Chapter 31

Policies, Procedures, and Quality Assurance Programs

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Introduction

The ASHP Minimum Standard for Pharmacies in Hospitals states, "The pharmacy shall be responsible for the procurement, distribution, and control of all drug products used in the hospital for inpatient and ambulatory patients. Policies and procedures governing these functions shall be developed by the pharmacy with input from other appropriate hospital staff and committees."[1]

Writing Policies and Procedures

Tomich and Dydek define policies and procedures:

> Policies are written statements that provide guidance on the position and values of an organization. They are often considered broad operational guidelines, but they should clearly define the direction and activities of an organization or department. Procedures are written instructions that describe the recommended methods of sequential steps to follow to perform a task or activity. In short, procedures help define the process for completing a task.[2]

In compounding most sterile preparations, final sterility and accuracy testing is not possible. Thus, having robust policies and procedures and consistent work practices is mandatory and compounders must use them correctly each time for consistency and uniformity of compounded sterile preparations (CSPs).

Policies and procedures should be organized (e.g., numbered under headings) so that they are easy for employees to find. Policies and procedures can be available either in written form or electronically stored but in printable documentation. Policies and procedures have numerous benefits[2]:

- Inter- and intra-departmental communication

Note: The author acknowledges E. Clyde Buchanan who authored this chapter in the previous edition.

- Creation of standards of care
- Mechanism to document standards of care and other important activities
- Enhancement of staff orientation and training
- Ability to systematically, objectively, and efficiently measure staff and departmental performance
- Promotion of patient safety practices
- Consistency with state regulations
- Quality improvement processes
- Cost-effective use of resources
- Effective administrative tool for planning, developing, and improving pharmacy services and patient care
- The comprehensive source of information about departmental operations

Policies and procedures, also known as standard operating procedures (SOPs), should be available to all involved personnel. SOPs should be drafted by or in cooperation with personnel who are actually doing compounding processes. SOPs should be updated at least annually, by the sterile compounding supervisor and department head, to reflect current standards of practice. Revisions of policies and procedures should be communicated to affected personnel.

Tomich and Dydek describe the format and style for writing policies and procedures. Although many policy and procedure formats have been described, most policy and procedure manuals have the following headings in their format[2-4]:

- Policy title
- Policy number
- Policy statement
- Purpose of the policy
- References for the policy
- Applicability to work areas or personnel types
- Use of definitions, terms, acronyms, words, or abbreviations
- Responsibilities of personnel involved with the procedure
- Procedure

Appendix 31-A shows an example of a typical policy and procedure as to format, style, and content.

All significant procedures performed in the compounding areas must be covered by SOPs and must have records or documentation. Procedures should be developed for the facility, equipment, personnel, preparation, labeling, packaging, and storage of compounded preparations to ensure accountability, accuracy, quality, safety and uniformity in compounding practice. Documentation should enable the compounding supervisor, whenever necessary, systematically to trace, evaluate, and replicate the steps included throughout the process of compounding a sterile preparation.

Job Descriptions

Complete job descriptions for personnel compounding sterile preparations are essential to hiring and orientation and are often included in policy and procedure manuals. Job descriptions should include the following:

- Basic qualifications (e.g., education level, certification, registration, and length and type of experience)
- Physical requirements (e.g., ability to lift moderately heavy weights, push carts, and perform rapid, repetitive, and accurate manipulations)
- Working conditions (e.g., shifts, environment, hazards, and attire)
- Responsibilities and competencies (e.g., ability to compound a pharmaceutical preparation that is free of errors in content and free of microbial, particulate, and pyrogenic contaminants)

Responsibility of Compounding Personnel

This chapter notes the topics pertinent to compounding sterile preparations that should be covered in a policy and procedure manual. The same topics are presented in detail throughout this book and the appendices. According to USP Chapter <797> Pharmaceutical Compounding—Sterile Preparations and USP Chapter <800> Hazardous Drugs—Handling in Healthcare