

Meeting

Accreditation Standards

A PHARMACY PREPARATION GUIDE

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Dedication

To Susan, Ella, Luke, Mason, and Olivia

To Kurt

To Jean and Herbert Brown

Contents

Acknowledgments	vii
Editors	viii
Contributors	ix
Preface	x
Chapter 1 Centers for Medicare & Medicaid Services	1
<i>Kurt A. Patton, MS, RPh</i>	
Chapter 2 The Joint Commission	45
Chapter 3 National Integrated Accreditation for Healthcare Organizations Surveys	61
<i>Cynthia Williams, BS Pharm, FASHP</i>	
Chapter 4 Healthcare Facilities Accreditation Program Surveys	73
Chapter 5 Center for Improvement in Healthcare Quality Surveys	89
Chapter 6 Achieving Continuous Compliance	107
<i>Amanda J. Hays, PharmD, MHA, BCPS, CPHQ</i>	
Chapter 7 Documents Checklist	113
Chapter 8 Medication Management Standards Checklist	157
Chapter 9 National Patient Safety Goals Checklist	221
<i>Natasha C. Nicol, PharmD, FASHP</i>	
Chapter 10 Infection Prevention and Control Checklist	253
Chapter 11 Environment of Care Checklist	269
Chapter 12 Human Resources Standards Checklist	297
Chapter 13 <i>United States Pharmacopeia (USP) Compounding Standards: Chapters <795>, <797>, <800>, and <825></i>	313
Chapter 14 Medication Management System Tracers	327
<i>Dima Awad, PharmD, MS</i>	
Chapter 15 Pharmacy and Therapeutics Activities	341
<i>Dustin D. Spencer, PharmD, MBA, BCPS, BCCP</i>	
Chapter 16 Medication Safety Improvement	349
<i>Natasha C. Nicol, PharmD, FASHP</i>	
Chapter 17 Pain Management	373
<i>Nisha P. Singh, PharmD, BCOP</i>	
Chapter 18 Antimicrobial Stewardship	381
<i>Katherine M. Shea, PharmD, BCIDP</i>	
Chapter 19 Quality and Performance Measures	393
<i>Iris Young, PharmD, CPHRM, CPHQ</i>	
Appendix A Resources	401
Appendix B Example Forms	405
<i>Robert C. Jordin, RPh</i>	
Example 6-1 Suggested Activity Frequency Chart	406
Example 7-1 Policy and Procedure for Nonformulary Medication Requests	407

Example 7-2	Verification of Licensure/Registration/Certification for Pharmacy Personnel	408
Example 7-3	Power of Attorney for DEA Form 222 and Electronic Orders	409
Example 7-4	Medical Staff Information Record.....	410
Example 8-1	Confidentiality of Patient Information Agreement.....	411
Example 8-2	Formulary Addition Request Form	412
Example 8-3	Nonformulary Medication Request Form	414
Example 8-4	Nonformulary Medication Summary.....	415
Example 8-5	Notification of Shortage and Outage.....	416
Example 8-6	Refrigerator/Freezer/Warmer Monthly Temperature Log	417
Example 8-7	Monthly Refrigerator Temperature Graph Log	418
Example 8-8	Monthly Freezer Temperature Graph Log	419
Example 8-9	Controlled Substances Inventory Cover Page.....	420
Example 8-10	Controlled Substances Biennial Inventory Record.....	421
Example 8-11	Registrant Record of Controlled Substances Destroyed	422
Example 8-12	Medication Sample Receiving and Dispensing Log	424
Example 8-13	Medication Prepackaging Log.....	425
Example 8-14	Medication Area Inspection	426
Example 8-15	Medication Area Inspection—Clinics	427
Example 8-16	Inspection Assignment Grid.....	428
Example 8-17	Emergency Medication Container Inspection Record.....	429
Example 8-18	Patient’s Personal Medications Storage Record	430
Example 8-19	Receipt and Disposal of Patients’ Personal Medications Record	431
Example 8-20	Intervention Log.....	432
Example 8-21	Pharmacy Competence Checklist and After-Hours Medication Retrieval	433
Example 8-22	Individuals Authorized to Remove Medications from After-Hours Stock	435
Example 8-23	After-Hours Pharmacy Log	436
Example 8-24	Recalled Medication Record.....	437
Example 8-25	Medication Error Report.....	438
Example 8-26	Adverse Drug Reaction Report.....	440
Example 8-27	Notice of Drug Reaction Form	442
Example 8-28	Adverse Drug Reaction Summary	443
Example 8-29	Adverse Drug Reaction Rates/Monthly Adverse Drug Reaction Summary	444
Example 10-1	Laminar Airflow Workbench Cleaning Record	445
Example 12-1	Orientation Record	447
Example 12-2	Education Program/Meeting Record.....	450
Example 12-3	Pharmacy Education and Training Program Record	451
Example 12-4	Continuing Education Record.....	452
Example 12-5	Skills Test for Pediatric and Adolescent Patients	453
Example 12-6	Skills Demonstration Checklist for Pediatric and Adolescent Patients	456

Example 12-7	Sample Job Description and Competence Assessment for Staff Pharmacists.....	457
Example 15-1	Example of Pharmacy and Therapeutics Committee Minutes.....	465
Index	467

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Editors

The editors have helped hundreds of health-system pharmacies comply with accreditation and other standards. This book reflects their experiences in guiding pharmacies through more than 3,000 accreditation, certification, and other surveys since 1980.

Authors

The contributing authors are actively involved in helping health-system pharmacies incorporate The Joint Commission and other standards into their everyday practice. They participated in the planning, writing, review, and critique of this book, and their contributions, experiences, and suggestions are reflected in every chapter.

Cardinal Health Innovative Delivery Solutions Pharmacists

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ASHP

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Preface

There have been a number of changes in the accreditation process since the eighth edition of *Assuring Continuous Compliance with Joint Commission Standards: A Pharmacy Guide* was published in 2010. There are currently four accrediting organizations that the Centers for Medicare & Medicaid Services (CMS) recognize to have deemed status for their standards: The Joint Commission, Det Norske Veritas (DNV-GL) Healthcare, Healthcare Facilities Accreditation Program (HFAP) of the Accreditation Association for Hospitals/Health Systems, Inc. (AAHHS), and the Center for Improvement in Healthcare Quality (CIHQ). There is increased emphasis on standards and requirements for CMS's Conditions of Participation directly involved for deemed status. In addition, there is an increased emphasis on the safety of the patient, including medication safety. Topics, such as the appropriate use of antimicrobials and pain medications, compounding of sterile and other preparations, and handling of hazardous products, have risen to the top of surveyors' expectations. As always, healthcare organizations are expected to be continuously in full compliance with standards. *Preparing* for a survey is no longer practical as surveys have evolved into unannounced evaluations of how organizations continuously comply with the standards and improve care, treatment, services, and safety.

This new edition, now entitled *Meeting Accreditation Standards: A Pharmacy Preparation Guide*, reflects the accrediting industry's increased emphasis on safety for the patient, employees, and the general public. To that end, it aims to help pharmacies comply with critical standards and incorporate them into their everyday practice.

Since the eighth edition of *Assuring Continuous Compliance with Joint Commission Standards: A Pharmacy Guide* was published, CIHQ has received deemed status from CMS. The other accrediting organizations have revised their survey processes and streamlined their standards to emphasize CMS's focus on safety and improving the quality of patient care. A prime example is that The Joint Commission has revised medication management standards, numerous other standards, and its National Patient Safety Goals (NPSGs). As a result of its Project REFRESH, many redundant standards have been eliminated, and others have been consolidated. A primary goal of the project was to simplify the survey process and enhance the clarity of standards and NPSGs.

Every chapter in this book has been completely reviewed, updated, and expanded to reflect current standards, requirements, expectations, and interpretations. Some chapters from the previous edition have been consolidated for easier use and new chapters for CIHQ, Antimicrobial Stewardship, and Pain Management have been added. Standards and requirements effective from July 2019 are addressed to the extent they are known. New standards, requirements, expectations, and interpretations can be announced at any time. Appendix A lists services and resources to help pharmacists stay current. Readers are encouraged to review the literature and monitor all accrediting organizations' websites, including The Joint Commission's.

Although some of the changes are significant, for most pharmacies compliance with the current standards are not much more difficult than compliance with previous standards and goals. In some cases, compliance may be even easier if the pharmacy's services have been improved since the last survey.

Improvements to This Book

This book contains a number of changes aimed at improving compliance and the ease of using this edition. Although The Joint Commission's standards and NPSGs serve as the basis for this edition, the information contained therein may be used for any of the four accrediting organizations or for CMS certification. Standards that are quoted from the CoPs or from one of the four accrediting organizations are displayed in Gill Sans font. Authors' text is in Times New Roman font, and Authors' Comments, Experiences and Suggestions are displayed in Times New Roman *italics*. Updated checklists clearly distinguish the authors' notes from the "check-off" items. These changes in format and the expanded index should make it easier for the reader to navigate through the book. However, compliance is not a guarantee. For example, interpretation of standards may change, staff may fail to document, and/or documents may be misplaced.

Meeting Accreditation Standards: A Pharmacy Preparation Guide contains the most up-to-date medication management (MM) standards and requirements and the medication-related 2020 NPSGs and their requirements. It also contains the most current standards, other than MM standards, that pharmacies must comply with to have a successful survey.

The book also contains a chapter that describes CMS's Conditions of Participation for hospitals related to medication management. In addition to Joint Commission-related information, two other chapters provide information on the accreditation programs and standards of the National Integrated Accreditation for Healthcare Organizations (NIAHO) of DNV-GL Healthcare and HFAP.

In August 2013, CMS recognized CIHQ as an organization that provides a national accreditation program for hospitals wishing to participate in the Medicare or Medicaid program. A new chapter provides information about the CIHQ accreditation process, the CIHQ standards, and its requirements for medication management.

Overview of This Book

This book provides a guide for achieving continuous compliance with accreditation standards relating to pharmacy and medication use. It reflects onsite experiences and survey report results from hundreds of hospitals.

- **Chapter 1** summarizes current medication- and pharmacy-related CoPs and CMS standards.
- **Chapter 2** is a general discussion of The Joint Commission and the role of accreditation in improving care, treatment, and services. It describes The Joint Commission's survey process and includes updated examples of survey agendas.
- **Chapter 3** summarizes current medication- and pharmacy-related standards of the NIAHO of DNV-GL Healthcare.
- **Chapter 4** summarizes current medication- and pharmacy-related standards of HFAP/AAHHS.
- **Chapter 5** is a new chapter that summarizes current medication- and pharmacy-related standards of CIHQ, the newest accrediting organization.
- **Chapter 6** provides an organized approach to achieving continuous compliance with Joint Commission standards.
- **Chapters 7 through 12** are updated checklists that address frequently requested documents and policies and procedures, compliance with medication management standards, each medication-related 2020 NPSG and its requirements for hospitals, infection prevention and control standards, environment of care standards, and human resources standards, respectively.
- **Chapter 13** provides information on the National Institute for Occupational Safety and Health (NIOSH) Recommendations for Handling Hazardous Drugs, and the United States Pharmacopeial Convention (USP) Compounding Standards for USP General Chapters <795>, <797>, <800>, and <825>.
- **Chapter 14** describes the medication management individual-based system tracer.
- **Chapter 15** addresses pharmacy and therapeutics activities.
- **Chapter 16** is devoted to medication safety, adverse drug reactions, and medication errors, including an overview of the Food and Drug Administration's MedWatch program and the MEDMARX program.
- **Chapter 17** is a new chapter that provides information on standards regarding pain management.
- **Chapter 18** is a new chapter that discusses standards and surveyor's expectations regarding antimicrobial stewardship activities.
- **Chapter 19** discusses quality and performance improvement activities, including an overview of The Joint Commission's ORYX initiative.
- **Appendix A** contains contact information (e.g., names, addresses, telephone numbers, and websites) for the organizations mentioned in the book.
- **Appendix B** contains example forms that are useful in pharmacy practice and for documenting continuous compliance with the standards. You may use the examples as they are or customize them to meet your needs.

How to Use This Book

Begin by reading—Begin by reading the first chapter of this book and the chapter related to the accreditation organization your hospital uses. Identify and read other chapters as you address the standards relative to your organization's survey.

Determine whether standards in other accreditation manuals apply—Determine whether standards in other accreditation manuals of standards apply to your organization (see Chapter 6).

Complete the checklists—Complete the checklists in this book (i.e., Chapters 7 through 12).

Identify current deficiencies—Use the checklists to identify current deficiencies, and develop an action plan for progressing toward continuous compliance (see Develop an Action Plan in Chapter 6).

Work with the organization's leaders—Work closely with the organization's leaders and share information with the entire organization as appropriate as described in Chapter 6.

Focus on problematic areas—Give special attention to the problematic areas described in Chapter 6.

Follow the suggestions in Chapter 6—Chapter 6 contains additional suggestions for using this book such as organizing documents and conducting mock surveys and tracers. Attention to these suggestions provides an organized approach to progressing toward continuous compliance.

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December 2019

CHAPTER 10

Infection Prevention and Control Checklist

The Joint Commission, in its prevention and control of infection (IC) standards, requires organizations to take precautions to reduce the risk of acquiring and transmitting infections. Organizations must have effective, organization-wide IC programs. All departments and services must participate in the organization's IC efforts.

Note: Organizations surveyed under the *Comprehensive Accreditation Manual for Hospitals* must comply with the IC standards that are applicable to them. Organizations surveyed under other Joint Commission accreditation manual(s) should review the appropriate manual. (See Chapter 2, The Joint Commission.)

CHECKLIST ORGANIZATION

This chapter presents infection control precautions for health-care personnel in a checklist format. They are consistent with The Joint Commission's IC standards, current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines (see NPSG.07.01.01 in Chapter 9), and the provisions of the United States Pharmacopeia (USP) General Chapter <797> Pharmaceutical Compounding—Sterile Preparations (see Chapter 13).^{1,3}

Note: Although this checklist does not address these precautions completely, it should help to reduce the risk of acquiring and transmitting infections. Healthcare organizations should check for new and updated standards on The Joint Commission's website, and for new and updated hand hygiene guidelines on the CDC's website (see Appendix A). Pharmacies should contact their board of pharmacy and other state agencies to determine how their state integrates USP General Chapter <797> provisions into its regulations.

Authors' Comments, Experiences, and Suggestions

The notes, set in *italics*, are compliance expectations and suggestions that are based on the authors' personal experiences, reports from surveyed organizations, and surveyors' statements. They include suggestions for complying with the EPs, such as requiring specific documentation, metrics, or attention to implementation of specific care. Some notes reflect legal requirements, clarifying statements from Joint Commission standards, previous Joint Commission standards, or commonly accepted standards of practice. Other notes reflect variations in interpretation of the standards.

Checklist Symbols

Special attention should be paid to Elements of Performance (EPs) preceded by an icon. The checklist uses a  icon before an EP if documentation is required, and a  icon before an EP identified as a high risk area where noncompliance could result in patient harm.

CHECKLIST USAGE SUGGESTIONS

To assess compliance, use the checklist and proceed systematically. Mark the item "Yes" if you are currently compliant and are sure you will continue to be compliant. Mark the item "No" if you are currently not compliant (even if you are sure you will be compliant later). If you are not sure of your answer, leave a *blank* response. A few items may be not applicable (*NA*). Make comments, as appropriate (e.g., reasons for noncompliance and location of documents). Concentrate your efforts on resolving all "No" and *blank* responses.

	Yes	No	NA
Checklist			
Infection Risk Identification			
Accidents, incidents, unsafe practices, and unsanitary conditions that pose a risk of infection for patients, visitors, and staff are identified.	_____	_____	_____
Infection Risk Reporting			
Accidents, incidents, unsafe practices, and unsanitary conditions that pose a risk of infection for patients, visitors, and staff are reported.	_____	_____	_____
Authors' Comments, Experiences, and Suggestions			
<ul style="list-style-type: none"> <i>Infection control–related incidents are usually reported to the Infection Control Committee or a designated individual. The organization's infection control plan should contain specific information on how to submit these reports.</i> 			
Infection Control Surveillance			
Each department or service participates in infection control surveillance activities as required by the organization.	_____	_____	_____
Cleaning and Disinfecting			
The pharmacy and areas where medications are stored, compounded, dispensed, prepared, and administered are clean and uncluttered.	_____	_____	_____
Staff uses organization-approved cleaning procedures and cleaning and disinfecting agents.	_____	_____	_____
There are an adequate number of sinks and sufficient space and materials for cleaning equipment and washing hands.	_____	_____	_____
Authors' Comments, Experiences, and Suggestions			
<ul style="list-style-type: none"> <i>Cleaning should be coordinated with environmental services personnel, and cleaning agents and procedures approved by the Infection Control Committee must be used. Particular attention must be given to prepackaging, compounding, and sterile preparation areas as well as areas likely to harbor microorganisms that could contaminate medications or transmit disease to staff.</i> 			
Alcohol-based hand rub containers are appropriately located.	_____	_____	_____
Cleaning agents and supplies are available to staff.	_____	_____	_____
Containers of cleaning agents are replaced when empty and not “topped off” to refill.	_____	_____	_____
If ready-to-use products are not used, cleaning and disinfecting agents are appropriately diluted.	_____	_____	_____
Cleaning and disinfecting agents are appropriately labeled.	_____	_____	_____
Equipment is kept clean and stored in a clean area.	_____	_____	_____

Yes No NA

Authors' Comments, Experiences, and Suggestions

- *Areas under sinks are not clean areas. Mortars, pestles, glassware, and other equipment that must be kept clean must be stored in a clean area. Most organizations prohibit storage under sinks.*

Medication preparation, packaging, and dispensing devices (e.g., mortars, pestles, pill crushers, pill splitters, counting trays, graduated cylinders, unit-dose packaging devices, and balances) are cleaned after each use and decontaminated and disinfected if necessary. _____

Devices used for crushing or splitting tablets are cleaned immediately after use according to manufacturers' recommendations and instructions. _____

Medication carts, drawers, and bins containing individual patient's medications are kept clean. _____

Automated dispensing cabinets and bins are cleaned according to the manufacturer's recommendations and instructions. _____

Authors' Comments, Experiences, and Suggestions

- *Many organizations develop a schedule for cleaning equipment and devices.*

Boxes and Other Shipping Containers

Cardboard boxes and other external shipping containers are stored off the floor. _____

Shipping containers or any corrugated cardboard containers are not stored or opened (i.e., torn or cut) in any area reserved for prepackaging medications or compounding preparations. _____

Authors' Comments, Experiences, and Suggestions

- *Handling and storing shipping containers (e.g., cardboard boxes) must be done with minimal air disturbances and dissemination of dust particles. Intravenous (IV) bags and bottles and related supplies must be removed from cartons and wiped with an approved agent prior to placing them in the sterile preparation area.*

Waste

Staff disposes of waste in accordance with the organization's infection control policies and procedures. _____

Waste does not create a nuisance or a breeding place for insects, rodents, and vermin or otherwise permit the transmission of disease. _____

Waste disposal containers are close to the area of use. _____

Noninfectious waste is not mixed with infectious waste. _____

Hazardous materials waste is handled per organizational policy. _____

Infectious Waste

Staff disposes of infectious waste in accordance with the organization's infection control policies and procedures. _____

	Yes	No	NA
Infectious waste does not create a nuisance or a breeding place for insects, rodents, and vermin or otherwise permit the transmission of disease.	_____	_____	_____
Infectious waste disposal containers are close to the area of use.	_____	_____	_____
Infectious waste is placed in specially marked containers (e.g., red bags) and disposed of separately from routine trash.	_____	_____	_____

Authors' Comments, Experiences, and Suggestions

- Check the organization's policies on disposal of trash and infectious waste.

Items used in patient rooms are not returned to the pharmacy.	_____	_____	_____
---	-------	-------	-------

Attire

Personnel wear appropriate attire in all pharmacy and hospital areas.	_____	_____	_____
---	-------	-------	-------

Attire worn in the sterile compounding area is clean and minimizes the potential for shedding and contamination, and meets the organization's policy and state regulations.	_____	_____	_____
---	-------	-------	-------

Authors' Comments, Experiences, and Suggestions

- Some organizations require personnel who compound sterile preparations to wear hospital-laundered scrubs in the buffer area.
- USP compounding chapters (<795> for nonsterile compounding, <797> for sterile compounding, and <800> for handling hazardous drugs) have specific requirements for garb and personal protective equipment (PPE) (see Chapter 13).

Personnel remove jewelry and cosmetics prior to compounding sterile preparations.	_____	_____	_____
---	-------	-------	-------

Hygiene

Personnel are attentive to personal cleanliness and hygienic practices.	_____	_____	_____
---	-------	-------	-------

Personnel with rashes, sunburn, weeping sores, conjunctivitis, or active respiratory infection do not prepare sterile preparations.	_____	_____	_____
---	-------	-------	-------

Fingernail length complies with the organization's policies and procedures.	_____	_____	_____
---	-------	-------	-------

The use of artificial fingernails complies with the organization's policies and procedures.	_____	_____	_____
---	-------	-------	-------

Authors' Comments, Experiences, and Suggestions

- Artificial nails or extenders should not be worn by personnel who compound sterile preparations. Organizations often prohibit the wearing of artificial fingernails by individuals who have contact with patients.

Immunizations

Pharmacy staff participate in the organization's annual influenza vaccination program (see IC.02.04.01, EP 1).	_____	_____	_____
--	-------	-------	-------

Yes No NA

Authors' Comments, Experiences, and Suggestions

- *The organization must offer immunization against influenza to staff and licensed independent practitioners (see IC.02.04.01). The organization must provide access to influenza vaccination at an accessible site (see IC.02.04.01, EP 3).*
- *Education about the following is provided to pharmacy staff:*
 - ◆ *Influenza vaccination*
 - ◆ *Nonvaccine control and prevention measures (i.e., the use of appropriate precautions)*
 - ◆ *The diagnosis, transmission, and impact of influenza. (See IC.02.04.01, EP 2.)*
- *The organization must annually evaluate vaccination rates and reasons for nonparticipation in the immunization program. The organization must implement enhancements to the program to increase participation (see IC.02.04.01, EP 4 and EP 5).*

Employee Health Program

Staff participate in the organization's employee health program as required (e.g., tuberculin skin testing).

Authors' Comments, Experiences, and Suggestions

- *Most organizations provide an employee health program. This program often includes pre-employment physical examinations, blood tests, chest x-rays, and tuberculin skin tests (and annual follow-ups as required) as a condition of employment to ensure that employees are free from communicable diseases.*
- *The employee health program may restrict the activities of employees and visitors. For example, persons with communicable diseases may be prohibited from contact with patients.*
- *All staff must participate in the organization's employee health program and comply with the organization's employee health policies and procedures. Furthermore, staff must be examined, treated, and immunized as required by the organization.*

Pharmacy employees who receive, store, or compound hazardous drugs and those who would respond to clean a hazardous drug spill must be fit-tested for N-95 respirators unless the organization uses a different National Institute for Occupational Safety and Health (NIOSH)-approved respirator that does not require fit-testing.

Authors' Comments, Experiences, and Suggestions

- *Personnel must also be aware of the medical surveillance and alternative duty policies of their employee health services.*

Hand Hygiene (Routine)

Hand washing is the single most important procedure for preventing healthcare-associated infections. The organization's infection control policies and procedures must address hand washing and require staff to comply with hand hygiene guidelines.^{2,4,5}

Yes No NA

Authors' Comments, Experiences, and Suggestions

- *The Joint Commission requires organizations to comply with either current World Health Organization (WHO) hand hygiene guidelines or CDC hand hygiene guidelines. Most organizations follow the CDC guidelines (see NPSG.07.01.01 in Chapter 9).*

Routine hand washing is performed at the beginning of the shift, after visiting the restroom, before and after eating, and when the hands are obviously soiled. (The areas under the fingernails must be kept clean.)

Personnel who have contact with infected or potentially infected patients, body fluids, and contaminated or potentially contaminated objects wash their hands promptly after such contact.

Staff uses a hand-washing technique and cleaning agent that are approved by the organization.

Authors' Comments, Experiences, and Suggestions

- *The following routine hand-washing technique is typical of most organization-approved techniques:*
 - ◆ *Use liquid soap and lukewarm (not hot) water: (Lukewarm water removes less oil from the skin and is less drying.)*
 - ◆ *Rub all surfaces of lathered hands together vigorously for at least 15 seconds.*
 - ◆ *Rinse hands thoroughly under a stream of water.*
 - ◆ *Dry the hands with a disposable (e.g., paper) towel or air dryer.*
 - ◆ *Use a towel to turn off the water.*

Staff use alcohol-based hand rubs as permitted by CDC hand hygiene guidelines, organization policy, and manufacturers' recommendations.²

Hand Hygiene (Sterile Preparation Compounding)

Personnel wash their hands thoroughly prior to compounding sterile preparations.

Personnel who leave the sterile preparations compounding area rewash their hands prior to resuming compounding.

Authors' Comments, Experiences, and Suggestions

- *Staff must use a hand washing technique and cleaning agent that meet USP General Chapter <797> requirements and are approved by the organization.*
- *The following technique for washing hands prior to compounding sterile preparations is typical of most organization-approved techniques:*
 - ◆ *Remove debris from under fingernails using running warm water and a nail cleaner*
 - ◆ *Moisten hands with water and apply a lather of a cleaning agent approved by the organization. The lather must extend to the wrists and forearms (i.e., up to the elbow).*
 - ◆ *Wash hands under running water for at least 30 seconds.*
 - ◆ *Rinse hands thoroughly under running water. Hold hands so that the direction of water flow is from the fingertips to the wrists.*
 - ◆ *Dry the hands with a low-lint disposable wiper.*

Yes No NA

- ◆ *Apply a waterless alcohol-based hand rub with persistent activity following the manufacturer's recommendations. Allow hands to dry.*
- ◆ *After donning sterile powder-free gloves, apply sterile alcohol. Allow the gloves to dry.*

Standard Precautions

Staff observe standard precautions to reduce the risk of transmission of infection.⁴

Authors' Comments, Experiences, and Suggestions

- *Standard (formerly known as universal) precautions apply to all patients receiving care in hospitals, regardless of their diagnosis or presumed infection status.*
- *Standard precautions apply to (1) blood; (2) all body fluids, secretions, and excretions except sweat, regardless of whether or not they contain visible blood; (3) nonintact skin; and (4) mucous membranes.*
- *Standard precautions are designed to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection in hospitals.*
- *Occupational Safety and Health Administration (OSHA) rules and regulations (Title 29 CFR §1910.1030) require employers to implement plans to dispose of blood and contaminated waste, provide warnings on such waste, and keep records that account for the disposal of the waste.⁶ Employers must ensure that healthcare workers take special precautions to reduce the risk of contracting and transmitting AIDS, hepatitis, and other diseases from exposure to blood and other body fluids.*
- *Standard precautions must be included in the employer's exposure control plan. Healthcare organizations must regularly educate employees about their exposure control plan and standard precautions. Organizations must offer medical attention, evaluation, testing, and treatment in accordance with their exposure control plan.*

Isolation

Staff understand the organization's isolation policies and procedures.

Only medications needed for the patient's immediate use are taken into an isolation room.

Gowning, masking, and gloving are done as specified in the organization's isolation policies.

All items taken into an isolation room are placed in a designated receptacle after use.

Hand hygiene procedures are performed as specified in the organization's isolation policies after leaving the isolation room.

Preparing Stock for Use in Sterile Compounding Areas

After stock is received from suppliers, but prior to its placement in stock, containers that will be stored in sterile compounding areas must be wiped to help remove potential microbial contamination from the outside of the container.

	Yes	No	NA
After stock is received from suppliers, but prior to its placement in stock, containers of hazardous drugs must be wiped to help remove potential hazardous drug contamination from the outside of the container.	_____	_____	_____

Authors' Comments, Experiences, and Suggestions

- *Items that will be placed inside the ISO 5 hood must also be wiped with 70% sterile isopropyl alcohol (see information below).*

Sterile Preparation Compounding Area

Areas for compounding sterile preparations minimize opportunities for particulate and microbial contamination of the preparations.	_____	_____	_____
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Authors' Comments, Experiences, and Suggestions

- *Areas for compounding sterile preparations must meet the requirements of USP General Chapter <797> and state regulations (see Chapter 13).*

Primary Engineering Controls (PECs)

Sterile preparations are compounded in a properly maintained laminar airflow workbench (LAFW), biological safety cabinet (BSC), compounding aseptic isolator (CAI), or compounding aseptic containment isolator (CACI).	_____	_____	_____
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Authors' Comments, Experiences, and Suggestions

- *Staff must be aware that primary engineering controls ("hoods") do not create a sterile area but maintain an aseptic area that is suitable for compounding sterile preparations.*
- *Ideally, all sterile preparations are compounded in the pharmacy in a USP <797> compliant facility. However, USP General Chapter <797> has provisions for the preparation of some compounds that are needed for immediate patient use. If permitted by hospital policy, preparing medications with a short stability or for urgent use is acceptable if done in a clean, well-lighted, functionally separate area by competent personnel. There must be no intervening steps between the compounding and administration of the sterile preparations.*

Compounding of sterile preparations, including IVs, irrigations, ophthalmics, parenteral nutrition, antineoplastic and other hazardous agents, cardioplegia, and other preparations that require specialized knowledge or equipment usually found only in the pharmacy are compounded in the pharmacy by specially trained staff.	_____	_____	_____
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Cleaning the Nonsterile Compounding Area

Areas used for compounding nonsterile preparations must be clean and uncluttered. No carpeting is permitted in compounding areas.	_____	_____	_____
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Floors, walls, and ceilings in the nonsterile compounding areas are cleaned in accordance with USP General Chapter <795> requirements.	_____	_____	_____
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Cleaning the Sterile Preparation Areas

Floors, walls, and ceilings in the ante and buffer areas are cleaned in accordance with USP General Chapter <797> requirements.	_____	_____	_____
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Yes No NA

Authors' Comments, Experiences, and Suggestions

- *USP General Chapter <797> contains requirements for cleaning floors, walls, and ceilings in the ante and buffer areas. If environmental services personnel clean these areas of the rooms, they must have documented competence to clean these areas.*

Cleaning and Disinfecting Primary Engineering Controls

Primary engineering control surfaces are cleaned and disinfected frequently, including the following:

- at the beginning of each work shift, _____
- before each batch preparation is started, _____
- every 30 minutes during continuous compounding activity, _____
- when spills occur, and _____
- whenever surface contamination is known or suspected. _____

For hazardous drug areas, decontaminate the surfaces using a product intended for this use. _____

Authors' Comments, Experiences, and Suggestions

- *Bleach (in about a 2% concentration) has traditionally been used, but most organizations use a ready-to-use product designed for use to decontaminate hazardous drug surfaces.*

If residue is present, sterile water is used to remove the residue. _____

Use a hospital-approved detergent to clean the primary engineering control. _____

Use sterile 70% isopropyl alcohol to disinfect the primary engineering control following cleaning. _____

Authors' Comments, Experiences, and Suggestions

- *Only compounding personnel are permitted to clean the primary engineering control.*

All items (including syringes, vials, and other extraneous items) are removed from the PEC before cleaning it. _____

Authors' Comments, Experiences, and Suggestions

- *Clean the work surface, side panels, and other accessible surfaces, starting at the top and rear and working downward and toward the front, unless the manufacturer recommends a different procedure. The cover to the high-efficiency particulate air (HEPA) filter, often referred to as a grill, needs to be included in the cleaning, but be careful to avoid getting the cleaning agent on the high-efficiency particulate air (HEPA) filter. Do not spray anything into the HEPA covering.*
- *Document the daily and monthly cleaning. Surveyors frequently look at documentation of cleaning (e.g., a monthly cleaning log) (see Example 10-1).*

	Yes	No	NA
Primary Engineering Control Maintenance			
Routine maintenance, such as cleaning or replacing prefilters, is performed regularly and according to manufacturers' specifications and certifier's recommendations.	_____	_____	_____

Authors' Comments, Experiences, and Suggestions

- *These activities must be documented.*

HEPA filters are replaced or repaired when recommended by a qualified certifier.	_____	_____	_____
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Certification of Sterile Preparation Areas

Primary engineering controls are checked and certified by an independent qualified certifier when they are first placed in service, at least every 6 months, when maintenance is completed, or they are moved to a new location.	_____	_____	_____
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Secondary engineering controls (anterooms, buffer rooms, segregated compounding areas, and containment segregated compounding areas) are checked and certified by an independent qualified certifier upon commissioning (first use), and at least every 6 months.	_____	_____	_____
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The certification report provided by the certifier must be reviewed. If any areas fail or need attention, correction and documentation must be completed.	_____	_____	_____
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Environmental Monitoring of Sterile Preparation Area

Viable (i.e., microbial and fungal contamination) environmental monitoring is performed as required by USP General Chapter <797> and state regulations (see Chapter 13).	_____	_____	_____
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The environmental monitoring results must be reviewed. If any areas fail or need attention, correction and documentation must be completed.	_____	_____	_____
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Results of environmental monitoring are reported to the organization.	_____	_____	_____
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Authors' Comments, Experiences, and Suggestions

- *Most organizations report this to the Infection Control Committee.*

Primary Engineering Control Techniques

Proper techniques and precautions are observed when using primary engineering controls (PECs).	_____	_____	_____
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Authors' Comments, Experiences, and Suggestions

- *When using PECs, the following precautions are recommended:*
 - ◆ *Ensure that the PEC runs continuously.*
 - ◆ *Assemble and organize all necessary materials in or near the PEC before beginning work, and keep unnecessary items (e.g., labels, worksheets, notepads, pens and pencils) out of the PEC.*
 - ◆ *Work within the PEC in the appropriate workspace identified by the manufacturer and confirmed by the certifier. Generally, this is at least 6 inches within the hood.*

Yes No NA

- ◆ *Keep a clear path between the HEPA filter and sterile objects (i.e., avoid blocking airflow with vials and equipment).*
- ◆ *Do not allow objects (especially sharp or pointed objects) or liquids to contact the HEPA filter.*
- ◆ *Avoid unnecessary talking or movement.*

Aseptic Technique

Proper aseptic technique is used in compounding sterile preparations.

Authors' Comments, Experiences, and Suggestions

- *Touch is the primary source of contamination.*
- *The following aspects of aseptic technique are emphasized:*
 - ◆ *Compounding in the pharmacy must comply with USP General Chapter <797>.*
 - ◆ *Perform hand hygiene procedures before handling medications and as needed during the procedure.*
 - ◆ *Don proper garb.*
 - ◆ *Work with moderate speed to minimize errors.*
 - ◆ *Inspect containers for cracks, holes, leaks, and evidence of contamination before and after preparation.*
 - ◆ *Do not touch sterile areas of containers or allow nonsterile objects to come in contact with sterile areas.*
- *The exteriors of all containers must be wiped with sterile 70% isopropyl alcohol immediately prior to placement in the primary engineering control. Do not spray alcohol or other solutions in hazardous drug areas.*
- *Clean diaphragms, injection ports, ampule necks, and vial tops with sterile 70% isopropyl alcohol and allow to dry.*
- *Cover ampule necks with a sterile pad and break ampules by snapping toward the side of the primary engineering control. Use a filter straw or needle to withdraw contents of the ampule.*
- *Ensure that seals on syringe and needle packages are intact. Do not use items if the sterility is questionable.*
- *Ensure that touch contamination does not occur when attaching needles to syringes and when mixing medications and diluents.*
- *Dispose of used syringes, needles, and other waste in accordance with the organization's policies and procedures.*

Beyond-Use Dates for Compounded Nonsterile Preparations

All compounded nonsterile preparations are labeled with beyond-use dates.

Beyond-use dates for compounded nonsterile preparations do not exceed the periods specified in USP General Chapter <795> (see Chapter 13).

Yes No NA

Beyond-Use Dates for Compounded Sterile Preparations

All compounded sterile preparations are labeled with beyond-use dates. _____

Beyond-use dates for compounded sterile preparations do not exceed the periods specified in USP General Chapter <797> (see Chapter 13). _____

Sterile Preparations Inspections

Compounded sterile preparations are quarantined and inspected by a pharmacist prior to release from the pharmacy. _____

Organizational policy must address if redispensing unused compounded sterile preparations is acceptable. _____

Authors' Comments, Experiences, and Suggestions

- *The inspection must include checking for defective containers, cloudiness, turbidity, leaks, precipitates, particulate matter; evidence of contamination, and evidence of incompatibility.*
- *Labels must be checked for completeness and accuracy.*
- *When possible, the individual who performs the inspection should not be the individual who compounded the preparation.*
- *Defective and doubtful preparations must be destroyed.*
- *The individual who checks the final preparation must verify that the preparation has passed a final examination and is suitable for administration (i.e., compounded accurately and free from incompatibilities and particulate matter).*
- *An individual's written signature or initials on the label is a common means of indicating that the preparation has been checked.*

Sterile Product Storage

Manufactured sterile products are properly stored. The storage temperature is within the manufacturer's requirements and FDA and USP guidance. _____

Sterile Preparations Storage

Compounded sterile preparations are properly stored. The storage temperature is within the range established in USP General Chapter <797>. _____

Authors' Comments, Experiences, and Suggestions

- *Compounded sterile preparations should be administered as soon after preparation as possible. Storage time limits and storage conditions must maximize stability, minimize microbial growth, and be consistent with the requirements of USP General Chapter <797> (see Chapter 13).*
- *Protection from light may be necessary if the preparation is light-sensitive. Check manufacturer and other literature carefully for stability data and storage guidelines.*

	Yes	No	NA
Compounding Devices			
Automated compounding devices (e.g., automated compounders, repeater pumps, IV workflow software components) are cleaned at least daily when compounding occurs.	_____	_____	_____
Volumetric and gravimetric devices are checked each compounding day to ensure accurate delivery volume. IV workflow software is checked per manufacturer's recommendations and organizational policy.	_____	_____	_____
Authors' Comments, Experiences, and Suggestions			
<ul style="list-style-type: none"> Personnel must be knowledgeable about the safe and proper operation of these devices. USP General Chapter <797> provides information relating to the use of these devices. In addition, personnel must consult the manufacturer's information for specific instructions (see Chapter 13). 			
Syringes			
A sterile syringe is used for each medication withdrawn.	_____	_____	_____
Syringes are used on one patient only and then disposed of properly.	_____	_____	_____
Authors' Comments, Experiences, and Suggestions			
<ul style="list-style-type: none"> Organizations must be especially attentive to syringes used in anesthetizing areas and other areas where special procedures are performed. 			
Needles			
A sterile needle is used for each medication withdrawn.	_____	_____	_____
Containers for disposal of used needles and other sharp objects are available, used properly, and not overfilled.	_____	_____	_____
Needles are not recapped unless required for dispensing.	_____	_____	_____
Single-Use Containers			
Single-use containers opened outside of ISO 5 are not reused.	_____	_____	_____
Authors' Comments, Experiences, and Suggestions			
<ul style="list-style-type: none"> Single-use containers may be used for multiple doses/patients if used in a USP <797> compliant manner.⁷ Single-use containers should be used whenever feasible. 			
Pharmacy bulk packages (PBPs) of electrolytes, antibiotics, and other products are used in the pharmacy for no more than 4 hours after the initial entry into the container unless the manufacturers' product information provides a different time period. Any unused portions are discarded.	_____	_____	_____

Yes No NA

Authors' Comments, Experiences, and Suggestions

- *A PBP is a container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes.⁷*

Single-use containers are discarded immediately after use in accordance with the organization's policies.

Multiple-Dose Vials

Multiple-dose vials that will be reused after the first puncture are labeled with an appropriate beyond-use date.

Multiple-dose vials are not used beyond the time specified by the organization's policies.

Multiple-dose vials opened or punctured in a direct patient care area are used only for that patient.⁸

Authors' Comments, Experiences, and Suggestions

- *The time period must not exceed 28 days, or the time period specified by the manufacturer, whichever is shorter.⁸ Whatever the policy, the period must not conflict with the manufacturer's recommendations nor extend beyond the manufacturer's expiration date.*

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