INFECTION PREVENTION AND CONTROL AUDIT for Endoscopy

Name of Facility:

Location: _____ Date: YYYY_____ MM_____ DD_____

Time: _____hours / ____AM ____PM Manager: _____

Auditor (print): _____ Signature: _____

NOTE: This audit tool may be used by those who do Endoscopy, endoscope reprocessing or Infection Prevention and Control (IP&C), or as a joint tool by those in Endoscopy and IP&C.

Abbreviations:

ABHR	Alcohol-Based Hand Rub
AER	Automated Endoscope Reprocessor
AP	Additional Precautions
DIN	Drug Identification Number
HLD	High-Level Disinfection
MSDS	Materials Safety Data Sheet
N/A	Not Applicable
N95	NIOSH-Certified Respirator
PPE	Personal Protective Equipment
PPM	Parts Per Million
WHMIS	Workplace Hazardous Materials Information System

Audit Toolkit supported in part by Virox Technologies Inc.

Revised September 28, 2012

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.

Automated Endoscope Reprocessor (AER): Machine designed to assist with the disinfection of endoscopes. Some AERs may also assist with the cleaning prior to disinfection.

Chemical Sterilant: A chemical product that is used to achieve sterilization.

Cleaning: Physical removal of foreign (e.g., dust, soil) and organic (e.g., blood, secretions, excretions, microorganisms) materials. Cleaning physically removes microorganisms. It is accomplished with water, detergents and mechanical action. If the detergent used has microbial killing ability, microbial killing during the cleaning process may occur.

Critical Medical Devices: Medical equipment/devices that enter sterile tissues, including the vascular system (e.g. biopsy forceps, foot care equipment, dental hand pieces, etc.). Critical medical devices present a high risk of infection if the device is contaminated with any microorganisms, including bacterial spores. Reprocessing critical devices involves meticulous cleaning followed by sterilization.

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).

Detergent: An agent or formulation that can emulsify oil and suspend soil to facilitate cleaning. A detergent may contain surfactants that do not precipitate in hard water and may also contain protease enzymes (see *Enzymatic Cleaner*) and whitening agents. Low temperature detergents are specially formulated to clean in cold water.

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.

Endoscope – Semicritical: Fiberoptic or video endoscopes used in the examination of the hollow viscera. These endoscopes generally invade only semicritical spaces, although some of their components might enter tissues or other critical spaces. Examples of semicritical endoscopes are laryngoscopes, nasopharyngeal endoscopes, transesophageal probes, colonoscopes, gastroscopes, duodenoscopes, sigmoidoscopes and enteroscopes.

Enzymatic Cleaner: A cleaning agent that contains protease enzymes that break down proteins such as blood, body fluids, secretions and excretions from surfaces and medical devices. Most enzymatic cleaners also contain detergents. Enzymatic cleaners are used to loosen and dissolve organic substances prior to reprocessing.

High-Level Disinfectant: A chemical product that is used to achieve high-level disinfection.

High-Level Disinfection (HLD): The level of disinfection required when processing semicritical medical devices. High-level disinfection processes destroy vegetative bacteria, mycobacteria, fungi and enveloped (lipid) and non-enveloped (non-lipid) viruses, but not necessarily bacterial spores. Devices must be thoroughly cleaned prior to high-level disinfection.

Manufacturer's Instructions: The written directions provided by the manufacturer or distributor of a product that contain the necessary information for the safe and effective use and reprocessing of the product.

N95 Respirator: A personal protective device that is worn on the face and covers the nose and mouth to reduce the wearer's risk of inhaling airborne particles. A NIOSH-certified N95 respirator filters particles one micron in size, has 95% filter efficiency and provides a tight facial seal with less than 10% leak.

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

Qualification in Reprocessing: At minimum, a certificate indicating successful completion of a recognized training course in reprocessing.

Reprocessing: The steps performed to prepare used medical equipment/devices for use (e.g., cleaning, disinfection and sterilization).

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.

Semicritical Medical Device: Medical device that comes in contact with nonintact skin or mucous membranes but ordinarily does not penetrate them (e.g., respiratory therapy equipment, transrectal probes, specula). Reprocessing semicritical devices involves meticulous cleaning followed by, at a minimum, high-level disinfection.

Single-Use/Disposable: Medical device designated by the manufacturer for single-use only. Single-use devices must not be reprocessed except by an approved and FDA cleared 3rd party reprocessor.

Sterilization: The level of reprocessing required when processing critical medical devices. Sterilization results in the destruction of all forms of microbial life including bacteria, viruses, spores and fungi. Devices must be cleaned thoroughly before effective sterilization can take place.

Ultrasonic Washer: A machine that cleans medical devices by the cavitations produced by ultrasound waves.

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.

Endoscope Reprocessing

Reprocessing Methods (✓ check all methods used)				
Cleaning	☐	Manual Cleaning		
		Ultrasonic washer	Name:	Model:
			Name:	Model:
	☐	Automated washer	Name:	Model:
			Name:	Model:
Sterilization	☐	Automated liquid chemical	Sterilant Name: DIN #: Yes ☐ No ☐	Active Ingredient:
			Sterilant Name: DIN #: Yes ☐ No ☐	Active Ingredient:
	☐	Steam	Name:	Model:
			Name:	Model:
Chemical High Level Disinfection (HLD)	☐	Manual Disinfection	HLD Product Name: DIN #: Yes ☐ No ☐	Active Ingredient:
	☐	Automated Disinfection	HLD Product Name: DIN #: Yes ☐ No ☐	Active Ingredient:
			Name:	Model:
			Name:	Model:
			Name:	Model:

Reprocessing Staff (✓ indicate all persons involved in reprocessing)						
Performed by:	☐	Medical Assistant	☐	Nurse	☐	Other (specify):
Qualified?	☐	Yes	☐	No		Date of qualification:
Performed by:	☐	Medical Assistant	☐	Nurse	☐	Other (specify):
Qualified?	☐	Yes	☐	No		Date of qualification:
Performed by:	☐	Medical Assistant	☐	Nurse	☐	Other (specify):
Qualified?	☐	Yes	☐	No		Date of qualification:
Performed by:	☐	Medical Assistant	☐	Nurse	☐	Other (specify):
Qualified?	☐	Yes	☐	No		Date of qualification:
Performed by:	☐	Medical Assistant	☐	Nurse	☐	Other (specify):
Qualified?	☐	Yes	☐	No		Date of qualification:
Performed by:	☐	Medical Assistant	☐	Nurse	☐	Other (specify):
Qualified?	☐	Yes	☐	No		Date of qualification:

INFECTION PREVENTION AND CONTROL AUDIT for Endoscopy

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					
1.1	The department maintains written infection prevention and control (IP&C) policies and procedures and reviews them at least annually				
1.2	Written procedures and instructions are readily available to reprocessing staff				
1.3	There are policies and procedures regarding the use of single-use medical equipment/devices				
1.4	There is a policy that prohibits the purchase of endoscopes that cannot be cleaned and reprocessed according to recommended standards				
1.5	There are written, detailed device-specific procedures for the handling (including disassembly and reassembly), cleaning and disinfection/ sterilization of each type of endoscope and accessories, that follow the manufacturer's instructions				
1.6	There are written procedures and manufacturer's instructions for the use of automated endoscope reprocessors (AERs), sterilizers or other equipment used in reprocessing				
1.7	There are policies and procedures for Routine Practices and Additional Precautions that include the use of personal protective equipment (PPE)				
1.8	There is a policy and procedure for quality monitoring and documentation				
1.9	There is a policy and procedure for the recall of improperly reprocessed equipment that includes notification of IP&C, assessment of patient risk and notification of patients, other facilities and/or regulatory bodies, if indicated				
1.10	There is a policy that requires scheduled maintenance of equipment by qualified individuals, with written documentation that this has occurred				
2.0 Education and Training					
2.1	The health care setting has access to infection prevention and control expertise				
2.2	The health care setting has access to an occupational health and safety program				

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Element		Compliance			Deficiency Noted
		Yes	No	N/A	
	Staff receive annual infection prevention and control (IP&C) education that includes:				
2.3	• hand hygiene with alcohol-based hand rub (ABHR) and soap and water				
2.4	• correct and consistent use of Routine Practices (RP) and Additional Precautions (AP)				
2.5	• appropriate use of personal protective equipment (PPE)				
2.6	• prevention of blood and body fluid exposure, including sharps safety and waste handling				
2.7	• management of accidental exposure to blood/ body fluids				
2.8	Staff assigned to reprocess endoscopes have completed a recognized qualification/certificate course, or are certified by an accredited body, in reprocessing				
2.9	All staff training and education is documented				
2.10	All staff training and education is evaluated				
2.11	There is additional training with documented competency when new endoscope or AER models are introduced				
2.12	Competency testing of personnel who reprocess endoscopes is performed at least annually and documented				
3.0 Physical Space					
3.1	There is a one-way work flow from dirty to clean to prevent cross-contamination				
3.2	Engineering controls are in place for performing bronchoscopy under negative pressure, are monitored on a regular basis and results are documented				
3.3	There is adequate space for the storage and holding of clean and soiled materials that is separate from other activities and controlled to prohibit public contact				
3.4	There is a dedicated processing room(s) for cleaning and decontaminating instruments that is/are physically separated from clean areas, client/patient/resident care areas and procedure rooms (*see Appendix*)				
3.5	Processing/decontamination room(s) is/are provided with utility sink(s) appropriate to the size and type of endoscope used, the volume of work and method of decontamination used				

Element		Compliance			Deficiency Noted
		Yes	No	N/A	
3.6	Processing/decontamination room(s) has a dedicated hand washing sink with hands-free controls				
3.7	PPE is available and readily accessible in appropriate sizes at point of care				
3.8	There is sufficient cleanable, non-porous counter space to handle the volume of work				
3.9	There is space and utility connections for AER(s), if used				
3.10	The reprocessing area has engineering controls to ensure good air quality, specifically: • air-exchange equipment (e.g., ventilation system, exhaust hoods) is in place to minimize the exposure of all persons to potentially toxic vapours				
3.11	• there is documented, regular maintenance of the air-exchange equipment				
3.12	• chemical products are maintained in closed, covered, labelled containers at all times				
3.13	There is a clean equipment area with well-ventilated storage cabinets that allow endoscopes to hang vertically without touching the bottom of the cabinet				
4.0 Cleaning Procedures					
4.1	The endoscopy suite is cleaned at least once daily and additionally as required				
4.2	The treatment area is cleaned between clients/patients/residents				
4.3	Single-use items are not reprocessed				
4.4	Cleaning and disinfecting products are labelled according to WHMIS requirements				
4.5	Materials Safety Data Sheets (MSDS) for cleaning/disinfecting products are readily available				
4.6	Chemical products containing a disinfectant have a drug identification number (DIN) from Health Canada				
4.7	Immediately following completion of the endoscopy procedure: ○ all endoscope channels are flushed with enzymatic detergent or water, according to manufacturer's instructions				
4.8	○ the exterior is wiped with damp cloth				

Element		Compliance			Deficiency Noted
		Yes	No	N/A	
4.9	○ the endoscope and accessories are placed in a covered, leak proof container and transported to the designated decontamination area				
4.10	The following steps are included in the cleaning procedure: • the manufacturer's recommendations for cleaning and cleaning products are followed				
4.11	• a leak test is performed after each use, prior to cleaning, according to the manufacturer's instructions				
4.12	• an endoscope that fails the dry leak test does not undergo the immersion leak test and is sent for repair				
4.13	• all immersible endoscope components are soaked and manually cleaned with water and a recommended cleaning agent prior to automated or further manual disinfection or sterilization				
4.14	• endoscope components (e.g., air/water and suction valves) are disconnected and disassembled as far as possible and completely immersed in enzymatic cleaner				
4.15	• external surfaces of the endoscope and accessories are cleaned using a soft, lint-free cloth, sponge or brush				
4.16	• all channels and lumens of the endoscope are flushed and brushed (where appropriate) while submerged to remove debris and minimize aerosols				
4.17	• brushes used for cleaning lumens are: ○ of an appropriate size				
4.18	○ inspected before and after use				
4.19	○ discarded or cleaned, high-level disinfected and dried following use				
4.20	• the endoscope and all components are thoroughly rinsed with clean, fresh tap water prior to disinfection/sterilization and excess rinse water is removed from the channels by purging with forced air				
4.21	• damaged endoscopes/accessories are identified and immediately removed from service				
4.22	• enzymatic cleaner is discarded after each use and sink is cleaned				

Element		Compliance			Deficiency Noted
		Yes	No	N/A	
4.23	• non-disposable cleaning items are discarded if worn or damaged				
4.24	• disposable cleaning items are discarded				
4.25	• nondisposable cleaning items are thoroughly cleaned and high-level disinfected/sterilized between uses				
4.26	Single-use endoscopic accessories are discarded after each use				
4.27	Reusable semicritical endoscopic accessories are cleaned (e.g., in an ultrasonic washer), then receive high-level disinfection (HLD) according to manufacturer's instructions				
4.28	Reusable critical endoscopic accessories (e.g., biopsy forceps, cytology brushes, papillatomes) are cleaned, then sterilized according to the manufacturer's instructions				
4.29	Reprocessing staff wear PPE as required during endoscope reprocessing (e.g., gloves, facial protection, gown)				
5.0 High-Level Disinfection (HLD)					
5.1	Semicritical endoscopes (including bronchoscopes and cystoscopes) receive, at minimum, high-level disinfection				
	The following steps are included in the disinfection/sterilization procedure:				
5.2	• the disinfectant/chemical sterilant is compatible with the endoscope				
5.3	• if a high-level disinfectant is used, the minimum effective concentration of the disinfectant is monitored before each use with test strips available from the disinfectant product manufacturer				
5.4	• high-level disinfectant test strips specific to the product are checked for efficacy when each bottle is opened				
5.5	• high-level disinfectant test strip bottles are dated when opened and discarded as per the manufacturer's instructions				
5.6	• a written log of high-level disinfectant concentration monitoring is maintained				
5.7	• when high-level disinfectants are opened, the container is dated and the disinfectant is not used past the expiry date or date indicated by the manufacturer				

Element		Compliance			Deficiency Noted
		Yes	No	N/A	
5.8	• the manufacturer's directions are followed regarding the disinfectant's ambient temperature and duration of contact (e.g., 2% glutaraldehyde = 20 minutes at 20°C)				
5.9	• the endoscope/endoscope components are completely immersed in the disinfectant/chemical sterilant and all channels are perfused				
5.10	• following high-level disinfection: ○ endoscope is rinsed and channels are flushed with bacteria-free water (preferably sterile water)				
5.11	○ if tap water is used for the final rinse, endoscope channels are flushed with 5 to 10 mls. of 70-90% ethyl or isopropyl alcohol				
5.12	○ all channels are dried with filtered, medical air				
5.13	The water bottle and its connecting tube, used for cleaning the endoscope lens and irrigation during the procedure, is sterilized at least daily				
5.14	The water bottle is filled with sterile water				
5.15	If manual disinfection is performed, the disinfectant container is kept covered during use and washed, rinsed and dried when the solution is changed				
5.16	During manual disinfection, the endoscope is completely submerged and lumens are flushed with disinfectant for the appropriate time, according to the manufacturer's instructions				
5.17	Endoscope reprocessing utilizing a chemical sterilant is performed according to the manufacturer's instructions for the endoscope and for the sterilant				
6.0 Sterilizers and Automated Endoscope Reprocessors (AER)					
6.1	The sterilizer/AER is licensed in Canada				
6.2	The AER is compatible with all endoscopes to be reprocessed in the AER				
6.3	Installation qualifications confirm that the sterilizer/AER has been installed and connected in accordance with the manufacturer's specifications				
6.4	Operational qualifications verify that the sterilizer/AER meets the manufacturer's operating specifications and is consistently sterilizing/high-level disinfecting the equipment				

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Element		Compliance			Deficiency Noted
		Yes	No	N/A	
6.5	Performance qualifications confirm the sterilizer/AER performs consistently and produces the expected results when routinely operated				
6.6	If an AER is used, the following are included in the procedure: • the manufacturer's instructions for use of the AER are followed				
6.7	• only cleaning agents and high-level disinfectants/chemical sterilants approved by the AER manufacturer are used				
6.8	• there is written documentation that the endoscope and endoscope components to be reprocessed are compatible with the AER used				
6.9	• channel connectors and caps for both the AER and the endoscope are compatible				
6.10	• channel connectors are attached to the AER according to the AER and endoscope manufacturer's instructions				
6.11	• after each use, brushes and instruments used to clean the endoscope are meticulously cleaned, then placed in the AER for disinfection				
6.12	• the AER is not opened or stopped once started				
6.13	• If a single-use disinfectant is used, it should be completely drained between cycles				
6.14	There is a process to routinely review alerts, advisories and the scientific literature for reports of AER deficiencies				
6.15	AER process indicators are monitored for each run and results are recorded in a logbook that includes identification of endoscopic equipment processed (*see Record-Keeping,below*)				
6.16	There is a documented preventive maintenance program(s) for the AER(s)				
6.17	Rinse water is discarded after each use/cycle				
6.18	Following sterilization, all channels are dried with filtered, medical air				

Element		Compliance			Deficiency Noted
		Yes	No	N/A	
7.0 Storage of Endoscopes					
7.1	All endoscopes must be dry before being placed in storage				
	Storage procedures include the following:				
7.2	• reprocessing date is identified for each endoscope				
7.3	• caps, valves and other detachable components are removed during storage and reassembled just before use				
7.4	• detachable components are stored close to the endoscope in a manner that minimizes contamination				
7.5	• after HLD, endoscopes are stored by hanging vertically in a well-ventilated area in a manner that minimizes contamination or damage				
7.6	• sterile endoscopes are stored in their sterilization containers				
7.7	• endoscopes are prevented from coiling or touching the floor or bottom of the cabinet while hanging				
	• endoscope storage cabinets are:				
7.8	○ constructed of non-porous, cleanable material				
7.9	○ ventilated (ideally, HEPA-filtered)				
7.10	○ cleaned and disinfected at least weekly				
7.11	Colonoscopes are reprocessed if not used within seven days				
8.0 Endoscope Transport					
8.1	Endoscopes are transported in a lidded, leak proof container that protects the endoscope from damage				
8.2	Transport containers used to carry contaminated endoscopes are cleaned and disinfected after each use				
8.3	There is a system in place to differentiate transport containers used for clean and contaminated endoscopes (e.g., colour-coding)				
8.4	If the same container is used for clean and contaminated endoscopes, it is clearly labelled when a contaminated endoscope is being transported				
8.5	Carrying cases are only used to transport endoscopes and are not used for storage				

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	Element	Compliance			Deficiency Noted
		Yes	No	N/A	
9.0	**Record-Keeping**				
	For each procedure, the following are documented:				
9.1	• patient's name and record number				
9.2	• date and time of the procedure				
9.3	• type of procedure				
9.4	• name of endoscopist				
9.5	• serial number or other identifier of both the endoscope and the sterilizer/AER				
	A record is kept of each sterilization/HLD cycle, including:				
9.6	• the load control label which includes the sterilizer/AER number, load number and date of sterilization/HLD				
9.7	• recording chart or printout of the physical parameters of the sterilization/HLD cycle				
9.8	• load contents				
9.9	• person responsible for the sterilization/HLD cycle				
9.10	A log is kept of chemical indicator monitoring results				
9.11	A log is kept of all maintenance and interventions associated with a positive chemical indicator				
9.12	The endoscope number is recorded in the client/patient/resident record				
9.13	Records are retained according to the policy of the health care setting				
10.0	**Occupational Health and Safety**				
10.1	Staff have been offered hepatitis B immunization				
10.2	Staff have received education in the prevention of transmission of blood-borne pathogens (e.g., hepatitis B) and the management of body fluid exposures				
10.3	An N95 respirator is worn by all staff present for bronchoscopy, even if the room is under negative pressure				

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:

Total number of 'yes'
_____ x 100 = % compliance (compliance score)

Total number of 'yes' and 'no'

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:

Appendix – Sample Reprocessing Area Set-up

All Areas: Alcohol-based Hand Rub, Hand Wash Sink, Liquid Soap, Paper Towels (in dispensers)

DIRTY AREA*	CLEAN AREA*	CLEANEST AREA*
Decontamination, Disassembly, Cleaning and Rinsing	Inspection, Drying, Reassembly and Packaging	High-Level Disinfection (HLD), Sterilization and Storage

DIRECTION OF WORK FLOW: WORK PROGRESSES FROM "DIRTY" TO "CLEAN" TO "CLEANEST"

Ultrasonic Cleaner	"Dirty" Sink	Washer-disinfector	Clean Drying and Inspection Area/ Counter		Sterilization	
Sharps Container		Hand Hygiene Station	Clean Supplies Storage		High-Level Disinfection (HLD) (Thermal / Chemical)	
Decontamination, disassembly, cleaning PROCEDURE MANUAL			Inspection, reassembly, packaging PROCEDURE MANUAL		Sterilization / HLD PROCEDURE MANUAL	Quality Monitoring

SUPPLIES:

- Covered containers for contaminated equipment transport
- PPE (gowns, masks, eye protection, hair covers, shoe covers, gloves)
- Enzymatic/ detergent solutions
- Disposable brushes, pipe cleaners etc.
- Sink(s)
- Filtered or distilled water
- Hand wash sink, hand soap

SUPPLIES:

- Clean counter/ work space
- Clean work attire, hair covering
- Lint-free drying cloths
- Sterilization pouches/ wraps/ containers (all required sizes)
- Chemical indicators
- Indicator tape
- Approved marking pens
- Medical air for drying

SUPPLIES:

- PPE (gowns, gloves, masks, eye protection)
- Approved HLD
- HLD testing strips
- Biological indicators
- Process challenge devices
- Bowie-Dick air removal test
- Separate storage area for sterile/ clean equipment

All Areas: Garbage and laundry containers by door and approved environmental cleaning/disinfecting agents and equipment readily available

**** NOTE: This sample layout can be adjusted to fit into one, two or more room locations based on space availability***

IDEALLY, high-level disinfection and sterilization are done in different areas/rooms.

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Provincial Resources:
Best Practices and Guidelines developed by provinces have also been used as resources for this audit tool. These may be found at: http://www.chica.org/links_evidence_guidelines.php#prov.