Computed Tomography Radiation Safety

Issues in Ontario

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Executive Summary

Issue

Computed tomography (CT) is a powerful tool for the accurate and effective diagnosis and treatment of a variety of conditions because it allows high-resolution three-dimensional images to be acquired very quickly. Therefore, the use of CT has increased substantially over the past decade, resulting in growing concern over the radiation dose from CT. CT technological advances, such as the 64-slice CT scanner released in 2005, have led to new clinical CT applications that could result in further increases in patient radiation dose.

Purpose of this Report

In April 2005, the Ontario Health Technology Advisory Committee reviewed the available evidence on the use of multi-detector CT imaging, focusing on coronary artery disease, and found that the additional clinical benefit of images obtained by new CT technology was unknown. As a result, one of the committee's recommendations was that the Ministry of Health and Long-Term Care request the Healthcare Human Factors Group at the University Health Network to determine how to best balance CT image quality and patient radiation safety.

This appraisal discusses the CT radiation dose issues found through a literature review, a CT survey conducted of 20 Ontario healthcare institutions (18 respondents) with 64-slice CT scanners, and interviews with CT experts. The topics that are appraised in this report include methods to reduce radiation dose, testing and inspection of CT scanners, coronary CT angiography radiation issues, and dental CT radiation issues.

Summary of Findings and Recommendations
Overview of the CT Radiation Dose and Risks

In Canada, CT examinations grew by 8% from 2003/2004 to 2004/2005.(1) At a major Canadian hospital, CT examinations increased threefold between 1991 and 2002.(2) CT is estimated to account for approximately 10% of diagnostic examinations, but over 60% of the total effective radiation dose from diagnostic imaging.(2-4)

The effective radiation dose from a typical CT examination of the chest is approximately equivalent to three times the amount of natural background radiation that each Canadian receives per year. The effective dose from CT, however, can be orders of magnitude greater than a traditional plain film examination (e.g., 400 times more radiation dose from a typical CT chest examination compared to a plain film chest x-ray).(5, 6)

From 1991 to 1996 data, the cumulative risk of cancer to age 75 years attributable to diagnostic x-rays was estimated to be 1.1% in Canada, corresponding to 784 cases of cancer per year.(7) These figures might be an underestimate because of the increasing radiation dose from diagnostic x-rays over the past years. The cancer risk from 100 mSv (equivalent effective radiation dose of 10 typical abdominal CT examinations) was estimated by the National Research Council (8) to be one out of 100 people, and six out of 1000 people by the International Commission on Radiological Protection (9). Lifetime radiation risks are particularly a concern for children because of their increased sensitivity and they have more expected years of life after radiation exposure compared to adults.(10, 11)

As a result of these findings of significantly increasing frequency of CT use and its associated radiation dose, CT examinations in Ontario should be more closely monitored and standards should be developed.

> *It is recommended that there be an establishment of a provincial CT safety steering committee responsible for development of CT standards and monitoring of:*
> - *Patient and staff CT radiation exposure*
> - *CT protocols and other methods of dose reduction*
> - *Testing and inspection of CT scanners*

Dose Reduction Methods

The method to achieve the greatest patient dose reduction from CT examinations is the utilization of CT protocol parameters that minimize radiation exposure without compromising the required diagnostic image quality. Surveys have found that patient radiation dose can vary up to a factor of 40 for the same examination at different healthcare institutions. (12-14) The Ontario CT survey performed for this report also found that *significant variations in CT protocols, and therefore radiation doses, exist between healthcare institutions in Ontario*.

> *It is recommended that methods (e.g. web-based repository) to help share best-practice CT protocols between heathcare institutions be developed.*

The establishment of diagnostic reference levels, such as in the UK, has been found to be an effective method of reducing patient radiation dose from diagnostic examinations including CT. Diagnostic reference levels can be used to identify institutions that consistently use higher radiation doses for the same clinical indications compared to other institutions in the same region.

> *It is recommended that the distribution of radiation dose for various CT examinations in Ontario be determined and diagnostic reference levels be established. The cycle*

> *of surveying CT radiation dose and setting diagnostic*
> *reference levels should be repeated periodically.*

Examples of other techniques to reduce CT radiation dose include the use of the automatic exposure control feature on CT scanners and patient shielding. The Ontario CT survey revealed ***significant variations in practice between healthcare institutions, such as if automatic exposure control is used and the amount and type of patient shielding used***.

> *It is recommended that standardized guidelines for patient*
> *shielding and CT imaging techniques be developed to*
> *reduce patient radiation dose.*

Testing and Inspection of CT Scanners

There are no Ontario or federal regulations and guidelines specifically intended for CT scanner testing. CT is excluded from the Ontario *HARP Act Regulation 543 X-ray Safety Code* (15), but a federal safety code for the installation, use, and control of radiological x-ray equipment including CT scanners is scheduled for publication in 2007/2008. In addition, unlike other diagnostic x-ray machines, CT scanners are not specifically inspected by the Ontario X-ray Inspection Services. ***The lack of comprehensive Ontario CT regulations, guidelines, and standards have led to significant variability in the frequency and methods of CT scanner testing***, as found in the Ontario CT survey.

> *It is recommended that the HARP Act and its regulations*
> *be amended to include guidelines on the installation*
> *process, use, and testing of CT scanners, and to permit*
> *provincial inspection and oversight.*

Coronary CT Angiography

Coronary CTA has been suggested as a replacement for conventional diagnostic fluoroscopic coronary angiography (CA). The dose estimates from coronary CTA have been found to range from 7 to 13 mSv, while the dose estimates from conventional diagnostic CA have been found to range from 3 to 25 mSv.(16) ***Therefore, the patient radiation dose from coronary CTA appears to be within the same range as that from conventional diagnostic CA. The use of appropriate coronary CTA protocol parameters and techniques have been found to substantially reduce patient radiation dose.***(17)

> *It is recommended that guidelines on coronary CTA*
> *protocol parameters and techniques (e.g. prospective ECG*
> *gating) be established to minimize radiation exposure.*

Dental CT

CT scanners designed for dental imaging in dental offices and oral radiology centres employ cone-beam CT technology (CBCT), which in general leads to lower radiation exposure than conventional CT. The radiation dose from CBCT is comparable to low-dose CT, but can be up to 15 times lower than conventional CT with standard protocols.(18) *CBCT examinations can provide more clinically useful information than panoramic radiography examinations, but studies have found that the radiation dose from dental CBCT can be 4-15 times higher than panoramic radiography*.(18) In Ontario, there are five installations of dental CBCT scanners which are generally operated by dental assistants.

> *It is recommended that requirements for the installation of new dental CBCT scanners in Ontario (e.g. monitoring of frequency, purpose, and dose), and for training and continuing education of dental CBCT operators (and dentists who interpret and order) be developed.*

CT is undoubtedly an important modern medical tool with great diagnostic and therapeutic value. The purpose of this report is to propose approaches to reduce patient radiation exposure while retaining the benefits of this modality.

Abbreviations

AEC	automatic exposure control
ALARA	as low as reasonably achievable
BEIR Committee	Biological Effects of Ionizing Radiations Committee
CA	coronary angiography
CAD	coronary artery disease
CBCT	cone beam computed tomography
CT	computed tomography
CTA	computed tomography angiography
CTDI	computed tomography dose index
DAP	dose-area product
DICOM	Digital Imaging and Communications in Medicine
DLP	dose-length product
DRL	diagnostic reference level
E	effective dose
ECRI	Emergency Care Research Institute
FOV	field of view
Gy	gray (unit of radiation dose)
HARP Act	Healing Arts Radiation Protection Act
HPA	Health Protection Agency
ICRP	International Commission on Radiation Protection
ImPACT	Imaging Performance Assessment of CT scanners
kVp	kilovolts peak (unit to describe x-ray tube voltage)
LNT model	linear no-threshold model
mA	milliamperes (unit to describe x-ray tube current)
MDCT	multi-detector computed tomography
MOSFET	metal oxide semiconductor field effect transistor
mSv	millisievert (thousandth of a unit of effective dose)
NCRP	National Council on Radiation Protection and Measurements
NPDD	National Patient Dose Database
NRPB	National Radiological Protection Board
OECD	Organization for Economic Co-operation and Development
PACS	picture archiving and communication system
PET/CT	positron emission tomography/computed tomography
PR	panoramic radiography
R	roentgens (unit of radiation exposure)
RED Act	Radiation Emitting Devices Act
RPO	Radiation Protection Officer
Sv	seivert (unit of effective dose)
TLD	thermo-luminescent dosimeter
UK	United Kingdom
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
US	United States

Issue

The use of CT for medical diagnosis has substantially increased over the past decade, resulting in increasing patient radiation dose from this imaging modality.(2, 4, 14, 19) The introduction of 64-slice CT scanners has further increased the patient throughput and the indications for CT. There is a growing concern that radiation exposure from diagnostic imaging will increase the risk of cancer.(7)

In April 2005, the Ontario Health Technology Advisory Committee reviewed the available evidence on the use of multi-detector CT imaging, with an emphasis on 64-slice CT scanners and coronary artery disease. It was found that the additional clinical benefit of images obtained by new CT technology was unknown. As a result, one of the committee's recommendations was that the Ministry of Health and Long-Term Care request the Healthcare Human Factors Group at the University Health Network to determine how to best balance CT diagnostic image quality and patient radiation safety.

This report is divided into the following five areas:
- General 64-slice CT technology and the associated radiation issues
- Methods that can be used to reduce radiation dose from 64-slice CT
- Testing and inspection of CT scanners with respect to radiation and quality control
- Radiation dose issues from coronary CT angiography compared to conventional coronary angiography
- Radiation dose issues surrounding dental CT scanners

Review Strategy

The information for this review was gathered from three main sources: literature reviews, responses from a questionnaire sent to Ontario healthcare institutions with 64-slice CT scanners, and interviews, including site visits, with CT experts.

Literature Review
Published peer-reviewed literature on CT radiation was reviewed, with a focus on 64-slice CT, coronary CT angiography, and dental CT. Guidelines, regulations, reports, and articles from provincial, national, and international organizations regarding radiation exposure from diagnostic medical imaging were also reviewed. These organizations included governmental bodies, as well as associations and societies (e.g. the Radiological Society of North America). AuntMinnie.com, a comprehensive community Internet site for radiologists and related professionals in the medical imaging industry, provided current updates on advances in CT technology. Some of the main international organizations that regulate and advise on radiation exposure are listed in Appendix 1.

Ontario CT Survey
On May 15, 2006, a questionnaire was sent to 20 Ontario healthcare institutions with 64-slice CT scanners in order to gain an understanding of the current CT utilization practices. The questionnaire was electronically sent to the Director/Manager of the Medical Imaging Department and the Chief Executive Officer of each of the healthcare institutions. The survey included questions on the development and use of CT scanning protocols, the use of low-dose CT protocols, patient and staff radiation shielding practices, screening women of child-bearing age, types and numbers of CT examinations performed, the use and recording of patients' radiation dose histories, testing of CT scanners, and the number and brand of 64-slice CT scanners installed. Each Director/Manager of the Medical Imaging Department was asked to forward the questionnaire to the appropriate CT technologist(s) and/or radiologist(s) for completion, and to return the responses electronically within a week. Out of the 19 healthcare institutions that were sent a questionnaire, 18 provided a response. A summary of the results is provided in Appendix 2.

Interviews and Site Visits
For each of the four 64-slice CT scanner manufacturers, a site visit was made to a healthcare institution that installed at least one of their 64-slice CT scanners. Interviews were also conducted with radiologists, interventional radiologists, dentists, CT technologists (including representatives from the Ontario Association of Medical Radiation Technologists), representatives from each 64-slice CT manufacturer, representatives from Ontario government agencies, CT physicists, representatives from the dental CT manufacturers, Radiation Protection Officers, Radiation Safety Officers, etc.

Exclusions

The following topics are excluded from this report:
- Indications for MDCT examinations
- Use of alternative imaging modalities, such as Magnetic Resonance Imaging
- Screening with MDCT
- CT for radiotherapy treatment localization
- CT angiography other than for diagnostic coronary angiography, focusing on coronary artery disease detection
- MDCT for calcium scoring
- Training/certification of medical radiation technologists for CT
- Radiation awareness by staff and patients
- Technologies combining CT and another imaging modalities, such as PET/CT (Positron Emission Tomography/Computed Tomography)

Benefits of CT

CT is an important, and sometimes life-saving tool for diagnostic medical examinations and guidance of interventional and therapeutic procedures. It allows rapid acquisition of high-resolution three-dimensional images, providing radiologists and other physicians with cross-sectional views of the patient's anatomy. CT can be used to image many types of tissues, such as soft tissues, bones, lungs, and blood vessels. CT examinations are also non-invasive, although a contrast agent is sometimes administered to the patient. As a consequence of the benefits of CT examinations, it has become the gold standard for a variety of clinical indications, such as diagnosing certain cancers, surgical planning, and identifying internal injuries and bleeding in trauma cases.

Radiation Dose and Risks

CT Utilization and Increased Radiation Dose

Diagnostic examinations are the largest source of man-made radiation exposure to the general population, contributing about 40% of the total annual worldwide exposure from all sources in Group of Eight countries like Canada.[4, 20, 21] They are the second largest source of radiation exposure, with natural background radiation being the first.[4] Radiation exposure from CT has been steadily increasing and is now by far the largest component of the total radiation exposure from diagnostic imaging.[2, 4, 19]

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) reported that during 1991-1996, on average for Health-care level I countries, CT represented 6% of all diagnostic medical x-ray examinations but accounted for 41% of the total population dose. Globally, CT accounted for 34% of the collective dose between 1991-1996, up from 14% of the collective dose between 1985-1990.[19]

Aldrich, Lentle, and Vo [21] performed a study in 1997 on behalf of the Advisory Committee on Radiological Protection of the Atomic Energy Control Board of Canada, estimating the radiation dose to Canadians from diagnostic medicine using Statistics Canada data from 1991. The per capita effective dose was found to be 0.94 mSv for x-ray procedures. CT was found to account for about 3% of x-ray procedures but 20% of the radiation dose.

A 2003 study by Hart and Wall [3] found that in the UK, CT doubled its contribution to the radiation dose from medical x-rays in the past decade. CT represented 7% of all x-ray examinations (excluding mammographic screening) but was responsible for 47% of the total population dose. The number of CT examinations increased by 39% in the 4 years between 1997/1998 to 2001/2002.

Mettler et al. (4) found that at their American institution, the number of CT examinations increased from 6.1% to 11.1% of all radiology procedures between 1990 and 1999. CT contributed to 67% of the radiation dose from diagnostic x-ray procedures. They also found that 19% of all patients seen in the radiology department in the last year had at least one CT scan, with more than half having multiple CT scans on the same day.

A study by Aldrich and Williams (2) found that at a Canadian hospital, the effective dose from CT accounted for 60% of total patient dose from diagnostic examinations by 2002. The number of CT examinations increased threefold between 1991 and 2002. The proportion of CT examinations increased fourfold between 1995 and 2002. The authors also reported a 28% increase in the total number of patient examinations from 1991 to 2002 and that the effective dose per patient from diagnostic imaging nearly doubled (3.3. mSv in 1991 to 6.0 mSv in 2002).

According to the 2005 Canadian Institutes of Health Information report, *Medical Imaging in Canada*, the number of CT scanners in Canada has increased 19% from five years earlier.(1) Canada is ranked 15th among the Organization for Economic Co-operation and Development (OECD) countries in CT scanners per million population, with 11.3 per million. The median was 14.0 per million population. In 2005, a total of 108 CT scanners were installed in Ontario, and 361 in all of Canada (an increase from the 303 CT scanners in place five years earlier). In the same year, the number of CT examinations in Ontario was 80 exams per 1000 population, which was below the Canadian average of 87. In comparison, the US performs 173 CT examinations per 1000 population, nearly double that of Canada. The number of Canadian CT examinations in 2005 grew by 8.0% over the previous year.(1)

The development of MDCT has introduced a variety of new CT applications such as CT angiography, and has increased the indications for CT in established areas such as imaging of the chest.(22) The increased use of MDCT, therefore, has also increased the challenge of radiation protection. Although there are numerous methods to minimize radiation dose from CT, as described in the *Radiation Dose Reduction Methods* section, the reduction of radiation exposure to young patients, patients receiving multiple CT examinations, and those with benign disease is of particular concern.

To justify a CT examination, the potential or proven benefit should outweigh the risks from the radiation dose.(23) Alternative imaging modalities that deliver less ionizing radiation (e.g. traditional plain film radiology) or no ionizing radiation at all (e.g. magnetic resonance imaging and ultrasound), should be considered as an alternative to a CT examination when clinically appropriate and accessible. A FDA Public Health Notification: *Reducing Radiation Risk from Computed Tomography for Pediatric and Small Adult Patients* lists as one of its recommendations to "eliminate inappropriate referrals for CT".(24) It states, "It is important to triage these examinations to eliminate inappropriate referrals or to utilize procedures with less or no ionizing radiation." Indication guidelines are available, such as those from the American College of Radiology (25) and the *2004 CT Quality Criteria* by the European Commission (26).

CT Radiation Dose in Perspective

The amount of natural background radiation that each Canadian receives each year is between 2 and 4 mSv.(27) The maximum amount of radiation people are allowed to receive in the workplace is regulated. The Canadian dose limits for exposure to licensed sources of radiation is set by Health Canada at 100 mSv over 5 years (50 mSv annual maximum) for workers.(28) The limit for a pregnant worker, once pregnancy has been declared, is 4 mSv for the remainder of the pregnancy.(27) The Canada Labour Code also sets occupational radiation exposure limits, and there are provincial workplace radiation protection regulations as well. Occupational radiation exposure limits are further discussed in the Staff Safety section.   According to Health Canada, the average yearly radiation exposure of a monitored worker is about 0.3 mSv, but this figure varies depending on the job.(27)

Patient radiation exposure from diagnostic medical imaging, however, is not regulated. Health Canada's *Safety Code 20A: X-ray Equipment in Medical Diagnosis Part A: Recommended Safety Procedures for Installation and Use* states, "While for radiation workers and the general public maximum permissible levels of exposure have been defined, no specific levels have been recommended for patients undergoing diagnostic x-ray procedures."(29)

The effective dose from CT can be orders of magnitude larger than traditional plain film examinations, depending on the examination type. Table 1 compares typical plain film and CT effective doses for a few sample examinations for illustrative purposes. The data are from the International Commission on Radiation Protection (ICRP).(5) Table 2 compares the effective dose from typical diagnostic procedures to the number of chest x-rays for equivalent effective dose, as well as to the time period for equivalent effective dose from natural background radiation. Table 2 was sourced from the American Food and Drugs Administration website.(6)

Examination Type	CT Effective Dose (mSv)	Plain Film Effective Dose (mSv)
Chest	8.0	0.02
Head	2.0	0.07
Abdomen	10.0	1.0
Pelvis	10.0	0.7

Table 1. Typical effective doses from plain film x-ray and CT. Data from ICRP.(5)

Diagnostic Procedure	Typical Effective Dose (mSv)	Number of Chest X-rays (PA film) for Equivalent Effective Dose[1]	Time Period for Equivalent Effective Dose from Natural Background Radiation[2]
Chest x-ray (PA film)	0.02	1	2.4 days
Skull x-ray	0.07	4	8.5 days
Lumbar spine	1.3	65	158 days
Upper G.I. exam	3.0	150	1.0 year
Barium enema	7.0	350	2.3 years
CT head	2.0	100	243 days
CT abdomen	10.0	500	3.3 years

Table 2. Effective dose comparisons. Source: American Food and Drug Administration.
http://www.fda.gov/cdrh/ct/risks.html
1. Assuming average effective dose from chest x-ray (PA) of 0.02 mSv
2. Assuming average effective dose from natural background radiation of 3 mSv per year

Increased Radiation Dose with MDCT

With conventional plain film x-ray images, increasing the radiation dose will eventually lead to image degradation (i.e., film blackening). However, with digital imaging systems, such as CT, increasing the radiation dose will increase image quality by reducing the noise. This may lead to the patient being exposed to more radiation than is necessary. Ideally, the minimum radiation dose should be used to provide the required diagnostic quality. This is known as the ALARA (as low as reasonably achievable) principle. Studies suggest that there is a lack of awareness of the actual risks and the estimated dose from CT. A 2003 UK questionnaire study by Shiralker et al. (30) found that 97% of physicans' answers regarding the radiation dose of commonly requested radiological investigations were underestimated. Another study by Lee et al. found that 44% of emergency department physicians and 56% of radiologists at an American academic medical centre underestimated the radiation dose from a given CT examination.(31, 32)

MDCT scanners have generally lower geometric efficiency compared to single-slice CT scanners, resulting in higher radiation dose. Geometric efficiency is determined by physical aspects of the CT scanner that contribute to wasted radiation dose and those that minimize wasted radiation dose. MDCT scanners have gaps between detector elements in the detector array and use wider x-ray beams. In single-slice CT scanners, the radiation in the penumbra (edge of the x-ray beam) is used in the formation of the image. The penumbra for MDCT scanners is not used for image formation, but contributes to patient radiation dose. The effect of the penumbra on radiation dose is greatest on CT scanners with four detector rows, and lessens with increasing number of detectors because "a fractional effect of the penumbra per detector row becomes proportionally less."(33) Studies by Brix et al. (34) and Yates et al. (35) suggest that the average

increase in effective dose per patient of MDCT verses single-slice CT is 10% (single-slice CT scanners compared with 4-slice CT scanners) and 35% (single-slice CT scanners compared with one 2-slice, six 4-slice, and one 16-slice CT scanners) respectively.

Helical (also known as spiral) mode CT scanning is when the scanner table continuously advances during the scan, as opposed to the conventional slice-by-slice scanning where the scanner table advances incrementally after each 360 degree gantry rotation. Helical scanning allows rapid acquisition of image data over large volumes. With helical mode, however, the interpolation technique for image reconstruction requires an additional slice of data on each end of the scanning volume. This leads to an increased effective dose of up to 10%.(36) MDCT scanners pay this radiation dose penalty in helical mode and also require additional radiation at the beginning and end of the scan volume that is not used for image reconstruction. This is because only the first detector row contributes to the image at the beginning of the acquisition, with additional detector rows entering the imaging volume as the scan progresses. An analogous effect occurs at the end of the acquisition.(37) A 2005 study using MDCT found that the effective dose from helical scans was greater than axial scans by 13.1%, 35.8%, 29.0%, and 21.5%, for head and neck, chest, abdomen and pelvis, and trunk studies, respectively.(38)

MDCT scanners have eliminated a number of constraints of single-slice CT scanners, but this has resulted in higher radiation dose to patients. MDCT has increased throughput of patients undergoing CT and has permitted use of CT for new indications, such as CT angiography. On single-slice CT scanners, radiation output was limited by the x-ray tube heat capacity which resulted in constraints on scan length and tube current. MDCT scanners have high heat capacity x-ray tubes, meaning that longer scan lengths are possible with narrower slices. Also, because the scan times can be much shorter with MDCT compared to single-slice CT, the duration of breath holds are often no longer a barrier.(39)

Radiation Risks from CT

High doses of radiation lead to an increased risk of developing cancer and may cause genetic effects in the children of irradiated individuals. While there is much less data on the risk at the lower dose levels associated with diagnostic radiology, the main international advisory bodies support the theory that risks exists with even low levels of radiation doses.

Recent evidence has led to further support of the conventional linear no-threshold (LNT) model, which is the most conservative of the models for diagnostic imaging radiation risk. For example, a 2005 study of nuclear workers by Cardis et al. showed that low doses of radiation cause cancer.(40) In 2000, Pierce and Preston used atomic bomb survivor information to conclude that the risk estimates for doses as low as 50 to 100 mSv were not overestimated by the LNT model (i.e., linearly extrapolating from effective

doses in the 0.5 to 2 Sv range).(41) Appendix 3 provides a comprehensive discussion on the various theories of radiation risk and their supporting evidence.

The National Academy of Sciences Committee on Biological Effects of Ionizing Radiations (BEIR V) (42) and the International Commission on Radiological Protection (9) have both provided estimates of organ-dependent lifetime cancer mortality risks (per unit dose) of men and women at various ages of exposure.   The estimates assume a linear extrapolation of risks from intermediate to low doses (i.e. LNT model) using data from atomic bomb survivors.

A 2005 report by the National Research Council (8) updates 1990 findings of risks from exposure to low levels of radiation, which are mainly based on Japanese survivors of the 1945 atomic bomb attacks. The report found that a dose of about 100 mSv can be expected to cause cancer in one out of every 100 people, or in one out of 1000 people from 10 mSv of effective radiation dose. This is in comparison to the estimation of one individual in 100 who would be expected to develop cancer from a lifetime (70 years) exposure to natural background radiation. The report also notes that approximately 42 additional people in the same group would be expected to develop solid cancer or leukemia from other non-radiation causes with about half of the cancers resulting in death.

The International Commission on Radiological Protection (ICRP) Publication 60 states that the estimated cancer mortality risk is 5% per Sv, and the risk of nonfatal cancer is 1% per Sv for the general population.(9) This corresponds to 6 out of 1000 people who are estimated to develop cancer (fatal and nonfatal) from 100 mSv of effective radiation dose.

Berrington de Gonzalez and Darby (7) estimated the cancer risk from diagnostic x-rays in 15 developed countries, including Canada. The estimates were based on a worldwide survey of medical radiation use between 1991 and 1996.(19) They reported that the estimated cumulative risk of cancer to age 75 years attributable to diagnostic x-rays ranged from 0.6% to 1.8%, except for Japan, where it was over 3%. In Canada, the attributable risk was reported to be 1.1%. This translates to 784 cases of cancer per year. With increasing radiation dose from diagnostic x-rays over the years, these figures could be an underestimate of the current attributable risk.

Pediatric CT Radiation Risks

In general, the doses and risks to children from CT examinations are not well understood, and are more difficult to calculate from CT scanner parameters.

In an 2002 editorial, Slovis (10) noted that there is an increased sensitivity to radiation in children compared to adults of up to 10 times, with girls being more radiosensitive than boys. Also, the lifetime radiation risks are higher for children because they have more

expected years of life after the radiation exposure than adults.(11) Shrimpton et al. (43) found through a 1989 UK survey that approximately 4% of CT examinations were performed on children who were under 15 years of age. In 1998, Coren et al. (44) reported a 63% increase in requests for pediatric CT between 1991 and 1995 at a particular British hospital.

In 2001, Brenner et al. (11) assessed the lifetime cancer mortality risks attributable to pediatric CT radiation. They reported that the estimated lifetime cancer mortality risks attributable to the radiation exposure from a CT examination of a one year old are 1 in 550 for a single abdominal CT, and one in 1500 for a head CT. They claimed that the risks are an order of magnitude higher than for adults. Although this is a small increase in cancer mortality over the natural background rate, Brenner et al. reported that of the 600,000 abdominal and head CT examinations performed on American patients under 15 years of age, approximately 500 might ultimately die from cancer attributable to CT radiation.

De Jong et al. (45) estimated the cancer mortality associated with repetitive CT scanning of children with cystic fibrosis. They found that the survival reduction associated with annual scans from 2 years old to death was approximately 1 month if the median survival was 26 years of age, and 2 years if the median survival was 50 years of age. They also found that cumulative cancer mortality was approximately 2% and 13% at age 40 and 65 years, respectively.

Canadian Radiation Regulations and Safety Codes

The Consumer and Clinical Radiation Protection Bureau of Health Canada defines the requirements for the safe use of radiation emitting devices through a number of safety codes. *Safety Code 20A: X-ray Equipment in Medical Diagnosis Part A: Recommended Safety Procedures for Installation and Use* (29) covers the following:

1. specifies minimum standards of safe design, construction and performance for diagnostic x-ray equipment;
2. presents recommended practices for minimizing patient and operator exposures and ensuring that diagnostic x-ray equipment is used in a safe manner;
3. supplies information and methods for calculating or otherwise determining the effectiveness and adequacy of shielding in attenuating primary and scattered radiation; and
4. sets out the relative responsibilities of the owner, responsible user, operator and other personnel.

For CT, the relevant code is *Safety Code 31: Radiation Protection in Computed Tomography Installations (1994).* However, this code is now outdated and a new *Safety Code: Recommended safety procedures for the installation, use and control of X-ray*

equipment in large radiological facilities will merge Safety Code 20A and Safety Code 31, and is aimed for publication during fiscal year 2007/2008. A draft version has been prepared. This new code will include sections on:

- Responsibilities and Protection: This section will set out the responsibilities that the owner, users, operators and other staff have for the safe installation, operation and control of the equipment, and will set out practices to minimize radiation doses to patients, staff and the public.
- Facility and Equipment Requirements: This section will set out requirements for the facility design and will set out equipment standards.
- Quality Assurance Programme: This section will set out requirements for Quality Assurance programmes including Acceptance Testing and Quality Control procedures.

The federal safety codes are intended to complement x-ray equipment design, construction, and performance standards regulated under the Radiation Emitting Devices (RED) Act (R.S., 1985, c. R-1).(46) Although the RED Act covers all diagnostic x-ray equipment, CT equipment is specifically excluded in the *Part XII Diagnostic X-ray Equipment RED Regulations* (C.R.C., c. 1370).

Health Canada's safety codes state that facilities under provincial jurisdiction may be subject to requirements specified under provincial statutes. In Ontario, diagnostic x-ray machine installation, use, and testing are covered under the Healing Arts Radiation Protection (HARP) Act.(15) In the HARP Act, "x-ray machine" is defined as "an electrically powered device the purpose and function of which is the production of X-rays for the irradiation of a human being for a therapeutic or diagnostic purpose". (R.S.O. 1990, c.H.2, s.1(1)). Within the HARP Act, *Regulation 543 X-ray Safety Code* provides specifics on operation, use, and testing of x-ray equipment. *Regulation 543 X-ray Safety Code* defines "diagnostic x-ray machine" as "an x-ray machine that is used for the examination of a human being but does not include a radiation therapy simulator or a computerized transaxial tomographic x-ray machine". (R.R.O. 1990, Reg. 543, s.1). Therefore, CT scanners are excluded from the *HARP Act Regulation 543 X-ray Safety Code.*

The HARP Act stipulates that a hospital or facility must be designated by the Minister of Health to install and operate CT scanners. The Minister also designates the number of CT scanners that each hospital or facility may install. A Letter of Designation is required by the Minister for new CT scanner installations, but is not required for CT scanner upgrades. Designation by the Minister is unique to CT scanners, in that it is not required for any other x-ray machine. Upon receiving a Letter of Designation, the room plans, specifications, and information prescribed by the regulations must be submitted to the Director of X-ray Safety. The Director must accept the proposal in writing prior to installation.

The HARP Act also stipulates that the owner of an x-ray machine must designate a Radiation Protection Officer (RPO). The RPO is responsible "for ensuring that every X-

ray machine operated in the facility is maintained in safe operating condition", and "for such other matters related to the safe operation of each X-ray machine in the facility as are prescribed by the regulations."

Quantification of Radiation

The two most common dose indicators used to quantify patient radiation dose are the CT dose index (CTDI) measured in mGy and the dose-length product (DLP) measured in mGy-cm. Radiation exposure in units of roentgens (R), radiation dose in units of gray (Gy) or rad, and effective dose in units of milliSievert (mSv) are also used to measure radiation. A comprehensive discussion of CT radiation metrics is provided in Appendix 4.

The ImPACT (Imaging Performance Assessment of CT scanners) group in London, UK, evaluates and reports on the dose and imaging performance of CT scanners. The ImPACT group is manufacturer independent and aims to provide impartial advice about CT scanners. According to the ImPACT group,

> *Image noise, scan plane spatial resolution and imaged slice width are fundamental parameters describing the amount of object information retrievable from an image, or its image quality. Radiation dose can be regarded as a 'cost' of this information. In general, it is meaningless to quote any one of these measurements without reference to the others.*(47)

The Q_2 measure is used by the ImPACT group. It incorporates dose, noise, spatial resolution and slice width into one number. A high Q_2 value corresponds to CT scanners that produce images with lower noise at a set spatial resolution, with dose and image width taken into account.(47)

64-Slice Computed Tomography

64-Slice CT Scanners in Ontario

MDCT scanners were introduced in 1998 with the release of four-slice CT scanners.(48) In 2004, 64-slice CT scanners were introduced.(49) All four major CT manufacturers offer 64-slice CT scanners. They are:
- LightSpeed VCT by GE Medical Systems
- Brilliance 64 by Philips Medical Systems
- Somatom Sensation 64 by Siemens AG
- Aquilion 64 by Toshiba Medical Systems

Through correspondence with the four manufacturers of 64-slice CT scanners, as of April 2006, the number of 64-slice CT scanners in Ontario was estimated to be 49. These 64-slice CT scanners were spread across approximately 34 healthcare institutions.

Comparison of 64-Slice CT Scanners

The ImPACT group has produced publications evaluating and comparing CT scanners, including detailed comparisons of available 64-slice CT scanners.(47, 50) The specification data in the ImPACT reports were manufacturer supplied, and have not been independently verified. At the time of the publications (September 2005), the ImPACT group had not tested any of the 64-slice CT scanners.

Basic specifications for each of the available four brands of 64-slice CT scanner are provided in Table 3.

	GE LightSpeed VCT	Philips Brilliance 64	Siemens Sensation 64*	Toshiba Aquilion 64
Detector Banks (# x mm)	64x0.625	64x0.625	32x0.6 and 8x1.2	64x0.5 mm
Collimation (mm)	40	40	28.8	32
Max. Gantry Rotation Speed (s)	0.35	0.4	0.37 (0.33 option)	0.4

Table 3. Basic 64-slice CT Scanner Specifications

* Although the Sensation 64 only has 32x0.6 mm detector rows, the Sensation 64 can acquire 64 slices with its "z-Sharp^{TM} Technology". This technology employs a flying focal spot along the z-axis to double-sample each detector row.

All 64-slice CT scanners display the DLP and $CTDI_{vol}$ on the console, as most other MDCT scanners have in the past. All 64-slice CT scanners are also able to perform automatic exposure control, with respect to mA adjustment for patient size, mA adjustment along the z-axis, and mA modulation during rotation (except the Toshiba Aquilion 64 cannot perform mA modulation during rotation). In addition, all 64-slice CT scanners have some form of adaptive filtration for noise reduction, algorithms for artifact reduction, and cone beam correction. According to the interviewed CT technologists, physically selecting protocols and modifying the parameters on 64-slice CT scanner consoles are relatively simple processes, and adequate alerts warn against inadvertent changes.

The values of CTDI for a standard head and a standard body phantom are slightly different for each 64-slice CT scanner manufacturer, as this depends upon such factors as efficiency, scanner geometry, and attenuating filters. The CTDI values reported by each manufacturer are shown in Table 4.

	GE LightSpeed VCT	Philips Brilliance 64	Siemens Somatom Sensation 64	Toshiba Aquilion 64
CTDI settings for standard head and body phantoms	120kVp, 20mm	120kV, 40mm	120kV, 28.8mm	120kV, 16 mm
CTDI, centre of head phantom	12.9	10.4	13.6	10.0 (wedge 1) 18.4 (wedge 2)
CTDI, periphery of head phantom	13.7	11.3	13.9	11.1 (wedge 1) 21.5 (wedge 2)
CTDI, centre of body phantom	3.5	3.4	4.4	3.5 (wedge 1) 6.6 (wedge 2)
CTDI, periphery of body phantom	8.3	6.8	7.9	7.3 (wedge 1) 14.8 (wedge 2)

Table 4. Manufacturers' CTDI Values in (mGy/100 mAs) (from the ImPACT Report 05068) (47)

Radiation Dose Reduction Methods

Protocol Selection

Protocol Variability

Protocol parameters vary widely and not always with apparent justification.(23)
Shrimpton et al. found through the 1991 UK CT dose survey that the effective dose of a
CT scan could differ between 10 and 40 times for the same application.(12) The follow
up survey in 2003 found that the effective dose variations for specific examinations on
adults still varied widely.(51) Orerud reported that the typical effective dose of CT
examinations for the same application in CT laboratories throughout Norway could differ
between 8 and 20 times.(13) These wide variations are mainly attributed to the protocols
being selected, because differences in geometric efficiency of equipment have been found
to generally contribute at most a factor of three to the variations, and less than a factor of
two for routine examinations on more recent scanners.(39, 52, 53)

A 2004 survey by Aldrich et al. (14) across 18 hospitals in British Columbia, Canada,
found that the radiation dose for standard CT exams of the head, chest, abdomen, and
pelvis varied by up to a factor of 10 between the hospitals. The patient radiation doses
were higher than those found in similar surveys performed in the UK and the European
Union, but were similar to a survey in Germany.

The Nationwide Evaluation of X-ray Trends survey of the US Food and Drug
Administration has been measuring radiation exposures since 1973. The data from the
1990 Computed Tomography survey suggested that there is high variability in the amount
of patient radiation dose from various facilities. For example, for a head CT, the
maximum radiation dose was found to be 140 mGy while the minimum radiation dose
was found to be 16 mGy.(54, 55)

Several studies have shown that for certain indications, low-dose CT protocols can be
used without compromising image quality. For example, studies have reported a 90%
dose reduction of high resolution CT of the face in patients with orbit trauma (56), a 50%
dose reduction with low-dose chest CT (22, 57), and a 25-fold reduction in radiation dose
for CT determination of adipose and muscle tissue area and volume.(58) Besides
phantom studies, computer-simulated dose-reduction software can also be used to
evaluate the effects of low-dose CT on image quality without subjecting patients to
unnecessary additional radiation. This technique involves noise being added to images to
simulate acquiring the same image with a lower tube current (i.e. lower radiation dose).
Computer-simulated dose-reduction software has been applied to examinations such as
chest CT and pediatric abdominal CT.(59, 60)

The Ontario survey of healthcare institutions with 64-slice CT scanners revealed that
about 30% of the healthcare institutions never used low-dose CT protocols. Of the 70%
that did use some low-dose CT protocols, the types of low-dose protocols widely varied.

The most common low-dose protocols were for chest and renal colic examinations. Two of the 18 healthcare institutions that responded to the survey indicated that low-dose pediatric protocols were used. Only three sites used low-dose protocols developed at other healthcare institutions. The low-dose protocols were mainly developed through their own experience, from literature, their own testing, or from the CT scanner manufacturer.

Factors Leading to Protocol Variability

Ideally, data from clinical trials and other research studies on CT protocols that minimize patient radiation dose and maximize image quality would be used to optimize CT protocols. However, Golding (2005) (23) suggests that there are few studies that relate exposure to acceptable image quality, and thus the evidence base for practice is small.

One of the reasons that CT protocols have not been well studied is because of the complex interaction of CT scanner parameters and image noise (image quality decreases with image noise). Prior to the relatively recent implementation of automatic exposure control, adjustment of scanner parameters had to be performed manually by the CT technologists. Image noise is related to the scanning parameters and patient attenuation (i.e. patient body size) as follows:
- Noise is inversely related to the square root of the tube current (mAs)
- Noise is inversely related to the tube voltage (kVp)
- Noise is inversely related to the square root of slice thickness
- Noise is approximately linearly related to patient weight or effective diameter

MDCT scanners are installed with manufacturer pre-set protocols for various indications. In Ontario, radiologists from each institution decide on which of the pre-set protocols to customize. From the Ontario survey of institutions with 64-slice CT scanners, it was found that 44% of the healthcare institutions almost always modified or replaced the manufacturer's standard protocols, and 33% usually modified them. Of the respondents, 78% only occasionally used protocols developed by institutions with specific expertise (e.g. hospitals specializing in pediatric imaging). Automatic exposure control was always or almost always used by 78% of the healthcare institutions, and the remaining 22% usually used automatic exposure control.

The survey also found that in all the healthcare institutions, the CT technologists occasionally modified the protocol parameters. CT technologists would modify protocol parameters in situations such as when the patient was very large or small compared to an average sized patient, and when the patient could not hold their breath for the entire standard CT scan.

Diagnostic Reference Levels

Optimizing CT protocols for each indication is a difficult and time-consuming task. A survey of current practice is an alternative method of reducing patient radiation dose, because it can establish typical dose levels and highlight centres which use unusually high radiation dose. A diagnostic reference level (DRL), also known as a diagnostic reference value, is the radiation dose above which, an investigation should be performed or decision should be made. The ICRP recommends the use of DRLs. The *Radiological Protection and Safety in Medicine, ICRP publication no. 73 (2)* (55, 61) states:

> *(101) Diagnostic reference levels are supplements to professional judgment and do not provide a dividing line between good and bad medicine. It is inappropriate to use them for regulatory or commercial purposes.*
>
> *(102) Diagnostic reference levels apply to medical exposure, not to occupational and public exposure. Thus, they have no link to dose limits or constraints. Ideally, they should be the result of a generic optimization of protection. In practice, this is unrealistically difficult and it is simplest to choose the initial values as a percentile point on the observed distribution of doses to patients. The values should be selected by professional medical bodies and reviewed at intervals that represent a compromise between the necessary stability and the long-term changes in the observed dose distributions. The selected values will be specific to a country or region.*

In 1994 the European Commission set up a working group on image quality and dose in CT. DRLs, as well as image quality indicators, have been developed for CT by the European Commission. *The Quality Criteria for Computed Tomography: EUR 16262* published in 1999 provides structured advice on diagnostic requirements, criteria for radiation dose to the patient, example of good imaging technique, and clinical conditions with impact on imaging performance.(62) With respect to DRLs, the guidelines state:

> *Diagnostic reference dose values provide quantitative guidance to help identify relatively poor or inadequate use of the technique rather than an indication of satisfactory performance. Further dose reduction below reference values may be achievable without compromising the diagnostic value of an individual examination, and this should always be pursued.*

The 2004 Quality Criteria for MSCT is an updated edition of the European Commission guidelines that takes into account the changes in CT practice due to MDCT.(26) The document sets out the "key elements of current MSCT, with particular regard to image quality, radiation dose and dosimetry, and makes recommendations on good examination approach in key areas".(26)

In the UK, the *Ionising Radiation (Medical Exposure) Regulations 2000* (63) require that DRLs are established for radiological examinations and that they are regularly assessed. The 2003 study on the UK population dose from medical x-ray examinations found that the UK's annual per capita effective dose of 0.38 mSv was low in comparison to other countries with similarly developed healthcare systems. The authors attribute the relatively low effective dose party to the "increasing attention given in recent years in the

UK to radiation protection for conventional examinations, with the development of national patient dosimetry protocols, and reference doses."(3) The 2003 UK CT dose survey revealed that the overall levels of exposure per examination were in general lower by 10-40% compared with the national UK CT dose survey published in 1991.(51) Although the authors do not explain this change, it is presumably due to the use of DRLs, as mostly single-slice helical scanners were being used in the 2003 survey. However, a study by Berrington de Gonzalez and Darby also found that out of 15 developed countries, the UK had the lowest annual frequency of diagnostic x-ray examinations.(7)

In North America, the American Association of Physicists in Medicine also recommends using DRLs for four radiographic projections, computed tomography, fluoroscopy, and dental radiography. From national American surveys, information was gathered on the radiation doses from similar diagnostic x-ray equipment. The DRLs created from the American survey were approximately the 80th percentile of recorded radiation doses, and therefore diagnostic scans exceeding the DRLs have radiation dose levels higher than 80% of the equipment in the survey.(55) Examinations exceeding the DRLs should be investigated to determine if the doses are justified or if the imaging system should be further optimized. The American Association of Physicists in Medicine Task Group on Reference Values for Diagnostic X-ray Examinations have set DRLs for CT of the head at 60 mGy (CT dose index measured at the centre of the phantom) and CT of the body at 40 mGy (CT dose index measured at 1 cm beneath the surface of the phantom).(55)

Appendix 4 further discusses DRLs and provides sample DRLs for British Columbia, the European Union, and the UK.

CT Scanner Optimization

Technological advances aimed to reduce radiation dose usually improve scanning efficiency or image quality to allow lower radiation to be used during the acquisition.(37) Some of these technological advances are described below.

A major advance in CT technology has been the recent introduction of automatic dose reduction systems that take into account the attenuation of the patient. All 64-slice CT scanners are able to adjust the tube current with automatic exposure control (AEC), reducing radiation dose up to 50%.(64, 65) For example, x-rays attenuate less when traveling through the chest from anterior to posterior compared to laterally because the chest is thicker laterally. With AEC, the tube current is adjusted automatically depending on the directional attenuation differences to maintain a constant signal-to-noise ratio. AEC can also be applied along the z-axis (i.e. for attenuation differences from different slices). The purpose of AEC is to reduce radiation dose while maintaining image quality.(33)

X-ray filters are used to remove the soft x-rays that will not be able to penetrate the patient, and therefore only add to the absorbed radiation. In 2001, Itoh et al. (66)

reported a 17% reduction in radiation exposure and a 9% decrease in noise at very-low-dose CT with an aluminum filter (tube current of 30 mA) compared to a conventional filter (tube current of 20 mA). Toth (67) reported in 2002 a 50% surface radiation reduction with bow-tie or beam-shaping filters that minimize radiation exposure at the thinner portions of the patient compared to flat filters.

Noise reduction filters (also known as adaptive filters) can help to improve the image quality of CT images in order to allow the use of less radiation.(68) These noise reducing reconstruction algorithms can be used on the raw data set or used for post-processing.(68, 69)

Patient Shielding

Although there are no recommended maximum patient radiation dose levels for diagnostic imaging, one of the principal aims of Safety Code 20A is to minimize patient exposure in medical diagnostic radiology. Patient shielding is one method that can be used to protect radiosensitive organs during CT examinations. For example, shielding of the gonads and breasts during pelvic and thoracic CT scanning, respectively, can reduce radiation exposure to the patient. Shielding of the eyes and thyroid during head CT scans will also reduce radiation exposure to these radiosensitive areas. Phantom studies have shown that in-plane bismuth shields can reduce absorbed doses to the breast and eyes by around 30% to 50% respectively without compromising image quality.(70, 71)

The radiation in CT scanning, however, is not confined to the scanning volume. Scatter radiation, divergence of the x-ray beam, and beam collimation limitations also contribute to the radiation exposure.(37) Beaconsfield et al. reported that shielding regions of the body that are not in the direct path of the x-ray beam can significantly reduce radiation dose.(72) For example, it was found that the thyroid and breast radiation doses were reduced by on average 45% and 76% during head CT examinations of 110 patients.

In Ontario, there are no comprehensive standardized guidelines on patient shielding for CT examinations. However, some recommendations do exist. For example, Health Canada's *Safety Code 20A: X-ray Equipment in Medical Diagnosis Part A: Recommended Safety Procedures for Installation and Use* states under section 10.1.2 that:
> *Gonad shields. - Appropriate use of specific area gonad shielding is strongly advised when:*
> - *the gonads, of necessity, lie within, or are in close proximity to, the primary x-ray beam;*
> - *the patient has reasonable reproductive potential; and*
> - *clinical objectives will not be compromised.*

The practices of patient shielding in Ontario are variable depending on the policies of each healthcare institution. The Ontario survey of healthcare institutions with 64-slice

CT scanners provided insight to the degree of variability from centre to centre. Out of the 18 institutions, 15 responded that some type of patient shielding policy/guideline was followed. The amount and types of shielding varied significantly. Some institutions responded that they shielded only pediatric patients, some shielded the gonads of all male patients and females patients of childbearing age as well as pediatric patients, and some shielded all patients whenever possible. Some respondents indicated use of 0.25 mm or 0.5 mm lead equivalency aprons, eye, and thyroid shielding. At 83% of the institutions, the CT technologists had discretion in the type and amount of patient shielding. For example, CT technologists adjusted the shielding based on the area of interest for imaging. Two centres also responded that an additional layer of shielding is given to patients who request it.

Almost 90% of the respondents provide special shielding (i.e., different shielding compared to the standard adult shielding used at the particular institution) for pregnant patients who absolutely required CT examinations, usually by doubling or tripling the lead aprons. All institutions except one question women of childbearing age before the CT examination as to whether they might be pregnant and sometimes ask for the date of their last menstrual cycle. Blood tests are performed to determine pregnancy, if required. About 50% of the respondents provide special shielding for pediatric patients, usually in the form of doubling the aprons used for adult CT scanning.

Recording Patient Radiation Dose

The $CTDI_{vol}$ and DLP values from each examination are displayed on the scanner console and can be recorded from all 64-slice CT scanners.(47) Although these values are calculated (i.e. not measured) and assume an average sized patient is being scanned, they provide an estimate of the relative amount of radiation that patients are being exposed to during CT examinations. These values can be saved in the healthcare institution's Picture Archiving and Communications System (PACS) and are part of the newest DICOM image header. The Ontario survey of healthcare institutions with 64-slice CT scanners found that 88% of the centres recorded CT radiation dose parameters, usually on the PACS (two centres recorded the information on CD, and one in a logbook). Of all the institutions that recorded CT radiation dose parameters, both the $CTDI_{vol}$ and DLP values were saved, except for two institutions that recorded only the DLP value.

Monitoring radiation dose from each facility across Ontario for various types of scans can provide data to set DRLs, to optimize patient radiation exposure, and to determine collective and trends in radiation exposure levels. The recorded cumulative radiation dose of individual patients can be used for clinical decision-making. For example, an alternative imaging modality without the use of ionizing radiation might be chosen if a patient's cumulative radiation dose is substantial. Recording of cumulative radiation dose of individual patients would likely require a pan-Canadian or at least a provincial electronic patient record, which currently do not exist. Also, the utility of recorded cumulative radiation dose for individual patients could be questionable without clear

guidelines on what would be considered substantially high cumulative radiation dose levels. Of the 18 Ontario healthcare institutions that responded to the CT survey, 12 stated that patient radiation exposure/dose history was not taken into consideration for the use of CT or the chosen CT protocol. Of those that did consider patient radiation history, the modifications included low-dose protocols used for patients who required multiple follow-up CT examinations and for cancer patients.

In the UK, the Health Protection Agency (HPA) maintains the National Patient Dose Database (NPDD) (73), which contains entrance surface dose values for individual medical and dental radiographs, and dose-area product (DAP) values for complete examinations. This database was set up in 1992 following publication of the *National protocol for patient dose measurements in diagnostic radiology*.(74) Patient dose measurements are made by hospital x-ray departments throughout the UK on a voluntary basis according to the national protocol, and are sent to the HPA Radiation Protection Division for national collation and analysis. The database is reviewed every five years and the results of the analysis are published. The current NPDD does not include information on CT examinations, but a national survey of CT practice and patient doses was conducted by the NRPB around 1991, and another in 2003.(51, 75) A long term, sustainable national CT patient dose database is being set up and will be periodically reviewed by HPA.

The HPA CT survey data-collection form is availabe online as a model.(75) The response rate to this detailed UK survey was about 30%. A simpler survey data-collection form was created for the CT survey in British Columbia, and is also available as a model. The response rate to the British Columbia CT survey was 75%.

Staff Safety

Regulations and Guidelines on Staff Radiation Dose

Occupational radiation exposure is governed by the Ontario Ministry of Labour and is covered through the Occupational Health and Safety Act (R.R.O. 1990, Regulation 861) X-ray Safety.(76) The Act stipulates that:

> **10.** (1) *The dose equivalent received or that may be received by a worker shall be as low as is reasonably achievable, and in any case,*
>
> *(a) an X-ray worker shall not receive a dose equivalent in excess of the annual limits set out in Column 3 of the Schedule; and*
>
> *(b) a worker who is not an X-ray worker shall not receive a dose equivalent in excess of the annual limits set out in Column 4 of the Schedule.*
>
> *(2) Despite subsection (1), an employer shall take every precaution reasonable in the circumstances to ensure that the mean dose equivalent received by the*

abdomen of a pregnant X-ray worker does not exceed 5 millisieverts during the pregnancy. R.R.O. 1990, Reg. 861, s. 10.

SCHEDULE

Part of body irradiated	Exposure conditions and comments	Dose equivalent annual limit (millisieverts)	
		X-ray workers	Other workers
Column 1	Column 2	Column 3	Column 4
Whole body or trunk of body	Uniform irradiation	50	5
Partial or non-uniform Irradiation of body	The limit applies to the EFFECTIVE DOSE EQUIVALENT defined in Note (a)	50	5
Lens of eye	Irradiated either alone or with other organs or tissues	150	50
Skin	The limit applies to the mean dose equivalent to the basal cell layer of the epidermis for any area of skin of 1 square centimetre or more	500	50
Individual organs or tissues other than lens of eye or skin	The limit on effective dose equivalent applies, with an overriding limit on the dose equivalent to the individual organ or tissue	500	50

The International Commission on Radiological Protection (ICRP) recommends that the maximum permissible dose for occupational exposure should be 20 mSv per year averaged over 5 years with a maximum of 50 mSv in any one year. The HARP Act Safety Code (R.R.O. 1990, Reg. 543, s. 3.) stipulates:

> **3.** *(1) Every installation of an x-ray machine shall be shielded with a primary protective barrier and a secondary protective barrier so that,*
>
> *(a) no x-ray worker receives a whole-body-dose-equivalent of more than 1 millisievert (100 millirem) per week; and*
>
> *(b) no person, other than the patient undergoing an application of therapeutic or diagnostic x-rays, who is not an x-ray worker, receives a whole-body-dose-equivalent of more than 0.1 millisievert (10 millirem) per week.*

Included in the Occupational Health and Safety Act are the requirements for personal dosimeters for x-ray workers. Specifically, the Act stipulates:

> **12.** *(1) An employer shall provide to each X-ray worker a suitable personal dosimeter that will provide an accurate measure of the dose equivalent received by the X-ray worker.*

(2) An X-ray worker shall use the personal dosimeter as instructed by the employer.

(3) An employer shall ensure that the personal dosimeter provided to an X-ray worker is read accurately to give a measure of the dose equivalent received by the worker and shall furnish to the worker the record of the worker's radiation exposure.

(4) An employer shall verify that the dose equivalent mentioned in subsection (3) is reasonable and appropriate in the circumstances, and shall notify an inspector of any dose equivalent that does not appear reasonable and appropriate.

(5) An employer shall retain an X-ray worker's personal dosimeter records for a period of at least three years. R.R.O. 1990, Reg. 861, s. 12.

Staff Shielding

Room shielding minimizes radiation exposure to staff when they are outside the CT suite, and protective clothing minimizes radiation exposure to staff when they must be inside the CT suite during image acquisition. The HARP Act Safety Code (R.R.O. 1990, Reg. 543, s. 3.) stipulates compliance to the protective barriers (room shielding) standards in Health Canada's *Safety Code 20A: X-ray Equipment in Medical Diagnosis Part A: Recommended Safety Procedures for Installation and Use.*

Except in very rare situations, staff members are outside the CT suite during CT image acquisition. Interventional procedures with real-time CT fluoroscopy, such as CT guided biopsies, are an exception. From the Ontario survey of healthcare institutions with 64-slice CT scanners, 16 out of the 18 respondents indicated that they perform interventional CT procedures. However, at five of the centres the staff is always outside of the CT suite during image acquisition.

The radiation exposure to the patient and staff is dependent on the length of time required for the fluoroscopy procedure and the CT protocol parameters. The time required for the procedure is dependent on factors such as the type of interventional procedure, the particular patient, the expertise of the interventional radiologist, and the ergonomics of the CT suite. Radiation exposure to staff members is also dependent on the radioprotective clothing worn, and procedure techniques (e.g., how far the interventionalist's hands are away from the primary radiation beam). Of the 11 surveyed institutions at which the staff is sometimes in the CT suite during image acquisition, staff members wear lead aprons and thyroid collars. Some institutions also use radioprotective goggles and gloves. One centre uses a portable lead partition to shield staff members.

In 2003, Buls et al. (77) measured staff members' (including eyes, thyroid, and both the hands) and patients' radiation doses during 82 CT fluoroscopy guided procedures (46

biopsies, 22 drainage and aspirations, and 14 RF-ablations). The average staff entrance skin doses per procedure measured with TLDs on the skin, were found to be 0.21 mSv at eye level, 0.24 mSv at the thyroid, 0.18 mSv at the left hand, and 0.76 mSv at the right hand. The average estimated patient effective dose was 19.7 mSv, and the patient entrance skin dose was 374 mSv. The authors concluded that "CT fluoroscopy doses are markedly higher than classic CT-scan doses and are comparable to doses from other interventional radiological procedures." They also suggested that, "An important potential for dose reduction exists by limiting the fluoroscopic screening time and by reducing the tube current (mA) to a level sufficient to provide adequate image quality."

In 2001, Teeuwisse et al. (78) measured the radiation dose from CT guided biopsy, drainage, and coagulation. They found that the effective doses to patients were in the same range as those observed for regular diagnostic CT examinations. For a biopsy procedure, they estimated an average effective dose of 9.3 mSv. This value is considerably lower than the 19.7 mSv value reported in the Buls et al. report. Buls et al. attributed this discrepancy to the differences in CT protocol parameters used and fluoroscopic screening time.(77) Teeuwisse et al. found that the maximum dose to a worker measured outside the lead apron was 28 µSv during a single procedure, the average dose per procedure was below 10 µSv for radiologists, and below 1 µSv for radiographers. They concluded that, correcting for attenuation of the lead apron, the doses to workers are very low.

Section 6.3 of Health Canada's *Safety Code 20A: X-ray Equipment in Medical Diagnosis Part A: Recommended Safety Procedures for Installation and Use* stipulates protective clothing requirements. Specifically, Safety Code 20A states:

> *6.3.1 Protective body aprons*
> *Protective body aprons used for radiographic or fluoroscopic examinations with peak x-ray tube potentials of up to 150 kVp **must** provide attenuation equivalent to at least 0.5 mm of lead. The lead equivalent thickness of the material used must be permanently and legibly marked on the apron.*
> *6.3.2 Gonad shields*
> *Contact-type gonad shields used for routine diagnostic radiology must have a lead equivalent thickness of at least 0.25 mm and should have a lead equivalent thickness of 0.5 mm at 150 kVp. Contact-type gonad shields must be of sufficient size and shape to exclude the gonads completely from primary beam irradiation.*
> *6.3.3 Protective gloves*
> *Protective gloves used in fluoroscopy must provide attenuation equivalent to at least 0.25 mm of lead at 150 kVp. This protection must be provided throughout the glove, including fingers and wrist.*

Section 8(3) of the *HARP Act Safety Code* also stipulates that protective accessories of at least 0.5 millimetres lead equivalent at 150 kilovolts peak must be made available by the radiation protection officer for use by those who receive x-ray exposure. "Protective accessory" is defined as a device that is used to protect a person in an x-ray facility from receiving unnecessary radiation.

MDCT Scanner Testing and Inspection

CT Scanner Radiation Testing

Although there are no requirements for testing of CT scanners under the HARP Act and its regulations, CT acceptance testing at time of installation was performed by all of the surveyed healthcare institutions in Ontario. The *HARP Act Regulation 543 X-Ray Safety Code* stipulates that, "Every radiation protection officer shall provide to the Director of X-ray Safety, within sixty days of the installation of a new x-ray machine in a facility where he or she is the radiation protection officer, written results of the tests conducted to verify whether or not the x-ray machine complies with the provisions of the *Radiation Emitting Devices Act* (Canada) and the regulations made thereunder." (R.R.O. 1990, Reg. 543, s.8(4)).(15) Of the surveyed Ontario healthcare institutions, 72% indicated that their CT scanner acceptance testing results were sent to the X-Ray Inspection Services. Copies of the CT acceptance testing results were kept in the Medical Imaging Department at 78% of the surveyed centres.

Detailed acceptance testing procedures are available from the X-ray Inspection Services (79) for x-ray machines but CT scanners are not included. Therefore, the number and types of tests are variable, depending on the individual performing the tests. Acceptance testing is usually performed by a representative from the CT scanner manufacturer, a third party service provider, or a combination of the two. Only one of surveyed Ontario healthcare institutions responded that acceptance testing was performed by in-house staff members.

For CT dose measurements, different types of detectors can be used, such as TLDs, MOSFETs (Metal Oxide Semiconductor Field Effect Transistors) and pencil ionization chambers.(80) The various detectors provide different advantages and disadvantages with respect to cost and accuracy. Eight radiographic quality control devices were evaluated by the ECRI.(81) Various standard phantoms are also available for dose measurements, such as the CATPHAN 500, the RANDO phantom, and the CIRS Model 610 AAPM CT Performance Phantom.(82, 83) Image quality verification can be performed using these phantoms to measure parameters such as the sensitivity profile, contrast, standard deviation, mean, and CT linearity of the images.

Besides acceptance testing, the *HARP Act Regulation 543 X-Ray Safety Code* also stipulates that, "Every medical radiation protection officer and every chiropractic radiation protection officer shall ensure that at the facility where the officer acts, the procedures and tests set out in Column 1 of Table 5 are conducted at the frequencies set out opposite thereto in Column 2 of Table 5." (R.R.O. 1990, Reg. 543, s.8(10)). The testing requirements include photographic quality control testing every operational day, and patient entrance exposure measurements, collimation, and half-value layer testing every six months and upon alteration or servicing of the machine. Of the surveyed Ontario healthcare institutions, 47% indicated that periodic CT radiation dose measurements are not taken. Of the centres that do perform periodic CT radiation dose

measurements, the frequency ranged from monthly to annually, and sometimes only after alteration of the CT scanner. The measurements were performed in-house, by a third party, or by representatives from the CT scanner manufacturer.

Preventive Maintenance

Technical specialists from CT scanner manufacturers suggest procedures and frequency of preventive maintenance for their CT scanners. Of the Ontario healthcare institutions surveyed, 78% perform preventative maintenance monthly. The rest perform preventative maintenance every 3 months. All of the surveyed centres indicated that preventative maintenance is performed by representatives from the CT scanner manufacturers. One institution responded that members of its in-house service department also perform preventative maintenance, while two other centres also employ a third party.

Preventive maintenance usually consists of checking the error log file, physical inspections (e.g., verifying all screws are secure), cleaning (e.g., removing debris from moving parts), checking the x-ray tube for any arcing or instability, and image quality calibration (e.g., water calibration, air calibration, and verification with a phantom). Radiation dose is not usually directly measured during preventive maintenance.

Daily Quality Control

CT specialists from the CT scanner manufacturers provide CT technologists with training and the required phantom for quality control testing. CT quality control testing software is specific to the CT scanner brand. Therefore, various phantoms, procedures, and protocols are used for quality control testing for each CT scanner brand. The radiation dose is not directly measured during daily quality control tests.

Quality control testing is usually recommended by the CT specialists to be done on a daily basis, which includes recording the resulting mean and standard deviations of the specified regions of interest within the CT image. CT, however, is excluded from the daily quality control testing requirements of the *HARP Act Regulation 543 X-ray Safety Code*. Of the Ontario healthcare institutions surveyed, 82% perform daily image quality assurance testing, usually in the morning. Two centres responded that quality control testing is done at least once a week, and one centre responded that it was done less than once a week.

Regulated Inspections

X-ray Inspection Services perform inspections of healthcare x-ray machines. The healthcare institution or facility is usually informed only a few weeks prior of the upcoming inspection. The x-ray machines at a particular institution or facility are usually inspected every two or more years. X-ray machines are often tested by the inspectors, and the reports that were submitted to X-ray Inspection Services by the institution or facility are compared to the findings by the inspectors. Although inspectors can request records on the testing of CT scanners by the institution, CT scanners are not specifically inspected and are not tested by the inspectors.

Health Canada Safety Code (2007/2008)

In 2007/2008 a safety code titled *Recommended safety procedures for the installation, use and control of X-ray equipment in large radiological facilities* will be released by Health Canada. A draft version of the safety code is under revision. The new safety code will include quality assurance program requirements for CT scanners. The draft version of the safety code states, "A Quality Assurance programme includes Quality Control procedures for the monitoring and testing of x-ray equipment and related component, and administrative methodologies to ensure that monitoring, evaluation and corrective actions are properly performed." Items required for CT scanner acceptance testing are also included in the draft version of the safety code, as well as daily, weekly, monthly, quarterly, semi-annual, and annual quality control testing. The semi-annual quality control tests include patient dose measurements (CTDI measurements with phantoms).

Testing and Inspection Guidance from the UK Model

The UK provides a potential model for testing and inspection of CT scanners in Ontario. In the UK, the *Ionising Radiations Regulations 1999* (84) enforced by the Health and Safety Executive and the *Ionising Radiation (Medical Exposure) Regulations 2000* (63) enforced by the Health Care Commission are the main regulations that protect individuals against the dangers of ionising radiation from medical exposure. Among the duties of the Health and Safety Executive is the inspection of x-ray equipment. CT scanners are inspected by Health and Safety Executive inspectors during hospital audits, which total 10 to 20 per year. Inspectors usually do not perform direct radiation dose measurements from the CT scanner. Failures that result in patient radiation exposure much greater than intended must be reported for investigation to the Health and Safety Executive if it is a result of equipment failure, or to the Health Care Commission if it is due to a procedural or human error.

Although there are no UK regulations that require periodic inspections of diagnostic x-ray equipment, formal establishment of programmes for quality assurance in x-ray

departments and quality control testing for medical x-ray equipment is required under the *Ionising Radiations Regulations 1999. Work with ionising radiation: Ionising Radiations Regulations 1999 Approved code of practice and guidance* (85) and the *Medical and Dental Guidance Notes 2002* (86, 87) both provide supplemental advice. Compliance to the regulations is assessed during the hospital audits.

The Ionising Radiations Regulations 1999 stipulate that equipment used for medical exposure:

> *4) Without prejudice to the generality of paragraph (3), the quality assurance programme required by that paragraph shall require the carrying out of -*
>
> *(a) in respect of equipment or apparatus first used after the coming into force of this regulation, adequate testing of that equipment or apparatus before it is first used for clinical purposes;*
>
> *(b) adequate testing of the performance of the equipment or apparatus at appropriate intervals and after any major maintenance procedure to that equipment or apparatus;*
>
> *(c) where appropriate, such measurements at suitable intervals as are necessary to enable the assessment of representative doses from any radiation equipment to persons undergoing medical exposures.*

Guidelines for CT scanner acceptance testing are available from the ImPACT group. The ImPACT group has developed a practical guide, in a form of a leaflet, to the tests required at the acceptance and commissioning of a CT scanner. This leaflet is titled *Information Leaflet No.1: CT Scanner Acceptance Testing* (88)*,* and is available from the ImPACT website. The intent of the leaflet is for "direct use within the ionizing radiation legislative framework that exists in the UK, although similar tests are likely to be applicable internationally." (88, 89) Recommended standards for routine testing of diagnostic x-ray machines are available by the Institute of Physics and Engineering in Medicine in *Report 91: Recommended Standards for the Routine Performance Testing of Diagnostic X-Ray Imaging Systems.*(89) This report includes a chapter recommending the types of tests and frequency of testing for CT. The basis of the revised CT recommendations in *Report 91* was from a survey of diagnostic CT quality assurance practice in the UK and Ireland conducted by the CT Users Group in 2002. Guidance for the measurement of performance characteristics of diagnostic x-ray systems, including CT scanners, is available in the Institute of Physics and Engineering in Medicine *Report 32: Part III: Computed Tomography X-Ray Scanners.*(90)

Coronary Computed Tomography Angiography

Advantages of 64-Slice CT for Coronary Angiography

With the recent CT scanner temporal and spatial resolution improvements, coronary CT angiography (CTA) has been suggested as a replacement for conventional diagnostic coronary angiography (CA) using fluoroscopy machines.(91) The increased number of detector rows to 64 means that fewer scanner rotations are required. Fewer scanner rotations lead to shorter breath hold times and decreased misregistration artifacts.(92)

Coronary CTA is considered to be non-invasive or at most minimally invasive (requires injection in the patient's arm of a contrast medium), whereas conventional CA is an invasive procedure requiring insertion of a cardiac catheter. The total time required for a coronary CTA examination would typically take between 15-45 minutes, whereas conventional CA requires up to one hour.(93)

Coronary CTA Efficacy

Several reports have addressed the efficacy of using MDCT scanners for coronary angiography compared to the gold standard of CA. The Ontario Ministry of Health April 2005 report titled *Multi-Detector Computed Tomography Angiography for Coronary Artery Disease* consisted of a literature review between 2003 and January 2005. At the time of the report, there was no published literature on 64-slice CT for any indications. The report concluded, "there is insufficient evidence to suggest that 16-slice or 64-slice CT angiography is equal to or better than coronary angiography to diagnose Coronary Artery Disease (CAD) in people with symptoms or to detect disease progression in patients who had previous cardiac interventions. An analysis of the evidence suggested that in investigating suspicion of CAD, a substantial number of patients would be missed."(93) The reported sensitivity of detection of CAD in symptomatic patients ranged from 60% to 96%, but specificity was over 95%. It was also found that the false positive rate ranged from 5% to 8%, but the false negative rate ranged from 10% to 30%.(93)

Although there are limited data on 64-slice CT for coronary CTA, a study published in 2006 by Fine et al. compared conventional CA with 64-slice CT in 66 patients being evaluated for the presence of obstructive CAD.(94, 95) Both procedures were performed on the patients within 30 days of each other. The sensitivity and specificity of the 64-slice CTA were 95% and 96% respectively. The positive predictive value was 97% and the negative predictive value was 92% for lesions causing greater than 50% stenosis. There was a 100% agreement between coronary CTA and conventional CA among vein graft evaluation (9 subjects). The authors concluded, "these metrics are vastly improved from the 16-slice generation and support 64-slice cardiovascular CT as a reliable diagnostic tool." The editorial accompanying the study outlined the following limitations

with the use of coronary CTA. "Although MDCT can assess the thickness of the atherosclerotic wall and can readily identify calcific deposits, further plaque characterization (e.g., lipid pools and fibrous tissue), a prerequisite for the identification of the most vulnerable lesions, is not yet a workable reality, even with the 64-slice machines in their current configurations."(16)

A study by Raff et al. published in 2005 compared 64-slice coronary CTA and CA in 70 patients undergoing elective invasive conventional CA.(96) Coronary CTA was performed within 30 days of catheterization. Prospective ECG gating was not used in order to allow maximal flexibility in reconstruction intervals. The authors quoted estimated effective doses of 13 mSv for men and 18 mSv for women. The presence of significant coronary artery disease was defined as a stenosis greater than 50% in any artery. Specificity, sensitivity, and positive and negative predictive values for the presence of significant stenoses were 86%, 95%, 66%, and 98% respectively by vessel segment (n=935), and 95%, 90%, 93%, and 93% respectively by patient. The mean difference of percent diameter stenosis of individual lesions determined by 64-slice CT and conventional CA was 1.3%, with a standard deviation of 14.2%. This indicated that 64-slice CT can predict conventional CA results "within one qualitative stenosis grade (25%) with about 90% probability". The authors concluded that 64-slice CT provided high diagnostic accuracy compared to conventional CA in a broad spectrum of patients, including those with marked coronary calcification, relatively high heart rates, and obesity. However, the authors cautioned that because the patients were referred for catheterization, there was a high incidence of true disease (54%) that could have led to increased sensitivity. The high negative predictive value led the authors to suggest that 64-slice CTA could be a "suitable means for rapid triage of patients presenting to emergency centers with chest pain, and for evaluation of patients with equivocal stress test results who might otherwise require invasive angiography", but that further studies were required to determine if the resolution from 64-slice CT scanners was adequate to delineate complex and unstable lesions.

A multi-centred clinical trial in Ontario is under development to determine the efficacy of coronary CTA compared to conventional CA. The clinical trial is under the direction of the Program for Assessment of Technology in Health, at McMaster University.(97) As of March 2006, the research proposal is under Research Ethics Board review. This clinical trial does not include measurements of radiation doses, but collection of parameters from the 64-slice CT scanners and the fluoroscopy machines to estimate the radiation dose from coronary CTA (i.e. DLP values) and conventional CA (i.e. DAP values) has been proposed as an adjunct to the study.

Comparing Radiation Dose from Coronary CT Angiography and Conventional Diagnostic Coronary Angiography

Studies using phantoms have measured the radiation dose from coronary CTA and conventional CA. However, the results vary due to different scanners, scanning

protocols, and measuring techniques that were used.(33) Radiation dose measurements for coronary CT angiography also depend highly on the amount of anatomy being imaged (i.e., the number of slices being acquired and the thickness of the slices). In addition, the amount of time to perform fluoroscopy for conventional CA is directly related to the amount of radiation dose to the patient, which is dependent on the physician performing the procedure and the complexity of the procedure.

A 2001 study by Lobotessi et al. (98) found a range of fluoroscopy time of 3 to 37 minutes for 18 patients undergoing conventional CA. The mean fluoroscopy time was 9 minutes. The mean estimated effective dose was 13 mSv, with a range of 5 to 25 mSv. Leung and Martin's 1996 study (99) found an estimated effective dose of 3.1 mSv (mean fluoroscopy times of 3.1 minutes). A 1997 study by Broadhead et al. (100) found estimated effective doses of 9.4 mSv and 4.6 mSv from two different fluoroscopy machines in separate rooms (mean fluoroscopy time of 5.7 minutes).

For multi-slice CTA, radiation dose generally increases when thinner beam collimations are used. However, as additional detector rows are added (i.e. 16-slice and 64-slice compared to 4-slice CT), the ratio of excess radiation that does not contribute to actual image generation decreases. Increases in pitch and scan volume will increase the radiation exposure.(101)

In 2003, Hunold et al. (102) calculated the effective doses from coronary CTA (4-slice Somatom Volume Zoom), conventional CA (HiCor; Siemens, Erlangen, Germany), and electron-beam CT[1] (C-150 XP CT; Imatron, San Francisco, Calif) by using the same dose measurement method with an anthropomorphic phantom equipped with TLDs. Coronary CTA was simulated on the phantom using three different scanning protocols and retrospective ECG triggering. A mean time of 2.4 minutes (consistent with the mean times required to perform diagnostic procedures in the study site's cardiology department but lower than other studies reporting fluoroscopy time for conventional CA) was used to perform the conventional CA measurement. The effective dose from coronary CTA was found to be 6.7-10.9 mSv for male patients and 8.1-13.0 mSv for female patients. The effective dose from conventional CA was found to be 2.1 mSv for male patients and 2.5 mSv for female patients. The effective dose from electron-beam CT coronary angiography was found to be 1.5 mSv for male patients and 2.0 mSv for female patients. The authors cautioned that the conventional CA dose measurements "may have been too low, because the Alderson phantom that we used is a simulation of a slim patient (body weight, 70 kg)". A larger patient would have resulted in a higher effective dose measurement.

The 2006 study by Coles et al. (103) compared the radiation dose from 16-slice coronary CTA with a Sensation 16 scanner (Siemens, Forchheim, Germany) with retrospective ECG-gating versus conventional CA with three Siemens cardiac catheterization units

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[1] Electron-beam CT is used to detect calcium build-up in the coronary arteries, and therefore has limited utility in cardiac imaging (does not detect lipid-rich soft plaques). It has lower spatial resolution than MDCT but higher temporal resolution.

(Axiom Artis FC single-place, Axiom Artis BC biplane, and HiCor single-plane unit). The effective doses were estimated with the CTDI values for coronary CTA and DAP values for conventional CA. Of the 91 patients, the mean effective dose for coronary CTA was 14.7 mSv (SD 2.2) and for CA was 5.6 mSv (SD 3.6). The authors concluded that the effective dose for coronary CTA was significantly higher than for conventional CA.

The 2006 editorial by Gertz et al. (16) summarized the literature regarding radiation dose from coronary CTA compared to conventional CA. It should be noted that most of the effective dose estimates were not measured values (Hunold study is an exception), but instead were calculated values from scan parameters. Gertz et al. reported that dose estimates from coronary CTA range from 7 to 13 mSv (101, 104). This corresponds to an estimated 0.06% to 0.1%, increase in death from cancer, based on the assumption that there is a 0.08% increase in cancer deaths for each 10 mSv. The dose estimates from conventional CA range from 3 to 25 mSv (increase in deaths from cancer estimated to range from 0.02% to 0.2%). The authors conclude, "although the radiation from MDCT angiography is substantial, it can sometimes be less than that from conventional coronary angiography, depending on which protocols are being compared."

In 2004, Bae et al. (33) also quoted coronary CTA effective doses between 7.1-11.9 mSv from previous studies.(102, 105, 106) They also noted that significant variations of radiation doses are reported in literature because of differing scan parameters, ranging from 120-140 kVp and 150-225 mA.(107, 108) The authors state that the radiation dose from coronary CTA is similar to the radiation dose from a typical abdominal and pelvic CT examination, and similar to the annual natural background radiation dose.

In a 2003 review article, McCollough (17) suggested that a coronary CTA examination that once required an effective dose of about 10 mSv with retrospective ECG triggering can be reduced to 5 mSv with prospective ECG triggering. "These effective dose values are of similar magnitude to those from a chest CT examination (5-7 mSv) or a conventional (diagnostic) coronary angiogram (3-10 mSv)."

Coronary CT Angiography Technological Advances

ECG Gating and Protocol Selection

In order to generate motion-free cardiac images, electrocardiograph (ECG) signals are acquired during the CT scan. This ECG signal can either be used prospectively or retrospectively. For prospective ECG triggering (also known as prospective ECG gating), the heart is scanned only during specific times during the cardiac cycle, so the patient does not receive radiation during the entire examination. Prospective ECG triggering can be used on patients with steady heart rates (i.e. in the absence of arrhythmia).(101) Cardiac motion is least during diastole and greatest during systole. Therefore, there will be fewer motion artifacts with the diastole projection data, and so

the tube current can be reduced during systole. The dose reduction from prospective ECG triggering was found to be approximately 50%.(109) For retrospective ECG triggering, the heart is continuously imaged, and the images are then generated from the scan data at certain ECG points retrospectively. The radiation is thus higher for retrospective ECG triggering than prospective ECG triggering. Retrospective ECG triggered CT scans, however, can provide functional information of the heart because data is collected continuously.

A 2005 phantom study by Gerber et al. (110) measured the radiation dose of coronary CTA with and without prospective ECG gating with a 16-slice CT scanner (Somatom Sensation Cardiac; Siemens Medical Solutions, Forchheim, Germany). The effective dose was found to be 3-13 mSv without ECG gating. The dose was reduced by 28% with ECG gating with a simulated heart rate of 70 beats per minute. The authors also compared the dose from variations in tube voltage and tube current. Changing the tube voltage from 80 kVp to 120 kVp resulted in an average increase in radiation dose of 215%, contrast-to-noise ratio of 150%, and a decreased image noise of 48%.   An increase of the effective product of tube current multiplied by exposure time (mAs_{eff}) of 17% led to an increased radiation dose of 17%, a increased contrast-to noise ratio of 4%, and a decreased image noise of 9%.

256-Slice CT Scanners

A prototype 256-slice CT scanner by Toshiba Medical has recently been used in Japan for cardiac imaging.(111) The 256-slice CT scanner can cover 125 cm per rotation, and can acquire an image of the entire heart within one heartbeat. It was reported that the images demonstrated satisfactory assessment of the coronary arteries. The estimated effective dose from a whole heart scan is 14.2 mSv. At the 2005 RSNA meeting in Chicago, Toshiba estimated that their 256-slice CT scanner was two years from market. The 256-slice CT scanners, however, will be installed at selected research centres around the world prior to that date.

Dental CT

Dental CT Technology

CT scanners specifically manufactured for dental applications are cone-beam computed tomography (CBCT) systems.(18) CBCT, also known as digital volume tomography (DVT), provides high-resolution images with short scanning times (approximately 20 seconds) and high geometric accuracy. One of the advantages of CBCT over MDCT is that CBCT requires lower radiation exposure. CBCT scanners are different from MDCT scanners in that they use 2D digital detector arrays instead of a series of linear arrays, and the radiation beam from the x-ray source to the detector array forms a cone-shape instead of a fan-shaped beam. The detector array and the x-ray source move once around the patient's head, and 3D volumetric data set is generated with back-projection algorithms. This 3D volumetric data set can be used to generate images of any desired plane. The scan is completed with one rotation of the x-ray source, and so unlike MDCT, there is no overlap of slices.

CBCT provides clear images of highly contrasted structures and is therefore well suited for dental imaging. CBCT technology has been used for almost two decades. Only recently, however, have inexpensive x-ray tubes, high-quality detector systems and powerful personal computers been available for the production of affordable dental CBCT scanners.(18)

Dental CBCT Applications

CBCT enables 3-dimensional views and multiple cross-sectional views, while conventional panoramic radiography (PR) provides a 2-dimensional projection view (i.e. structures are superimposed on each other). CBCT scanners are suited for clinical dental practices because they are smaller and less expensive to purchase than conventional CT scanners.

CBCT images are particularly useful for dental implant planning.(112) Orthodontics is also an area that CBCT images have more recently been applied.(113, 114) Additional applications include imaging impacted teeth and teeth that have not erupted, surgical assessment of pathology, Temporomandibular joint assessment and pre- and postoperative assessment of craniofacial fractures.(18) In general, CBCT scanners can be used as a replacement for PR. CBCT scanners are not used for caries (i.e. cavities) detection because caries that are adjacent to metal fillings are difficult to determine due to scatter artifacts. Bite-wings (patient bites down on the paper tab to hold a piece of x-ray film in place so the crown portion of the upper and lower teeth can be imaged) are still required for caries detection.

Hatcher and Aboudara (113) provide examples of potential advantages of CBCT over traditional orthodontic imaging. They suggest that CBCT provides valuable detailed information for investigating impacted teeth, temporomandibular joints, implant planning, and pathology. They further state that traditional orthodontic imaging techniques provide poor visualization of some areas of anatomy. They suggest that 3-dimensional CT scans are able to give "valuable information about other areas of the dentition, such as the position of the maxillary incisor roots relative to the lingual cortical border of the palate to plan retraction" and "the position of the mandibular incisor roots in bone".

Nakajima et al. (114) in 2005 illustrated some of the benefits of CBCT through case studies. For example, they found that in tooth impaction, CBCT provided more precise information than conventional radiographic images such as "improved observation of the long axis of the tooth, root condition, and overlap with bone."

Radiation Dose from Dental CBCT

There are three manufacturers of dental CBCT scanners that are currently licensed in Canada: the CB MercuRay by Hitachi, the i-CAT by Imaging Sciences International, and the NewTom by Aperio Services. The i-CAT and CB MercuRay are upright scanners (i.e. the patient sits during the examination), while the patient lies on the scanner table with the NewTom scanner. The radiation dose from a dental CT scan depends on the FOV, the tube current times the scan time (mAs), and the tube voltage (kVp) chosen. Typically only a single scan is required per patient. Comparisons of effective dose from various manufacturers are difficult because different scanning protocols and phantoms are used.

In December 2004, Ludlow, Davies-Ludlow, and Brooks performed dosimetry measurements with TLDs and the RANDO phantom (Nuclear Associates, Hicksville, NY) on the NewTom 3G, i-CAT, and CB MercuRay scanners.(115) Preliminary data have been reported comparing the i-CAT and the NewTom scanners, but there are plans to publish the full data set including image quality considerations.   The effective doses were calculated with tissue-weighting factors for both the 1990 and the proposed 2005 ICRP guidelines. The proposed 2005 ICRP guidelines include specific weights for salivary glands and the brain. Because the salivary glands are in the primary beam during head CT, the calculated effective doses are considered more valid with the proposed 2005 ICRP guidelines.(115)

The full FOV i-CAT scan resulted in an effective dose of 68.7 μSv using the 1990 tissue weights and 101.5 μSv using the 2005 tissue weights (120 kVp, 22.85 mAs). The full FOV NewTom 3G scan resulted in an effective dose of 43.1 μSv using the 1990 tissue weights and 56.5 μSv using the 2005 tissue weights (110 kVp, 8.1 mAs). Although the reported effective dose is higher for the i-CAT scanner than the NewTom 3G, the image quality from the scanners should also be considered. The operating parameters for the i-CAT scanner are generally not adjustable by the operator (some software modifications

could be made that would allow lower kVp and mAs to be used), but the exposure from the NewTom 3G is automatically adjusted based on a prescan.(115)

In a 2005 study, Tsiklakis et al. (116) found that the radiation dose from CBCT can be reduced with lead shielding by measuring the radiation dose from the NewTom CBCT scanner, with and without thyroid and cervical spine lead shielding. This study used 75 TLDs to measure the radiation dose at the brain, eyes, salivary glands, thyroid gland, bone marrow of the mandible, bone marrow of the cervical spine, stomach, lungs, breasts, oesophagus, and skin. The effective doses, as calculated according to the $ICRP_{60}$, were 0.035 mSv and 0.023 mSv for non-shielding and shielding techniques respectively. Because the absorbed doses of the salivary glands were found to be among the highest of the measured weighted organs and the $ICRP_{60}$ does not include the salivary glands in the list of individually weighted tissues or remainder organs, the authors recalculated the effective doses with the salivary glands taken into consideration. The effective doses including the salivary glands were 0.064 mSv and 0.052 mSv for non-shielding and shielding techniques respectively.

Comparison of Radiation Dose from PR, CBCT, and MDCT

Phantom studies have been performed to compare the radiation dose from PR, CBCT, and conventional CT. The different studies used a variety of brands of PR, CBCT, and conventional CT scanners, as well as a variety of protocols and dosimetry equipment. The studies described below all used the RANDO phantom (Alderson Research Laboratories, Stanford, CN, USA).

In 2003, Mah et al. (117) measured the effective dose of acquiring images of a maxillomandibular volume with a NewTom 9000 (Aperio Inc, Sarasota, Fla). Using the same dosimetry phantom, the effective doses from the GE 9800-Quick CT scanner, and the Planmeca PM 2002 Proline PR scanner were also calculated. The effective doses were: 50.3, 3.9, 250 µSv for the CBCT, PR and conventional CT respectively. A summary of the results of previous studies on radiation dosimetry was also included in the report, but the authors stated, "the data are not directly comparable because of many differences among the studies. With this in mind, we recommend the standardization of certain parameters where possible, such as the anatomic areas imaged, phantom composition, the location of dosimeters, and tissues of interest, to ensure more direct and meaningful comparisons."

A 2002 study by Cohnen et al. (118) found that the maximum doses were 0.65, 4.2, and 23 mGy for PR (Orthophos C), CBCT (NewTom 9000), and conventional CT (Somatom Plus 4 single-slice dental CT scanner) respectively. However, for low-dose conventional CT protocols, the radiation dose ranged from 6.1-10-.9 mGy. There was no difference in image noise when comparing the conventional CT scans with the CBCT scans. The data from the CT technologies provided more useful information than the PR scans, but only the conventional CT allowed analysis of soft tissue. The authors concluded that the

radiation dose from CBCT is similar to low-dose conventional CT, and therefore should not be recommended as a replacement for PR in dental radiology.

In 2004, Rustemeyer et al. (119) compared the radiation dose between a low-dose dental CT protocol, a standard CT protocol, CBCT, and PR. A Somatom Plus 4 CT scanner (Siemens, Erlangen, Germany) and a PM 2002 CC PR system (Planmeca, Helsinki, Finland) were used for this study. The CBCT effective dose from literature (0.11-0.5 mSv) was used. The radiation dose was found to be up to nine times less when employing a low-dose CT protocol compared to a standard CT protocol, without any reduction in image quality or diagnostic information. The effective dose was 3.4 mSv for the dental CT protocol, 0.4 mSv for the dose-reduced CT protocol, and 0.04 mSv for PR. The authors concluded that the low-dose protocol resulted in radiation exposure comparable to CBCT, but that in some cases, low-dose dental CT might be superior to CBCT because conventional CT can be used to evaluate soft tissue instead of only structures with high contrast.

A 2006 review article by Scarfe et al. (18) summarized that the radiation dose from CBCT scanners have been reported to be 15 times lower than those of conventional CT scanners. The effective dose from CBCT scanners have been reported to range from 0.04-0.05 mSv, which is a reduction of up to 98% compared with conventional CT scans (1.3-3.3 mSv for imaging the mandible and 1.0-1.4 mSv for imaging the maxilla). A CBCT scan is therefore approximately 4-15 times that of a single PR scan (0.003-0.011 mSv).

Current Installations of Dental CBCT Scanners

The three manufacturers of Canadian licensed dental CBCT scanners have indicated that there are five installations of dental CBCT scanners in Ontario as of March 2006 (one NewTom, one CB MercuRay, and three i-CAT scanners). Further information on the installation and use of the dental CBCT scanners in Ontario was found through correspondence with representatives from the facilities owning the dental CBCT scanners. The NewTom scanner is installed in a private dental office in Ancaster. The CB MercuRay system is installed in a dental radiology practice in Toronto. The radiology practice is run by an oral radiologist who employs medical radiation technologists who operate the CBCT scanner. Two i-CAT scanners are located in Toronto, and one is located in Ottawa. The i-CAT scanners in Toronto are located in private radiology practices, with one of them employing an oral radiologist. The i-CAT scanner in Ottawa is installed in a dental office. Requests by dental facilities for installation of additional CBCT scanners have been requested but are not being approved until further notice.

All of the dental CBCT scanners are operated by dental assistants, except for one imaging centre in Toronto that employs medical radiation technologists. Dental assistants are "HARP certified" to operate dental x-ray machines, as described in the *Regulations and*

Guidelines for Dental CT section of this report. Explicit qualifications and continuing education requirements for CBCT scanner operation are undefined. The engineers and representatives from the CBCT scanner manufacturers usually spend approximately two days on-site for installation and training. Further operator training is sometimes requested by the dental offices or radiology practices. Unlike conventional CT scanners, there are generally only a few scanning parameters that need to be manually selected on dental CBCT scanners, such as full-view or limited-view scanning. The scanning parameters for various dental CBCT scans are defined by the dentists/radiologists.

As with traditional dental x-ray imaging, the prescribing and interpretation of dental CBCT images are usually performed by dentists. Oral radiologists are affiliated with two of the five facilities with dental CBCT scanners located in Ontario.

A HARP advisory group has been created to investigate a number of issues surrounding dental CT, including required training for CBCT scanner operation. The group includes dental, X-ray Inspection Services, CT physics, and HARP Commission representation. As of March 2006, the group is gathering information and preparing a document and recommendations.

Regulations and Guidelines for Dental CBCT

Provincial, federal, and international regulations and guidelines exist to promote radiation safety of dental radiology. Some of the most relevant regulations and guidelines are described below, although none of them specifically mention dental CBCT scanners.

In Ontario, the HARP Act covers installation, use and testing of dental x-ray machines but does not explicitly address the use of dental CBCT scanners. It stipulates that operators of an x-ray machine in a dental diagnostic x-ray facility must complete one of the following:
1. A course in dental radiation safety approved by the Commission.
2. A program or course in dental assisting that is approved by the Commission at a College of Applied Arts and Technology.
3. On and after the 1st day of January, 1981, a dental assisting program that is approved by the Commission at, [seven institutions listed].
4. A program or course in dental assisting offered by the Canadian Armed Forces. R.R.O. 1990, Reg. 543, s. 4

The Health Canada *Safety Code 30: Recommended Safety Procedures for the Use of Dental X-Ray Equipment* prepared by the Radiation Safety Bureau, provides "specific guidance to the dentist, dental hygienist, dental assistant and other support personnel concerned with safety procedures and equipment performance."(120) Safety Code 30:
- Sets out the relative responsibilities of the owner, dentist, and operator;

- Presents recommended practices for minimizing radiation exposure to patients and operators and for ensuring that dental X-ray equipment is used safely;
- Specifies minimum standards of design, construction and performance for dental X-ray equipment;
- Provides guidance on implementing and operating a Quality Assurance program; and
- Provides information for determining adequacy of shielding in absorbing primary and stray radiation.

Section 9.2 of Safety Code 30 provides guidelines for protecting the patient during radiographic examinations. Item 7 of Section 9.2 states:

> *The patient must be provided with a shielded apron, for gonad protection, and a thyroid shield, especially during occlusal radiographic examinations of the maxilla. The use of a thyroid shield is especially important in children. The shielded apron and thyroid shield should have a lead equivalence of at least 0.25mm of lead. In panoramic radiography, since the radiation is also coming from the back of the patient, a conventional lead apron is not adequate and dual (front and back) lead aprons should be worn.*

The 2004 report *Radiation Protection 136: European guidelines on radiation protection in dental radiology: The safe use of radiographs in dental practice* (121) was produced for the European Commission by the Victoria University of Manchester (United Kingdom), but has not been approved by the Commission. The intent of this report was to update and extend the technical guidelines in *Radiation Protection 81* (1995). The objective of the report was to provide a practical guide to radiation protection for professional groups of dentists and their assistants. The report addresses the use of conventional CT scanners, but does not specifically address the issues surrounding CBCT scanners.

Article 7 of the *Medical Exposures Directive: Directive 97/43/Euratom of 30 June 1997, on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure*, stipulates that dental practitioners must have adequate theoretical and practical training for the purpose of radiological practice as well as relevant competence in radiation protection. Article 7 also stipulates that continuing education and training after qualification are required. *Radiation Protection 136* further states "in the special case of new techniques, for example when a dentist buys a new type of equipment or changes to using digital radiography, specific training should be sought."(121)

Appraisal

General CT Radiation Dose Considerations

- CT is estimated to account for about 10% of diagnostic examinations, but up to two-thirds of the total effective radiation dose from diagnostic imaging. The use of CT has been steadily increasing.
- The effective dose from CT can be orders of magnitude larger than traditional plain film examinations, depending on the examination type. For example, a typical chest CT (approximately 8 mSv) can result in an effective dose 400 times larger than a plain film chest x-ray.
- MDCT has a number of benefits over single-slice CT scanners, such as faster examinations and improved image quality, but the radiation dose is estimated to be between 10% to 35% higher because of lower geometric efficiency.
- Estimates of cancer risks from diagnostic x-rays are usually based on data from atomic bomb survivors. A radiation dose of about 100 mSv is estimated to cause cancer in one out of every 100 people over their lifetime according to the Nuclear Regulatory Commission BEIR VII report. The ICRP Publication 60 estimates that the cancer mortality risk is 5% per Sv, and the risk of nonfatal cancer is 1% per Sv. This corresponds to 6 out of 1000 people who are estimated to develop cancer (fatal and nonfatal) from 100 mSv of effective radiation dose.
- In Canada, the attributable lifetime cancer risk from all diagnostic x-rays is estimated to be 1.1%. This translates to 784 cases of cancer per year. The data used for the estimates were from 1991 to 1996, so these figures might presumably be higher today.
- Children are more sensitive to radiation than adults (estimated to be 10 times more). Children also have a higher estimated lifetime risk because they have more expected years of life after the radiation exposure than adults. Pregnant women are also of particular concern because of the potential induction of cancer and malformations from the radiation exposure to the fetus.
- A number of metrics are used to describe radiation, which can make comparisons from different studies and sources difficult. Standard radiation metrics also do not incorporate the resulting image quality from the radiation dose.
- In Ontario, diagnostic x-ray machine installation, use, and testing are covered under the *Healing Arts Radiation Protection (HARP) Act*. However, there are no standards or guidelines for CT in the *HARP Act Regulation 543 X-ray Safety Code.* A new federal safety code will be available in 2007/2008, and will cover many aspects of CT, such as responsibilities and protection of owners, users, and operators of CT scanners, facility and equipment requirements, and quality assurance requirements.

Radiation Dose Reduction Methods Considerations

- CT protocols with varying patient radiation dose are required for different indications. Significant reductions in radiation exposure are possible by selecting CT protocols that employ minimal radiation for the necessary image quality for the particular indication (e.g., low-dose CT protocols may be appropriate). In Ontario, CT protocols used for the same indications vary (e.g. varying use of low-dose CT protocols and automatic exposure control).
- Developing diagnostic reference levels (DRLs) has been shown to be an effective method to reduce radiation dose.
- Monitoring radiation dose for various types of scans can provide data to set DRLs, optimize patient radiation exposure, and to determine collective and trends in radiation exposure levels. The majority of Ontario healthcare institutions with 64-slice CT scanners already record $CTDI_{vol}$ and/or DLP values for each CT examination.
- Technological advances in MDCT scanners, such as automatic exposure control and filters, have been shown to reduce patient radiation dose.
- Studies have shown that patient shielding can significantly reduce radiation exposure, but comprehensive guidelines on the types and amount of patient shielding for various CT examinations are not readily available in Ontario. Patient shielding practices during CT examinations vary between Ontario healthcare institutions.
- The amount of occupational radiation exposure is legislated, but no guidelines (or legislation) exist for patient radiation exposure during diagnostic examinations.
- The radiation exposure to staff and patients is of concern with CT fluoroscopy-guided interventional procedures.

CT Scanner Testing and Inspection Considerations

- The frequency and methods of radiation testing of CT scanners are highly variable in Ontario.
- Unlike other diagnostic x-ray machines, regulations on radiation acceptance testing and periodic testing are undefined. There are no standards or guidelines for CT in the *HARP Act Regulation 543 X-Ray Safety Code*, but a new Health Canada safety code, including CT, will be released in 2007/2008.
- Unlike other diagnostic x-ray machines, CT scanners in Ontario are not specifically inspected by the X-ray Inspection Services.

Coronary CTA Considerations

- Coronary CTA has been suggested as a replacement for conventional fluoroscopy CA for diagnostic procedures because coronary CTA is less invasive and requires less time.
- The limited data available on 64-slice coronary CTA indicate sensitivity and specificity improvements over coronary CTA with 16-slice CT scanners, but it has been suggested that plaque characterization, besides assessment of the thickness of the atherosclerotic wall and identification of calcific deposits, might be limited with coronary CTA.
- The radiation dose from coronary CTA is dependent on the protocol parameters used for the examination, and whether prospective ECG gating is used. The radiation dose from conventional CA is highly dependent on the fluoroscopy time. The dose estimates from coronary CTA have been found to range from 7 to 13 mSv, while the dose estimates from conventional CA have been found to range from 3 to 25 mSv.
- Manufacturers have reported a variety of technological advances in coronary CTA, including those that allow coronary CTA to be performed in a single short breath hold.

Dental CBCT Considerations

- Dental CT scanners employ cone-beam CT (CBCT) technology as opposed to conventional CT technology.
- The radiation dose from dental CBCT is comparable to low-dose CT, but can be up to 15 times lower than conventional CT with standard protocols.
- The advantage of the CBCT compared to MCDT is the size, cost, and potential accessibility, but conventional CT can be used to evaluate soft tissue as well as high contrast tissue.
- CBCT examinations can generally replace PR examinations. Bite-wings are still required for caries detection because CBCT produces scatter artifacts from metal fillings.
- The CBCT examinations provide more clinically useful information than panoramic radiography (PR) examinations, but the radiation dose from PR can be 4-15 times lower than CBCT.
- There are five CBCT scanners currently installed in Ontario (three in radiology practices and two in dental offices). The scanners are operated by dental assistants or in the case of a single installation, by medical radiation technologists. The scans are usually prescribed and interpreted by dentists, except at two radiology practices, where there are oral radiologists.
- Provincial, federal, and international regulations and guidelines for radiation protection in dental radiology exist, but they do not specifically address CBCT scanners.

Recommendations

General CT Radiation Dose Recommendations

- Recommend establishment of a CT Radiation Safety committee consisting of experts to advise, oversee, and implement methods to promote CT radiation safety. The CT experts should include but not be limited to radiologists, medical radiation technologists, physicists, dentists, Ministry of Health and Long-Term Care representation, and CT scanner manufacturer representation.
- Recommend updating the HARP Act and its regulations to include the operation, use, testing, and inspection of CT scanners. The new federal safety code will be available in 2007/2008 (*Safety Code: Recommended safety procedures for the installation, use and control of X-ray equipment in large radiological facilities*), which will cover many aspects of CT, such as responsibilities and protection of owners, users, and operators of CT scanners, facility and equipment requirements, and quality assurance requirements. The new federal safety code may assist in setting the standards.

CT Scanner Testing and Inspection Recommendations

- Recommend establishment of guidelines for proper methods of CT scanner acceptance testing and periodic quality control testing, similar to the detailed guidelines currently available by the X-ray Inspection Services for other diagnostic x-ray equipment. The guidelines should be developed by the X-ray Inspection Services in collaboration with other physicists, engineers, and CT scanner manufacturer representatives. These guidelines should supplement the proposed 2007/2008 federal safety codes that will cover items such as frequency of testing. Information from the practical guide on CT scanner testing, *Information Leaflet No.1: CT Scanner Acceptance Testing,* developed by the ImPACT group could be incorporated.
- Recommend strengthening the existing resources for X-ray Inspection Services to provide field surveillance of CT scanners.

Radiation Dose Reduction Methods Recommendations

- Recommend development of methods (e.g. web-based repository) to help share best-practice CT protocols (and supporting data on adequacy of image quality) between heathcare institutions. Through protocol selection, radiation dose can be reduced in some cases by an order of magnitude without compromising image quality.
- Recommend collection and analysis of radiation dose information from institutions across Ontario on the various types of CT scans.
- Recommend development of DRLs. CT radiation dose data collected from institutions across Ontario can be used to set DRLs at say, 80th percentile of recorded radiation doses. Although existing DRLs from countries such as the US and the UK could be adopted, it would be more meaningful for Ontario institutions to compare their CT radiation dose output with Ontario (or Canadian) DRLs.

- Recommend establishment of specific guidelines on patient shielding for various types of CT scans.
- Recommend development of a training program for interventional radiologists on CT fluoroscopy. No such training program exists in Ontario. The training program should be developed by interventional radiologists who are experts in CT fluoroscopy, in collaboration with CT scanner manufacturers.

Coronary CTA Recommendations
- Recommend establishment of guidelines on coronary CTA protocol parameters and techniques (e.g. prospective ECG gating) to minimize radiation exposure.

Dental CBCT Recommendations
- Recommend establishment of stipulations for the installation of new CBCT scanners in Ontario (e.g. monitoring of frequency, purpose, and dose from the examinations). The existing HARP dental CT advisory committee could be instrumental in developing the stipulations.
- Recommend development of training and continuing education requirements for operators of dental CBCT scanners (and dentists who interpret and order dental CBCT images). The existing HARP dental CT advisory committee could be instrumental in developing the training and continuing education requirements. Training and continuing education programs could be developed in collaboration with educational institutions, such as the Michener Institute for Applied Health Sciences.

Appendices

Appendix 1: International Organizations on Radiation Exposure and Risks

This appendix lists some of the main international authorities on radiation exposure and risks.

UNSCEAR (United Nations Scientific Committee on the Effects of Atomic Radiation) was established by the General Assembly of the United Nations in 1955. Its mandate in the United Nations system is to assess and report levels and effects of exposure to ionizing radiation. Governments and organizations throughout the world rely on the Committee's estimates as the scientific basis for evaluating radiation risk and for establishing protective measures.

The International Commission on Radiation Protection (ICRP) is an independent Registered Charity. Its mission is to "advance for the public benefit the science of radiological protection, in particular by providing recommendations and guidance on all aspects of protection against ionising radiation."(122) ICRP offers its recommendations to regulatory and advisory agencies and provides advice intended to be of help to management and professional staff with responsibilities for radiological protection. The ICRP has published a report in 2002 titled: *ICRP Publication 87: Managing Patient Dose in Computed Tomography*.

The European Commission has developed a set of guidelines titled: *2004 CT Quality Criteria* "to provide an operational framework for radiation protection initiatives for this modality, in which technical parameters required for image quality were considered in relation to patient dose".(26) "The European Commission embodies and upholds the general interest of the Union and is the driving force in the Union's institutional system. Its four main roles are to propose legislation to Parliament and the Council, to administer and implement Community policies, to enforce Community law (jointly with the Court of Justice) and to negotiate international agreements, mainly those relating to trade and cooperation."(123)

The ImPACT (Imaging Performance Assessment of CT scanners) group in London, UK evaluates and reports on the dose and imaging performance of CT scanners, as well as assesses their user interface and usability. The ImPACT group is manufacturer independent and therefore aims to provide impartial advice about CT scanners. The ImPACT group is funded by the Centre for Evidence-based purchasing at the UK's National Health Service Purchasing and Supplies Agency, but also provides consultancy services.

The CT Users Group in the UK was created to enable members to discuss new developments, share expertise discuss problems, to advance knowledge, and to facilitate

collaborative projects in the fields of CT physics. Members include physicists, technicians, radiographers, radiologists, etc.

The Radiation Protection Division of the Health Protection Agency (formerly known as the National Radiological Protection Board) in the UK "carries out the Health Protection Agency's work on ionising and non-ionising radiations. It undertakes research to advance knowledge about protection from the risks of these radiations; provides laboratory and technical services; runs training courses; provides expert information and has a significant advisory role in the UK."(124)

The US National Council on Radiation Protection and Measurements (NCRP) seeks to "formulate and widely disseminate information, guidance and recommendations on radiation protection and measurements which represent the consensus of leading scientific thinking. The Council is always on the alert for areas in which the development and publication of NCRP materials can make an important contribution to the public interest."(125)

The National Research Council established committees on the Biological Effects of Ionizing Radiations (BEIR) to prepare a series of reports to advise the U. S. government on the health consequences of radiation exposures. The BEIR V committee published the report, *Health Effects of Exposure to Low Levels of Ionizing Radiation* in 1990.(42) The BEIR VII committee published the report, *Health Risks from Exposure to Low Levels of Ionizing Radiation* in 2005.(8)

Institute of Radiation Protection is part of the National Research Center for Environment and Health (GSF) in Germany. The aim of the GSF is to "identify health risks posed by environmental factors, to elucidate mechanisms of disease development, and to develop concepts for the protection of human health and the natural basis of life for now and the future."(126)

Appendix 2: Computed Tomography Questionnaire Responses from 18 Ontario Healthcare Institutions

The following questionnaire was sent to 20 Ontario healthcare institutions with 64-slice CT scanners on May 2006. The cumulative responses from the 18 respondents are indicated. Summaries of the responses to the questions requiring free-text are provided, but the actual comments have been omitted. A small percentage of the respondents did not answer all of the questions, resulting in the total responses to occasionally add up to less than 18.

1. Development and Use of CT Scanning Protocols

1.1. The manufacturer's standard protocols are: *(Please choose one)*

    _____ Always used
    __2__ Occasionally modified
    __2__ Sometimes modified
    __6__ Usually modified
    __8__ Always or almost always modified/replaced

    Other/Comments:

1.2. Protocols from other healthcare institutions are: *(Please choose one)*

    __1__ Never used
    _14__ Occasionally used
    __2__ Sometimes used
    __1__ Usually used
    _____ Always or Almost always used

    Other/Comments:

1.3. If available on the CT scanner, Automatic Exposure Control (i.e. tube current modulation) is: *(Please choose one)*

    _____ Never used
    _____ Occasionally used
    _____ Sometimes used
    __4__ Usually used
    _14__ Always or Almost always used

    Other/Comments:

1.4. Are protocol parameters sometimes modified by the CT technologists?
        _____ No
        _18__ Yes. If yes, please describe when and how are they modified:

CT technologists would modify protocol parameters in situations such as when the patient was very large or small compared to an average sized patient, and when the patient could not hold their breath for the entire standard CT scan.

2. Are low-dose protocols used in your institution? For this questionnaire, "low-dose" will be defined as 50% or greater radiation exposure savings compared to standard protocols.
        __6__ No. *If No, please skip to question 3.*
        _12__ Yes

2.1. Please list the low-dose scan protocols in use at your institution:

The types of low-dose protocols widely varied. The most common low-dose protocols were for chest and renal colic examinations. Two of the 17 healthcare institutions that responded to the survey indicated that low-dose pediatric protocols were used.

2.2. How are **low-dose** protocols developed in your institution? *(Please check all that apply)*
        __6__ Developed iteratively based on experience
        __6__ Developed based on literature
        __4__ Developed based on formal testing/research
        __3__ Low-dose protocols are used from other healthcare institutions
        __6__ Low-dose protocols are used from the CT scanner manufacturer

        Other/comments:

3. Patient and Staff Shielding

3.1. Does your institution follow specific patient shielding standards?
        __3__ No
        _15__ Yes. If yes, please describe which standards are followed (in-house or
                otherwise):

The amount and types of shielding varied significantly. Some institutions responded that they shielded only pediatric patients, some shielded the gonads of all male patients and females patients of childbearing age as well as pediatric patients, and some shielded all patients whenever possible. Some respondents indicated use of 0.25 mm or 0.5 mm lead equivalency aprons, eye, and thyroid shielding.

3.2. Does the CT technologist have any discretion in the type and amount of patient shielding?

    __3__ No

    _15__ Yes. If yes, please describe how decisions are made on the amount and types of patient shielding:

CT technologists adjusted the shielding based on the area of interest for imaging. Two centres also responded that an additional layer of shielding is given to patients who request it.

3.3. Is special shielding used for pregnant women? (i.e., different compared to standard adult shielding)

    __2__ No

    _16__ Yes. If yes, please describe the shielding used for pregnant women:

Lead aprons are usually doubled or tripled for pregnant women.

3.4. Is special shielding used for children? (i.e., different compared to standard adult shielding)

    __9__ No

    __8__ Yes. If yes, please describe the shielding used for children:

Lead aprons are usually doubled for children.

3.5. Does your healthcare institution perform interventional CT procedures?

    __1__ No (1 did not respond)

    __5__ Yes, but staff are always outside of the CT suite during CT acquisition

    _11__ Yes, and sometimes the staff are within the CT suite during CT acquisition. Please list the types of radioprotective clothing that the staff wears:

Of the 11 surveyed institutions at which the staff is sometimes in the CT suite during image acquisition, staff members wear lead aprons and thyroid collars. Some institutions also use radioprotective goggles and gloves. One centre uses a portable lead partition to shield staff members.

4. Is screening performed on women of child-bearing age before CT examinations are performed?

    __1__ No

    __17_ Yes. Please describe the methods used for screening women of child-bearing age:

At all institutions except one, women of childbearing age are questioned before the CT examination as to whether they might be pregnant and are sometimes asked for the date of their last menstrual cycle. Blood tests are performed to determine pregnancy, if required.

5. Please list all the types of CT examinations and the number of CT examinations performed each week at your institution. Three examples are provided, but please add to the list as applicable.

Type of CT Examination	Number of Examinations per week
CT Head	
CT Chest	
CT Abdomen	

Responses to the types and number of CT examinations were variable between the institutions, and have not been listed.

6. Patient Radiation Exposure/Dose History

6.1. Is the radiation exposure/dose recorded per CT examination?

__3__ No

_15__ Yes. If yes, please list which parameters are recorded (e.g. CTDI, DLP, kVp, mA, etc.) and how (e.g. log book, PACS, etc.):

6.2. Is the patient radiation exposure/dose history taken into consideration for the use of CT and/or the CT protocol to be used?

_12__ No

__6__ Yes. If yes, please describe how the patient radiation dose history is taken into consideration:

Of the healthcare institutions that did consider patient radiation history, the modifications included low-dose protocols used for patients who required multiple follow-up CT examinations and for cancer patients.

7. Testing of CT Scanners

7.1. Is acceptance testing of your CT scanner performed at time of installation?

_____ No. If no, please skip to question 7.4.

_18_   Yes

7.2. CT scanner acceptance testing is performed by: *(Please check all that apply)*
    _10_   Representative from the CT scanner vendor
    __1__   In-house by the Medical Engineering/Medical Imaging Department
    _13_   Third party

    Other/comments:

7.3. The acceptance testing results are: *(Please check all that apply)*
    _13_   sent to the X-Ray Inspection Services (Ontario government)
    _14_   kept in the Medical Imaging Department
    __2__   kept in the Medical Engineering Department

    Other/comments:

7.4. CT scanner image quality assurance testing is performed: *(Please choose one)*
    _11_   daily in the morning
    __3__   daily in the evening
    _____   daily, but the times vary
    _____   once every two days
    __2__   at least once a week
    __1__   less than once a week

    Other/comments:

7.5. CT scanner image quality assurance testing is performed by:
    _17_   CT technologists
    __1__   Medical Engineering
    __9__   Representative from the CT scanner vendor

    Other/comments:

7.6. CT scanner preventative maintenance is performed: *(Please choose one)*
    _____   weekly
    _____   bimonthly
    _14_   monthly
    __4__   every 3 months

    Other/comments:

7.7. CT scanner preventative maintenance is performed by:
  __2__   A third party
  __1__   Medical Engineering
  _____   Medical Imaging
  _18__   Representative from the CT scanner vendor

  Other/comments:

7.8. Are periodic CT radiation dose measurements taken?
  __8__   No
  __9__   Yes. If yes, please state by whom, how, and the frequency these
          measurements are taken:

*Of the centres that do perform periodic CT radiation dose measurements, the frequency
ranged from monthly to annually, and sometimes only after alteration of the CT scanner.
The measurements were performed in-house, by a third party, or by representatives from
the CT scanner manufacturer.*

8. Please enter the number of 64-slice CT scanners installed in your institution.

  _11__   GE LightSpeed VCT
  __0__   Philips Brilliance 64
  __4__   Siemens Sensation 64
  _13__   Toshiba Aquilion 64

Appendix 3: Theories of Radiation Risk

The traditional linear no-threshold (LNT) model assumes that there is a linear relationship between radiation dose and risk. This means that even at very low doses, there is a deleterious effect. Linear-quadratic and quadratic models have also been proposed, but the LNT model assumes the worse outcome for low doses, and therefore provides the greatest protection. On these grounds, in 1960, the International Commission on Radiation Protection (ICRP) and the US National Council on Radiation Protection and Measurements (NCRP) decided to adopt the LNT model. This model has been developed in ICRP Publication 26 (1977) and ICRP Publication 60 (1991).(9) The ICRP and NCRP have recently reiterated their belief that there is no safe radiation dose threshold.(127, 128)

A 2005 study by Cardis et al. (40) found that low doses of radiation cause cancer. This was the largest study of nuclear workers ever conducted with data from 15 countries with over 407,000 workers. Deaths from cancer attributable to radiation among the workers were found to be 1-2%. The excess relative risk (ratio of incidence rates in the exposed and unexposed cohorts minus 1) for cancers other than leukemia was found to be 0.97 per Sv (95% confidence interval 0.14 to 1.97). The excess relative risk for leukemia excluding chronic lymphocytic leukemia was 1.93 per Sv (95% confidence interval <0 to 8.47).

Pierce and Preston (2000) (41) studied the radiation-related cancer risks at low doses (less than 500 mSv) among atomic bomb survivors. They found that the risk estimates for doses as low as 50 to 100 mSv were not overestimated by linear risk estimates computed from higher effective doses (0.5 to 2 Sv range). They concluded that, "there is no evidence in these data that linear risk estimates from a wider dose range overestimate low-dose risks, and considerable evidence that the linear risk estimates are appropriate."

Appendix 4: CT Radiation Metrics

Radiation Dose and Radiation Exposure
The amount of radiation energy deposited in a medium is called the radiation dose. Radiation dose is measured in the units of gray (Gy), where 1 Gy = 1 joule (J) absorbed in 1 kg of material. An older unit of radiation dose is the rad (1 Gy = 100 rad), and is now mainly only used in the US. Radiation exposure is related to the amount of ionization produced by an x-ray beam per kilogram of air (C/kg), and was derived from the earliest ways in which radiation was quantified. Radiation exposure is often replaced by Air Kerma, which is the radiation dose to air. Radiation dose can be calculated from the measured radiation exposure by applying a conversion factor that depends on the absorbing material (e.g. bone, soft tissue) and the position of the tissue. Radiation dose can also be measured directly from solid-state detectors.

Effective Dose
For radiation protection purposes, in order to account for the sensitivities of various organs to stochastic effects, effective dose is computed by weighting the individual organs by their radiation sensitivity and then summing these values. The effective dose (E) describes the relative "whole-body" dose and uses many assumptions such as mathematical model of a "standard" human body. Effective dose has units called sieverts (Sv). Effective dose is useful when comparing the potential stochastic biologic risk of various forms and sources of radiation. Radiation dose in mGy can be used to monitor deterministic effects like erythema (reddening of the skin caused by dilatation and congestion of the capillaries) or alopecia (hair loss).(33) Effective dose was developed by ICRP (Report 60) for radiation protection purposes.

Effective dose can be calculated with software packages based on the data from either the National Radiological Protection Board (NRPB) in the UK or the Institute of Radiation Protection (GSF) in Germany. The European Working Group for Guidelines on Quality Criteria in CT (26) has come up with a generic estimation method using the DLP (described below) to overcome the differences in effective dose values due to calculation methodology and data sources.

The CT dose index (CTDI) and dose-length product (DLP) are common parameters used to estimate dose from CT. The DLP and the $CTDI_{vol}$ are displayed on MDCT scanner consoles. The CTDI represents the integrated dose, along the z-axis, from one axial CT scan, and is measured in gray or rad. There are also CTDI derivatives, such as $CTDI_{100}$, $CTDI_w$ and $CTDI_{vol}$, which are measured using standardized CTDI phantoms. $CTDI_{100}$ represents the radiation exposure measured with an ionization chamber with a length of 100 mm. Radiation exposure at the centre and edge of phantoms are different. The average $CTDI_{100}$ across the field-of-view is calculated by the weighted CTDI ($CTDI_w$), where $CTDI_w$ = 2/3 CTDI(edge) + 1/3 CTDI(centre).(17) The volume CTDI ($CTDI_{vol}$) takes into account the gaps and overlaps between radiation dose profiles from consecutive rotations of the x-ray source. $CTDI_{vol}$ is defined as: $CTDI_{vol}$ = (N*T/I)*

$CTDI_w$, where N is the number of simultaneous axial scans per x-ray source rotation, T is the thickness of one axial scan (mm), and I is the table increment per axial scan (mm). In helical CT, the pitch is defined as: pitch = (N*T)/I. Therefore, $CTDI_{vol} = CTDI_w$/pitch.

The $CTDI_{vol}$ estimates the average radiation dose within the irradiated volume, but does not take into the account the length of the scan or the total number of successive scans. The DLP is therefore, used to represent the overall dose delivered by a scan protocol. The DLP is defined as: DLP = $CTDI_{vol}$ * scan length, and has units of milligray centimeters (mGy*cm). The effective dose can be estimated from the DLP by using a conversion factor (mSv per mGy/cm) that depends on the sensitivities of the various organs to radiation damage. It should be noted that the effective dose for specific protocols derived from the DLP are estimated mathematically from CT scanner geometry and beam quality and do not reflect the characteristics of the patient being scanned. Although the effective doses from the DLP are not measured quantities, they have been found to be remarkably consistent with more rigorous calculation methods, with a maximum deviation from the mean of approximately 10-15%.(17)

Diagnostic Reference Levels (DRLs)

DRLs are intended to allow comparison of performance. The most common CT DRLs are based on the $CTDI_{vol}$ and DLP values because they are conveniently displayed on the CT scanner consoles. Also, conversions from the $CTDI_{vol}$ or DLP values to effective doses are available to only a standard 70 kg person. To determine DRLs, each region administers a survey to determine typical patient doses from CT examinations. Such surveys establish the current state of practice, not necessarily the best practice. The DRLs are set at a certain level, say third-quartile, of the distribution of the $CTDI_{vol}$ or DLP values. Countries such as the UK, who have been monitoring the DRLs for a number of years have found a gradual decrease in the values, as the healthcare institutions with doses above the DRLs reduce their radiation doses. Individual regions establish their own DRLs instead of using DRLs from other regions because average patient weights and builds may vary depending on the region. Sample DRLs from British Columbia, the European Union, and the UK are provided in Table 5.(14)

Study	British Columbia 2004	European Union 1999	United Kingdom 2003
Head	1300	1050	930
Chest	600	650	580
Abdomen	920	900	470
Pelvis	650		
Abdomen-pelvis	1100	780	560

Table 5. Comparison of reference DLP values (mGy*cm) calculated from surveys in British Columbia, the European Union, and the UK.(14)

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