<table>
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<tr>
<th>QA</th>
<th>CONTROLS</th>
<th>FREQUENCY</th>
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| FACILITIES | Verification of compounding area for Level A requirements (clean, orderly, good state of repair, appropriate storage, space reserved for compounding) | • At least every 6 months  
• When the compounding area is installed  
• When new equipment is installed  
• When area or equipment are repaired or maintained  
• When a contamination problem is identified |
| | Verification of compounding rooms for Level B or Level C requirements (appropriate ventilation, suitable materials storage, clean, orderly, good state of repair) | • At least every 6 months (more frequently at the start of the quality assurance program)  
• When the controlled room is installed  
• When new equipment is installed  
• When the controlled room or equipment is repaired or maintained (e.g., when HEPA filter is changed)  
• When a contamination problem is identified  
• When investigation of a contamination problem or non-compliance in the preparation process requires exclusion of malfunctioning facilities  
• According to an internal verification program |
| | Verification that daily temperature and humidity readings are documented in controlled areas | • Monthly |
| EQUIPMENT | Certification of C-PEC (Level B or Level C requirements) | • Before first use  
• Every 6 months  
• When a new C-PEC is installed  
• When the C-PEC is repaired or maintained  
• When a contamination problem is identified  
• When investigation of a contamination problem or non-compliance in the preparation process requires exclusion of malfunctioning equipment |
| | Temperature verification (e.g., refrigerator, freezer) | • Verify logs monthly (more often if problems are identified)  
• Calibrate temperature probes yearly |
| | Operational indicators of C-PEC and other instruments (e.g., for automated compounding) | • Verify logs monthly |
| PERSONNEL | Skills assessment (technique, following procedures, appropriate PPE, etc.) | • At initial qualification: theoretical and practical aspects  
• Periodically, to ensure compliance with policies and procedures  
• After extended leave  
• When assessing incidents and accidents  
• When a contamination problem is identified |
| FINAL PREPARATION | Verification of Master Formulation Records (usage and maintenance) | • Yearly or when new information becomes available |
| | Verification that preparation matches prescription; protocols have been followed; ingredients have been verified; preparation has been assessed for clarity, odour, colour and consistency; and labelling/container are appropriate | • Quarterly review of documentation |
| | Verification that documentation of procedures, compounder’s initials and entry in logs are being carried out | • Quarterly review of documentation |
| DOCUMENTATION | Policies and procedures are in place and updated regularly | • Every 3 years, or when new information becomes available |
| | Compounding records meet all regulatory requirements, and all logs are kept up to date | • Quarterly |
| | Current references and safety data sheets are available | • Yearly |

HEPA = High efficiency particulate air; C-PEC = containment primary engineering control; PPE = personal protective equipment.