National Survey of Canadian Mammographic Facilities

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Abstract

A national survey comprising approximately 60% of all Canadian mammographic facilities was conducted in 1994-95. The survey, which was coordinated by Health Canada, was a cooperative undertaking of the federal and all provincial and territorial governments in Canada. The survey protocol, which was developed by the U.S. Food and Drug Administration (USFDA), was used for U.S. national surveys in 1985, 1988 and 1992 and is similar to U.S. accreditation requirements of the Mammography Quality Standards Act and the Canadian accreditation requirements of the Canadian Association of Radiologists (CAR). The use of a standardized protocol and intercalibration of survey equipment will permit direct comparisons of the findings with other North American survey data to be made. This report describes the protocol and presents the material findings.

This document was prepared by G.R. Symonds, P.Eng., of the X-Ray Section, Consumer and Clinical Radiation Hazards Division, Radiation Protection Bureau, Health Canada.

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Data analyses were ably assisted by Dr. Fred Rueter of Derwood, MD, USA (phantom image scoring and advice on NEXT) and Steve Harper of the Radiation Protection Bureau (shipping, receiving, data verification and entry).

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Introduction

Since its inception, the Radiation Protection Bureau has carried out programs to protect the health of Canadians. The Bureau meets this challenge using a variety of tools. The *Radiation Emitting Devices Act*, a federal statute, and associated regulations present safety requirements for radiation emitting equipment before it may be legally sold, leased or imported into Canada. A series of *Safety Codes* which set mandatory requirements for all persons working for the federal government or for organizations subject to the *Canada Labour Code* deal with all aspects of equipment installation and operation. These Safety Codes are routinely used by others, including provincial governments, as the basis for their radiation safety requirements. An *Inspection program* is maintained to perform regular safety inspections of federally operated radiation equipment in law enforcement, transportation and scientific laboratories. Inspection services are also provided under contract to those organizations lacking the in-house capability.

The Radiation Protection Bureau works closely with its provincial and territorial partners, who have primary responsibility for health care delivery in Canada. The present survey, which resulted from a Bureau proposal that Canadian mammography facilities be evaluated using a standardized survey protocol, is an excellent example of such a cooperative undertaking. This proposal grew from the fact that similar surveys in the United States revealed deficiencies which resulted in comprehensive congressional action in the certification of mammography facilities

Every year in Canada, over 17,000 new cases of breast cancer are diagnosed and over 5,400 women die. Early diagnosis is the most effective weapon against this disease, and mammography is considered the only diagnostic tool proven for use in the detection of non-palpable lesions and as a screening tool for the general population.

As with all diagnostic radiography procedures, however, film/screen mammography carries with it both risks and benefits. The induction of new cancers in healthy tissue by the ionizing radiation beam (the risk) must be weighed against the value of the radiograph in diagnosis and screening (the benefit). With properly designed and operated equipment, the diagnostic information contained in a mammogram is the maximum possible for the radiation dose used, thus simplifying any risk/benefit analyses. For this to be the case, all aspects of the mammography system must be optimized.

This report deals with equipment related aspects of the mammography process, which is to say those events which occur between the time that the patient is positioned for the examination and the processed film is delivered to the radiologist for clinical diagnosis. It is artificial in nature in that, instead of human subjects, a lucite breast phantom containing arrays of test objects representative of the fibrils, tumour-like masses and speck-like microcalcifications representative of the pathology being sought is used. The radiation dose is also measured using the breast phantom. This standardization is required to permit detailed analyses of equipment performance and intercomparison of results between facilities. Currently, breast phantoms designed to more closely mimic actual clinical conditions while maintaining their technical measurement capabilities are under development.

Purpose

The purpose of the 1994-95 Canadian Mammography Survey was to provide a baseline for the assessment of future radiation protection initiatives and to permit the comparison of the performance of Canadian mammographic facilities with that of other similar surveys. Equipment performance was assessed using the Nationwide Evaluation of X-Ray Trends (NEXT) protocol, originally developed by the Center for Devices and Radiological Health (CDRH) of the USFDA. NEXT is a collaborative state-federal program coordinated by the Conference of Radiation Control Program Directors (CRCPD) in the United States. Special emphasis was placed on standardized equipment calibration and image scoring, so that the data contained in this report may be directly compared with those of the U.S. 1992 NEXT mammography survey and ongoing data collection from the *U.S. Mammography Quality Standards Act* (MQSA) of 1992.

Nationwide Evaluation of X-Ray Trends (NEXT)

The NEXT program was developed in 1972 by the then Bureau of Radiological Health (now the Center for Devices and Radiological Health) of the USFDA. It was designed to track the effectiveness of radiation protection programs established by participants, usually state, provincial and territorial governments, over time (the Trends) by a series of equipment performance surveys (the Evaluations) conducted at regular intervals.

NEXT surveys feature: nationwide participation, centralized coordination, equipment calibration and data analysis, a standardized survey protocol and random sampling of facilities to be surveyed. All radiation dose and imaging data are measured using artificial phantoms. In addition to mammography, protocols, including any required dosimetry and imaging phantoms, have been developed for the posterior-anterior (PA) chest, abdomen, fluoroscopy, dental and most recently paediatric procedures. Future NEXT protocols in Canada may include a revised mammography protocol and computed tomography, with an emphasis on paediatrics.

The Radiation Protection Bureau has been an active participant in the NEXT program almost since its inception, with continuing close cooperation between the Bureau and the USFDA.

Methodology and Experimental Procedures

Sample Selection

Facilities to be included in the first Canadian mammography survey were chosen using stratified random sampling, with the twelve participants (ten provinces and two territories) representing the strata. An initial national sample size of 200 facilities was chosen, this number being prorated to each participant (stratum) on the basis of population, using 1991 census data.

Each participating province or territory submitted a complete list of all mammography facilities in its jurisdiction, including hospitals, screening clinics and private practice. From each of the twelve lists the candidate facilities were chosen at random using the computer program PERMUTE[1]. Based on this selection, the provinces and territories then scheduled and carried out the surveys.

During the actual performance of the surveys, some of the participants chose to use the opportunity to survey all of the facilities in their jurisdiction, and these census samples are included in the data analysis. The resulting final count of facilities in the survey was 338, representing approximately 60% of all Canadian mammography facilities at the time of the survey.

Information was collected from each mammography unit in each selected facility to permit assessment of film processing, radiation dose and image quality. Administrative information, including identification, certification and workload (number of mammograms performed) was also collected.

Film Processing

Film processing was evaluated using the *Sensitometric Technique for the Evaluation of Processing* (STEP), developed by Dr. Orhan Suleiman of CDRH[2]. This technique permits the determination of a numerical value for processing speed, normalized to a value of 100 for films processed according to manufacturer's recommendations for standard processing. Films with processing speeds of less than 80 are regarded as underprocessed, while those exceeding 120 are considered to be overprocessed. Under or overprocessed films may not present the maximum amount of diagnostic information available from the radiation dose delivered, or may introduce artifacts into the diagnostic image. Overprocessing ("push" or "extended" processing), which is intended to produce satisfactory image contrast with reduced radiation dose, may be a deliberate choice of the facility.

Since no absolute standards exist for x-ray film sensitometry or film processors, de facto "primary" reference standards are maintained in the form of "trusted" (based upon years of experience) equipment: a set of reference sensitometers (X-Rite Corp., Grandville, MI, USA, model 334) having an optical density tablet with increments of 0.15 density per step, and a film processor (Kodak Corp., Rochester, NY, USA, model RA-480). Suitable commercial standards exist for densitometry.

For the 1994-95 Canadian mammography survey, Kodak Min-R M, a widely-used single emulsion film of the time, was chosen. Sufficient film to conduct the entire survey was acquired, ensuring that it was all from the same emulsion lot. The sensitometers used were calibrated directly against the CDRH reference units. To determine the "reference step" value (i.e., a normalized processing speed index of 100), the sensitized films were processed according to the manufacturer's specific recommendations for Min-R M film.

The processing speed index relative to the previously determined "reference step" value was determined for each facility, a darkroom fog test was performed where applicable and the processing speed determined according to the method described in[2]. Darkroom fog levels are important as they contribute to the background noise in the diagnostic image.

Radiation Dose

Radiation dose was measured using an MDH (Radcal Corp., Monrovia, CA, USA) 1015 or 1515 ionization chamber survey meter, which measures both exposure and exposure time. Because of wide usage and availability from previous NEXT surveys, standard 6 cc ion chambers were used in most surveys. The survey instruments and ion chambers were carefully calibrated in the 20 to 30 kVp range, with typical correc-

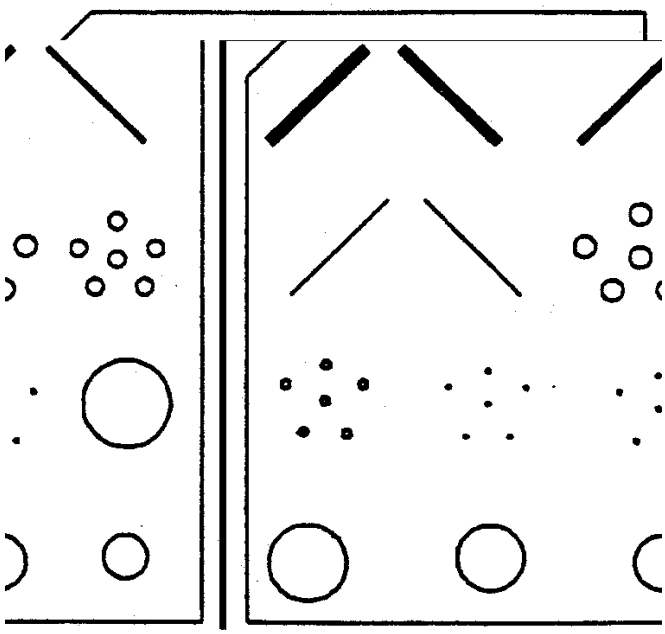
tion factors ranging from about 1.1 at 30 kVp to 1.2 at 20 kVp for the 6 cc general-purpose chambers. The data from those surveys which used other survey meter types or different ion chambers were adjusted accordingly.

The half value layer in mm of Al was computed by interpolation between the two ESE/Al attenuator values which bracketed $ESE_{(0\ mm\ Al)}/2$. The computation was considered sufficiently accurate if the end points of the interpolation interval fell within 15% of the actual interpolated value[7]. Normally, the NEXT protocol HVL computation requires a series of points on the attenuation curve to be measured and the HVL obtained using a least squares technique, but insufficient data for this method was available from a significant number of the surveys.

Image Quality

To simulate a “standard breast”, a mammographic phantom, similar to the RMI (Gammex/RMI, Middleton, WI, USA) model 156 phantom, was developed by the CDRH in 1991. This phantom, which is made of polymethylmethacrylate (lucite), has a thickness of 3.63 cm and a cavity containing an image quality insert, giving an overall thickness of 4.5 cm. The attenuation equivalence is that of 4.2 cm of compressed breast consisting of 50% glandular and 50% adipose tissue for imaging with typical film-screen energies. The image quality insert used was a standard RMI 156 model containing 16 test objects embedded in a wax matrix. Details of the insert are as follows:

Dosimetry Phantom Insert



The CDRH phantom incorporates a 0.75", 10-step wedge along one edge for optional optical density measurements.

To maintain direct comparability with previously reported U.S. survey data[4, 6], the phantom images were scored by the same individual who has scored all previous NEXT mammography surveys in North America, and was also a co-developer of the NEXT mammography protocol.

The data here reported include[1] the average of three scorings using the NEXT 1992 protocol (once in the field by the surveyor and twice in the office) and[2] an additional scoring following current Canadian Association of Radiologists (CAR) methodology, which is identical to that developed by the American College of Radiologists (ACR). Both agencies are active in the accreditation of mammography facilities.

The principal difference between the NEXT 1992 and CAR/ACR film scoring protocols is the introduction of a subtractive correction for artifacts in the latter, with the existence of artifacts resulting in lower scores and higher failure rates.

Film-screen contact was evaluated using a numerical criterion which is an extension of the traditional Pass/Fail test[3]. A standard mammographic mesh was radiographed and the resulting image examined for contact irregularities. It was noted during examination of the films that many facilities which achieved a passing score (no one irregularity greater than 1 cm in diameter) nevertheless had several small image imperfections. The number of these small irregularities are reported in the results. In several of the film-screen contact radiographs, foreign objects and dirt particles were observed; these are principally the result of a lack of cleanliness and routine cleaning procedures.

Results

The data have been divided into four categories: general facility information, film processing, radiation dose and image quality. The data are summarized in Table 1, and the distributions are presented in the following sections.

Table 1

	Film Processing Method		
Characteristic	All	Regular	Extended
Mean Optical Density	1.31	1.27	1.34
Mean Processing Speed	130	100	146
Passing Darkroom Fog Level <0.05 OD	49%	42%	51%
Passing Film-Screen Contact <1 cm dia	82%	86%	79%
Mean Film-Screen Contact Imperfections	3.7	4.5	3.2
Use of Dedicated Film Processor	52%	16%	71%
Glandular Dose (mGy) Mean	1.13	1.21	1.09
Median	1.06	1.12	1.03
Mean Half Value Layer (mm A1)	0.32	0.32	0.32
Mean kVp Setting	26	26	26
Passing (NEXT – no artifact substraction)	97%	97%	97%
Score (ACR – artifact substraction)	90%	89%	91%
Facilities in Survey	338	122	216

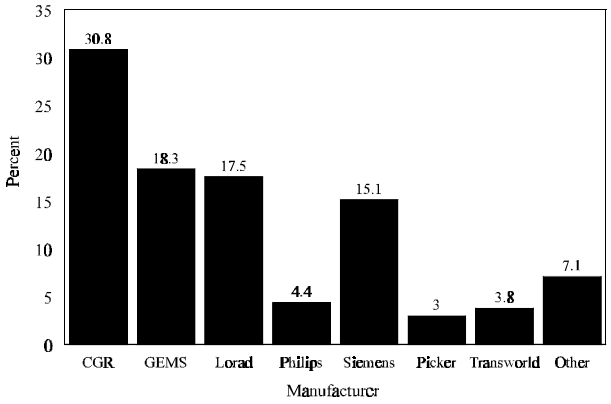
General

All facilities reported the use of dedicated-design x-ray systems, routine compression and craniocaudal projection.

The disappearance of Xeroradiography as an imaging modality was confirmed, with all surveys reporting the use of film-screen image receptors. Anti-scatter grids and automatic exposure control were used by more than 98% of the facilities surveyed.

The distribution of X-ray control equipment by manufacturer is given in Figure 1. Since the survey began, the most popular brand, CGR, has become part of the General Electric organization.

Figure 1. X-Ray Control Manufacturer



Figures 2 through 4 detail by manufacturer the utilization of processors, film and chemistry.

Figure 2. Film Processor Manufacturer

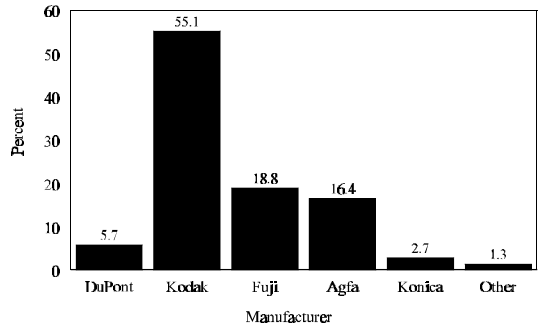


Figure 3. Film Manufacturer

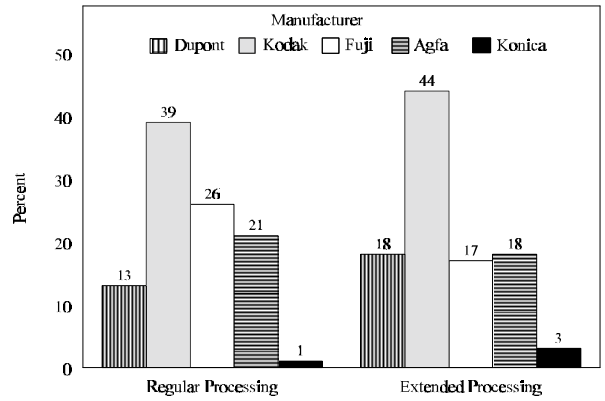
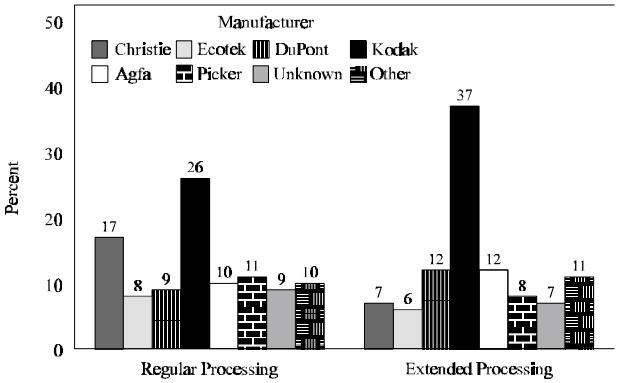


Figure 4. Chemistry Manufacturer



The extent of the routine use of dedicated film processors and extended ("push") processing is given in Figures 5 and 6.

Figure 5. Dedicated Film Processor

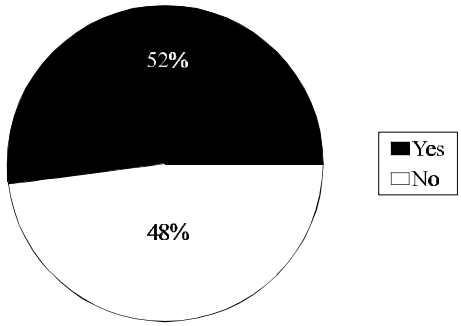
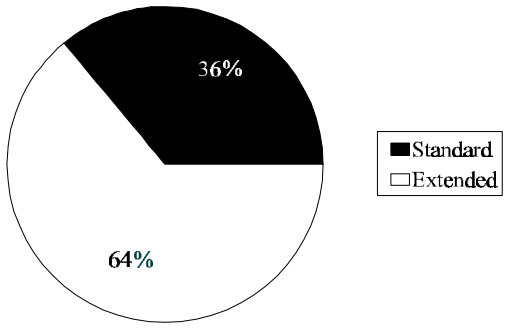


Figure 6. Film Processing Method



Darkroom Fog

The results of the darkroom fog tests and processing speed index measurements, for regular and extended processing, are given in Figures 7 through 9.

Figure 7. Darkroom Fog Level

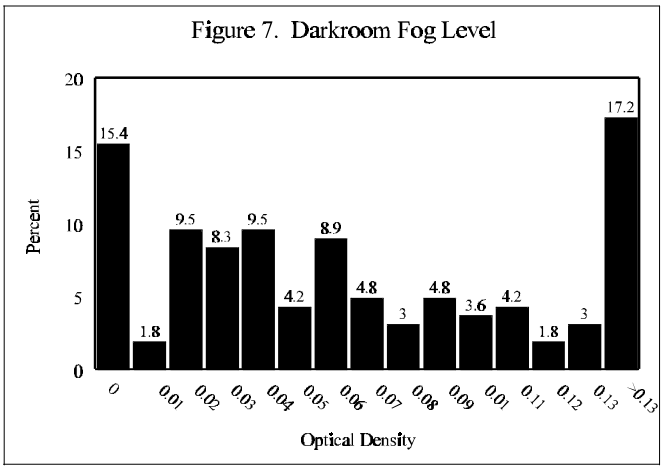


Figure 8. STEP Processing Speed - Standard (36%)

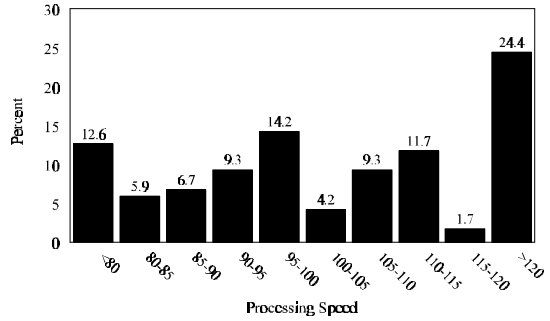
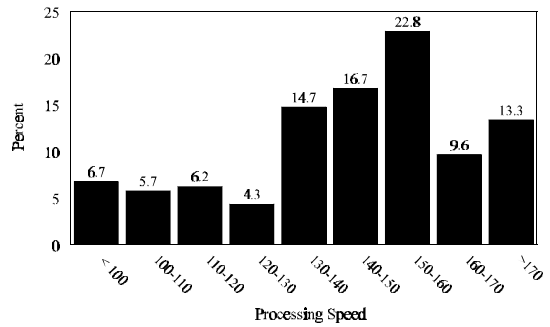


Figure 9. STEP Processing Speed - Extended (64%)



Radiation Dose

The kVp, half-value layer and mean glandular dose results are given in Figures 10 through 12.

Figure 10. KVP

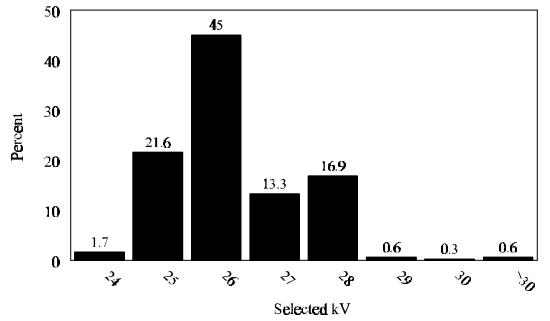


Figure 11. Calculated Half-Value Layer

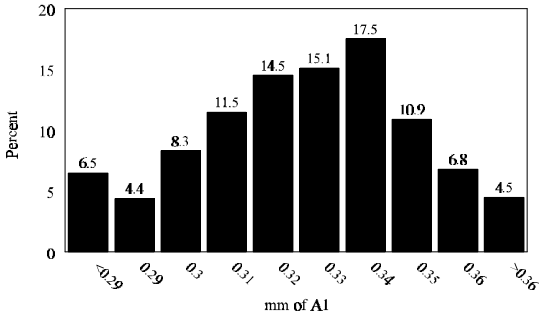


Figure 12. Mean Glandular Dose

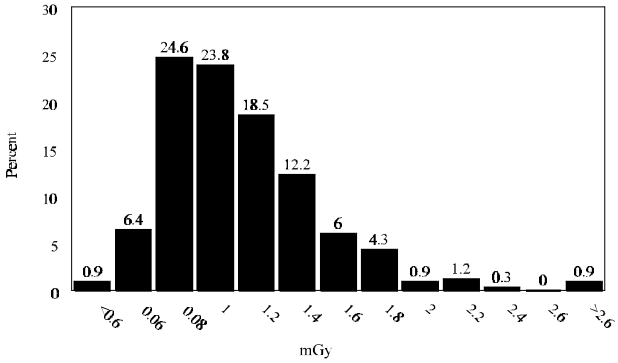


Image Quality

The optical film densities, pass/fail statistics and scores for both the NEXT and ACR scoring protocols are given as Figures 13 through 17.

Figure 13. Phantom Image Optical Density

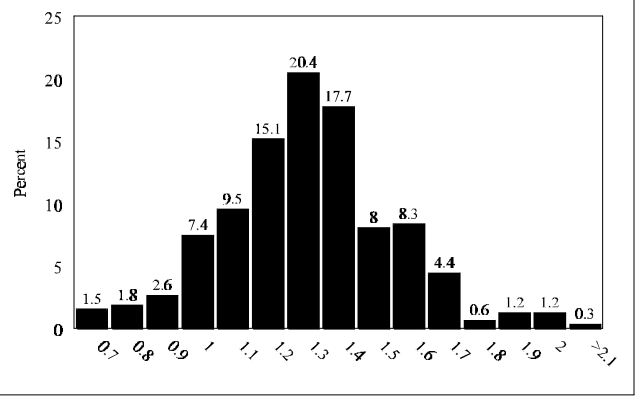


Figure 14. Phantom Image Score - NEXT Protocol

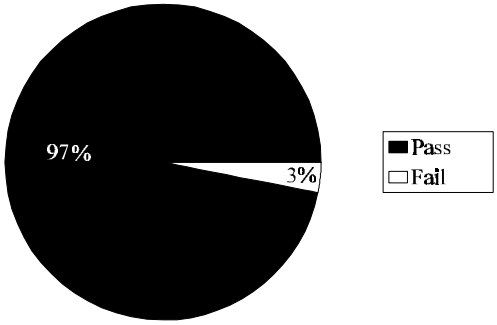


Figure 15. Phantom Image Score - ACR Protocol

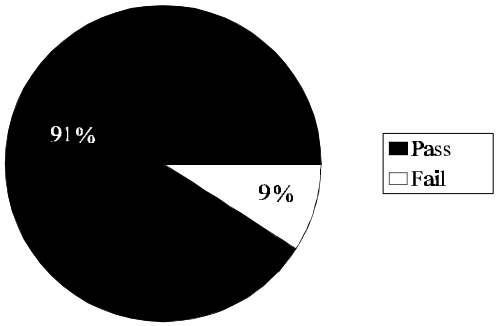


Figure 16. Phantom Image Score - NEXT Protocol

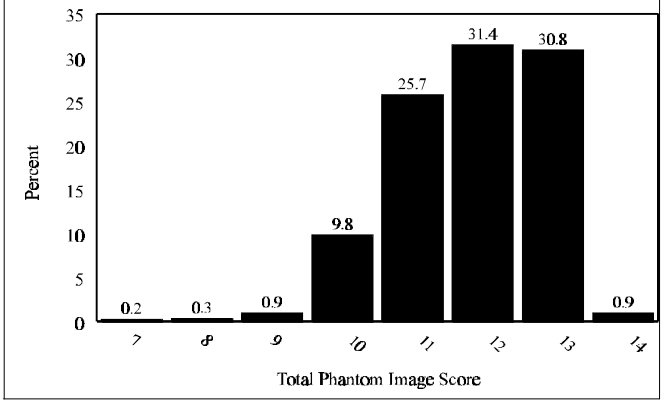
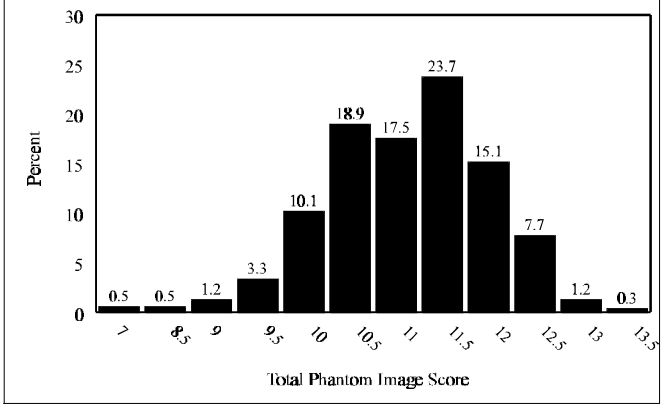


Figure 17. Phantom Image Score - ACR Protocol



The pass criteria for both protocols (minimum number of objects seen) are: fibres – 4, specks – 3, masses – 3.

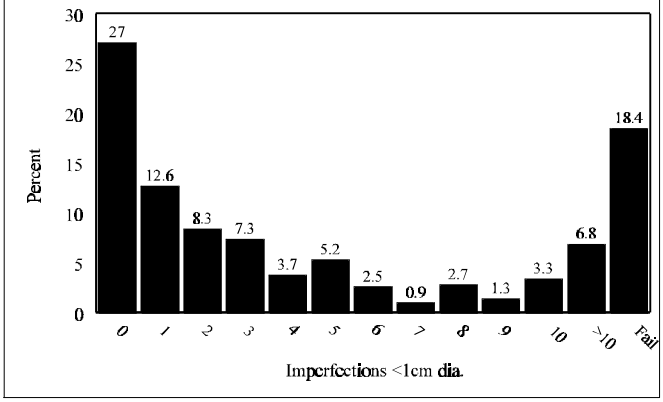
The majority of failures were due to the inability of the imaging system to produce sufficiently detailed images of fibres, as indicated in the following table (the total failing scores are less than the sum of the individual object failures due to multiple object failures at some facilities):

	Protocol	
	NEXT	ACR
Fail Fibres	1.8%	5.6%
Fail Specks	<0.1%	2.4%
Fail Masses	1.2%	3.6%
Fail Any	3.0%	9.5%

Film Screen Contact

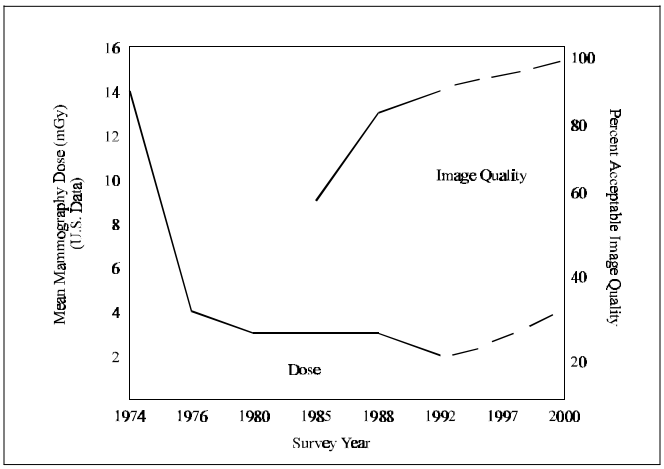
The film-screen contact data are presented as Figure 18. A standard test using a wire mesh was employed, and in addition to traditional scoring (a pass requiring no contact imperfection greater than 1 cm in diameter), the total number of visible imperfections smaller than 1 cm in diameter was also noted.

Figure 18. Film-Screen Contact



Discussion/Interpretation

The principal goal of radiation protection programs monitored by NEXT surveys has initially been the reduction of unessential radiation dose. The dose reduction achieved in the last twenty years has been remarkable, considering the improvement of image quality in the same period. It should be noted from the following that, in all NEXT protocols, the rate of reduction of delivered dose curve has flattened considerably since about 1980, while image quality continued to improve[4]:



For a given film-screen radiographic system operated in an optimal manner, increased optical density of the radiographic image requires increased radiation dose. The radiation dose required for a given film optical density, which is related to image quality, is thus a measure of system optimization. US NEXT and MQSA survey data from 1985 to 1995[5] show both the delivered dose and optical density to have increasing trends, suggesting the post-1992 dashed extensions added to the dose curve of the above graph. If indeed this is the case, the implication is that mammographic systems are being operated in an increasingly optimal manner.

The film processing data presented in Figures 7 through 9 indicate that:

- for those facilities where darkroom fog levels were measured (168 of 338), approximately 50% reported fog levels in excess of 0.05 optical density units, the generally acceptable upper limit. Extreme fog levels in excess of 0.10 were reported by approximately 25% of these facilities, which indicates that darkroom light leakage had in all probability never been part of a quality control program.
- for facilities using standard processing, the mean film speed index (STEP value) was 108, an acceptable value. The data show, however, 6% of facilities clustered in the 140–170 range, which may indicate that extended processing was in use and not accurately reported. A STEP value of 100 indicates that the film was developed according to the recommendations of the manufacturer, with values in the range of 80 (underprocessing) to 120 (overprocessing) being considered acceptable[2].
- for facilities using extended processing, the mean film speed index was 144, a typical value. Again, the reporting by the facility may be in question as a result of 6% of facilities reporting in the 90–110 range, a typical value for standard processing.

A preliminary investigation of the relationship between film contrast, optical density and image quality[8] concluded that the proposed U.S regulatory limits of 3.0 mGy for radiation dose and 1.2 for optical density[9] will not impede the full potential quality of mammographic film-screen imaging. The report also concluded that although quantum noise is reduced at higher densities of phantom images, the fact that phantom image quality correlates strongly with film contrast (the mathematical derivative of the sensitometric response or “gamma” curve of the film) and image quality scores eventually drop with increasing density, contrast is probably the dominating factor. Further, for the films studied, MinR-M and Microvision, the density values associated with the top 10 percentile of scores included those associated with dose levels of 2.0 mGy or less. The mean optical density for all facilities was 1.3 optical units, a value considered acceptable in current practice.

The mean glandular dose observed in this survey was 1.13 mGy, significantly less than the proposed maxima of 2.0 or 3.0 mGy or other current reported values of approximately 1.5 mGy[6]. This low glandular dose may be accounted for by a combination of more widespread use of extended processing and decreased optical densities.

The goal of the quality assurance program at mammography facilities should be to ensure that the equipment is operating in an optimal manner, thus making the risk/benefit (radiation dose/image quality) tradeoff a conscious clinical decision on the part of the radiologist.

Conclusions

Among the key lessons learned from this study is the reinforcement of the importance of, and deficiencies in, film processing. Mammography places extremely stringent quality requirements on film processing, well beyond the requirements of routine radiology. Film processing in Canadian mammographic facilities remains problematic, with particularly high levels of darkroom fog encountered. The number of artifacts introduced by poor film-screen contact, even in those facilities achieving a passing score using the standard criterion, was unexpectedly high. These problems, which can result in either false negative or false positive diagnoses, are often the result of not following established quality control procedures or the failure to implement an appropriate quality control program in the first place. Quality control programs are easily undermined by the cumulative effect of ignoring seemingly minor problems as they arise.

The results of this study demonstrate a need for facilities to adopt and document standards for film sensitometry and processing as part of any quality control program.

The unexpectedly low levels of radiation dose found in the survey may be at least partially explained by the widespread use of extended processing and the acceptance of reduced optical densities in the resulting images. Low optical density of the diagnostic image has been shown to correlate with lower dose[8]. A correlation between image quality and dose may or may not exist.

Phantom Image scores lie between North American data predating this survey (USA, 1992) and current (USA, 1996) data, and can thus be described as typical of North American practice. This observed continuous improvement in mammographic image quality is in all likelihood due to advances in methodology and procedures, equipment technology and/or quality control.

The original intent of the Nationwide Evaluation of X-Ray Trends series of surveys was to:

(1) perform an Evaluation to determine the current situation
(2) put a program in place to address deficiencies
(3) resurvey to assess the success of the program in (2).
This will give one point on the Trends curve.

As this series of events is repeated, the resulting Trends line will indicate the effectiveness of the process. With regard to mammography in Canada, the current survey establishes the first point on the Trends curve, with future surveys being required to assess the effectiveness of consequent quality improvement programs.

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Appendix A

Glandular Dose Computation Table

The original table has been extended by extrapolation – the values added to the data published by Barnes, Wu and Tucker are shown in italics.

		Tube Kilovoltage (kVp)												
		23	24	25	26	27	28	29	30	31	32	33	34	35
Half Value Layer (mm Al)	0.21	*114*	*116*	Mean Glandular Dose = ESE * Tabular Value * 10^{-3} (mrad) = ESE * Tabular Value * 10^{-5} (mGy), where ESE = Mean Exposure at Skin Entrance corrected for survey meter energy response										
	0.22	*116*	*118*											
	0.23	118	*121*	*125*										
	0.24	122	125	*128*	*128*									
	0.25	126	129	132	*133*	*134*								
	0.26	129	132	136	137	*139*	*142*							
	0.27	134	137	140	142	143	*145*	*144*						
	0.28	140	142	144	146	148	149	*149*	*148*					
	0.29	145	147	149	150	152	153	154	*154*	*156*				
	0.30	150	152	154	155	157	157	158	159	*161*	*162*			
	0.31	154	156	158	160	161	162	163	165	166	*166*	*170*		
	0.32	159	160	162	164	166	167	168	169	170	171	*174*	*178*	
	0.33	164	165	167	168	170	171	172	173	175	176	177	*180*	*177*
	0.34	*168*	170	172	173	175	176	177	179	180	181	182	183	182
	0.35	*171*	*174*	176	178	179	180	182	183	184	184	185	186	187
	0.36	*174*	*177*	*180*	182	184	185	186	187	188	189	189	190	191
	0.37	*176*	*180*	*185*	*187*	188	189	190	191	192	193	194	195	196
	0.38	*177*	*183*	*189*	*191*	*193*	193	194	195	196	197	198	199	201
	0.39		*185*	*192*	*196*	*197*	*197*	199	200	201	202	203	204	205
	0.40			*196*	*201*	*201*	*201*	*203*	204	205	206	207	208	209
	0.41				*205*	*206*	*203*	*206*	*209*	208	209	210	212	213
	0.42						*205*	*210*	*213*	*212*	214	214	215	216
	0.43							*214*	*218*	*216*	218	218	219	220
	0.44								*224*	*219*	*222*	*221*	*221*	*223*
	0.45									*223*	*227*	*223*	*222*	*225*
	0.46										*231*	*226*	*223*	*228*
	0.47											*227*	*225*	*229*
	0.48												*228*	*231*
	0.49													*231*

Table N: ESE to Glandular Dose Conversion Factors (After Barnes, Wu and Tucker)