LM100498

00498

UNITED STATES
GENERAL ACCOUNTING OFFICE

Radiation Exposure From Diagnostic X-Rays Could Be Reduced

Food and Drug Administration
Department of Health, Education, and Welfare

The Radiation Control for Health and Safety Act provides for a program to protect the public health and safety from electronic product radiation. The Food and Drug Administration, which is responsible for administering the act, has issued performance regulations for diagnostic X-ray equipment, implemented a program to insure compliance with those regulations, and conducted educational programs to improve operator techniques in the use of X-ray equipment.

The agency's program could be strengthened by establishment of a uniform nationwide operator credentialing program, full implementation of compliance programs to insure the safety of diagnostic X-ray equipment, and issuance of guidance on who should be given diagnostic X-rays and when such X-rays are justified.

HRD-77-22

NOV. 24, 1976

UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

HUMAN RESOURCES
DIVISION

B-164031(2)

The Honorable
The Secretary of Health,
Education, and Welfare

Dear Mr. Secretary:

This report discusses our review of certain Food and Drug Administration and other Department of Health, Education, and Welfare activities to protect the public health from unnecessary exposure to radiation from diagnostic X-rays. The report contains recommendations to you for strengthening these activities.

As you know, section 236 of the Legislative Reorganization Act of 1970 requires the head of a Federal agency to submit a written statement on actions taken on our recommendations to the House and Senate Committees on Government Operations not later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report.

We are sending copies of this report to the appropriate Senate and House committees and subcommittees and to the Director, Office of Management and Budget.

We would appreciate being advised of your views and any action you plan to take regarding the matters discussed in this report.

Sincerely yours,

Gregory J. Ahart
Director

Contents

		Page
DIGEST		i
CHAPTER		
1	INTRODUCTION	1
2	NEED FOR UNIFORM NATIONWIDE OPERATOR CREDENTIALING PROGRAM	3
	Recognition of need for credentialing	4
	Moratorium on State credentialing	5
	Status of operator credentialing	7
	Proposed legislation	8
	Conclusion	9
	Recommendation	9
3	REGULATION OF X-RAY EQUIPMENT	10
	Many manufacturer reports not reviewed	10
	Limited inspections of manufacturers	11
	Conclusion	12
	Recommendation	12
4	NEED FOR GUIDANCE ON ORDERING X-RAY EXAMINATIONS	13
	Studies on need for criteria	13
	Criteria issued by FDA	14
	Conclusion	15
	Recommendation	15

ABBREVIATIONS

FDA	Food and Drug Administration
HEW	Department of Health, Education, and Welfare

BLANK

GENERAL ACCOUNTING OFFICE
REPORT TO THE SECRETARY OF
HEALTH, EDUCATION, AND WELFARE

RADIATION EXPOSURE FROM DIAGNOSTIC X-RAYS COULD BE REDUCED

Food and Drug Administration
Department of Health, Education, and Welfare

D I G E S T

In 1970, about 130 million civilians in the United States received 209 million diagnostic X-ray examinations during which 661 million X-rays were taken. Some of the radiation exposure from these X-rays was avoidable.

The Food and Drug Administration estimates that exposure to avoidable radiation may cause about 1,800 cancer deaths a year. The agency estimates that the annual cost for direct health care due to genetic damage from radiation is about $1.4 billion. (See p. 1.)

The Radiation Control for Health and Safety Act provides for a program to protect the public health and safety from electronic product radiation.

The Food and Drug Administration, which is responsible for administering the act, has issued performance regulations for diagnostic X-ray equipment, implemented a program to insure compliance with those regulations, and developed and conducted educational programs to improve operator techniques in the use of X-ray equipment. (See pp. 1 and 2.)

The Department of Health, Education, and Welfare (HEW) has authority under the Public Health Service Act to help develop and implement an operator credentialing program. (See p. 3.)

The agency's program could be strengthened by establishment of a uniform nationwide operator credentialing program, full implementation of compliance programs designed

to insure the safety of diagnostic X-ray equipment, and issuance of guidance on who should be given diagnostic X-rays and when such X-rays are justified.

The use of improper procedures by X-ray machine operators can result in unnecessary X-ray exposure to patients and operators. For several years HEW officials have recognized the need for improved operator performance and for some type of uniform credentialing for operators.

In January 1975, more than 100,000 persons were operating diagnostic X-ray equipment; about two-thirds were credentialed by State governments or private professional organizations as having achieved a certain level of education or competency. (See p. 3.)

Studies have indicated that many operators without credentials are not qualified to give diagnostic X-ray examinations and that existing credentialing programs do not insure that all credentialed operators are competent enough to properly protect the public health from the potential radiation hazards of X-ray examinations. (See p. 6.)

To minimize the risks to the public health from diagnostic X-ray radiation, the Secretary of HEW should work more vigorously with States and nonprofit private organizations to establish a uniform national operator credentialing program that would better insure the competency of X-ray machine operators. (See p. 9.)

Part of the Food and Drug Administration's program to insure compliance with its regulations includes (1) reviewing reports that manufacturers must submit on how each type of X-ray system and major component they market will meet the equipment performance standards and (2) inspecting manufacturers' records and facilities.

As of September 30, 1976, the agency had neither reviewed all reports submitted by manufacturers nor inspected all manufacturers' records and facilities.

According to agency officials, their responsibilities for regulating radiologic health have increased in recent years but resources necessary to effectively carry out these responsibilities have not.

As of September 30, 1976, the agency had reviewed 557 of 1,561 reports submitted by manufacturers. As a result of problems noted in 431 of these reports, the agency required manufacturers to either submit additional data or delay the sale of their equipment until the problems were corrected. Agency officials estimated that reviewing the other 1,004 reports would take at least 2 more years.

In addition, the agency had inspected only 57 of the 118 manufacturers. The officials estimate that inspections of the other manufacturers will be completed by September 30, 1977.

The Food and Drug Administration's review of manufacturers' reports and inspections of manufacturers' facilities are important steps in its program to assure compliance with Federal standards.

Therefore, the Secretary of HEW should direct the Commissioner of Food and Drugs to consider allocating additional resources to expedite the review of manufacturers' diagnostic X-ray equipment reports and the inspection of manufacturers. (See ch. 3.)

X-rays are important in diagnosing many diseases and injuries, but they are sometimes taken for reasons that are not medically indicated. These include routine X-ray screening of the general population and X-rays taken to protect against potential litigation.

The Food and Drug Administration has issued a policy statement discouraging the use of community chest X-ray programs for the general population.

On December 15, 1975, the agency issued a notice of its intention to issue proposed guidelines on medical radiation exposure of women of childbearing age. According to the notice, those guidelines will be among several to be proposed by the Commissioner for areas or activities inappropriate for mandatory control and they will be implemented through educational programs and cooperative activities with professional organizations and State health agencies.

The proposed guidelines concerning women of childbearing age are not expected to be issued until the fall of 1977. Issuance dates for guidelines on other uses of diagnostic X-rays have not been set.

The Secretary of HEW should direct the Commissioner of Food and Drugs to develop and publish additional policy statements regarding the use of diagnostic X-ray examinations. (See ch. 4.)

CHAPTER 1

INTRODUCTION

We have reviewed certain Food and Drug Administration (FDA) and other Department of Health, Education, and Welfare (HEW) activities to protect the public health from unnecessary exposure to radiation from diagnostic X-rays. FDA has estimated that the use of X-ray machines for diagnosis and therapy accounts for more than 90 percent of the total man-made ionizing radiation to which the U.S. population is exposed. Public Health Service estimates indicate that in 1970, the most recent year for which comprehensive data is available, about 130 million civilians in the United States received 209 million diagnostic X-ray examinations during which 661 million X-rays were taken.

The National Research Council of the National Academy of Sciences has stated that much of today's medical diagnostic X-ray exposure is unnecessary. Such exposure can cause effects in the individual exposed (somatic effects) as well as effects in offspring (genetic effects).

The major somatic illness caused by radiation is cancer. FDA estimates that exposure to avoidable radiation may cause about 1,800 cancer deaths a year. At the levels of radiation exposure used in diagnostic examinations, however, somatic illnesses generally do not appear until years after the initial exposure. Therefore, a direct causal relationship in individual cases generally cannot be established, and the relationship between illnesses and radiation in humans can only be shown statistically.

Exposure to ionizing radiation may also cause genetic mutations and chromosome changes. Some genetic changes, such as birth defects, are obvious and occur in the first generation; other effects may not appear for generations. Chromosome changes may cause malformations of offspring or embryonic death. FDA estimates that the annual cost for direct health care due to genetic damage from radiation exposure is about $1.4 billion.

On October 18, 1968, the Public Health Service Act (42 U.S.C. 201) was amended by the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263b) to provide for the establishment of an electronic product radiation control program to protect the public health and safety.

The program must include (1) the development and administration of performance standards to control radiation emissions from electronic products such as X-ray equipment and (2) research and investigation into the effects and control of radiation emissions.

FDA's Bureau of Radiological Health is responsible for developing and administering the radiation control program. Under this program the Bureau is responsible for establishing policies, standards, and procedures to protect the public health and safety and for conducting compliance activities to insure that manufacturers meet program requirements.

Most States also have radiation control programs and regulate X-ray equipment usage. An FDA regional radiological health representative and radiation control officer in each of 10 HEW regions assists officials of State radiation control programs by providing technical data, training, and specialized knowledge.

FDA has issued performance regulations for diagnostic X-ray equipment designed to protect the public from unnecessary exposure to radiation from such equipment and has implemented a program to insure compliance with those regulations. FDA also develops and conducts educational programs to improve operator techniques in the use of X-ray equipment. We believe FDA's program could be strengthened by (1) establishment of a uniform nationwide operator credentialing program, (2) full implementation of programs designed to insure the safety of diagnostic X-ray equipment, and (3) issuance of guidance on who should be given diagnostic X-rays and when such X-rays are justified.

CHAPTER 2

NEED FOR UNIFORM NATIONWIDE OPERATOR CREDENTIALING PROGRAM

The use of improper procedures by X-ray machine operators can result in unnecessary X-ray exposure to patients and operators. Unnecessary X-ray exposure can result from an operator's failure to (1) use lead-impregnated shields to protect body parts not being examined, (2) restrict the X-ray beam to the size of the image receptor, (3) limit the intensity of the X-ray beam to the lowest acceptable level, and (4) use proper exposure techniques (time, voltage, current, etc.) to avoid the need for retakes.

To insure that X-ray machine operators are competent, some State governments and professional organizations provide for operator credentialing. Credentialing takes three forms--accreditation, certification, or licensure.

--Through accreditation a government agency or professional organization recognizes an institution or program of study as meeting certain predetermined criteria or standards.

--Through certification a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications, such as graduation from an accredited or approved program, acceptable performance on a qualifying examination, or completion of a given amount of work experience.

--Through licensure a government agency grants permission for persons to engage in a given profession or occupation by certifying that they are competent enough to insure that the public health, safety, and welfare will be reasonably well protected.

In January 1975, the Bureau of Radiological Health estimated that more than 100,000 persons were operating diagnostic X-ray equipment. About two-thirds of the operators were licensed or certified by States or private professional organizations, such as the American Registry of Radiologic Technologists and the American Registry of Clinical Radiography Technologists.

Although the Public Health Service Act does not require the Department of Health, Education, and Welfare to develop

and implement an operator credentialing program, it does, according to HEW officials, give HEW authority to help States and nonprofit private organizations develop and implement such a program. Under section 792(c)(2)(F) of the act (42 U.S.C. 295), the Secretary of HEW is authorized to make grants or enter into contracts for special projects related to training or retraining allied health personnel, including developing, demonstrating, or evaluating techniques for appropriate recognition of previous training or experience.

RECOGNITION OF NEED FOR CREDENTIALING

As early as 1966, HEW officials recognized the need to improve X-ray operators' performance. In April 1966 HEW's National Advisory Committee on Radiation advised the Surgeon General that minimum legal standards of education, training, and experience for radiologic technologists would apparently be required to improve the way radiologic services are delivered to the public.

In June 1967 an HEW Task Force on Environmental Health and Related Problems observed that better control over radiation hazards was needed and stated that "all persons using X-ray equipment should be licensed to do so, after fulfilling written examinations as to their competency."

In its 1969 annual report to the Congress, dated April 1, 1970, on the administration of the Radiation Control for Health and Safety Act, HEW recommended that:

> "The Public Health Service should vigorously promote the licensure or certification of users of radiation sources in the healing arts. Licensure or certification should be uniformly applied at Federal and State levels. Full use should be made of model regulations to assure compatibilility between States."

In October 1970, HEW published, for use by the States, "Model Legislation for Users of Ionizing Radiation in the Healing Arts" to

> "* * * promote reductions in population exposure to radiation through improvement in the technological qualifications of the professional practitioners and technical personnel in the use of equipment and materials for medical radiation applications."

The model legislation provided for State regulation of persons who apply or supervise the application of ionizing radiation to human beings. It recommended minimum standards for the education, training, and experience of these persons and suggested that examinations be required for the licensed practitioners at the professional level and others at the technical level. In the preface to the model legislation, the Director of the Bureau of Radiological Health stated:

> "A major purpose of the Model Legislation is to encourage the establishment of an internal regulatory framework for certification of users of ionizing radiation which is consistent among the States."

MORATORIUM ON STATE CREDENTIALING

In July 1971 the Secretary of HEW submitted a report to the Congress entitled "Report on Licensure and Related Health Personnel Credentialing," as required by the Health Training Improvement Act of 1970 (P.L. 91-519). The report indicated that the need to improve the present systems of health-manpower credentialing seemed well documented. The report added, however, that it would be unwise to develop new statutes that would perpetuate existing State credentialing problems, such as the imposition of unnecessary requirements and conditions which limit the number of practitioners and place unnecessary economic burdens on persons attempting to become credentialed. The Secretary recommended that beginning on January 1, 1972, all States observe a 2-year moratorium on enacting legislation to establish new licensing programs. The moratorium encouraged the States and health professionals to review their total policy regarding licensure and the credentialing of health personnel. This report, according to an HEW official, was distributed to all State health professional licensing boards and health commissioners.

Two national health organizations--the American Hospital Association and the American Medical Association--also supported a moratorium on licensure. The American Hospital Association believed a moratorium was needed as a "holding action until long-range solutions are developed." The American Medical Association identified the need to remove obstacles to geographic mobility of health manpower caused by nonuniform State licensure laws. Neither association suggested how long the moratorium should last.

In November 1972, the National Academy of Sciences' Advisory Committee on the Biological Effects of Ionizing Radiations, in response to a 1970 request from the Federal Radiation Council, 1/ issued a report entitled "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation." The report recommended that appropriate training and certification of personnel be considered as a way to reduce radiation exposure from medical radiology.

In a June 1973 report entitled "Developments in Health Manpower Licensure," HEW recommended that the moratorium be extended for 2 years through December 31, 1975. The report stated:

> "* * * it is clear that more time is needed to assess properly some of the new directions that have been taken by State legislatures, licensing boards, professional organizations, and the educational community with respect to the credentialing of health manpower.
>
> "* * * during this time period, the examination of licensure and manpower credentialing, which continues as a significant Departmental activity, will result in rational manpower policies that will reflect the individual competence and proficiency of health practitioners and the concomitant availability of access to high-quality health care."

According to an HEW official, this report was transmitted to all State Governors, legislative bodies, health professional licensing boards, and health commissioners.

Two investigations, a proficiency examination and a survey of operator performance, completed during the 4-year moratorium indicated that many operators were not qualified to give X-ray examinations. These investigations indicated that the competency of both credentialed and noncredentialed operators needed to be improved.

Of the 666 credentialed (licensed or certified) operators who took the proficiency examination, 85 percent failed

---

1/The activities of the Federal Radiation Council were transferred to the Environmental Protection Agency when the latter was established on December 2, 1970.

to achieve the suggested passing score. Of the 217 noncredentialed operators, 99 percent failed. The operator performance survey showed that 46 percent of the 300 credentialed operators and 70 percent of the 260 noncredentialed operators evaluated failed to properly restrict the X-ray beam to the size of the film.

On March 31, 1974, the Institute of Public Administration and Robert R. Nathan Associates reported on their joint study of the feasibility of a national voluntary (non-Federal) certification system for health personnel, including X-ray technologists. The report, prepared under an HEW Resources Administration contract, concluded that a national system based on voluntary collaboration of certifying bodies is feasible. The report recommended that the system be administered by a "Council of Certifying Organizations for Allied Health Personnel" and that its members consist of certifying agencies, professional organizations, and other health-related organizations.

The report stated that the functions of such a council might include (1) establishing standards for certifying bodies, (2) determining operator certification criteria, (3) encouraging cooperation and joint activities, and (4) providing common administrative services.

STATUS OF OPERATOR CREDENTIALING

HEW's Public Health Service Subcommittee on Health Manpower Credentialing has drafted a proposal for a voluntary nongovernmental system of certification for persons in health occupations. Recommendations in the proposal include:

--Establishing a national certification council to (1) develop and evaluate criteria and policies for approving certification organizations, (2) help develop national standards for credentialing health occupations, and (3) apprise the Federal Government of approved certification organizations.

--Developing national credentialing standards to be adopted by a national council and State licensure agencies.

--Limiting reimbursement from Federal health care financing programs to health personnel who are licensed or certified.

--Encouraging States to strengthen the accountability and effectiveness of licensure boards to assure high-quality health services.

--Using proficiency examinations to measure competency of health personnel before credentialing.

--Adopting requirements and procedures to assure continued competency of health personnel.

The subcommittee is considering comments on the proposal from State and professional organizations.

PROPOSED LEGISLATION

During the 94th Congress, four bills (H.R. 559, S. 1261, S. 3239, and H.R. 5546) were introduced to amend the Public Health Service Act to provide for protection of the public health from unnecessary medical radiation exposure by improving the quality of X-ray technologists.

Under these bills the Secretary of HEW would be required to develop and issue to the States criteria and minimum standards for

--accrediting educational institutions conducting programs for training radiologic technologists or medical and dental practitioners and

--licensing radiologic technologists.

The Secretary would also be required to issue Federal criteria and standards within 1 year of the date of enactment. The States would be required to adopt similar criteria and standards within 2 years. The Secretary would be authorized to grant the States a 2-year extension. If a State failed to adopt such standards, the Federal Government would enforce Federal standards in the State. The States would be eligible to receive grants from the Secretary in amounts up to two-thirds of the first year and one-third of the second year costs of adopting criteria and standards for accreditation and licensure.

In testimony on H.R. 559 before the Subcommittee on Health and the Environment, House Committee on Interstate and Foreign Commerce, HEW officials stated that HEW favored protection of people from unnecessary exposure to radiation but opposed enactment of the bill. They said that

HEW favored Federal assistance to States that establish a licensure program. They added that HEW was considering several alternatives for improving performance of health personnel, including developing uniform national standards and establishing a voluntary national credentialing system.

CONCLUSION

For several years, HEW officials have recognized the need for some type of uniform credentialing for persons in health occupations, including those who operate diagnostic X-ray machines. Studies have indicated that many noncredentialed operators are not qualified to give diagnostic X-ray examinations and that existing credentialing programs do not insure that credentialed operators are competent enough to properly protect the public health from the potential radiation hazards of X-ray examinations.

A nationwide credentialing program would provide better control over operator performance.

RECOMMENDATION

To minimize the risks to the public health from diagnostic X-ray radiation, we recommend that the Secretary of HEW work more vigorously with States and nonprofit private organizations to establish a uniform national operator credentialing program that would better insure the competency of X-ray machine operators.

CHAPTER 3

REGULATION OF X-RAY EQUIPMENT

On August 15, 1972, the Food and Drug Administration issued performance regulations (21 C.F.R. 1020.30) for diagnostic X-ray products. The regulations prescribe performance standards for X-ray systems and their components manufactured after August 1, 1974, and require that they be certified by the manufacturer after that date as being in compliance with the standards. FDA permitted equipment to be certified before this date if such equipment met the performance standards.

Part of FDA's program to insure compliance with its regulations includes (1) reviewing reports that manufacturers must submit on how each type of X-ray system and major component they market will meet the standards and (2) inspecting manufacturers' records and facilities. FDA's efforts, however, have been limited because it lacks resources to fully implement these aspects of its regulatory program for diagnostic X-ray equipment.

According to officials of the Bureau of Radiological Health, FDA's responsibilities for regulating radiological health have increased in recent years but resources necessary to effectively carry out these responsibilities have not.

MANY MANUFACTURER REPORTS NOT REVIEWED

FDA regulations (21 C.F.R. 1010.2) require every manufacturer of diagnostic X-ray systems and components covered by Federal standards to certify that the equipment conforms to those standards. The regulations (21 C.F.R. 1002.10) also require that, before sale, the manufacturer submit to FDA an initial report for each model giving information on (1) model labeling, (2) intended and known uses, (3) compliance with applicable safety standards and specifications, (4) testing and measuring methods to insure quality control, and (5) installation and operation instructions. FDA reviews these reports to verify compliance with the standards.

After the required information has been submitted to FDA, the manufacturer may certify and sell the equipment. However, FDA can at any time disapprove the manufacturer's testing program upon determining (1) that the program does

not insure the adequacy of safeguards against hazardous electronic product radiation or (2) that the product does not comply with applicable standards. In such cases the manufacturer may not be allowed to certify or sell additional equipment until corrections are made, and he must correct, without cost to the purchaser, problems on equipment already sold.

As of September 30, 1976, FDA had received 1,561 initial and supplemental reports from 118 manufacturers but had reviewed only 557 reports from 90 manufacturers. In 431 of these reports, FDA identified problems and required the manufacturers to either submit additional data or delay sale of their equipment until the problems were corrected.

FDA officials estimated that reviewing the other 1,004 reports would take at least 2 more years.

LIMITED INSPECTIONS OF MANUFACTURERS

FDA regulations (21 C.F.R. 1002.31) provide for FDA's inspection of X-ray manufacturers' records to determine whether the manufacturers have complied with the Federal standards.

According to FDA officials, visits to manufacturers are made by teams of two or three FDA personnel. During the inspection the team generally (1) examines records to evaluate the firm's quality control and product identification programs, (2) determines if any major radiation safety problems exist, (3) verifies information submitted in the equipment reports, (4) tours the firm's manufacturing plant, and (5) interprets Federal performance standards. Problems noted are discussed with the firm's officials at the end of the visit, and FDA issues a trip followup letter to the firm. This letter includes important points discussed with the officials and actions the firm is to take as a result of the onsite visit.

As of September 30, 1976, FDA had visited, at least once, 57 of the 118 manufacturers who have been certifying diagnostic X-ray equipment for sale in the United States. Visits have been made to plants in the United States as well as some in Japan and several European countries. Several problems FDA identified during these visits related to component labeling and product testing procedures. Manufacturers of products not in compliance with performance standards were required to make corrections to units already sold as well as those in production or inventory.

FDA officials estimate that inspections of the other manufacturers will be completed by September 30, 1977.

CONCLUSION

FDA's review of manufacturers' reports on diagnostic X-ray equipment certification and its inspections of manufacturers' facilities are important steps in its program to assure compliance with Federal standards. Therefore, we believe FDA should complete those reviews and inspections not yet performed as soon as possible. Completing these steps would help insure that such equipment meets applicable standards.

RECOMMENDATION

We recommend that the Secretary of HEW direct the FDA Commissioner to consider allocating additional resources to expedite the review of manufacturers' diagnostic X-ray equipment reports and the inspection of manufacturers.

CHAPTER 4

NEED FOR GUIDANCE ON

ORDERING X-RAY EXAMINATIONS

X-rays are important in diagnosing many diseases and injuries, but they are sometimes taken for reasons that are not medically indicated. For example:

--Physicians and hospital administrators may require X-rays to protect against potential litigation.

--Firms may routinely require new employees to receive X-rays to provide a medical history in case of disability claims.

In a speech before the Health Physics Society in 1974, the Director of the Bureau of Radiological Health noted that radiology was one of the more useful diagnostic tools available. However, he said that a Public Health Service survey of medical and dental X-ray examinations showed that, between 1964 and 1970, the number of persons exposed to radiation one or more times increased 20 percent while the U.S. population grew only 7 percent. According to the Director, such an increase is understandable when one remembers the introduction in 1966 of Medicare, which provided elderly persons with more extensive health care. However, he questioned the clinical value of all these examinations and the need for multiple X-rays for one person.

STUDIES ON NEED FOR CRITERIA

Several study reports and articles by health personnel point out the need for criteria for deciding who should receive X-ray examinations and when they should be given.

--HEW's Advisory Committee on the Biological Effects of Ionizing Radiations reported in 1972 that X-ray exposure could and should be reduced by limiting its use to clinically indicated procedures. The committee recommended that consideration be given to restricting the use of X-rays to cases where there is a reasonable probability of detecting disease.

--According to an article in the April 1973 issue of Practical Radiology based on work performed under an HEW contract, the number of X-ray examinations

could have been reduced by up to 30 percent had they been used only when clinically indicated rather than as legal protection by firms against future job-related disability injuries or by physicians against malpractice suits.

--Radiation exposure of women has been of concern for many years because of the potential hazard to an unborn child. Some researchers and standard-setting organizations have recommended that, if practicable, women should be X-rayed only during the 10 to 14 days following the last menstrual period. The August 1974 report on an FDA-funded study conducted by the University of California's San Francisco Medical Center concluded, however, that there is no safe time for irradiating the lower abdomen or pelvis of women of reproductive age and suggested that a policy regarding exposure of women be developed.

--In January 1973 HEW, other Federal agencies, and professional organizations sponsored a conference to discuss the justification for X-ray examinations of the lower back required by some employers as legal protection against workmens' compensation claims. Some industrial physicians who participated in the conference indicated that preemployment lower back X-ray examinations are not useful in predicting back injury. The conference report recommended that the Federal Government study the efficacy of this type of X-ray examination. According to an FDA official, such a study has not been made.

CRITERIA ISSUED BY FDA

The Director, Bureau of Radiological Health, told us that criteria used in the selection of patients for X-ray examinations need to be improved and that FDA policy statements are an effective way to accomplish this.

In April 1973 FDA published a policy statement entitled "The Chest X-ray as a Screening Procedure for Cardiopulmonary Disease." The statement recognized that screening groups of the public may be productive, particularly in areas where incidences of tuberculosis are high and X-ray facilities are limited. However the statement noted that the community chest X-ray programs for the general population

are not productive in screening to detect tuberculosis, other pulmonary disease, or heart disease and recommended that such programs be stopped. This is FDA's only policy statement regarding the use of diagnostic X-ray examinations.

In the Federal Register of December 15, 1975, FDA issued a notice of its intention to issue proposed guidelines on medical radiation exposure of women of childbearing age. According to the notice, the agency was considering the development of guidelines to minimize unnecessary radiation exposure of developing human embryos and fetuses to ionizing radiation from diagnostic radiological examinations. These guidelines were to be among several to be proposed by the Commissioner to provide guidance on techniques for reducing unnecessary exposure from electronic product radiation. The notice further stated that some of these guidelines might be established for areas or activities inappropriate for mandatory control and that they would be implemented through educational programs and cooperative activities with professional organizations and State health agencies. The proposed guidelines concerning women of childbearing age are not expected to be issued until the fall of 1977. Issuance dates for guidelines on other uses of diagnostic X-rays have not been set.

Bureau personnel explained that, for most X-ray examinations, useful guidance cannot be developed without extensive research, which is costly in terms of both money and staff.

CONCLUSION

There is a need for Federal policy statements that provide health personnel, including physicians and clinical personnel, with criteria on who should be selected for X-ray examinations and when such examinations would be justified. Such criteria would help reduce the public's exposure to unnecessary X-ray examinations.

RECOMMENDATION

We recommend that the Secretary of HEW direct the Commissioner of FDA to develop and publish additional policy statements on the use of diagnostic X-ray examinations.