2013 USP <797> Compliance Study

2013 Hospital Compliance: Items less than 50% compliance	2013
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.	0.0%
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 to those who said they use a filter to sterilize solutions)*	15.5%
The effectiveness of dry heat sterilization is verified using appropriate Biologic Indicators.	28.6%
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.	31.2%
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 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%
The specific procedure for depyrogenation by dry heat including a description of the cycle and duration of specific load items is included in the compounding location's written policy and procedure.	33.3%
This compounding location conducts sterility testing. *(only asked of those who must perform sterility testing based on answer to question 9 any combination of a, b, and/or c)*	33.6%
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)	35.0%
Does the compounding location have a written procedure requiring notification of the physician and patient to whom a potentially contaminated CSP was administered?	35.9%
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 indicated that they perform high risk compounding)*	36.8%
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.	37.7%
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.	40.0%
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. *(asked only of those required to perform such)*	41.7%
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.	42.8%
The specific procedure for dry heat sterilization includes conditions and durations for specific CSP types is included in the compounding location's written policies and procedures. *(asked only of those who indicated they use dry heat sterilization)*	42.9%
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).	44.8%
The compounding location performs bacterial endotoxin (pyrogen) testing on all high risk level CSPs, (except those for inhalation and ophthalmic administration) that have been prepared: in groups >25 identical single dose packages or in MDVs for administration to multiple patients that have been exposed longer than 12 hours to 2-8 degrees Celsius and longer than 6 hours to warmer than 8 degrees Celsius before they are sterilized. *(only asked of those who indicated they perform this type of compounding)*	45.8%
The sink in the ante-area is equipped with hands-free controls for water and soap dispensing.	46.4%
Does the compounding location have a policy that specifies actions to be taken in the event of a positive sterility test which may include rapid and systematic investigation of aseptic technique as well as environmental control and other sterility assurance controls to identify potential sources of contamination and correct problems in processes or methods?	48.7%
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.	49.1%