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NCRP Mammography Update

CE - Screen - Film Mammography 2
AAPM Montreal, July 18, 2002

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E = Epidemiologist, P = Physicist, R = Radiologist, S = NCRP Staff

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Background

Committee reconstituted to revise:

NCRP Report No. 85:
Mammography--A User's Guide

Published in 1986

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By 1991: Significant Changes

- New Low Dose Screen-Film Systems
- Data from ACR-MAP, CRCPD
- End of Xeroradiography
- New Risk & Benefit Data
- Only Dedicated Mammography Units
- New National Recommendations
- Significant New Publications
- New Technology

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Revised NCRP Mammo Report

Revision Completed in 2002

Draft Report Is Currently Being Reviewed by Council

Material Presented Here Was Developed by Committee SC-72, But Has Not Yet Been Approved by NCRP

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Caveat

- Report has not yet been fully reviewed by either the full NCRP Council or Critical Reviewers
- NOTHING presented represents NCRP Policy
- Final Report MIGHT be different
- Note:
  Effort to agree with ACR/MQSA Documents

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Introduction

- Usefulness of mammography
- Usefulness of mammography for breast cancer screening
- Purpose and Scope of Report

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Clinical Mammography

- Breast anatomy
- Viewing a mammogram
- Film identification
- Breast positioning - C.C. and M.L.O. views
- Clinical considerations
  - Grid
  - Magnification
  - AEC reliability
  - Compression
  - Technical decisions
- Double interpretation of mammograms

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Equipment

- X-Ray Unit
- Screens
- Films
- Processing Systems

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X-Ray Unit

- Mechanical Assembly/General
  - C-Arm
  - Locks
  - Compression
  - Image Receptor Support Device
  - Radiation Shield
  - Recording System

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X-Ray Unit

- X-Ray Source Assembly
  - Target
  - Window
  - Filter
  - Field Coverage
  - Focal Spot
  - Resolution

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X-Ray Unit

- X-Ray Generator
  - 3 to 10 kW
  - High Frequency generator
  - kVp Selection: 24 - 32 in 1 kV steps
- X-Ray Beam Energy and Intensity
  - kVp/100 to kVp/100+0.1 mm Al
  - 200 $\mu C\ kg^{-1}\ s^{-1}$ at breast (28 kVp, 3 s)

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X-Ray Unit

- Exposure Control
  - AEC: OD ± 0.12 - 2 to 6 cm
  - Detector: 3 pos, indicator, right size
  - Density Adjustment: 9 steps (10 - 15 %
  - Post-Exposure Display
  - Back Up Timer: indicator, 250 - 600 mAs
  - Manual: 2 to 600 mAs, display, 5% to AEC

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X-Ray Unit

- Compression Device
- Grid
  - 4:1 to 5:1, thin septa, 32 l/cm, interlock,
  - moving, carbon fiber, rigid, two sizes
- Magnification Stand

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Screens, Films, Processing

- Screens
  - Single, thin
- Films
  - Single emulsion, silver halide & gelatin
- Processing
  - Cycle Time: 90 to 150 s
  - Temperature: 33 to 39 C
  - Chemicals, Replenishment, Agitation, Drying

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Darkroom Processor/Maintenance

- Correct electrical current
- Correct water flow
- Darkroom air, ventilation, temperature
- Eliminate dust and artifacts
- Humidity
- Safelight illumination
- Film Storage

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Digital X-Ray Mammography

- Detectors - spatial considerations
- Digital system designs
  - Area detectors - full field
  - Scanned beam detectors
- Display monitors
- Exposure techniques

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Digital Mammography Applications

- Real time image display
- Post acquisition image enhancement
- Image archiving an retrieval
- Teleradiology
- Dual-energy subtraction
- Computer-aided image analysis
- Computer-aided instruction
- Future developments

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Stereotactic Breast Biopsy

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Image Quality

- Factors Which Affect Quality (Table)
  - Contrast
    - » Subject contrast
      - Scatter, grids, compression
    - » Receptor contrast
  - Spatial resolution
    - » Motion, Geometry, Image receptor
- Noise
- Artifacts
  - X-Ray Unit, Receptor, Processing, Handling

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Dose Evaluation

- Risk Related Dose
- Dose Evaluation Procedures
- Published Data
  - Dose Recommendations
  - Dose Survey Results

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Assumptions: Dose Calculation

- Firm Compression
- Uniform Cross Section
- 0.5 cm Adipose Layer - Top & Bottom
- Adipose / Gland Mix:
  - 100% / 0%
  - 50% / 50%
  - 0% / 100%

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f - Factors

- Adipose: 5.4 mGy/R
- Glandular: 7.9 mGy/R

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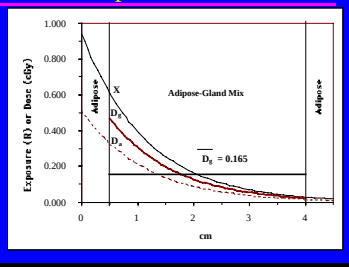
Dose and Exposure vs Thickness



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Steps: Dose Calculation

- Measure X_a, Exposure In-Air at Surface
- Determine kV_p & Target Material
- Determine Compressed Breast Thickness
- Measure HVL (Type 1145 Aluminum)
- Estimate Adipose / Glandular Mix
- Look Up $(D_{gN})_{ave}$ in Table
- Calculate $(D_g)_{ave} = (D_{gN})_{ave} * X_a$

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Dose Recommendations / Surveys

- Screen - Film with Grid
- 4.5 cm Compressed Breast
- 50% Adipose / 50% Glandular

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Dose Recommendations: Screen-Film with Grid

MQSA	3 mGy
ACR-MAP	3 mGy
NCRP SC -72	3 mGy
NY State	3 mGy
California	3 mGy

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Published Dose Surveys

All Facilities Screen Film with Grid

- ACR-MAP: 6265 Facilities
  - 1992 1.27 mGy
- CDRH / MQSA: 4172 Facilities
  - First Inspection 1.5 mGy
  - Second Inspection 1.6 mGy

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Quality Assurance

- Current Status of QA in US
- Essential Elements of Effective QA
- Quality Administration
  - Medical Audit
- Legislative Issues Relating to QA
  - OBRA: Passed 11/90, Effective 1/91
  - MQSA: Passed 10/92, Effective 10/94
  - States

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Elements of a QA Program

- Selection of Mammography Equipment
- Selections of Screens and Films
- Selection of Film Processing Conditions
- Quality Control Procedures
  - ACR QC Manuals
- Acceptance Testing Procedures

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Quality Administration-Medical Audit

- How to Conduct an Audit
- Audit Results from an Expert Practice
  - Radiologist Demographics
  - Disposition of Abnormal Interpretations
  - Biopsy Results
  - Characteristics of Breast Cancers
- How to Interpret Audit Results
- How to Use Audit Results Effectively

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Benefits / Risks - Mammography

- Benefits
- Radiation Risk
- Benefit vs. Risk Analysis

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Benefits: Considerations

- Mammography vs. Physical Exam
- Biases:
  - Lead Time Bias
  - Length Bias
  - Selection Bias

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Benefits

Case-Control Studies
- Dutch
- Italian
- United Kingdom Correlation Trial

Follow-Up Studies
- BCDDP

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Benefits: Randomized Clinical Trials

- HIP of New York
- Malmo Trial
- Stockholm Trial
- Swedish Two-County Trial
- Canadian NBSS
- Edinburgh Trial
- Meta-Analysis

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Benefits

- Women Over 50
  - General Agreement on Benefit
  - Annual Screening Recommended
- Women 40 - 49
  - Benefits Have Been Somewhat Controversial
  - Varying Recommendations from Professional Organizations and Advisory Bodies

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Randomized Controlled Trial (RCT)

The study design that most effectively removes such differences and minimizes selection bias is the Randomized Controlled Trial (RCT- sometimes Randomized Clinical Trial.) Additionally, this design is straightforward: Subjects are randomly assigned to two (or more) groups at time zero, and deaths (or adverse events) due to the target disease are counted during the time between randomization and some predetermined end of the study.

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Benefits - RCT Data Including Women 40 - 49

- HIP, NY
- Malmo Sweden
- Kopparberg, Sweden
- Ostergotland, Sweden
- Edinburgh, Scotland
- Stockholm, Sweden
- Gothenburg, Sweden
- Canadian National Breast Screening Study

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RCT Including Women All Ages Combined

Study	Age at Entry	Vws	Freq (mo)	Rds	CBE	Fol Up (y)	Rel Risk	Mort Red
HIP-NY (1963-69)	40-64	2	12	4	A	18	0.77 (0.61-0.97)	23%
Malmo (1976-86)	45-69	1-2	18-24	5	N	12	0.81 (0.62-1.07)	19%
2Cty-K (1977-85)	40-74	1	23-33	4	N	20	0.68 (0.59-0.80)	32%
Edin (1979-88)	45-64	1-2	24	4	A	14	0.71 (0.53-0.95)	29%
Stock (1981-85)	40-64	1	28	2	N	8	0.80 (0.53-1.22)	20%
Goth (1982-88)	40-59	2	18	4	N	7	0.86 (0.54-1.37)	14%
CNBSS-2 (1980-87)	50-59	2	12	5	A	13	*1.02 (0.78-1.33)*	*-2%*

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RCT Including Women 49 and Younger

Study	Age at Entry	Vws	Freq (mo)	Rds	CBE	Fol Up (y)	Rel Risk	Mort Red
HIP-NY (1963-69)	40-49	2	12	4	A	18	0.77 (0.53-1.11)	23%
HIP-NY (1963-69)	40-49	2	12	4	A	18	0.76 (0.59-0.97)	24%
Malmo (1976-86)	45-49	1-2	18-24	5	N	12.7	0.64 (0.45-0.89)	36%
2Cty-K (1977-85)	40-49	1	24	4	N	15.2	0.67 (0.37-1.22)	33%
2Cty-O (1977-85)	40-49	1	24	4	N	14.2	*1.02 (0.59-1.77)*	*-2%*
Edin (1979-88)	45-49	1-2	24	4	A	14	0.75 (0.48-1.18)	25%
Stock (1981-85)	40-49	1	28	2	N	11.4	*1.08 (0.54-2.17)*	*-8%*
Goth (1982-88)	39-49	2	18	5	N	12	0.55 (0.31-0.96)	45%
CNBSS (1980-87)	40-49	2	12	4-5	A	10.5	*1.14 (0.83-1.56)*	*-14%*

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Variations - RCT's

- Number of Views: 1 or 2
- Screening Frequency:12 to 28 Months
- Years of Follow Up:10 to 18 Years
  - Still Increasing
- Clinical Breast Exam may not be included
- Relative Risk: 0.55 to *1.14*
- Mortality Reduction: +45% to *-14%*

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Successive Meta-Analyses: RCT

Trials	Foll-up (y)	RR (95% CI)	Ref Yr
6 + NBSS	5 - 7	1.08 (0.85-1.39)	1993
All 8	7 - 18	0.95 (0.77-1.18)	1995
All 8	7 - 18	0.92 (0.75-1.13)	1995
All 8	7 - 18	0.84 (0.69-1.02)	1995
All 8	10.5 - 18	0.82 (0.71-0.95)	1997

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Successive Meta-Analyses: RCT

Trials (Population Based)	Foll-up (y)	RR (95% CI)	Ref Yr
6	5 - 7	0.99 (0.74-1.32)	1993
All 7	7 - 18	0.76 (0.62-0.95)	1995
All 7	7 - 18	0.76 (0.62-0.93)	1996

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Successive Meta-Analyses: RCT

Trials	Foll-up (y)	RR (95% CI)	Ref Yr
5 Swedish	7 - 12	0.87 (0.63-1.20)	1993
5 Swedish	10 - 15	0.77 (0.54-1.01)	1996
5 Swedish	11.4 - 15.2	0.71 (0.57-0.89)	1997

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Benefits - Meta-Analysis of RCT's

- Relative Risk: 0.71 to 0.82
- Mortality Reduction: 18 to 29%

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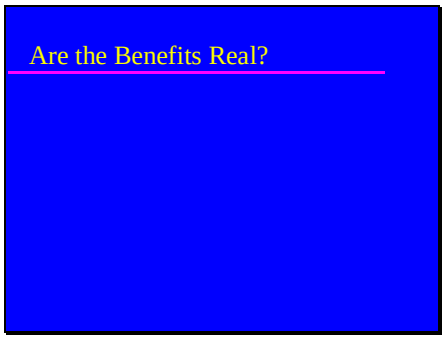

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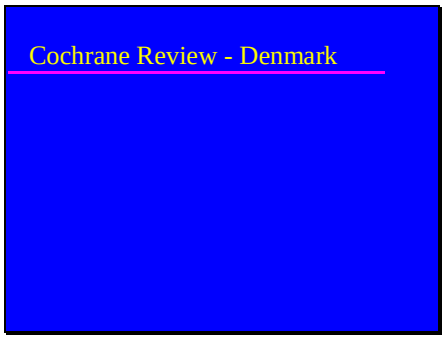

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Follow-up to
2000 Olsen &
Gøtzsche Paper
in Lancet:
6 Pages of
Letters in
Lancet 2/26/00

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Risk Negligible for Diagnostic Exam of a Given Woman

Benefits and Risks Must Be Known for Screening of Asymptomatic Women

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Risk Data: Radiation Exposures

- Japan A-Bomb Survivors
- Massachusetts TB Patients - Chest Fluoro
- Nova Scotia TB Patients - Chest Fluoro
- Swedish Benign Breast Disease Radiation
- Rochester Postpartum Mastitis Radiation

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Risk Data - Key Results (1)

- Increased Incidence following Irradiation
- Linear Function Generally Fits Data
- Age of Exposure - Higher Risk for Younger
- Latent Period of at Least Five Years
- No Major Effect from
  - Dose Fractionation
  - Reduced Dose Rate

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Risk Data - Key Results (2)

- No Evidence that Risk Returns to Bkgd
- Interaction with Other Risks
  - Relative Risk Model Chosen
- Radiation Cancers Same as Other Cancers
- Substantial Contribution to Risk Estimates for Doses below 1 Gy

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Risk Negligible for Diagnostic Exam of a Given Woman

Benefits and Risks Must Be Known for Screening of Asymptomatic Women

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Risk-Benefit:Assumptions (1)

- Natural Incidence Taken from SEER Data
- Lifetime Refers to Age 99
- Average Dose/Two Views = 3 mGy
- Incidence and Mortality from BEIR V Models Starting Five Years after Exam
- Baseline Incidence Multiplied by RR

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Risk-Benefit:Assumptions (2)

- Benefit Modelled as % Reduction Mortality starting 2 yr after first screen and ending 15 years after last screen
- Benefit Calculated for Both Decrease in Deaths and Years of Life Saved

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Risk-Benefit:Decrease in Deaths

Starting Age	Total Cases	Excess Cases	Total Deaths	Decrease in Deaths with Benefit of 0%	20%	30%	40%
40	16,131	18	3,273	-4	525	792	1,059
45	15,591	9	3,207	-2	508	764	1,021
50	14,569	4	3,087	-1	478	719	960
55	13,211	2	2,910	0	436	656	876
60	11,610	0	2,694	0	386	619	774
65	9,935	0	2,457	0	328	518	658

100,000 Women Have Annual Screenings with Dose of 4 mGy until Age 69
Excess Cases Assumes Radiation Risk Only, No Benefit from Screening
Total Cases and Total Deaths Are Natural Incidence at Given Age

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Risk - Benefit: Years Gained

Starting Age	Increase in Years of Life with Benefit of: 0	20%	30%	40%
40	-55	9,406	14,152	18,910
45	-26	8,631	12,975	17,328
50	-12	7,540	11,328	15,122
55	-6	6,260	9,406	12,554
60	-2	4,947	7,427	9,915
65	0	3,691	5,541	7,392

100,000 Women Have Annual Screenings with Dose of 4 mGy until Age 69

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Other Breast Imaging Modalities

- Ultrasonography
- Thermography
- Transillumination
- Computed Tomography
- Magnetic Resonance Imaging
- Magnetic Resonance Spectroscopy
- Digital X-Ray Mammography

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Ultrasonography

- Distinguishes Cystic from Solid masses
- Less accurate for Benign vs. Malignant
- Can not demonstrate cancers <1 cm
- Tomographic - many images needed
- High false positive for dense breasts
- Doppler does not distinguish malignant
- Not recommended for routine screening

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Computed Tomography

- Can detect early cancer, but only with iodine contrast - before/after scans
- Routine scanners require computer assistance for diagnosis
- High radiation dose - entire chest must be penetrated
- High cost of exam

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Magnetic Resonance Imaging

- No ionizing radiation
- Dense fibroglandular tissue imaged well
- Large and some small masses well imaged
- Spatial resolution well below screen-film
- Breast coils usually needed
- High cost of exam

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Magnetic Resonance Spectroscopy

- Biochemical Differences - specific metabolic processes measured
- ^{31}P MR Spectral Profiles
- Large Voxel Size

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Summary and Conclusions

- Summary
- ***DRAFT*** Conclusions of SC 72 Proposed to and currently being reviewed by NCRP

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SC-72 *DRAFT* Conclusions

1. Mammography, in conjunction with physical examination, is the method of choice for early detection of breast cancer. Other methods should not be substituted for mammography in diagnosis or screening, but may be useful adjuncts in specific diagnostic situations.

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SC-72 *DRAFT* Conclusions

2. Diagnostic mammography of symptomatic women should always be performed when indicated, utilizing recommended equipment and techniques and well-trained, knowledgeable personnel.

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SC-72 *DRAFT* Conclusions

3. Screen-film mammography requires dedicated x-ray units, firm compression, and an x-ray spectrum produced by an appropriate combination of x-ray tube target, tube window, filtration, peak generating potential, screen-film combination, film processors, technique, and viewing conditions. Craniocaudal and mediolateral oblique views are recommended as the standard views for all types of mammography

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SC-72 *DRAFT* Conclusions

4. Mammographic equipment should be chosen to provide acceptable image quality at a typical average glandular dose [for a two-view examination] of 6 mGy or less for screen-film with grid for a patient having 4.5 cm thick compressed breasts of 50% adipose / 50% glandular tissue composition.

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SC-72 *DRAFT* Conclusions

5. Image quality and appropriate dose level should be maintained by a quality assurance program conducted by a quality assurance technologist and medical physicist, involving specified periodic measurements and readjustment of all aspects of the imaging / viewing system.

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SC-72 *DRAFT* Conclusions

6. Average glandular dose should be determined at each installation for the techniques used at representative breast thicknesses. This dose can be calculated from data supplied in this report by measuring beam quality and in-air exposure at the entrance surface of the breast.

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SC-72 *DRAFT* Conclusions

7. Annual mammographic examinations appear to provide favorable benefit-risk ratios in terms of breast cancer mortality in women age 50 or above, if acceptable image quality and dose are maintained.

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SC-72 *DRAFT* Conclusions

8. Results of randomized clinical trials of screening mammography for women age 40 to 49, for which 20 or more years of follow-up is available, have shown evidence of a substantial benefit in reducing mortality which exceeds any risk of radiation-induced breast cancer.