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PART V


FEDERAL REGISTER

# THE PRESIDENT

# RADIATION PROTECTION GUIDANCE TO FEDERAL AGENCIES FOR DIAGNOSTIC X RAYS

## Approval of Recommendations

presidential documents

[3195-01]

# Title 3—The President

## Recommendations approved by the President January 26, 1978

### Radiation Protection Guidance to Federal Agencies for Diagnostic X Rays

Recommendations 1 through 12 contained in the above[1] memorandum are approved for the guidance of Federal agencies; the Administrator and the Assistant Secretary for Health are directed to conduct programs, in accordance with their respective authorities and their Memorandum of Understanding (42 FR 5123), to interpret and clarify, as necessary, each of these recommendations in cooperation with affected Federal agencies; the Administrator is authorized to issue these interpretations and clarifications in the FEDERAL REGISTER; and this memorandum shall be published in the FEDERAL REGISTER.

Jimmy Carter

Recommendations have been developed and are hereby transmitted for the guidance of Federal agencies in providing radiation protection for patients in the application of diagnostic x rays.

Executive Order 10831 and Public Law 86-373 (42 U.S.C. 2021(h)) charge the Administrator of the Environmental Protection Agency (EPA) to ". . . advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States." In addition, the Assistant Secretary for Health in the Department of Health, Education, and Welfare (HEW) has a variety of responsibilities under the Public Health Service Act (Sections 301, 310, 311, and 354-360(f)) and the Federal Food, Drug, and Cosmetic Act bearing on the setting of health care policy and the use of radiation in the healing arts. These responsibilities, which have been delegated to the Food and Drug Administration (FDA), include research and training concerning radiation hazards, the development and promulgation of recommendations for radiation users, advise to the States, information for the public, performance standards for electronic products that emit radiation, and regulations for the sale, distribution, and use of medical devices.

Because of the special responsibilities of HEW involving national health care policy, which Federal radiation guidance for diagnostic x rays may impact directly, the Administrator and the Assistant Secretary join in requesting your approval of these recommendations. In this regard, on January 18, 1977, the two Agencies entered into a Memorandum of Understanding (42 FR 5123), which provides for the future development, within each Agency's respective authorities, of radiation protection guidance and, when necessary, updating of such guidance for uses of radiation in the healing arts.

*BACKGROUND*

Information on the diagnostic use of x rays in medicine and potential controls that could be applied without compromising benefits have been reviewed, and scientists and professionals within and outside the Government have been consulted in developing these recommendations. In this regard, we have benefited from the effort begun by the National Academy of Sciences—National Research Council for the former Federal Radiation Council to evaluate, interpret, and advise with respect to new knowledge on radiation effects and sources of population exposure. The report of the NAS-NRC Committee on Biological Effects of Ionizing Radiation was issued in 1972. One of its significant findings was that "[m]edical diagnostic radiology accounts for at least 90% of the total man-made radiation dose to which the U.S. population is exposed." More importantly, the Committee recommended that "[m]edical radiation exposure can and should be reduced considerably by limiting its use to clinically indicated procedures utilizing efficient exposure techniques and optimal operation of radiation equipment."

It is widely recognized by medical practitioners, medical physicists, and other scientists concerned with radiation protection that exposure due to medical uses of ionizing radiation represents a significant and growing source of exposure for the U.S. population and is also one that can be reduced by good practice. The National Council on Radiation Protection and Measurements

[1] In the original document Recommendations 1-12 preceded the statement of Presidential approval.

has concluded that whereas ". . . there can be no rational means . . . to limit radiation exposure prescribed for patients for necessary and proper diagnostic or therapeutic purposes[,] . . . steps can be taken to minimize unnecessary or medically unproductive radiation exposure. . . . Advantage should be taken of any new technology or procedure that will significantly reduce unnecessary diagnostic or medical exposure, both in individual examinations and treatments, and in the adoption of group screening practices."

An Interagency Working Group on Medical Radiation was formed by the Administrator on July 5, 1974, to assist in developing proposed guidance for diagnostic x rays. The Interagency Working Group determined that it is desirable and possible to reduce exposure from the diagnostic use of x rays in Federal facilities by: (1) eliminating clinically unproductive examinations, (2) assuring the use of optimal technique when examinations are performed, and (3) requiring appropriate equipment to be used. As a result of this consensus a subcommittee on prescription was established to examine factors to eliminate clinically unproductive examinations. Another subcommittee on technique was formed to examine the second and to some extent the third subject area where it might not be regulated by FDA's x-ray equipment performance standards, which became effective August 1, 1974. The reports of these subcommittees were made available for comment (41 FR 10705 and 27998) prior to completion of the Interagency Working Group report.

Proposed recommendations based upon the report of the Interagency Working Group were published for public comment (42 FR 4884) on January 26, 1977. In addition, there has been extensive commentary and discussion between EPA and HEW, as well as formal review by Public Health Service and other affected Federal agencies. The comments received have been carefully considered and a complete record, including a response to comments, is available to the public from the Public Information Reference Unit, Room 2922, U.S. Environmental Protection Agency, 401 M Street SW, Washington, D.C. 20460.

These recommendations were developed and reviewed in accordance with standard EPA procedures. Development of new or revised recommendations will be carried out under the Memorandum of Understanding referred to above, which provides also, when applicable, for the use of HEW procedures.

*DISCUSSION*

The most important factor in reducing radiation exposure is to avoid the prescription of clinically unproductive examinations. Appropriate prescription of x-ray examinations involves two major considerations: (1) the clinical decision to order a particular examination, and (2) the minimization of the number of radiographic views required in an examination. In particular, attention should be given to the qualifications of those who order examinations, the elimination of unproductive screening programs, and the use of appropriate clinical procedures to assure that unproductive views are not performed.

Although the largest savings in radiation exposure may be realized from avoiding the prescription of an unproductive x-ray examination, patient exposure can also be reduced by assuring that the examination is performed with good technique. The fundamental objective in performing an x-ray examination is to obtain optimum diagnostic information with minimum patient exposure. Achievement of this objective requires assurance that: (1) equipment is calibrated and properly functioning, (2) equipment is operated only by adequately qualified personnel, (3) the patient is appropriately prepared, and (4) technique factors that will minimize exposure are selected.

It has been demonstrated that the same technique factors used with different x-ray generators may produce widely varying patient exposures. Thus, the performance of x-ray equipment utilized for diagnostic x-ray procedures is an important factor in limiting patient and operator exposure. The Federal Diagnostic X-Ray Equipment Performance Standard (21 CFR Part 1020) requires that x-ray equipment manufactured after August 1, 1974, be certified by manufacturers to comply with radiation safety requirements issued by the FDA pursuant to the Radiation Control for Health and Safety Act of 1968 (PL 90-602). Utilization of medical and dental x-ray equipment that performs in accordance with the requirements of this performance standard by Federal health care facilities would provide a significant contribution to the minimization of patient exposure.

Without question the use of x rays in the healing arts provides large benefits to society through improved health care; thus, in developing guidance for radiation protection for diagnostic x rays it is essential to assure that benefits to patients from the use of medical and dental x rays are maintained. Medical personnel in both the Federal and the private sectors have been consulted and we are confident that these recommendations will neither interfere with the doctor-patient relationship nor impair the ability of Federal agencies to provide necessary radiologic services.

Appropriate follow-up and coordination with Federal agencies is also important to assure that these recommendations are implemented so as to maximize their effectiveness in reducing unnecessary radiation exposure, but at the same time to avoid any deleterious impact on the delivery of health care. The Memorandum of Understanding between EPA and HEW referred to above is designed to assure that the dual objectives of radiation protection and health care delivery are achieved in the implementation of this or any future radiation protection guidance applicable to the healing arts.

*RECOMMENDATIONS*

In view of the considerations presented above, the following recommendations are made for the guidance of Federal agencies in their conduct of radiation protection for diagnostic uses of x rays in the healing arts:

1. General radiographic or fluoroscopic examinations should be prescribed only by licensable Doctors of Medicine or Osteopathy or, for specified limited procedures, postgraduate physician trainees and qualified allied medical professionals under their direct supervision; specialized studies should be prescribed only by those physicians with expertise to evaluate examinations in the particular specialty. Exception for specified procedures may be made for dentists and podiatrists.

2. Prescription of x-ray studies should be for the purpose of obtaining diagnostic information, should be based on clinical evaluation of symptomatic patients, and should state the diagnostic objective and detail relevant medical history.

3. Routine or screening examinations, in which no prior clinical evaluation of the patient is made, should not be performed unless exception has been made for specified groups of people on

the basis of a careful consideration of the magnitude and medical benefit of the diagnostic yield, radiation risk, and economic and social factors. Examples of examinations that should not be routinely performed unless such exception is made are:

a. chest and lower back x-ray examinations in routine physical examinations or as a routine requirement for employment,

b. tuberculosis screening by chest radiography,

c. chest x rays for routine hospital admission of patients under age 20 or lateral chest x-rays for patients under age 40 unless a clinical indication of chest disease exists,

d. chest radiography in routine prenatal care, and

e. mammography examinations of women under age 50 who neither exhibit symptoms nor have a personal or strong family history of breast cancer.

4. Prescription of x-ray examinations of pregnant or possibly pregnant patients should assure that medical consideration has been given to possible fetal exposure and appropriate protective measures are applied.

5. The number, sequence, and types of standard views for an examination should be clinically-oriented and kept to a minimum. Diagnosticians should closely monitor the performance of x-ray examinations and, where practicable, direct examinations to obtain the diagnostic objectives stated by clinicians through appropriate deletion, substitution, or addition of prescribed views. Technique protocols for performing medical and dental x-ray examinations should detail the operational procedures for all standard radiographic projections, patient preparation requirements, use of technique charts, and image receptor specifications.

6. X-ray equipment used in Federal facilities should meet the Federal Diagnostic X-Ray Equipment Performance Standard, or as a minimum for equipment manufactured prior to August 1, 1974, the Suggested State Regulations for Control of Radiation (40 FR 29749). General purpose fluoroscopy units should provide image-intensification; fluoroscopy units for nonradiology specialty use should have electronic image-holding features unless such use is demonstrated to be impracticable for the clinical use involved. Photofluorographic x-ray equipment should not be used for chest radiography.

7. X-ray facilities should have quality assurance programs designed to produce radiographs that satisfy diagnostic requirements with minimal patient exposure; such programs should contain material and equipment specifications, equipment calibration and preventive maintenance requirements, quality control of image processing, and operational procedures to reduce retake and duplicate examinations.

8. Operation of medical or dental x-ray equipment should be by individuals who have demonstrated proficiency to produce diagnostic quality radiographs with the minimum of exposure required; such proficiency should be assessed through national performance-oriented evaluation procedures or by didactic training and practical experience identical to, equivalent to, or greater than training programs and examination requirements of recognized credentialing organizations.

9. Proper collimation should be used to restrict the x-ray beam as much as practicable to the clinical area of interest and within the dimensions of the image receptor; shielding should be used to further limit the exposure of the fetus and the gonads of patients with reproductive potential (21 CFR Part 1000.50) when such exclusion does not interfere with the examination being conducted.

10. Technique appropriate to the equipment and materials available should be used to maintain exposure as low as is reasonably achievable without loss of requisite diagnostic information; measures should be undertaken to evaluate and reduce, where practicable, exposures for routine nonspecialty examinations which exceed the following Entrance Skin Exposure Guides (ESEG):

| Examination (Projection) | ESEG (milliroentgens)* |
|---|---|
| Chest (P/A) | 80 |
| Skull (Lateral) | 300 |
| Abdomen (A/P) | 750 |
| Cervical Spine (A/P) | 250 |
| Thoracic Spine (A/P) | 900 |
| Full Spine (A/P) | 800 |
| Lumbo-Sacral Spine (A/P) | 1000 |
| Retrograde Pyelogram (A/P) | 900 |
| Feet (D/P) | 270 |
| Dental (Bitewing or Periapical) | 700 |

*Entrance skin exposure determined by the Nationwide Evaluation of X-Ray Trends program for a patient having the following body part/thickness: head/15 cm, neck/13 cm, thorax/23 cm, abdomen/23 cm, and foot/8 cm.

11. X-ray examinations for dental purposes should be prescribed only by licensable Doctors of Dental Surgery or Dental Medicine or properly supervised postgraduate dentists on the basis of prior clinical evaluation or pertinent history; neither a full-mouth series nor bitewing radiographs should be used as a routine screening tool in the absence of clinical evaluation in preventive dental care. Exception may be made for justifiable forensic purposes.

12. Open-ended shielded position-indicating devices should be used with the paralleling technique to perform routine intra-oral radiography and should restrict the x-ray beam to as near the size of the image receptor as practicable.

It is expected that each Federal agency will use these recommendations as a basis upon which to develop detailed standards tailored to meet its particular requirements. In order to assure appropriate implementation of these recommendations, the Administrator and the Assistant Secretary for Health will cooperate in carrying out their respective functions in accordance with the Memorandum of Understanding (42 FR 5128). The necessary coordination will be conducted to achieve an effective Federal program, including periodic interpretation and clarification of each of

the recommendations as required to reflect new information and changing technology. By so doing, it is expected that an achievable and reasonable reduction in x-ray exposure will be accomplished commensurate with a continuation of the vital benefits realized by the utilization of this important technology.

If the foregoing recommendations are approved by you as guidance for Federal agencies in providing radiation protection for patients in the application of diagnostic x-rays, it is further recommended that this memorandum be published in the FEDERAL REGISTER.

DOUGLAS M. COSTLE,
*Administrator,*
*Environmental Protection Agency.*

JULIUS B. RICHMOND, M.D.,
*Assistant Secretary for Health,*
*Department of Health, Education, and Welfare.*

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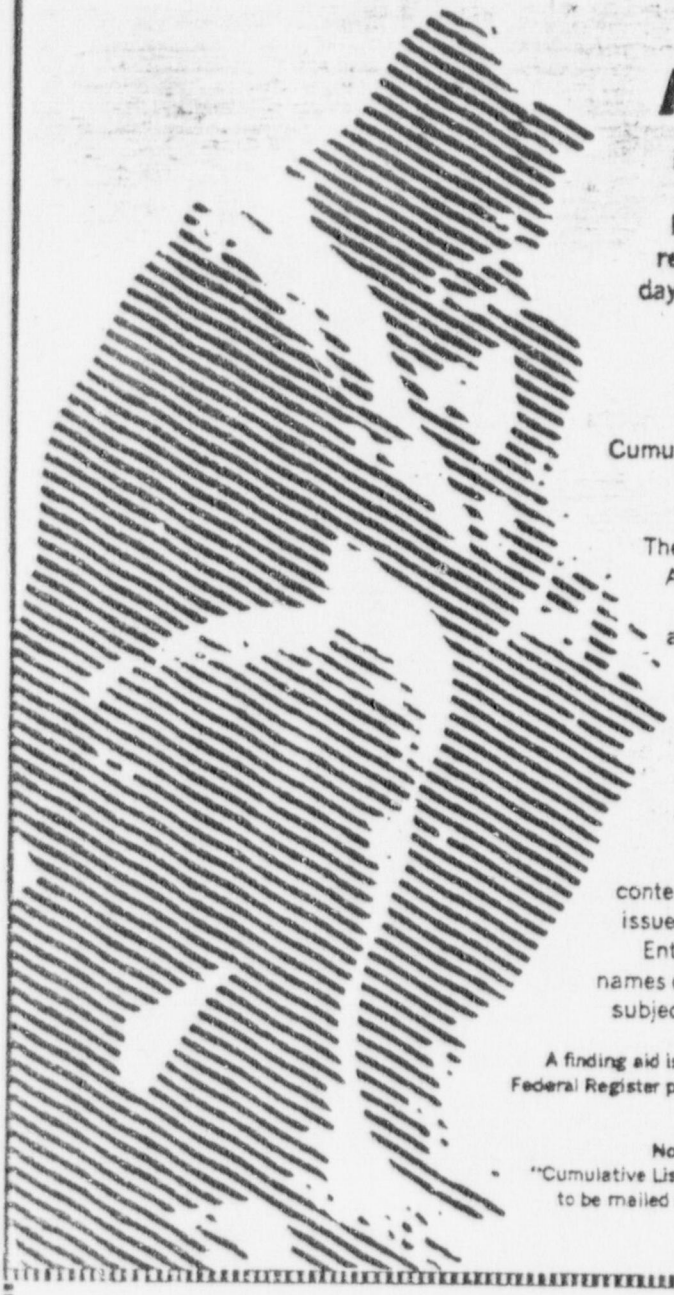

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