INFECTION PREVENTION AND CONTROL AUDIT for Pharmacy

Name of Facility:

Location: _____ Date: YYYY_____ MM_____ DD_____

Time: _____hours / ____AM ____PM Manager: _____

Auditor (print): _____ Signature: _____

Abbreviations:

ABHR	Alcohol-Based Hand Rub
ADM	Automated Dispensing Machine
AP	Additional Precautions
CSA	Canadian Standards Association
CSP	Compounded Sterile Preparation
DIN	Drug Identification Number
IP&C	Infection Prevention and Control
N/A	Not Applicable
PPE	Personal Protective Equipment
RP	Routine Practices
TPN	Total Parenteral Nutrition
WHMIS	Workplace Hazardous Materials Information System

Audit Toolkit supported in part by Virox Technologies Inc.

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Glossary:

Additional Precautions (AP): The precautions (i.e., Contact Precautions, Droplet Precautions, Airborne Precautions) that are necessary in addition to Routine Practices for certain pathogens or clinical presentations. These precautions are based on the method of transmission (e.g., contact, droplet, airborne).

Alcohol-Based Hand Rub (ABHR): A liquid, gel or foam formulation of alcohol (e.g. ethanol, isopropanol) which is used to reduce the number of microorganisms on hands in clinical situations when the hands are not visibly soiled. ABHRs contain emollients to reduce skin irritation and are less time-consuming to use than washing with soap and water. ABHR is available at concentrations of 60-90%; however, a minimum concentration of 70% is recommended.

Cold Chain: The process used to maintain optimal conditions during the transport, storage and handling of vaccines.

Compounded Sterile Preparations (CSP): Admixtures that are compounded using multiple sterile additives to create batch preparations (e.g., pooled admixtures, parenteral nutrition solutions, nuclear pharmaceuticals).

Dedicated Hand Washing Sink: A sink for cleaning soiled hands that is not used for any other purpose (e.g., cleaning of equipment, emptying of solutions).

Disinfectant: A product that is used on medical devices or environmental surfaces that is designed to kill microorganisms, resulting in disinfection of the device/surface. Disinfectants are applied only to inanimate objects. Some products may have both cleaning and disinfecting abilities. Disinfectants require a DIN number from Health Canada.

Drug Identification Number (DIN): In Canada, disinfectants are regulated as drugs under the Food and Drugs Act and Regulations. Disinfectant manufacturers must obtain a drug identification number (DIN) from Health Canada prior to marketing, which ensures that labelling and supporting data have been provided and that the product has undergone and passed a review of its formulation, labelling and instructions for use.

Hand Hygiene: A general term referring to any action of hand cleaning. Hand hygiene relates to the removal of visible soil and removal or killing of transient microorganisms from the hands. Hand hygiene may be accomplished using soap and running water or an alcohol-based hand rub. Hand hygiene includes surgical hand antisepsis.

Hand Washing: The physical removal of microorganisms from the hands using soap (plain or antimicrobial) and running water.

Personal Protective Equipment (PPE): Clothing or equipment worn by staff for protection against hazards.

Respiratory Etiquette: Personal practices that help prevent the spread of bacteria and viruses that cause acute respiratory infections (e.g., coughing or sneezing into a tissue or into one's sleeve or elbow, care when disposing of tissues and the performance of hand hygiene). This is also referred to as '*respiratory hygiene*' or '*cough etiquette*'.

Routine Practices (RP): The system of infection prevention and control practices recommended by the Public Health Agency of Canada to be used with all clients/patients/residents during all care to prevent and control transmission of microorganisms in all health care settings.

Workplace Hazardous Materials Information System (WHMIS): The Workplace Hazardous Materials Information System (WHMIS) is Canada's national hazard communication standard. The key elements of the system are cautionary labelling of containers of WHMIS 'controlled products', the provision of Material Safety Data Sheets (MSDSs) and staff education and training programs.

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NOTE: See the **Table of Contents** for additional audit tools that expand on individual elements of these audit tools (e.g., Hand Hygiene, PPE, Routine Practices, Environmental Cleaning)

	Element	Compliance			Deficiency Noted
		Yes	No	N/A	
1.0	**Policies and Procedures**				
	There are policies and procedures for infection prevention and control (IP&C) practices that are reviewed at least annually and include:				
1.1	• hand hygiene				
1.2	• Routine Practices and Additional Precautions, including putting on and taking off personal protective equipment (PPE)				
1.3	• respirator fit-testing				
1.4	• scheduled environmental cleaning				
1.5	• scheduled equipment cleaning				
1.6	• disposal of sharps and other biohazardous waste				
1.7	• handling and dispensing medications				
	There are Occupational Health and Safety (OH&S) policies and procedures that include:				
1.8	• staff immunization				
1.9	• chemical/cytotoxic exposure management				
1.10	• annual WHMIS training				
1.11	• work restrictions related to exposures and infections/infectious diseases				
	There are policies and procedures for handling and storage of vaccines that include:				
1.12	• regular refrigerator and freezer maintenance				
1.13	• designated vaccine coordinator responsible for ensuring that all vaccines are handled correctly, procedures are documented and all personnel receive appropriate cold chain training				
1.14	• vaccine inventory management				
1.15	• storage requirements for each vaccine and diluent in inventory				
1.16	• transport and receipt of vaccine shipments				
1.17	• disposal of vaccines and diluents as directed by jurisdictional policy or guidelines				
1.18	• action to be taken when vaccine storage temperatures fall outside the recommended range				

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Element		Compliance			Deficiency Noted
		Yes	No	N/A	
2.0 Education					
	Staff receive training and education in IP&C that includes:				
2.1	• hand hygiene				
2.2	• Routine Practices				
2.3	• Additional Precautions				
2.4	• putting on and taking off PPE				
2.5	• respiratory etiquette				
2.6	• prevention of sharps injuries				
2.7	• aseptic technique				
2.8	• cold chain management for vaccines				
2.9	All training and education is documented				
2.10	All training and education is evaluated				
3.0 Physical Space					
3.1	Floors and floor coverings can be easily cleaned				
3.2	Walls and ceilings can be easily cleaned				
3.3	Paint is maintained in good condition (i.e., not chipped or cracked)				
3.4	There is a supply of potable water in rooms where pharmaceuticals are prepared, compounded, dispensed or stored				
3.5	There are facilities for washing utensils used in the preparation, service or storage of pharmaceuticals				
3.6	There is a dedicated hand washing sink located in a convenient location in the pharmacy				
3.7	There is alcohol-based hand rub (ABHR) available at all work stations				
3.8	PPE supplies are readily available and easily accessible in appropriate sizes				
3.9	Laminar airflow hoods and cabinets are certified at least annually or according to local standards (e.g., Canadian Standards Association standards)				
3.10	Materials surrounding laminar airflow hoods and cabinets are non-particle shedding				
3.11	Air ducts and vents do not interfere with airflow in the area				
3.12	Traffic is limited in laminar airflow hood/cabinet areas				

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Element		Compliance			Deficiency Noted
		Yes	No	N/A	
4.0 Aseptic Technique and Preparing Compounded Sterile Preparations (CSP)					
4.1	Hand hygiene facilities (soap, hot water, ABHR) are available in the immediate area where pharmaceuticals are being dispensed or prepared				
4.2	Hands and forearms are cleaned prior to preparation of compounded sterile preparations (CSPs)				
4.3	Facility-approved antiseptic soap is used for hand washing				
4.4	A gown, mask, hair/beard covering and sterile gloves are worn as per facility policy when preparing sterile products				
4.5	Pharmacy staff use aseptic technique				
4.6	Rubber stoppers are cleaned with 70% alcohol prior to entry into vial				
4.7	All CSPs are prepared in a laminar airflow hood or biological safety cabinet				
4.8	Hood/cabinet is operated continuously or at least 1 hour prior to use				
4.9	All work is done at least 15 cm. (6 inches) inside hood/cabinet				
4.10	Work surface inside hood/cabinet is disinfected prior to use				
4.11	Work surface inside hood/cabinet is disinfected after use				
4.12	Automated devices for compounding are disinfected before use				
4.13	Unopened vials and other products are discarded according to the manufacturers' expiration dates				
4.14	Single-dose injectable medications and solutions are dedicated to a single patient and entered one time only				
4.15	Medication vials are refrigerated after opening (if recommended by the manufacturer)				
4.16	Multiple-dose vials are discarded within 28 days after first opening (unless otherwise specified by the manufacturer)				
5.0 Environmental Cleaning					
5.1	Disinfectants used for cleaning have a Drug Identification Number (DIN) from Health Canada				

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		Yes	No	N/A	
5.2	Rooms where pharmaceuticals are prepared, compounded, dispensed or stored are free of clutter and equipment not regularly used in the room				
	The following items/areas are cleaned daily and when visibly soiled:				
5.3	• furniture and appliances (e.g., refrigerators)				
5.4	• floors				
5.5	• sinks				
5.6	• storage shelves and bins				
5.7	• washrooms				
5.8	• water filtration systems				
5.9	• counselling rooms				
5.10	• frequently touched items (e.g., telephones, computers, doorknobs, cash registers)				
5.11	• rooms used for the storage, compounding or dispensing of pharmaceuticals				
5.12	Equipment and tools used to prepare pharmaceuticals are cleaned and disinfected after use, or prior to use if contamination is suspected (e.g., funnels, scales/weights, cylinders, bottles, mortars/pestles, spatulas, pill counters)				
5.13	Wall-mounted automated dispensing machines (ADM) are cleaned after each use				
5.14	Exterior hood surfaces of laminar airflow hoods and biological safety cabinets are cleaned according to a fixed schedule				
5.15	There are sufficient containers for storing refuse in a sanitary manner				
	Waste is:				
5.16	• placed in covered containers that are not overfilled				
5.17	• removed when the container is full				
5.18	• removed from the premises at least twice weekly and more often if necessary to maintain a sanitary condition				
5.19	Soiled linen is contained in leak-proof bags that are not over-filled (e.g., gowns, lab coats)				
5.20	Puncture-resistant sharps containers are accessible at point-of-use				
5.21	Sharps containers are changed when contents reach the fill line and are not overfilled				

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Element		Compliance			Deficiency Noted
		Yes	No	N/A	
6.0 Storage of Pharmaceuticals					
6.1	Pharmaceuticals are stored on or in shelves, drawers or fixtures provided for that purpose				
6.2	There is a refrigerator for the exclusive storage of pharmaceuticals requiring refrigeration (i.e., does not contain food or non-pharmaceuticals)				
6.3	Temperatures of refrigerators and freezers used to store pharmaceuticals are checked daily (including ward refrigerators) and recorded				
6.4	Temperatures of refrigerators used to store vaccines are checked twice daily and recorded				
6.5	Refrigerators for the storage of pharmaceuticals are: • fitted with continual temperature monitoring alarms that register out-of-range temperatures				
6.6	• fitted with thermometers that have been calibrated within ±1°C				
6.7	• maintained at a temperature between 1.3° C and 10°C				
6.8	• kept clean and in a sanitary condition				
6.9	• located in an area not accessible to the public				
6.10	Vaccines are: • kept refrigerated at a temperature between 2°C and 8°C				
6.11	• kept frozen at a temperature of -15°C				
6.12	• protected from light if required				
6.13	• not stored in refrigerator doors				

Compliance Score (see calculation below)				
Total number of 'Yes'				**Compliance Score:**
Total number of 'No'				
Total number of items ('Yes' and 'No', exclude 'N/A')				

Scoring:

$$\frac{\text{Total number of 'yes'}}{\text{Total number of 'yes' and 'no'}} \times 100 = \%\ \text{compliance (compliance score)}$$

Feedback on Compliance:
There is a process in place to address audit deficiencies and to provide timely feedback, on a priority basis (e.g., safety issues would be addressed immediately).

Additional Comments:

Bibliography:

1. Canadian Standards Association. CAN/CSA-Z8000-11. **Canadian health care facilities**. Mississauga, Ont.: Canadian Standards Association; 2011.
2. Canadian Society of Hospital Pharmacists. **Sterile Preparation of Medicines: Guidelines for Pharmacies** 1996 (currently under revision) [cited June 12, 2013]; Available from: http://www.cshp.ca/members/dmsgetfile.asp?file=%7B92427335-FD74-405D-9920-1BDD40406AD0%7D.
3. Ontario College of Pharmacists. **Infection Control for Regulated Professionals. Pharmacists' Edition.**; 2005. [cited March 8, 2010]; Available from: http://www.ocpinfo.com/client/ocp/OCPHome.nsf/object/Infection+Control/$file/Infect_Control.pdf.
4. Kastango ES, St. John KH, Weber DJ. **Chapter 61 - Pharmacy Services**. In: Carrico R, Online version editor. APIC Text of Infection Control and Epidemiology: Association for Professionals in Infection Control and Epidemiology, Inc.; 2009.
5. Association for Professionals in Infection Control and Epidemiology, Inc. APIC Position Paper: **Safe Injection, Infusion and Medication Vial Practices in Healthcare**. July 2009. Available from: http://www.apic.org/Content/NavigationMenu/GovernmentAdvocacy/PublicPolicyLibrary/SafeInjections_final.pdf.
6. National Advisory Committee on Immunization. **Canadian immunization guide**. 7th ed. [Ottawa]: Canadian Medical Association; 2006. Available from: http://www.phac-aspc.gc.ca/publicat/cig-gci/pdf/cig-gci-2006_e.pdf.
7. Public Health Agency of Canada. **National Vaccine Storage and Handling Guidelines for Immunization Providers (2007)**; 2007. [cited May 18, 2011]; Available from: http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/index-eng.php.
8. American Society of Health-System Pharmacists. **The ASHP Discussion Guide for Compounding Sterile Preparations**; 2004. [cited March 14, 2010]; Available from: http://www.scribd.com/doc/26711088/Compounding-Sterile-Preparations.
9. Centers for Disease Control and Prevention. **Vaccine Storage and Handling Toolkit**. [cited March 14, 2010]; Available from: http://www2a.cdc.gov/vaccines/ed/shtoolkit/.
10. Public Health Agency of Canada. **Hand Hygiene Practices in Healthcare Settings**. Ottawa 2012 [cited May 5, 2013]; Available from: http://www.chica.org/pdf/2013_PHAC_Hand%20Hygiene-EN.pdf.
11. Public Health Agency of Canada. **Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings**. Ottawa 2012 [cited May 8, 2013]. Available from: http://www.chica.org/pdf/2013_PHAC_RPAP-EN.pdf.
12. Ontario. Provincial Infectious Diseases Advisory Committee. **Best Practices for Environmental Cleaning for Prevention and Control of Infections in All Health Care Settings.** May 2012 [cited December 2, 2012]; 1-151.Available from: http://www.oahpp.ca/resources/pidac-knowledge/best-practice-manuals/environmental-cleaning-for-prevention-and-control-of-infections.html.
13. Ontario. Provincial Infectious Diseases Advisory Committee. **Best Practices for Hand Hygiene in All Health Care Settings**. May 2008; revised 2010 [cited May 5, 2010]; 1-111.Available from: http://www.oahpp.ca/resources/pidac-knowledge/best-practice-manuals/hand-hygiene.html.
14. Ontario. Provincial Infectious Diseases Advisory Committee. **Routine Practices and Additional Precautions in All Health Care Settings**. November 2012 [cited November 25, 2012]; 1-111. Available from: http://www.oahpp.ca/resources/documents/pidac/RPAP_2012%20Revision_ENGLISH_2012-12-

24_FINAL%5B2%5D.pdf

15. British Columbia. Vancouver Island Health Authority. **Infection Prevention and Control Manual** (2013). [cited April 11, 2013]. Available from: http://www.viha.ca/NR/rdonlyres/18AA28E4-E3F1-4AE7-8A3F-E4EC3A18D5E5/0/ipcp_manual.pdf

16. Manitoba Health. **Routine Practices and Additional Precautions: Preventing the Transmission of Infection in Health Care**. April 2012 [cited April 11, 2013]. Available from: http://www.gov.mb.ca/health/publichealth/cdc/docs/ipc/rpap.pdf

17. Newfoundland/ Labrador. **Guideline for Routine Practices and Additional Precautions**. [cited March 12, 2013]. Available from: http://www.health.gov.nl.ca/health/publichealth/cdc/routine_practices_additional_precautions.pdf

18. O'Grady NP, Alexander M, Dellinger EP, Gerberding JL, Heard SO, Maki DG, et al. **Guidelines for the prevention of intravascular catheter-related infections**. Infect Control Hosp Epidemiol 2002;23(12):759-69. Available from: http://www.cdc.gov/MMWR/PREVIEW/MMWRHTML/rr5110a1.htm.

19. Sehulster L, Chinn RY. **Guidelines for environmental infection control in health-care facilities.** Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR Recomm Rep 2003;52(RR-10):1-42. Available from: http://www.cdc.gov/mmWR/preview/mmwrhtml/rr5210a1.htm.