503B Outsourcing Facility Inspection

	Code Section	Question
1	40-43-83(F) & 40-43-86(C)(1)	Permit displayed (F) Permits issued under this section must be displayed in a conspicuous place in the permitted facility for which it was issued in such a manner that will enable an interested person to determine the name of the permittee, permit number, and permit expiration date. The permits are not transferable.
2	Regulation 99-15	Pharmacists Annual Renewal Certificate Displayed 99–15. Display of Annual Renewal Certificate. Any person who is a licensed pharmacist and who has charge of or is employed in a pharmacy or other permitted facility within this State shall display his annual renewal certificate in a conspicuous place in the primary pharmacy or other permitted facility of which he is in charge or in which he is employed, so that the annual renewal certificate is easily and readily observable by the public.
3	40-43-82(A)(3)	Technician Registration Displayed (3) A pharmacy technician shall display his or her current registration in a conspicuous place in the primary pharmacy or drug outlet in which the technician is employed, so that the current registration is easily and readily observable by the public. A technician working in a pharmacy or drug outlet where the technician's registration is not posted must have his or her wallet registration card with him or her.
4	40-43-84(B)	Intern Certificate Displayed (B) An intern/extern may not represent himself as a pharmacist. The board shall issue to an intern/extern a certificate for purposes of identification and verification of his role as an intern/extern. The internship certificate must be displayed in the pharmacy or site in which the experience is being gained. No individual who has not been issued a certificate by the board as an intern/extern shall take, use, or exhibit the title of intern/extern, or any other term of similar like or import.
5	40-43-86(A)(1)	Sufficient space for safe & proper storage (A)(1) be of sufficient size to allow for the safe and proper storage of prescription drugs and for the safe and proper compounding and preparation of prescription drug orders;
6	40-43-86(A)(1)	Sufficient space for safe & proper compounding (A)(1) be of sufficient size to allow for the safe and proper storage of prescription drugs and for the safe and proper compounding and preparation of prescription drug orders;
7	40-43-86 (A) (11)	Sink with hot and cold running water (11) have access to a sink with hot and cold running water that is in the compounding area;
8	40-43-86 (A) (12)	Pharmacist responsible for security of facility (12) have a pharmacist who, while on duty, is responsible for the security of the pharmacy department including provision of effective control against theft or diversion of drugs or devices, or both;
9	40-43-86 (A) (15)	Equipment and supplies maintained according to manufacturer’s specifications (15) carry, utilize, and maintain according to manufacturer's specifications the equipment and supplies necessary to conduct a pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws;
10	40-43-86(A)(16)	Area clean and orderly and free from contamination; free from dust, insects, rodents, etc (16) maintain the area and equipment in which prescriptions are compounded and dispensed in a clean and orderly condition and
11	40-43-88(F)	Standard operating procedures which address the operations of the sterile compounding process present, updated, and in use; includes training process (F) Policies and procedures must be developed and implemented for the pharmacy. These policies and procedures must include the following as applicable:
12	40-43-88(B)(c)	Facility design, equipment and devices are appropriate for risk level of CSP’s prepared by the facility.
13	40-43-88(D)(7)	An appropriate facility-specific environmental sampling procedure must be documented and followed for airborne viable articles based on a risk level assessment of compounding activities performed.

14	40-43-88(D)	Clean room and hood certified every 6 months and when relocated
15	40-43-88(D)	Environmental air sampling conducted every 6 months
16	40-43-88 (D) (5)	Documentation of pre-filter changes
17	40-43-86 (CC) (5)	Equipment used in compounding is routinely inspected & calibrated
18	40-43-88 (E)	Hazardous medications compounded in appropriate area
19	40-43-88 (C) (10)	Logs maintained for proper temperature and humidity range of storage areas (pharmacy, refrigerator, freezer and compounding area)
20	40-43-88 (F) (3)	Logs maintained for cleaning and disinfecting (3) cleaning and disinfecting of the sterile compounding areas and devices with supporting documentation;
21	40-43-88 (D) (6)	Logs for pressure differential maintained if applicable
22	40-43-86 (CC) (3)	Training and/or continuing education in compounding is documented; visual observation to confirm necessary skills (ie hand hygiene, garbing, aseptic technique, cleaning, and disinfecting)
23	40-43-88 (E) (8)	Training in hazardous materials handling and precautions is documented
24	40-43-88 (F)(1)	Personnel uses appropriate outer and over-wear (gowning, gloving etc) (F) Policies and procedures must be developed and implemented for the pharmacy. These policies and procedures must include the following as applicable (1) annual training and evaluation of sterile compounding personnel to include skills observation of antiseptic hand cleansing, other personnel cleansing, media-fill challenge, glove fingertip testing, cleaning of compounding environment, donning protective garb, maintaining or achieving sterility of CSPs;
25	40-43-88 (D) (1)	Aseptic manipulations are properly executed; training documented prior to compounding
26	40-43-88 (B)	BUD's are assigned according to Risk Level of CSP or as verified by sterility test or process validation
27	40-43-88 (I)	Preparations labeled properly
28	40-43-88 (F) (1)	Annual training and evaluation of sterile compounding personnel (1) annual training and evaluation of sterile compounding personnel to include skills observation of antiseptic hand cleansing, other personnel cleansing, media-fill challenge, glove fingertip testing, cleaning of compounding environment, donning protective garb, maintaining or achieving sterility of CSPs;
29	40-43-88 (F) (2)	Semi-annual media fill test for all compounding personnel (2) semiannual media-fill test representative of high-risk compounding must be performed by all personnel authorized to prepare high-risk CSPs;
30	40-43-88 (F) (3)	Appropriate documentation of cleaning & disinfecting (3) cleaning and disinfecting of the sterile compounding areas and devices with supporting documentation;
31	40-43-88 (F) (4)	Process to ensure identity, quality & purity of ingredients 4) ensuring identity, quality, and purity of ingredients;
32	40-43-88 (F) (5)	Sterilization methods for CSP's 5) sterilization methods for high-risk CSPs;
33	40-43-88 (F) (6)	Establishments of appropriate storage requirements and BUD's (6) establishment of appropriate storage requirements and BUDs;
34	40-43-88 (F) (7)	Measuring, mixing, dilution, purification, packaging and labeling 7) measuring, mixing, dilution, purification, packaging, and labeling;
35	40-43-88 (F) (8)	Unpacking & introducing supplies into sterile compounding environment (8) unpackaging and introducing supplies into the sterile compounding environment;
36	40-43-88 (F)(9)	Compounding activities that require the manipulation & disposal of hazardous material (9) compounding activities that require the manipulation and disposal of a hazardous material;
37	40-43-88 (F) (10)	Expiration dating of single dose and multiple dose containers (10) expiration dating of single-dose and multiple-dose containers;
38	40-43-88 (F) (11)	Quality Control & Quality Assurance of CSP processes (11) quality control and quality assurance of CSP processes;
39	40-43-88 (F) (14)	Written Procedures for required equipment calibration, maintenance, monitoring for proper function within specific time frames (14) written procedures outlining required equipment calibration, maintenance, monitoring for proper function, and controlled procedures for use of the equipment and specified time frames for these activities must be established and followed. Results from the equipment calibration, semiannual certification reports, and routine maintenance must be kept on file for two years;

40	40-43-88 (J)	Bulk or unformulated drug substances and added substances or excipients stored properly and labeled J) Bulk or unformulated drug substances and added substances or excipients must be stored in tightly closed containers under temperature, humidity, and lighting conditions that are either indicated in official monographs or approved by suppliers. The date of receipt by the compounding facility must be clearly and indelibly marked on each package of ingredients. After receipt by the compounding facility, packages of ingredients that lack a supplier's expiration date cannot be used after one year unless either appropriate inspection or testing indicates that the ingredient has retained its purity and quality for use in CSPs.
41	40-43-88(F)(11)	Quality control has authority and responsibility to approve or reject all components, drug product containers or closures, end process materials, labeling and drug products (11) quality control and quality assurance of CSP processes;
42	40-43-88(F)	All written quality procedures are current and approved (F) Policies and procedures must be developed and implemented for the pharmacy. These policies and procedures must include the following as applicable
43	40-43-88(F)	Quality Control follows their procedures (F) Policies and procedures must be developed and implemented for the pharmacy. These policies and procedures must include the following as applicable
44	40-43-88(C)(10)	The control of air pressure, dust, humidity and temperature is adequate for the manufacturing, processing, storage (10) Maintain areas at temperatures and humidity levels to ensure the integrity of the drugs prior to their dispensing as stipulated by the USP/NF or the labeling of the manufacturer or distributor, or both.
45	40-43-88(F)(1) 40-43-88(B)(2)(d) 40-43-86(CC)(9)	The facility has written procedures that describe in sufficient detail the cleaning schedule, methods, equipment, training, and material 88(F)(1) annual training and evaluation of sterile compounding personnel to include skills observation of antiseptic hand cleansing, other personnel cleansing, media-fill challenge, glove fingertip testing, cleaning of compounding environment, donning protective garb, maintaining or achieving sterility of CSPs; 88(B)(2)(d) The specifications for cleaning and disinfecting the sterile compounding area, personnel training and responsibilities, aseptic procedures, and air sampling must be followed as described in subsection (F). 86(CC)(9) All significant procedures performed in the compounding area must be covered in written policies and procedures. These procedures must be developed for the facility, equipment, personnel, preparation, packaging, and storage of compounded preparations and ingredients to ensure accountability, accuracy, quality, safety, and uniformity in compounding as appropriate for the level of compounding performed at the facility.
46	40-43-88(F)(c)	Facility has documentation of equipment calibration, maintenance, cleaning
47	40-43-88(D)(7)(d)	Adverse changes in the environment are investigated and promptly remediated (d) Corrective actions must be taken when CFU counts for each ISO classification are exceeded, or when microorganisms are identified that are potentially harmful to patients receiving CSPs.
48	40-43-88(D)(6)	Air pressure differentials are continuously monitored and demonstrate that a cascading pressure differential is maintained throughout the compounding area during production of sterile compounding (6) A pressure gauge or velocity meter must be installed to monitor the pressure differential or airflow between the buffer area and the ante area and between the ante area and the general environment outside the compounding area.
49	40-43-86(CC)(2)(d)	Facility ensures API's are manufactured in registered FDA facilities where possible (d) A compounder shall first attempt to use components manufactured in an FDA-registered facility. When components cannot be obtained from an FDA-registered facility, a compounder shall use his professional judgment in selecting an acceptable and reliable source and shall establish purity and safety by reasonable means, to include Certificate of Analysis, manufacturer reputation, and reliability of source.
50	40-43-86(CC)(6)(b)	Written procedures include documentation of correct weight or measure and proper identification of container (b) The pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate at each stage of the compounding procedure to conform to the formula being prepared. Any chemical transferred to a container from the original container must be labeled with the same information as on the original container and the date of transfer placed on the label.
51	40-43-88(F)(8)	Policies and procedures are developed and implemented regarding unpackaging and introducing
		supplies into the sterile compounding environment (8) unpackaging and introducing supplies into the sterile compounding environment
52	40-43-86(CC)(6)(a) 40-43-86(I)(1)(b)	All components are identified on batch records and traceable to the finished product. Facility maintains complete batch records for all compounded sterile products 86(CC)(6)(a) The pharmacist shall ensure that there are formulas and logs maintained either electronically or manually. Formulas must be comprehensive and include ingredients, amounts, methodology, and equipment, if needed, and special information regarding sterile compounding. 86(I)(1)(b) A log book must be maintained identifying the repackager, the name of the drug, the lot number, the manufacturer, the facility control number, the expiration date, the quantity, and the initials of the pharmacist.
53	40-43-88(F)(6)	Written procedures indicate how and who verifies that correct containers and packages are used for the finished product. (6) establishment of appropriate storage requirements and BUDs;
54	40-43-86(CC)(7)(c)	Written procedures require that the representative samples of units be visually examined upon completion of packaging to verify correct labeling (c) At the completion of compounding the prescription, the pharmacist shall examine the prescription for correct labeling.