey, its member pharmacies use "duration of therapy" as opposed to the 25 percent of the time remaining.

RESPONSE: The Board recognizes that duration of therapy is included in USP 795 and notes that duration of therapy can vary amongst patients. The Board chose to use the 25 percent criterion because it is product specific, which the Board believes provides better protection for patients. The Board further notes that N.J.A.C. 13:39-11A.11(c) allows pharmacists to exceed the beyond-use date limits established in N.J.A.C. 13:39-11A.11 when there is supporting valid scientific stability information that is directly applicable to the specific preparation.

18. COMMENT: One commenter expressed concern that the beyond-use date for water-containing formulations prepared from ingredients in solid form in proposed new N.J.A.C. 13:39-11A.11 is from an outdated version of USP 795. The commenter contends that the current USP 795 guidelines state that the beyond-use-date for water-containing oral dosage forms shall not be later than 14 days when stored between 36 degrees and 46 degrees Fahrenheit, and that all other water-containing preparations, including dermal and mucosal liquids and semi-solid formulations, have a beyond-use-date no later than 30 days when stored between 36 degrees and 46 degrees Fahrenheit. The commenter suggests that these rules be revised to reflect the current edition of USP 795.

RESPONSE: The Board believes proposed new N.J.A.C. 13:39-11A.11 is consistent with the current USP 795 guidelines. Proposed new N.J.A.C. 13:39-11A.1(b)2 specifies that for water-containing formulations (prepared from ingredients in solid form) the beyond-use date shall not be later than 14 days for liquid preparations when stored at cold temperatures between two degrees and eight degrees Celsius (36 degrees and 46 degrees Fahrenheit). The rule further provides in N.J.A.C. 13:39-11A.1(b)3 that for all other formulations, including water-containing preparations (including dermal and mucosal liquids and semi-solid formulations) the beyond-use date shall not exceed the intended duration of therapy or 30 days, whichever is earlier. The Board declines to revise the rules as suggested by the commenter because the rules reflect the current edition of USP 795.

19. COMMENT: One commenter suggested that proposed new N.J.A.C. 13:39-11A.13 be amended to include a requirement to state "this medicine was specially compounded in our pharmacy for you at the direction of your prescriber." The commenter also suggested adding a

requirement, for office use only, that the non-sterile compounding preparation label include the phrase, "not for resale."

RESPONSE: The Board requires at a minimum the information specified in proposed new N.J.A.C. 13:39-11A.13, but does not preclude a licensee from choosing to include additional information. The Board does not believe that the commenter's suggested statement is required to ensure the health and safety of patients and declines to require it. Because the limited resale of medication is permitted (see N.J.S.A. 45:9-22.11), the Board declines to require including the phrase "not for resale."

20. COMMENT: One commenter asked the Board to clarify in proposed new N.J.A.C. 13:39-11A.14 whether the responsibility of the compounding pharmacist under proposed new N.J.A.C. 13:39-11A.10(a)3 to require that technicians are "capable of performing and qualified to perform their duties" imposes any training of this personnel in each area of non-sterile compounding and equipment used. The commenter also asked if there is a training requirement, what are the documentation and frequency requirements.

RESPONSE: In recognizing that the size, scope, and complexity of the compounding services offered by each pharmacy are different, the Board did not intend to prescribe specific training requirements. The pharmacist-in-charge is responsible for developing the pharmacy's training protocols specific to the individual pharmacy's practice. The Board expects the compounding pharmacist, similar to the responsibilities of the pharmacist-in-charge set forth in N.J.A.C. 13:39-6.2(f), to ensure that the compounding personnel are competent in keeping with the size, scope, and complexity of the compounding services provided by the pharmacy and the specific functions performed by the compounding personnel. N.J.A.C. 13:39-11A.10(a)3 requires the compounding pharmacist to ensure that the compounding personnel are capable of performing and qualified to perform their assigned duties. This responsibility inherently requires that the compounding pharmacist satisfy him- or herself that the compounding personnel have the requisite knowledge and proficiency and continually monitor the work performed.

Federal Standards Statement

A Federal standards analysis is not required because the adopted amendments, repeals, recodifications, and new rules do not exceed, and in some cases, incorporate by reference, standards and requirements set forth in USP 797 and 795, which may be viewed as establishing and setting forth Federal standards and requirements for sterile and non-sterile compounding. N.J.A.C. 13:39-11.23(b)1i and 11A.10(b) regarding the reporting requirements of confirmed incidents of product contamination do not exceed Federal standards because USP 797 and 795 do not set forth any requirements for reporting to state regulators.

Full text of the adoption follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks *[thus]*):

SUBCHAPTER 11. COMPOUNDING STERILE PREPARATIONS IN RETAIL AND INSTITUTIONAL PHARMACIES

13:39-11.1 Purpose and scope

The rules in this subchapter regulate the practice of sterile compounding and shall apply to all retail and institutional pharmacies that compound and dispense sterile preparations. This subchapter establishes standards for the quality and control of processes, components, and environments associated with compounded sterile preparations and for the skill and knowledge of pharmacy personnel who prepare compounded sterile preparations.

13:39-11.2 Definitions

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

"Ante area" means an ISO class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, labeling, and other high-particulate-generating activities are performed. The "ante area" is also a transition area that:

1. Provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas; and

2. Reduces the need for the heating, ventilating, and air-conditioning (HVAC) control system to respond to large disturbances.

"Biological safety cabinet" means a ventilated cabinet for compounded sterile preparations that has an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhaust air for environmental protection.

"Buffer area" means an ISO class 7 area where the primary engineering control is physically located and where the preparation and staging of components and supplies used in compounding sterile preparations occurs.

"Cleanroom" means a room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness (ISO) class. Microorganisms in the environment are

monitored, so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class. A "cleanroom" includes a buffer area or room and an ante area or room.

"Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device as the result of a practitioner's prescription or medication order or initiative based on the relationship of the practitioner or the 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 prescriptions or medication orders based on routine, regularly-observed prescribing patterns. Compounding includes mixing, reconstituting, or assembling a drug according to the product's labeling or to the manufacturer's directions.

"Compounding aseptic containment isolator" means a compounding aseptic isolator designed to provide worker protection from exposure to [page=1404] undesirable levels of airborne hazardous drugs throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (high-efficiency particulate air (HEPA) minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded.

"Compounding aseptic isolator" means a form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer process. Air exchanges into the isolator from the surrounding environment should not occur unless the air has first passed through a microbially retentive filter (high-efficiency particulate air (HEPA) minimum).

"Immediate use compounded sterile preparations" means preparations intended for emergency patient care and involve only simple aseptic measuring and transfer manipulations of no more than three sterile non-hazardous commercial drug and diagnostic radiopharmaceutical drug products, including an infusion or diluent solution. Unless required for the preparation, the compounding process occurs continuously without delays or interruptions and does not exceed one hour. Administration of immediate use compounded sterile preparations shall begin within one hour of preparation or the compounded sterile preparations shall be discarded. Immediate use compounded sterile preparations shall not be compounded and stored for anticipated needs and shall not be compounded as batch preparations. At no time during the compounding process, nor prior to administration, are critical sites and ingredients of the compounded sterile preparation directly exposed to contact contamination, such as human touch, cosmetic flakes, or particulates, blood, human body substances, and non-sterile inanimate sources.

"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) that is supplied by high-efficiency particulate air (HEPA) or HEPA-filtered air.

"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) that is supplied by high-efficiency particulate air (HEPA) or HEPA-filtered air.

"ISO class 8 air quality conditions" means conditions in which the air particle count is no greater than a total of 3,520,000 particles of 0.5 micrometers and larger per cubic meter of air (100,000 particles per cubic foot) that is supplied by high-efficiency particulate air (HEPA) or HEPA-filtered air.

"Negative pressure room" means a room that is at a lower pressure than the adjacent spaces and, therefore, the net airflow is into the room.

"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.

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 [page=1405] 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.

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. (No change.)

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

3. (No change.)

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.

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 *[vinyl floor]* ***a*** covering *[and]* ***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) (No change.)

(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.

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.-4. (No change.)

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.

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 [page=1406] 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.

13:39-11.9 Compounding of antineoplastic agents and other hazardous substances

(a) For purposes of this section, hazardous substances are those substances identified as hazardous by the National Institute for Occupational Safety and Health (NIOSH) in NIOSH Publication No. 2004-165: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings, Appendix A (2012 Edition). The sample list of drugs that shall be handled as hazardous (Appendix A) is incorporated herein by reference, as amended and supplemented, and can be found at the Centers for Disease Control and Prevention website, www.cdc.gov, specifically, www.cdc.gov/niosh/docs/2004-165/.

(b) Pharmacies shall not prepare antineoplastic agents and other hazardous substances as immediate use compounded sterile preparations.

(c) Pharmacies shall compound antineoplastic agents and other hazardous substances only in:

1. A compounding aseptic containment isolator or a Class II or Class III biological safety cabinet in a negative pressure cleanroom. When handling volatile hazardous drugs, such devices shall be vented to the outside air; or

2. A compounding aseptic containment isolator located outside of a negative pressure cleanroom, consistent with N.J.A.C. 13:39-11.8. When handling volatile hazardous drugs, such devices shall be vented to the outside air.

(d) Correct room pressurization shall be maintained at all times when compounding antineoplastic agents and other hazardous substances, consistent with N.J.A.C. 13:39-11.4(d).

(e) Personnel who compound and dispense antineoplastic agents and other hazardous substances shall adhere to standards established by the Occupational Health and Safety Administration (OSHA) set forth in Section VI, Chapter 2 of OSHA's Technical Manual on Controlling Occupational Exposure to Hazardous Drugs (effective date January 20, 1999). OSHA's Technical Manual is incorporated herein by reference, as amended and supplemented, and can be found at the OSHA website, www.osha.gov, specifically, www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html. Personnel shall also comply with the standards established by NIOSH in NIOSH Publication No. 2004-165: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings. The NIOSH Publication No. 2004-165 (2012 Edition) is incorporated herein by reference, as amended and supplemented, and can be found at the CDC website, www.cdc.gov, specifically, www.cdc.gov/niosh/docs/2004-165/.

(f) Antineoplastic agents and other hazardous substances used to compound sterile preparations shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure. Such storage is preferable within a containment area such as a negative pressure room. The storage area shall have sufficient general exhaust, at least 12 air exchanges per hour to dilute and remove any airborne contaminants. Antineoplastic agents and hazardous substances used to compound sterile preparations shall be handled with caution using appropriate chemotherapy gloves during distribution, receiving, stocking, inventorying, preparing for administration, and disposal.

13:39-11.10 Institutional pharmacy use of airflow workbenches not in a buffer area for low-risk level compounded sterile preparations

A pharmacy holding an institutional pharmacy permit may utilize ISO class 5 laminar airflow workbenches not located in a buffer area to prepare low-risk level compounded sterile preparations provided that the administration of such preparations commences within 12 hours of

the preparation or as recommended by the manufacturer, whichever is less. Such workbenches shall be located in an area which is maintained under sanitary conditions and which is traveled only by persons engaging in the compounding of sterile preparations. Such workbenches shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to areas including, but not limited to, construction sites, warehouses, or food preparation. Sinks may not be located adjacent to the ISO class 5 workbench environments and must be separated from the immediate area of ISO class 5 workbenches. Personnel engaged in sterile compounding in such areas shall follow the procedures relating to cleansing and garbing set forth in N.J.A.C. 13:39-11.14.

13:39-11.11 Compounding immediate use compounded sterile preparations in an institutional pharmacy

A pharmacy holding an institutional pharmacy permit may prepare non-hazardous immediate use compounded sterile preparations outside of an ISO class 5 laminar airflow workbench when the delay resulting from the use of the workbench would harm the patient, including situations in which the patient experiences a sudden change in clinical status.

13:39-11.12 Pharmacist-in-charge responsibilities

(a) The pharmacist-in-charge shall supervise all sterile compounding performed by pharmacy personnel. The pharmacist-in-charge shall be trained in aseptic manipulation skills.

(b) The pharmacist-in-charge shall be responsible for, at a minimum, the following:

1. Determining the procedural, environmental, and quality control practices that are necessary for the risk levels he or she assigns to specific compounded sterile preparations;

2. Ensuring that the selected sterilization method both sterilizes and maintains the strength, purity, quality, and packaging integrity of the compounded sterile preparations;

3. Ensuring the placement in buffer areas and ante areas of equipment (for example, refrigerators), devices (for example, computers and printers) and objects (for example, carts and cabinets) that are not essential to compounding is dictated by their effect on the required environmental quality of air atmospheres and surfaces, which shall be verified by monitoring;

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

5. Ensuring that all packaging and labeling of all compounded sterile preparations in the pharmacy are performed under the immediate personal supervision of a pharmacist;

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

7. Recording all transactions of the pharmacy as may be necessary under applicable State, Federal, and local laws and rules, to maintain accurate control over, and accountability for, all pharmaceutical materials, and ensuring that policies and procedures exist with respect to the maintenance of the audit trail required pursuant to N.J.A.C. 13:39-11.20;

8. Ensuring that all pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs who compound sterile preparations are trained and evaluated consistent with the requirements of N.J.A.C. 13:39-11.16;

9. Establishing procedures for maintaining the integrity of the product and the manufacturer's control identity when repackaging sterile [page=1407] products. A pharmacist shall check all repackaging and shall initial the repackaging records;

10. Disposal of all unused drugs and materials used in compounding sterile preparations, including antineoplastic agents and other hazardous substances, in accordance with accepted professional standards, and the Medical Waste Act, N.J.S.A. 13:1E-48.1 et seq., so as not to endanger the public health;

11. Ensuring that the compounding area and its contents and other areas where compounded sterile preparations are present are secured, so as to prevent access by unauthorized personnel;

12. Ensuring that the pharmacy contains, in addition to the minimum reference library mandated in N.J.A.C. 13:39-5.8(a)1, references pertinent to compounding sterile preparations;

13. Ensuring that records are maintained that document, at least once daily, that appropriate controlled cold (refrigerator), controlled freezer, if applicable, and controlled room temperatures, as these terms are defined in United States Pharmacopeia 797, are maintained. Such records shall be maintained for no less than five years and shall be made available to the Board for inspection upon request;

14. Ensuring that all information required to be maintained as part of a pharmacy's patient profile

record system pursuant to N.J.A.C. 13:39-7.19 or 9.19 is maintained for all compounded sterile preparations;

15. Ensuring that initial and ongoing multidisciplinary clinical monitoring and comprehensive care plans are maintained and readily available; and

16. Maintaining a policy and procedures manual detailing the pharmacy's standard operating procedures with regard to compounded sterile preparations, consistent with the requirements of N.J.A.C. 13:39-11.23, and maintaining a written quality assurance program, consistent with the requirements of N.J.A.C. 13:39-11.24.

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. (No change.)

(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.

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.

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.

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," [page=1408] 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.

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:

1. Documents a history of valid prescriptions or medication orders subsequently received, within the beyond-use dating time of each product, which have been generated solely within an established professional prescriber-patient-pharmacist relationship;

2. Maintains the prescription or medication order on file for all such products dispensed at the pharmacy;

3. Documents the batch preparation process, including selection of the drugs, containers, and diluents, lot numbers and expiration dates of the drugs, containers, and diluents, if any, and verification that the compounded sterile preparation has been visually inspected to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling. Each batch shall be given a unique batch number to identify the specific batch; and

4. Ensures that the labeling requirements set forth at N.J.A.C. 13:39-11.21(a)1, 5, 7, 9, and 10 are satisfied.

(b) Pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs, consistent with

N.J.A.C. 13:39-11.13, may batch prepare compounded sterile preparations for use by a licensed prescriber in his or her practice without a prescription, pursuant to N.J.A.C. 13:39-11.18, provided the pharmacist:

1. Complies with all requirements of N.J.A.C. 13:39-11.18; and

2. Documents the batch preparation process in accordance with N.J.A.C. 13:39-11.20(c).

13:39-11.18 Compounded sterile preparations for prescriber practice use

A pharmacy may prepare compounded sterile preparations for a licensed prescriber for use in the prescriber's practice without a prescription consistent with State and Federal laws pertinent to the prescriber's health care practice.

13:39-11.19 Stability criteria and beyond-use dating

(a) For purposes of this section, stability means the extent to which a preparation retains, within specified limits and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of compounding.

(b) In the absence of supporting valid scientific sterility testing and stability information that is directly applicable to specific preparations, the following dates and times for storage and initiation of administration of the compounded sterile preparations shall apply, according to the assigned risk level of the preparation, unless the manufacturer's package indicates a different stability time:

1. For low-risk level compounded sterile preparations, in the absence of passing a sterility test:

i. Administration shall begin within 48 hours when the preparation is stored at controlled room temperature (20 degrees Celsius to 25 degrees Celsius);

ii. Administration shall begin within 14 days when the preparation is stored at cold temperatures (two degrees Celsius to eight degrees Celsius);

iii. Administration shall begin within 45 days when the preparation is stored in a solid frozen state (-20 degrees Celsius); and

iv. For products prepared in an airflow workbench not located in a buffer area in accordance with N.J.A.C. 13:39-11.10, administration shall begin within 12 hours or less of preparation;

2. For medium-risk level compounded sterile preparations, in the absence of passing a sterility test:

i. Administration shall begin within 30 hours when the preparation is stored at controlled room temperature (20 degrees Celsius to 25 degrees Celsius);

ii. Administration shall begin within nine days when the preparation is stored at cold temperatures (two degrees Celsius to eight degrees Celsius); and

iii. Administration shall begin within 45 days when the preparation is stored in a solid frozen state (-20 degrees Celsius);

3. For high-risk level compounded sterile preparations, in the absence of passing a sterility test:

i. Administration shall begin within 24 hours when the preparation is stored at controlled room temperature (20 degrees Celsius to 25 degrees Celsius);

ii. Administration shall begin within three days when the preparation is stored at cold temperatures (two degrees Celsius to eight degrees Celsius); and

iii. Administration shall begin within 45 days when the preparation is stored in a solid frozen state (-20 degrees Celsius); and

4. For immediate use compounded sterile preparations, administration shall begin no less than one hour following the start of preparing the compounded sterile preparation.

(c) The administration dates and times established in (b) above shall not be exceeded or extended for compounded sterile preparations without verifiable supporting valid scientific sterility and stability information that is directly applicable to the specific preparation or compound.

(d) A pharmacist shall determine the beyond-use date for a compounded sterile preparation consistent with (b) above and assign an appropriate discard-after date for the compounded sterile preparation. The discard-after date shall appear on the label consistent with the requirements of N.J.A.C. 13:39-11.21.

(e) Opened or needle-punctured single-dose containers of sterile products (for example, bags, bottles, syringes, and vials) used in the compounding of sterile preparations for immediate use in an institutional pharmacy pursuant to N.J.A.C. 13:39-11.11, shall be used within one hour if opened in worse than ISO Class 5 air quality, and any remaining contents shall be discarded.

(f) Single-dose vials used in the compounding of sterile preparations exposed to ISO Class 5 or cleaner air quality may be used up to six hours after initial puncture.

(g) Opened single-dose ampules used in the compounding of sterile preparations shall not be stored for any period of time.

(h) Opened or needle-punctured multiple-dose vials used in the compounding of sterile preparations shall be used within 28 days after initially entering the vial, unless otherwise specified by the manufacturer.

13:39-11.20 Documentation; audit trail

(a) The pharmacist shall ensure that compounded sterile preparations have been properly prepared, consistent with the assigned risk level of the preparation, labeled, controlled, stored, dispensed, and distributed in accordance with the provisions of this subchapter. The pharmacist shall be responsible for the accuracy and appropriateness of the compounded prescription. When more than one pharmacist is involved in the steps of the compounding process, the pharmacist shall be responsible for the accuracy and appropriateness of each step he or she performed or he or [page=1409] she approved and reviewed, and his or her unique and secure user identifier(s) shall be recorded in the audit trail.

(b) A pharmacy shall maintain an audit trail for all compounded sterile preparations consistent with the requirements of N.J.A.C. 13:39-7.6.

(c) A pharmacy shall maintain a compounding record for each compounded sterile preparation that contains the following information:

1. Selection of the drugs, container, and diluent prior to their being compounded, including documentation of lot numbers and expiration dates of the drugs, containers, and diluents, if applicable;

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

3. Verification that the prescription or medication order label complies with the requirements of N.J.A.C. 13:39-11.21;

4. Verification that the compounded sterile preparation has been visually inspected to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling; and

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

13:39-11.21 Information required to appear on prescription label

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

1. The date and time prepared;

2.-4. (No change.)

5. The name and strength or quantity of all active ingredients, and the name and volume of the diluent, vehicle, and base solution(s), if applicable;

6. (No change.)

7. The phrase "use by" followed by the preparation's use by date and time (if no time is stated, it is presumed to be 11:59 P.M. of the stated use by date).

8. (No change.)

9. As pertinent, a warning, consistent with applicable Federal and State law, that antineoplastic agents and other hazardous substances are biohazardous;

10. As pertinent, the requirements for proper storage; and

11. In a retail pharmacy, for those medications not dispensed pursuant to the requirements of N.J.A.C. 13:39-9, the prescription number.

(b) For immediate use compounded sterile preparations, when the preparation is not administered by the person who prepared it, or its administration is not witnessed by the person who prepared it, the compounded sterile preparation shall be labeled consistent with the requirements of (a) above and shall also include the name or identifier of the person who prepared the compounded sterile preparation.

13:39-11.22 Handling, packaging, and delivery

(a) The pharmacy shall be responsible for the proper handling and packaging of compounded sterile preparations for delivery from the pharmacy to the patient in order to assure and maintain

the integrity, efficacy, stability, and sterility of these preparations. The pharmacist-in-charge shall ensure that:

1. Tamper-evident packaging is utilized;

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

3. (No change.)

13:39-11.23 Policy and procedures manual

(a) The pharmacy's policy and procedures manual shall set forth in detail the pharmacy's standard operating procedures with regard to compounded sterile preparations.

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

1. A risk-management program, including, but not limited to, documentation of incidents, adverse drug reactions, and product contamination.

i. The risk-management program shall require that the pharmacist-in-charge report all confirmed incidents of product contamination to the New Jersey Board of Pharmacy within 48 hours of becoming aware of such incidents;

2.-3. (No change.)

4. Cleaning and disinfecting standards and procedures, consistent with the requirements of N.J.A.C. 13:39-11.15;

5. Reference materials as set out in N.J.A.C. 13:39-5.8 and 11.12(b)12;

6. (No change.)

7. Patient recordkeeping as set forth in N.J.A.C. 13:39-11.12(b)14;

8. (No change.)

9. A quality assurance program as set forth in N.J.A.C. 13:39-11.24;

10. Verification of training and competency guidelines as set forth in N.J.A.C. 13:39-11.16;

11. (No change.)

12. Documentation as set forth in N.J.A.C. 13:39-11.20;

13. Description of appropriate garb and garbing procedures, consistent with the requirements of N.J.A.C. 13:39-11.14;

14. Conduct guidelines for personnel in the cleanroom;

15. (No change.)

16. Patient education;

17. Protocol and procedures to maintain the integrity of the interior work area of the laminar airflow workbenches, compounding aseptic isolators, compounding aseptic containment isolators, and biological safety cabinets; and

18. (No change.)

(c) The policy and procedures manual shall be reviewed, at a minimum, once every 24 months and shall be updated, on a continuous basis, to reflect current practice. Documentation of the review shall be made available to the Board upon request.

13:39-11.24 Quality assurance program

(a) The pharmacy's quality assurance program shall require, at a minimum, that:

1. A reasonable effort shall be made by the 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 for each unique type of compounded sterile preparation dispensed;

3. After the preparation of every admixture, the contents of the container are thoroughly mixed and then visually inspected to ensure the absence of particulate matter in solutions, the absence

of leakage from vials and bags, or any other defects, and the accuracy and thoroughness of labeling;

4. All pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs involved in compounding sterile preparations shall have their aseptic technique tested consistent with the requirements of N.J.A.C. 13:39-11.16;

5. All high-risk level compounded sterile preparations that are prepared in groups of more than 25 identical individual single-dose packages (for example, ampules, bags, syringes, vials), or in multiple-dose vials for administration to multiple patients, or that are exposed longer than 12 hours at two degrees to eight degrees Celsius and longer than six hours at warmer than eight degrees Celsius before they are sterilized, and all compounded sterile preparations whose beyond-use date has been exceeded, shall be tested to ensure that they are sterile before they are dispensed or administered. The USP membrane filtration method shall be used where feasible. Another method may be used if verification results demonstrate that the alternative is at least as effective and reliable as the membrane filtration method or the USP direct inoculation of the culture medium method, consistent with the standards set forth in USP 797 concerning "Sterility Testing," 2012 edition, incorporated herein by reference, as amended and supplemented, and available for purchase at the United States Pharmacopeia website, www.usp.org.

i. When high-risk level compounded sterile preparations are dispensed before receiving the results of the sterility tests set forth in (a)5 above, the written quality assurance procedure shall require daily observation of the incubating test specimens and immediate recall of the dispensed compounded sterile preparations when there is any evidence of microbial [page=1410] growth in the test specimens. The patient and the physician of the patient to whom a potentially contaminated compounded sterile preparation was administered shall be notified immediately of the potential risk. Positive sterility tests shall require rapid and systematic investigation of aseptic technique, environmental control, and other sterility assurance controls in order to identify sources of contamination and to take corrective action.

ii. All high-risk level compounded sterile preparations, except those for inhalation and ophthalmic administration, shall be tested to ensure that they do not contain excessive bacterial endotoxins;

6. Air and surface sampling for microbial organisms in ISO class 5 primary engineering controls, such as laminar airflow workbenches, compounding aseptic isolators, compounding aseptic containment isolators, and biological safety cabinets, and in all other ISO classified areas is done once every six months and at any time when microbial contamination is suspected;

7. Pressure differential monitoring shall be conducted consistent with the requirements of

N.J.A.C. 13:39-11.4(d). A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante area and between the ante area and the general environment outside the cleanroom. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device;

8. Laminar airflow workbenches, compounding aseptic isolators, compounding aseptic containment isolators, and biological safety cabinets shall be certified every six months, and every time they are moved, by an independent certification company to ensure that these primary engineering controls meet appropriate ISO classifications;

9. A cleanroom shall be certified by an independent certification company every six months and whenever the room or a primary engineering control in the room is relocated or altered, or whenever major service to the facility is performed, to ensure that the cleanroom meets appropriate ISO classifications. Such certifications shall be performed consistent with procedures outlined in the Controlled Environment Testing Association (CETA) Certification Guide for Sterile Compounding Facilities (CAG-003-2006) (revised December 8, 2008), incorporated herein by reference, as amended and supplemented, and which may be found at the CETA website, www.cetainternational.org, specifically, www.cetainternational.org/reference/CETAAsepticCompoundingCertificationGuide.pdf; and

10. Whenever test results indicate that the cleanroom or any primary engineering controls do not meet the standards established in this section, the pharmacy shall immediately cease using the cleanroom or primary engineering control that is out of compliance until such time that the cleanroom and/or the primary engineering control meets the requisite standards. Test results indicating non-compliance with the requisite standards shall require re-evaluation of all procedures associated with the production of compounded sterile preparations in the impacted cleanroom or primary engineering control and documentation with respect to the period of time that the cleanroom and/or primary engineering control was out of compliance.

SUBCHAPTER 11A. COMPOUNDING NON-STERILE PREPARATIONS IN RETAIL AND INSTITUTIONAL PHARMACIES

13:39-11A.1 Purpose and scope

The rules in this subchapter regulate the practice of non-sterile compounding and shall apply to all retail and institutional pharmacies that compound and dispense non-sterile preparations. This subchapter establishes standards for the quality and control of processes, components, and environments associated with compounded non-sterile preparations, and for the skill and knowledge of pharmacy personnel who prepare compounded non-sterile preparations. The

requirements in this subchapter establish minimum good compounding practices that will enhance a pharmacist's ability to compound non-sterile preparations that are of acceptable strength, quality, and purity.

13:39-11A.2 Definitions

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

"Compounding" means the preparation, mixing, assembling, packaging, and labeling of a drug or device as the result of a practitioner's prescription or medication order 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 prescriptions or medication orders based on routine, regularly observed, prescribing patterns.

"Compounding pharmacist" means a pharmacist who performs or supervises any part of the compounding process.

13:39-11A.3 Prohibited compounding

(a) A pharmacist shall not compound preparations that contain drug products that appear on the Federal Food and Drug Administration's list of Drug Products Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness, codified at 21 CFR 216.24.

(b) A pharmacist shall not compound any commercially available drug products except as provided in N.J.A.C. 13:39-11A.4.

13:39-11A.4 Compounding commercially available products

(a) A pharmacist shall not compound commercially available products unless:

1. The commercially available product is modified to produce a significant difference, in the professional judgment of the prescriber, between the compounded product for the patient and the comparable commercially available product; or

2. The commercially available product is not available from normal distribution channels in a timely manner to meet the patient's needs, and the dispensing of the compounded product has been approved by the prescriber and the patient.

(b) A pharmacist who compounds a commercially available product consistent with the requirements of (a) above shall maintain documentation of the reason for such compounding.

13:39-11A.5 Batch preparation

A pharmacist may compound non-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 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 the prescription or medication order is retained on file at the pharmacy, consistent with the requirements of N.J.A.C. 13:39-7.19. The pharmacist shall document the batch preparation process in accordance with the requirements of N.J.A.C. 13:39-11A.15.

13:39-11A.6 Compounded non-sterile preparations for prescriber practice use

A pharmacy may prepare compounded non-sterile preparations for a licensed prescriber for use in the prescriber's practice without a prescription consistent with State and Federal laws pertinent to the prescriber's health care practice.

13:39-11A.7 Preparation of pharmacy generated products (PGPs) for over-the-counter sale

(a) A pharmacist may prepare a pharmacy generated product to be sold over-the-counter without a prescription or medication order provided that:

1. The product does not contain an ingredient that exceeds allowable strengths and doses for over-the-counter drugs; and

2. The finished product is not one for which a prescription or medication order is required.

(b) A finished product that is prepared pursuant to (a) above shall be properly labeled with the following:

1. The product name;

2. The name of all ingredients;

3. The strength or quantity of all active ingredients;

4. The package size;

5. Directions for use;

6. The use by date, consistent with the requirements of N.J.A.C. 13:39-11A.11;

[page=1411] 7. The name, address, and telephone number of the pharmacy;

8. Any ancillary and cautionary instructions, as needed; and

9. As pertinent, the requirements for proper storage.

(c) A pharmacy generated product shall be sold directly to the consumer only after professional interaction or consultation between a pharmacist and the consumer.

(d) A pharmacy generated product shall be stored in such a manner as to be inaccessible to the public.

(e) A pharmacy generated product shall not be sold to any entity for resale purposes.

(f) The preparation of pharmacy generated products shall be documented in accordance with the requirements of N.J.A.C. 13:39-11A.15(b)1 and 6 through 14.

13:39-11A.8 Compounding area

(a) A pharmacy that regularly engages in compounding shall have an area specifically designated for the safe and orderly compounding of drug products. Such area shall allow for the orderly placement of equipment and materials in order to minimize the potential for errors.

(b) A pharmacy that engages in occasional compounding shall prepare an area prior to each compounding activity that allows for the safe and orderly compounding of drug products. The area shall allow for the orderly placement of equipment and materials in order to minimize the potential for errors.

(c) A pharmacy engaged in compounding shall ensure that:

1. All compounding areas are well-lighted and ventilated and are maintained in a clean and sanitary condition;

2. Heating and air conditioning systems are controlled to avoid decomposition of chemicals;

3. Sewage, trash, and other refuse in and from the pharmacy and immediate drug compounding area are maintained, and disposed of, in a timely, safe, and sanitary manner; and

4. The compounding area is easily accessible to hot and cold running water, exclusive of the bathroom sink; soap or detergent; and air dryers or single source towels.

13:39-11A.9 Equipment and supplies

(a) A pharmacy shall possess equipment appropriate to the type of compounding performed at the pharmacy.

(b) Equipment used in compounding drug products shall be of appropriate design and capacity, and shall be suitably located to facilitate operations for the intended use, cleaning, and maintenance of the equipment.

(c) Equipment used in compounding drug products shall be of suitable composition. Equipment surfaces that contact components shall not be reactive, additive, or adsorptive, so as to alter the safety, identity, strength, quality, and purity of the compounded product.

(d) Equipment used in compounding drug products shall be thoroughly cleaned and sanitized after each use, and when necessary, prior to use, in order to prevent cross-contamination of ingredients and preparations.

(e) Equipment used in compounding drug products shall be stored in a manner to prevent cross-contamination of ingredients and preparations.

(f) Automated, mechanical, or electronic equipment may be used in compounding non-sterile preparations. All equipment utilized in compounding non-sterile preparations shall be inspected, maintained, and validated at appropriate intervals, consistent with manufacturer's recommendations, to ensure the accuracy and reliability of equipment performance.

(g) When antineoplastic agents and hazardous substances are utilized in the compounding of non-sterile preparations, a pharmacy shall adhere to standards established by the Occupational Health and Safety Administration (OSHA) set forth in Section VI, Chapter 2 of OSHA's Technical Manual on Controlling Occupational Exposure to Hazardous Drugs (effective date January 20, 1999). OSHA's Technical Manual is incorporated herein by reference, as amended and supplemented, and can be found at the OSHA website, www.osha.gov, specifically, www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html. Personnel shall also comply with the standards established by National Institute for Occupational Safety and Health (NIOSH) in NIOSH Publication No. 2004-165: Preventing Occupational Exposure to Antineoplastic and

Other Hazardous Drugs in Health Care Settings. The NIOSH standard is incorporated herein by reference, as amended and supplemented, and can be found at the CDC website, www.cdc.gov, specifically, www.cdc.gov/niosh/docs/2004-165/.

1. For purposes of this subsection, hazardous substances are those substances identified as hazardous in NIOSH Publication No. 2004-165, Appendix A.

13:39-11A.10 Responsibilities of the compounding pharmacist; reporting requirement

(a) A compounding pharmacist shall be responsible for the ensuring that:

1. Compounded non-sterile preparations have been properly prepared, labeled, controlled, stored, dispensed, and distributed in accordance with the provisions of this subchapter;

2. All aspects of the compounding process set out in N.J.A.C. 13:39-11A.15 are documented and that accurate compounding records for all compounded non-sterile preparations prepared by the pharmacy are maintained;

3. Compounding personnel are capable of performing and qualified to perform their assigned duties;

4. Ingredients used in compounding have their expected identity, quality, and purity consistent with the requirements of N.J.A.C. 13:39-11A.12;

5. Compounded preparations are of acceptable strength, quality, and purity, with appropriate packaging and labeling, and are prepared in accordance with good compounding practices, official standards, and relevant scientific data and information;

6. Critical processes are recorded and validated to ensure that procedures will consistently result in the expected qualities in the finished preparation;

7. The compounding environment is suitable for its intended purpose;

8. Appropriate stability evaluation is performed or is determined from the literature for establishing reliable beyond-use dating to ensure that the finished preparations have their expected potency, purity, quality, and characteristics, at least until the labeled beyond-use date;

9. Compounding conditions and procedures are in place to minimize the potential for errors;

10. Adequate procedures and records exist for investigating and correcting failures or problems

in compounding, testing, or in the preparation itself; and

11. The patient is advised that the product dispensed is a compounded preparation.

(b) Any confirmed incidents of product contamination shall be reported by the pharmacist-in-charge to the New Jersey Board of Pharmacy within 48 hours of becoming aware of any such incidents.

13:39-11A.11 Beyond-use dates

(a) The beyond-use date is the date after which a compounded non-sterile preparation shall not be used. The beyond-use date shall be determined from the date the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, beyond-use dates may be assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products.

(b) In the absence of stability information that is applicable to a specific drug product and preparation, the following are the maximum beyond-use dates for non-sterile compounded drug preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature unless otherwise indicated:

1. For nonaqueous liquids and solid formulations:

i. Where the manufactured drug product is the source of the active ingredient, the beyond-use date shall not be later than 25 percent of the time remaining until the product's expiration date or six months, whichever is earlier;

ii. Where a United States Pharmacopeia-National Formulary (USP-NF), analytical reagent (AR), certified American Chemical Society (ACS), or Food Chemicals Codex (FCC) grade substance is the source of the active ingredient, the beyond-use date shall not be later than six months or the expiration date of the ingredient, whichever is earlier; and

[page=1412] iii. Where there is more than one ingredient, the beyond-use date shall be no longer than six months or the expiration date of the first ingredient to expire, whichever is earlier;

2. For water-containing formulations (prepared from ingredients in solid form), the beyond-use date shall not be later than 14 days for liquid preparations when stored at cold temperatures between two degrees and eight degrees Celsius (36 degrees and 46 degrees Fahrenheit); and

3. For all other formulations, the beyond-use date shall not be later than the intended duration of

therapy or 30 days, whichever is earlier.

(c) The beyond-use date limits established in this section may be exceeded only when there is supporting valid scientific stability information that is directly applicable to the specific preparation (that is, the same drug concentration range, pH, excipients, vehicle, water content, etc.).

13:39-11A.12 Ingredient selection

(a) All ingredients used to compound non-sterile preparations shall be United States Pharmacopeia-National Formulary (USP-NF), analytical reagent (AR), certified American Chemical Society (ACS), or Food Chemicals Codex (FCC) grade substances. If a USP-NF, AR, ACS, or FCC grade substance ingredient is not available, the pharmacist shall establish the purity and safety of the ingredient by reasonable means, which may include lot analysis, manufacturer reputation, or reliability of source study.

(b) A manufactured drug product may be utilized as the source of an active ingredient. Only manufactured drug products from containers labeled with a batch control number and an unexpired expiration date shall be utilized as sources of active ingredients. When compounding with manufactured drug products, the compounding pharmacist shall consider all ingredients present in the drug product relative to the intended use of the compounded non-sterile preparation.

(c) Components used in the compounding of non-sterile preparations such as aliquots, triturates, stock solutions, buffering agents, or isotonic solutions may be prepared in advance and stored as pharmacy stock. The preparation of such products shall be documented in accordance with the requirements of N.J.A.C. 13:39-11A.15(b)1 and 6 through 14.

13:39-11A.13 Information required to appear on prescription label

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

1. In a retail pharmacy only, the name of the prescriber.

i. An institutional pharmacy compounding non-sterile preparations for out-patient use shall include the name of the prescriber on the label, consistent with the requirements of N.J.A.C. 13:39-9.1(b);

2. The name of the patient;

3. The name of all active ingredients;

4. Directions for use;

5. The use by date, consistent with the requirements of N.J.A.C. 13:39-11A.11;

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

7. Any ancillary and cautionary instructions as needed; and

8. As pertinent, the requirements for proper storage.

13:39-11A.14 Pharmacy technicians, pharmacy interns, and pharmacy externs; required supervision

(a) The compounding pharmacist shall provide immediate personal supervision to pharmacy technicians, pharmacy interns, or pharmacy externs who are performing non-sterile preparation compounding.

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

13:39-11A.15 Audit trail; compounding record documentation

(a) A pharmacy shall maintain an audit trail for all non-sterile compounded preparation prescriptions dispensed consistent with the requirements of N.J.A.C. 13:39-7.6.

(b) Except as provided in (c) below, a pharmacy shall maintain a compounding record for each compounded non-sterile preparation that contains the following information:

1. Selection of the ingredients and documentation of source, lot numbers, and expiration dates of all ingredients used;

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

3. Verification that the prescription or medication order label complies with the requirements of N.J.A.C. 13:39-11A.13;

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

5. Strength of preparation;

6. Date of preparation;

7. Name or personal identifier of the person(s) who performed each step of the compounding process and the compounding pharmacist(s) who verified the preparation;

8. Reference(s) for formulation, if available;

9. Total quantity;

10. Detailed steps of the compounding process to ensure that the exact same compound can be duplicated at a future date;

11. Type of dispensing container used when a drug has specific storage requirements;

12. Beyond-use date of the finished product consistent with the requirements in N.J.A.C. 13:39-11A.11;

13. The assigned internal identification number for the preparation or the prescription number; and

14. Instructions for use, storage, and handling of the compounded preparation.

(c) A compounding record shall not be required for:

1. Mixing, reconstituting, or assembling a drug according to the product's labeling or the manufacturer's directions; and

2. Product flavoring.