PROFESSIONAL PRACTICE GUIDELINES AND POLICY STATEMENTS FOR CANADIAN SONOGRAPHY
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INTRODUCTION:

Sonography Canada is the single national voice for Canadian sonographers. Created on January 1st, 2014 from the amalgamation of its predecessor organizations the Canadian Society of Diagnostic Medical Sonographers (CSDMS) and the Canadian Association of Registered Diagnostic Ultrasound Professionals (CARDUP), the objectives of Sonography Canada are to:

- Foster excellence in patient care and professional interaction:
- Promote the highest level of professional standards of practice for sonographers in Canada; and
- Develop and deliver Canadian entry-to-practice examinations and to provide the national registry for Canadian credentialed sonographers.

The following professional practice guidelines and policy statements were originally published by CSDMS in 2011. They have been revised as of the current publication date only with respect to the context of Sonography Canada which now provides both the professional practice and entry-to-practice credentialing under a single national entity.

DEFINITION OF THE PROFESSION:

Diagnostic medical sonography in Canada is a diverse and dynamic profession. Sonographers are active in many areas of healthcare, with credentials available in general, cardiac and vascular sonography. Credentialing in Canada is based on clinical competency and knowledge-based exams.

Sonographers are an integral part of the healthcare team, playing a critical role by providing key information that facilitates diagnosis and patient management. The quality of an ultrasound study is highly dependent on the skill of the sonographer. In order to perform a thorough ultrasound, the sonographer must adapt their study in response to their sonographic findings.

Sonographers bring together an important combination of skills, including technical competency, decision-making and critical thinking. The sonographer must have an educational background that is strong in ultrasound physics, anatomy, physiology and pathology. They must analyze data, make judgements and differentiate normal from abnormal based on real-time physiologic information as well as effectively communicate with patients and other members of the healthcare team.

The final diagnostic report relies on information compiled by the sonographer concerning patient history, clinical symptoms and sonographic findings.

Professional certification is considered the standard of practice in Canadian sonography. Individuals who are not yet certified should reference the Scope of Practice as a professional model and strive to become Sonography Canada certified.

SONOGRAPHY CANADA

Sonography Canada is the national voice for diagnostic medical sonographers in Canada. A coalition of sonographers, physicians and students, Sonography Canada strives to advance the profession and further define the role of sonographers in the Canadian healthcare system.

Sonography Canada gives sonography a powerful, unified voice representing the profession to other organizations, government and the wider community.
SONOGRAPHER QUALIFICATIONS

Sonography Canada recommends the following:

- Successful completion of a Canadian Medical Association (CMA) accredited diagnostic medical sonography educational program. The recognized Canadian entry-to-practice standards are described in the National Competency Profiles (NCP). The NCP provides the foundation for curriculum development in Canada’s accredited sonography programs.
- Registration with Sonography Canada as a Generalist, Cardiac, and/or Vascular sonographer through the completion of Sonography Canada credentialing examinations and Canadian Clinical Skills Assessment

It is strongly recommended that sonographers only perform examinations in the specialties for which they have received academic and clinical training and in which they are registered or eligible for registration.

SONOGRAPHY CANADA CREDENTIALS:

1. **CRGS® – Canadian Registered General Sonographer**
   The holders of this credential would be qualified in general sonography including abdominal, superficial structures, obstetrics, gynecology, carotid and lower extremity veins.

2. **CRCS® – Canadian Registered Cardiac Sonographer**
   The holders of this credential would be qualified in adult echocardiography.

3. **CRVS® – Canadian Registered Vascular Sonographer**
   The holders of this credential would be qualified in vascular sonography.

PROFESSIONAL PRACTICE GUIDELINES

These standards are designed to reflect behaviour and performance levels expected in clinical practice for the Diagnostic Medical Sonographers and are based on the National Competency Profiles (NCP’s) for Diagnostic Medical Sonography as developed by Sonography Canada. The core competencies describe the principles and skills that are common to all sonographic specialties within the diagnostic medical sonography profession. Individual specialties or subspecialties may adopt competencies that extend or refine these core competencies and better reflect the day-to-day practice of these specialties. Certification is considered the national standard of practice in Canadian medical sonography.

The national practice standards for Canadian medical sonography are detailed in the *National Competency Profiles (NCP)* Version 5.0, April 2014. The NCP’s are available online on the Sonography Canada website and form the foundation of both the Standards of Practice and the Certification processes in Canada.
PROFESSIONAL LIABILITY INSURANCE COVERAGE STATEMENT

It is strongly recommended that sonographers maintain individual professional liability insurance. The liability insurance available to sonographers through Sonography Canada provides coverage for all professional activities described within the Scope of Practice for Canadian sonography.

Sonography Canada members performing ultrasound for non-diagnostic purposes and/or entertainment should be aware that liability insurance does not cover these activities.

PROTOCOL GUIDELINES FOR ULTRASOUND EXAMINATIONS

One of the important mandates of Sonography Canada is to work closely with other national and international healthcare organizations to develop and promote best practices in all specialty areas of diagnostic medical sonography.

It is the recommendation of Sonography Canada that each ultrasound department should compile a complete set of examination protocols for procedures carried out in their facility. The following guidelines published by the international diagnostic medical sonography community and endorsed by Sonography Canada can be used in the development of this resource.

The Society of Obstetricians and Gynaecologists of Canada (SOGC) http://www.sogc.org/clinical-practice-guidelines/

The American Institute of Ultrasound in Medicine (AIUM) http://www.aium.org/resources/guidelines/documentation.pdf


The Intersocietal Commission for the Accreditation of Echocardiography Laboratories (ICAEL) http://www.intersocietal.org/echo/main/echo_standards.htm

CONSENT FOR ULTRASOUND PROCEDURES

Obtaining informed consent prior to beginning any ultrasound procedure is part of Sonography Canada’s National Competency Profile and Scope of Practice of Sonographers. The elements of informed consent are defined in the Health Care Consent Act, written in 1996 and amended in 2004:

Elements of Consent:

- Person must have capacity to give consent.
- Consent must relate to procedure.
- Consent must be informed.
- Consent must be given voluntarily.
- Consent must not be obtained through misrepresentation or fraud.

Informed Consent

Consent is informed if:

- Patient understood information on elements of consent
- A reasonable person would consider they had enough information
- The patient received responses to requests for additional information

Consent can be given verbally. The need for written consent is dependent upon the type of procedure and the policies of the facility.
USE OF ULTRASOUND FOR ENTERTAINMENT OR NON-DIAGNOSTIC PURPOSES

Sonography Canada defines diagnostic medical ultrasound as a medical diagnostic investigation procedure that uses high frequency sound waves (ultrasound) to interrogate organs, tissues or blood flow inside the body and produce dynamic visual images. The interrogation and interpretation of the images are used to formulate a diagnosis. Diagnostic medical ultrasound is a procedure that is requested by a physician, performed by a sonographer and interpreted and reported by a physician with expertise in the field. The areas and structures of the body that can be examined using ultrasound are vast and include the heart, many of the abdominal, pelvic and reproductive organs, arteries and veins, muscles and tendons as well as developing fetuses.

When performed on a fetus, diagnostic ultrasound is used to determine fetal well-being through the acquisition of a series of specific images which document and evaluate the internal and external anatomy of the fetus and provide detailed measurements of certain structures. When performed by a registered sonographer, it is a valuable tool for dating a pregnancy, ensuring fetal health and appropriate growth, and assessing fetal development. It is central in assisting healthcare professionals provide optimal care for the mother and her fetus.

Ultrasound has been found to be relatively safe when performed by a qualified sonographer under the directive of a physician and with consideration to prudent use and limited exposure. Sonography Canada endorses Health Canada’s position statement which recommends that diagnostic fetal ultrasound be done only when the expected medical benefits outweigh any foreseeable risks. According to Health Canada the ALARA (as low as reasonably achievable) principle should be used to reduce unnecessary, potentially hazardous exposure to individuals.

In contrast to this justified form of assessment, ultrasound for entertainment is simply an elaborate version of a portrait. For a variable fee, the surface of the fetus is skinned over and clients are provided with keepsake images or a DVD of their fetus.

There are no measurements taken during this exam, no morphological assessment performed and no dictated diagnostic report of findings. Essentially there are no diagnostic benefits to the exam and uninformed parents may be falsely reassured that the beautiful portrait indicates a normal fetus. Entertainment ultrasound facilities may operate outside of medical guidelines and without any controls, which may result in a lack of technical safeguards, operator expertise or governance of technical competency. These facilities do not comply with the ALARA principle which could result in increased fetal exposures.

Sonography Canada does not support persons or facilities that participate in ultrasound for entertainment activities. Liability insurance purchased through the Sonography Canada group insurance plan does not cover any activities carried out for entertainment ultrasound purposes.

Other leaders in Canadian medicine support our statement:

In 2005, the SOGC (Society of Obstetrics and Gynaecologists of Canada) published an article entitled “Obstetrical Ultrasound Biological Effects and Safety”, and their conclusion was that “the theoretical risk of adverse bio-effects even from standard 2D obstetrical ultrasound makes it hard to justify its use for non-medical reasons such as sex-determination, making non-medical photos or video, or for commercial purpose.” The SOGC recommends that ultrasound be used prudently and that energy exposure be limited to the minimum that is medically necessary. The SOGC further recommends a complete ban on the non-medical use of fetal ultrasound and encourages government to join with society to find appropriate means to deal with this public health issue.

The CAR (Canadian Association of Radiologists) makes a similar statement: “The CAR strongly opposes the use of diagnostic ultrasound equipment for non-medical purposes and considers the use of medical ultrasound for entertainment to be a misuse of the technology especially if fetal subjects are involved.”

Sonography Canada Board of Directors officially endorses the AIUM, SDMS and CAR statements on the use of ultrasound for non-diagnostic purposes.
ROLE OF THE SONOGRAPHER AND TECHNICAL IMPRESSIONS

The role of the sonographer is to perform the ultrasound scan and to document observations. The sonographer’s written technical impressions are intended as a form of communication between the sonographer and the reporting physician. These observations must be reviewed and subsequently reported by the reporting physician. Issuing of a final report/diagnosis represents the practice of medicine and is therefore the domain of the reporting physician.

SUPERVISION

The reporting physician must be available for consultation, via telephone or through the Picture Archiving and Communication System (PACS). Sonographers should not be left in a position where their technical impressions are likely to be taken as a diagnosis in the absence of a timely response by a reporting physician.

SONOGRAPHER’S OBSERVATIONS

Written technical impressions should follow a detailed format appropriate for the examination, with a clearly visible disclaimer stating that the technical impressions are preliminary and that a final report by the reporting physician will follow. The technical impressions should not include interpretations or differential diagnoses.

PICTURE ARCHIVING AND COMMUNICATION SYSTEM (PACS)

Sonographer’s technical impressions that are stored electronically through PACS must not be changed. Any conclusions, comments or diagnoses of the reporting physician may be appended to the sonographer’s technical impressions provided that these additional comments are dated and clearly attributed to the reporting physician.

It is highly desirable that PACS systems be installed in such a manner as to ensure that sonographer’s technical impressions are recorded as committal data entries. In addition, it is highly desirable that PACS installations be configured such that the sonographer’s technical impressions are available only to the reporting physician.

GENDER DETERMINATION AND DISCLOSURE

Sonography Canada supports the Society of Obstetricians and Gynaecologists of Canada’s (SOGC’s) clinical practice guideline. Content of a Complete Routine Second Trimester Obstetrical Ultrasound Examination and Report.


Please see the following SOGC policy statements for guidance concerning gender determination and disclosure.

Fetal Sex Determination and Disclosure:


Ultrasound for the Sole Purpose of Gender Determination.

Sonography Canada’s Professional Liability Insurance Coverage in Gender Determination:

If there is documented proof of the fetal sex (image of genitalia) recorded and presented in the preliminary findings, then the sonographer is covered under Sonography Canada’s Professional Liability Insurance Policy.

It remains the responsibility of the reporting physician to diagnose fetal gender based on direct observation or by assessment of diagnostic images, and to report it to the referring physician.
SAFETY AND BIOEFFECTS

While ultrasound exposure has not been proven to be cumulative in the adult or fetus to this date, Sonography Canada recommends that sonographers adhere to the general principle of ALARA as a practice standard. This is the use of minimum acoustic power output and minimum exposure time to obtain the necessary clinical information.

The following statements have been provided by AIUM and are endorsed by Sonography Canada. Please reference: http://www.aium.org/resources/statements.aspx for additional resources.

AIUM STATEMENT OF IN VITRO BIOEFFECTS

It is often difficult to evaluate reports of ultrasonically induced in vitro biological effects with respect to their clinical significance. The predominate physical and biological interactions and mechanisms involved in an in vitro effect may not pertain to an in vivo situation. Nevertheless, in vitro effect must be regarded as a real biological effect.

Results from the in vitro experiments suggest new endpoints and serve as a basis for design of in vivo experiments. In vitro studies provide the capability to control experimental variables and thus offer a means to explore and evaluate specific mechanisms. Although they may have limited applicability to in vivo biological effects, such studies can disclose fundamental intercellular or intracellular interactions.

While it is valid for authors to place their results in context and to suggest further relevant investigations, reports which do more than that should be viewed with caution.

AIUM STATEMENT ON CLINICAL SAFETY

Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound in Medicine herein addresses the clinical safety of such use:

No confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh any risks that may be present.

AIUM STATEMENT OF SAFETY IN TRAINING AND RESEARCH

Diagnostic ultrasound has been in use since the late 1950s. There are no confirmed adverse biological effects on patients resulting from this usage. Although no hazard has been identified that would preclude the prudent and conservative use of diagnostic ultrasound in education and research, experience from normal diagnostic practice may or may not be relevant to extended exposure times and altered exposure conditions. It is therefore considered appropriate to make the following recommendation:

In those special situations in which examinations are to be carried out for purposes other than direct medical benefit to the individual being examined, the subject should be informed of the anticipated exposure conditions, and of how these compare with conditions for normal diagnostic practice.
ULTRASOUND GEL BOTTLE RECOMMENDATIONS

These recommendations have been provided by Health Canada, Health Products and Food Branch Inspectorate:

Sterile Gels

- Sterile gels must be used for all invasive procedures that pass a device through tissue (e.g., needle aspiration, needle localization, and tissue biopsy) for all procedures involving sterile environment or non-intact skin, and on neonates.
- Sterile gels should be used for procedures performed on intact mucous membranes (e.g., oesophageal, gastric, rectal or vaginal) and in patients with immunodeficiencies or on immunosuppressive therapy.
- Aseptic technique should be followed when using sterile gels.

Non-sterile Gels

- Single use containers are recommended for non-sterile gels.
- If reusable containers are used, they must be emptied, washed in hot soapy water or hospital-grade disinfectant rinsed thoroughly and dried prior to refilling. Bottles should not be "topped up". Cracked reusable bottles should be discarded.
- When filling a reusable container, ensure that the large bulk container has not passed the expiration date.
- Bottles should be filled using a dispensing device on the large bulk container, not by inserting the tip of the refillable bottle into the bulk container to aspirate the contents.
- Bottles should be refilled as close as possible to the time of use.
- When opening a new gel bottle or a newly refilled bottle, date the bottle and discard unused gel after one month.
- Tips of containers or dispensing nozzles must not come in direct contact with a patient, staff, instrumentation or the environment. Gel should be dispensed into a medicine cup or on a clean disposable cloth and then to the patient’s skin.
- If a medicine cup or a disposable cloth is not used, wipe the dispensing nozzle clean with an alcohol swab and wipe the outside of the container with a disinfectant between patients.
- If a gel is being used on a patient who is in droplet or contact isolation, use a single-use gel container, or leave the reusable container in the room if repeat procedures are necessary and discard the gel when isolation of the patient is discontinued.
- For infrequent procedures, use small or single-use containers.

Warming of Gel

- Warmed gel should only be used when required.
- Bottles should be removed from the warmer as soon as possible and dried immediately.
- Gel warmers must be cleaned weekly with low level hospital-approved disinfectant, and immediately if the warmer becomes soiled.

Storage of Ultrasound and Medical Gels

- Products must be stored in areas that are dry and protected from potential sources of contamination, such as dust, moisture, insects, rodents, etc.
- If evidence of contamination is present or package integrity has been breached, the product must be discarded.
- Products should be rotated when restocking takes place.
REPROCESSING POLICY

Endocavity Transducers

Preparation and Cleaning

• Sonographers and sonologists should wear gloves and protective eyewear as per MSDS guidelines and CSA (Figure 1; CSA, 2008). Probe covers should be used on all endocavity probes. Non-latex condoms/ gloves should be available for latex sensitive patients.

• Sterile gel or bacteriostatic gels should be used to lubricate the exterior of the probe covers. (Health Canada, 2004)

• Probe covers should be removed using gloves and disposed of immediately. Care must be taken not to contaminate the probe with the patient's secretions.

• Following each exam, the transducer should be disconnected from the system and the gel should be wiped off the transducer and cable with a soft, dry wipe.

• Avoid cross contamination within the transducer cleaning area, reprocessing room or station; keep flow one way, from dirty to clean (Figure 3; CSA, 2008). Probes should be soaked in an enzymatic detergent prior to the high-level disinfection process. If necessary, a medical instrument brush should be used to remove any debris or blood products. (Figure 4; CSA, 2008)

• The entire cord should be wiped thoroughly with a manufacturer-approved disinfectant. (Figure 5; CSA, 2008)

• The probe must be soaked in a high-level disinfectant solution as per the manufacturer’s guidelines. (Figure 6; CSA, 2008) Care must be taken to ensure that the solution does not enter the device or connector.

• The probe must be thoroughly rinsed with potable water after the use of a high-level disinfection solution. Do not allow any solutions to air dry on the transducer. (Figure 7; CSA, 2008)

• The highly disinfected probe should have a “HIGH LEVEL DISINFECTION” label placed on it and be kept in an area labelled as a high-level disinfection area. (CSA, 2008)

• Perform hand hygiene. (Figure 8; CSA, 2008)

• After high-level disinfecting of the probe, the sonographer should document the reprocessing procedure with the patients ID number, probe serial number, soaking time, date, and the name of the person who cleaned the probe. (Figure 9; CSA, 2008)

• All high-level disinfection solutions should be tested on a daily basis using test strips. (Figure 10; CSA, 2008)

• A neutralizing substance may be used to neutralize the disinfectant before it is poured down the drain.

• There should be a log book to record all high-level disinfection solution changes (Figure 11; CSA, 2008)

• Some type of fume hood should be available for venting/absorbing the high-level disinfection gases. (Figure 12; CSA, 2008)

• Protective equipment should be used as per MSDS and manufacturer guidelines. (Figure 13; CSA, 2008)

• A spill kit should be available for department use. (Figure 14; CSA, 2008)

• Endocavity probes should be examined regularly for any damage, and leak testing should be performed annually. If damage is evident, discontinue use of the probe and contact the manufacturer. (Figure 15; CSA, 2008)

• A review and update of the reprocessing techniques should be done on an annual basis. (Figure 16; CSA, 2008)

• do not use any alcohol, bleach, ammonium chloride or hydrogen peroxide on TEE probes.

• All other transducers and cords should be wiped clean of gel with a dry wipe and then a disinfecting wipe after each examination.

• All other transducers performing biopsies should use a disposable sterile transducer cover, and aseptic technique should be used.
REFERENCE

Canadian Standards Association (CSA)
Decontamination of reusable medical devices (2008)

- Figure 1: Page 17 – 6.7.1
- Figure 3: Page 5, page 14, 6.3.3 (c) (iv), page 19 – 7.1
- Figure 4: Page 30 – 10.3, page 31, 10.4, page 52 – 13.4
- Figure 5: Page 51 – 13.4
- Figure 6: Page 36 – 10.6, page 37 – 10.7, page 38 – 10.8, page 42 – 10.8.5
- Figure 7: Page 26 – 7.6.7, 7.6.8, 7.6.9, page 43 – 10.8.5.4
- Figure 8: Page 15 – 6.6.3
- Figure 9: Page 43 – 10.8.5.6, page 57 – 13.5, page 60 – 13.9.3
- Figure 10: Page 41 – 10.8.3, page 60 – 13.9.3
- Figure 11: Page 43 – 10.8.5.6, page 60 – 13.9.3
- Figure 12: Page 21 – 7.3, page 51 – 13.3
- Figure 13: Page 15 – 6.6.1, page 16 – 6.7.1
- Figure 14: Page 18 – 6.8
- Figure 15: Page 44 – 10.11, page 52 – 13.4.4
- Figure 16: Page 9 – 4.5.7, page 49 – 13, page 50 – 13.2

Health Canada:

Health Canada:

Panel Recommendations:

Recommendation 3: To follow established national standards and guidelines. These shall include the CSA Healthcare Technology series of standards (e.g., Z314.1 ETO, Z314.3 Steam, Z314.8 Decontamination, etc.), HC Infection Control Guidelines, and other consensus guidelines and standards of practice. ISO sterilization series should also be used as a guide.
UNIVERSAL PRECAUTIONS

All sonographers should practice Universal Precautions. Universal Precautions apply to blood, all body fluids, secretions and excretions regardless of whether or not they contain visible blood, non-intact skin and mucous membranes. Proper and appropriate cleaning and/or disinfections of transducers, cords, work surfaces and patient surfaces are important. Hand washing between cases or after contamination is imperative.

QUALITY CONTROL

The use of regular audits is recommended to ensure ongoing quality management within an ultrasound department. Audits can be an invaluable tool in assessing the functionality of a department and in helping to achieve/maintain the highest level of patient care. Possible types of audits include, but are not limited to:

1. Personnel
Show active registry status and current professional liability insurance coverage.

2. Procedures and Protocols
Review the Policy and Protocols manual to update or clarify information to enhance efficiency, productivity and level of care.

3. Quality of Patient Care
Examine patient waiting times, reporting mechanisms and review processes used to address patient communication concerning overall facility performance.

4. Safety and Bioeffects
Review equipment service records to ensure regular ongoing maintenance of equipment and timely identification of potential problems.

5. Image quality
Peer review of studies performed within the department to evaluate image quality and adherence to departmental requirements.

WORKPLACE HAZARDOUS MATERIALS INFORMATION SYSTEMS (WHMIS)

WHMIS is a national program that identifies how to safely handle any chemicals and products used in your immediate workplace. All sonographers should participate in comprehensive WHMIS training.

LATEX ALLERGIES

Patients should always be asked if they have a latex allergy/sensitivity prior to exposing them to a latex-containing product.