Independent Health Facilities

Clinical Practice Parameters and Facility Standards

Computed Tomography

THE
COLLEGE
OF
PHYSICIANS
AND
SURGEONS
OF
ONTARIO

The College of Physicians and Surgeons of Ontario

Vision Statement

The best quality care for the people of Ontario by the doctors of Ontario.

Mission Statement

The College of Physicians and Surgeons of Ontario merits the trust and respect of the public and the profession by:

1. Maintaining a rigorous and efficient regulatory process,
2. Focusing on the ongoing improvement of quality,
3. Being open and accountable,
4. Communicating clearly and effectively,
5. Promoting excellence in health care,
6. Working with others to achieve our vision.

We demand of ourselves the same exacting standards that we expect of the profession.

Goals

The vision of Council will be implemented by:

1. Advocating for quality health care in partnership with other stakeholders,
2. Integrating the roles of clinical education, evidence-based clinical practice and regulatory responsibilities to improve patient care at the individual and system level,
3. Evaluating and improving the effectiveness and efficiency of the current investigative and disciplinary processes and identifying potential alternatives,
4. Accelerating efforts to find creative ways to address physician resource needs without compromising registration standards,
5. Providing publicly accessible regulatory information about physicians
6. Engaging stakeholders in a public debate about the limits of medicine and focusing on what patients can expect from their physicians,
7. Establishing a comprehensive and effective communication plan to improve recognition of the CPSO by its stakeholders,
8. Establishing an effective and transparent governance model for the College.

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First Edition, January 2003:

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Preface

The Independent Health Facilities Act (IHFA), proclaimed in April 1990, and amended in 1996 and 1998, gives the College of Physicians and Surgeons of Ontario the primary responsibility for carrying out quality assessments in Independent Health Facilities. These out-of-hospital facilities may provide some of the following insured services:

- in diagnostic facilities: radiology, ultrasound, magnetic resonance imaging, computed tomography, nuclear medicine, pulmonary function, and sleep studies
- in treatment or surgical facilities: one or more of a variety of procedures in peripheral vascular disease, plastic surgery, obstetrics and gynaecology, dermatology, nephrology, ophthalmology, and their related anaesthetic services and perhaps other specialties.

The College of Physicians and Surgeons of Ontario has a legislative mandate under the Act to perform quality assessment and inspection functions. This responsibility, and others set out by agreement with the Ministry of Health and Long-Term Care, contribute to the College achieving its goals as stated in the College's Mission Statement. An important goal of the College is to promote activities which will improve the level of quality of care by the majority of physicians. The Independent Health Facilities program helps reach this goal by developing and implementing explicit clinical practice parameters and facility standards for the delivery of medical services in Ontario, assessing the quality of care provided to patients, and as a result, promotes continuous quality improvement.

Purpose of Clinical Practice Parameters

The Independent Health Facilities clinical practice parameters and facility standards are designed to assist physicians in their clinical decision-making by providing a framework for assessing and treating clinical conditions commonly cared for by a variety of specialties. The primary purpose of this document is to assist physicians in developing their own quality management program and act as a guide for assessing the quality of patient care provided in the facilities.

Note: The parameters and standards are not intended to either replace a physician's clinical judgement or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by certain parameters and that a particular parameter will rarely be the only appropriate approach to a patient's condition.

In developing these clinical practice parameters, the objective is to create a range of appropriate options for given clinical situations, based on the available research data and the best professional consensus. The product, therefore, should not be thought of as being "cast in stone", but rather subject to individual, clinically significant patient differences.

Role of the College of Physicians and Surgeons

At the beginning of this process, the College adopted the role of a facilitator for the development of clinical practice parameters and facility standards. Representatives of national specialty societies and sections of the Ontario Medical Association, and individuals with acknowledged skill, experience and expertise formed specialty-specific Task Forces.

The Task Force members' initial work, distributed in March 1991, was sent to the following organizations for their review and comments:

- all relevant specialty physicians in Ontario, national specialty societies and specialty sections of the Ontario Medical Association
- Ontario Chapter of the College of Family Physicians of Canada
- Canadian Medical Association
- American Medical Association
- Canadian Council on Health Facilities Accreditation (now renamed the Canadian Council on Health Services Accreditation)
- College of Nurses of Ontario

The Task Forces continue to adhere to the following principles:

- clinical practice parameters must be based on the appropriate mix of current, scientifically-reliable information from research literature, clinical experience and professional consensus.
- any parameter-setting exercise must be done exclusively from the quality perspective. That may well mean that some of the conclusions reached could add to medical care costs.
- parameters have to be flexible enough to allow for a range of appropriate options and need to take into account the variations in practice realities from urban to rural areas.
- parameters need to be developed by consensus and consultation with the profession at large.
- parameters should provide support and assistance to physicians without boxing them in with "cookbook formulas."
- parameters will need to be regularly updated based on appropriate research studies.

- parameters should reduce uncertainty for physicians and improve their clinical decision-making.
- information on practice parameters must be widely distributed to ensure that all physicians benefit from this knowledge.

Responsibilities of the College

Responsibilities of the College include:

- assessing the quality of care when requested by the Ministry. The College will maintain a roster of physicians, nurses, technologists and others to serve as inspectors and assessors as required.
- inspecting the illegal charging of facility fees by unlicensed facilities when requested by the Ministry.
- monitoring service results in facilities. The College's information system will monitor individual and facility outcome performance. This is a unique feature of the legislation, which for the first time in North America, requires facility operators to establish and maintain a system to ensure the monitoring of the results of the service or services provided in a facility.
- providing education and assisting facilities so that they may continually improve the services they provide to patients. The College will work with and assist physicians in these facilities so that they can develop their own quality management programs based on the parameters and standards, monitor facility performance by conducting quality assessments, work with facilities to continually improve patient services, assist in resolving issues and conducting reassessments as necessary.

Updating this Document

These parameters and standards are subject to periodic review, and amendments in the form of replacement pages may be issued from time to time. Such pages will be mailed automatically to all relevant independent health facilities. It is planned to issue new editions of the parameters and standards at intervals not greater than five years. The external review process will be repeated to validate the new parameters as they are developed.

Radiology Guiding Principles

Extracted from the first edition (February 1995) of Clinical Practice Parameters and Facility Standards for Diagnostic Imaging, *Appendix I: Goals and Objectives.*

A diagnostic imaging practice is a consultative physician service rendered by qualified specialists who have completed an accredited residency program in diagnostic radiology which includes using all modalities in the imaging portrayal of human morphology and physiological principles in medical diagnosis.

The elements of radiologic consultation include:

- pre-examination evaluation by a referring physician.
- a request for radiologic consultation. The requisition includes pertinent clinical findings, a working diagnosis, and signature of referring physician or other qualified professional.
- a safe patient environment in which the radiologist supervises a qualified staff whose efforts are directed at producing a radiologic examination yielding maximum diagnostic information and consistent with the least possible exposure to radiation.

Diagnostic imaging is a patient care specialty and it is an important function of the radiologist to advise referring physicians about the best sequence of examinations for resolving a clinical problem expeditiously and with the least risk and cost.

It is not possible to establish a “minimum” or “optimum” standard of care. Guiding principles and attributes for appropriate care in diagnostic imaging can be summarized as follows.

- Examinations and procedures are performed with the greatest benefit and least risk to the patient.
- Examinations and procedures are interpreted with the highest degree of competence using all available information including comparison with previous examinations and procedures.
- Examination/procedure findings and conclusions are communicated promptly and expeditiously to the referring physician.
- Referring physicians are consulted in order to select and perform only the most useful examinations/procedures.
- Flow of data including storage, retrieval, and general handling of images, diagnostic data, and reports are managed efficiently.
- Patient services provided are considerate of the human side of care as well as the purely technical component of care.

- Patient services are managed so that productivity is maintained and optimal use of available resources is assured.

These principles should constitute the basis for the evaluation of desirable and undesirable practice patterns.

Independent Health Facilities: Clinical Practice Parameters and Facility Standards: Computed Tomography

Volume 1

Facility Standards

Chapter 1 Staffing a Facility

Overview

Diagnostic imaging services are provided by qualified imaging physicians and technologists.

There is a current written plan describing the organization of the facility and its services.

There are sufficient numbers of qualified physicians, technologists, and clerical personnel available to meet the stated goals and objectives. Duties and responsibilities of all diagnostic imaging services staff are specified in job descriptions.

Staff require education in Workplace Hazardous Materials Information System (WHMIS) and this is documented.

A radiologist or designated physician with Advanced Cardiac Life Support (ACLS) certification is personally and immediately available during the administration of contrast injections.

At least one staff member with current Basic Cardiac Life Support (BCLS) certification is on site at all times during hours of scanner operation. Documentation regarding BCLS certification is maintained on site.

Qualifications of Physicians

All physicians must maintain and document current Advanced Cardiac Life Support (ACLS) certification.

Physicians performing or interpreting Computed Tomography (CT) examinations are:

- certified in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and have a certificate of registration to practice in Ontario

AND

- have demonstrated competence (6 months of CT training with 1500 reported cases) in an appropriate facility and under the full-time supervision of a radiologist fully trained in CT as per the description of a CT Director.

Appropriate training centres for radiologists seeking to obtain the required CT credentials are:

- an academic centre with a diagnostic radiology residency program

OR

- a hospital CT facility in Ontario under the supervision of the CT Director.

Note: Where training occurs at a hospital CT center not associated with a university center, the training should also include at least 160 hours of training through ACCME, RCPSC-recognized CME courses or equivalent (a full range of clinical applications of CT as well as CT physics, instrumentation, QA, and radiation safety) within 2 years prior to start of practice.

A letter signed by the CT Director attesting to the training of all CT Radiologists, including the CT Director, will be required. This letter should be kept on file at the facility.

Note: For the following, "CT Radiologist" means a radiologist satisfying the above criteria.

CT Radiologists who have not been in active practice of CT (i.e. performing less than 100 patient cases/year) or who have not actively provided CT services for two years or more but were fully trained in the past will require re-training at an appropriate CT facility as described earlier in this section. A minimum of one month of re-training at an appropriate CT facility will include reporting a minimum 300 patient cases, with an appropriate case mix, under the direct supervision of a qualified CT Director-level radiologist. A letter shall be provided from the preceptor, attesting to competence, will need to be presented to the CT Director and kept on file by the licensed facility.

All physicians attend Continuing Medical Education (CME) programs relevant to their practice, which comply with their Royal College requirements for maintenance of certification. Documentation of annual CME courses in CT-related courses must be submitted to the CT Director no later than the end of each calendar year.

CT Director/Quality Advisor

Each licensed facility has a CT Radiologist who is appointed as both the CT Director and Quality Advisor. The CT Director/Quality Advisor shall have demonstrated competence (one year of CT training) and is qualified to provide additional on-site training to the other CT radiologists in the licensed facility.

As outlined in the IHF Regulations "Every licensee shall appoint a Quality Advisor to advise the licensee with respect to the quality and standards of services provided in the independent health facility."

Every CT Director/Quality Advisor shall:

- be responsible for the development and maintenance of a procedure to ensure that only services which are indicated and medically appropriate are provided ***(see Preface: Radiology Guiding Principles)***.
- be physically present at the independent health facility on a regular basis, on average at least 8 hours per week. The CT Director or a designated CT Radiologist should be available by phone for consultation at any time when services are provided and documented.
- be the Radiation Protection Officer for the facility or designate the role according to the HARP Act.
- seek advice from other health professionals where necessary to ensure that all aspects of the services provided through the independent health facility are provided in accordance with generally accepted professional standards.
- consult with the quality advisory committee at least quarterly if the independent health facility has more than six full-time staff equivalents even if there is another quality advisor for other imaging modalities, otherwise at least semi-annually, and to document the substance of the discussion, the actions agreed upon and the completion date for any actions agreed upon.
- ensure that safe CT practice guidelines are established and maintained as current and appropriate for the facility ***(see Chapter 2, Quality Control)***.
- consult with the facility staff after any serious CT safety incidents and, as a minimum, update the CT safety guidelines on a yearly basis.
- approve and annually review all CT imaging protocols performed by the licensed facility. All requisitions will be assigned a specific protocol by a CT radiologist associated with the facility prior to the study being performed. Changes to the assigned protocol can only be modified by the CT Director or another designated CT Radiologist.

The CT Director/Quality Advisor shall advise the facility licensee and document this advice concerning the following:

- qualifications, selection and ongoing education of the professional and technical staff working in the independent health facility.
- performance of any professional or technical staff who do not have sufficient qualifications for the procedures being performed but who are being permitted to practise because of special circumstances.
- whether adequate and appropriate staffing, equipment and procedures are available to ensure patient and staff safety in the independent health facility.
- whether a physician or other practitioner should be physically present for the performance of any category of procedure.

- testing being performed on a periodic basis to ensure the accuracy and reliability of the independent health facility's equipment.
- proper design of consultation requests, performance protocols (including, where appropriate, reference values for procedures), documentation and reports used at the independent health facility.
- implementation and adherence to the facility's safe CT practice guidelines.
- facility's policies regarding the maintenance of all appropriate clinical records, including their maintenance for the required length of time.
- facility policies that are consistent with government regulations regarding the confidentiality and handling of patient information particularly if the information is being shared and stored in an electronic format.
- quality and the maintenance of the imaging equipment and the related technology for the electronic viewing, archiving, and communication of imaging information produced or in the responsible possession of the facility.
- development and maintenance of a quality assurance program for the facility.
- other such matters as deemed by the CT Director/Quality Advisor to be important to the maintenance of quality assurance practices that are consistent with those observed in hospital CT facilities as well as with quality standards and international accreditation guidelines by recognized bodies such as the Canadian Association of Radiologists and the American College of Radiologists.

Every licensee shall have a written agreement with the CT Director/ Quality Advisor requiring and authorizing the CT Director/Quality Advisor to fulfill the requirements as set out above.

Whenever the CT Director/Quality Advisor has reasonable grounds to believe the conduct of the diagnostic imaging services might jeopardize the safety of patients or the proper performance and interpretation of diagnostic imaging services and where, in the judgement of the CT Director/Quality Advisor, he or she is constrained from correcting the perceived deficiencies by actions taken or not taken by the licensee, then the CT Director/Quality Advisor reports those concerns in writing to the Director, Independent Health Facilities as required by the Regulations under the Independent Health Facilities Act.

It is understood that the sections above do not in any manner remove from the licensee or impose upon the CT Director/Quality Advisor the obligation or responsibility for operating the facility; it being understood that the CT Director/Quality Advisor's sole responsibility is to provide advice to the licensee on the matters specified.

Radiation Protection Officer (RPO)

According to the HARP Act, an RPO must be designated for the facility. This role may be assumed or designated by the CT Director/Quality Advisor.

Medical Physicist

A medical physicist has the responsibility for the initial acceptance testing of equipment and related systems/components and for implementing and overseeing quality control testing of the CT scanner. The acceptance test must be repeated on at least an annual basis and after any major hardware upgrades ***(see Chapter 2, Quality Control)***.

The medical physicist is certified in Diagnostic Radiology by the Canadian College of Physicists in Medicine, the American Board of Radiology, or the American Board of Medical Physics and has specific training and experience in CT. Training and experience includes detailed knowledge of CT physics, system components and performance, safety procedures, acceptance testing, and quality control testing.

The medical physicist acquires Continuing Medical Education (CME) credits on a yearly basis relevant to their practice that complies with their board requirements for continued certification.

Qualifications of Technologists

Medical Radiation Technologists

Medical Radiation Technologists have a current and valid certificate of registration with the College of Medical Radiation Technologists of Ontario (CMRTO).

Technologists have completed cross sectional anatomy of the brain, neck and body. Technologists have completed an injection course and are certified by a Radiologist as per facility policy. Training specific to CT is to be documented.

All technologists must maintain and document current Basic Cardiac Life Support (BCLS) certification.

Continuing Medical Education

CT Technologists attend and document their attendance at relevant continuing medical education programs, as mandated by the CMRTO or as identified by the CT Director. This documentation must be provided to the CT Director no later than at the end of the calendar year.

Charge Technologist Qualifications

The designation of a Charge Technologist is mandatory. Their qualifications must include:

- current and valid certificate of registration with the College of Medical Radiation Technologists of Ontario (CMRTO).
- certificate in BCLS with recertification yearly.

Charge Technologists have completed an injection course and are certified by a Radiologist as per facility policy. Their qualifications should also include 4 years of full-time CT experience.

Charge Technologist Responsibilities

The Charge Technologist is current with changing technical trends in CT by attending conferences, meetings, or other CME, and reading current relevant literature. Documentation of CME is maintained.

Charge Technologists are responsible for the day-to-day operation of the CT suite, including:

- training of technologists to include Quality Control, safety, injections, policies and procedures
- reporting to/advising the CT Director/Quality Advisor
- ensuring that all technologists remain current with all qualifications and CME requirements
- ensuring that all support staff receive and implement CT safety guidelines
- inputting site-specific protocols into the CT unit
- writing and updating CT policy and procedure manual on at least an annual basis
- ensuring implementation of policies and procedures
- maintaining records of equipment calibration, maintenance, and repair procedures
- maintaining copies of test observations and reports
- ensuring that safety policies and the equipment and facilities necessary for their implementation are in place and in working order

- implementing infection control measures
- maintaining all necessary facility supplies
- performing and documenting Quality Control procedures

Injection Certification

The Charge Technologist is responsible for supervising the technologists for injection certification. The CT Director/Quality Advisor certifies the technologist.

Certification includes:

- Successful completion of a certified program for the injection of contrast media.
- Review of all policies with the candidate regarding the injection of contrast media (patient consent, contraindications, contrast reaction protocol, premedication, radiologist availability, sterile technique, contrast protocols and facility standards).
- Successful performance of 20 intravenous injections under the direct supervision of the CT Charge Technologist. These will be logged and initialed by the CT Charge Technologist.
- Observation and recommendation of the candidate's competence to inject contrast media under specific conditions, by the CT Director.
- Presentation of a certificate of competence to the candidate by the Radiologist. This certificate is signed by the CT Director/Quality Advisor. This certificate is kept along with a copy of proof of certification and a copy of the course curriculum.
- Annual recertification for contrast injections at the discretion of the CT Director/Quality Advisor.

Chapter 2 Facilities, Equipment and Supplies

Overview

The facility has adequate space, equipment, and supplies for the safe and efficient performance of diagnostic imaging services.

Oral or sublingual anxiolytic medications may be administered in an IHF, but intravenous sedation or parenteral (e.g. intramuscular) sedation must be referred to a hospital. Patients who have received or taken any sedation or anxiolytics must be provided with safety instructions (i.e. should not drive home) prior to leaving the facility. **Patients under the age of 18 requiring sedation are not examined in an IHF.**

Facilities, Equipment and Supplies

Facilities have sufficient space to meet workload requirements and ensure the effective care and privacy of patients.

Appropriate safety precautions are maintained and documented against electrical, mechanical, and radiation hazards as well as against fire and explosion, so that personnel and patients are not endangered.

The thermoluminescent dosimeter (TLD) monitoring service of the Personnel Dosimetry Services of Health Canada, Bureau of Radiation and Medical Devices, is used and documented to ensure the safety of personnel. Records are posted in the facility for staff information.

For patient imaging, the CT scanner meets or exceeds the following specifications:

- New when installed in the facility and manufactured within 12 months prior to installation, with current technology, multi-detector CT scanner with at least 4 slice rotations.
- A clear upgrade pathway, defined to keep the technology current, will be implemented by the facility.
    - *In recognition of changing technology standards, machines need to be upgradeable to future state-of-the-art requirements.*
- Current dose reduction technology.
- Scan times: minimum not more than 2 seconds.
- Slice thickness: minimum not more than 2 mm.
- Interscan delay: minimum not more than 4 seconds.

- Power Injector- the injector shall be pressure limited and have adjustable rate and volume.
- Must pass all quality assurance tests at the time of installation as outlined by organizations such as the American Association of Physicists in Medicine (AAPM) or the American College of Radiology (ACR).

Note: The Ministry of Health and Long-Term Care must give approval to install and operate a CT scanner under the Healing Arts Radiation Protection Act (HARP Act) R.S.O. 1990, c.H.2 clauses 23(2) (a) and (b). Under section 3 of the HARP Act, the written approval of the Director of X-ray Safety is required for CT equipment to be installed.

Safety Concerns and Resuscitation Equipment

Patient monitoring equipment and facilities for cardiopulmonary resuscitation including vital signs monitoring, support equipment, and an emergency crash cart are immediately available. Radiologists, technologists, and staff members are able to assist with procedures, patient monitoring, and patient support. A written policy is in place for dealing with emergency procedures such as cardiopulmonary arrest.

The facility has alternate materials available for patients with known or suspected latex allergies.

Contrast-enhanced studies require the presence of a physician who is trained and experienced in the recognition and management of adverse effects of these agents (ACLS) and other life threatening events. If this physician is not the CT Radiologist, then he/she must also have appropriate training and experience in CT safety. Technologists are trained in resuscitation (BCLS). The IHF is very different from hospital-based CT units where experienced teams manage codes of differing severity, therefore the IHF must have an emergency protocol in place to deal with these types of emergencies.

As paediatric patients receive contrast, specific pediatric doses/drugs and paediatric resuscitation equipment are clearly labelled and colour coded for age groups.

Facility monitoring equipment and procedures are appropriate to the patient mix and procedures are documented.

When seated at the console, CT technologist should have a direct view of the patient. If this is not the case, then a closed television camera/monitor is installed to provide this view of the patient.

Requirements of the HARP Act and regulations must be fulfilled.

Facilities provide a means of moving patients in difficulty to an adjacent area, which is equipped to handle any adverse reactions up to and including respiratory and cardiac arrest.

Major Resuscitative and Monitoring Equipment Required

Excellent guidelines, such as the Manual on Contrast Media (*Contrast Media 4th Edition American College of Radiology 1998*) are published, however, it is recommended that for each site a plan of action and formulary be developed in consultation with local anaesthetists and internal medicine specialists responsible for their hospital arrest teams.

- ECG monitor
- defibrillator
- oxygen source with mask
- oxygen & suction
- oxygen saturation monitor
- humidifier and sterile distilled water
- resuscitation drugs
  - Basic treatment medication (atropine, epinephrine, Beta 2-agonist inhaler) is kept in a kit in the room where contrast is injected. An emergency kit is available consisting of the following drugs essential for Contrast Reaction:
    - •Atropine sulfate 0.1 mg/ml (pre-filled syringe)
    - •Lidocaine
    - •Corticosteroids for intravenous administration (Hydrocortisone sod succ 500 mg)
    - •Anti-convulsive drugs (i.e. Diazepam 5 mg/ml)
    - •Dopamine infusion 200 mg
    - •Epinephrine 1:1,000 (pre-filled syringe)
    - •Epinephrine 1:10,000 (pre-filled syringe)
    - •Sterile water for injection (30ml)
    - •Dextrose 5% in water (mini-bags for medication infusion)
    - •Beta 2-agonist metered dose inhaler
    - •I.V. Fluids—normal saline or Ringers solution
    - •Alcohol skin prep
    - •Antihistamine H1—suitable for injection
    - •Antihistamine H2 (e.g. Cimitidine/Rantidine)

- Anti-emetic - parenteral
- Appropriate IV needles and syringes

The contents of the resuscitation tray are checked monthly for expiry dates on all drugs and sterile equipment. These activities are documented and kept with the resuscitation equipment.

Minor Equipment

- stethoscope
- sphygmomanometer
- IV pole
- wheelchair
- laryngoscope and endotracheal tubes (sized for adults/paediatrics)
- oropharyngeal airways (sized for adults/paediatrics)
- ambu bag or equivalent (sized for adults/paediatrics)

Quality Control

All scanners are assessed by a medical physicist after installation. Quality control activities include, but are not limited to, the following:

- facility has documented policies and procedures for monitoring and evaluating the effective management, safety and operation of CT equipment, as outlined by the provincial standard.
- scanners are properly maintained and calibrated every 6 weeks, or as recommended by the manufacturer.
- All safety measures are in compliance with federal and provincial laws/ regulations (HARP Act or equivalent). Tests include:
    - CTDI (computed tomography dose index) must be measured to verify that it meets the unit manufacturer's specifications
    - CT number accuracy must be measured to verify that it meets the unit manufacturer's specifications in all protocols used
    - CT pixel noise must be measured to verify that it meets the unit manufacturer's specifications
    - Limiting spatial resolution must be measured to verify that it meets the unit manufacturer's specifications
    - Radiation beam width must be measured to verify that it meets the manufacterer's specifications

- •Slice sensitivity profile must be measured to verify that it meets the manufacterer's specifications
- •Accuracy of slice alignment indicators must be measured to verify that it meets the manufacterer's specifications
- •verify no unusual artifacts

- written records of preventative maintenance and equipment calibration are maintained.
- a quality assurance program that is designed to minimize patient, personnel and public radiation risks while maximizing the quality of the diagnostic information.
- A CT value Phantom test is performed:
  - at least weekly if less than 60 exams/day

or

  - A CT value test is performed daily if more than 60 exams/day.

These values are recorded and compared to the standard values set by qualified service personnel.

Chapter 3 Developing Policies and Procedures

Overview

There are current written policies and procedures to provide diagnostic imaging staff with clear direction on the scope and limitations of their functions and responsibilities for patient care.

Developing Policies and Procedures

The procedure manual is available for consultation by all diagnostic imaging personnel. The manual is reviewed annually, revised as necessary, and dated to indicate the time of the last review or revision.

There is documentation to indicate who makes the policies, sets the standards, and who supervises physicians, technologists, and other staff.

Procedures in the manual include, but are not limited to, the following:

- A facility policy for certification of technologists for injection of contrast media.
- imaging protocols detailing the sequences involved in examining a target organ for both adult and paediatric patients. These include, but are not limited to:
    - •oral contrast - volume and type
    - •IV contrast - volume and rate and type of administration
    - •slice interval
    - •scanning region
    - •patient position
- the following scanned parameters must be recorded on the patient film:
    - •slice thickness
    - •mAs and kVp
- paediatric/small adult protocols preprogramed in scanner with reduced patient dose
- instructions regarding routine preparation of patients.
- safety of patients who have taken oral or sublingual anxiolytics
    - •particularly for patients departing the facility
- techniques for managing patients with claustrophobia, anxiety and emotional distress.

- adult sedation.
- delegated acts.
- scope and limitations of diagnostic imaging services provided by the facility.
- patient-booking systems.
- patient consent, written or verbal, based on the scope of practice in the facility.
- infection control.
- pregnancy of patients/facility staff.
- use of protective devices.
- contraindications for performing tests.
- pre-medication for known contrast allergy.
- latex anaphylaxis
    - there are many areas of latex allergy which are important for the IHF to know about -from knowing the symptoms of the allergy (urticaria, dermatitis, rhinitis and asthma) to the management of anaphylactic reactions. The following represents some basic guidelines to use when developing a policy for the facility:
        - All patients at risk for latex allergy should have a careful history for questions of possible latex allergy. A latex allergy questionnaire may be helpful. ***(See Appendix II, Sample Questionnaire)***
    - procedures on all patients with latex specific IgE antibody should be done in a latex-safe environment which is defined as one in which there is no latex glove use by any personnel. In addition, no direct patient contact should occur with other latex devices (catheters, condoms, adhesives, tourniquets and anaesthetic equipment)
- specific first aid measures to be followed in the event of an adverse health effect, including a description of the arrangements for transferring patients to an acute care facility when required.
- documentation of and method for receiving written and telephone referrals for consultation.
- methods for preliminary interpretations and/or telephone calls of reports, and for the subsequent written interpretation of images by qualified diagnostic imaging physicians.
- maintenance of requisitions, imaging media and interpretation reports ***(See Appendix I, Independent Health Facilities Act- Ontario Regulation 57/92 - Amended to O.Reg. 14/95)*.**
- confidentiality.
- safety and safety training for medical & non-medical staff.

- Material Safety Data Sheets (MSDS) for all chemicals maintained in the facility.
- routine maintenance and calibration of equipment.
- performance of additional views and examinations.
    - any additional views or examinations are identified in the imaging report with reasons.

Chapter 4 Requesting and Reporting Mechanisms

Overview

The content of this overview has been extracted from the CAR Guidelines on Communication (approved in June 1997; reviewed in September 2001--www.car.ca).

Communication is a critical component of the art and science of medicine and is especially important in Diagnostic Radiology. Diagnostic Radiology is one of the most important consultative services in medicine.

The final product of any consultation is the submission of a report on the results of the consultation. In addition, the diagnostic radiologist and the referring physician have many opportunities to communicate directly with each other during the course of a patient's case management. Such communication should be encouraged because it leads to more effective and appropriate utilization of Diagnostic Radiology in addressing clinical problems and focuses attention on such concerns as radiation exposure, appropriate imaging studies, clinical efficacy, and cost-effective examinations.

These principles apply to all radiology consultations irrespective of the technology used including Picture Archiving & Communication Systems (PACS) or an equivalent electronic work station with an archival system.

In order to afford optimal care to the patient and enhance the cost-effectiveness of each diagnostic examination, radiological consultations ought to be provided and images interpreted within a known clinical setting. No screening radiological examination should be performed unless evidence-based or part of an organized population-based screening program.

The Canadian Association of Radiologists supports radiologists who insist on clinical data with each consultation request and IHF Task Force supports this same principle.

Teleradiology should not be used for primary reporting until the College of Physicians and Surgeons of Ontario has a policy in place. The interpreting radiologist should be based in Ontario in close geographic proximity to the IHF CT facility.

Requesting Procedures

Written requisitions and forms to screen the patient for CT compatibility must be completed by the referring physician. All CT requests must be approved by a radiologist prior to booking the test.

When a consultation for a procedure is requested by telephone, the person to whom the consultation was requested writes the procedure(s) requested, the working diagnosis, the name of the requisitioning physician, the date and time of the request, and signs the record of the request.

An appropriate request for all radiological consultations specifies:

- the basic demographic information of the patient such as name, health number, date of birth, and sex.
- the name of the referring physician and the names of any other physicians who are to receive copies of the report.
- the type of procedure requested for the patient including any special instructions where applicable.
- pertinent clinical information including indications, pertinent history, and provisional diagnosis.
- whether a “stat report” is required.

This is the responsibility of the referring physician. If a patient arrives with requisitions and screening form containing incomplete information, the diagnostic imaging physician contacts the referring physician.

It is recommended that patients be provided written information about computed tomography procedures prior to an appointment.

Reporting Procedures

Previous diagnostic images and ultrasound scans are available for the interpreting physician.

Reports of the interpretation of imaging procedures include the following:

- name of the patient and another identifier such as birth date, pertinent identification number.
- name of the ordering physician, most responsible physician and/or other physicians.
- name or type of examination.
- dates of examination, dictation, and transcription.
- limitations, technical factors, or patient anatomy.

- reasons for additional views or examinations if deemed necessary.
- findings using precise anatomical and radiological terminology to describe the findings accurately and a description of the procedures performed and any contrast media (agent, concentration, volume and reaction, if any), medications, catheters, devices, if not reported elsewhere.
- any pertinent clinical issues raised in the request for the imaging examination.
- comparative information with previous examinations.
- a "conclusion" section unless the study is being compared with other recent studies and no changes have occurred during the interval, or the body of the report is brief. The report should also contain:
  - a precise diagnosis whenever possible
  - a differential diagnosis when appropriate
  - recommendations, when appropriate
  - follow-up and additional diagnostic radiological studies to clarify or confirm the conclusion.

The final report is proofread carefully to avoid typographical errors, deleted words, confusing or conflicting statements.

Note: If this is not possible, a disclaimer statement is stated on the report that the report has not been proofread

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The report is authenticated by a radiologist, whenever possible. Electronic or rubber-stamp signature devices, instead of a written signature, are acceptable if access to them is secure.

- if this is not possible, the name of the radiologist who dictated the report should appear on the report.

Reports of the interpretation of diagnostic imaging examinations are transmitted to the referring physician within 24 hours if possible.

Unusual, unexpected, or urgent findings which may require immediate case management decisions are communicated to the referring physician by the interpreting physician, or as directed by the interpreting physician.

Direct or attempted direct communication is documented.

Any discrepancy between a preliminary report and the final written report is directly communicated to the referring physician or representative.

A copy of the diagnostic image is retained as the permanent record. It is essential that these images are on a PACS or equivalent electronic work station with an archival system. The mAs, kVp, name, age, ID#, slice thickness and use of contrast or not, should be displayed on the CT image.

The images must be of sufficient quality to record permanent findings, to be used for comparison with subsequent examinations, and enable third party Radiologists to confirm the diagnosis.

- the facility must have the ability to retrieve and/or produce a copy of the image(s),within 24 hours of the request as required.

The imaging media and reports are filed using an accepted coding system which allows films and reports to be retrieved by patient identification information.

Unusual and interesting examinations are maintained for educational purposes.

Chapter 5 Providing Quality Care

Overview

A Quality Advisory Committee is established as per the IHF Act. The advisory committee shall consist of health professionals who provide health services in or in connection with the independent health facility. Regular meetings are held and minutes maintained (IHF Act Regulation 57/92 amended to 14/95--see ***Appendix I***).

To provide quality of care, there is evidence that patients' needs for diagnostic imaging services are assessed. The services planned and provided are consistent with those needs and assure diagnostic reliability and patient safety.

Facility staff should have meetings at least quarterly and maintain minutes.

Providing Quality Care

The performance of CT examinations complies with the standards accepted by the College of Physicians and Surgeons of Ontario as described in the Clinical Practice Parameters section.

A CT Radiologist is available for consultation with the technologist on a case-by-case basis. For cases requiring monitoring, ideally, the CT Radiologist is on-site and available to participate in the examination when required.

Although optimally a designated CT Radiologist is present for all cases, this is not always possible. For cases that do not require monitoring, a designated CT Radiologist should always be available by phone to consult with the technologist and referring physician.

Whenever contrast is administered, a designated physician must be personally and immediately available. There must be adequate equipment/medications available to treat an adverse reaction.

A CT-trained radiologist should visit the facility on a regular basis to review imaging procedures and provide technologist supervision. Ideally there should be a CT radiologist present at the facility on a daily basis. Even at remote sites, a CT-trained radiologist should be on site at least one day per week. A daily log of visits to the facility by the radiologist should be maintained.

CT imaging procedures are carried out in a manner in which patient privacy is respected.

Monitoring Quality of Care

The facility establishes and maintains a system to monitor the results of the services provided.

The facility establishes a quality management program appropriate for its size, volume and types of services provided. It is recognized that quality management programs will vary depending on the facility size, scope of practice, and geographical considerations.

Each facility has written goals and objectives as part of their quality management program.

Components of quality management include a review of:

- goals and objectives.
- policies and procedures.
- incidents, adverse drug reactions, complications.
- clinical data, for example, assessing the accuracy of interpretations and the appropriateness of procedures.
- recommendations from other assessing bodies such as the Ministry of Health X-ray Inspection Services and HARP or equivilent.
- quality control activities.
- staff performance appraisals.
- in-service education using recent patient records
- patient/referring physician surveys.

Staff receive the results of such reviews.

Staff participate in planning strategies to overcome any deficiencies and to continually improve the services provided to patients.

Independent Health Facilities: Clinical Practice Parameters and Facility Standards: Computed Tomography

Volume 2

Clinical Practice Parameters

The following Clinical Practice Parameters have been developed by the Canadian Association of Radiologists and have been adopted by the IHF MRI & CT Task Force, College of Physicians and Surgeons of Ontario. Also adopted by the IHF Task force:

All Clinical Practice Parameters contained within this document should be read in conjunction with the Facility Standards (Volume 1) developed by the IHF Task Force.

CAR Standard for Performing and Interpreting Diagnostic CT Scans

Adopted: March 2002

Reviewed by the Expert Advisory Panel on CT: David Bach, MD, London, Paul Fenton, MD, Kingston, Kendra Fisher, MD, Saskatoon, David Gianfelice, MD, Montreal, Howard Greenberg, MD, Winnipeg, John Loewy, MD, Toronto, Chair, William Maloney, MD, Halifax, Michael Mitchell, MD, Halifax, Sam Share, MD, Calgary, Robert Willinsky, MD, Toronto

Each standard, representing a policy statement by the Canadian Association of Radiologists, has undergone a thorough consensus process. The standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques as described in each document.

CAR Website Url: www.car.ca

I. INTRODUCTION

The past several years have seen major changes in CT technology. The major advances have been in the ability to perform spiral techniques, as well as the advent of multidetector systems. These advances allow rapid scanning during a breathold, tracking contrast through the various vascular phases, and increased throughput of cases. The smorgasboard of approaches now available depending on the equipment will not be fully covered, especially as this is still an evolving change. Rather general principles of CT will be stressed.

Computed tomography is a well accepted and established imaging technique which utilizes ionizing radiation to obtain cross sectional images. The applications for CT technology include:

1. Head and Neck diagnosis.
2. Evaluation of spinal disorders.
3. Assessment of the thorax.
4. Abdominal and pelvic imaging studies.
5. Imaging of the musculoskeletal system.
6. Guidance of interventional procedures.

Studies should be performed by qualified and knowledgeable physicians and/or technologists using appropriate equipment and technique. Examinations should be supervised and interpreted by appropriately trained and credentialed medical imaging specialists.

All imaging facilities should have policies and procedures to reasonably attempt to identify pregnant patients prior to the performance of any diagnostic examination involving ionizing radiation. If the patient is known to be pregnant, the potential radiation risks to the fetus and clinical

benefits of the procedure should be considered before proceeding with the study. Due consideration to the radiation dose of all studies needs to be revisited from time to time.

II. PROFESSIONAL CREDENTIALS CRITERIA (for Ontario guidelines, see Volume I, Chapter 1, Staffing a Facility)

That Physicians involved in the performance, supervision and interpretation of CT should be Diagnostic Radiologists and must have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec. Also acceptable are Radiologists qualified in other jurisdictions who hold special licenses within a Canadian University.

As new imaging modalities and interventional techniques are developed additional clinical training, under supervision and with proper documentation, should be obtained before radiologists interpret or perform such examinations or procedures independently. Such additional training must meet with pertinent provincial/regional regulations. Continuing professional development must meet with the requirements of the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.

III. TECHNOLOGIST CREDENTIALS CRITERIA (for Ontario guidelines, see Volume I, Chapter 1, Staffing a Facility)

The Medical Radiation Technologist must have Canadian Association Medical Radiation Technologist certification or be certified by an equivalent licensing body recognized by the CAMRT.

Under the overall supervision of the Radiologist the Technologist will have the responsibility for patient comfort and safety, for examination preparation and performance, for image technical evaluation and quality, and applicable quality assurance. The training of Technologists specifically engaged in CT shall meet with applicable and valid National and Provincial Specialty qualifications.

IV. DOCUMENTATION

Adequate documentation of CT studies should include a permanent record of the examination and its interpretation. Images should be appropriately labelled with the examination date and time, patient identification, image orientation, scan parameters, dose of I.V. contrast administered and any other information which would be necessary or useful for interpretation of the study and for comparison with previous or subsequent examinations by any qualified Radiologist. Written consultation should be included with the patients records. A scout image should be included for all examinations.

Images shall be retained on file either in electronic format or hard copies for a statutory time period consistent with clinical needs and relevant legal and local health care requirements as a permanent record. Digital recording of the case to be kept for longer time periods will be at the discretion of the Imaging Department.

Each examination must generate a written report documenting any significant abnormality that should remain with the patients imaging file.

V. EQUIPMENT AND QUALITY CONTROL (for Ontario guidelines, see Volume I, Chapter 2, Facilities, Equipment and Supplies)

Each imaging facility should have documented policies and procedures for monitoring and evaluating the effective management, safety, and operation of imaging equipment. The quality control program should be designed to minimize patient, personnel and public radiation risks and maximize the quality of the diagnostic information.

The guidelines of the Provincial Ministries for monitoring equipment performance must be followed.
There should be review of the standards for equipment and radiation safety that are currently recognized by such national organizations as the Canadian College of Physicists in Medicine and other appropriate federal and provincial regulatory bodies.

VI. EQUIPMENT SPECIFICATIONS (for Ontario guidelines, see Volume I, Chapter 2, Facilities, Equipment and Supplies)

A. Performance Standards

For patient imaging, the CT scanner should meet or exceed the following specifications:

1. Scan times: minimum, not more than 2 seconds.
2. Slice thickness: minimum, not more than 2- mm.
3. Interscan delay: minimum, not more than 4 seconds (may be longer if intravascular contrast material is not used).
4. Limiting spatial resolution: must be measured to verify that it meets the unit manufacturer's specifications.

B. Patient monitoring equipment and facilities for cardiopulmonary resuscitation including vital signs monitoring, support equipment, and an emergency crash cart should be immediately available. Radiologists, technologists, and staff members should be able to assist with procedures, patient monitoring, and patient support. A written policy should be in place for dealing with emergency procedures such as cardiopulmonary arrest.

VII. QUALITY IMPROVEMENT

Procedures should be systematically monitored and evaluated as part of the overall quality improvement program of the facility. Monitoring by periodic audit should include the evaluation of the accuracy of radiologic interpretations as well as the appropriateness of the examination.

Incidence of complications and adverse events should be recorded and periodically reviewed in order to identify opportunities to improve patient care. The data should be collected in a manner which complies with statutory and regulatory peer review procedures in order to protect the confidentiality of the peer review data.

VIII. GENERAL COMMENTS ON PERFORMANCE OF CT EXAMINATIONS

Although many of the operations of a CT scanner are automated, a number of technical parameters remain operator dependant. As these can significantly affect the diagnostic value of a CT examination, it is necessary to acquire thorough familiarity with the following factors which must be specified for each examination:

1. Exposure factors

   Optimization of image quality requires selection of appropriate exposure factors. These may vary considerably depending on patient size, body weight and age.

2. Collimation.

   Diagnostic accuracy requires appropriate selection of slice thickness. This choice will reflect clinical indications for the study as well as the, size location and orientation of structures to be imaged.

3. Slice spacing

   Scans may be acquired either contiguously or non-contiguously. This choice depends on the clinical indications for the study as well as the potential for defining select regions of interest.

4. Field of view

   The diameter of the field of view has a profound effect on image quality. Although it is generally sufficient to adjust and match the diameter of the field of view to the diameter of the body part to be imaged, narrow fields of view may be selected both prospectively or retrospectively, from raw imaged data (targeted reconstruction).

5. Window settings

For each image, operators must select a portion of the CT number range to be displayed using electronic windows. Window width and levels must be selected to optimize visualization of pertinent structures as well as regions of interest. Multiple window settings may be required. For example, a minimum of 2 window settings should be obtained in CT examinations of the chest: one for visualizing lung parenchyma, and one for assessing soft tissue structures in the mediastinum, hila and chest wall. In examinations of the spine, brain and other body regions, additional settings to emphasize osseous and soft tissue structures may be required as well. In general, use of these multiple window settings should be documented on the hard copy.

6. Algorithm of reconstruction

The computed software used to reconstruct the CT image can markedly affect image characteristics. Choice of the appropriate algorithm profoundly affects diagnostic accuracy. A proper understanding of high contrast/standard resolution algorithms versus high spatial resolution or edge enhancing algorithms is necessary for optimal performance of CT imaging.

7. Patient factors

In general, patients are scanned in the supine position. However changes in patient position including the use of prone and/or decubitus positioning may be of value in select cases. Phase of respiration must also be taken into consideration during imaging of the neck, chest, abdomen and pelvis. In general, images should be obtained at the same phase of respiration during the imaging of a particular body region. Scans obtained in various phases of respiration may be of some additional value in select cases.

8. Contrast media

The choice of whether or not to administer intravenous contrast will depend on the clinical indication for the study. Operators should be knowledgeable concerning various means of administering intravenous contrast including various rates and volumes of administration, and be informed regarding the timing of the various vascular phases-venous and arterial. Familiarity with bolus detection software when available is also needed.

9. On-line monitoring

Ideally each study would be monitored directly by the interpreting physician. However realities of time constraints and potential limitations on physician availability necessitate that many scans be

performed without on-line monitoring. In this setting, optimization of the CT examination requires development of an appropriate CT protocol based on careful review of clinical indications as well as all prior available imaging studies.

10. Protocols

Protocols should be prepared by region of interest and medical indication for investigation. For each area of interest or indication they should indicate the following:

a. The volume, rate and type of oral contrast material to be administered .
b. The volume and rate of administration of intravenous contrast material, and the relationship to initiating scanning.
c. Slice thickness.
d. Slice interval.
e. Superior and inferior extent of the region of interest to be imaged, generally from a level just cephalad to the structure or region of interest to a level just caudad to the structure or region of interest.

These protocols should be reviewed and updated periodically. Following are specific comments about CT examinations for particular anatomic regions and indications. These are meant to be general comments recognizing that the performance of any examination should be tailored depending on the individual characteristics of each patient, the clinical problem and the available equipment. These standards are based on the standard of practice at the time that this document was prepared. However practice patterns may change as new information becomes available and equipment is modified, so regular review of the protocols is required.

CT OF THE HEAD:

Indications

Primary indications: acute head trauma, suspicion of acute intracranial hemorrhage; detection or evaluation of calcification; immediate evaluation for postoperative surgical conditions such as assessment of tumor, hemorrhage or hemorrhagic lesions, treated/ untreated vascular lesions, shunted hydrocephalus, or shunt revision. Other primary indications are mental status change, increased intracranial pressure, headache, acute neurologic deficits, suspected intracranial infection, suspected hydrocephalus, congenital lesions (such as, but not limited to, craniosynotosis, macrocephaly, and microcephaly), evaluation of patients with psychiatric disorders, brain herniation, suspected mass or tumor, and

patients presenting with symptoms of acute cerebral infarction, including those who are being evaluated for possible systemic and/ or endovascular thrombolysis.

Secondary indications: (when access to magnetic resonance (MR) imaging is not available, when MR imaging may be contraindicated, or if the supervising physician deems CT to be appropriate) diplopia, cranial nerve dysfunction, seizures, apnea, syncope, ataxia, suspicion of neurodegenerative disease, developmental delay, neuroendocrine dysfunction, encephalitis, vascular occlusive disease or vasculitis (including use of CT angiography and/ or venography), aneurysm, drug toxicity, cortical dysplasia, and migration anomalies or other morphologic brain abnormalities, and study of the skull base.

Examination Specifics

CT protocols in neuroradiology require close attention and development by the supervising physician, according to specified indications. The supervising physician should be familiar with the indications for each examination, patient history, potential adverse reactions to contrast media, exposure factors, window and center settings, field of view, collimation, slice intervals, and reconstruction algorithms. Certain indications require administration of intravenous contrast medium or intrathecal contrast (e. g., cisternography) during imaging of the brain, head, and neck. Intravenous (IV) contrast enhancement should be performed using appropriate injection protocols and in accordance with the institution's policy on IV contrast utilization. CSF contrast administration requires use of nonionic agents approved for intrathecal use.

For CT of the brain, contiguous or overlapping axial slices with a slice thickness of no greater than 10 mm in the supratentorial regions in older children and adults and no greater than 5 mm in the neonatal child are preferred. Imaging for evaluation of the posterior fossa should be with no greater than 5- mm slice thickness in the adult or pediatric patient. In the setting of trauma, images should be obtained and/ or reviewed at window settings appropriate for demonstration of soft tissue and bony abnormalities, or other abnormalities, as suspected by the physician, including subdural window widths when appropriate. For imaging of the cranial base, an axial slice thickness no greater than 3- mm with spiral techniques and 2- mm without spiral technique should be used for 2D reformatting or for 3D reconstruction.

Unenhanced studies are performed in the setting of suspected hemorrhage or stroke. If a low index of suspicion for neurosurgical disease exists (i.e. chronic headaches, dementia etc.) a screening study without contrast is sufficient. If an inflammatory process, mass or vascular malformation is

suspected, an enhanced study is done. On an enhanced study, it may be difficult to differentiate blood from calcium, necessitating a repeat study without contrast.

The sella and pituitary gland should be imaged in the coronal plane with thin, contiguous slices (1-3 mm.) from anterior to the sella (tuberculum) to posterior to the dorsum. Indications include a search for a mass or hemorrhage. The scan plane should be chosen to minimize artefacts from dental amalgam. If the neck cannot be extended then reformations in the coronal plane should be done from axial images. Axial images may be necessary for confirmation of pathology seen on the coronal study or for assessment of parasellar extension of a mass. The examination should be done with intravenous contrast unless there is suspicion of hemorrhage. Images should be acquired within 10 minutes of contrast administration.

CT OF THE FACE AND NECK

Indications

Primary indications: fractures of the orbit, temporal bone, skull, and face; detection or evaluation of calcification; evaluation of the skull base for primary and secondary osseous lesions; evaluation of the temporal bone, mastoids, paranasal sinuses, larynx and salivary glands; craniocervical anomalies; evaluation of vascular structures, including CT angiography and CT venography; reconstructions for preoperative three-dimensional planning of the cranial base, vault, or dental abnormalities.
Secondary indications: (when MR imaging may be contraindicated or unavailable CT may be an alternative modality, or if the supervising physician deems CT to be appropriate) evaluation of lesions involving the orbit; nasopharynx; oropharynx; oral cavity; hypopharynx; masticator; parapharyngeal, retropharyngeal, carotid and prevertebral spaces; soft tissue spaces of the face; posterolateral neck; extracalvarial region; and the thyroid and parathyroid gland where US is insufficient.

Specifications of examination

For CT of the face and neck, a slice thickness of no greater than 5- mm in children and adults. Thinner images (3- mm) may be indicated for the evaluation of infants or smaller anatomic structures. Images can be performed with either standard or bone algorithms. If bone disease is the primary diagnostic consideration, a bone reconstruction algorithm should be employed. For CT of the orbit, slice thickness no greater than 3 mm should be used for both axial and direct coronal imaging. CT of the paranasal sinuses should be performed with a slice thickness no greater than 5 mm for either axial or direct coronal imaging. Axial slice thickness no greater than 2- mm should be used for 2D reformatting or 3D reconstruction of the orbits or sinuses. For imaging of the facial bones and jaw, slice thickness no greater than 3 mm should be used in infants and no greater than 5 mm in older children and adults for either axial or

coronal sections. An axial slice thickness no greater than 1.5 mm should be used for reformatting or for reconstructions. For temporal bone imaging, slice thickness should not exceed 2 mm for axial or coronal sections and should be no greater than 1.5 mm for axial slices to be used in reformatting.

A) CT OF THE ORBIT:

Indications include delineation of or exclusion of a mass. Axial 1.5-5.0 mm. contiguous slices should be done in the plane of the orbital cone (from 0o - 10o from the canthomeatal line) from the mid maxillary sinus to the mid frontal sinus. True coronal slices are useful if a mass is found, or for better delineation of muscle size or for further assessment of the optic nerves. Contrast is helpful in selected patients.

B) CT OF THE SINUSES/FACE:

Screening for endoscopic surgery:

Studies should be in the coronal plane using 3-5 mm. contiguous slices. A wide window (ie. 4000) allows a clear differentiation of bone, mucosa and air. It might be helpful for patients to be on decongestants for two days prior to the study and to blow their nose just prior to the scan.

Screening for or delineation of mass lesions:

Studies should be in the axial or coronal plane from the frontal sinus to hard palate using 5 mm. contiguous slices after a bolus injection of intravenous contrast. A soft tissue algorithm (ie. window 300-400) should be used. When a mass is evident a wide window setting for assessment of bony structures is required and true coronal images should be performed. On the true coronal slices angulation should be selected so as to avoid dental restorations.

Facial trauma:

Studies should be in the axial plane from the frontal sinus to hard palate using contiguous 3-5 mm. slices. A bone algorithm with a wide window setting (ie. 4000) is required. In addition, slices through the orbit should be imaged with a soft tissue setting. If clinically feasible, true coronals, from the nasal bone to the sphenoid sinus should be done. If the mandible is involved clinically, additional axial slices to the symphysis are required.

C) CT OF THE TEMPORAL BONE:

Temporal bone imaging is often done in addition to a study of the posterior fossa. Indications include masses in the middle or external ear, VIIth nerve paresis and hearing loss. To image the external, middle and internal ear anatomy, thin (ie. 1.5 mm) contiguous axial and coronal slices should be done through one or both petrous bones. A bone algorithm with a wide window (ie. 4000) is required.

D) CT OF THE PHARYNX, LARYNX AND NECK:

The soft tissues of the head and neck are imaged to search for or delineate masses. Studies should be performed in the axial plane from the nasion to the thoracic inlet using 5 mm. contiguous slices. A dynamic or rapid-sequence acquisition should be done in concert with a rapid pump or hand injection of contrast such that intravascular contrast is easily evident on the entire study. A true coronal study should be added when pathology involves the skull base or when the area of interest is obscured by dental restorations. Staging of laryngeal carcinoma may require additional thin (ie. 1.5 mm.) axial slices through the larynx.

CT SPINE

Primary indications: acute trauma, acute or chronic fractures, spinal stenosis, detection or evaluation of calcification, evaluation of osseous lesions, craniocervical anomalies, congenital anomalies, primary and secondary neoplasms, as an adjunct to myelography or MR. In the cervical and thoracic regions, pain only, is a poor indication for CT, unless plain films, bone scans or clinical findings direct attention to a particular level.

Secondary indications: (when MR imaging may be contraindicated, CT may be an alternative modality, or if the supervising physician deems CT to be appropriate) evaluation of degenerative diseases of the spine, and in failed back syndrome. CT/myelography may be useful for examination of the spinal cord, roots, thecal sac and canal.

Scanning can be accomplished with contiguous 3-5 mm. axial slices in the plane of the disc spaces. An alternative method would include selective angulation in the plane of each disc space. This should extend from the pedicle above to the pedicles below each disc level to cover the entire intervertebral foramina and pars interarticulares. For reformations, overlapped cuts are recommended from images perpendicular to the table. CT with contrast is helpful in mass lesions or inflammatory processes, and in selected patients with a cervical radiculopathy.

1. Cervical: Axial images with a slice thickness no greater than 3- mm allow for optimal imaging of the cervical spine in the setting of trauma as well as in degenerative disease. Coronal and sagittal reformations can be also obtained with this slice thickness. IV contrast injection can be useful in increasing the detection of small disk herniations and can also provide better delineation of anatomic detail, particularly when beam- hardening artifact is present. IV contrast material can also be administered in conjunction with 25- 30 second spiral thin- cut acquisitions. Images should be performed and/ or reviewed with both soft tissue and bone windows. Three-dimensional volume surface reconstructions may also be obtained. Bilateral oblique reconstructions are advantageous in evaluating the intervertebral foramina. Intrathecal contrast provides excellent detail of the thecal contents including the spinal cord.

2. Thoracic spine: In the setting of trauma and specified suspected affected levels, slice thickness no greater than 3mm should be used. Sagittal, coronal, and oblique reformations can also be employed. Three- dimensional reconstructions with thin sections are also possible. Routine imaging may be performed with 3- 5 mm slice thickness parallel to the disk spaces. IV and intrathecal contrast may enhance visualization of anatomic detail. Spiral techniques can also be employed with contrast- enhanced or postmyelographic CT of the thoracic spine. Images should be performed and/ or reviewed with both soft tissue and bone windows. In the neonate, slice thickness no greater than 3- mm should be employed for routine imaging, and thinner sections may be used where appropriate.

3. Lumbar spine: In the setting of trauma, slice thickness no greater than 3- mm should be employed with sagittal, coronal, and oblique reformations as may be necessary. For routine imaging in older children and adults, contiguous or overlapping 3- 5mm thick sections should be performed parallel to the disc spaces. In the neonate, slice thickness should not exceed 3mm. Images should be performed and/ or reviewed with both soft tissue and bone windows. Three-dimensional reconstructions as well as spiral imaging may be performed as needed. Intrathecal contrast can be utilized to enhance visualization of the conus, cauda equina and adjacent anatomy.

CT OF THE EXTREMITIES

Computed tomography is a valuable adjunct in the evaluation of a wide variety of bony and calcific musculoskeletal disorders following routine radiographic evaluation. Potential applications include the assessment of trauma, intra-articular pathology, soft tissue or bony neoplasia, osseous or joint infection and guidance of interventional procedures. As most examinations are performed for a specific clinical indication, the examination should be tailored to each problem. An edge enhancing

(bone) algorithm may be utilized to optimize bone detail. Images obtained should be displayed in both soft tissue and skeletal window settings and recorded permanently on hard copy. Intravenous contrast administration while not required in many examinations may be useful in suspected soft tissue infection, evaluation of soft tissue masses, and in trauma with suspected visceral injury.

Trauma

In general, plain films should be obtained prior to CT scanning. This allows optimum planning of scan plane and slice thickness where CT is necessary to confirm the presence of bony or soft tissue injury, to evaluate fracture displacement, or to evaluate fracture healing. An imaging plane perpendicular to the fracture plane or expected fracture plane is optimal. Slice thickness should be decreased (3 mm. or less) if the scan plane cannot be perpendicular to allow for later reconstruction in a suitable plane. While a slice thickness of 10 mm. may be adequate for larger anatomic regions, in the evaluation of small osseous structures or joint incongruity slice thickness should be 5 mm. or less.

Intra-articular pathology

CT scanning may be useful in detecting intra-articular osseous bodies and capsular, ligamentous, or tendon tears about a joint. Intra-articular injection of contrast (air and/or iodinated contrast material) is often useful in assessing soft tissue disruption about a joint or intra-articular loose body. Scan thickness depends upon the joint to be imaged but is typically 5 mm. or less in large joints and 3mm or less in small joints.

Neoplasia

In neoplasms of the skeletal system, CT scanning is complementary to plain film radiography and nuclear medicine techniques. CT scanning allows visualization of bone destruction, matrix calcification/ossification and soft tissue extension. Slice thickness depends upon the size of the lesion (10mm or less) and scans obtained should include normal bone above and below the lesion. Intravenous contrast administration may aid in better defining the anatomic limits of the neoplasm.
While MRI is the modality of choice in the assessment of soft tissue neoplasia CT may be valuable in characterizing the extent and distribution of the neoplasm if MRI is not readily available. Slice thickness depends on the size of the suspected lesion.

Infection

In suspected acute osteomyelitis, CT is an important complimentary study to plain film radiographs and nuclear medicine studies. Unenhanced thin section (5 mm or less) images through the region of interest may detect subtle osseous destruction in osteomeylitis.

In chronic osseous infection, CT scanning may be useful in demonstrating disease activity by identifying sequestra, sinus tracts, or soft tissue abscesses. Unenhanced thin slices (5 mm or less) through the suspected region will often be diagnostic. Intravenous contrast may aid in identifying soft tissue extent.

CT OF THE ABDOMEN AND PELVIS

Indications and contraindications

Indications for abdominal or pelvic CT examinations include, but are not limited to:

A. Evaluation of abdominal or pelvic pain;
B. Evaluation of known or suspected abdominal or pelvic masses or fluid collections, primary or metastatic malignancies, abdominal or pelvic inflammatory processes, and abnormalities of abdominal or pelvic vascular structures;
C. Evaluation of abdominal or pelvic trauma;
D. Clarification of findings from other imaging studies or laboratory abnormalities;
E. Guidance for interventional diagnostic or therapeutic procedures within the abdomen or pelvis;
F. Treatment planning for radiation therapy.

There are no absolute contraindications to abdominal or pelvic CT examinations. As with all procedures, the relative benefits and risks of the procedure should be evaluated prior to the performance of iodinated abdominal and pelvic CT. Appropriate contrast-enhanced precautions should be taken to minimize patient risk.

Most abdominal CT examinations are performed for specific indications and the examination should therefore be tailored accordingly (see below). A standard CT protocol should be established for those patients undergoing examinations for less specific indications such as abdominal pain. A typical screening CT examination of the abdomen and pelvis would be axial images from the level of the diaphragm to the symphysis pubis with 10 mm. slice thickness and 10-15 mm. table incrementation.

The gastro-intestinal tract should be opacified with iodinated or water oral contrast material unless medically contra-indicated, or occasionally in other circumstances. Particularly in the pelvis consideration to filling the rectum or bladder should be weighed.

During any examination of a single organ or region all scans should be obtained in the same suspended state of respiration (e.g. expiration). Axial scans should be obtained through the entire area of interest. The

field of view should be optimized for each individual patient. Slice thickness should not exceed 10 mm. Table incrementation will generally not exceed 10 or 15 mm.

For many indications, the examination should be performed with intravenous contrast material, using appropriate bolus technique, where indicated and appropriately timed for the arterial or venous phase. Abnormal findings on a non-enhanced examination may require further evaluation with contrast enhancement in order to confirm a suspected pathology, characterize an abnormal finding, reassure the radiologist of the normalcy of the area in question, or stage the disease process properly.

Appropriate window settings should be used routinely to view the visceral organs, the intra-abdominal fat and muscles, the pulmonary parenchyma at the lung bases, and the osseous structures.

A) CT OF THE LIVER:

CT of the liver is performed for the detection of intra-hepatic abnormalities (e.g. rule out metastases) and for the characterization of known masses suspected to be a hemangioma or other tumor. For the detection of intra-hepatic metastatic disease a dynamic contrast enhanced examination is more sensitive than a non-contrast examination or an examination in which most of the liver images are obtained more than 3 minutes after the intravenous contrast administration. For suspected hepatoma and suspected vascular metastases, enhanced scans during the arterial phase are more sensitive than scans in the portal venous phase. Occasionally a non-contrast exam is also needed for the detection of some calcific metastases. Occasionally, delayed images are required for the complete assessment of a liver mass such as a hemangioma. Where partial hepatectomy is a consideration CT portography is performed.

B) CT OF THE PANCREAS:

CT examinations are performed for the detection and characterization of neoplasms of the pancreas, and for the detection and staging of inflammatory disease of the pancreas. The examination must be tailored accordingly.

In the assessment of pancreatic inflammatory disease, contiguous scans of 10 mm. slice thickness are generally obtained. Non-contrast scans are helpful to determine the presence of calcifications. In severe acute pancreatitis, a dynamic contrast enhanced examination (i.e. the rapid administration of intravenous contrast material, with rapid acquisition of axial images), is performed in order to maximize pancreatic parenchymal enhancement and thus to allow the detection of non-viable pancreatic tissue.

In acute pancreatitis the examination should be extended to include the entire abdomen and pelvis in order to document the presence of remote pancreatic fluid collections or other complications.

The evaluation and staging of pancreatic tumors are usually performed with contiguous scans of 5mm or less slice thickness. Usually dynamic contrast-enhanced scans are performed. Administration of adequate volumes of oral contrast is necessary to obtain proper opacification of the duodenum and adjacent loops of small bowel. Occasionally, images are obtained with the patient in the decubitus position.

C) CT OF THE BILIARY TREE:

CT for the evaluation of biliary obstruction should be performed with contiguous scans of 5 mm. slice thickness and should generally include the entire biliary tree. More cephalically located scans through the superior portions of the liver may well be helpful but can be adequately performed at 10 mm. slice thickness. For the detection of choledocholithiasis, the study may be performed without intravenous or oral contrast material.

D) CT OF THE ADRENALS:

Computed tomographic examinations performed specifically for visualization of the adrenal glands should be performed with 5 mm or thinner slice thickness and in a contiguous fashion. In the evaluation of suspected pheochromocytoma, intraveous contrast is contraindicated. If the adrenal glands are negative, the entire abdomen may be scanned using IV contrast and paying special attention to the liver for vascular metastases.
When intra-adrenal hemorrhage is a consideration, a non-contrast examination should be performed. For other indications, the examination may be performed as either a non-contrast or contrast study. In particular, intravenous contrast administration may be helpful for the evaluation of primary adrenal carcinoma. Targeted reconstruction is useful particularly in the evaluation of small adrenal lesions such as aldosterone producing tumors causing Conn's syndrome.

E) CT OF THE KIDNEYS AND/OR URETERS:

CT examination for evaluation of renal substance or renal collecting system can generally be performed with contiguous 10 mm slices. Thinner sections may be required for the evaluation of smaller renal masses. Preliminary unenhanced CT examination may be helpful for the detection of renal calcification, particularly calculi and medullary nephrocalcinosis. However, an unenhanced CT examination of the kidneys may not be adequate for the detection of small renal masses.

Intravenous contrast administration is necessary for the characterization of renal masses, the staging of tumors, and evaluation of the renal veins. A combination of unenhanced CT and scans in the corticomedullary and nephrographic phases may be helpful in the detection and characterization of renal masses and in staging. Contrast administration is also necessary in the assessment of ureteric obstruction or suspected ureteric mass.

F) CT OF THE AORTA:

CT examination for the assessment of the abdominal aorta is generally performed with scans of 10 mm maximum slice thickness and table incrementation of 10-15 mm. Targeted reconstruction may aid in the interpretation of suspected dissection or aneurysmal complications.

G) CT IN ABDOMINAL TRAUMA:

CT evaluation of the abdomen in the setting of blunt or penetrating abdominal trauma will necessarily be tailored depending upon the clinical status of the patient and the specific clinical question to be answered. Intravenous contrast should be administered whenever possible to optimize demonstration of hepatic, splenic and renal parenchyma as well as major vascular structures. Oral contrast should also be administered when feasible. Scans are generally performed in contiguous fashion with 10 mm. slice thickness from the level of the diaphragms to the lower poles of both kidneys. The examination should continue in 10 or 15 mm. increments to include the entire pelvis to the level of the symphysis pubis in order to facilitate the detection of unexpected bowel or mesenteric injury and to facilitate the detection of hemoperitoneum which may occasionally be subtle in the upper abdomen but appear more extensive within the pelvis.

H) CT OF THE PELVIS:

Most CT examinations of the pelvis are performed for specific indications and the examination should be tailored accordingly.

As for CT examinations of the abdomen, adequate opacification of the gastro-intestinal tract is critical. Consideration should be given in selected cases to the administration of additional contrast material per rectum in order to facilitate identification of the sigmoid colon. In female patients the placement of a tampon in the vagina will facilitate identification of the vagina and cervix. The urinary bladder may be distended with fluid or opacified with intravenously administered contrast material, on delayed scans. The bladder may also be opacified with low concentration, e.g. 5%, iodinated contrast material

instilled directly into the bladder under gravity. This manouvre should especially be considered in cases of possible traumatic bladder rupture.

CT EXAMINATION OF THE CHEST

Computed tomography is currently the imaging modality of choice, following routine chest radiography, for evaluating intrathoracic disease. Optimal performance of chest CT requires considerable knowledge of anatomy and pathophysiology, as well as intimate familiarity with computed tomographic techniques, including spiral CT.

The indications for the use of thoracic CT include but are not limited to:

1) Evaluation of abnormalities seen or suspected on a routine chest radiograph
2) Evaluation of the thorax in patients with clinically suspect pathology
3) Evaluation of symptoms inadequately assessed by more conventional imaging studies
4) Performance of CT guided biopsy and drainage procedures for parenchymal, mediastinal, and pleural processes
5) Normal chest x-ray in a patient with abnormal pulmonary function tests

Standard Chest CT

The field of view should be optimized as for all other anatomic regions. For most routine chest CT examinations, suspended inspiration is the preferred phase of respiration. Scans should be obtained through the entire area of interest. Slice thickness should not exceed 10mm (typically 7-8mm) and scan interval should not exceed 10 mm (typically 7-8mm). Images are routinely viewed on both the mediastinal setting (W 350 HU, L 40 HU) and the lung setting (W 1200 to1500 HU, L -600 to -700 HU). Mediastinal images are obtained with the standard soft tissue algorithm and the parenchymal images are obtained with the lung algorithm (if available), bone algorithm, or a lung filter applied to the standard algorithm. The administration of oral contrast is not required in the majority of cases, although it may be of value in patients with known or suspected esophageal disease. Intravenous (IV) contrast administration is generally not required when performing CT of the chest as a metastatic survey or for the assessment of diffuse parenchymal disease. IV contrast is particularly helpful in the evaluation of pulmonary lesions abutting the hila or mediastinum, and in the evaluation of mediastinal lymphadenopathy or other mediastinal pathology. The risks vs benefits for the use of iodinated IV contrast must be considered in each individual case, and contraindication guidelines must be followed.

CT Angiographic Studies

The introduction of helical CT, with the ability to image during the phase of dynamic enhancement, has greatly increased the indications for IVcontrast studies, particularly in the areas of evaluation of suspected pulmonary embolus and other vascular pathology. An unenhanced CT scan may be helpful prior to the contrast study in patients suspected of aortic dissection. A timing bolus to determine the time to maximum enhancement is generally performed. Slice thickness and pitch are calculated to cover the volume of interest in a single breath hold timed to the patients breatholding ability, with the slice thickness preferably 3 - 5 mm. In the event that the patient cannot hold their breath, the study is performed with quiet respiration. In general, the pitch should not exceed 2 in a dynamic vascular study. It is also customary to reconstruct the images at an interval equal to half the slice thickness for improved 2D and 3D reformatting.

High Resolution CT of the Chest (HRCT)

Acquisition of slices in the order of 1 - 2 mm with a 10 - 20 mm slice spacing is mandatory for assessment of diffuse parenchymal disease. A high spatial resolution or edge enhancing algorithm should be employed when performing HRCT. Targeted reconstruction with a narrow field of view is particularly useful for assessing diffuse parenchymal disease. Images taken in full expiration may be helpful for further evaluation of diseases where air trapping is suspected, and for further evaluation of the lung parenchyma when a mosaic pattern of attenuation is present or suspected on the inspiratory HRCT.

Acquisition of contiguous thin slices in the range of 1 - 3 mm is extremely helpful in the evaluation of solitary pulmonary nodules (SPNs) or masses. These should be acquired (or reconstructed) on the standard algorithm when assessing for the presence of fat or calcification within a lesion on the mediastinal setting. Targeted reconstruction with a narrow field of view is also useful in assessment of SPNs.

Appendix I Independent Health Facilities Act - Ontario Regulation 57/92 -Amended to O. Reg. 14/95

General

Quality Advisor and Advisory Committee

1 (1)Every licensee shall appoint a quality advisor to advise the licensee with respect to the quality and standards of services provided in the independent health facility.

(2)If the quality advisor dies or ceases to be the quality advisor, the licensee shall appoint a new quality advisor forthwith.

(3)The quality advisor must be a health professional who ordinarily provides insured services in or in connection with the independent health facility and whose training enables him or her to advise the licensee with respect to the quality and standards of services provided in the facility.

(4)It is a condition of a licence that the quality advisor be a physician if all the insured services provided in the independent health facility that support the facility fees that the licensee may charge are provided by physicians.

(5)In subsection (4), an insured service supports a facility fee if the facility fee is for or in respect of a service or operating cost that supports, assists or is a necessary adjunct to the insured service.

(6)A licensee who is qualified under subsection (3) may appoint himself or herself as the quality advisor only if there is no other health professional who is qualified to be the quality advisor who will consent to be the quality advisor. O Reg 57/92, s.1.

2 (1)Every licencee shall appoint an advisory committee to advise the quality advisor.

(2)The advisory committee shall consist of health professionals who provide health services in or in connection with the independent health facility.

(3)The quality advisor shall be the chair of the advisory committee.

(4)Every licensee shall use his or her best efforts to ensure that there is a representative on the advisory committee from the health profession and each specialty and sub-specialty of medicine, practitioners of which provide health services in or in connection with the independent health facility. O Reg. 57/92, s.2.

3 (1)Every licensee shall give the Director the name of the quality advisor in writing forthwith after the quality advisor is appointed.

(2)If the quality advisor dies or ceases to be the quality advisor, the licensee shall inform the Director in writing forthwith.

(3)Every licensee shall give the Director, on request, the names of the members of the advisory committee in writing. O. Reg. 57/92, s.3.

Standards

4 (1)Every licensee shall ensure that all aspects of the services provided in the independent health facility are provided in accordance with generally accepted professional standards.

(2)Every licensee shall ensure that the persons who provide services in the independent health facility are qualified, according to generally accepted professional standards, to provide those services.

(3)If the quality advisor has reasonable grounds to believe that this section is not being complied with, he or she shall inform the Director forthwith. O. Reg. 57/92, s.4.

5 Every licensee shall keep a system to monitor the results of the services provided in the independent health facility. O. Reg. 57/92, s.5.

6 (1)Every licensee shall ensure that all tissues removed from a patient during an operation or curettage performed in an independent health facility are sent to a laboratory for examination and report unless the physician performing the operation or curettage is of the opinion that it is not necessary according to generally accepted medical standards.

(2)The licensee shall ensure that a short history of the case and a statement of the findings of the operation or curettage are sent with the tissues. O. Reg. 57/92, s.6.

Records of Employees

7 (1)Every licensee of an independent health facility shall maintain, for each employee of the facility who is not a physician, an employment record setting out the employee's qualifications and employment history including a record of any registration with or licensing by the governing body of a health profession.

(2) Every licensee shall retain an employee's employment record for at least two years after the employee ceases to be an employee. O. Reg. 57/92, s.7.

8 (1)Every licensee of an independent health facility shall maintain a record of qualifications and work history for:

(a)each person the licensee contracts with to manage the facility; and

(b)each person who is not a physician who the licensee contracts with to provide patient-related services in the facility.

(2)The record shall include a record of any registration with or licensing by the governing body of a health profession.

(3)Every licensee shall retain the record for a person the licensee contracts with for at least two years after the licensee ceases to contract with the person. O. Reg. 57/92, s.8.

9 (1)Every licensee shall maintain a declaration of professional standing for each physician who provides professional services in the independent health facility.

(2)A declaration of professional standing must include the following information:

1. The physician's name

2. The physician's registration number with the College of Physicians and Surgeons of Ontario

3. The physician's number registered with the Health Insurance Division of the Ministry of Health.

4. The class of the physician's licence issued under Part III of the *Health Disciplines Act* and any terms and conditions attached to it.

5. The physician's specialty.

(3) Every licensee shall give the Director a copy of each declaration of professional standing, forthwith after the obligation to maintain it begins under subsection (1).

(4)Every licensee shall give the Director a written statement of any change in a declaration of professional standing forthwith after the change.

(5)Subsections (3) and (4) do not apply with respect to physicians providing services on a temporary basis for less than twelve weeks. O. Reg. 57/92, s.9.

Patient Records

10 (1)Every licensee of an independent health facility shall keep, for each person who is or was a patient, a health record relating to the health services provided in the facility.

(2)A patient's health record must include:

(a) the patient's name and home address

(b) the patient's date of birth

(c) the patient's health number

(d) the name of any attending physician or practitioner and his or her number as registered with the Health Insurance Division of the Ministry of Health

(e) the name of any referring physician or practitioner and his or her number as registered with the Health Insurance Division of the Ministry of Health

(f) a history of the patient

(g) a written record of any orders for examinations, tests, consultations or treatments

(h) particulars of any examination of the patient

(i) any reports of examinations, tests or consultations including any imaging media from examinations and any physicians' interpretive or operative reports

(j) any reports of treatment including any physicians' operative reports

(k) any orders for and reports of any discharge of the patient from supervised care

(l) any consents; and

(m) any diagnoses of the patient.

(3) A patients health record need not contain a history of the patient if the patient came to the independent health facility for diagnostic services only and received only such services.

(4) Every licensee shall ensure that every part of a patient's record has a reference on it identifying the patient or the record.

(5) If information in a patient's record is kept in the form of a chart, each entry in the chart must be dated and it must be initialled by the person authorizing the entry. O. Reg. 57/92, s.10.

11 (1) Every licensee shall retain a patient's health record or a copy of it for at least six years following:

(a) the patient's last visit; or

(b) if the patient was less than eighteen years old when he or she last visited the facility, the day the patient became or would have become eighteen years old.

(2) Despite subsection (1), a licensee is not required to retain imaging media from any examination other than a mammography for more than three years following:

(a) the patient's last visit; or

(b) if the patient was less than eighteen years old when he or she last visited the facility, the day the patient became or would have become eighteen years old.

(3) Every licensee shall retain the film from a mammography for at least ten years following the patient's last visit. O. Reg. 57/92, s.11.

12 (1) No licensee shall allow any person to examine a patient's health record or give any person any information, copy or thing from a patient's health record except as required by any Act or regulation made under an Act or as required or allowed by this section. O. Reg. 57/92, s.12(1).

(2) Every licensee shall provide copies from a patient's health record to any of the following persons on request:

1. The patient.

2. A personal representative who is authorized by the patient to obtain copies from the record.

3. If the patient is dead, the patient's legal representative

4. If the patient is incapable of giving an authorization described in paragraph 2,

i. a lawfully authorized substitute decision maker

ii. a person to whom the patient is married

iii. a person of the opposite or same sex, with whom the patient is living in a conjugal relationship outside marriage if the patient and the person:

A. Have cohabited for at least one year

B. Are together the parents of a child, or

C. Have together entered into a cohabitation agreement under section 53 of the *Family Law Act*

iv. the patient's child if the child is sixteen years old or older

v. the patient's parent. O. Reg. 57/92, s. 12(2); O. Reg. 14/95, s.1

(3)A licensee may provide copies from a patient's health record to any person authorized by a person to whom the licensee is required to provide copies under subsection(2).

(4)A licensee may, for the purpose of providing health care, or assisting in the provision of health care, to a patient, allow a health professional to examine the patient's health record or give a health professional any information, copy or thing from the health record.

(5)A licensee may provide to the person described in subsection (6) information or copies from a patient health record if anything which could identify the patient is removed from the information or copies.

(6)Subsection (5) applies to:

1. Any person if the information or copies are to be used for health administration or planning or health research or epidemiological studies and the use is in the public interest as determined by the Minister.

2. The Ontario Cancer Treatment and Research Foundation.

(7)A licensee may charge a reasonable fee for any information, copies or thing provided under this section. O. Reg. 57/92, s.12(3-7).

Books and Accounts

12.1(1)This section applies to licensees of independent health facilities that are funded under section 24 of the Act, other than independent health facilities whose funding is based solely on the Ministry of Health publication titled “Schedule of Facility Fees”.

(2)Every licensee shall keep the following records in relation to the independent health facility:

1. Current financial records showing:

   i. the amounts paid by the Minister to the licensee under section 24 of the Act.

   ii. the revenue earned by the licensee from facility fees charged by the licensee for or in respect of services or operating costs that support, assist or are a necessary adjunct to the primary insured services set out in the licensee’s licence, and

   iii. the expenditures, assets and liabilities of the facility that relate to the costs paid by the Minister under section 24 of the Act.

2. A reporting record listing each service provided in the facility that is a primary insured service set out in the licensee’s licence and each service provided in the facility that is a funded service under section 24 of the Act and showing how many of each of such services are provided.

3. An annual income and expense statement showing the income received and the expenses incurred by the licensee in connection with the services mentioned in paragraph 2.

4. An annual inventory of the assets of the facility that have an acquisition cost exceeding $3,500 and that relate to the costs paid by the Minister under section 24 of the Act.

(3)Every licensee shall ensure that the records required under section (2):

(a) are kept in the independent health facility; and

(b) are kept in a bound or looseleaf book or are recorded by a system of mechanical or electronic data processing or any other information storage device.

(4)Every licensee shall ensure that any part of a record required under subsection (2) that relates to a period of time is retained for at least six years following the end of the period.

(5)Every licensee shall ensure that the accounts of the independent health facility are audited by a person licensed under the *Public Accountancy Act.* O. Reg. 283/94, s.1, *part.*

12.2 Every licensee of an independent health facility shall furnish such information and accounts as the Director may require. O. Reg. 283/94, s.1, *part*.

Notices

13. Every licensee of an independent health facility,

(a) who decides to cease operating the facility at a future date shall give the Director, as soon as possible, written notice of the date; and

(b) who ceases operate the facility shall give the Director, within seven days after the date the licensee ceases to operate the facility, written notice of the date. O. Reg. 57/92, s.13.

14. Every licensee of an independent health facility shall give the Director:

(a) if the licensee is a corporation, written notice of any change in the location of the licensee's head office within ten days after the change; and

(b) written notice of any change in the name under which the licensee carries on business within ten days after the change. O. Reg. 57/92, s.14.

Miscellaneous

15.It is a condition of a licence that the licensee post the first page of the licence in a conspicuous place in the independent health facility. O. Reg. 57/92, s.15.

16 (1)The fee for a licence is $100.

(2)The fee for the transfer of a licence is $100.

(3)The fee for the renewal of a licence is $100. O. Reg. 57/92, s.16.

17.The administrative charge for the purposes of section 36 of the Act is $50. O. Reg. 57/92, s.17.

Appendix II Sample Latex Allergy Questionnaire

Overview

A sample Latex Allergy Questionnaire is provided on the following pages.

Latex Allergy Questionnaire

I. Risk Factor Assessment

Please circle Y or N to answer the following questions

Exposure History:

Are you a health care worker?	Y	N
Do you wear latex gloves regularly or are you otherwise exposed to latex regularly?	Y	N
Do you have a history of eczema or other rashes on your hands?	Y	N
Do you have a medical history of frequent surgeries or invasive medical procedures?	Y	N
Did these take place when you were an infant?	Y	N
Do you have a history of “hay fever” or other common allergies?	Y	N
Do your fellow workers wear latex gloves regularly?	Y	N
Do you take beta-blocker medication?	Y	N

List any foods below that cause hives, itching of the lips or throat, or more severe symptoms when you eat or handle them:

II. Contact Dermatitis Assessment

For patients who wear latex gloves frequently

Do you have rash, itching, cracking, chapping, scaling, or weeping of the skin from latex glove use?	Y	N
Have these symptoms recently changed or worsened?	Y	N
Have you used different brands of latex gloves?	Y	N

II. Contact Dermatitis Assessment cont'd

If so, have your symptoms persisted?	Y	N
Have you used non-latex gloves?	Y	N
If so, have you had the same or similar symptoms as with latex gloves?	Y	N
Do these symptoms persist when you stop wearing all gloves?	Y	N

III. Contact Urticaria (Hives) Assessment

For patients who wear latex gloves frequently

When you wear or are around others wearing latex gloves do you get hives, red itchy swollen hands within 30 minutes or, "water blisters" on your hands within a day?	Y	N

IV. Aerosol Reaction Assessment

When you wear or are around others wearing latex gloves, have you noted any of the following:

Itchy, red eyes, fits of sneezing, runny or stuffy nose, itching of the nose or palate?	Y	N
Shortness of breath, wheezing, chest tightness or difficulty breathing?	Y	N
Other acute reactions, including generalized or severe swelling or shock?	Y	N

V. History of Reactions Suggestive of Latex Allergy

Do you have a history of anaphylaxis or of intra-operative shock?	Y	N
Have you had itching, swelling or other symptoms following dental, rectal or pelvic exams?	Y	N
Do condoms, diaphragms or latex sexual aids cause itching or swelling?	Y	N
Do rubber handles, rubber bands or elastic bands or clothing cause any discomfort?	Y	N

Appendix III Sample Patient Survey: Quality of Care

Please rate the following things about your visit to this clinic in terms of whether they were poor, fair, good, very good, or excellent. Circle the number 1 for poor; 2 for fair; 3 for good; 4 for very good, and 5 if you felt it was excellent. If something doesn't apply to your visit or you don't have an opinion, please circle the number 8.

Please rate each item by circling the number that best describes your opinion	**Poor**	**Fair**	**Good**	**Very Good**	**Excellent**	**Not Applicable No Opinion**
1. Waiting time: how long you had to wait to get an appointment at this clinic	1	2	3	4	5	8
2. Waiting time: how long you had to wait in the clinic waiting room for your appointment	1	2	3	4	5	8
3. Instructions: how well the clinic staff (doctors, receptionists, technologists etc.) told you how to prepare for the test(s) and what to expect both before and/or during the test(s)	1	2	3	4	5	8
4. Ease of getting information: willingness of clinic staff to answer your questions	1	2	3	4	5	8
5. Information you were given: how clear and complete the explanations were about any possible risks and complications of the test(s)	1	2	3	4	5	8
6. Concern and caring by clinic staff: courtesy and respect you were given, friendliness and kindness; how well clinic staff listened to what you had to say; how well the clinic staff understood what you thought was important	1	2	3	4	5	8
7. Safety and security: the provisions for your safety and the security of your belongings	1	2	3	4	5	8
8. Privacy: how well your privacy was considered, for example, type of gowns used, privacy while changing clothes	1	2	3	4	5	8
9. Instructions on leaving: how clearly and completely you were told what to do and what to expect when you left the clinic	1	2	3	4	5	8

PLEASE TURN OVER THIS PAGE

Please answer the following questions by circling 1 for Yes or 2 for No.	YES	NO
10. Were you told to leave the clinic before you felt ready to do so?	**1**	**2**
11. Did you have to visit a physician, walk-in clinic, emergency room, urgent care centre or hospital in the days following this service because your health got worse as a result of the service(s) received at the clinic?	**1**	**2**
12. Would you recommend the clinic to a friend or family member if they needed services that it provides?	**1**	**2**

Please rate this item by circling the number that best decribes your opinion	Poor	Fair	Good	Very Good	Excellent	Not Applicable No Opinion
13. Overall quality fo care: how you evaluate the services you received and the way you were treated	**1**	**2**	**3**	**4**	**5**	**8**

14. If there were some things you could change about this visit to improve it, what would they be?

Thank you for completing this survey. Please double check that you have answered all questions and then place the survey in the envelope provided. Your answers will be kept completely confidential.

Thank you again for your help!

Appendix IV Sample Referring Physician Survey-Independent Health Facilities Program

_____

name of facility

Please answer the following questions regarding your experience with the above facility by filling in the blank or circling the number that best decsribes your answer.

1. How long have you referred patients to this facility?

_____years or _____months

Please base your answers on your contact with the facility in the past 6 months.

2. How satisfied are you with how long it generally takes: *(Please rate each item by circling the number that best describes your opinion)*

	Not Applicable	Very Dissatisfied	Dissatisfied	Neutral	Satisfied	Very Satisfied
to get an appointment for a patient at this facility?		**1**	**2**	**3**	**4**	**5**
to obtain written results (a written consultation) from this facility, once your patient is seen?		**1**	**2**	**3**	**4**	**5**
to get an oral report from this facility when it is required because of an urgent or emergency situation, once your patient is seen?	**0**	**1**	**2**	**3**	**4**	**5**

3. How often do you speak to a physician at the IHF regarding the patient's clinical condition <u>before</u> your patient receives a diagnostic work-up?

Never	Rarely	Occasionally	Sometimes	Often	Almost all the time
1	2	3	4	5	6

4. Approximately how many patients have you referred to this facility in the past 6 months? _____(number of patients referred)

5. Do you refer your patients to more than one facility of this type?

1 No *(if you circled No, please **skip to Question number 7**)*

2 Yes

6. What are the reasons you refer patients to this particular facility? *(Please circle all that apply.)*

1 Nearer Patient's home
2 Has specialized equipment needed for test requested
3 Turn around time to receive the results is shortest
4 Has staff that speak other languages, and thus can better understand my patients
5 Is able to quickly see patients when feedback is urgently required
6 Has convenient hours of operation
7 Quality of the services provided
8 Other, please describe _____

Please skip to Question number 8.

7. What are the reasons you refer patients only to this facility? *(Please circle all that apply.)*

1 Only facility of its type in this community
2 Our group has a service contract with this facility
3 Facility is located near this practice and is thus convenient for patients
4 Has staff that speak other languages and thus can better understand my patients
5 Has specialized equipment needed for tests requested
6 Turn-around time to receive results is short
7 Nearest patients' homes
8 Is able to quickly see patients when feedback is urgently required
9 Quality of the services provided
10 Has convenient hours of operation
11 Other, please describe_____

8. Please rate each item by circling the number that best describes your experience with the IHF based on your contacts in the last 6 months.

	Never	Seldom	Sometimes	Frequently	Usually
The waiting period for a test to be done is long.	**1**	**2**	**3**	**4**	**5**
Requests for consultation are handled promptly.	**1**	**2**	**3**	**4**	**5**
The facility accommodates patients when the test is urgently required.	**1**	**2**	**3**	**4**	**5**
The interpreting physician is available to you for consultation.	**1**	**2**	**3**	**4**	**5**
This facility meets the needs of my patients whose first language is other than English or French.	**1**	**2**	**3**	**4**	**5**
The recommendations received are useful in patient management.	**1**	**2**	**3**	**4**	**5**
The recommendations are clearly stated.	**1**	**2**	**3**	**4**	**5**
The reports received are too wordy.	**1**	**2**	**3**	**4**	**5**
Reports of results are sent out in a timely fashion.	**1**	**2**	**3**	**4**	**5**
The consulting physician orders tests in addition to those you requested.	**1**	**2**	**3**	**4**	**5**
When tests are added the resulting recommendations add information important to patient care.	**1**	**2**	**3**	**4**	**5**
The interpreting physician's findings are generally consistent with your clinical findings.	**1**	**2**	**3**	**4**	**5**

9. Have you been dissatisfied with a consult you received from this facility in the past six months? 1 No 2 Yes

If 2 (Yes), please explain:

10. Overall, how satisfied are you with the contacts you have had with this facility in the past six months?

Very Dissatisfied	Dissatisfied	Neutral	Satisfied	Very Satisfied
1	2	3	4	5

Thank you for participating in this survey. Please return the survey in the envelope provided.

Our address is:

Appendix V CT Screening Policy Statement

Adopted by the CAR on March 2002

Cancer (lung and colon) and cardiovascular disease are the leading causes of death in Canada. With the aging of the population the prevalence of those ailments will become more important and Canadians are looking for ways to reduce the risk for those diseases.

Based on the premise that early diagnosis will yield positive Health benefits we have witnessed in recent years, an interest in CT screening for lung cancer, coronary calcium screening, virtual colonoscopy and total body scans.

However, to date, there is no evidence that CT screening is cost-effective or is effective in the management of those diseases.

CORONARY CALCIUM SCORING

Traditional cardiovascular disease risk factors are incomplete in predicting the risk of future cardiovascular events. In fact 50% of individuals with accurate myocardial infraction have a normal cholesterol profile. Coronary calcium is a marker of the extent of the disease and one of an array of tools that may help discriminate individuals who are at highest risk of future cardiac events.

Preliminary findings suggest that the presence of coronary calcium is indicative of a relative risk of having a cardiac event it is not yet know if the information is additive or simply redundant. Therefore, the cost-effectiveness for coronary calcium scoring has not been demonstrated and the information on age, gender and other variables are not yet available.

VIRTUAL COLONOGRAPHY

CT colonography has many advantages over other techniques. CT colonography eliminates the discomfort or risks that are associated with a barium enema and a conventional colonoscopy. However, some studies indicate that the sensitivity and specificity of CT colonography are lower than that for traditional colonoscopy. Research on the benefits and effectiveness of this screening technique is ongoing and data is not yet available. Given the lack of data it is impossible to determine its cost-effectiveness and usefulness which raises the question of whether or not screening tests should be performed on asymptomatic or low risk patients.

LUNG CANCER

Several screening trials using CT have issued preliminary findings with encouraging survival rates results. However, it is thought that survival statistics can be quite misleading as there might be no relation between variables.

In the screening trials, lead time bias and over diagnosis were identified as areas of concerns and further studies are needed before its effectiveness can be demonstrated.

WHOLE BODY CT

Whole Body CT is the most controversial of all the new screening mechanisms.

Based on the assumption that diseases may not yield symptoms before the occurrence of a life threatening event it has been recommended as part of a routine yearly exam and for individuals wishing to take charge of their health.

However, it has been found not to be uncommon to detect a series of abnormalities with whole body CT screening test that later, after more test are performed, to be of no consequence for the patient. The anxiety and additional expenses for no proven benefits for patients or society is of concern here in Canada and in the US.

Those tests, not being medically necessary, are not covered by any medicare system in Canada. Furthermore, these CT examinations are done without normal physician referral or any type of utilization review nor control on appropriateness.

One of the impact of such screening test being performed in a private for profit situation is the potential for abuse and the increased utilization of publicly funded medical services in follow-up or in additional diagnostic work-up of suspicious findings, which over utilize precious human and material resources of the public health care system.

PATIENT INFORMED CONSENT

Resolution MW-02-16 of the CAR, adopted in March 2002, indicates that if CT screening is offered (CAR standards are in opposition to CT screening, but in cases where colleges have not looked into the ethical and liability issues, it is practiced), it is asked that adequate informed consent be obtained before performing the examination.

Appendix VI FDA Public Health Notification: Reducing Radiation Risk from Computed Tomography for Pediatric and Small Adult Patients

(You are encouraged to copy and distribute this information)

November 2, 2001

To: Radiologists

Radiation Health Professionals

Risk Managers

Hospital Administrators

While the benefits of computed tomography are well known in diagnosing diseases and trauma and in the guidance of interventional and therapeutic procedures, those benefits are not without risks. This Notification is to emphasize the importance of keeping radiation doses during CT procedures as low as reasonably achievable, especially for pediatric and small adult patients, who may sometimes receive more radiation than needed to obtain diagnostic imag es.To prevent this, we want to stress the importance of adjusting CT scanner parameters appropriately for each individual's weight and size, and for the anatomic region being scanned.

Background

The individual risk from the radiation associated with a CT scan is quite small compared to the benefits that accurate diagnosis and treatment can provide. Still, unnecessary radiation exposure during medical procedures should be avoide d.This is particularly important when the patient is a child, since children exposed to radiation are at a relatively greater risk than adults.[1] The American College of Radiology has noted, "Because they have more rapidly dividing cells than adults and have longer life expectancy, the odds that children will develop cancers from x-ray radiation may be significantly higher than adults."[2] It has been estimated by the National Research Council's Committee on the Biological Effects of Ionizing Radiation that children less than 10 years of age are several times more sensitive to radiation than middle-aged adults.[3] Unnecessary radiation may be delivered when CT scanner parameters are not

appropriately adjusted for patient size.[4] When a CT scan is performed on a child or small adult with the same technique factors that are used for a typically-sized adult, the small patient receives a significantly larger effective dose than the full-sized patient. To compound the problem, the overexposure of children or small adults during CT procedures can easily go unrecognized .In conventional x-ray procedures, medical personnel can tell if the patient has been overexposed because the resulting film is overexposed, producing a dark image.[5] But with CT, there is no obvious evidence that the patient has been overexposed because the quality of the image may n o t b e c o m p r o m i s e d .

Several recent articles stress that it is important to use the lowest radiation dose necessary to provide an image from which an accurate diagnosis can be made, and that significant dose reductions can be achieved without compromising clinical efficacy.[2,5,6,7,8,9,10]

Recommendations

Here are the steps we are recommendin g .They are not new .Indeed, many facilities are already taking measures to protect children and other small patients from unnecessary exposure during CT procedures.[11,12,13]

1. Optimize CT Settings. Based on patient weight or diameter and anatomic region of interest, evaluate whether your CT operating conditions are optimally balanced between image quality and radiation exposure. To reduce dose while maintaining diagnostic image quality:

- **Reduce tube current.** With all other factors held constant, patient radiation dose is directly proportional to x-ray tube cur r ent.For example, a 50 percent reduction in tube current results in a 50 percent decrease in radiation dose.[9]
- **Develop and use a chart or table of tube-current settings based on patient weight or diameter and anatomical region of interest.** See reference 9 for an example of tube current settings based on patient weight and anatomical region of interest (i.e., chest, pelvis or abdomen) for a single-detector helical-scanning CT unit. The diameter of the patient may be a better predictor of the tube-current required than body weight because patient diameter better correlates with the x-ray beam attenuation in the patient.[10] Your facility's medical physicist and the scanner manufacturer can help in developing this chart or table.
- **Increase table increment (axial scanning) or pitch (helical scanning).** If the pitch is increased, the amount of radiation needed to cover the anatomical area of interest is decreased.[2,14] One study showed that increasing the pitch from 1:1 to 1.5:1 decreased the radiation dose by 33 percent without loss of diagnostic information.[15] Consult your facility's medical physicist, who can advise you on optimal tube-current and pitch settings for diagnostic requirements. You can also contact the manufacturer of the CT scanner for recommendations specific to your model.

Note that some newer CT scanners may automatically suggest or implement an increase in mA if pitch is increased. For these models, increasing the pitch may not result in a lower radiation dose. Contact the CT scanner's manufacturer for recommendations on your model's automatic current adjustment features.

2. Reduce the number of multiple scans with contrast material . Often, CT scans are done before, during, and after injection of IV contrast material. When medically appropriate, multiple exposures may be reduced by eliminating pre-contrast images (i.e., unenhanced images).[9]

3. Eliminate inappropriate referrals for CT . In some cases, conventional radiography, sonography, or magnetic resonance imaging (MRI) can be just as effective as CT, and with lower radiation exposure. Most conventional x-ray units deliver less ionizing radiation than CT systems, and sonography and MRI systems deliver no x-ray radiation at all. It is important to triage these examinations to eliminate inappropriate referrals or to utilize procedures with less or no ionizing radiation.[9]

Reporting adverse events to FDA

We encourage you to report computed tomography equipment malfunctions. You can report these directly to the device manufacturer. You can also report to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch one of four ways: online at ***http://www.accessdata.fda.gov/scripts/medwatch/***; by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

Getting more information

All of the FDA medical device postmarket safety notifications can be found on the World Wide Web at ***http://www.fda.gov/cdrh/saefty.html***. Postmarket safety notifications can also be obtained through e-mail on the day they are released by subscribing to our list server. You may subscribe at ***http://list.nih.gov/archives/dev-alert.html***. You may also subscribe by sending an email to ***listserv@list.nih.gov***. In the body of the text, type "SUBSCRIBE DEV-ALERT firstname lastname".

Sincerely yours,

David W. Feigal, Jr., MD, MPH

Director

Center for Devices and Radiological Health

Food and Drug Administration

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Updated November 5, 2001

AppendixVII Whole Body Scanning Using Computed Tomography (CT)

The following was recently provided on the Food and Drug Administration's Website on April, 2002. As per their online copyright information, it is being reproduced here:

http://www.fda.gov/ (for full original text)

Currently some medical imaging facilities are promoting a new use of computed tomography (CT), also called computerized axial tomography (CAT) scanning. This use is referred to as whole-body CT scanning or whole-body CT screening, and it is marketed as a preventive or proactive healthcare measure to healthy individuals who have no symptoms or suspicion of disease. **At this time the FDA knows of no data demonstrating that whole-body CT screening is effective in detecting any particular disease early enough for the disease to be managed, treated, or cured and advantageously spare a person at least some of the detriment associated with serious illness or premature death.** Any such presumed benefit of whole-body CT screening is currently uncertain, and such benefit may not be great enough to offset the potential harms such screening could cause. Public health agencies and national medical societies-the **American College of Radiology**, the **American College of Cardiology**, the **American Association of Physicists in Medicine**, and the **American Heart Association** -do not recommend CT screening.

Important information regarding whole-body CT screening:

- **Such screening provides uncertain benefit with potential for some risk** - The most likely outcomes of CT screening of a healthy person with no symptoms of illness are:

    1. Normal findings or
    2. Suspicious findings requiring follow-up tests

    Normal findings carry the possibility of inaccuracy and false reassurance. For suspicious findings, follow-up may involve simple, non-invasive testing. It may also involve invasive procedures associated with surgical risks of anesthesia, bleeding, infection, scarring, or it may entail additional radiological exams, associated with radiation risk and the potential risk of allergic reaction to injected contrast material. In any case, it is unlikely that CT screening will benefit an individual lacking signs or symptoms of disease by detecting a serious disease early enough to treat it and alter the outcome significantly.

- **Radiation Dose** - CT screening subjects the individual screened to radiation exposure from x rays. The dose a patient receives during a typical CT procedure is generally much larger than the radiation doses associated with most conventional x-ray imaging procedures. The principal risk associated with the radiation dose resulting to a person from a CT procedure is the small possibility of developing a radiation-induced cancer some time later in that person's life. For a patient with a medical need, the benefit of a diagnostic or therapeutic CT procedure recommended by a physician normally far exceeds the small cancer risk associated with a CT procedure. For a person without symptoms, CT screening is unlikely to discover serious disease, and the potential harm to the individual may be greater than the presumed benefit.
- **Scientific Studies** - There are no data demonstrating that **whole-body** CT screening of individuals without symptoms provides a greater probability of benefit than harm. Nor is there any scientific study known to be underway to develop such data. Although there are several ongoing investigational studies of the effectiveness of using CT to screen people, the studies are focused on high-risk groups for specific diseases (e.g., cigarette smokers for lung cancer). In such studies only a limited portion of the body is irradiated, not the whole body, and only screening for a specific type of disease is being evaluated, rather than screening for just anything that might be found anywhere in the body.
- **No Food and Drug Administration (FDA) Approval of CT for Screening** - Statements by CT imaging facilities that imply FDA "approval," "clearance," or "certification" of CT for screening procedures misrepresent the actual situation. FDA has never approved or cleared or certified any CT system specifically for use in screening (i.e., of individuals without symptoms), because no manufacturer has ever demonstrated to the FDA that their CT scanner is effective for screening for any disease or condition.

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