

POLICY STATEMENT(S):

1. Technical functions as specified in the Hospital Pharmacy Standards of Practice, section 10 may be delegated to pharmacy assistants in accordance with the *Hospital Pharmacy Standards of Practice*.
2. The pharmacist may delegate the function of verifying sterile products to a pharmacy assistant under the following conditions:
 - the pharmacist is responsible for ensuring that the verification procedure has the sensitivity and accuracy to detect all possible errors.
 - the pharmacy must have established written policies and procedures for all aspects of the verification of sterile products, including quality assurance procedures and checks, procedures if an error occurs, and documentation records.
3. A pharmacy assistant may verify either the medication contents of patient specific compounded sterile products against a label or pick-list (e.g. refills) or the medication contents of a compounded sterile batch products against an approved written procedure or compounding record. A pharmacy assistant may only verify another assistant's preparation of compounded sterile products.
4. The pharmacist at the telepharmacy central site may delegate the function of verifying patient specific compound sterile products against a label or pick-list (eg. refills) or the medication contents of a compounded sterile batch products against an approved written procedure or compounding record to a pharmacy assistant certified to verify compounded sterile products. A hospital policy and procedure for all aspects of the sterile product verification process must be established. The policy must include quality assurance procedures and checks, procedures if an error occurs and copies of all documentation.
5. The verification process may occur between central/remote sites or between remote/remote sites.
6. A pharmacy assistant may not verify his or her own work.

Prior to verifying sterile products, the pharmacy assistant must be trained and certified in the delegated function.

Qualifications

7. In order to verify compounded sterile products, a pharmacy assistant must:
 - be a graduate of a recognized pharmacy technician training course prior to January 2011* or have an equivalent of two years experience in a hospital pharmacy setting, and
 - work sufficient hours to maintain competence in the function, as determined by the hospital pharmacy manager, and
 - be trained in aseptic technique and qualified to prepare sterile products, and
 - complete a standard departmental training program on verifying compounded sterile products, and
 - demonstrate, on an ongoing basis, a commitment to exemplary accuracy in verifying compounded sterile products, as determined by the hospital pharmacy manager.

Training

8. A pharmacist or pharmacy technician with relevant expertise must ensure that the required knowledge and skills are appropriately taught. The required knowledge and skills may be acquired through a combination of educational modules, inservice programs and work experience with the opportunity for repeated practice of the skills under supervision. Work experience must be at the site where the verifying will be done but didactic educational programs or inservices may be conducted either in-house or at another hospital pharmacy.

Initial Certification

9. Pharmacy assistants must be trained and assessed prior to becoming certified to verify compounded sterile products. The supervising pharmacist or pharmacy technician may grant certification if the assistant achieves an accuracy rate of 100%***. (See Appendix A).

Quality Control

10. The certified assistant must maintain an accuracy rate of 100%.
 - (a) If an error occurs during the day-to-day checking activities, the institution must have written procedures to address this situation.
 - (b) The accuracy of all pharmacy assistants who verify medication containers must be audited at least annually and if possible conducted without the assistant's knowledge. The results of the audit must be discussed with the audited assistant. An assistant who is certified to verify both non-sterile and sterile products may be audited on a balanced combination of the two types of products to achieve the audit quantity.

Decertification

11. If the accuracy rate of a verifying assistant falls below the established standard, a minimum of 2 re-audits will be performed shortly after the first failed audit. If the pharmacy assistant fails to meet the minimum standard on any re-audit, s/he must be decertified and removed from the verifying function.
12. The pharmacy manager or supervisory pharmacist or pharmacy technician for the area may decertify an assistant at any time if there is any reason to believe that the assistant is not capable of safely carrying out the delegated function. The assistant may be recertified only if the problem is resolved to the satisfaction of the pharmacy manager.
13. A decertified checker must reenter and complete the training and certification process prior to being reassigned to verify compounded sterile products.

Documentation

14. A log or record showing the training, certification and quality assurance for each pharmacy assistant who verifies compounded sterile products must be maintained. The identification of the pharmacy assistant or any other person who prepares or compounds sterile products must be documented. This record must be retained for at least three years.

Continuous Quality Improvement

15. An ongoing process of continuous quality improvement must be implemented to prevent or eliminate system errors. Documentation of the continuous quality improvement process must be retained for at least three years.

BACKGROUND:

The expected outcome of every sterile preparation and distribution system is that 100% of the parenteral medication doses will be correct when administered to the patient. Recognizing that "human failure" may create errors in any segment of the process, the processes of compounding and labelling sterile products must be designed with numerous checks to identify and remove potential errors prior to dispensing. Errors and other potential problems must be constantly identified and eliminated through a process of continuous quality improvement (CQI).

Compounding and labelling sterile products involves both technical functions and cognitive or professional functions.

Examples of professional functions, which may **not** be delegated to a pharmacy assistant, are:

- checking the accuracy of a transcription of a written medication order into the computer,
- checking a new medication order against the patient medication profile for therapeutic appropriateness,
- approving the stability or compatibility information or calculations for a new product or formula.

Examples of technical functions, which may be delegated to a pharmacy assistant, are**:

- verifying diluents and volumes of reconstituted sterile medications according to an approved procedure,
- verifying the label and content of a compounded sterile product prepared in a batch,
- verifying the medication container contents against a patient-specific label or fill list.

** Prior to 2011 some training programs graduated "pharmacy technicians" whereas they are now graduating "pharmacy assistants" until the programs have been accredited by the Canadian Council for Accreditation of Pharmacy Programs.*

***These functions relate to Role 2: Produce and Distribute Drug Preparations and Products, and Role 3: Contribute to the Effective Operation of the Pharmacy from the Framework of Professional Practice (April 2003).*

**** This document is meant as a guide to institutions to enable them to establish a tech-check program to meet their specific needs. Each institution should set certification and audit numbers that will reflect a measurement that is logistically feasible to ensure a level of acceptable performance and is reflective of all order types.*

Patient-Specific Sterile Products

Patient-specific sterile products generally consist of a 24-hour supply of individually labelled compounded or purchased sterile product. These sterile products are labelled according to a refill or pick list or from labels generated from the patients' computerized medication profiles.

Verification of the individual sterile product units against a label or list will include a check to ensure correct:

- patient name,
- patient location,
- medication,
- amount added,
- solution and volume,
- dosage form,
- number of doses or units,
- ingredients are within expiry dates,
- compounded sterile product expiry date,
- auxiliary label(s), if applicable,
- integrity of the final product.

Compounded Sterile Product Batches

Compounded sterile products are usually prepared in non-patient specific batches, in anticipation of individual patient medication orders. Each batch must be documented with a compounding worksheet or record.

Verification of compounded sterile product batches against the compounding record will include a check to ensure correct:

- medication,
- amount added,
- solution and volume,
- admixture devices,
- number of units,
- ingredient expiry dates and lot numbers documented,
- compounding expiry date and lot number for the batch,
- labelling,
- integrity of the final product.