Radiation exposures in medical imaging: FDA's past and present efforts

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Food and Drug Administration

Silver Spring MD

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The National Academies
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Radiological Health Efforts: 1950's

Observations of Dade W. Moeller, Public Health Service[1,2,3]

- US PHS, Wash DC- 1952
  - Task: estimation of exposure to patient and workers during DX exams
    - Medical and dental x-ray, fluoroscopy
    - Workers- initial estimate: get 0.43-2.62 mGy (50 – 300 mR) / week
  - Initial effort focused on 20 USPHS Hospitals
- Delivery item: *Guide for the Inspection of Medical and Dental Diagnostic X-ray Installations* (Ingraham SC, Terrill JG Jr., Moeller DW. PHS, 1953)

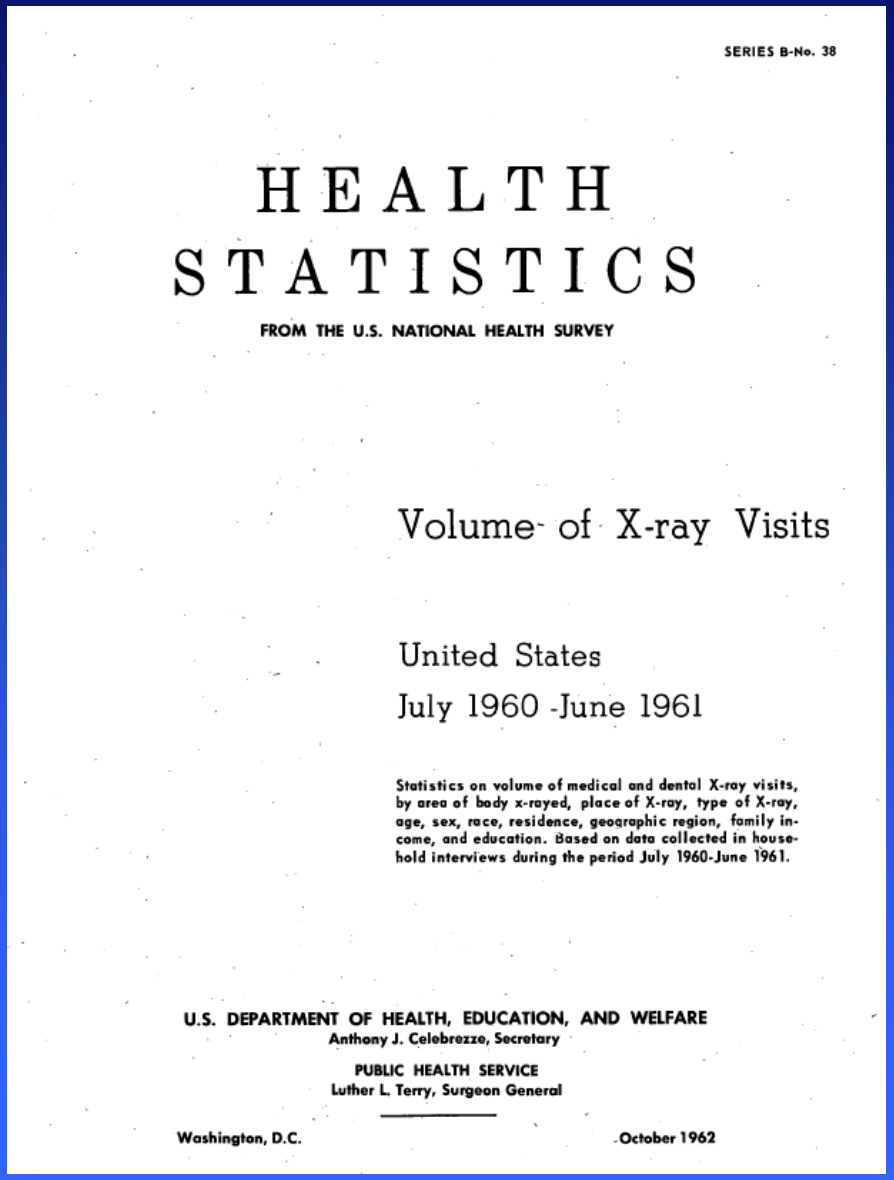
Radiological Health Efforts: 1950's
Observations of Dade W. Moeller, Public Health Service

- Survey meters- custom modified @ NIH to measure exposure
- Moeller volunteered to be "patient", later used coconut
- Medical X-ray:
- Technical observations- Medical X-ray
  - X-ray tubes- really bad or missing collimation- for chest film, nearly entire patient X-ray'd
  - X-ray tubes seldom had filtration
  - Dental: intraoral exposures typically exceeded 44 mGy (5R)

Findings: Early 1950's

- Professional Survey: Professional Bureau, American College of Radiology[4]:
  - 125,000+ x-ray units (diagnostic X-ray and therapy)
    - 55,000- medical
    - 65,000 dental
    - 11,000 osteopathic and chiropractic uses
    - 25 million x-ray exams annually by radiologists (avg 306 days/yr spent conducting exams)

- Patient Exposure: PHS survey of hospitals and other published findings[2] :
  - Radiographic- 24 mGy (2.7 R) (52% of exams)
  - Photofluorographic- 8.8 mGy (1.0 R) (34% of exams)
  - Fluoroscopic- cumulative- 569 mGy (65 R) (14% of exams)
  - Dental film- 44 mGy (5 R) per image



SERIES B-No. 38

HEALTH STATISTICS

FROM THE U.S. NATIONAL HEALTH SURVEY

Volume of X-ray Visits

United States

July 1960 -June 1961

Statistics on volume of medical and dental X-ray visits, by area of body x-rayed, place of X-ray, type of X-ray, age, sex, race, residence, geographic region, family income, and education. Based on data collected in household interviews during the period July 1960-June 1961.

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Anthony J. Celebrezze, Secretary

PUBLIC HEALTH SERVICE
Luther L. Terry, Surgeon General

Washington, D.C. October 1962

- 1957: PHS National Center for Health Statistics initiates the National Health Survey (NHS)
- Goal: To characterize State of US public health.
- Major component: Household interview
- 1960-1961: NHS collects data regarding diagnostic x-ray practice[4]
- 38,000 households visited/125,000 respondents interviewed
- Among their findings[4]:
  - 82 million visits to clinical sites for medical x-ray (diagnostic)
  - Most frequent exam: chest (51 million)
  - 49 million dental exams

X-ray Exposure Study- XES
PHS surveys 1964 and 1970[5,6,7]

- 1964 Survey: Planned as extension of U.S. National Health Survey to include capture of X-ray visits:
- Two components:
  - Household interview of U.S. population sample
  - Follow-up mail packet to clinical sites- x-ray equipment and exam data, estimation of patient exposure -> dosimetry

- Data regarding x-ray exam history was collected for 31,289 persons / 9653 households (1964)
- Survey was repeated in 1970
  - 22,500 households interviewed/67000 persons

XES surveys: 1964 and 1970

- Scope: Dental & medical x-ray, fluoroscopy, and x-ray therapy
- Film packs: sent to clinical sites- capture beam size and dosimetry[7]
  - Separate film packs for each modality
  - Fluoro: Two packs:
    - large area film recorded patient exam, scanning densitometer records approximately 1386 readings from each film- 1.5 million data points
    - Folding film pack captures beam geometry to infer source-table top distance

Dosimetry[7]

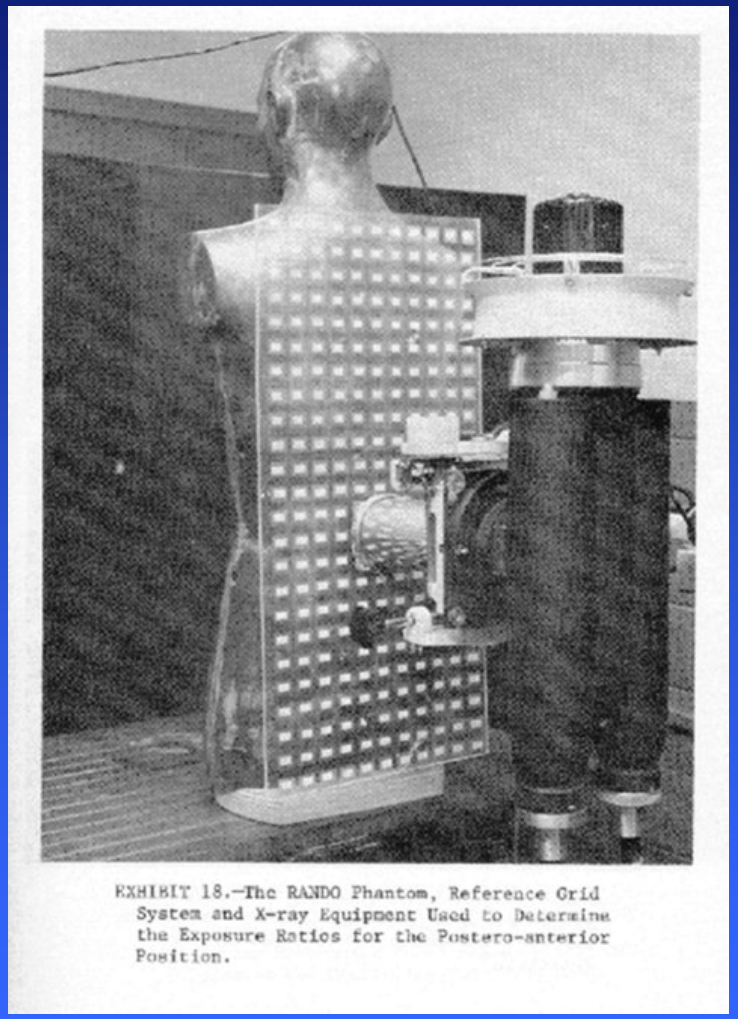


EXHIBIT 18.—The RANDO Phantom, Reference Grid System and X-ray Equipment Used to Determine the Exposure Ratios for the Postero-anterior Position.

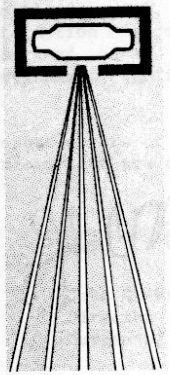
- BRH developed models to compute patient exposure based on reported x-ray technique, collimation and film packet measurement

- Doses were computed using RANDO phantoms- exposure ratios and scatter were measured for dose calculations.

- Surveyed exams included dental, radiographic, and fluoroscopic procedures.

EXHIBIT 10.—Measuring Beam Size Recorded on Radiographic Film Packs.

GONAD DOSES AND GENETICALLY SIGNIFICANT DOSE FROM DIAGNOSTIC RADIOLOGY U.S., 1964 and 1970



April 1976

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Food and Drug Administration
Bureau of Radiological Health
Rockville, Maryland 20852

For sale by the Superintendent of Documents, U.S. Government Printing Office
Washington, D.C. 20402 - Price $1.30

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NOTE: For further information regarding this report, direct all inquiries to: Office of Information, Bureau of Radiological Health, 5600 Fishers Lane, Rockville, Maryland, 20852.

*Key personnel as of the time period during which the Study was conducted.
**National Center for Health Statistics.

Mammography

Breast Exposure: Nationwide Trends- BENT [8,9]

Cooperative effort: FDA's Bureau of Radiological Health and National Cancer Institute with field support provided by state programs.

Objectives

- Characterize patient exposure
- Identify reasons for very high/very low exposures
- Reduce unnecessary exposure via improved QA practices

4 components

- Identified mammo sites completed questionnaire.
- Sites mailed dosimetry card (TLD's) to expose.
  NOTE: approx 10% of mammo units equipped w/ AEC
- Exposures evaluated, follow-up visits -> corrective actions
- Revisit follow-up sites after 1 year

BENT

- Pilot phase: 19 states reported data on 1567 x-ray units
- Exposures ranged from 0.25 R to 16 R !! (2.2 – 140 mGy)
- Nationwide site visits began in late 1970's
- Participation: 42 states, P.R., DC, NYC, PHS hospitals, US Army, Navy, Air Force, 3 Canadian provinces.
- Observations:
  - Technology in use (% of all units, avg. exp @ skin entrance):
    - direct-exposure film (10%)
    - xeromammography (45%)
    - screen-film (S/F) (45%)
  - 58% of S/F systems needed follow-up- doses high (7%) / low (22%) (remaining % of follow-up revisits for other findings)[9]
  - High HVL, inappropriate kVp for target (W vs Mo)[9]

Preliminary Data — As of 3/11/77

TABLE FOUR. Exposure by Type of Image Receptor in BENT Pilot States.

	All Image Receptors	Direct Exposure Film	Film/Screen Combinations	Xerox
No. of x-ray units	435	75	198	162
No. of patients examined in 1 month	18,759	1,071	6,201	11,487
mean exposure (R)	1.49	3.21	0.60	1.80
standard deviation	2.07	3.74	0.74	1.41
minimum	0.00*	0.18	0.00	0.18
1st quartile	0.32	1.10	0.13	0.89
median	0.91	2.00	0.33	1.40
3rd quartile	1.70	3.50	0.74	1.90
maximum	16.60	16.60	5.00	6.90
range (max - min)	16.60	16.42	5.00	6.78

*Actual min value is 0.025 R, stated in FDA report to CRCPD, Seattle 1977

Unit of Exposure: Roentgens free-in-air at the skin entrance site (6 cm above the tabletop or the equivalent plane) from a single craniocaudal view of a "medium-density, medium-size" breast. Backscatter is NOT included.

Dental Exposure Normalization Technique: DENT[10]

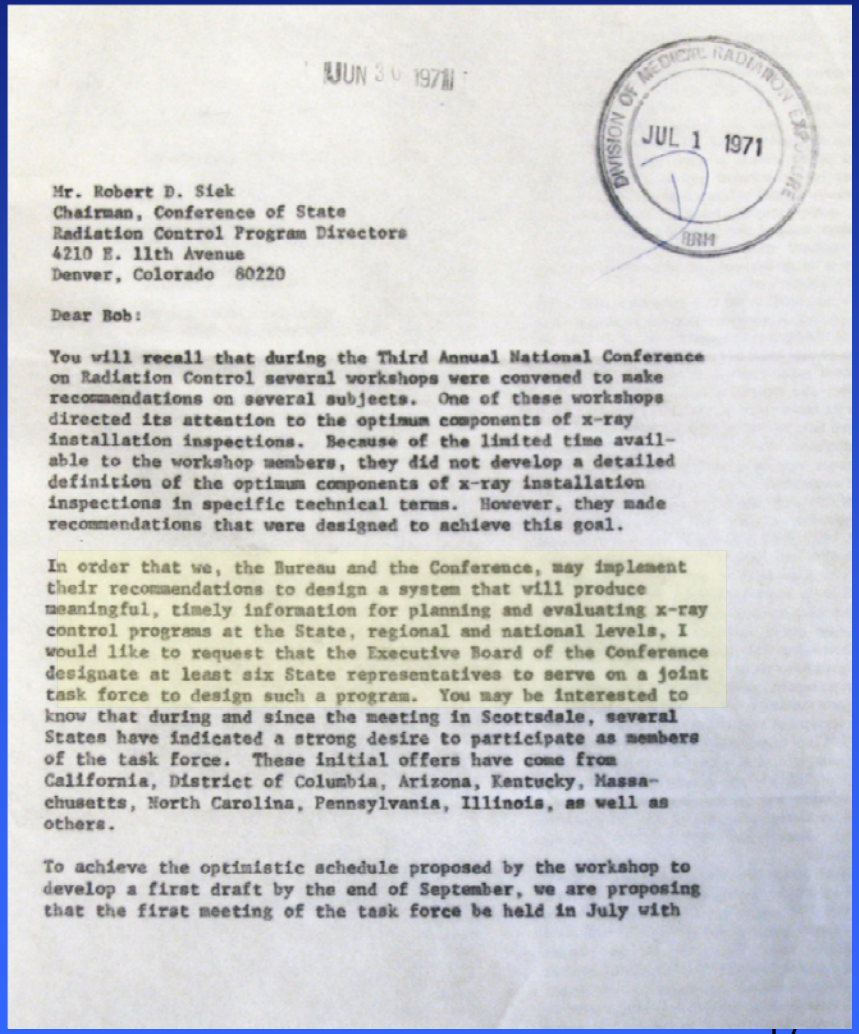
- Early 1970's: Intraoral exposures up to 44 mGy (5 R) per film;
- Bureau of Radiological Health (BRH)- studies problem, derives optimal range of exposures for radiographs
- Pilot study: 46% of surveyed sites in RI and NH have exposures exceeding recommendations
- BRH develops DENT as a QA process for identified dental offices
- State Rad Health programs conduct site visits, BRH provides equipment, planning support.

Radiation Experience Data- RED[11]

- 1980 Survey of U.S. hospitals
- Sample drawn from master listing of 6657 known short-stay hospitals.
- Original sample size- 126, only 81 sites participate in survey
- Fills in gaps in NEXT lineup: Captures patient volumes for imaging modalities: DX, CT, US, NM
- NO Dose data are collected/measured
- Selected findings of the study:
  - 130.2 million conventional x-ray procedures performed in short-stay hospitals- an increase of 59% over 1970 (81.7 million).
  - 52 million chest x-rays, accounting for 40% of all x-ray exams
  - 2.2 million CT exams, 73% of head.

Nationwide Evaluation of X-ray Trends- NEXT[12]

- Early 1970's: FDA's BRH and CRCPD initiate effort to characterize state of U.S. diagnostic X-ray practice in a standardized, practice-representative way.
- By 1972 NEXT begins surveying 12 commonly performed exams.
- Surveys continue through 1982.
- 1984- focus on single exam
- patient-equivalent phantoms
- Film processing quality, darkroom fog, and related aspects of diagnostic x-ray practice are characterized.



JUN 30 1971

DIVISION OF MEDICAL RADIATION EXPOSURE
JUL 1 1971
BRH

Mr. Robert D. Siek
Chairman, Conference of State
Radiation Control Program Directors
4210 E. 11th Avenue
Denver, Colorado 80220

Dear Bob:

You will recall that during the Third Annual National Conference on Radiation Control several workshops were convened to make recommendations on several subjects. One of these workshops directed its attention to the optimum components of x-ray installation inspections. Because of the limited time available to the workshop members, they did not develop a detailed definition of the optimum components of x-ray installation inspections in specific technical terms. However, they made recommendations that were designed to achieve this goal.

In order that we, the Bureau and the Conference, may implement their recommendations to design a system that will produce meaningful, timely information for planning and evaluating x-ray control programs at the State, regional and national levels, I would like to request that the Executive Board of the Conference designate at least six State representatives to serve on a joint task force to design such a program. You may be interested to know that during and since the meeting in Scottsdale, several States have indicated a strong desire to participate as members of the task force. These initial offers have come from California, District of Columbia, Arizona, Kentucky, Massachusetts, North Carolina, Pennsylvania, Illinois, as well as others.

To achieve the optimistic schedule proposed by the workshop to develop a first draft by the end of September, we are proposing that the first meeting of the task force be held in July with

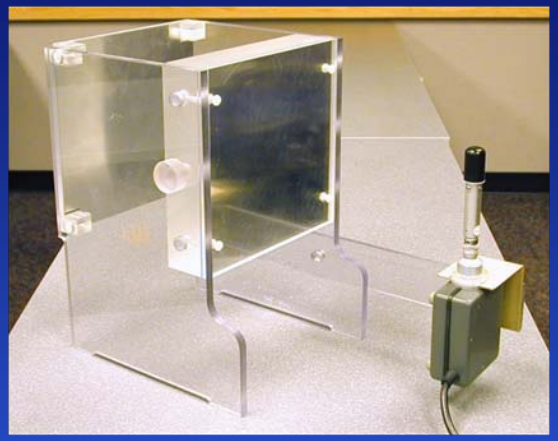
NEXT Surveys

Examination	Survey Years
Chest radiography	1984, 1986, 1994, 2001
Mammography	1985, 1988, 1992
Abdomen and lumbo-sacral (LS) spine radiography	1987, 1989, 1995, 2002
Fluoroscopy {upper GI (91, 96, 03), cardiac cath labs and mobile C-arms (96), *coronary angiography (2008)*}	1991, 1996, 2003, 2008
Computed tomography (CT)	1990, 2000, 2005
Dental radiography	1993, 1999, 2013
Pediatric Chest	1998

Teamwork

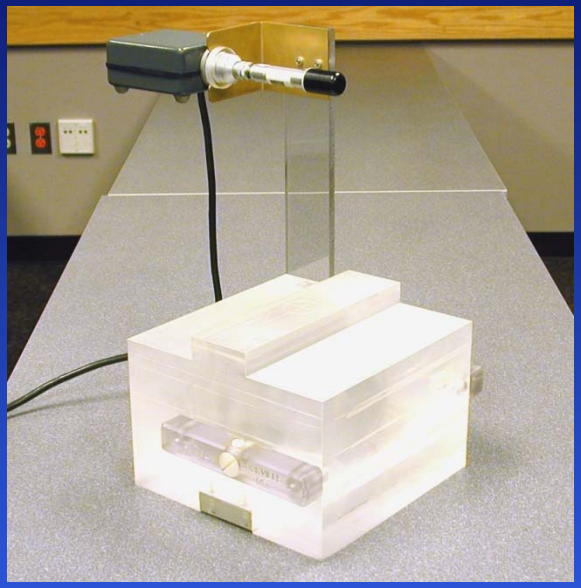
Survey participation- 2005-06 CT

NEXT Phantoms



Adult PA Chest

Adult Abdomen and lumbosacral spine



CT Body Phantom

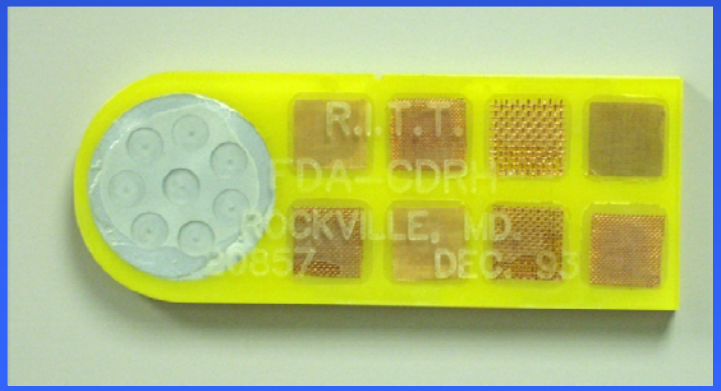
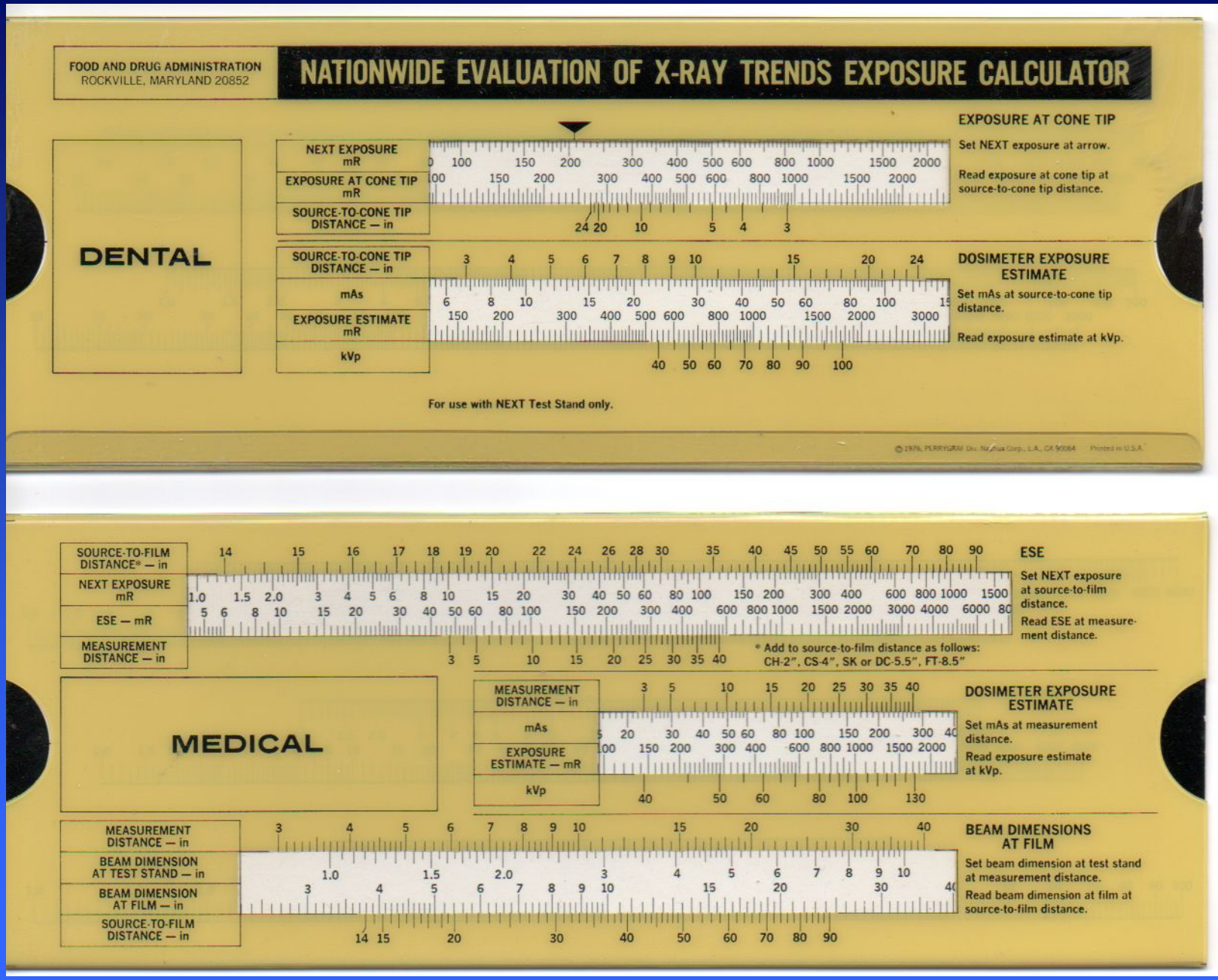
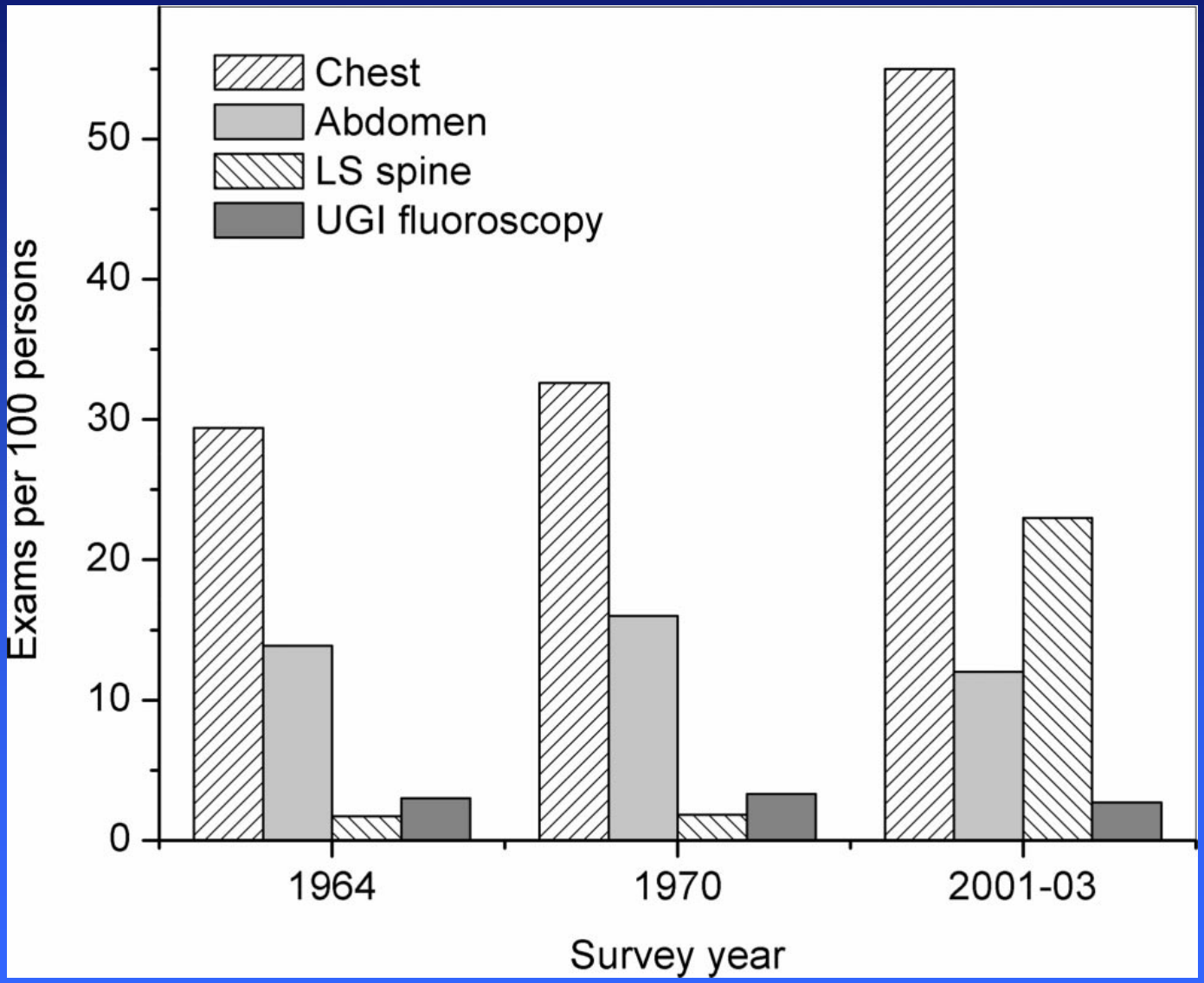


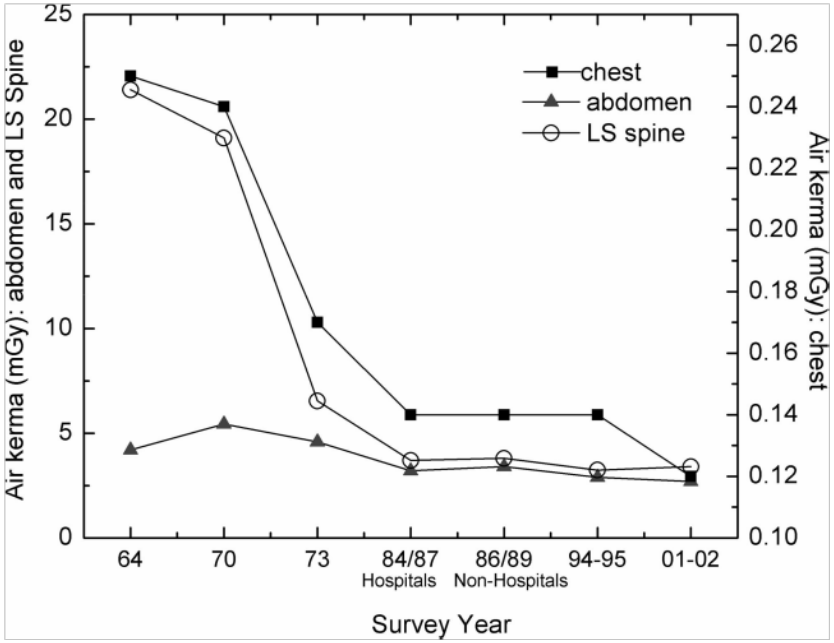
Image Quality Test Tools

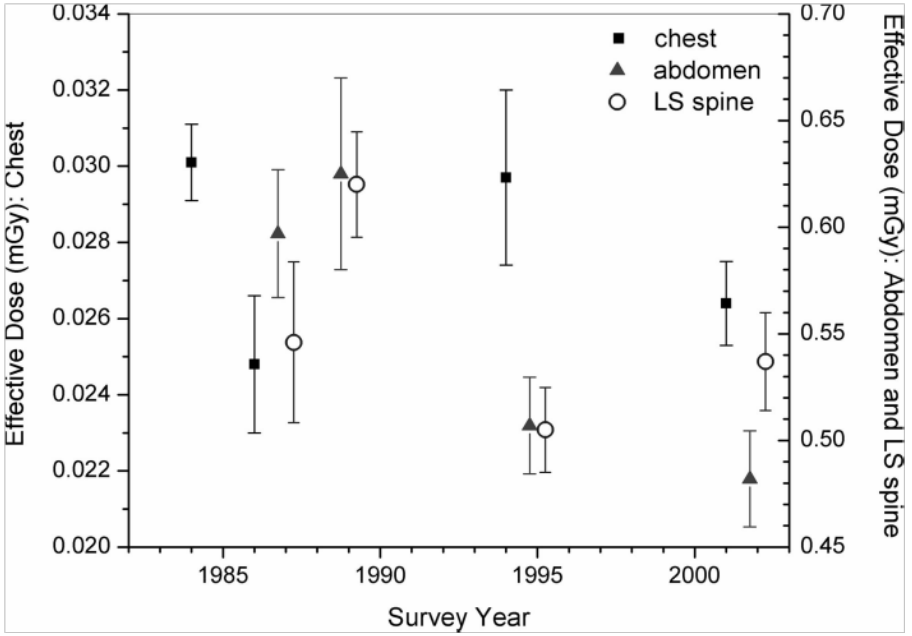

FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852
NATIONWIDE EVALUATION OF X-RAY TRENDS EXPOSURE CALCULATOR
DENTAL
NEXT EXPOSURE mR
EXPOSURE AT CONE TIP mR
SOURCE-TO-CONE TIP DISTANCE — in
EXPOSURE AT CONE TIP
Set NEXT exposure at arrow.
Read exposure at cone tip at source-to-cone tip distance.
SOURCE-TO-CONE TIP DISTANCE — in
mAs
EXPOSURE ESTIMATE mR
kVp
DOSIMETER EXPOSURE ESTIMATE
Set mAs at source-to-cone tip distance.
Read exposure estimate at kVp.
For use with NEXT Test Stand only.
SOURCE-TO-FILM DISTANCE* — in
NEXT EXPOSURE mR
ESE — mR
MEASUREMENT DISTANCE — in
ESE
Set NEXT exposure at source-to-film distance.
Read ESE at measurement distance.
* Add to source-to-film distance as follows:
CH-2", CS-4", SK or DC-5.5", FT-8.5"
MEDICAL
MEASUREMENT DISTANCE — in
mAs
EXPOSURE ESTIMATE — mR
kVp
DOSIMETER EXPOSURE ESTIMATE
Set mAs at measurement distance.
Read exposure estimate at kVp.
MEASUREMENT DISTANCE — in
BEAM DIMENSION AT TEST STAND — in
BEAM DIMENSION AT FILM — in
SOURCE-TO-FILM DISTANCE — in
BEAM DIMENSIONS AT FILM
Set beam dimension at test stand at measurement distance.
Read beam dimension at film at source-to-film distance.

Trends in Diagnostic X-ray Practice[13]

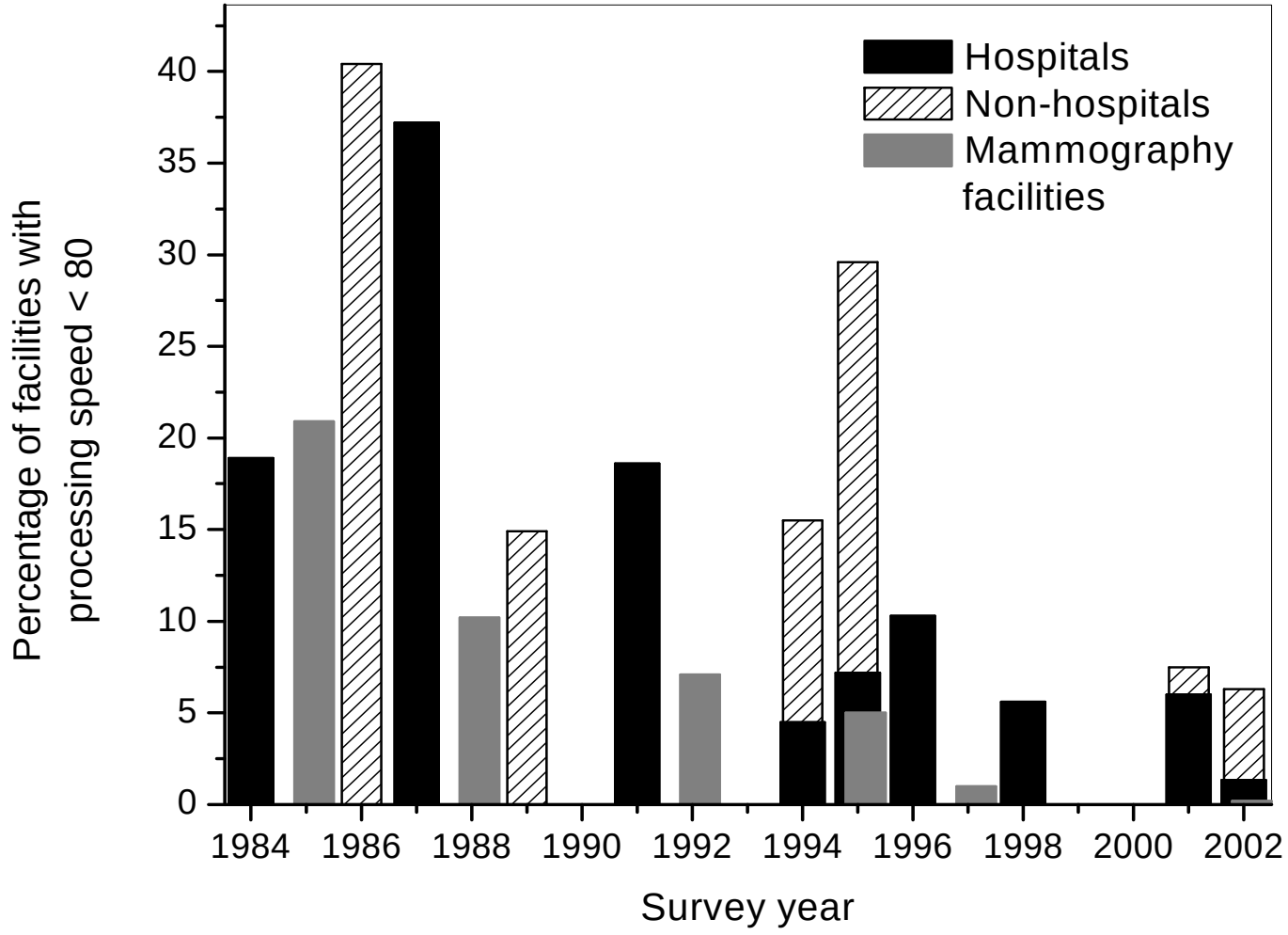


Trends in Diagnostic X-ray Practice[13]





Film Processing Quality[14,15]



NEXT 2008-09 Cardiac Catheterization Clinical Dose Log Form[16]

Facility Staff: Please enter dose display values from the *SAME* fluoroscopic unit the NEXT surveyor collected data from.

Dose-Area Product (DAP) or Kerma-Area Product (KAP)

Please indicate units of measurement (check appropriate box or write in the units after "Other")

- mGy-cm² [X]
- µGy-m² [ ]
- Gy-cm² [ ]
- Other: [ ]

Air Kerma

Please indicate units of measurement (check appropriate box or write in the units after "Other")

- mGy [X]
- cGy [ ]
- Gy [ ]
- Other: [ ]

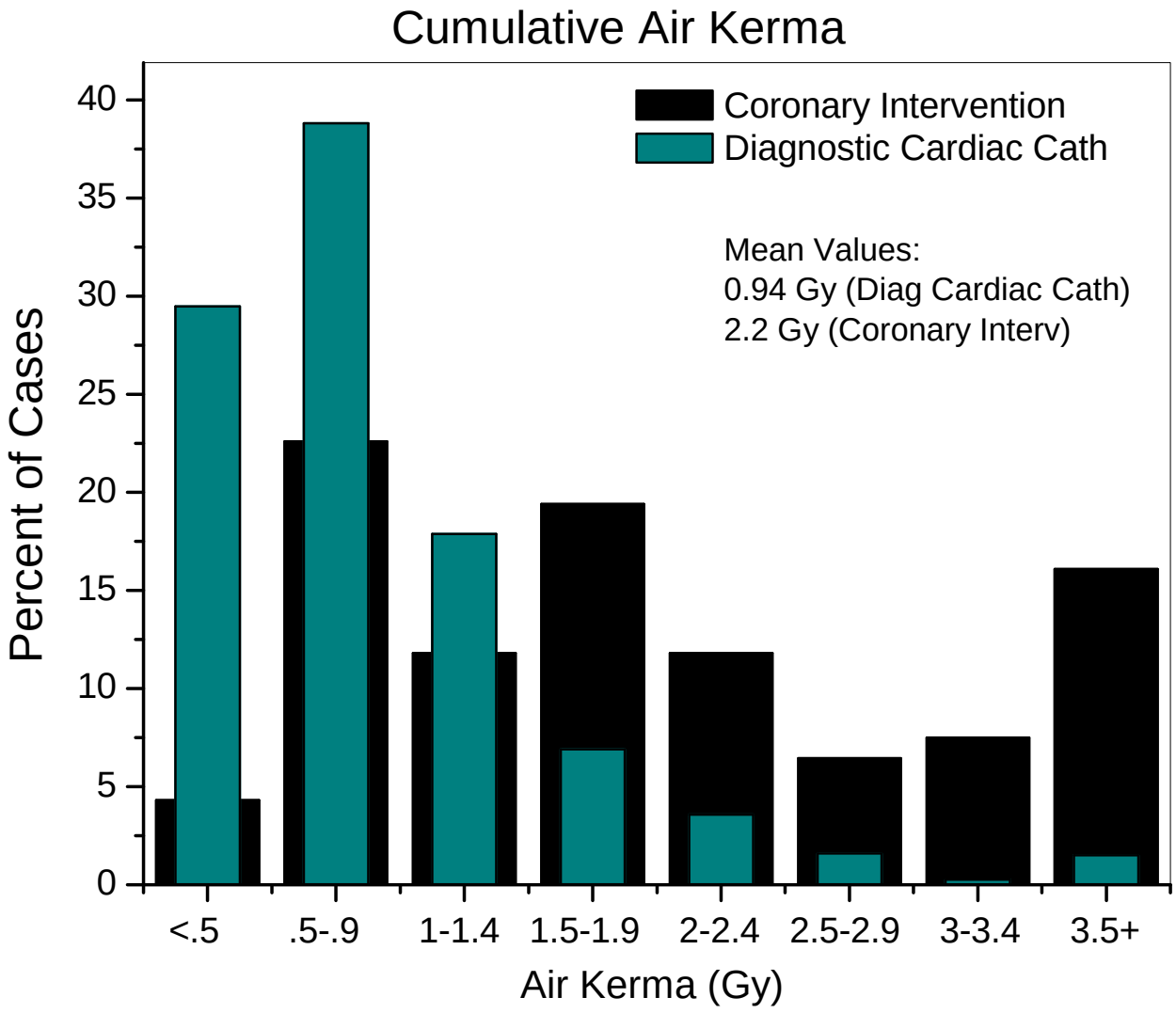
Date	Code	Total fluoro Time (m)	No cine runs	DAP FL+ cine	DAP FL only	DAP Cine only	Air kerma FL + cine	Air Kerma FL only	Air Kerma Cine only
01/16/200	C	22.7	27	173485	112757	60728	2394.05		
01/16/2010	A	4.4	7	34364	16177	18187	472.02		
01/17/2010	A	16.4	10	199620	140406	59214	1418.96		
01/18/2010	A	1.2	11	31097	4810	26287	299.63		
01/19/2010	D	3.9	0	26487	0	26487	102.22		
01/19/2010	A	3.6	12	42515	17147	25368	469.38		
01/20/2010	D	12.7	1	98615	97763	852	501.57		
01/22/2010	F	12.3	18	147860	92681	55179	1510.93		
01/22/2010	E	13.8	21	312182	94715	217467	1180.23		
01/25/2010	C	27.1	41	281676	203262	78414	3875.16		
01/25/2010	A	5.1	8	99125	63470	35655	841.80		
01/25/2010	F	3.5	15	95831	27070	68761	851.58		

NEXT Procedure Codes

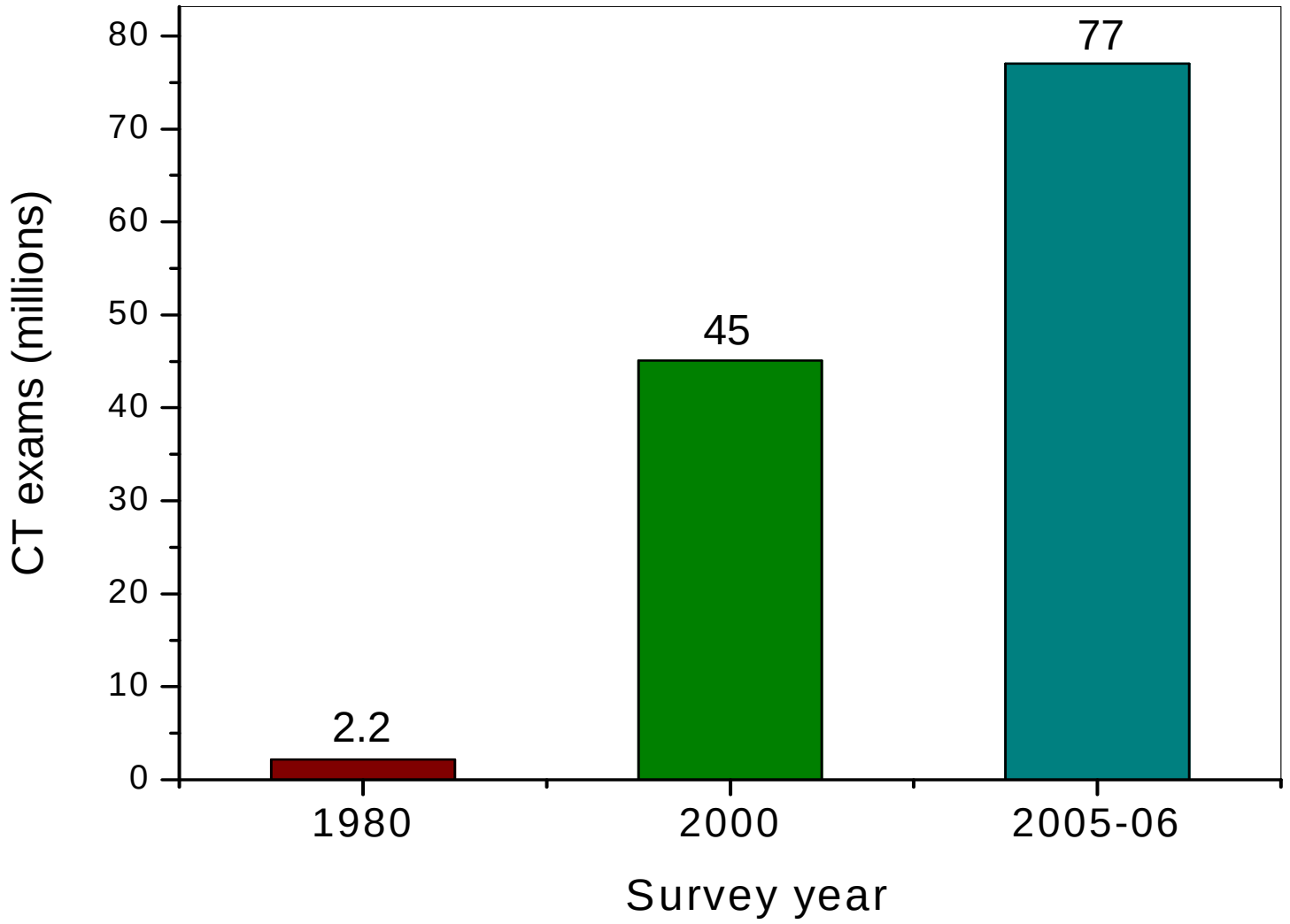
(A) Cardiac catheterization diagnostic only (for example, coronary artery angiography)
(B) Coronary Intervention (for example, coronary artery angioplasty and stent insertion)
(C) Combined diagnostic coronary angiogram and coronary artery intervention
(D) Other cardiac-intervention only procedures (for example, ASD, PFO, valvuloplasties)
(E) Other non-cardiac only procedure
(F) Combined cardiac and non-cardiac procedure

Comments

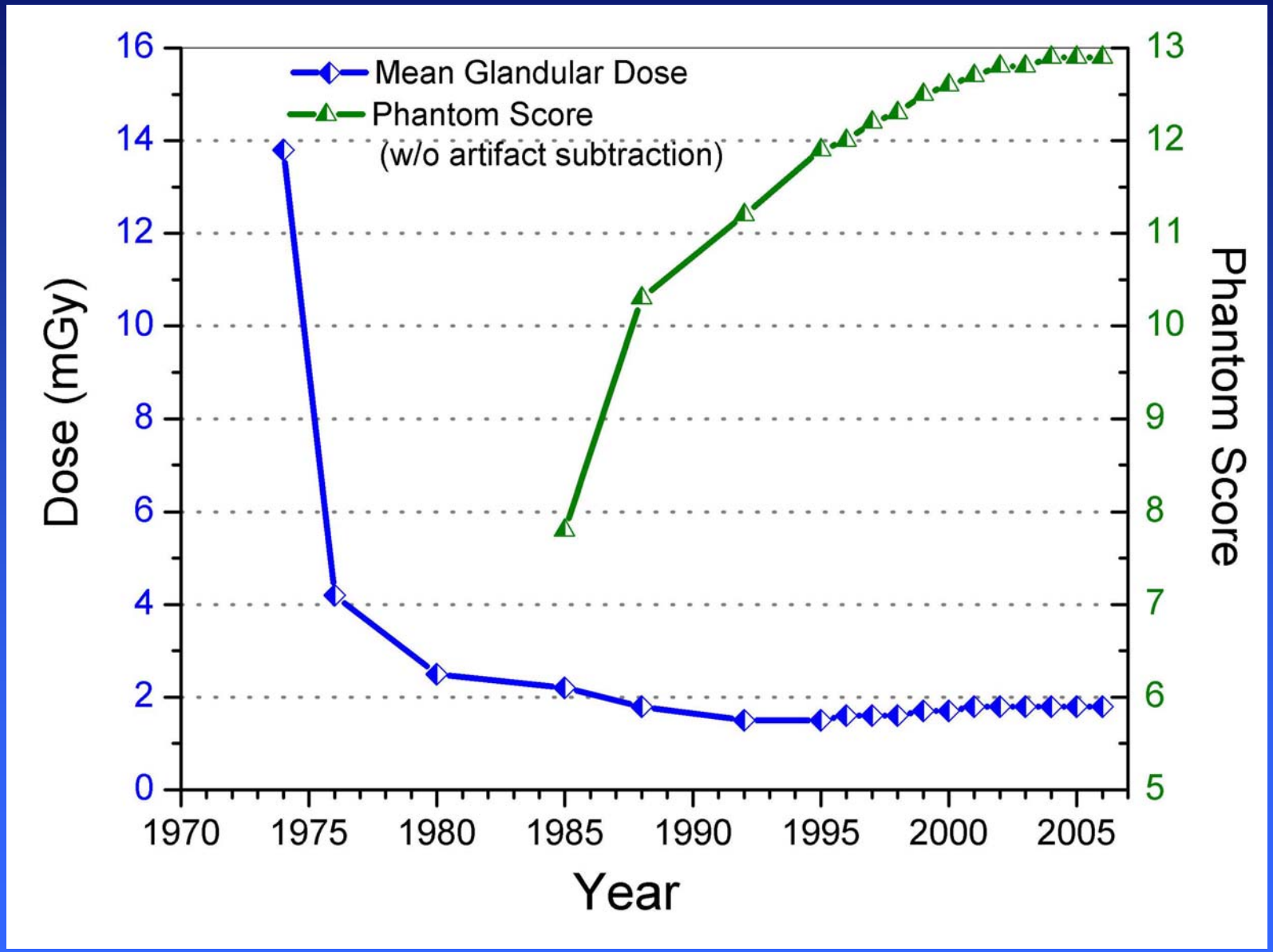
2008-09 NEXT Survey: Cardiac Catheterization[16]



Trends in CT Procedure Volumes[17,18]



Dose and Image Quality in Mammography[19]



NEXT and Public Health Activities

- Mid 1980's: NEXT goes to Sweden[20]:
  - *Survey of chest radiography using NEXT protocol and phantom*
- *Inquiries regarding conducting surveys in: Canada, Malaysia, S Africa, Finland, Australia, Spain, Greece, Ireland*
- IAEA: Code of Practice adopts the NEXT chest and Abdomen/LS spine phantoms for dosimetry[22].
- Approximately twenty states have medical/dental exposure action limits- *Patient Exposure and Dose Guide (2003)*[21]

What's down the road for NEXT

- Challenges:
  - Human and $$ resources limited
  - Technology changing faster than ability to develop, execute and publish surveys
- Fork in the road:
  - Compliment / coordinate with newer efforts to capture complex data via dose registries
  - Focus on surveys of exams / modalities that are presently outside the scope of current efforts to automate dose collection

Many thanks to…

- State Radiation Control offices- voluntary efforts
- ACR- supports NEXT training courses
- Equipment manufacturers- important resource regarding equipment
- Professional Societies- CRCPD, AAPM, NCRP, SCAI
- Fellow NEXT colleagues, past and present: Stanley Stern, Richard Kaczmarek, Orhan Suleiman, Mike Hilohi, Steve Balter, and many others.

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Image Quality scores are reported for following phantoms.

1985: RMI 152 phantom with 'C' insert

1988: RMI 156 phantom with 'C' insert

1992 to present: RMI 156 phantom with 'D' insert (or equivalent)

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