2013 USP <797> Compliance Study

2013 Overall Compliance by Items with Compliance Less than 60%	%
Since your compounding location uses a filter in compounding to sterilize solutions, is it the policy to routinely follow its use with a filter integrity test (bubble point test)? *(only asked of those who said they use a 0.22 micron filter to sterilize solutions)*	26.9%
You have indicated that your compounding location's isolators are not placed inside ISO Class 7 buffer areas and they do not meet the exclusion criteria outline in Chapter <797>, so is the compounding that occurs within those isolators limited to nonhazardous and radiopharmaceutical CSPs that are given a 12 hour or less BUD?	33.3%
There is written confirmation (example below) by each compounding employee of reproductive age (male or female) that they understand the risk of handling hazardous CSPs.	34.9%
All compounding personnel (including supervising pharmacists) successfully complete at least 3 gloved fingertip/thumb sampling procedures (success is 0 CFUs) all of which are documented before initially being allowed to compound CSPs.	41.5%
The effectiveness of dry heat depyrogenation is verified using endotoxin challenge vials (ECVs) to verify that the cycle was capable of achieving a 3-log reduction in endotoxins.	45.2%
Cleaning materials that are reused (mop handles, mop heads, etc.) are labeled according to their location of use AND policies and procedures have been developed regarding maintenance of the reusable items so that repeated use does not increase the bioburden of the controlled environments.	45.5%
The sink in the ante-area is equipped with hands-free controls for water and soap dispensing.	47.1%
There is detailed written policy and procedure on all aspects of surface sampling and viable air sampling which includes preparation of plates, labeling of plates according to the Environmental Sampling Plan, reading plates; documentation of results as well as procedure for sending them to contracted lab (in the event that is applicable).	48.2%
This compounding location conducts sterility testing.	48.4%
The organization stores hazardous CSPs in a negative pressure room such as the hazardous drug compounding room.	51.1%
The hazardous drug compounding buffer area has been certified to have at least 30 air changes per hour (ACPH) from the HEPA filtered air supplied to the room.	52.8%
Surface sampling occurs regularly and the frequency, location and action levels of surface sampling are detailed within the Environmental Sampling Plan and written policies and procedures.	52.9%
The organization employs two tiers of containment (e.g., closed system transfer device (CSTD)) within a BSC or CACI. (asked if they said they perform HD compounding in an area that is not separate and dedicated to HD compounding).	53.2%
Surface sampling is performed at the conclusion of compounding (before the area is disinfected with an appropriate disinfectant).	53.4%
Does the compounding location have a written procedure requiring daily observation of the incubating sterility test specimens and a procedure for immediate recall of the dispensed CSPs in the event of any evidence of microbial growth in the test specimens? *(asked of those who said they may release CSPs before final sterility test results)*	53.7%
Is viable and non viable environmental sampling performed in ISO Class 5 compounding environments located outside of ISO Class 7/8 buffer areas?	54.5%
The Environmental Sampling Plan includes all of the following: sample locations, method of collection, frequency of sampling, volume of air sampled (for viable air sampling), time of day in relation to compounding and action levels.	55.2%
Has your certifier verified that an airflow velocity of at least 40 feet per minute is maintained across the line of demarcation? *(for those with open architecture design)*	55.4%
The specific procedure for bacterial endotoxin testing includes the description of the procedure and specific endotoxin unit limits based on USP Endotoxin Test is included in the compounding location's written policies and procedures.	55.4%

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2013 Overall Compliance by Items with Compliance Less than 60%	%
All compounding staff (and supervising pharmacists) perform ongoing Gloved Fingertip/Thumb Sampling of both hands at least annually at the time of their employee media fill testing. *(asked of those who do not perform high risk compounding)*	55.5%
The Quality Assurance/Performance Improvement Program includes specific monitoring and evaluation activities; details on how results are reported; and delineation of the persons responsible.	56.0%
At your organization, if CSPs compounded outside an ISO Class 5 environment are not used immediately by the person who prepared them, then they are labeled and that labeling includes all of the following elements: identifier information; names and amounts of the ingredients; name or initials of the person who prepared the drug and the exact 1 hour beyond use date and time.	56.0%
Personnel who perform cleaning receive training in and successfully pass initial and ongoing competency assessments.	56.9%
During the initial gloved fingertip/thumb sampling (that which occurs during and is part of the initial hand hygiene and gowning competency assessment), fingertip/thumb samples are taken of both gloved hands onto media plates immediately after compounders perform hand hygiene and garbing but before their gloves are cleaned with sterile 70% IPA.	57.0%
All compounding staff (and supervising pharmacists) perform ongoing Gloved Fingertip/Thumb Sampling of both hands at least semi-annually at the time of their employee media fill testing. *(asked of those who perform high risk compounding)*	57.3%
Employees who handle, dispose or compound hazardous CSPs successfully complete a Hazardous CSPs Competency Assessment (example below) prior to working with hazardous CSPs and annually thereafter.	57.9%
There is a current written Environmental Sampling Plan which documents where viable air sampling and surface sampling occurs within the controlled environments.	58.0%
A line of demarcation in the ante-area or segregated compounding area separates the dirty area from the clean area.	58.1%
The storage area for hazardous CSPs has exhaust ventilation of at least 12 ACPH to dilute and remove potential airborne contaminants.	58.1%
There is evidence that mechanisms exist to report excursions, repair defects, and document actions taken as a result of any out of limit pressure/airflow condition until resolution.	58.4%
There is evidence of a logical plan of actions to be taken in the event that results of viable air or surface sampling exceed established Action Levels which includes: examination of samples by an accredited laboratory, speciation of growth results and re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, as well as air filtration efficiency until resolution of the problem is found.	59.1%
A plate (size 24-30 cm^2) containing tryptic soy agar medium with polysorbate and lecithin added to neutralize cleaning agents (TSApl) is used to collect and incubate each surface regardless of whether the method of sampling is by plate or swab.	59.2%