

Medical Exposures of the U.S. Population: New Developments Since NCRP Report No. 160



David A. Schauer
Executive Director

American Statistical Association Radiation and Health Meeting

*Radiation Exposures in Medicine:
Biological and Public Health Significance*

June 13-16, 2010
Annapolis, MD

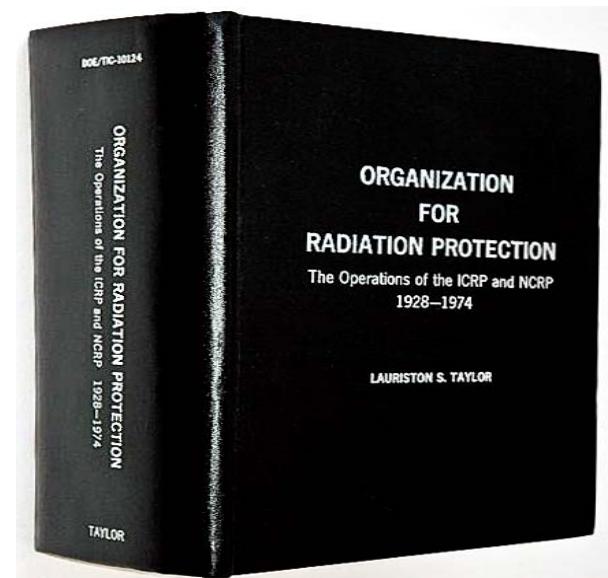
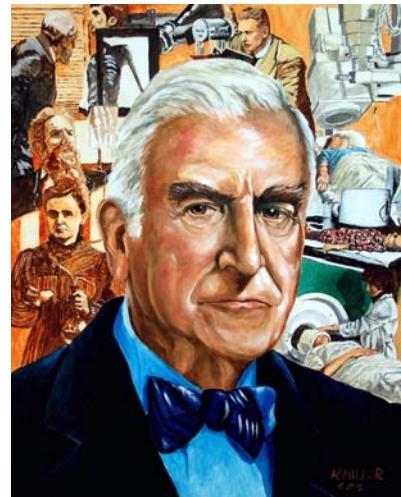
Key Dates in NCRP's History



1929: U.S. Advisory Committee on X-ray and Radium Protection

1946: U.S. National Committee on Radiation Protection

1964: National Council on Radiation Protection and Measurements (NCRP) chartered by U.S. Congress (Public Law 88-376)



Key Elements of NCRP's Charter Under U.S. Public Law 88-376



Cornerstones of role in radiation health protection:

1. *Collect and analyze* information and recommendations in the public interest about:
 - protection against radiation; and
 - radiation measurements, quantities and units.
2. *Develop* basic concepts of radiation protection;
3. *Facilitate* effective use of combined resources of organizations concerned with radiation protection; and
4. *Cooperate* with national and international governmental and private organizations; and
5. *Disseminate* the Council's work.

Radiation Protection Goals: NCRP Report No. 116



1. prevent the occurrence of clinically significant radiation-induced deterministic effects by adhering to dose limits that are below the apparent threshold levels; and
2. limit the risk of stochastic effects, cancer and genetic effects, to a reasonable level in relation to societal needs, values, benefits gained and economic factors.

Radiation Protection Objectives: NCRP Report No. 116



1. justify any activity which involves radiation exposure on the basis that the expected benefits to society exceed the overall societal cost (justification*);
2. ensure that the total societal detriment from such justifiable activities or practices is maintained ALARA, economic and social factors being taken into account (optimization); and
3. apply individual dose limits to ensure that the procedures of justification and ALARA do not result in individuals or groups of individuals exceeding levels of acceptable risk (limitation).

*Also read NCRP Commentary No. 13, An introduction to efficacy in diagnostic radiology and nuclear medicine (justification of medical radiation exposure)

11th Report on Carcinogens (2004)*

X-Radiation and Gamma Radiation*



Known to be Human Carcinogens

Carcinogenicity

- X-radiation and gamma radiation are *known to be human carcinogens* based on sufficient evidence in humans.
- Epidemiological studies of radiation exposure provide a consistent body of evidence for the carcinogenicity of X-radiation and gamma radiation in humans.
- Exposure to X-radiation and gamma radiation is most strongly associated with leukemia and cancer of the thyroid, breast, and lung; associations have been reported at absorbed doses of less than 0.2 Gy.

11th
Report on
Carcinogens
2004

*U.S. Department of Health and Human Services
Public Health Service
National Toxicology Program
Pursuant to Section 301(b) (4) of the Public Health Service Act as Amended by Section 262, PL 95-622



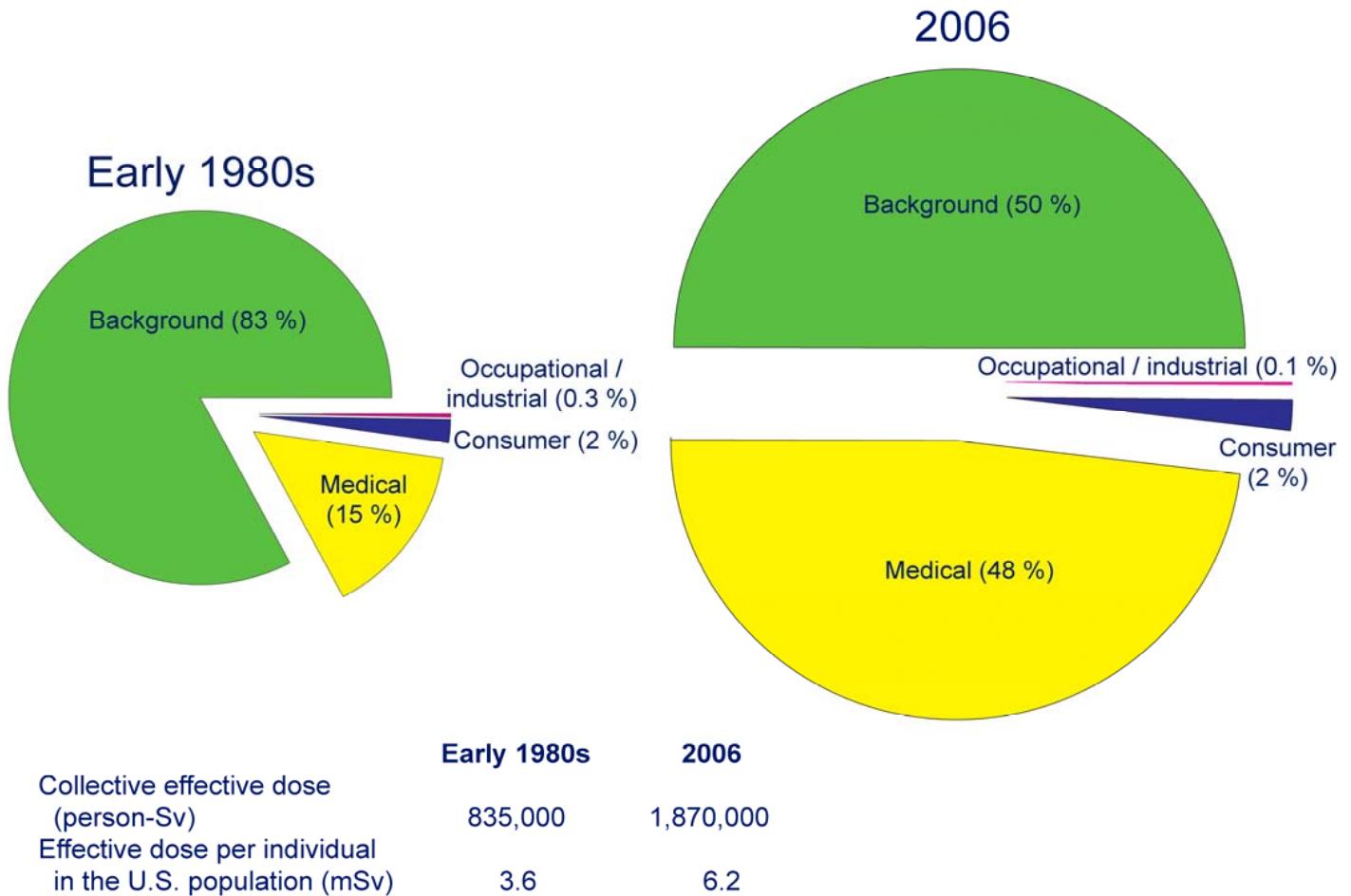


NCRP REPORT No. 160

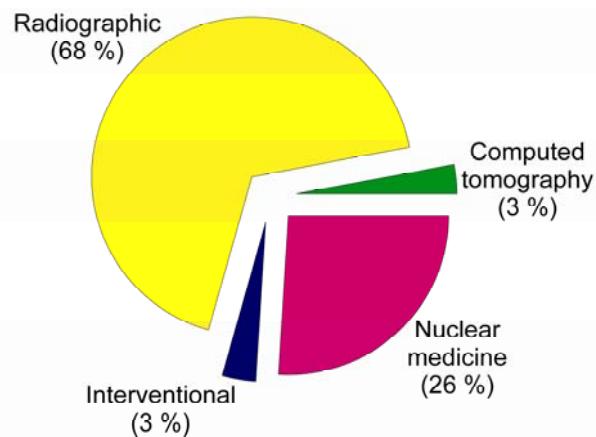
IONIZING RADIATION EXPOSURE OF THE POPULATION OF THE UNITED STATES

|N|C|R|P| 1929
2009

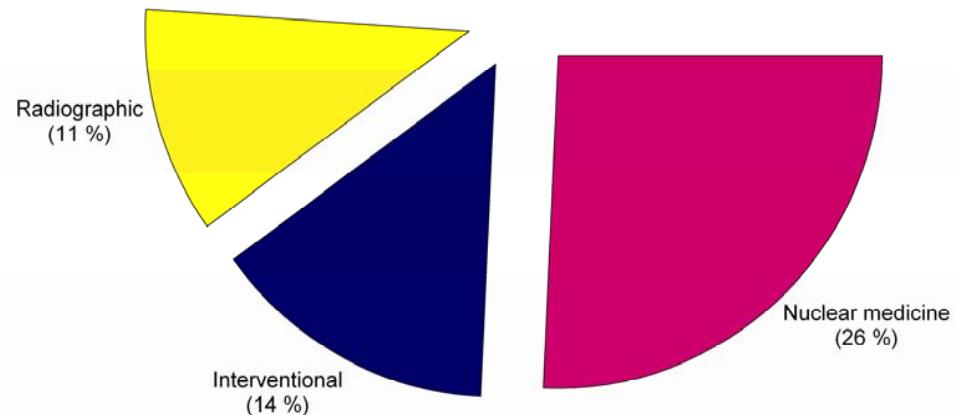
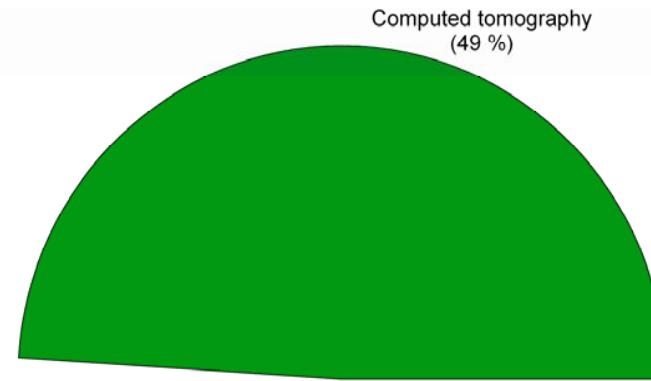
NCRP Report No. 160, *Ionizing Radiation Exposure of the Population of the United States*



Medical Exposure of Patients
Collective H_E (percent), early 1980s



Medical Exposure of Patients
 S (percent), 2006



INSTITUTE FOR
RADIATION
PROTECTION
AND
NUCLEAR
SUSCEPTIBILITY

Radiation Exposure to US Population - Medical Exposures



PRINCETON

	Number of Procedures (millions)	%	Collective Effective Dose (person Sv)	%	E _{US} (mSv)
Computed Tomography	67	17	438,000	49	1.5
Nuclear Medicine	18	5	231,000	26	0.8
Interventional	17	4	128,000	14	0.4
Conventional Radiography & Fluoroscopy	292	74	99,000	11	0.3
TOTALS	426	100	898,000	100	~3
(600 % increase)					

Justification of Medical Exposures



- How – use of ACR appropriateness criteria, ACC appropriate use criteria or EU referral guidelines through computerized physician order entry (CPOE);
- Why has this become a significant issue?
 - Supplier-induced Demand (IOM, 2010[#])
 - “If the physician is ordering a study where the payment exceeds the cost, there is a true profit potential. Even in the presence of strong ethical adherence to the Hippocratic oath and similar constructs, the physician may have incentives to over-order imaging studies.”
 - Self Referral (GAO report, 2008^{*})
 - Physicians who refer patients for imaging in their own office are at least 1.7 to 7.7 times more likely to order imaging than those physicians in the same specialty who do not self-refer.

[#]Value in Health Care – Accounting for Cost, Quality, Safety, Outcomes and Innovation,

^{*}GAO-08-452, Rapid Spending Growth and Shift to Physician Offices Indicate Need for CMS to Consider Additional Management Practices

Justification of Medical Exposures



- In the absence of direct financial gain, there may be additional payoffs (IOM, 2010)
 - The ordering physician may be able to reduce effort by having a briefer or less intense physical examination.
 - The ordering physician may avoid malpractice costs (real or perceived)
 - Defensive Medicine (Massachusetts Medical Society Report, 2008)
 - Approximately 33 % of CT scans ordered by OB/GYN, EDs and family practitioners were not motivated by medical need.
- Lack of appropriate training (credentials) and certification for facilities

Justification of Medical Exposures

- What is being done about this issue by Congress?
 - MIPPA - Public Law 110-275, Sec. 135. Imaging Provisions
 1. Demonstration Project to Assess Appropriate Use of Imaging Services
 2. Accreditation Requirement
 - *Centers for Medicare and Medicaid Services named three national accreditation organizations to accredit suppliers seeking to furnish the technical component of advanced diagnostic imaging services under the Medicare program:
 - » American College of Radiology (ACR);
 - » Intersocietal Accreditation Commission (IAC); and
 - » The Joint Commission (TJC).



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Congress of the United States
Washington, DC 20515

April 16, 2010

The Honorable Gene L. Dodaro
Acting Comptroller General of the United States
U.S. Government Accountability Office
441 G Street, NW
Washington, D.C. 20548

Dear Mr. Dodaro:

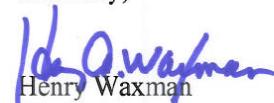
As you know, the physician self-referral law, set forth in section 1877 of the Social Security Act, prohibits physicians from referring Medicare patients for imaging services, radiation therapy services, and certain other designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship. However, there are exemptions to the self-referral prohibition. For example, the 'in-office ancillary exemption' allows a physician, under certain conditions, to provide imaging services, radiation therapy services, and some other designated health services in his or her office.

Proponents of the in-office ancillary exemption note that the ability to self-refer may help improve patient access to services and better enable physicians to make rapid diagnoses and initiate treatment. However, there are also concerns that the potential financial incentives associated with self-referral could lead to the overprovision of imaging and radiation oncology services. In fact, studies have suggested that physicians tend to be responsive to these financial incentives and that self-referral may be a contributing factor in the rapid increase of use of these services.

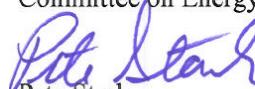
Consequently, we request that GAO conduct a study to evaluate the extent of physician self-referral arrangements for advanced imaging and radiation oncology services provided to Medicare beneficiaries and the effects of such arrangements on Medicare spending. Specifically, the study should focus on (1) prevalence, patterns, and trends in physician self-referral for advanced imaging and radiation oncology services, (2) Medicare spending on these physician self-referred services,

and (3) the extent to which self-referral may have led to increases in the provision of, and Medicare spending for, advanced imaging and radiation oncology services. Thank you for your attention to this important matter. If you have any questions about this request, please contact Tim Gronniger of Committee on Energy and Commerce at (202) 225-5056 and John Barkett with the Committee on Ways and Means at (202) 225-3943.

Sincerely,


Henry Waxman
Chairman

Committee on Energy and Commerce


Pete Stark
Chairman

Subcommittee on Health
Committee on Ways and Means


Sandy Levin
Chairman
Committee on Ways and Means

Justification of Medical Exposures

- What is being done about this issue by the medical community?
 - “Increasing the Appropriateness of Outpatient Imaging: Effects of a Barrier to Ordering Low-Yield Examinations”, Vartanians, *et al.*, (June 2010), *Radiology*
 - American Society of Nuclear Cardiology, “Recommendations for Reducing Radiation Exposure in Myocardial Perfusion Imaging”, Cerqueira *et al.*, (May 2010), *Journal of Nuclear Cardiology*
 - Imaging e-Ordering Coalition
 - require referring physician to enter clinical information (e.g., patient’s symptoms, known diagnoses, age, etc) in a decision support program.
 - processed through an algorithm that relies on ACR’s appropriateness criteria to create a decision score.



Optimization of Medical Exposures

- “American College of Radiology White Paper on Radiation Dose in Medicine”, *JACR* 4:272-284; (2007)
- Image Gently, Step Lightly and Image Wisely Campaigns
- AAPM CT Dose Summit
- Medical Imaging and Technology Alliance (MITA)
 - NEMA Standards Publication XR 25-2010 “CT Dose Check” (draft):
 - Notification Value
 - Alert Value



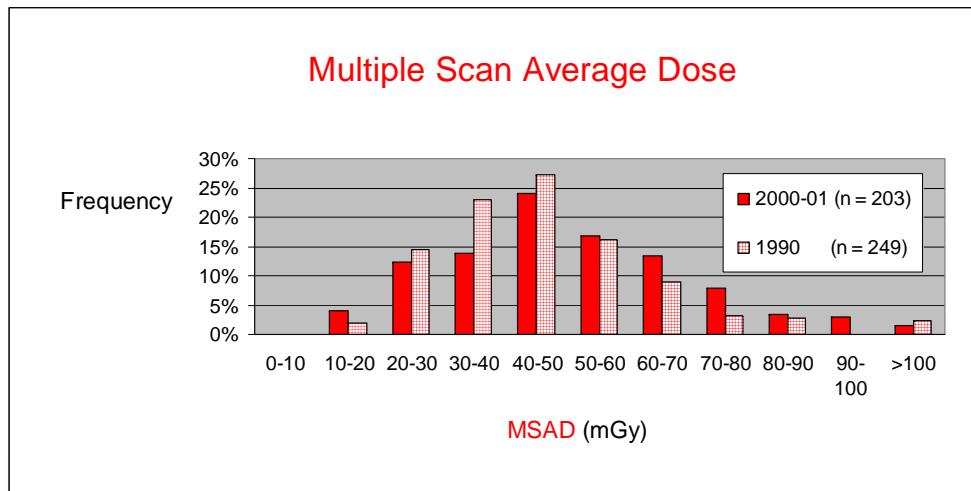
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Optimization of Medical Exposures

- NCRP scientific committee 4-3, “Diagnostic Reference Levels in Medical Imaging: Recommendations for Application in the United States”



NCRP



	MSAD Survey Year 2000-01 (mGy)	Survey Year 1990 (mGy)
mean	50.3	45.9
standard error of sample mean	1.4	1.1
standard deviation	19.4	18.1
n	203	249

“DRLs may be more necessary, because we may be optimizing image quality, and compromising on high patient doses because technology allows us to.” Moore and Iball, Leeds General Infirmary

Putting it All Together

- FDA *Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging*
 1. Support informed clinical decision making (justification)
 - develop and adopt appropriate use criteria for CT, fluoroscopy, and nuclear medicine procedures
 2. Promote safe use of medical imaging devices (optimization)
 - develop nationally recognized diagnostic reference levels for medical imaging procedures that use radiation
 3. Increase patient awareness (communication)
 - provide patients with tools to track their personal medical imaging history

Aim: To help patients get the right imaging exam, at the right time, with the right radiation dose.

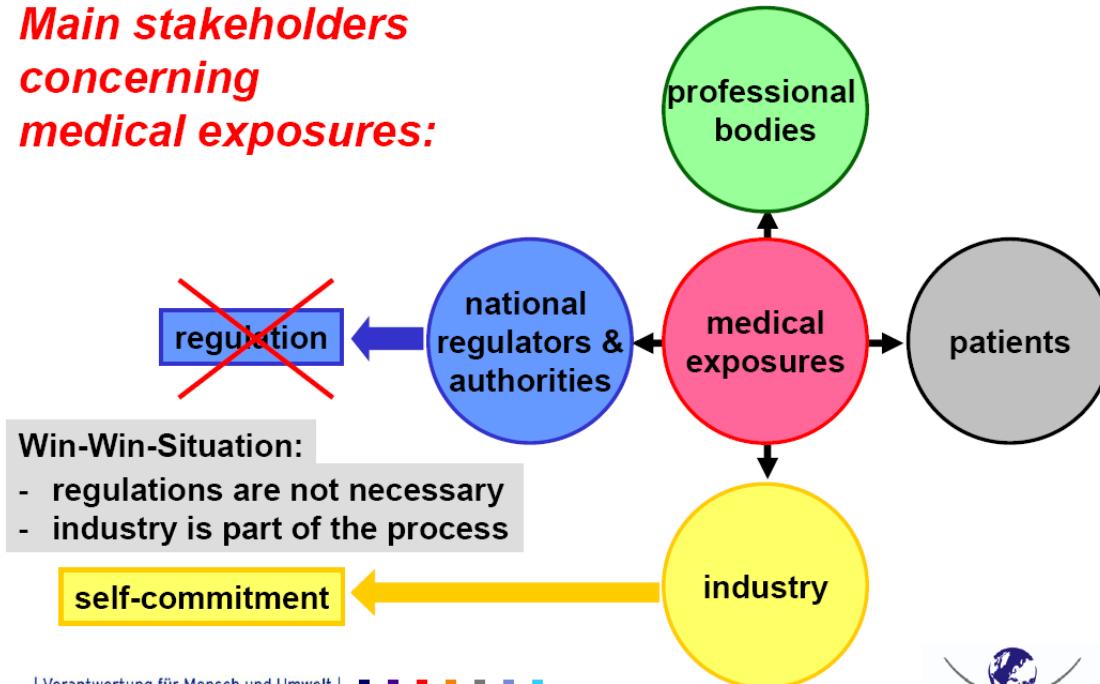


View from the European Union

Rationale for the HERCA Meeting



Main stakeholders concerning medical exposures:



HERCA – Heads of European Radiation Control Authorities

COCIR - European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry. Similar to Medical Imaging and Technology Alliance (MITA) in the U.S.

Key meeting of both groups in Bern on June 14th

NCRP Publications – “Disseminate”



NCRP

- NCRP reports and current activities are described online at
<http://NCRPonline.org>
Publications can be purchased online at
- <http://NCRPpublications.org>
- Institutional license agreements for NCRP publications are now available through:
 - **Knovel** (<http://www.Knovel.com>)
 - **NetLibrary** (<http://www.NetLibrary.com>)
 - **ebrary** (<http://www.ebrary.com>)