

RETURN TO REGULATORY CENTRAL FILES 2/2/77
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VALUE IMPACT STATEMENT FOR PROPOSED REGULATORY GUIDE 8.XX,
INFORMATION RELEVANT TO ASSURING THAT OCCUPATIONAL RADIATION EXPOSURES AT
MEDICAL INSTITUTIONS WILL BE AS LOW AS IS REASONABLY ACHIEVABLE

I. VALUE

This Regulatory Guide has been prepared to provide medical institutions that have not already developed adequate programs for achieving ALARA occupational exposures with ready access to the more important safety procedures for various types of activities in hospitals using licensed radioactive materials. In addition to a summary of the more important things to do to achieve ALARA exposures, a list is provided of the more important recommendations and guides, and addresses of where to obtain them. This information provides the licensee with the necessary data and information to establish adequate radiation safety procedures for meeting ALARA exposures and satisfying regulatory and licensing requirements.

The values of this guide include all of the general values that constitute the aim of the regulatory guide series:

- a) Appropriate guidance is very helpful in the selection of optimum radiation safety procedures and in the reduction of overdesign or inefficient design of facilities and equipment;
- b) Codification and standardization of procedural and equipment recommendations reduces misunderstanding of licensing requirements and results in less waste of effort by both the applicant and the NRC licensing staff;
- c) Ready reference to the more important ALARA exposure efforts pertinent to respective facilities, and listed separately for each

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type of facility, makes it easier for the licensee to satisfy ALARA exposure and licensing requirements to reduce employee (and other) radiation exposures.

- d) The issuance of a Regulatory Guide on this topic provides the much needed NRC staff position as to what is meant, in the case of medical licensees, by §20.1(c) of 10 CFR Part 20, which states that licensees should maintain occupational exposures as low as is reasonably achievable.
- e) The staff believes that issuance of this guide will effect a substantial reduction in occupational exposures at certain medical licensee facilities.

There is evidence that, despite past NRC and state regulatory efforts and NCRP recommendations, there is still a wide variation in the degree to which individual nuclear medicine departments,⁽¹⁾ and individual medical institutions in general,^(2,3,4) adhere to ALARA philosophy. The fact that some medical licensees are performing their work with lower radiation doses than others clearly indicates that improvement is achievable.

Using an average exposure for nuclear medicine employees of 0.5 Rem/year,^(1,5) an average of more than 7 employees working with NRC-licensed radioactive materials alone⁽¹⁾ per licensed medical institution, and about 3,000 NRC-licensed institutions, we may estimate on the order of 10,000 man-rem occupational exposure from nuclear medicine procedures alone. (Exposure from additional licensed and non-licensed radiation sources in all medical institutions in the United States may be an order of magnitude higher.)

Exposure per mCi of Tc-99m administered has been shown to vary by a factor of more than 60 between 47 nuclear medicine departments surveyed.⁽¹⁾ Average exposures per employee increased about 25% over the 1968-73 period, and the integrated population (man-rem) dose increased 60% over the same period.⁽¹⁾ The use of licensed radionuclides in medical institutions is increasing at a rapid rate.⁽¹⁾

While the unnecessary dose is increasing, the average exposure per mCi injected has actually decreased from 0.47 mR/mCi to 0.11 mR/mCi,⁽¹⁾ and an estimated further reduction in Tc-99m exposures from 0.11 to 0.05 mR/mCi should be possible through the use of good radiation protection practice and properly planned facilities.^(1,6) This indicates that a factor of 2 reduction is probably achievable in the administration of Tc-99m. Other authors have also discussed the possibilities for reducing exposures from other radiation sources in hospitals, as well as from Tc-99m.⁽⁷⁻¹²⁾

Thus, it would seem reasonable to expect that exposure reductions of several thousand man-rem may result from the publication of this ALARA regulatory guide, which condenses into compact sections of one document the major recommendations of good radiation safety practice from over 50 literature sources and standards, as well as staff licensing and hospital experience.

II. IMPACT

There should be no adverse impact of this guide on any medical institution. Those medical institutions which, as indicated in the discussion section of the guide, have provided leadership in determining proper radiation safety procedures will already have established the programs recommended by

the guide. No new regulatory requirements that should cost money or extra time are included, since the recommendations can be found in one place or another in the already-established references cited, which basically document hospital experience in those institutions carrying out their safety responsibilities. The new license applicant, or hospital whose program is expanding, will be encouraged by this guide to provide better facilities, equipment and staffing in order to carry out regulatory requirements, license conditions, and ALARA objectives. Experience has indicated that provision of proper staffing and facilities in the areas of radiation safety (and associated medical physics) does not necessarily add to overhead costs, but may instead provide savings in the economy of operation of equipment and facilities and lower maintenance and repair costs. Ice⁽¹³⁾ has shown in a large university-medical complex that a properly organized and staffed Radiation Safety Office actually reduces costs by providing uniform standards and procedures, centralized control and processing of orders for radionuclides, professional consultation on research uses of radionuclides, and other services that would otherwise be paid for by individual investigators or physicians. A net favorable impact on health services may also accrue from the addition of science and engineering competence in using the many scientific tools in today's hospital.

The attached pages⁽¹⁴⁾ indicate a medical profession (ACR) opinion of the need and value of additional staffing in medical physics in hospitals. In most hospitals, the medical or radiological physics staff also carries at least part of the radiation safety responsibilities, and there is an interrelationship between the adequacy of the radiation safety program and management's recognition of staffing and facility requirements.

REFERENCES

1. R. C. Barrall, L. H. Lanzl, and J. W. Hilbert, "A Survey of Personnel Exposure in Nuclear Medicine," a special committee report to the American Association of Physicists in Medicine, August 3, 1975.
 2. S. R. Amtey and M. D. Douglas, "Personnel, Space, and Budget Needs of a University Radiation Safety Program," in P. L. Carson, W. R. Hendee, and D. C. Hunt, Eds., "Operational Health Physics," Proceedings of the Ninth Midyear Topical Symposium of the Health Physics Society, Feb. 9-12, 1976 (available from Central Rocky Mountain Chapter, Health Physics Society, P. O. Box 3229, Boulder, Colorado 80303). This reference also discusses medical institution programs in university medical centers.
 3. F. C. Watts, "An Analysis of the Roles and Responsibilities of the Medical Center Health Physicists," Health Physics 29, 924, 1975.
 4. A. Brodsky, S. Levin, and E. D. Durkosh, "Staff and Facility Requirements for Radiation Safety in Hospitals," Health Physics 29, 924, December 1975.
 5. R. P. Specht and A. Brodsky, "Log-Normal Distributions of Occupational Exposure to Medical Personnel," in press, Health Physics, 1976.
 6. R. C. Barrall and S. I. Smith, "Personnel Radiation Exposure and Protection from Tc-99m Radiation," presented at the annual meeting of the American Association of Physicists in Medicine, San Antonio, Texas, 1975 (available from Office of Health Physics, Safety and Health, 67 Encina Hall, Stanford University, Stanford, California 94305).
 7. J. St. Germain, "Operational Health Physics in Diagnosis," in DHEW Publication (FDA) 73-8029, "Health Physics in the Healing Arts," proceedings of the Seventh Midyear Symposium of the Health Physics Society, San Juan, Puerto Rico, Dec. 11-14, 1972 (available from Bureau of Radiological Health, FDA, DHEW, 5600 Fisher's Lane, Rockville, Maryland 20852).
 8. R. J. Cloutier and E. E. Watson, "Radiation Doses from Nuclear Medicine Procedures," in DHEW Pub. 73-8029, op. cit., pp 71-78.
 9. F. Dobrowolski, "Health Physics in Radiotherapy," ibid., pp 200-202.
 10. M. G. Mayes, R. L. Douglas, M. W. Carter, T. M. Grady, and E. van der Smissen, "Study of Radiation Exposure from Technetium Generators at Three Hospitals," ibid., pp 222-226.
 11. M. H. Lombardi, W. L. Beck, and R. J. Cloutier, "Survey of Radiopharmaceutical Use and Safety in Sixty-Nine Hospitals," ibid., pp 227-236.
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12. B. C. Fasiska, "Radiation Safety Procedures and Contamination Control Practices Involved in High Level I-131 Therapy Cases," in P. L. Carson, W. R. Hendee, and D. C. Hunt, Eds., op. cit., pp 287-291.
13. R. Ice, "Establishment of a University Radiation Safety Office," Health Physics 20, 444-446, 1971. (This paper also discusses a program encompassing a large university medical center complex.)
14. DHEW Publication No. (FDA) 74-8014, "Status and Future Manpower Needs of Physicists in Medicine in the United States," Preface by William S. Cole, M.D., 1973.

STATUS and FUTURE
MANPOWER NEEDS
of PHYSICISTS in MEDICINE
in the UNITED STATES

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by
The Joint Committee on Manpower Needs in Medical Physics
of
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and
The American Association of Physicists in Medicine

under
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U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
FOOD AND DRUG ADMINISTRATION
Bureau of Radiological Health
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PREFACE

This publication contains the final report of the American College of Radiology in cooperation with the American Association of Physicists in Medicine on the Status and Future Manpower Needs of Physicists in Medicine in the United States. The work for this publication was conducted as part of the continuing radiological health education project of the American College of Radiology and supported by the Bureau of Radiological Health through contract PH 86-67-202. The primary purpose of this study was to provide a basis for describing the job responsibilities of medical physicists in the radiological health sciences.

Included in the report is an estimate of the manpower needs for physicists and the influence of these needs on medical physics training programs. This estimate, based on the ratio of physicists to patient radiologic procedures at the responding institutions, reflects the present under-utilization of the profession. If the recommendation of the report (one medical physicist for each 300-bed hospital) is generally adopted, a doubling of this ratio may be considered conservative in terms of the rapid expansion in medical services but still within the currently available capacity for training medical physicists. However, the potential of staff physicists to increase quality of patient care, reduce radiation dosage, and increase efficiency of operation cannot be realized without the support of hospital administrators, chairmen of radiology departments, and licensing and accrediting agencies. Also needed are collaborative working relationships with radiologic technologists and radiologic engineers in both hospitals and industry.

This report is a continuation of supportive manpower activities in medical physics initiated by the Bureau of Radiological Health with publication of the 1965 "Research Report on the Training of Radiological Physicists," prepared by H. M. Parker. I hope this report will be useful in further promoting the role and training of physicists in medical radiation.

Mr. William C. Stronach (ACR), Mr. William K. Melton (ACR), Dr. Peter Almond (President, AAPM), and Dr. Robert D. Moseley (University of Chicago) deserve special thanks for their support and encouragement. Miss Linda Clark of LMC Consulting Company provided valuable advice on questionnaire layout and workup of computer data. Dr. William Van de Riet, Postdoctoral Fellow in Radiation Physics at the University of Cincinnati, provided valuable aid in data analysis and graphic presentation. The efforts of all AAPM members and Regional Medical Program Directors who completed the questionnaires are appreciated.

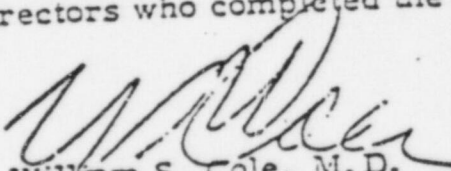

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TABLE 1
SUMMARY ANALYSIS OF PUBLIC COMMENTS **

		REG GUIDE 8.18	NUREG-0267
I. FAVORABLE*	TOTALS	30	27
a. Includes Suggestions for Changes		26	21
b. No Suggestions Given		4	6
II. NEUTRAL	TOTALS	25	18
a. Includes Suggestions for Changes		23	16
b. No Suggestions Given		2	2
III. UNFAVORABLE*	TOTALS	7	6
a. Includes Suggestions for Changes		3	3
b. No Suggestions Given		4	3

* Favorable - generally feel document is helpful;
Unfavorable - document generally detrimental
(value < impact)

** Includes letters of comment received from the public between January and July, 1978.