Table 6

QA	CONTROLS	FREQUENCY
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.