This file contains projections of benefits that may result from proposed amendments to the performance standard for diagnostic x-ray systems and their major components. The following caveat is adopted from the OSTP Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) Science Panel Report No. 9 (Washington, D.C., December 1992): These benefit projections are based on many assumptions, including estimations of radiation-associated cancer deaths derived from linear extrapolation of nominal risk estimates for lifetime total cancer mortality at 0.1 sievert (Sv). Other methods of extrapolation to the low-dose region could yield higher or lower numerical estimates of cancer deaths. At this time studies of human populations exposed at low doses are inadequate to demonstrate the actual level of risk. There is scientific uncertainty about cancer risk in the low-dose region below the range of epidemiologic observation, and the possibility of no risk cannot be excluded.

Estimated Benefits of Proposed Amendments to the FDA Radiation-Safety Standard for Diagnostic X-Ray Equipment

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The *FDA Center for Devices and Radiological Health* [1] is proposing nine changes to the U.S. Performance Standard for Diagnostic X-Ray Equipment that will reduce unnecessary radiation emitted during fluoroscopy. Principal radiation risks to patients are a long-term possibility for cancer induction and a short-term potential for skin burns. We estimate benefits of the proposed amendments in terms of years of life that would be spared cancer mortality attributable to excess radiation, numbers of radiation burns that would be avoided, and their respective pecuniary savings to society. The analysis and assumptions (described in the notes) consider three procedures—percutaneous transluminal coronary angioplasty, cardiac catheterization angiography, upper gastrointestinal fluoroscopy—and three of the proposed amendments. Using dose, demographic, and risk data from various sources, we infer that the benefits of the amendments would greatly exceed their estimated costs.

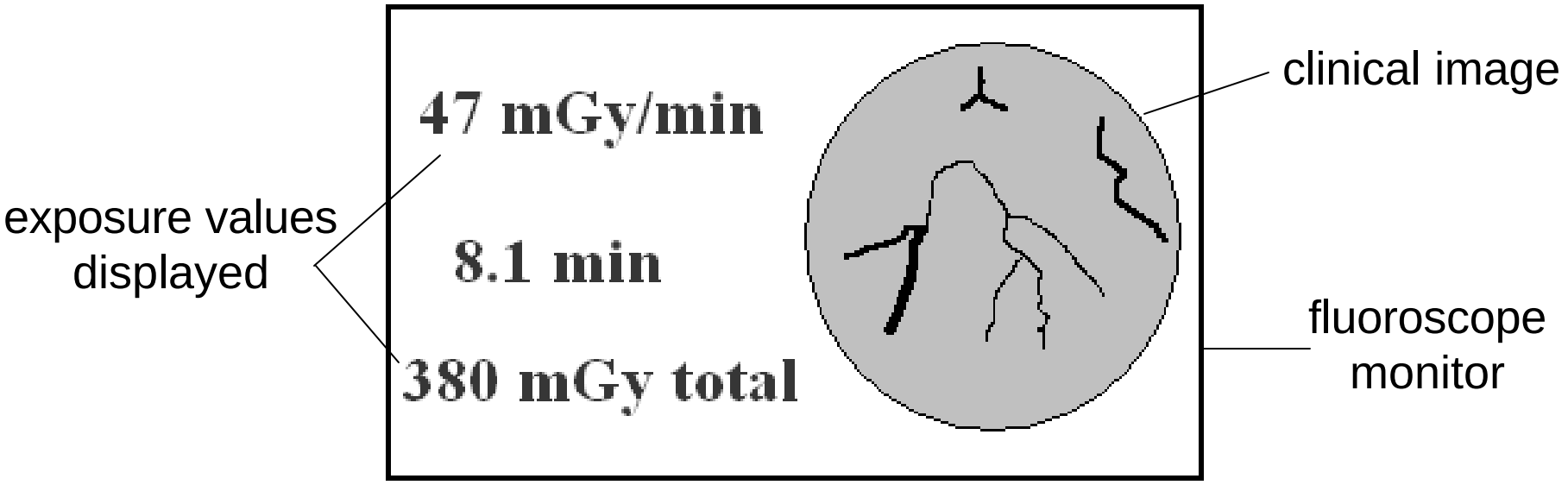
Proposed Amendments [2]

would require that new fluoroscopy equipment

- Display the rate, time, and cumulative total of radiation emission
- Filter out more of the lower energy x-rays to reduce dose to patient skin
- Collimate the x-ray field more “tightly” so that it’s used more efficiently

Note: Six other amendments are not evaluated in this study.

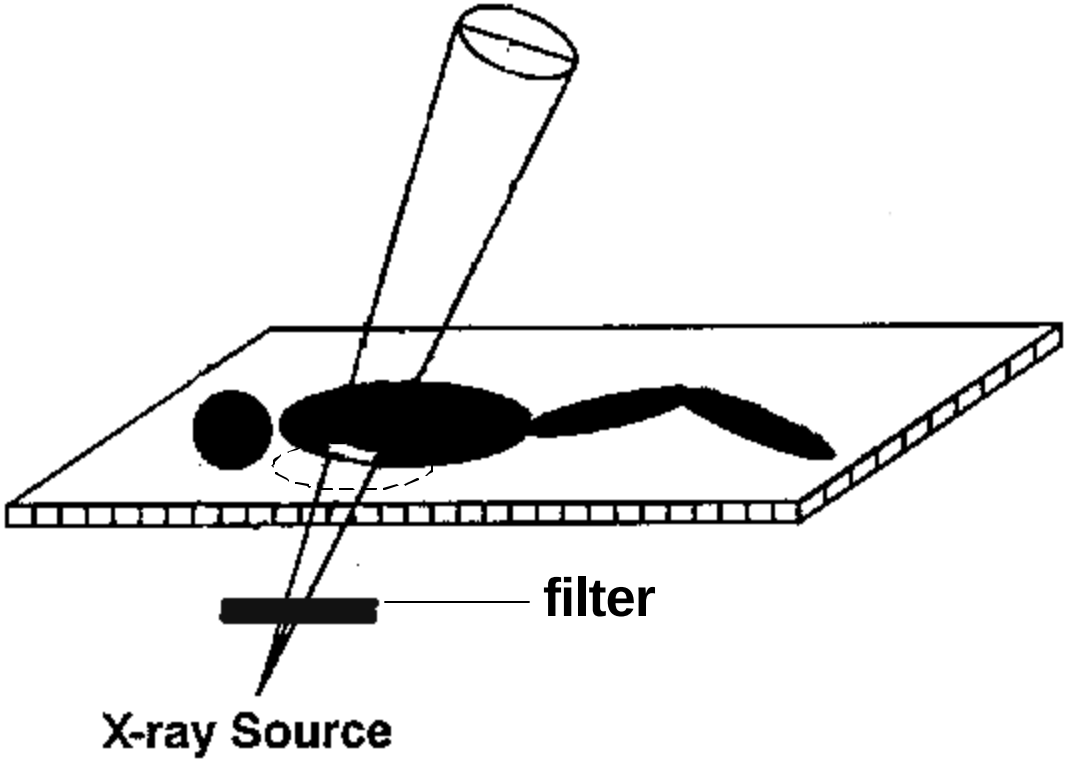
Display Amendment



- Rate, time, total amounts of radiation exposure displayed to radiologist
- Radiologist could use exposure data to optimize exam techniques
- Facility could compare, control emissions according to exam norms [3-8]

Impact: could **reduce overall patient dose ~ 16%** [9-12]

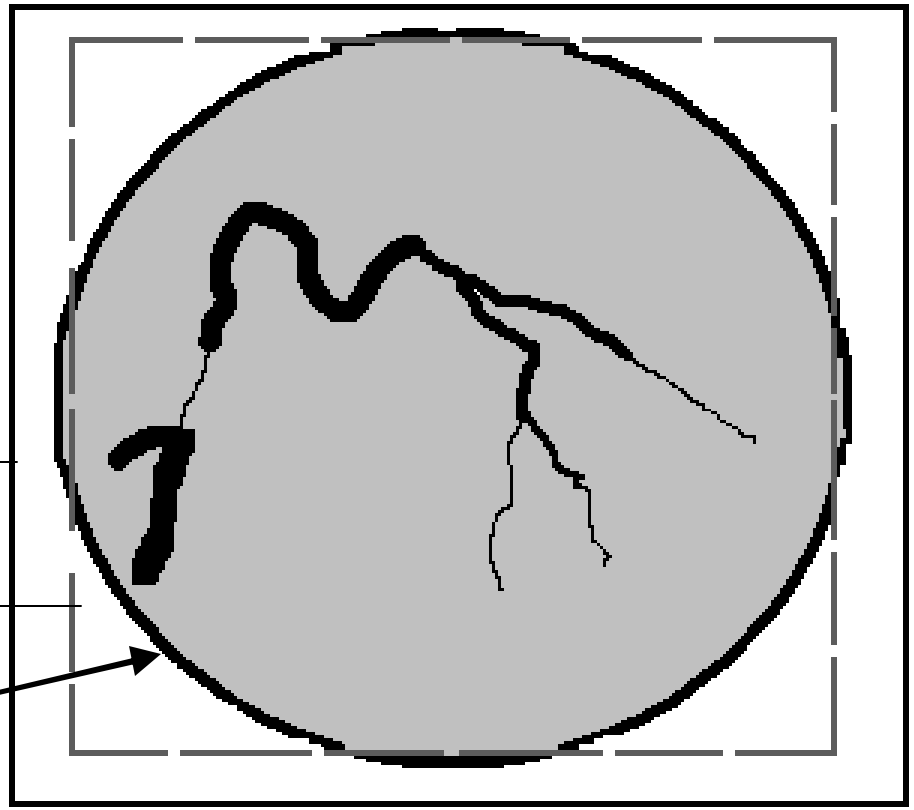
Filtration Amendment



- More filtration selectively absorbs low-energy x-rays [13]
- Spares the patient skin dose and potential radiation burn [14-17]

Impact: could **reduce overall patient dose ~ 6%** [13, 18, 19]

Collimation Amendment



•"Tighter" collimation: image area ≥ 80% x-ray field area

•Reduces radiation not used for imaging

Impact:

could **reduce overall patient dose** ~ **1%** (UGI) **- 3%** (cardio) [20-25]

Fluoroscopic Procedures Analyzed

Percutaneous transluminal coronary angioplasty (PTCA)

- 608,000 procedures per year in U.S. (1997) [26]
- effective (whole-body) dose per procedure 5.0 ± 1.9 mSv [28]

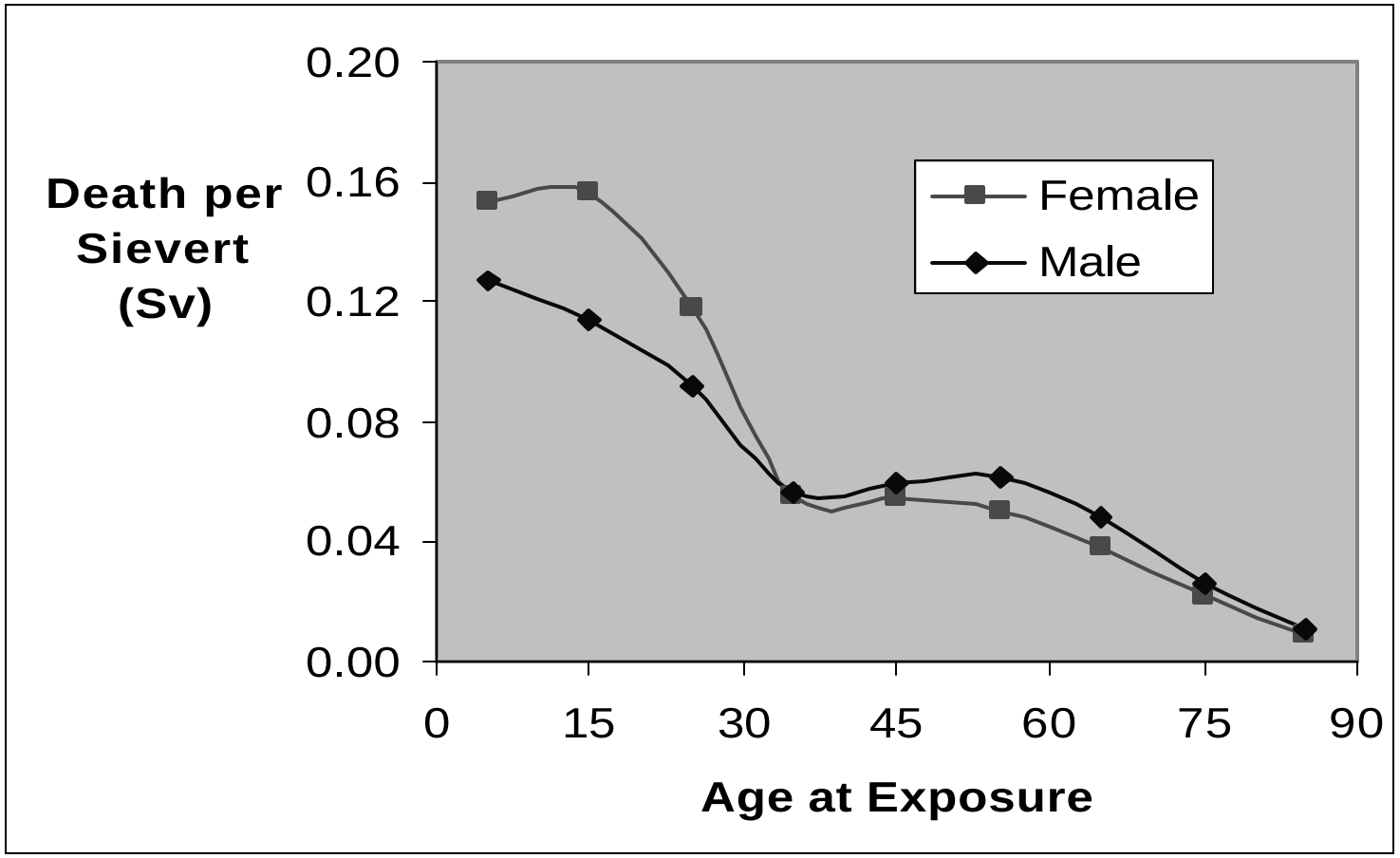
Cardiac catheterization, coronary arteriography & angiography (CA)

- may include ventriculography, left- and/or right-heart studies
- 3,870,000 procedures per year in U.S. (1997) [26]
- effective (whole-body) dose per procedure 3.1 ± 1.3 mSv [28]

Upper gastrointestinal series fluoroscopy and radiography (UGI)

- excludes barium swallow examinations
- 16,500,000 procedures per year in U.S. (1996) [29]
- effective (whole-body) dose per procedure 2.8 ± 1.7 mSv [42]

Lifetime Cancer Mortality from X-Ray Radiation [47]



- For an ***individual***, the **dose and risk of death are very small**
- For the ***population***, the **collective dose implies a number of excess deaths**
- Attribution of risk to the population is scientifically controversial [49] but generally accepted for the purpose of radiation protection

Radiation-Induced Skin Injuries [14, 17]

Injury	Threshold Dose to Skin (Sv)	Weeks to Onset
Early transient erythema	2	<<1
Temporary epilation	3	3
Main erythema	6	1.5
Permanent epilation	7	3
Dry desquamation	10	4
Invasive fibrosis	10	
Dermal atrophy	11	>14
Telangiectasis	12	>52
Moist desquamation	15	4
Late erythema	15	6-10
Dermal necrosis	18	>10
Secondary ulceration	20	>6

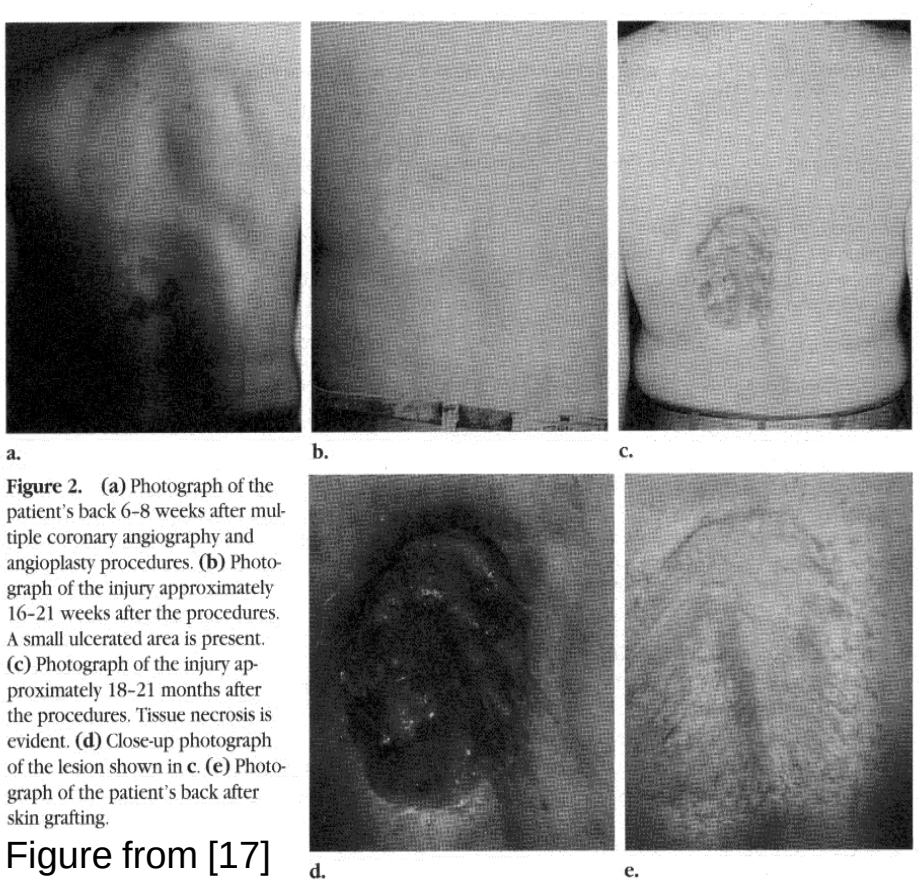


Figure 2. **(a)** Photograph of the patient's back 6–8 weeks after multiple coronary angiography and angioplasty procedures. **(b)** Photograph of the injury approximately 16–21 weeks after the procedures. A small ulcerated area is present. **(c)** Photograph of the injury approximately 18–21 months after the procedures. Tissue necrosis is evident. **(d)** Close-up photograph of the lesion shown in **c**. **(e)** Photograph of the patient's back after skin grafting.

Figure from [17]

- Skin "burns" are rare but possible for prolonged fluorocardio & other interventions
- FDA has received 60 reports of burns since 1994 ⇒ ~ 8.6 reported burns per year
- **How many radiation burns are not reported?**

Impact of New Amendments: Life Benefits

Assumption: savings start to accrue at the beginning of a decade in which all current fluoroscopy equipment is replaced by new equipment manufactured according to the proposed new standards.

Estimated benefits (highlighted in color): refer to ***annual*** projections ***10 years after the initial implementation*** of the proposed standards. Projected life savings would ultimately be realized only after an additional ~ 10-year interval of cancer latency [48] followed by 10 years of survival.

- dose savings per procedure = % dose reduction × effective dose per procedure
- collective dose savings = dose savings per procedure × no. of U.S. procedures
- no. of lives saved = collective dose savings × rad.-induced cancer excess mortality
- years of life saved = no. of lives saved × (years of life remaining minus 20) [50]
- no. of cancers precluded = no. of lives saved ÷ lethality fraction [51, 52]
- no. of skin burns precluded = percentage dose reduction × no. of skin burns [53]

Annual Life Benefit Projections in U.S.

10 Years after Implementation of New Standards *versus* Age at Exposure

Age at Exposure	Age < 1	Age 1-17	Age 18-44	Age 45-64	Age 65-84	Age => 85	Sub-total Male	Age < 1	Age 1-17	Age 18-44	Age 45-64	Age 65-84	Age => 85	Sub-total Female	Total
Procedure	**Collective Dose Savings (man-Sv)**							**Collective Dose Savings (woman-Sv)**							
PTCA	0		36	239	220	7	502	0		10	87	158	10	265	767
CA	4	4	151	811	858	30	1,857	3	4	64	414	691	42	1,217	3,075
UGI	507	230	790	1,092	1,861	463	4,952	442	223	775	1,132	2,324	770	5,669	10,621
							7,312							7,151	**14,463**
	Projected No. of Lives Saved (male)							**Projected No. of Lives Saved (female)**							
PTCA	0		3	14	6	0	23	0		1	4	4	0	9	32
CA	0	1	11	47	24	0	84	0	1	6	20	17	0	44	128
UGI	65	28	60	64	53	5	274	68	34	68	55	56	7	288	562
							382							341	**723**
	Projected Years of Life Saved (male)							**Projected Years of Life Saved (female)**							
PTCA	1		63	38	0	0	101	1		25	32	0	0	58	159
CA	25	22	264	127	0	0	439	25	28	163	151	0	0	367	806
UGI	3,345	1,223	1,386	172	0	0	6,126	3,969	1,743	1,989	414	0	0	8,114	14,240
							6,667							8,539	**15,206**

•Projection: 2 *reports* of fluorocardio skin burns precluded per year

Projection of Pecuniary Benefits
for 3 amendments and 3 procedures

We compute ***average*** *annual savings over the 10 years* in which all new fluoroscopic equipment will meet the new standards:

- Year 0 to year 10—dose savings increases from 0 to 14,500 person-Sv/year ⇒
- Year 20 to year 30—projected no. of lives saved increases from 0 to 723/year
- Year 20 to year 30—projected cumulative no. of lives saved is 3615

- Savings based on societal "willingness to pay" (WTP) premium for high-risk jobs
  $5 per one-in-a million chance of death [54-56] ⇒
  - net present WTP value = $1.3 M per life saved 20 years in future [57]
  - *average annual amortized savings* in first 10 years = **$462 M per year**

- Savings from **preclusion of cancer treatment** *$25,000* [58-61] and its **psychological impact** *$5,000 per cancer incidence* [62-67] ⇒
  - *average annual amortized savings* in first 10 years = **$57 M per year**

- Savings per **radiation burn preclusion**: *$67,600 per burn avoided* [68-70]

Summary / Conclusion

- Life savings and pecuniary benefits are estimated for three proposed amendments to fluoroscopic equipment performance standards
  - Display the rate, time, and cumulative total of radiation emission
  - Filter out more lower energy x-rays to reduce dose to patient skin
  - Collimate the x-ray field more “tightly” so that it’s used more efficiently
- Proposed amendments would reduce dose in at least three procedures
  - Percutaneous transluminal coronary angioplasty (PTCA)
  - Cardiac catheterization coronary arteriography & angiography (CA)
  - Upper gastrointestinal series fluoroscopy and radiography (UGI)
- Projection of **723 lives per year** spared radiation-induced cancer mortality 30 years from start of implementation of amendments
- Average annual **pecuniary savings of $519 M** in first 10 years of implementation greatly exceeds estimated average annual cost of $49 M to manufacturers and FDA [71]

Notes and References

1. The proposed amendments were developed in the CDRH Fluoroscopy Working Group, currently comprised of Robert Doyle, Robert Gagne, Richard Kaczmarek, Henry Knox, Thomas Shope (Chair), Stanley Stern, and Jennette Wade, with contributions from Thomas Jakub, Robert Phillips, Marvin Rosenstein, Orhan Suleiman, and Arlene Underdonk.

2. http://www.fda.gov/cdrh/fluoroamend.pdf.

3. Patient dose norms are called “reference values,” and they correspond to the 75th percentile of the distribution of measured values for particular radiological procedures. They were introduced in the United Kingdom—NRPB/RCR, "Patient Dose Reduction in Diagnostic Radiology," *Doc. NRPB* Vol. 1, No. 3, pp. 1-46 (1990), and refs [4-5]—and have been adopted throughout western Europe (refs [6, 7]). They are being proposed in the U.S. by a task group of the American Association of Physicists in Medicine (ref. [8]). Reference values are benchmarks to which a facility’s practice may be compared in a radiation-protection quality assurance program: When reference levels are exceeded in any particular examination, the facility may investigate to see if it’s possible to reduce exposure without adversely affecting image quality. As part of a quality assurance program, dose displays would be an essential tool needed for evaluation of patient dose in the first place.

4. Dosimetry Working Party of the Institute of Physical Sciences in Medicine, *National Protocol for Patient Dose Measurements in Diagnostic Radiology*, National Radiological Protection Board, Chilton, UK, (1992).

5. National Radiological Protection Board (UK), "Medical Exposure: Guidance on the 1990 Recommendations of the ICRP," *Doc. NRPB* Vol. 4, No. 2, pp. 43-74 (1993).

6. International Commission on Radiological Protection, *Radiological Protection and Safety in Medicine*, ICRP Publication 73, *Annals of the ICRP* Vol. 26, No. 2 (1996).

7. European Council, "Council Directive 97/43/Euratom of 30 June 1997 on Health Protection of Individuals Against the Dangers of Ionizing Radiation in Relation to Medical Exposure, and Repealing Directive 84/466/Euratom," *Official Journal of the European Communities*, No. L 180, pp. 22-27, July 9, 1997.

8. Joel E. Gray et al., *Report of the Task Group on Reference Values for Diagnostic X-Ray Examinations*, American Association of Physicists in Medicine, (unpublished draft, November 1, 2000).

9. The percentage dose savings that are projected to follow implementation of the display amendments corresponds to one-half the difference between 1995 UK survey levels (ref. [12]) and 1985 values (ref. [11]). See R.H. Corbett, "A European Radiologist's View of Diagnostic Reference Levels," *European Radiation Protection, Education and Training (ERPET), ERPET Course for Medical Physicists on Establishment of Reference Levels in Diagnostic Radiology, Passau, Germany, 13-15 September 1999, Proceedings*, EC Directorate General Science, Research and Development Doc. RTD/0034/20, (BfS-ISH, Oberscheissheim, July 2000), pp. 83-91, and ref. [10]. "Reference levels" based on the 1985 data were introduced into the UK in 1990 (refs. [3-5]). It is assumed that one-half of the UK dose reduction from 1985-1995 is due to to technology improvements alone (e.g., faster film-screen combinations and the use of digital spot films), whereas the other half of dose savings stems from the quality assurance use of reference levels and patient dose evaluation. Projections that we associate with the display amendments thus presume facility implementation of a quality assurance program making use of patient doses and reference levels.

10. A.T. Rogers et al., "The Use of a Dose-Area Product Network to Facilitate the Establishment of Dose Reference Levels," *European Radiation Protection, Education and Training (ERPET), ERPET Course for Medical Physicists on Establishment of Reference Levels in Diagnostic Radiology, Passau, Germany, 13-15 September 1999, Proceedings, EC Directorate General Science, Research and Development Doc. RTD/0034/20, (BfS-ISH,* Oberscheissheim, July 2000), pp. 255-260.

11. P.C. Shrimpton et al., *A National Survey of Doses to Patients Undergoing a Selection of Routine X-ray Examinations in English Hospitals*, NRPB-R200, National Radiological Protection Board, Chilton, UK (September 1986).

12. D. Hart et al., *Doses to Patients from Medical X-ray Examinations in the UK—1995 Review*, NRPB-R289, National Radiological Protection Board, Chilton, UK (July 1996).

13. R.M. Gagne, P.W. Quinn, and R.J. Jennings, "Comparison of Beam-Hardening and K-edge Filters for Imaging Barium and Iodine during Fluoroscopy," *Medical Physics* Vol. 21, No. 1, pp. 107-121 (January 1994). For upper gastrointestinal series, ref. [18] indicates a mean 99.29 kVp and mean HVL of 4.4 mm Al. This HVL exceeds the current standard minimum HVL (2.7 mm Al) by 1.7 mm Al. We assume that as newer equipment meeting a new minimum HVL requirement is introduced into practice over time, the mean HVL for upper gastrointestinal series--and presumably for fluorocardio procedures as well--will ultimately exceed the new requirement (3.6 mm Al) by 1.7 mm Al. Based on the ratio of added filtration to HVL for a system operating at 100 kVp (ref. [19]), we approximate the projected increase in HVL by an increment of 1.6 mm added Al filtration. Gagne et al. indicate that 1.6 mm Al added filtration would reduce the absorbed energy fluence rate (and hence the effective dose) by approximately 5.7%.

14. *Avoidance of Serious X-Ray-Induced Skin Injuries to Patients During Fluoroscopically-Guided Procedures,* Food and Drug Administration Important Information for Physicians and Other Health Care Professionals, September 9, 1994. The table of radiation-induced skin injuries was adapted from L.K. Wagner, P.J. Eifel, and R.A. Geise, "Potential Biological Effects Following High Xray Dose Interventional Procedures," *Journal of Vascular and Interventional Radiology*, Vol. 5, pp. 71-84 (1994).

15. *Avoidance of Serious X-Ray-Induced Skin Injuries to Patients During Fluoroscopically-Guided Procedures,* Food and Drug Administration Public Health Advisory, September 30, 1994.

16. *Recording Information in the Patient's Medical Record that Identifies the Potential for Serious X-Ray-Induced Skin Injuries Following Fluoroscopically Guided Procedures,* Food and Drug Administration Important Information for Physicians and Other Health Care Professionals, September 15, 1995.

17. Thomas B. Shope, "Radiation-induced Skin Injuries from Fluoroscopy," *RadioGraphics* Vol. 16, No. 5, pp. 1195-1199 (September 1996).

18. R. Kaczmarek, *Nationwide Evaluation of X-Ray Trends Summary of 1996 Fluoroscopy Survey*, (unpublished draft, November 2000).

19. R.F. Laitano et al., *Energy Distributions and Air Kerma Rates of ISO and BIPM Reference Filtered X-Radiations,* Comitato Nazionale per la Ricerca e per lo Sviluppo dell'Energia Nucleare e delle Energie Alternative, p. 29 (December 1990).

20. Ref. [18] indicates that over 60% of fluoroscopy units used for upper gastrointestinal (UGI) examinations in the U.S. have image intensifiers of diameter d = 9 inches (22.86 cm). We assume that all UGI units use rectangular collimation and that in meeting the current performance standard (ref. [21]) there is a uniform distribution of lengths exceeding those characterized in refs. [22, 23] by amounts from 0% to 3% of the SID to yield an average excess length of 1.5% of an average SID (refs. [22, 23]) of 80 cm = 1.2 cm. When both the width and length of the x-ray field exceed the diameter of the image intensifier, it is assumed that the average width excess is 1% and average length excess is 1% of the SSD. For d less than or equal to 34 cm, the proposed field limitation amendment would require that the ratio of the visible area of the image receptor (IR) to the x-ray field area at the IR plane be at least 80%. To meet the proposed field-limitation amendment, fluoroscopic equipment will need their x-ray field areas reduced by 8.4% for only 2 (stomach LPO and RAO) of the 12 views comprising the UGI series. We assume therefore that the effective dose savings for the fluoroscopic components of UGI would be approximately (8.4%)/6 = 1.4%. It is assumed furthermore that most UGI systems in the U.S. use spot films rather than digital radiographs of the image intensifier (ref. [18]) and that such spot films contribute approximately 40% of the kerma-area product (ref. [24]) to which the amendment is not applicable. For UGI examinations, the overall effective dose savings is therefore (60%)(1.4%)=0.84% on average with the implementation of the proposed field limitation amendment. For fluorocardio procedures, we use an average field-magnification diameter of 14 cm at the image intensifier (ref. [25]) and assume that the width and length of a rectangularly-collimated field each exceed the image-intensifier field bound by 1% (0.9 cm) of an average SID of 90 cm (ref. [25]) in order to meet the current performance standard (ref. [21]). Reducing the x-ray field area by 13.3% would meet the proposed requirement for systems with rectangular collimation. We assume approximately one-fourth of all fluorocardio procedures are performed on systems having rectangular rather than circular collimation and that therefore that the effective dose savings for all of these procedures would be approximately (13.3%)/4 = 3.3% on average with implementation of the proposed amendment.

21. 21CFR 1020.32(b)(2)(i).

22. O.H. Suleiman, *Development of a Method to Calculate Organ Doses for the Upper Gastrointestinal Fluoroscopic Examination*, Ph.D. dissertation, Johns Hopkins University School of Hygiene and Public Health, Baltimore, Maryland (1989).

23. M. Rosenstein et al., *Handbook of Selected Tissue Doses for the Upper Gastrointestinal Fluoroscopic Examination*, HHS Publication FDA 92-8282, U.S. Dept. Health Human Services, Pub. Health Service, Food and Drug Admin., Ctr. Devices and Rad. Health, Rockville, Maryland (June 1992).

24. J. Geleijns et al., "A Comparison of Patient Dose for Examinations of the Upper Gastrointestinal Tract at 11 Conventional and Digital Units in The Netherlands," *The British Journal of Radiology* Vol. 71, pp. 745-753 (July 1998).

25. S.H. Stern et al., *Handbook of Selected Tissue Doses for Fluoroscopic and Cineangiographic Examination of the Coronary Arteries (in SI Units)*, HHS Publication FDA 95-8289, U.S. Dept. Health & Human Services, Public Health Service, Food and Drug Administration, Center for Devices and Radiological Health, Rockville, Maryland (September 1995).

26. *Nationwide Inpatient Sample Release 6 for 1997*, compiled by HCUPnet, Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality, Rockville, MD, http://www.ahrq.gov/data/hcup/ (August 2000). Note: Per ref. [27], stents were inserted in ~55% of PTCA procedures in 1997 and in ~70% of PTCA procedures in 1998.

27. E.D. Peterson et al., "Evolving Trends in Interventional Device Use and Outcomes: Results from the National Cardiovascular Network Database," *American Heart Journal*, Vol. 139, No. 2, pp. 198-207 (February 2000). We are grateful to Eric Peterson and to Kevin Anstrom for providing the age and gender distributions of patients in this study.

28. The effective dose per procedure (± standard deviation of the mean) is the product of the kerma-area and the ratio of effective dose to the kerma-area. Each of these factors refers to respective means of values cited in several studies, where each mean is weighted by the study sample size (n). For PTCA procedures, a mean kerma-area of 69 ± 25 Gy-cm^2 is the weighted mean of values cited in refs. [30-36]; for cornary angiography a mean kerma-area of 44 ± 16 Gy-cm^2 is the weighted mean of values cited in refs. [32-37]. The ratio 0.07 mSv/Gy-cm^2 was inferred according to reference [25] (Tables E1, F1, Appendix D) from the particular case in reference [38] for an adult male left ventriculogram with left and right coronary angiography. The value obtained is consistent with that calculated for ref. [25] Table 12, which is comprised of average values whose technique inputs were based on a 230-procedure study (ref. [39]). It is assumed that this ratio of effective dose to kerma-area product is generally valid for PTCA as well.

29. Most UGI procedures are performed on an outpatient basis in hospital radiology departments or in radiology practices on referral from other physician offices. The number of hospital procedures was estimated from the hospital workload data cited in ref. [18] and the total number of U.S. hospitals cited in ref. [40]. The number of procedures performed in radiology practices is inferred as the product of the number of hospital procedures and the ratio of physician-office to hospital diagnoses of UGI morbidity. This ratio is assumed to be proportional to the weighted average of the numbers of corresponding diagnoses in reference [41] categories explicitly associated with the UGI tract plus one-half of the gastrointestinal diagnoses not specifically associated with the UGI or the lower gastrointestinal (lgi) tract. For the estimation of the distributions of savings in collective dose, lives, and years of life, the distributions of UGI procedures among genders and ages is assumed to be proportional to those of ref. [26] for barium swallow/UGI series.

30. T. Schmidt and M. Wucherer, "Radiation Safety," in *Joint WHO/ISH Workshop on Efficacy and Radiation Safety in Interventional Radiology*, edited by A. Bauml et al., BfS-ISH-Berichte 178, pp. 23-33 (February 1997).

31. R.L. Mini et al., "Dose-Area Product Measurements During Angiographic X Ray Procedures," in *Radiation Protection Dosimetry* Vol. 80, Nos. 1-3, op. cit., pp. 145-148 (1998).

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35. C.J. Huyskens and W.A. Hummel, *Radiation Exposure in Interventional Cardiology*, Eindhoven University of Technology, Radiation Protection Dept., Report No. SBD 10770b, Eindhoven, The Netherlands, (November 1993), and "Data Analysis on Patient Exposures in Cardiac Angiography," *Radiation Protection Dosimetry* Vol. 57, Nos. 1-4, pp. 475-480 (1995).

36. V. Tsapaki et al., "Patient Radiation Dose Survey in Interventional Cardiology Procedures," *European Radiation Protection, Education and Training (ERPET), ERPET Course for Medical Physicists on Establishment of Reference Levels in Diagnostic Radiology, Passau, Germany, 13-15 September 1999*, Proceedings, EC Directorate General Science, Research and Development Doc. RTD/0034/20, (BfS-ISH, Oberscheissheim, July 2000), pp. 269-276.

37. D.A. Broadhead et al., "Local Reference Doses During Cardiology Procedures," in *Radiation Protection Dosimetry* Vol. 80, Nos. 1-3, op. cit., pp. 149-150 (1998).

38. David Lewis Hykes, Sr., *Determination of Patient Radiation Doses Associated with Cardiac Catheterization Procedures using Direct Measurements and Monte Carlo Methods*, Ph.D. Dissertation, Medical College of Ohio, Toledo, Ohio, pp. 80, 81 (1994).

39. R. Haddadi et L. Renaud, *Projections et Conditions Technique en Usage en Angiocardiologie. Etude Statistique,* Rapport Technique, Service de Genie Biomedical, Institut de Cardiologie de Montreal (March 1993).

40. http://www.aha.org/resource/newpage.asp (January 12, 2001), excerpted from the American Hospital Association Hospital Statistics, 2001 edition (based on the 1999 Annual Survey).

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42. The effective dose per procedure (± standard deviation of the mean) is the product of the kerma-area and the ratio of effective dose to the kerma-area. Each of these factors refers to respective means of values cited in several studies, where each mean is weighted by the study sample size (n). For UGI procedures, a mean kerma-area of 9.4 ± 5.4 Gy-cm^2 is the weighted mean of values cited in refs. [24. 43-45]. The ratio 0.30 ± 0.04 mSv/Gy-cm^2 was inferred as the weighted mean of values cited in refs [24, 46]. Entrance air kerma is taken to approximate values actually cited in [46] as entrance surface dose.

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46. D. Hart, D.G. Jones, and B.F. Wall, *Estimation of Effective Dose in Diagnostic Radiology from Entrance Surface Dose and Dose-Area Product Measurements*, NRPB-R262, National Radiological Protection Board, Chilton, UK, (April 1994).

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48. *1990 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 60, *Annals of the ICRP*, Vol. 21, No. 1-3 (1991).

49. *Controversial Issues: The Linear No-Threshold (LNT) Debate,* in *Medical Physics*, Vol. 25, No. 3, March 1998: Daniel J. Strom, John R. Cameron, and Bernard L. Cohen, *Point/Counterpoint:* "The LNT model is appropriate for the estimation of risk from low-level (less than 100 mSv/year) radiation," and "Low levels of radon in homes should be considered harmful to health," pp. 273-278; Kenneth L. Mossman, "The linear no-threshold debate: Where do we go from here?" pp. 279-284; Warren K. Sinclair, "The linear no-threshold response: Why not linearity?" pp. 285-290; Rudi H. Nussbaum, "The linear no-threshold dose-effect relation: Is it relevant to radiation protection regulation?" pp. 291-299; E.W. Webster, "The linear no-threshold debate: A summary," p. 300. Also see Arthur C. Upton, "The Linear-Nonthreshold Dose-Response Model: A Critical Reappraisal," in the *Proceedings of the Thirty-Fifth Annual Meeting of the National Council on Radiation Protection and Measurements, April 7-8, 1999, Arlington, Virginia,* Proceedings No. 21, Henry D. Royal, Program Chairman, National Council on Radiation Protection and Measurements, Bethesda, Maryland, 1999, pp. 9-31.

50. The years of life saved is the product of the number of lives saved and the years of life that would have been lost to cancer fatality attributable to radiation. For any particular age at exposure, the years of life potentially lost to cancer is estimated as the difference between the actuarial number of years of life remaining (National Center for Health Statistics, *U.S. Decennial Life Tables for 1989-91*, Vol. 1, No. 1, Hyattsville, Maryland, 1997) and a 20 year combined interval of cancer latency and survival.

51. The lethality fraction is the ratio of fatal cancers to all incident cancers (ref. [48]) and is approximately 0.67 (ref. [52]) averaged over all types of cancer.

52. U.S. Environmental Protection Agency, *Estimating Radiogenic Cancer Risks* (June 1994).

53. We assume that the fraction of skin doses exceeding the threshold for skin injury are reduced 25% in proportion to the effective (whole-body) dose for PTCA and coronary angiography procedures and that therefore the number of skin burns is reduced in the same proportion.

54. K. Viscusi, *Fatal Tradeoffs: Public and Private Responsibilities for Risk*, (Oxford University Press, 1992).

55. A. Fisher et al., "The Value of Reducing Risks of Death: A Note on New Evidence," *J. Pol. Anal. and Man* Vol. 8, No. (1), pp. 88-100 (1989).

56. D. Mudarri, *Costs and Benefits of Smoking Restrictions: An Assessment of the Smoke-Free Environment Act of 1993*, Environmental Protection Agency (1994).

57. A discount rate of 7% is stipulated by the Office of Management and Budget for all regulatory agencies. Following general principles of accounting, we assume that benefits accrue at the end of the period and costs at the beginning. See C. Gushee, *Financial Compound Interest and Annuity Tables*, Pub. 376 (Financial Publishing Company, 1972).

58. According to NCI/SEER data (ref. [59]) of cancers distributed by stage (American Joint Committee on Cancer), 75% of all cancers are either stage 1 or 2 at time of presentation. These cancers have annual treatment costs of $23,000 to $28,000 (ref. [60]). In situ cancers are less expensive, and stage 3 and 4 cancers cost $50,000 to $60,000 annually to treat. (Also see ref. [61].) For our analysis, the annual treatment cost is estimated to be that associated with the modal stage.

59. U.S. National Cancer Institute, *Surveillance, Epidemiology, and End Results (SEER) Cancer Statistics Review (1973-1994), Annual*, pp. 123-143 (1997).

60. A. Legoretta et al., "Cost of Breast Cancer Treatment," *Arch. Int. Med.* Vol. 156, pp. 2197-2201 (1996).

61. M. Brown and L. Fintor, "The Economic Burden of Cancer," in *Cancer Prevention and Control*, edited by P. Greenwald et al. (Marcel Dekker Inc., 1995).

62. Psychological impact of dread, anxiety, or depression has long been noted in cancer treatment research (e.g., see refs. [63-65]). The literature estimates that symptoms associated with mental well-being contribute as much as 8% to one's overall sense of health. Of the sense of psychological well-being, depression scales have shown that worries about personal health account for approximately 1/6 of the of the 8% contribution, where other contributors include factors associated with family, finances, work, relationships, etc. Therefore, worries and concerns about personal health contribute approximately 1.3% to one's sense of personal well-being. Another way to put it is that society is willing to pay (WTP) approximately 1.3% of overall health costs to avoid such worries. The WTP for overall health is derived from the estimated annual WTP of $5 M to avoid a statistical death (refs. [54-56]). This value was derived from blue-collar males of about 30 years of age whose life expectancy is 41.3 years (adjusted for future expected bed and non-bed disability per refs. [66, 67]). Amortization of $5 M across 41.3 years at a discount rate of 7% implies a WTP of $373,000 per quality adjusted life-year (QALY). 1.3% of this QALY is approximately $5,000 per year for society's willingness to pay to avoid the sense of psychological dread associated with concerns about personal health generated by cancer treatments.

63. R. Kaplan et al., "Health Status: Types of Validity and the Index of Well-Being," *Health Service Research*, Winter Issue, pp. 478-507 (1976).

64. L. Radloff, “The CES-D Scale: A Self-Report Depression Scale for Research in the General Population,” *App. Psych. Meas.* Vol. 1, No. 3, pp. 385-401 (1977).

65. P. Shrout, “Scaling of Stressful Life Events,” in *Stressful Life Events and their Contexts,* ed. By B.S. Dowrenwend and B.P. Dowenrend, (Rutgers University Press, 1984).

66. M. Chen et al., “Social Indicators for Health Planning and Policy Analysis,” *Policy Sciences* Vol. 6, pp. 71-89 (1975).

67. U.S. National Center for Health Statistics, *Expectation of Life and Expected Death by Race, Sex, and Age, Vital Statistics of the United States* (1995).

68. Ref. [69] survey data on radiation burns indicate an average medical treatment cost of $23,000 and an average work loss of $20,700. Costs of pain and suffering are estimated from an index of the quality of well-being, where 1.0000 indicates perfect health, 0.0000 death (refs. [63, 66, 70]). Relative functionality is first based on mobility (ranging from driving a car without help to being in a special care unit), social activity (ranging from working to needing help with self-care), and physical activity (ranging from walking without problems to staying in bed). Each state has been assigned a relative wellness and is adjusted according to the cause of the state (e.g., bedridden with a stomach ache vs. bedridden with a broken leg). We assign two functional states to radiation burns—(1) 2 weeks of serious debilitation (relative wellness value 0.3599) and (2) 4 weeks of functional distress with some activity (relative wellness value 0.5108). An annual amortized average value of $373,000 (note [62]) for the societal willingness to pay (WTP) for a quality adjusted life year (QALY) equals about $7,200 per week for a quality adjusted life week (QALW), which corresponds to the base 1.0000 in the well-being index. Our estimate of the expected WTP to avoid a radiation burn is $[2 \times \$7{,}200 \times (1.0000 - 0.3599)] + [4 \times \$7{,}200 \times (1.0000 - 0.5108)] = \$23{,}200$. Adding this value to medical treatment and work loss costs results in a cost per burn of $67,600.

69. U.S. Consumer Product Safety Commission, *Estimating the Cost to Society of Consumer Product Injuries*, CPSC-C-95-1164, National Public Services Research Institute (January 1998).

70. R. Kaplan and J. Bush, "Health-Related Quality of Life Measurement for Evaluation Research and Policy Analysis," *Health Psych.* Vol. 1, No. 1, pp. 61-80 (1982).

71. http://www.fda.gov/cdrh/radhealth/fluoro/amendxrad.pdf (July 2000).