ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R035-06

§§1 to 67, inclusive, 69, 70 and 71 effective September 18, 2008
§68 effective March 18, 2010.

EXPLANATION – Matter in ***italics*** is new; matter in brackets [~~omitted material~~] is material to be omitted.

AUTHORITY: §§1-51, 54-57, 62-66 and 69-71, NRS 639.070; §52, NRS 639.0725 and 639.23288; §53, NRS 639.071 and 639.072; §§58-61 and 68, NRS 639.070 and 639.2807; §67, NRS 639.070 and 639.267.

A REGULATION relating to pharmacy; establishing requirements for pharmacies, pharmacists and pharmaceutical technicians concerning the compounding and dispensing of drug products; revising certain provisions relating to the compounding and dispensing of parenteral solutions; revising certain provisions concerning certain standards and publications adopted by reference; authorizing dispensing practitioners and dispensing technicians to compound drug products under certain circumstances; and providing other matters properly relating thereto.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 51, inclusive, of this regulation.

Sec. 2. ***"Active ingredient" means an ingredient added to a compounded drug product which provides the therapeutic effect desired from the compounded drug product. The term does not include an inert ingredient.***

Sec. 3. ***"Ante-area" has the meaning ascribed to it in chapter 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.***

Sec. 4. ***"Barrier isolator cabinet" means a device the interior of which creates an ISO Class 5 environment and provides an impermeable barrier to outside air at all times while it is***

being used for compounding purposes. The term includes, without limitation, compounding aseptic isolators and compounding aseptic containment isolators.

Sec. 5. *"Beyond-use date" has the meaning ascribed to it in chapter 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.*

Sec. 6. *"Buffer area" has the meaning ascribed to it in chapter 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.*

Sec. 7. *"Chart order" has the meaning ascribed to it in NAC 639.442.*

Sec. 8. *"Component" means an ingredient that is used to compound a drug product, including, without limitation, an ingredient that does not appear on the labeling of the compounded drug product.*

Sec. 9. *1. Except as otherwise provided in subsection 2, "compound" and "compounding" mean:*

(a) The preparation, mixing or assembling of a drug product of which at least one component is a prescription drug; and

(b) The packaging and labeling incident to the preparation, mixing or assembling of a drug product for the purpose of selling or dispensing the drug product pursuant to a prescription or chart order.

2. The terms "compound" and "compounding" do not include the mixing or reconstituting of a nonsterile drug product that is performed in accordance with:

(a) The directions contained in the labeling of the drug product that have been approved by the Food and Drug Administration and provided by the manufacturer of the drug product; or

(b) Any other directions provided by the manufacturer of the drug product that are consistent with the labeling of the drug product that have been approved by the Food and Drug Administration.

Sec. 10. *"Compounding aseptic containment isolator" has the meaning ascribed to it in chapter 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.*

Sec. 11. *"Compounding aseptic isolator" has the meaning ascribed to it in chapter 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.*

Sec. 12. *"Drug product" means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the Food and Drug Administration.*

Sec. 13. *"Gloved fingertip sampling" has the meaning ascribed to it in chapter 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.*

Sec. 14. *"Hazardous drug" means:*

1. A compounded drug product in which one or more of the components of the compounded drug product produce one or more of the following characteristics in humans or animals:

(a) Carcinogenicity;

(b) Teratogenicity or other developmental toxicity;

(c) Reproductive toxicity;

(d) Organ toxicity at low doses; or

(e) Genotoxicity; or

2. A compounded drug product in which the structure and toxicity profiles of the compounded drug product mimic an existing drug product which has components that produce one or more of the characteristics set forth in subsection 1.

Sec. 15. *"High-risk sterile compounded drug product" means a sterile compounded drug product which is compounded by a pharmacist or a pharmaceutical technician and which satisfies the requirements set forth in section 45 of this regulation.*

Sec. 16. *"Immediate-use sterile compounded drug product" means a sterile compounded drug product which is compounded by a pharmacist or a pharmaceutical technician and which satisfies the requirements set forth in section 48 of this regulation.*

Sec. 17. *"ISO Class 5" means the classification of an atmospheric environment that is made by the International Organization for Standardization based on an adaptation of Federal Standard 209E, as adopted by reference in paragraph (a) of subsection 1 of NAC 639.670, in which the atmospheric environment contains:*

1. Less than 3,520 particles that are 0.5 micron or larger in diameter per cubic meter of air; or

2. Less than 100 particles that are 0.5 micron or larger in diameter per cubic foot of air.

Sec. 18. *"ISO Class 7" means the classification of an atmospheric environment that is made by the International Organization for Standardization based on an adaptation of Federal Standard 209E, as adopted by reference in paragraph (a) of subsection 1 of NAC 639.670, in which the atmospheric environment contains:*

1. Less than 352,000 particles that are 0.5 micron or larger in diameter per cubic meter of air; or

2. Less than 10,000 particles that are 0.5 micron or larger in diameter per cubic foot of air.

Sec. 19. *"ISO Class 8" means the classification of an atmospheric environment that is made by the International Organization for Standardization based on an adaptation of Federal Standard 209E, as adopted by reference in paragraph (a) of subsection 1 of NAC 639.670, in which the atmospheric environment contains:*

1. Less than 3,520,000 particles that are 0.5 micron or larger in diameter per cubic meter of air; or

2. Less than 100,000 particles that are 0.5 micron or larger in diameter per cubic foot of air.

Sec. 20. *"Low-risk sterile compounded drug product" means a sterile compounded drug product which is compounded by a pharmacist or a pharmaceutical technician and which satisfies the requirements set forth in section 42 of this regulation.*

Sec. 21. *"Media fill test" has the meaning ascribed to it in chapter 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.*

Sec. 22. *"Medium-risk sterile compounded drug product" means a sterile compounded drug product which is compounded by a pharmacist or a pharmaceutical technician and which satisfies the requirements set forth in section 44 of this regulation.*

Sec. 23. *"Nonsterile compounded drug product" means a drug product the preparation and dispensing of which require compounding and which is not required to be sterile as described in section 25 of this regulation.*

Sec. 24. *"Parenteral nutrition" means nutrients provided intravenously.*

Sec. 25. ***"Sterile compounded drug product" means a drug product the preparation and dispensing of which require compounding and which is required to be sterile by either the provisions of chapter 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670, or the provisions of NAC 639.661 to 639.690, inclusive, and sections 2 to 51, inclusive, of this regulation.***

Sec. 26. ***1. A pharmacy or pharmacist engaged in the practice of compounding drug products shall:***

(a) Inspect and either approve or reject, without limitation, each component, container, closure, label and other material used in the process of compounding each drug product;

(b) Ensure the proper use, cleanliness and maintenance of any equipment used in the process of compounding each drug product; and

(c) Prepare the records required to be prepared pursuant to NAC 639.661 to 639.690, inclusive, and sections 2 to 51, inclusive, of this regulation concerning the compounding of each drug product to ensure that an error has not occurred in the process of compounding each drug product.

2. A pharmacy or pharmacist engaged in the practice of compounding drug products may not allow any food or drink to be stored or consumed in or at an area or room in the pharmacy that is designated for compounding.

Sec. 27. ***1. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products shall ensure that each pharmacist and pharmaceutical technician engaged in the practice of compounding drug products:***

(a) Is competent and proficient in compounding the drug products that the pharmacist or pharmaceutical technician will be authorized and expected to compound;

(b) Complies with the provisions of NAC 639.661 to 639.690, inclusive, and sections 2 to 51, inclusive, of this regulation concerning the drug products which the pharmacist or pharmaceutical technician compounds and the compounded drug products which the pharmacist or pharmaceutical technician dispenses at the pharmacy; and

(c) Receives, on an ongoing basis, sufficient training to maintain that competency and proficiency.

2. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products shall evaluate the competency and proficiency of a pharmacist and pharmaceutical technician:

(a) If the pharmacist or pharmaceutical technician is newly hired or is newly assigned to compound drug products, before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound drug products; and

(b) If the pharmacist or pharmaceutical technician will be assigned to compound drug products that involve a higher level of risk than the drug products which the pharmacist or pharmaceutical technician had previously been trained to compound, before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound those drug products.

Sec. 28. *1. A pharmacy engaged in the practice of compounding drug products shall establish and maintain written policies and procedures for compounding drug products to ensure that each final compounded drug product has the identity, strength, quality and purity which the compounded drug product is purported or represented to have. Such policies and procedures must include, without limitation:*

(a) Policies and procedures for:

(1) The processes used by the pharmacy to compound drug products;

(2) The equipment used by the pharmacy to compound drug products;

(3) Ensuring that the actual weights and measures of each component are within plus or minus 5 percent of the theoretical weights and measures required for the drug products compounded by the pharmacy;

(4) Tracking, recalling and destroying the drug products compounded by the pharmacy, which must include a requirement that the pharmacy ensure that all drug products which could have been compounded with a particular component be located, recalled and destroyed; and

(5) Identifying the drug products or components of drug products that will be considered hazardous drugs.

(b) Control procedures for monitoring each final compounded drug product and validating the compounding processes that may be responsible for causing variability in the final compounded drug product.

(c) Control procedures to ensure that:

(1) Each component is accurately weighed, measured or subdivided, as appropriate;

(2) Any variation in the actual yield of a drug product compounded by the pharmacy is within plus or minus 10 percent of the theoretical yield of the compounded drug product; and

(3) If a component is transferred from its original storage container to a new storage container, the new storage container is labeled with the date of the transfer and information that is sufficient to trace the contents of the new container to the original storage container.

2. A member of the staff of the Board may require a pharmacy engaged in the practice of compounding drug products to provide a sample of a drug product that is being compounded at the time of the request and any records related to that compounded drug product for

purposes of testing the compounded drug product for compliance with the provisions of NAC 639.661 to 639.690, inclusive, and sections 2 to 51, inclusive, of this regulation. The Board will share the costs of testing such a sample equally with the pharmacy.

3. If a sample tested pursuant to subsection 2 does not comply with the provisions of NAC 639.661 to 639.690, inclusive, and sections 2 to 51, inclusive, of this regulation, the Board will notify the pharmacy of the failure to comply and the pharmacy must:

(a) Provide to the Board a written plan for remediating or addressing the noncompliance; and

(b) If requested by a member of the staff of the Board, provide an additional sample of the compounded drug product for testing. The costs of a test conducted pursuant to this paragraph must be paid solely by the pharmacy.

4. If the sample provided to the Board pursuant to paragraph (b) of subsection 3 does not comply with the provisions of NAC 639.661 to 639.690, inclusive, and sections 2 to 51, inclusive, of this regulation, the Board will take such action as it deems necessary to correct the noncompliance or to prevent further noncompliance, including, without limitation:

(a) Suspending the license of the pharmacy pursuant to NRS 639.210;

(b) Suspending the ability of the pharmacy to compound certain drug products; and

(c) Requiring the pharmacy to perform any other remedial or protective measures the Board deems necessary to correct the noncompliance or to prevent further noncompliance.

Sec. 29. *1. Except as otherwise provided in section 39 of this regulation, each record required to be made pursuant to NAC 639.661 to 639.690, inclusive, and sections 2 to 51, inclusive, of this regulation must be:*

(a) Maintained by the pharmacy for which the record was made for at least 2 years after the date the record was made; and

(b) Available for inspection and copying by the Board or its representative.

2. Records made and maintained by a pharmacy pursuant to section 39 of this regulation must be available for inspection and copying by the Board or its representative after the 6-month period required by section 39 of this regulation if the pharmacy maintains the records longer than the required 6-month period.

Sec. 30. *1. A pharmacy may use an automated compounding device to:*

(a) Assist with the compounding of a drug product; or

(b) Produce a final compounded drug product.

2. If a pharmacy uses an automated compounding device as described in subsection 1, the pharmacy shall establish and maintain written policies and procedures, in addition to the policies and procedures established and maintained pursuant to section 28 of this regulation, that address:

(a) The qualifications that a pharmacist or a pharmaceutical technician must have to use the automated compounding device;

(b) The routine maintenance and cleaning required to be performed on the automated compounding device which, at a minimum, satisfies the requirements for maintenance and cleaning established by the manufacturer of the automated compounding device; and

(c) The testing required to be performed on the automated compounding device to ensure that the automated compounding device is measuring and dispensing the components of the compounded drug product and manufacturing the final compounded drug product within tolerances of not more than plus or minus 5 percent.

3. If a pharmacy uses an automated compounding device to assist with the compounding of a drug product for parenteral nutrition, the pharmacy shall establish safe maximum limits for each additive that may be used in compounding such a drug product. The pharmacy shall ensure that:

(a) The automated compounding device will cease compounding the drug product for parenteral nutrition if a maximum limit for an additive will be exceeded until a pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order; or

(b) If an automated compounding device cannot be programmed to cease the compounding process as described in paragraph (a):

(1) The automated compounding device is equipped with an audible alarm or some other mechanism that will alert the pharmacist if a maximum limit for an additive has been exceeded; and

(2) The pharmacy has written policies and procedures to prevent the continuation of the compounding process once a maximum limit for an additive has been exceeded until a pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order.

4. If the pharmacy uses a computerized order entry system in conjunction with the automated compounding device, the pharmacy must ensure that the computerized order entry system will cease processing the order if a maximum limit for an additive will be exceeded until a pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order.

5. A pharmacy shall make and maintain records that evidence compliance by the pharmacy with the policies and procedures required by this section.

Sec. 31. *For each compounded drug product that is in excess of the amount required by the prescription or chart order and each compounded drug product that is compounded in bulk quantities, the pharmacist who compounded or supervised the compounding of the compounded drug product shall prepare a record, either on paper or in the pharmacy's computer system, that includes, without limitation:*

1. The name of the compounded drug product;

2. A list of the components and quantities of components used to compound the drug product, including, without limitation, the manufacturer or supplier of the components used, the lot number of the components used and the expiration dates of the components used;

3. The internal control number assigned to the compounded drug product by the pharmacist or the number of the prescription of the compounded drug product;

4. The beyond-use date of the compounded drug product;

5. The date of preparation of the compounded drug product;

6. The initials of the pharmacist or pharmaceutical technician who compounded the compounded drug product;

7. If the drug product was compounded by a pharmaceutical technician, the initials of the pharmacist who supervised the pharmaceutical technician; and

8. The quantity of the final compounded drug product.

Sec. 32. *1. Each pharmacist engaged in the practice of compounding nonsterile compounded drug products shall label each nonsterile compounded drug product, including, without limitation, any amount of the nonsterile compounded drug product that is in excess of*

the amount required by the prescription or chart order and any nonsterile compounded drug product that is compounded in bulk quantities. The label must include, without limitation:

(a) The name of the final compounded drug product or the name of each active ingredient present in the nonsterile compounded drug product and, as appropriate, the concentration of each active ingredient in the final compounded drug product;

(b) The internal control number assigned to the compounded drug product by the pharmacist; and

(c) The beyond-use date of the compounded drug product;

2. Except as otherwise provided in subsection 3 or in the published data or data of the manufacturer, or as otherwise determined to be earlier in the judgment of the pharmacist, the latest beyond-use date of a nonsterile compounded drug product is:

(a) For nonaqueous liquids and solid formations, not later than the expiration date of the active ingredient present in the nonsterile compounded drug product with the earliest expiration date or 6 months after the date on which the nonsterile compounded drug product was compounded, whichever is earlier;

(b) For compounds which contain nonsterile water, not later than 14 days after the date on which the nonsterile compounded drug product was compounded; and

(c) For compounds other than those listed in paragraph (a) or (b), not later than the intended duration of the therapy or 30 days after the date on which the nonsterile compounded drug product was compounded, whichever is earlier.

3. Except as otherwise provided in subsection 7 of NRS 639.2801, a pharmacy may use a beyond-use date that is later than the dates described in subsection 2 if the pharmacy can

prove by appropriate testing or published data that the nonsterile compounded drug product is safe and effective using the extended beyond-use date.

4. Each pharmacist engaged in the practice of compounding nonsterile compounded drug products shall ensure that each nonsterile compounded drug product, including, without limitation, any amount of the nonsterile compounded drug product that is in excess of the amount required by the prescription or chart order, and any nonsterile compounded drug product that is compounded in bulk quantities is stored in the pharmacy in a manner that:

(a) Maintains the efficacy of the nonsterile compounded drug product; and

(b) Ensures that the nonsterile compounded drug product remains free from contamination.

Sec. 33. ***A pharmacy engaged in the practice of compounding nonsterile compounded drug products shall:***

1. Designate a specific area of the pharmacy in which nonsterile compounded drug products will be compounded;

2. Ensure that the area described in subsection 1 has adequate space in which to place, in an orderly manner, the equipment and materials that will be used in the compounding process;

3. Ensure that the area described in subsection 1 is cleaned using an antiseptic cleaning method before and after any compounding occurs in the area to prevent cross-contamination between the previously compounded drug products and any subsequently compounded drug products;

4. Ensure that any equipment used to compound a nonsterile compounded drug product is cleaned after the compounding of that drug product is completed to prevent cross-

contamination from occurring when the equipment is used in the compounding process of any subsequently compounded drug products;

5. If the pharmacy compounds both nonsterile compounded drug products and sterile compounded drug products, ensure that none of the equipment which is used to compound nonsterile compounded drug products is used to compound sterile compounded drug products unless the equipment is cleaned and sanitized before the compounding of sterile compounded drug products begins; and

6. Ensure that any employee of the pharmacy who compounds nonsterile compounded drug products washes his hands with soap and water or with an antimicrobial agent before and after compounding nonsterile compounded drug products.

Sec. 34. *A pharmacy engaged in the practice of compounding nonsterile compounded drug products shall, in addition to the requirements of section 28 of this regulation, establish and maintain written policies and procedures for compounding nonsterile compounded drug products to ensure that each final compounded drug product has the identity, strength, quality and purity which the compounded drug product is purported or represented to have. Such policies and procedures must include, without limitation:*

1. Policies and procedures for:

(a) Making and maintaining records concerning the components used to compound each nonsterile compounded drug product;

(b) The amount of each component used to compound each nonsterile compounded drug product;

(c) The order of each step in the process of compounding each nonsterile compounded drug product; and

(d) Including the information listed in paragraphs (a), (b) and (c) on the original hard copy of the prescription maintained in the written records of the pharmacy or in a computer system that may be accessed to provide information:

(1) For refilling the prescription; or

(2) Requested by the staff of the Board.

2. Control procedures for monitoring each final nonsterile compounded drug product and validating the processes for compounding that may be responsible for causing variability in the final nonsterile compounded drug product. Such control procedures must include, without limitation, procedures for evaluating:

(a) Any variation of more than plus or minus 10 percent in the weight of the capsules, tablets or any other solid form of a dosage of the same nonsterile compounded drug product;

(b) The adequacy of mixing to ensure uniformity and homogeneity of each nonsterile compounded drug product;

(c) If applicable, the clarity, completeness and pH of a nonsterile compounded drug product;

(d) If applicable, the even distribution of coloring agents; and

(e) Any variation of more than plus or minus 10 percent in the actual yield of a nonsterile compounded drug product compounded by the pharmacy as compared to the theoretical yield of the nonsterile compounded drug product.

3. Control procedures to ensure:

(a) If the final nonsterile compounded drug product is a capsule, that the capsule is properly locked;

(b) If the final nonsterile compounded drug product is a tablet or any other solid form of dosage, that the final compounded drug product is of a uniform size and is intact;

(c) If the final nonsterile compounded drug product is a suppository, that the suppository is properly sealed;

(d) If the final nonsterile compounded drug product is an oral liquid, that, to the extent possible, the liquid is palatable to the patient;

(e) If the final nonsterile compounded drug product is a suspension, that the visible suspended particles are of uniform size and are readily dispersed upon shaking; and

(f) If the final nonsterile compounded drug product is a topical compounded drug product, that the final compounded drug product is smooth and not gritty and has a uniform viscosity unless grittiness is required for a particular therapeutic purpose.

Sec. 35. *1. A pharmacy engaged in the practice of compounding nonsterile hazardous drugs shall:*

(a) Store the components of the hazardous drugs separately from all the other inventory at the pharmacy and in such a manner and location as to minimize the contamination of other drugs in and employees of the pharmacy;

(b) Handle the components of the hazardous drugs with caution by using appropriate gloves while distributing, receiving, stocking, inventorying, and preparing for administering and disposing of the components of a hazardous drug or a final compounded drug product;

(c) Ensure that an employee of the pharmacy involved with compounding hazardous drugs wears personal protective equipment, including, without limitation, gowns, face masks, eye protection, double gloves or chemotherapy gloves;

(d) Dispose of all waste relating to compounding hazardous drugs in a manner that complies with any applicable state, federal and local laws and regulations; and

(e) Ensure that any employees of the pharmacy who are known to the pharmacy to be at special risk with regard to the properties of the hazardous drugs are limited from exposure to those drugs.

2. A pharmacy engaged in the practice of compounding nonsterile hazardous drugs and dispensing compounded nonsterile hazardous drugs shall require each pharmacist and pharmaceutical technician who compounds nonsterile hazardous drugs to be trained in the storage, handling, compounding, safety procedures and disposal of such compounded drugs:

(a) Before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound a nonsterile hazardous drug that will be administered or dispensed to a patient; and

(b) At least once each year thereafter.

3. The training required pursuant to subsection 2 must, at a minimum, include information concerning:

(a) Safe manipulation practices that minimize exposure to the hazardous drug and protect employees of the pharmacy from any overt exposure to the hazardous drug;

(b) Procedures for containment, cleaning and disposal with regard to breaks and spills; and

(c) Treatment of employees of the pharmacy with regard to exposure by contact and inhalation.

4. The pharmacy shall make and keep a record of any training given pursuant to subsection 2.

Sec. 36. *1. Except as otherwise provided in section 41 of this regulation, a pharmacy engaged in the practice of compounding sterile compounded drug products shall provide an ISO Class 5 environment.*

2. If a pharmacy uses a laminar airflow hood as its ISO Class 5 environment within which to compound sterile compounded drug products, the pharmacy:

(a) Shall ensure that the laminar airflow hood is located within a room with a buffer area that maintains an ISO Class 7 environment under normal conditions of use.

(b) Shall maintain an ante-area or space in close proximity to any entrance to the room containing the laminar airflow hood that maintains an ISO Class 8 environment under normal conditions of use.

(c) Shall ensure that the room that contains the laminar airflow hood maintains a constant temperature and humidity that:

(1) Ensures the safety and efficacy of the compounded drug products, components and equipment; and

(2) Provides an environment in which the employees of the pharmacy can work comfortably for the duration of the compounding that will be conducted in the room.

(d) Shall require each employee of the pharmacy who enters the buffer area containing the laminar airflow hood to:

(1) Remove all jewelry from his hands and arms;

(2) Perform sanitizing scrubbing; and

(3) Wear fresh protective clothing, including, without limitation, gowns, shoe covers or dedicated shoes, and hair covers, in the ante-area or space in close proximity to an entrance to the room and to remove all such items of protective clothing whenever the employee leaves the

room. A gown may be used more than once within a 12-hour period if it is removed in the ante-area and is stored in the ante-area until it is used again.

(e) Shall require an employee to wear nonpowdered gloves and a face mask and beard cover, as applicable, before the employee enters the buffer area.

(f) Shall ensure, to the extent practicable, that all items located in or brought into the room containing the laminar airflow hood have nonporous, smooth, impermeable surfaces that:

(1) Can withstand being cleaned repeatedly with a disinfectant; and

(2) Do not shed particles which may become airborne in the room.

(g) Must have floors, walls and ceilings in the room containing the laminar airflow hood that are made of materials that can withstand being cleaned and disinfected repeatedly with solutions and products.

(h) Shall ensure, before any compounding can occur within the laminar airflow hood, that the laminar airflow hood is used according to the manufacturer's directions with regard to starting and using the laminar airflow hood in a manner which ensures that the interior of the laminar airflow hood creates and maintains an ISO Class 5 environment.

(i) Shall ensure that:

(1) The ISO Class 5 environment is cleaned:

(I) At the beginning of each work shift;

(II) Before the compounding of each batch preparation begins;

(III) At least every 30 minutes after the compounding of a sterile compounded drug product has begun during a period of continuous compounding activity;

(IV) After there has been a spill within the ISO Class 5 environment; and

(V) Whenever it is known or suspected that surface contamination exists as a result of a breach in procedure.

(2) The counters and easily cleanable work surfaces in close proximity to the laminar airflow hood and in, or in close proximity to, the buffer area are cleaned at least once each day in which the ISO Class 5 environment is used and whenever a counter or surface may require cleaning as a result of its use throughout the working day.

(3) The floors are cleaned at least once each day in which the ISO Class 5 environment is used and whenever the floors may require cleaning as a result of its use throughout the working day.

(4) The walls, ceilings, storage, shelving and other surfaces that are not easily cleaned are cleaned at least once each month.

3. If a pharmacy uses a barrier isolator cabinet that maintains an ISO Class 5 environment at all times when it is in use as its ISO Class 5 environment within which to compound sterile compounded drug products, the pharmacy shall ensure that:

(a) The barrier isolator cabinet is placed in the pharmacy at a location where:

(1) The compounding may occur without interruption or inconvenience; and

(2) The barrier isolator cabinet will not be compromised by its proximity to air vents, doorways or other pharmacy fixtures or equipment.

(b) Before any compounding may occur within the barrier isolator cabinet, the barrier isolator cabinet is used according to the manufacturer's directions with regard to starting and using the barrier isolator cabinet in a manner which ensures that the interior of the barrier isolator cabinet creates and maintains an ISO Class 5 environment.

(c) The barrier isolator cabinet is cleaned:

(1) At the beginning of each work shift;

(2) Before the compounding of each batch preparation begins;

(3) At least every 30 minutes after the compounding of a sterile compounded drug product has begun during a period of continuous compounding activity;

(4) After there has been a spill within the ISO Class 5 environment; and

(5) Whenever it is known or suspected that surface contamination exists as a result of a breach in procedure.

(d) The counters and easily cleanable work surfaces in close proximity to the barrier isolator cabinet are cleaned at least once each day in which the barrier isolator cabinet is used and whenever a counter or surface may require cleaning as a result of its use throughout the working day.

(e) The floors in close proximity to the barrier isolator cabinet are cleaned at least once each day in which the barrier isolator cabinet is used and whenever the floors may require cleaning as a result of its use throughout the working day.

4. A barrier isolator cabinet that cannot maintain an ISO Class 5 environment at all times when it is being used shall be deemed a laminar airflow hood for purposes of satisfying the requirements of this section.

5. As used in this section, "batch preparation" means the compounding of multiple units of sterile compounded drug products, not for immediate use, in a single process by the same person.

Sec. 37. *1. Except as otherwise provided in section 41 of this regulation, a pharmacy engaged in the practice of compounding sterile compounded drug products shall test the air in each of its controlled environments to ensure that the environments attain the air quality*

required by the provisions of NAC 639.661 to 639.690, inclusive, and sections 2 to 51, inclusive, of this regulation, for an ISO Class 5, ISO Class 7 or ISO Class 8 environment, as applicable.

2. The air quality testing required by subsection 1 must be performed randomly with regard to:

(a) The time of day the air samples are collected;

(b) The staff who is on duty when the samples are gathered; and

(c) The locations within the pharmacy from which the samples are collected.

3. A pharmacy engaged in the practice of compounding sterile compounded drug products shall have its ISO Class 5 environment certified pursuant to subsection 4:

(a) At least twice each year; and

(b) Before compounding a sterile compounded drug product after:

(1) A substantial change or renovation is made in the room that contains the laminar airflow hood or barrier isolator cabinet;

(2) Sizeable equipment is placed in the room that contains the laminar airflow hood or barrier isolator cabinet;

(3) The laminar airflow hood or barrier isolator cabinet is moved from the location at which the laminar airflow hood or barrier isolator cabinet was most recently tested; or

(4) The laminar airflow hood or barrier isolator cabinet is repaired.

4. The certification required by subsection 3 must be completed by a person who is independent of the pharmacy requesting the certification and who is capable of certifying that the ISO Class 5 environment can satisfy and maintain the minimum requirements set forth in section 17 of this regulation for air quality under normal conditions of use.

5. A pharmacy engaged in the practice of compounding sterile compounded drug products shall have each of its ISO Class 7 and ISO Class 8 environments tested or certified pursuant to subsection 7 for particulates:

(a) At least twice each year; and

(b) Before compounding a sterile compounded drug product after:

(1) A substantial change or renovation is made in the room that contains the laminar airflow hood or barrier isolator cabinet;

(2) Sizeable equipment is placed in the room that contains the laminar airflow hood or barrier isolator cabinet;

(3) The laminar airflow hood or barrier isolator cabinet is moved from the location at which the laminar airflow hood or barrier isolator cabinet was most recently tested; or

(4) A laminar airflow hood or barrier isolator cabinet is added to or removed from the room that contains the laminar airflow hood or barrier isolator cabinet.

6. The air quality testing required by subsection 5 must be performed randomly with regard to:

(a) The time of day the air samples are collected;

(b) The staff who are on duty when the samples are gathered; and

(c) The locations within the pharmacy from which the samples are collected.

7. The testing or certification required by subsection 5 must be completed by the pharmacy or by a person who is independent of the pharmacy requesting the certification and who is capable of testing or certifying that the ISO Class 7 or ISO Class 8 environment can satisfy and maintain the minimum requirements set forth in sections 18 and 19 of this regulation, respectively, for air quality under normal conditions of use.

8. If the pharmacy performs the testing or certification required by subsection 5, the testing or certification process of the pharmacy must be validated semiannually by the managing pharmacist.

9. If any of the results of the air quality testing or certification required by this section exceed the tolerances set forth in sections 17, 18 and 19 of this regulation, for the particular controlled environment, the pharmacy shall take whatever action is necessary to remediate the deficiency and retest the environment until the environment produces results within the tolerances for the particular controlled environment.

10. The pharmacy shall make and maintain records concerning the air quality testing and certification and any corrections and retesting that were conducted pursuant to this section.

Sec. 38. *1. Except as otherwise provided in subsections 4 and 5, a pharmacy engaged in the practice of compounding and dispensing sterile compounded drug products shall require each pharmacist and pharmaceutical technician who compounds sterile compounded drug products to pass a media fill test which must be conducted in the manner provided by chapter 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670, and which must be commensurate to the highest level of risk of compounding sterile compounded drug products that the pharmacist or pharmaceutical technician will be authorized by the pharmacy to perform:*

(a) Before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound a sterile compounded drug product that will be administered or dispensed to a patient;

(b) At least once each year thereafter if the pharmacy authorizes the pharmacist or pharmaceutical technician to compound low-risk sterile compounded drug products or medium-risk sterile compounded drug products; and

(c) At least twice each year thereafter if the pharmacy authorizes the pharmacist or pharmaceutical technician to compound high-risk sterile compounded drug products.

2. A pharmacy engaged in the practice of compounding and dispensing sterile compounded drug products shall ensure the competency and proficiency of each pharmacist and pharmaceutical technician at the highest level of risk of compounding sterile compounded drug products the pharmacist or pharmaceutical technician is authorized by the pharmacy to perform by:

(a) Requiring the pharmacist or pharmaceutical technician to provide a sample for a gloved fingertip sampling which must be conducted in the manner provided by chapter 797 of the United States Pharmacopeia - National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670;

(b) Testing a sample taken from a surface cleaned by the pharmacist or pharmaceutical technician to determine sterility;

(c) Ensuring the pharmacist or pharmaceutical technician receives, on an ongoing basis, sufficient training to maintain that competency and proficiency through attending in-house training programs or continuing education courses;

(d) Observing the pharmacist or pharmaceutical technician as he compounds sterile compounded drug products; or

(e) Correcting any error and initiating remedial measures for a pharmacist or pharmaceutical technician to take after an error has been noted with a sterile compounded drug product that was made or verified by the pharmacist or pharmaceutical technician.

3. A pharmacy shall make and maintain records concerning all the actions listed in subsection 2 which the pharmacy takes to ensure the competency and proficiency of each pharmacist and pharmaceutical technician who is authorized by the pharmacy to compound sterile compounded drug products.

4. A sterile compounded drug product that is compounded by a pharmacist or pharmaceutical technician who has not passed the media fill test required by paragraph (a) of subsection 1 may be dispensed and administered to a patient if:

(a) The managing pharmacist of the pharmacy determines that it is appropriate to dispense and administer the sterile compounded drug product; and

(b) The entire compounding process was personally witnessed by a pharmacist or pharmaceutical technician who passed the media fill test.

5. A pharmacy is not required to make a pharmacist or pharmaceutical technician pass a media fill test pursuant to paragraph (a) of subsection 1 if the pharmacist or pharmaceutical technician provides evidence of passing a media fill test:

(a) Within the immediately preceding 9 months if the pharmacist or pharmaceutical technician will compound low-risk sterile compounded drug products and medium-risk sterile compounded products; or

(b) Within the immediately preceding 5 months if the pharmacist or pharmaceutical technician will compound high-risk sterile compounded drug products.

Sec. 39. ***1. For all sterile compounded drug products compounded by a pharmacy, other than an institutional pharmacy, and for all sterile drug products for parenteral nutrition and sterile antineoplastic drug products compounded by an institutional pharmacy, a pharmacist shall make a record verifying the accuracy of each sterile compounded drug product that the pharmacist:***

(a) Compounded;

(b) Verified the accuracy of after it was compounded by a pharmaceutical technician; or

(c) Dispensed for administration to a patient in a medical facility.

2. A pharmacist required to make a record pursuant to subsection 1 shall:

(a) Make the record contemporaneous with the completion of the compounding, verifying or dispensing of the sterile compounded drug product;

(b) Include in the record information identifying the patient for which the sterile compounded drug product was made and the date the sterile compounded drug product was compounded; and

(c) Initial the record if it is a written record or enter an initial or other identifying mark onto the record if the record is made in a computerized system.

3. A pharmacy for which a record was made pursuant to subsection 1 shall ensure that the record is maintained for at least 6 months after the date the sterile compounded drug product was compounded, verified or dispensed.

4. If a sterile compounded drug product is compounded by a pharmaceutical technician, the pharmaceutical technician shall make a record of the compounding in the same manner as a pharmacist is required to make a record pursuant to this section.

Sec. 40. ***1. If, in the course of compounding a drug product, the seal of a single-dose container, including, without limitation, a bag, bottle, syringe or vial of a sterile drug product, is breached, the time and date of the breach must be marked upon the container and the contents of the container may be used:***

(a) Within 1 hour after the breach of the seal if:

(1) The breach occurred in an environment with an air quality that is worse than ISO Class 5; and

(2) The container is subsequently stored in an environment with an air quality that is worse than ISO Class 7;

(b) Within 6 hours after the breach of the seal if:

(1) The breach of the seal occurred and the contents of the container were used in an environment with an air quality that satisfies or exceeds ISO Class 5; and

(2) The container is subsequently stored in an environment with an air quality that satisfies or exceeds ISO Class 7; or

(c) Within 24 hours after the breach of the seal if the breach occurred in an environment with an air quality that satisfies or exceeds ISO Class 5 and the container remains in an environment with an air quality that satisfies or exceeds ISO Class 5.

2. If, in the course of compounding a drug product, the seal of a multidose container is breached:

(a) The container must be stored according to the requirements of the manufacturer; and

(b) The contents of the container may be used within 28 days after the breach of the seal occurred.

3. Any drug product that is not used within the periods set forth in subsection 1 or 2 may not be used and must be destroyed.

4. If the seal of a single-use ampule is breached or the entire seal has been removed from a multiuse vial and the contents are not used at the time of the breach, the contents may not be used and must be destroyed.

Sec. 41. *The Board may, upon application and for good cause shown, waive or modify any requirement set forth in sections 36 and 37 of this regulation for an institutional pharmacy engaged in the practice of compounding drug products if the institutional pharmacy serves an institution that:*

1. Has less than 100 beds licensed for providing acute care; and

2. Is located in a county:

(a) Whose population is less than 100,000; or

(b) Whose population is 100,000 or more if the hospital is designated as a rural hospital by the Nevada Office of Rural Health within the University of Nevada School of Medicine.

Sec. 42. *1. A compounded drug product is a low-risk sterile compounded drug product if:*

(a) The compounded drug product is required to be sterile for its effective administration;

(b) The sterile compounded drug product is at a low risk of contamination; and

(c) One or more of the following conditions are present:

(1) The compounding process involves aseptic manipulations that are performed entirely within an environment with an air quality of at least ISO Class 5 and uses only sterile ingredients, products, components and devices;

(2) The compounding process involves only transferring, measuring and mixing manipulations and uses not more than three commercially manufactured sterile drug products or other entries of a sterile drug product into one container, including, without limitation, a bag or vial, to make the final compounded drug product;

(3) The manipulations needed to compound the drug product are 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 or other sterile drug products and containers for storage and dispensing;

(4) The final compounded drug product contains a volume of 15 milliliters or less of a radiopharmaceutical and has an expiration time of 18 hours or less per dosage unit, including, without limitation, a dosage unit of a radiopharmaceutical prepared from an eluate by using a molybdenum-99technetiym-99m generator; or

(5) The final compounded drug product contains commercially manufactured cyclotron radiopharmaceuticals which contain preservatives and which have expiration times of 72 hours or less.

2. Unless sterility testing or potency limitations allow for a different period, the period of storage before administration of a low-risk sterile compounded drug product must not exceed:

(a) Forty-eight hours at a controlled room temperature that is at least 20 degrees Celsius (68 degrees Fahrenheit) but not more than 25 degrees Celsius (77 degrees Fahrenheit);

(b) Fourteen days at a temperature that is at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or

(c) Forty-five days in a solid frozen state that is -10 degrees Celsius (14 degrees Fahrenheit) or colder.

Sec. 43. ***If a nuclear pharmacy compounds radiopharmaceutical drug products, the nuclear pharmacy shall ensure that, in addition to satisfying the requirements of NAC 639.5828:***

1. The radiopharmaceutical compounded drug products are compounded in a vertical laminar airflow hood or Class II type B2 biological safety cabinet that is located in an environment with an air quality of ISO Class 8 or higher;

2. Only shielded vials, syringes and other devices and containers specifically manufactured for use with radiopharmaceutical components are used in the compounding process;

3. Each employee of the nuclear pharmacy who will compound radiopharmaceutical drug products is trained and knowledgeable with regard to compounding, handling, cleaning and any special techniques used with radiopharmaceutical drug products; and

4. Any special equipment or device that is used to compound radiopharmaceutical products, including, without limitation, a molybdenum-99technetiym-99m generator, is used, stored and maintained according to the directions of the manufacturer of the equipment or device.

Sec. 44. ***1. A compounded drug product is a medium-risk sterile compounded drug product if:***

(a) The compounded drug product is required to be sterile for its effective administration;

(b) The sterile compounded drug product is compounded using aseptic techniques pursuant to one of the conditions listed in section 42 of this regulation as a condition for a low-risk sterile compounded drug product; and

(c) One or more of the following conditions are present:

(1) Individual or small doses of sterile drug products are combined or pooled to prepare the final compounded drug product that will be administered to multiple patients or to one patient multiple times;

(2) The compounding process includes complex aseptic manipulations other than a single-volume transfer;

(3) The compounding process uses more than three commercially manufactured sterile drug products or other entries of a sterile drug product into one container, including, without limitation, a bag or vial, to make the final compounded drug product;

(4) The final compounded drug product does not contain broad-spectrum bacteriostatic substances and will be administered over a period which exceeds 24 hours; or

(5) The compounding process requires an unusually long duration, as determined by the managing pharmacist, including, without limitation, the period required to complete dissolution or homogeneous mixing.

2. Unless sterility testing or potency limitations allow for a different period, the period of storage before administration of a medium-risk sterile compounded drug product must not exceed:

(a) Thirty hours at a controlled room temperature that is at least 20 degrees Celsius (68 degrees Fahrenheit) but not more than 25 degrees Celsius (77 degrees Fahrenheit);

(b) Nine days at a temperature that is at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or

(c) Forty-five days in a solid frozen state that is -10 degrees Celsius (14 degrees Fahrenheit) or colder.

Sec. 45. *1. A compounded drug product is a high-risk sterile compounded drug product if:*

(a) The compounded drug product is required to be sterile for its effective administration;

(b) The sterile compounded drug product is contaminated with or at a high risk of becoming contaminated with infectious microorganisms; and

(c) One or more of the following conditions are present:

(1) One or more of the ingredients or devices used in the compounding process are nonsterile; or

(2) One or more of the ingredients or devices used in the compounding process were sterile but were exposed or are suspected of having been exposed for more than 1 hour to an air quality inferior to an ISO Class 5 environment.

2. Unless sterility testing or potency limitations allow for a different period, the period of storage before administration of a high-risk sterile compounded product must not exceed:

(a) Twenty-four hours at a controlled room temperature that is at least 20 degrees Celsius (68 degrees Fahrenheit) but not more than 25 degrees Celsius (77 degrees Fahrenheit);

(b) Three days at a temperature that is at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or

(c) Forty-five days in a solid frozen state that is -10 degrees Celsius (14 degrees Fahrenheit) or colder.

Sec. 46. *1. Except as otherwise provided in subsection 5, a pharmacy engaged in the practice of compounding and dispensing high-risk sterile compounded drug products shall ensure that each such compounded drug product is sterilized through filtration, by using steam in an autoclave or by dry heat. Except as otherwise provided in subsection 5, a*

pharmacist engaged in the practice of compounding high-risk sterile compounded drug products shall choose the method of sterilization that ensures the strength, purity, quality and packaging integrity of the final compounded drug product.

2. If a pharmacy sterilizes high-risk sterile compounded drug products using the filtration method, the pharmacy shall:

(a) Use commercially available sterile filters that are:

(1) Pyrogen-free and have a nominal porosity of 0.2 micron or 0.22 micron; and

(2) Certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta on each square centimeter of upstream filter surface area under conditions similar to the conditions of sterilization of the high-risk compounded drug products;

(b) Ensure that the filters used have sufficient capacity to permit the sterilization process to be completed rapidly and without compromising the sterility of the filtration process; and

(c) Subject the filtration units to the manufacturer's recommended integrity testing, including, without limitation, the bubble point test, after the filtration of the high-risk sterile compounded drug products is completed.

3. If a pharmacy sterilizes high-risk sterile compounded drug products using steam in an autoclave, the pharmacy shall:

(a) Expose each high-risk sterile compounded drug product to steam at 121 degrees Celsius (250 degrees Fahrenheit) under a pressure of 15 pounds per square inch for the duration of the sterilization process;

(b) Before starting the sterilization process, ensure that plastic, glass and metal devices are wrapped in low particle shedding paper or fabric or sealed in envelopes that prevent microbial

penetration after the sterilization of the high-risk sterile compounded drug products is completed;

(c) Ensure that the solutions that will be used to fill the vials which will be steam sterilized are passed through a filter having a porosity of not more than 1.2 microns to remove particulate matter immediately before filling those vials; and

(d) Verify the mass of the container that will be sterilized using steam in an autoclave to ensure that the container will be sterile after the period of exposure in that autoclave.

4. If a pharmacy sterilizes high-risk sterile compounded drug products using dry heat, the pharmacy shall ensure that:

(a) The heated air is filtered and evenly distributed by a blower throughout the chamber or oven used for the sterilization process; and

(b) The chamber or oven used for the sterilization process is equipped with accurate temperature controls and a timer.

5. A pharmacy may only use dry heat as a method of sterilization for a high-risk sterile compounded drug product if the final high-risk sterile compounded drug product would be damaged by moisture or is impermeable to moisture.

Sec. 47. *1. A pharmacy engaged in the practice of compounding and dispensing high-risk sterile compounded drug products for injection into the vascular system or central nervous system shall test a quantity of the high-risk sterile compounded drug product for:*

(a) Sterility using a membrane filtration method or an equivalent method, as determined by the Board, before any of the compounded drug product may be administered or dispensed to a patient; and

(b) Excessive bacterial endotoxins using an appropriate test, as determined by the Board, for the particular product at issue before any of the compounded drug product may be administered or dispensed to a patient.

2. A pharmacy engaged in the practice of compounding and dispensing high-risk sterile compounded drug products for inhalation or ophthalmic use shall test a quantity of each such high-risk sterile compounded drug product for sterility.

3. The provisions of subsections 1 and 2 apply only to high-risk sterile compounded drug products:

(a) Compounded in groups of more than 25 identical individual single-dose packages;

(b) Compounded in multiple-dose vials for administration to multiple patients; or

(c) That will be exposed for a period of more than:

(1) Twelve hours to temperatures of at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or

(2) Six hours to temperatures exceeding 8 degrees Celsius (46 degrees Fahrenheit) before the compounded drug product is sterilized.

4. If any high-risk sterile compounded drug product tested pursuant to this section tests positive for antimicrobial growth or endotoxin production, the high-risk sterile compounded drug product must not be administered or dispensed to a patient.

Sec. 48. *1. A sterile compounded drug product is an immediate-use sterile compounded drug product if:*

(a) The compounded drug product is intended only for the purpose of emergency care or immediate care of a patient;

(b) The compounding of the drug product occurs in an environment other than an ISO Class 5 environment and the compounding process consists of simple aseptic measuring and transfer manipulations performed with not more than six sterile nonhazardous commercial drug products and diagnostic radiopharmaceutical drug products, excluding infusion solutions or diluents;

(c) The preparation procedure occurs continuously without delays or interruptions and does not exceed 1 hour unless a period longer than 1 hour is required for the reconstitution of the compounded drug product;

(d) During compounding and before the administration of the compounded drug product, no part of the drug product or critical surfaces and ingredients of the drug product is directly exposed to contact contamination, including, without limitation, human touch, cosmetic flakes or particulates, blood or other bodily substances of a person or nonsterile inanimate sources; and

(e) Except as otherwise provided in paragraph (c), the administration of the compounded drug product begins not later than 1 hour after the start of the preparation of the compounded drug product and the compounded drug product is fully administered as soon as practicable but not longer than 24 hours after the administration of the compounded drug product began or the compounded drug product is disposed of promptly and safely.

2. If an immediate-use sterile compounded drug product is not immediately administered by direct injection into a patient by the person who compounded it, the compounded drug product must bear a label which includes, without limitation:

(a) The name and, if the patient has an identification number, the identification number of the patient;

(b) The name and amount of each ingredient of the compounded drug product;

(c) The initials of the person who compounded the compounded drug product; and

(d) The exact date and time of expiration of the compounded drug product.

3. An immediate-use sterile compounded drug product must not be stored for later use.

Sec. 49. *1. An immediate-use sterile compounded drug product that contains three or less commercial sterile drug products that will be stored more than 1 hour before administration is begun must comply with all compounding standards applicable to low-risk sterile compounded drug products.*

2. An immediate-use sterile compounded drug product which contains more than three commercial sterile drug products or which requires complex manipulations or complex preparation must comply with all compounding standards applicable to medium-risk sterile compounded drug products.

3. An immediate-use sterile compounded drug product that contains one or more nonsterile ingredients or components must comply with all compounding standards applicable to high-risk sterile compounded drug products.

Sec. 50. *1. A pharmacy engaged in the practice of compounding sterile hazardous drugs shall:*

(a) Store the components of the hazardous drugs separately from all the other inventory at the pharmacy and in such a manner and location as to minimize the contamination of other drugs in and employees of the pharmacy;

(b) Handle the components of the hazardous drugs with caution by using appropriate gloves during preparation, handling and disposal of the components of the hazardous drug or final compounded drug product;

(c) Compound the hazardous drugs pursuant to the requirements set forth in NAC 639.661 to 639.690, inclusive, and sections 2 to 51, inclusive, of this regulation and applicable to the risk level of the compounded hazardous drugs;

(d) Ensure that an employee of the pharmacy involved with compounding hazardous drugs wears personal protective equipment, including, without limitation, gowns, gloves, face masks, hair covers, shoe covers or dedicated shoes, and, if the hazardous drugs contain one or more antineoplastic agents or it is recommended by the drug manufacturer, double gloves or chemotherapy gloves;

(e) Dispose of all waste relating to the compounding of the hazardous drugs in a manner that complies with any applicable state, federal and local laws and regulations; and

(f) Ensure that any employees of the pharmacy who are known to the pharmacy to be at special risk with regard to the properties of the hazardous drugs are limited from exposure to those drugs.

2. A pharmacy shall ensure that the process of compounding sterile hazardous drugs is performed only in an ISO Class 5 environment in either a biological safety cabinet or a compounding aseptic containment isolator if one or more of the components of the hazardous drug are:

(a) An antineoplastic drug;

(b) A radiopharmaceutical drug; or

(c) A drug whose manufacturer has recommended that the drug only be compounded in an ISO Class 5 environment in either a biological safety cabinet or a compounding aseptic containment isolator.

3. The biological safety cabinet or compounding aseptic containment isolator described in paragraph (c) of subsection 2 must be vented to outside air during the compounding process through the use of high efficiency particulate air filtration if one or more of the components of the compounded hazardous drug are antineoplastic drugs.

Sec. 51. *1. A pharmacy engaged in the practice of compounding sterile hazardous drugs and dispensing sterile compounded hazardous drugs shall require each pharmacist and pharmaceutical technician who compounds sterile hazardous drugs to be trained in the storage, handling, compounding, safety procedures and disposal of such compounded drugs:*

(a) Before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound a sterile hazardous drug that will be administered or dispensed to a patient; and

(b) At least once each year thereafter.

2. The training required pursuant to subsection 1 must include, at a minimum, information concerning:

(a) Safe aseptic manipulation practices;

(b) Negative pressure techniques for use with a biological safety cabinet, compounding aseptic containment isolator or compounding aseptic isolator;

(c) The correct use of a vial transfer device in a closed system;

(d) Procedures for containment, cleaning and disposal with regard to breaks and spills; and

(e) Treatment of employees of the pharmacy with regard to contact and inhalation exposure.

3. The pharmacy shall make and keep a record of any training given pursuant to subsection 1.

Sec. 52. NAC 639.426 is hereby amended to read as follows:

639.426 1. A licensed pharmacy may practice as an Internet pharmacy only if the pharmacy is certified by the Board pursuant to this section. To be certified by the Board pursuant to this section, a pharmacy must apply to the Board for certification on an application provided by the Board.

2. The Board will grant an application for certification as an Internet pharmacy pursuant to this section if:

(a) The pharmacy is certified by the Verified Internet Pharmacy Practice Sites Program of the National Association of Boards of Pharmacy; or

(b) The Board determines that the pharmacy satisfies the requirements of subsection 3.

3. The Board will grant an application for certification pursuant to paragraph (b) of subsection 2 if the Board determines that the pharmacy:

(a) Is licensed to practice pharmacy in each state in which the pharmacy will practice pharmacy;

(b) Maintains and enforces policies and procedures which ensure that:

(1) The pharmacy is able to establish the authenticity of a prescription which the pharmacy receives;

(2) The pharmacy will not fill any prescription which has been previously filled by another pharmacy, and if the pharmacy fills any prescription, that prescription will not also be filled by another pharmacy;

(3) The identity of the patient and the prescribing practitioner is verified to be authentic;

(4) A prescription is filled in compliance with all applicable federal and state laws;

(5) A patient or the caregiver of the patient may make a complaint to the pharmacy regarding the prescription of the patient, and if such a complaint is made, the complaint will be investigated thoroughly, the results of the investigation will be communicated to the patient or caregiver ~~[,]~~ and , if the investigation reveals that the operations of the pharmacy resulted in an error in the processing or filling of the prescription, appropriate remedial action will be taken by the pharmacy;

(6) The pharmacy will communicate to a patient or a prescribing practitioner any delay that might jeopardize or alter the drug therapy of the patient with respect to delivering the prescribed drug or device; and

(7) The pharmacy will communicate to a patient information regarding recalls of drugs and the appropriate means to dispose of expired, damaged or unusable drugs or devices;

(c) Obtains and maintains patient information necessary to facilitate review of drug utilization and counseling of patients pursuant to any applicable statutes;

(d) Provides review of drug utilization and counseling of patients pursuant to the applicable statutes in the state in which the patient resides;

(e) Maintains controls of its computer system, information concerning patients and other such confidential information and documents to prevent unauthorized or unlawful access to all such confidential information and documents;

(f) Complies with applicable federal and state laws regarding:

(1) The dispensing of prescription drugs;

(2) Recordkeeping related to the patients served by the pharmacy, the purchase of prescription drugs, and the sale and dispensing of prescription drugs; and

(3) The sale of over-the-counter products, including, without limitation, any special requirements related to products that have been identified as precursors to the manufacture or compounding of illegal drugs;

(g) Ships prescriptions to a patient using a secure and traceable means; and

(h) Ships prescriptions to a patient using packaging or devices which will ensure that the prescription is maintained within appropriate standards pertaining to temperature, light and humidity as described in the *United States Pharmacopeia* ~~[, 25th edition, 2002, which is hereby]~~ ***- National Formulary, as*** adopted by reference ~~[. A copy of the publication may be obtained from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, for the price of $589, plus $13 for shipping and handling.]~~ ***in paragraph (c) of subsection 1 of NAC 639.670.***

Sec. 53. NAC 639.472 is hereby amended to read as follows:

639.472 A pharmacy must maintain a reference library that includes the following:

1. A current copy of:

(a) All state statutes and regulations relating to the practice of pharmacy and to the sale of drugs and controlled substances; and

(b) The Federal Controlled Substances Act (Title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242) and the regulations adopted pursuant thereto ~~[,]~~ or an official publication describing the requirements of that act and the regulations adopted pursuant thereto.

2. The American Hospital Formulary Service, with current supplements, or Facts and Comparisons, with current supplements.

3. At least one current text in one of the following subjects:

(a) Theoretical and practical pharmacy.

(b) Pharmacology.

(c) Therapeutics.

4. A current text relating to each of the following:

(a) Compatibility information, if parenteral admixture is performed by the pharmacy;

(b) Information concerning the interaction of drugs; and

(c) Information concerning antidotes.

5. Current copies of one of the following:

(a) *United States Pharmacopeia - National Formulary* ~~[;]~~ ***, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670;***

(b) *United States Pharmacopeia - Drug Information*; or

(c) *Remington's Pharmaceutical Sciences*.

6. A current copy of the Food and Drug Administration Approved Drug Products.

Sec. 54. NAC 639.5834 is hereby amended to read as follows:

639.5834 The immediate outer shield of the container of a radiopharmaceutical to be dispensed must be labeled with:

1. The name and address of the pharmacy.

2. The name of the prescriber.

3. The date of dispensation.

4. The serial number assigned to the order for the radiopharmaceutical.

5. The standard radiation symbol.

6. The words "CAUTION RADIOACTIVE MATERIAL."

7. The name of the procedure.

8. The radionuclide and chemical form.

9. The amount of radioactivity and the date and time of the calibration.

10. If the radiopharmaceutical is a liquid, the volume.

11. If the radiopharmaceutical is a solid, the number of items or weight.

12. If the radiopharmaceutical is a gas, the number of ampules or vials.

13. The molybdenum 99 content in accordance with the limitations prescribed in the *United States Pharmacopeia* ~~[.]~~ ***- National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.***

14. The name of the patient or the words "Physician's Use Only" in the absence of a patient's name.

15. If the prescription is for a radiopharmaceutical for therapeutic use or use in a blood product, the patient's name must appear on the label. The requirements of this subsection are met if the name of the patient is readily retrievable from the prescriber upon demand.

Sec. 55. NAC 639.598 is hereby amended to read as follows:

639.598 1. Each wholesaler shall store prescription drugs held in the facility in the manner prescribed in the *United States Pharmacopeia* ~~[, 22nd edition, 1990, which is hereby adopted by reference. A copy of the publication may be obtained from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, for the price of $91, plus $7 for shipping and handling.]~~ ***- National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.***

2. If there are no specific requirements concerning the temperature at which a prescription drug must be stored, the drug must be stored at a controlled room temperature as defined in the *United States Pharmacopeia* ~~[, 22nd edition, 1990.]~~ ***- National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.***

3. Each wholesaler shall provide the appropriate manual, electromechanical or electrical equipment to record the temperature and humidity of the area where the prescription drugs are stored.

Sec. 56. NAC 639.601 is hereby amended to read as follows:

639.601 1. A prescription drug that is outdated, damaged, deteriorated, misbranded or adulterated must be separated from other prescription drugs until it is destroyed or returned to the supplier.

2. A prescription drug whose immediate or sealed outer or secondary container has been opened or used must be identified as such and separated from other prescription drugs until it is destroyed or returned to the supplier.

3. If a prescription drug is returned to a wholesaler by a purchaser or purchasing wholesaler under conditions which cast doubt on the prescription drug's safety, identity, strength, quality or purity, the wholesaler shall destroy the prescription drug or return it to the supplier unless, after conducting an examination, testing or other investigation, the wholesaler determines that the prescription drug complies with the appropriate standards of safety, identity, strength, quality and purity as prescribed in the package insert as approved by the Food and Drug Administration or in the *United States Pharmacopeia - National Formulary* ~~[in effect as of March 1, 2000.]~~ ***, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.*** The wholesaler shall keep a record of any examination, testing or other investigation conducted and make any records available for inspection by the Board.

4. Unless the reason a prescription drug must be destroyed or returned to the supplier is related to the expiration date of the prescription drug, a wholesaler that is required to destroy a

prescription drug or return it to the supplier pursuant to subsection 3 shall provide to the Board a written notice that includes:

(a) The name of the prescription drug;

(b) The lot number and expiration date of the prescription drug;

(c) The quantity of the prescription drug;

(d) The name and address of the business that returned the prescription drug to the wholesaler;

(e) Whether the wholesaler will:

(1) Return the prescription drug to the supplier; or

(2) Destroy the prescription drug; and

(f) The reason for the action taken by the wholesaler.

5. Within 48 hours after receipt by the Board of a notice required pursuant to subsection 4, a member of the staff of the Board shall inspect the prescription drug at the facility of the wholesaler and may impound or remove the prescription drug. If the member of the staff of the Board does not impound or remove the prescription drug, the wholesaler may return the prescription drug to the supplier or destroy the prescription drug.

Sec. 57. NAC 639.639 is hereby amended to read as follows:

639.639 1. Each authorized warehouse shall store prescription drugs held in the facility in the manner prescribed in the *United States Pharmacopeia* ~~[, 22nd edition, 1990, which is hereby adopted by reference. A copy of the publication may be obtained from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, for the price of $91, plus $7 for shipping and handling.]~~ ***- National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.***

2. If there are no specific requirements concerning the temperature at which a prescription drug must be stored, the drug must be stored at a controlled room temperature as defined in the *United States Pharmacopeia* ~~[, 22nd edition, 1990.]~~ ***- National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.***

3. Each authorized warehouse shall provide the appropriate manual, electromechanical or electrical equipment to record the temperature and humidity of the area where the prescription drugs are stored.

Sec. 58. NAC 639.661 is hereby amended to read as follows:

639.661 As used in NAC 639.661 to 639.690, inclusive, ***and sections 2 to 51, inclusive, of this regulation,*** unless the context otherwise requires, the words and terms defined in NAC 639.663, 639.665 and 639.667 ***and sections 2 to 25, inclusive, of this regulation*** have the meanings ascribed to them in those sections.

Sec. 59. NAC 639.670 is hereby amended to read as follows:

639.670 ***1.*** The Board hereby adopts by reference the following:

~~[1.]~~ ***(a)*** Federal Standard ~~[209(b), "Clean Room and Work Station Requirements" of the Federal Supply Service, General Services Administration, as it exists on June 1, 1986.]~~ ***209E, "Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones," as revised on September 11, 1992, by the Institute of Environmental Sciences.*** A copy of this publication ~~[is available from the General Services Administration, Specifications Section, Room 6039, 7th and D Streets, S.W., Washington, D.C. 20407, for the price of $1.40.]~~

~~2. National Sanitation Foundation]~~ ***may be obtained free of charge at the Internet address http://www.set3.com/papers/209e.pdf.***

(b) NSF International Standard ~~[No. 49, as it exists on June 1, 1986, concerning]~~ ***49, "*** Class II (Laminar Flow) ~~[biohazard cabinetry and hoods.]~~ ***Biosafety Cabinetry," NSF/ANSI 49-2007, 2007 edition.*** A copy of this ~~[standard is available from the National Sanitation Foundation, P.O. Box 130140, Ann Arbor, Michigan 48113-0140, for the price of $2.]~~ ***standard may be obtained from Techstreet, 3916 Ranchero Drive, Ann Arbor, Michigan 48108, or at the Internet address http://www.techstreet.com/, for the price of $160.***

(c) United States Pharmacopeia - National Formulary, 2008 edition, published by the United States Pharmacopeial Convention. A copy of this publication may be obtained from the United States Pharmacopeial Convention, Customer Service Department, 12601 Twinbrook Parkway, Rockville, Maryland 20852, or at the Internet address http://www.usp.org/products/, for the price of $755.

(d) The Food Chemicals Codex, 6th edition, published by the United States Pharmacopeial Convention. A copy of this publication may be obtained from the United States Pharmacopeial Convention, Customer Service Department, 12601 Twinbrook Parkway, Rockville, Maryland 20852, or at the Internet address http://www.usp.org/products/, for the price of $495.

(e) Reagent Chemicals: Specifications and Procedures, 10th edition, published by the American Chemical Society. A copy of this publication may be obtained from the Oxford University Press, 2001 Evans Road, Cary, North Carolina 27513, or at the Internet address http://www.oup-usa.org, for the price of $274.50.

(f) Appendix A of Publication No. 2004-165, "Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings," published by the National Institute for Occupational Safety and Health. A copy of this publication may be

obtained free of charge by telephone at (800) 232-4636 or at the Internet address http://www.cdc.gov/niosh/docs/2004-165/.

2. The Board will periodically review the standards and publications adopted by reference pursuant to paragraphs (b) to (f), inclusive, of subsection 1 and determine within 120 days after the review whether any change made to those standards or publications is appropriate for application in this State. If the Board does not disapprove a change to an adopted standard or publication within 120 days after the review, the change is deemed to be approved by the Board.

Sec. 60. NAC 639.686 is hereby amended to read as follows:

639.686 ~~[Any]~~ ***In addition to the requirements of sections 28 and 30 of this regulation, any*** pharmacy providing parenteral solutions shall have written policies and procedures for the disposal of infectious materials and materials containing cytotoxic residues. The procedures must contain methods for the cleanup of spills and must be in conformance with the regulations of the local health authority. The pharmacy shall ensure the return of infectious materials and materials containing cytotoxic residues to the pharmacy or shall inform the provider of care of the procedures for the proper destruction of such materials.

Sec. 61. NAC 639.688 is hereby amended to read as follows:

639.688 ~~[Any]~~ ***In addition to the requirements of sections 28 and 30 of this regulation, any*** pharmacy***, other than an institutional pharmacy,*** engaged in the practice of compounding and dispensing parenteral solutions shall have written policies and procedures relating to:

1. The qualifications and training of employees of the pharmacy to compound and dispense parenteral solutions.

2. A determination of the necessity for administering the medication a patient requires in a parenteral form.

3. The compounding and control of the quality of parenteral solutions.

4. The distribution and delivery of parenteral solutions.

5. The clinical monitoring of parenteral therapy.

6. The availability of a practitioner, pharmacist and nursing personnel during the administration of parenteral therapy to a patient.

7. The availability of products and equipment which are necessary during the administration of parenteral therapy to a patient.

8. The communication of orders among the practitioner, pharmacist and nursing personnel for a patient who requires parenteral therapy.

9. The coordination of the care of a patient who requires parenteral therapy by the pharmacist, practitioner and nursing personnel, including documentation of participation in any conference relating to the care of that patient.

10. The education of a patient relating to:

(a) The self-administration of a parenteral solution;

(b) The proper maintenance and storage of a parenteral solution; and

(c) The operation of devices used to administer parenteral solutions.

11. The cleaning and maintenance of equipment used to administer a parenteral solution furnished to a patient by the pharmacy.

12. The provision of services relating to parenteral therapy furnished by the pharmacy in an emergency.

Sec. 62. NAC 639.742 is hereby amended to read as follows:

639.742 1. A practitioner who wishes to dispense controlled substances or dangerous drugs must apply to the Board on an application provided by the Board for a certificate of registration to dispense controlled substances or dangerous drugs. A practitioner must submit a separate application for each site of practice from which he wishes to dispense controlled substances or dangerous drugs. A certificate of registration to dispense controlled substances or dangerous drugs is a revocable privilege, and no holder of such a certificate of registration acquires any vested right therein or thereunder.

2. If a facility from which the practitioner intends to dispense dangerous drugs or controlled substances is not wholly owned and operated by the practitioner, the owner or owners of the facility must also submit an application to the Board on a form provided by the Board.

3. The dispensing practitioner and, if applicable, the owner or owners of the facility, shall ensure that:

(a) All drugs are ordered by the dispensing practitioner;

(b) All drugs are received and accounted for by the dispensing practitioner;

(c) All drugs are stored in a secure, locked room or cabinet to which the dispensing practitioner has the only key or lock combination;

(d) All drugs are dispensed in accordance with NAC 639.745;

(e) No prescription is dispensed to a patient unless the dispensing practitioner is on-site at the facility;

(f) All drugs are dispensed only to the patient personally at the facility;

(g) The price of each drug dispensed to a patient is separately itemized on any bill or statement provided to the patient;

(h) All drugs are dispensed only for medically necessary purposes and according to prevailing standards of care for practitioners practicing in the specialty claimed or practiced by the dispensing practitioner; and

(i) The certificate for each dispensing technician employed at the facility is displayed in the room or cabinet in which drugs are stored.

4. With regard to the filling and dispensing of a prescription at a facility, only the dispensing practitioner or a dispensing technician may:

(a) Enter the room or cabinet in which drugs are stored;

(b) Remove drugs from stock;

(c) Count, pour or reconstitute drugs;

(d) Place drugs into containers;

(e) Produce and affix appropriate labels to containers that contain or will contain drugs;

(f) Fill containers for later use in dispensing drugs; or

(g) Package or repackage drugs.

5. A dispensing practitioner may compound drug products if he complies with the provisions of NAC 639.661 to 639.690, inclusive, and sections 2 to 51, inclusive, of this regulation as if:

(a) He were a pharmacist;

(b) His practice site was a pharmacy; and

(c) Any dispensing technician involved in the compounding was a pharmaceutical technician.

Sec. 63. NAC 639.743 is hereby amended to read as follows:

639.743 1. A person to whom a dispensing practitioner is providing training and experience pursuant to subsection 4 of NAC 639.7425 must not be allowed access to the room or cabinet in which drugs are stored unless accompanied by the dispensing practitioner. After the person has completed his training and experience and the Board has received an affidavit from the practitioner pursuant to subsection 5 of NAC 639.7425:

(a) The person may access the room or cabinet in which drugs are stored without being accompanied by the dispensing practitioner, so long as the practitioner is on-site at the facility; and

(b) The dispensing practitioner is not required to observe the work of the person.

2. A practitioner who allows a dispensing technician to perform any function described in subsection 4 ***or 5*** of NAC 639.742 is responsible for the performance of that function by the dispensing technician. All such functions performed by a dispensing technician must be performed at the express direction and delegation of the dispensing practitioner. Each prescription with respect to which a dispensing technician performed such a function:

(a) Must be checked by the dispensing practitioner, and the dispensing practitioner shall indicate on the label of the prescription and in his record regarding the prescription that the dispensing practitioner has checked the work performed by the dispensing technician; and

(b) Must not be dispensed to the patient without the initials of the dispensing practitioner thereon. A prescription which has been so initialed must be handed to the patient only by the dispensing practitioner or an employee authorized by the dispensing practitioner.

Sec. 64. NAC 639.7435 is hereby amended to read as follows:

639.7435 1. The registration of a dispensing technician is nontransferable and limited to the dispensing practitioner to whom the dispensing technician is registered. The registration of a

dispensing technician expires at the same time that the certificate of registration of the dispensing practitioner expires. If a dispensing practitioner and the dispensing technician registered to that practitioner leave the facility at which they are registered, and the dispensing technician continues his employment with that practitioner at a different site, the dispensing practitioner shall, as soon as practicable, notify the Board of the change of address of employment of the dispensing technician.

2. If a dispensing technician no longer works as a dispensing technician for the dispensing practitioner to whom the dispensing technician is registered, the registration of the dispensing technician terminates. If that person is subsequently employed by another dispensing practitioner to work as a dispensing technician, the employing dispensing practitioner must, before the person may act as a dispensing technician for that practitioner:

(a) Register the person with the Board, showing the site of employment and the name of the dispensing practitioner; and

(b) Ensure that the person receives an additional 200 hours of training and experience provided by the dispensing practitioner. The additional training and experience must be provided in accordance with subsection 4 of NAC 639.7425. The dispensing practitioner shall not allow the person to be registered as a dispensing technician to enter the room or cabinet in which drugs are stored or perform any function described in subsection 4 ***or 5*** of NAC 639.742 without the dispensing practitioner observing the act by the person to be registered as a dispensing technician until that person has completed the 200 additional hours of training and experience.

Sec. 65. NAC 639.744 is hereby amended to read as follows:

639.744 1. A dispensing practitioner shall pay to the Board a fee of $40 for each dispensing technician whom that practitioner registers:

(a) At the time of application by the dispensing practitioner for initial registration of the person as a dispensing technician; and

(b) With the practitioner's renewal thereafter as a part of and in addition to the practitioner's renewal of his registration as a dispensing practitioner.

2. A dispensing practitioner may register more than one dispensing technician at a time, except that only one of those dispensing technicians may be designated and allowed to perform the functions described in subsection 4 ***or 5*** of NAC 639.742 at one time. A dispensing practitioner shall make and maintain a document on which must be recorded for each day the name of the dispensing technician so designated and allowed to perform the functions described in subsection 4 ***or 5*** of NAC 639.742, and maintain the record for not less than 2 years.

Sec. 66. NAC 639.757 is hereby amended to read as follows:

639.757 1. A pharmacy or pharmacist is not required to obtain a license as a manufacturer to compound drugs if:

(a) The compounded drugs are prepared in a quantity that is:

(1) Necessary to fill a prescription ~~[;]~~ ***or chart order;*** or

(2) Reasonably necessary to fill future prescriptions ***or chart orders*** based upon the previous history of practitioners and patients who regularly use the pharmacy;

(b) The compounded drugs are not sold or otherwise provided by the pharmacy or pharmacist to any person other than the ultimate user of the drugs, the agent of the ultimate user of the drugs or a practitioner who will be administering the drugs to a patient; ~~[and]~~

(c) The ***compounded drugs are dispensed pursuant to a prescription or chart order;***

(d) Except as otherwise provided in paragraph (e) and subsection 2, the active ingredients used to compound the drugs ***:***

(1) Have a monograph in and meet or exceed the standards of the *United States Pharmacopoeia - National Formulary* ~~[. If a component of the compounded drug]~~ ***, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670;***

(2) Have been components of drugs approved by the Food and Drug Administration; or

(3) Are authorized to be used in pharmacy compounding pursuant to 21 U.S.C. § 353a(b)(1) or the regulations adopted pursuant thereto; and

(e) Except as otherwise provided in subsection 2, for an active ingredient used to compound the drugs that does not have a monograph in the *United States Pharmacopoeia - National Formulary*, ~~[the component may still be used if the component is in a list of approved substances developed by the Secretary of Health and Human Services.]~~ ***as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670, the active ingredient is:***

(1) Prepared by a manufacturer or distributed by a distributor registered with the Food and Drug Administration;

(2) Accompanied by a certificate of analysis provided by the manufacturer or distributor of the ingredient; and

(3) Prepared to a grade that, at a minimum, satisfies the requirements set forth in:

(I) The Food Chemicals Codex, as adopted by reference in paragraph (d) of subsection 1 of NAC 639.670; or

(II) Reagent Chemicals: Specifications and Procedures, as adopted by reference in paragraph (e) of subsection 1 of NAC 639.670, if the active ingredient is a certified analytical reagent, is for use in high pressure liquid chromatography, is for use in spectrophotometric applications or is a primary standard grade for use in standard solutions for analytical purposes.

2. ~~[A]~~ ***In compounding a drug product, a pharmacy or pharmacist may use an active ingredient that does not satisfy the requirements of paragraphs (d) and (e) of subsection 1 if the pharmacy or pharmacist establishes the purity and safety of the ingredient by reasonable means, satisfactory to the Board, which include, without limitation, analysis of the lot in which the ingredient was packaged, the reputation of the manufacturer of the ingredient and the reliability of the source of the ingredient. A pharmacy shall make and maintain a record of the means that the pharmacy relied upon in determining that an ingredient was pure and safe pursuant to this subsection.***

3. Except as otherwise provided in this subsection, a pharmacy or pharmacist shall not compound a drug that has been withdrawn or removed from the market because the drug was found to be unsafe or ineffective.

~~[3.]~~ A pharmacy or pharmacist ***may compound a drug for veterinary use that has been withdrawn or removed from the market because the drug was found to be unsafe or ineffective for use in humans if the drug remains available for veterinary use.***

4. A pharmacy shall not sell or otherwise provide a compounded drug to ~~[:~~

~~(a) Another]~~ ***a retail*** pharmacy ~~[; or~~

~~(b) A]~~ ***or a*** practitioner, except that a pharmacy ~~[or pharmacist]~~ may sell or otherwise provide a compounded drug to ~~[a]~~ ***:***

(a) A practitioner who will be administering the drug to a patient ~~[.]~~ ***; or***

(b) A practitioner or another pharmacy if the compounded drug is:

(1) A highly concentrated drug product that is not commercially available; or

(2) Needed to fill a particular prescription or chart order in the possession of the receiving pharmacy at the time the receiving pharmacy orders the compounded drug from the compounding pharmacy.

5. The quantity of a compounded drug that is sold or otherwise provided to a practitioner or pharmacy pursuant to subsection 4 must not exceed the amount necessary for the practitioner or pharmacy to serve the present needs of the patients of the practitioner or pharmacy.

Sec. 67. NAC 639.760 is hereby amended to read as follows:

639.760 1. Dangerous drugs and controlled substances may be returned to the pharmacy which dispensed them, pursuant to subsection 3 of NRS 639.267, if they are packaged in unit doses by the original manufacturer, the packages and the packaging of which conform to chapters 661 and 671 of the *United States Pharmacopeia - National Formulary* ~~[which is in force on March 1, 2000. This publication is hereby incorporated by reference. This publication may be obtained from:~~

~~United States Pharmacopeial Convention, Inc.~~

~~Customer Service Department~~

~~12601 Twinbrook Parkway~~

~~Rockville, Maryland 20852,~~

~~for the price of $549, plus $9 for shipping.]~~ ***, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.***

2. A drug may not be returned to the issuing pharmacy unless its package contains the expiration date of the usefulness of the drug.

3. A person or agency returning the unused drugs and the pharmacy receiving the unused drugs shall maintain a current audit of the drugs which are returned and received on forms approved by the Board. Such forms will be furnished at the expense of the facility or pharmacy.

4. A prescription for a dangerous drug or controlled substance dispensed by a pharmacy that has been removed from the premises of the pharmacy may not be returned to the pharmacy pursuant to subsection 3 of NRS 639.267 for the destruction of the drug or substance, or for the return of the drug or substance to the stock of drugs of the pharmacy, if the dangerous drug or controlled substance is not packaged in a unit dose by its original manufacturer as required by subsection 1.

5. A drug dispensed by a pharmacy to a patient may be returned to the pharmacy to be repackaged or relabeled only if the drug will be dispensed by the pharmacy to the same patient.

6. Nothing in this section establishes any condition of reimbursement, credit or refund of a prescription purchased in a pharmacy.

Sec. 68. NAC 639.674, 639.678 and 639.684 are hereby repealed.

Sec. 69. Notwithstanding the provisions of sections 27, 28, 33, 34, 35 and 38 of this regulation, a dispensing practitioner or pharmacy engaged in the compounding of drugs, regardless of whether the practitioner or pharmacy is located within this State or outside this State, is not required to satisfy the amendatory requirements of those provisions until March 18, 2009.

Sec. 70. Notwithstanding the provisions of sections 36 and 37 of this regulation, a dispensing practitioner and a pharmacy engaged in the compounding of drugs, regardless of

whether the practitioner or pharmacy is located within this State or outside this State, is not required to satisfy the amendatory requirements of those provisions until March 18, 2010.

Sec. 71. 1. This section and sections 1 to 67, inclusive, 69 and 70 of this regulation become effective on September 18, 2008.

2. Section 68 of this regulation becomes effective on March 18, 2010.

TEXT OF REPEALED SECTIONS

639.674 Designated work area; equipment. (NRS 639.070, 639.2807)

1. A pharmacy engaged in the practice of compounding and dispensing of parenteral solutions shall have a designated room for the preparation of sterile products for dispensing which must:

(a) In accordance with Federal Standard 209(b), meet the standards for class 100 HEPA (high efficiency particulate air) filtered air such as having a laminar airflow hood or a clean room;

(b) Be maintained in a clean condition and have cleanable surfaces, including walls, ceilings and floors; and

(c) Be ventilated in a manner which does not interfere with the laminar airflow hood.

2. The laminar airflow hood must be certified annually, in accordance with Federal Standard 209(b). Records of certification must be retained for at least 2 years.

3. The pharmacy must be arranged so that the laminar airflow hood is located in an area which is exposed to a minimal flow of traffic and is separate from any area used for bulk storage

of items not related to the compounding of parenteral solutions. Items related to the compounding of parenteral solutions which are stored in the area where parenterals are compounded must not obstruct the intake of the laminar airflow hood.

4. There must be sufficient space which is well separated from the area of the laminar airflow hood for the storage of bulk materials, equipment and waste materials.

5. A sink with hot and cold running water must be provided within the pharmacy.

6. There must be a refrigerator, freezer, or both, of sufficient capacity to store all materials requiring refrigeration.

639.678 Preparation of cytotoxic agent: Certified vertical laminar airflow hood required. (NRS 639.070, 639.2807) In any pharmacy preparing parenteral cytotoxic agents, all compounding must be conducted within a certified vertical laminar airflow hood. The hood must be certified annually in accordance with National Sanitation Foundation Standard No. 49 or the manufacturer's specifications. Records of certification must be retained for at least 2 years.

639.684 Program to ensure clean and sanitary environment for preparation of sterile products. (NRS 639.070, 639.2807)

1. The managing pharmacist shall develop and maintain a program to ensure that there is a clean and sanitary environment for the preparation of sterile products and that the parenteral solutions produced are sterile. Records of the activities related to this program must be established and made available to the Board.

2. The program must include the following:

(a) The procedures for cleaning and sanitization of the area used for preparing parenteral solutions.

(b) Periodic documentation of the temperatures of the room and refrigerator in which compounded parenteral solutions are stored.

(c) The steps to be taken in the event of a recall of a drug.

(d) A written justification of the dates of expiration for compounded parenteral solutions.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R035-06

The State Board of Pharmacy adopted regulations assigned LCB File No. R035-06 which pertain to chapter 639 of the Nevada Administrative Code.

INFORMATIONAL STATEMENT

1. A DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED, A SUMMARY OF PUBLIC RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Public comment was solicited through public notices posted in county courthouses and through mailings to interested parties.

All interested parties may obtain a summary of public response by written or verbal request to: Nevada State Board of Pharmacy, 431 West Plumb Lane, Reno, Nevada, 89509.

2. THE NUMBER OF PERSONS WHO: (A) ATTENDED EACH HEARING; (B) TESTIFIED AT EACH HEARING; AND (C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

The number of persons who attended the hearing was __3___.
The number of persons who testified at the hearing was ___3__.
The number of agency submitted statements was __1___.

3. A DESCRIPTION OF HOW COMMENT WAS SOLICITED FROM AFFECTED BUSINESSES, A SUMMARY OF THEIR RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Comments were solicited from affected businesses through posting of public notices in the county courthouses, by direct mailings to all interested persons who have requested notices of board of pharmacy meeting agendas and by direct mailings to professional and trade associations.

All response from affected businesses relative to this proposed regulation expressed support for the amendment with suggested changes.

All interested parties may obtain a summary of public response by written or verbal request to: Nevada State Board of Pharmacy, 431 West Plumb Lane, Reno, Nevada, 89509.

4. IF THE REGULATION WAS ADOPTED WITHOUT CHANGING ANY PART OF THE PROPOSED REGULATION, A SUMMARY OF THE REASONS FOR ADOPTING THE REGULATION WITHOUT CHANGE.

The proposed regulation was adopted with amendments or changes suggested through comments received from the public.

5. THE ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH IT IS TO REGULATE AND ON THE PUBLIC. THESE MUST BE STATED SEPARATELY, AND IN EACH CASE MUST INCLUDE:

A) BOTH ADVERSE AND BENEFICIAL EFFECTS.

This regulation will benefit the public by greatly increasing the standards for and regulation of the ever-growing trend toward pharmaceutical compounding. The beneficial effect to participating pharmacies will be to provide a level playing field upon which competition and innovation fairly occur.

There will be no adverse effects to the public. The adverse effect to pharmacies will be that some pharmacies will need to spend considerable money to bring the pharmacies up to the new standards or else the pharmacies will need to stop making certain compounded products. The regulation has attempted to mitigate the adverse effects by allowing an 18-month period for compliance with the most expensive of the changes.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

All participating pharmacies will be required to bring their policies and procedures and operations up to the new standards immediately.

All participating pharmacies will have six months to bring some aspects into compliance and 18 months to bring the more expensive physical-plant aspects into compliance. Also, the regulations set certain testing standards that will perpetually add costs to participating pharmacies.

6. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

Enforcement of the regulation will be performed during annual inspections of all pharmacies. There will be no additional cost incurred by the board.

7. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH THE PROPOSED REGULATION OVERLAPS OR DUPLICATES AND A STATEMENT EXPLAINING WHY THE DUPLICATION OR OVERLAPPING IS NECESSARY. IF THE REGULATION OVERLAPS OR DUPLICATES A FEDERAL REGULATION, THE NAME OF THE REGULATING FEDERAL AGENCY.

The Board of Pharmacy is not aware of any similar regulations of other state or government agencies that the proposed regulation overlaps or duplicates.

8. IF THE REGULATION INCLUDES PROVISIONS WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISIONS.

The Board of Pharmacy is not aware of any similar regulations of the same activity in which the federal regulation is more stringent.

9. IF THE REGULATION PROVIDES A NEW FEE OR INCREASES AN EXISTING FEE, THE TOTAL ANNUAL AMOUNT THE AGENCY EXPECTS TO COLLECT AND THE MANNER IN WHICH THE MONEY WILL BE USED.

This regulation does not provide a new or increase of fees.