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# Health Canada Safety Code 35: Awareness of the Impacts for Diagnostic Radiology in Canada

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**Abstract**

Health Canada Safety Code 35 brings Canada's diagnostic imaging radiation output and protection standards to an international level. This Safety Code is comprehensive and will have broad implications for most health care facilities. This Safety Code outlines quality control procedures that will ultimately reduce patient dose while providing the best quality diagnostic images, all within a safe working environment. However, the Safety Code has some important omissions and errors of which radiologists should be aware, especially if they act as radiation safety officers. We hope that highlighting these issues will be the beginning of an ongoing dialogue between Health Canada, radiologists, medical physicists, and technologists that will not only bring awareness of Safety Code 35 but will provide a basis for updating, correcting, and improving future revisions of the Safety Code.

**Résumé**

L'adoption du Code de sécurité 35 de Santé Canada a permis d'harmoniser les normes canadiennes sur la radioprotection et l'irradiation en imagerie diagnostique aux normes internationales. Il s'agit d'une directive exhaustive qui aura de vastes répercussions sur la plupart des établissements de soins de santé. Ce code de sécurité indique les procédures de contrôle qualité qui permettront à terme de réduire les doses aux patients tout en produisant des images diagnostiques de la meilleure qualité qui soit dans un milieu de travail sécuritaire. Cependant, ce code de sécurité comporte quelques omissions et erreurs importantes que les radiologistes doivent connaître, surtout s'ils agissent à titre de responsables de la radioprotection. En soulevant ces problèmes, nous espérons entamer un dialogue continu entre Santé Canada, les radiologistes, les physiciens médicaux et les technologues qui non seulement favorisera la sensibilisation au contenu du Code de sécurité 35, mais servira de point de départ à la mise à jour, la correction et l'amélioration des versions à venir.


*Key Words:* Safety Code 35; Diagnostic imaging; X-rays

We applaud Health Canada for publishing Safety Code 35 (SC35), a document that imposes new standards on radiation output and protection in diagnostic imaging [1]. The new Safety Code brings Canada's standards in line with the standards that have been in place for many years in European countries [2], the United States [3,4], and internationally [5–7]. SC35 provides guidelines in all aspects of diagnostic imaging (except mammography and bone densitometers) in large medical imaging facilities, including acceptance testing; cyclical quality control (QC) testing; limitations on patient, worker, and public dose; x-ray quality; image processing, including digital methods and film; protective shielding; and an assignment of who should be responsible for each of these tasks. This document provides Canadians with assurance that, if the Safety Code is followed, then radiation imaging is being performed as safely as is reasonably achievable, which results in the best quality images at the lowest possible dose.

The Safety Code is a standard put forth by the federal government, and it is left to the provinces to implement and enforce. The predecessor to SC35, Safety Code 20A, was widely used across Canada as a basis for radiation protection and QC, and as a teaching text for technologists. SC35 is much more comprehensive than Safety Code 20A [8] and includes QC expectations for digital systems, which are absent in the former Safety Code, which focused on film

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technology. The expectation is that provincial governing bodies adopt these standards for diagnostic imaging facilities, big and small. For instance, in British Columbia, both the Diagnostic Accreditation Program and WorkSafeBC have adopted SC35 standards. The Diagnostic Accreditation Program was established by the College of Physicians and Surgeons of British Columbia to promote excellence in diagnostic health care and provides accreditation for British Columbia hospitals and clinics, such that ''every diagnostic facility must be accredited by the committee before it can render a diagnostic service'' [9]. WorkSafeBC regulates worker safety and has adopted SC35 recommendations on dose limits for radiation workers in diagnostic imaging. These 2 governing bodies have the authority to reprimand and close diagnostic imaging facilities if the recommendations set out by SC35 are not met.

SC35 clearly defines the requirements of radiologists, medical physicists, biomedical service personnel, radiation technologists, and a facility's radiation safety officer (RSO). Implementation of SC35 and, specifically, the QC program outlined within is the responsibility of the RSO. The entirety of the QC program cannot be performed by a single person, and a multidisciplinary approach to satisfying the requirements is required and should reflect expertise and equipment accessibility. SC35 suggests that facilities have either a medical physicist or RSO. A medical physicist can be the RSO and must be certified by the Canadian College of Physicists in Medicine. The RSO can be a radiologist, providing that he or she has the required qualifications outlined by the relevant federal, provincial, or territorial regulations or statues. In practice, the role of the RSO is often presently filled by radiologists or technologists at institutions throughout the country. This article contains technical information that will ensure that radiologists who carry the RSO title have a basic understanding of the testing limitations present in SC35.

In taking steps to bring our health regions into SC35 compliance, we have thoroughly reviewed the Safety Code and are in agreement with most of the recommendations. However, we believe that the current code has a few shortcomings, such as misconceptions on reference doses, omission of testing backup timers, and an incorrect methodology of monitoring radioscopic automatic intensity controls. It is our opinion that bringing these shortcomings and/or omissions to light will be healthy for diagnostic imaging physics in Canada and will open a dialogue to improve the understanding and testing procedures of SC35.

## Areas for Improvement of Interest to Radiologists

### *Diagnostic Reference Levels*

Section A3.5 advocates the use of a diagnostic reference level (DRL) for optimizing the trade-off between patient dose and diagnostic quality images. The concept of DRLs for patient dose was first introduced by the International Commission on Radiological Protection (ICRP) in 1996 [10]. A DRL for a given examination is established by performing a large survey of patient doses for a given patient weight (or a narrow range of weights). The third quartile of the distribution is typically stated as the DRL for that particular examination and patient weight. For the appropriate patient weight range, patient doses below the DRL are considered appropriate for the examination, whereas patient doses above the DRL may be considered too high and warrant an investigation. DRLs are used instead of reference doses, because a reference level should preferably be a dose indicator, a quantity that can be read directly from the x-ray unit, such as dose length product (DLP) for computed tomography (CT), and dose area product (DAP) for radiography and radioscopy. Reference doses are not recommended because the patient dose would have to be calculated for each examination and subsequently recorded on either the picture archiving and communication system or radiology information system. These doses are most easily calculated from dose indicators, which can automatically be included in the digital imaging and communications in medicine header for digital systems. One can consider the DRL approach to be the corollary of optimization; instead of performing a clinical trial for each diagnostic examination to determine the lowest dose which gives adequate diagnostic information-optimization, reference levels are used to determine what doses are above the norm. Both methods, dose optimization and reference levels, achieve the same goal: lower patient dose. It must be emphasized that a DRL is a single value for a specific examination for a specific patient weight. In SC35, DRL ranges are given (SC35 Tables 1–4) [1], which causes confusion regarding the definition of a DRL and the appropriate amount of examination dose.

DRLs are best set by surveying multiple hospitals that perform similar examinations and by comparing patient dose levels with published values, if available. However, SC35 suggests that ''a hospital or clinic can set up their own local DRL [values] if enough data is available'' [1]. A serious flaw exists with this reasoning; for example, if such a hospital or clinic delivers a dose at 4 times the level of all other hospitals, then using the ''local DRL'' will not sufficiently reduce the dose by a factor of 4. Performing a larger survey that involves multiple institutions or simply comparing a local survey with published DRL values, is a better way to monitor and reduce the patient dose.

We also are concerned that SC35 recommends the use of phantoms to define a DRL. Most of the published data on DRL values, including those quoted in SC35, were derived from surveys of actual patient examinations. Using the actual patient dose is far superior than the dose measured by using a phantom, because the patient dose incorporates all controllable (imaging technique: kVp, mAs) and uncontrollable (patient orientation, collimation, distance) factors. Typically, use of a phantom leads to nearly identical exposures and can only address controllable factors. Furthermore, unless very good anthropomorphic phantoms are used, the results will not be meaningful. For example, if a simple 23-cm solid phantom is used in the posteroanterior chest examination instead of actual patients, then no account can be taken of the various