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EPA 520/4-76-019

**FEDERAL GUIDANCE REPORT NO. 9** 

## **RADIATION PROTECTION GUIDANCE**

**FOR** 

**DIAGNOSTIC X RAYS** 



ENVIRONMENTAL PROTECTION AGENCY

WITERAGENCY WORKING GROUP ON MEDICAL RADIATION

### FEDERAL GUIDANCE REPORT NO. 9

## RADIATION PROTECTION GUIDANCE FOR DIAGNOSTIC X RAYS

Interagency Working Group on Medical Radiation U.S. Environmental Protection Agency Washington, D.C. 20460

October 1976

#### **PREFACE**

The authority of the Federal Radiation Council to provide radiation protection guidance was transferred to the Environmental Protection Agency on December 2, 1970, by Reorganization Plan No. 3. Prior to this transfer, the Federal Radiation Council developed reports which provided the basis for guidance recommended to the President for use by Federal agencies in developing standards for a wide range of radiation exposure circumstances. This report, which was prepared in cooperation with an Interagency Working Group on Medical Radiation formed on July 5, 1974, constitutes a similar objective to provide the basis for recommendations to reduce unnecessary radiation exposure due to medical uses of diagnostic x rays.

The Interagency Working Group developed its recommendations with the help of two subcommittees. The Subcommittee on Prescription of Exposure to X rays examined factors to eliminate clinically unproductive examinations and the Subcommittee on Technic of Exposure Prevention examined factors to assure the use of optimal technic in performing x-ray examinations. Both subcommittees also considered the importance of appropriate and properly functioning equipment in producing radiographs of the required diagnostic quality with minimal exposure. Reports by these subcommittees were made available for public comment. The recommendations of the Working Group, the results of public participation, and other considerations form the basis for guidance recommended to the President for use by Federal agencies.

The recommendations contained in this report represent consensus judgment of the Interagency Working Group for the practice of diagnostic radiology by Federal agencies. Since the body of knowledge on both the radiation exposure and efficacy of x-ray examinations is rapidly changing, comments and suggestions on the areas addressed by this report will assist the Agency to conduct periodic review and to make appropriate revisions.

Russell E. Train

**Administrator** 

# **CONTENTS**

									P/	AGE
PREFACE										i
<b>MEMBERS</b>	)									iii
	CTION									
	SCOPE									
	TION OF X-RAY STUDIES									
	Qualifications to Prescribe X rays Screening and Administrative Programs Self-referral Examinations									
EQUIPMEN	Procedure and Review									13
EQUIPMEN	General Radiographic Equipment Fluoroscopic Equipment	• •	• •	•	•	• •	•	•	• •	13
TECHNIC				_			_			15
	Quality Assurance Equipment Operator Performance Patient Exposure Considerations									
DENTAL F	RADIOGRAPHY									23
	Prescription of Dental X rays Dental Operator Qualifications Dental Technic									
SUMMARY	AND RECOMMENDATIONS									26
REFEREN	CES									29

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#### INTRODUCTION

One of the most significant factors in good medical care is the use of x rays to diagnose and define the extent of disease or physical injury. Because of its diagnostic value, the per capita use of x rays in medicine and dentistry has expanded rapidly in the United States. This expanded use is also due to wider availability of services, new equipment, and an increase in sophisticated diagnostic examinations. Although many procedures now require less exposure per film, the increased number of procedures and use has resulted in an increase in the per capita exposure as well as that to the population. A number of medical and scientific groups generally agree that there is unproductive radiation exposure from x-ray uses that could, and should, be reduced.

Because of these factors and trends, the Environmental Protection Agency undertook a program in 1974 to develop, in cooperation with Federal agencies, guidance for reducing unproductive exposures to medical radiation in Federal facilities while maintaining high standards of health care. This guidance was developed pursuant to 42 U.S.C. 2021(h) wherein "...[t]he Administrator shall 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."

The first memorandum from the Federal Radiation Council was approved by the President on May 13, 1960, as guidance for Federal agencies. The first two recommendations in the memorandum develop the basic radiation protection guidance for Federal agencies: 1) that there should not be any man-made radiation exposure without the expectation of benefit resulting from such exposure, and 2) that every effort should be made to maintain radiation doses as low as practicable. The memorandum also includes recommended numerical radiation protection guides for radiation workers and individuals in the population. The first two recommendations apply to all radiation exposure, including those in medicine and dentistry; the numerical guides do not apply, however, to the purposeful exposure of patients by practitioners of the healing arts. Subsequent reports (2 through 8) and memoranda to the President applied these two basic principles to several types of radiation exposure. The purpose of this report is to apply these same principles to the use of diagnostic x rays and to develop recommendations which would be implemented by Federal agencies.

The guidance on use of diagnostic x rays in Federal activities was developed by an Interagency Working Group on Medical Radiation. The basic approach taken by the Working Group for reducing exposure from diagnostic uses of x rays in Federal facilities involved three principal considerations: 1) eliminating clinically unproductive examinations, 2) assuring the use of optimal technic when examinations are performed, and 3) requiring appropriate equipment to be used. A Subcommittee on Prescription of Exposure to X rays (SPEX), was established to examine the first; the Subcommittee on Technic of Exposure Prevention (STEP) considered the second. Both Subcommittees examined the third subject area from the standpoint of assuring that Federal equipment is as consistent as practicable with the performance standards issued by the U.S. Food and Drug Administration prior to required conformity.

The Interagency Working Group recognized that the most important factor in reducing radiation exposure is to eliminate clinically unproductive examinations.

2

Appropriate prescription of x-ray studies involves two considerations: 1) the clinical decision to order a particular examination, and 2) the minimization of the number of radiographic views required in an examination. The qualifications of those who order examinations, the elimination of unproductive screening programs, and appropriate clinic procedures were viewed by SPEX as being especially important to eliminating unproductive exposure.

Although the largest reductions in radiation exposure may be to preclude the prescription of an unproductive x-ray examination, patient exposure can also be reduced by assuring that good radiographic technic is practiced. In order to promote principles of good radiography in Federal activities, the Subcommittee on Technic of Exposure Prevention developed recommendations on quality assurance, radiographic technic, operator qualifications, and exposure guides for selected standard examinations.

Both Subcommittee reports were published and were announced in the *Federal Register* inviting public comment on the various considerations for appropriate x-ray prescription, technic, and equipment. These reports and the comments received were considered by the Interagency Working Group. This report presents the various subject areas addressed by the two Subcommittees which have been adjusted, where appropriate, to be responsive to comments and information received. The report includes discussions on the scope of the problem, prescription of x-ray studies, equipment, technic, dental radiography, and recommendations that are appropriate for guidance to Federal agencies.

#### PROBLEM SCOPE

Over 50 percent of the population receives at least one radiographic examination annually (1). Although the attendant benefits from the use of x rays in medicine are well recognized, the extent of use and the rate of increase in radiographic procedures in medical practice raise the question of whether there may be unnecessary risks to public health. It is well recognized that any amount of exposure to ionizing radiation represents incremental risk to the person being exposed and, under some exposure conditions, to any subsequent progeny.

Early in 1970, the former Federal Radiation Council initiated a comprehensive review and evaluation of the relevant scientific information on radiation protection that had become available in the previous decade, including exposure of the population to radiation from consumer products. The major part of this review was undertaken by the Committee on the Biological Effects of Ionizing Radiation (BEIR Committee) of the National Academy of Sciences – National Research Council.

Two of the major conclusions in the BEIR Committee's report (issued in 1972) were that "...medical diagnostic radiology accounts for at least 90% of the total man-made radiation dose to which the U.S. population is exposed..." and "...that it appears reasonable that as much as a 50% reduction in the genetically significant dose from medical radiology might be possible through improved technical and educational methods" (1). The United Nations Scientific Committee on the Effects of Atomic Radiation reached a similar conclusion in its 1972 report in stating its awareness that "...protection of the patient is probably the greatest factor in the control of population exposure." The findings of the BEIR and UNSCEAR committees are corroborated by numerous other professional and scientific groups and others who are carrying out research on the efficacy of diagnostic radiologic procedures. In 1959 and again in 1966, the National Advisory Committee on Radiation apprised the Surgeon General of the Public Health Service of the apparent overuse of diagnostic x-ray examinations (2).

Although there appears to be significant potential for reducing x-ray exposures to the population, such activities must be mindful of the large benefits of improved medical care afforded to society by appropriate use of diagnostic x rays. Thus, insofar as requisite quality radiographs may be obtained with lesser exposure, the expected net benefits would be enhanced. This consideration is emphasized by the National Council on Radiation Protection and Measurements, the International Commission on Radiation Protection, The American Academy of Family Physicians, the American College of Radiology, and other organizations concerned with elimination of unnecessary and unproductive radiation exposure (3,4,5,6). According to the BEIR Committee, "...the aim is not only to reduce the radiation exposure to the individual, but also to have procedures carried out with maximum efficiency so that there can be a continuing increase in medical benefits accompanied by a minimum of radiation exposure." Fortunately, good radiologic procedures result in both improved diagnosis and minimal patient exposure.

The problem of unnecessary risks associated with unwarranted x-ray examinations is compounded by the marked increase in the number of diagnostic x-ray examinations performed in the United States over the last decade. This increase is estimated to range

from one to four percent per capita annually (7). Surveys of x-ray exposures in diagnostic radiology practice in 1964 and 1970 indicate the following significant changes (8):

- 1. There was a 20 percent increase in the number of persons receiving one or more x-ray procedures from 108 million in 1964 to 130 million in 1970. The population increased only 7 percent during this period.
- 2. There was a 22 percent increase in the number of x-ray examinations performed from 174 million in 1964 to 212 million in 1970.
- 3. There was a 30 percent increase in the number of films exposed from 506 million in 1964 to 661 million in 1970.
- 4. The average number of films per radiographic examination increased from 2.2 in 1964 to 2.4 in 1970.

These trends have probably continued since 1970, especially insofar as increased film usage is concerned.

In 1971 the National Conference of Radiation Control Program Directors initiated the Nationwide Evaluation of X-ray Trends (NEXT) to assess patient exposure from specific routine radiographic examinations. Analysis of data from this program indicates that the weighted mean exposure for 9 of the 12 radiographic projections surveyed increased between 1973 and 1975.

The use of diagnostic dental and medical x-ray units is widespread. It is estimated that there are approximately 143,000 dental units and 135,000 general purpose medical units in the United States; of the diagnostic medical units 31 percent are used in hospitals, 34 percent in doctors' offices, 9 percent in chiropractors' offices, 6 percent in clinics, and 4 percent in podiatrists' offices while the remainder (about 8,000) are used for veterinary, educational, and research purposes (9). Approximately 5,000 dental and medical units are being used for diagnostic purposes in the Federal health care sector. Although the exact numbers and classifications of these units are not known, it is estimated that 40 percent are dental units. The Veterans Administration, which handles the purchases of the majority of x-ray units for Federal facilities, currently estimates the useful life of a unit at 10 years. This would suggest that nearly 500 new units are purchased annually for use in Federal facilities.

In summary, the problem to be addressed with respect to uses of diagnostic x rays involves the following factors: 1) radiographic procedures provide over 90% of all manmade exposure, 2) past trends indicate that the rate of use of radiology procedures is increasing faster than the growth in the population, thus placing a larger segment of the population at risk, 3) the number of films per patient is increasing, and 4) most scientific groups have concluded that a significant proportion of radiologic procedures may be unwarranted and the exposure for a needed examination is often higher than necessary. The task addressed by the Interagency Working Group on Medical Radiation was not one of examining whether the overall risks outweigh the benefits to the population, but rather the prescription of unproductive examinations or the use of less than optimum equipment or technic.

#### PRESCRIPTION OF X-RAY STUDIES

The most important factor in reducing radiation exposure is to eliminate clinically unproductive procedures by appropriate prescription of x-ray studies. The factors involved in appropriate prescription of x-ray studies were examined by the Subcommittee on Prescription of Exposure to X rays. The Subcommittee's report was published and made available for public comment on March 12, 1976 (10). The following discussion broadly summarizes the Subcommittee's report and takes into account information and comments received.

The ideal basis for prescription of a diagnostic x-ray examination is for a physician or dentist to have determined that sufficient clinical symptoms or history necessitate the examination. Many x-ray examinations are prescribed, however, that do not necessarily satisfy such clinical/historical prerequisites (66,82). The Subcommittee on Prescription of Exposure to X rays concluded that some of the major factors involved in ordering unnecessary x-ray examinations are:

Administrative Control or Convenience

Criticism and Legal

Intellectual Curiosity

Inexperience

Public Health Screening

Appropriate prescription of x-ray examinations involves two major considerations: the clinical decision to order a given examination, and the choice of the number and type of views required to conduct it within the principles of good radiological practice. Establishment of routine examinations either for administrative non-medical reasons or efficiency of clinic operation tends to be counterproductive to minimizing exposure. No x-ray examination should ever be routine, but should be based on clinical evaluation of the patient to determine its medical necessity.

#### Qualifications to Prescribe X rays

The level of qualifications of medical personnel authorized to prescribe diagnostic x-ray examinations is the most important factor in limiting the prescription of unproductive examinations. Clinicians who prescribe an x-ray examination have a dual responsibility to assure that requisite diagnostic information is obtained and that the radiation administered is done so only with commensurate benefit. Requests for x-ray examinations in general radiography or fluoroscopy in Federal health care facilities should be made only by Doctors of Medicine or Osteopathy who are eligible for licensure in the United States or one of its territories or possessions. Properly trained and physician-supervised individuals such as physician assistants, nurse practitioners, and persons in postgraduate medical training status do not have to meet the above requirements, but they should be under the supervision of a licensable physician.

6

In addition to the privileges for which broad qualifications are needed, there are a number of specialties which require only limited types of x-ray examinations. For example, Doctors of Dental Surgery or Dental Medicine may request appropriate examinations of the head, neck, and chest, although such requests are normally confined to the oral region. Podiatrists who have been granted clinical privileges may request x-ray examinations appropriate to their specialty.

It is recognized that medical students, interns, residents, and some physician assistants may not have developed medical judgment as to which test would be most efficacious. Such lack of experience is remedied by work under conditions where there is sufficient expert supervision to monitor the prescription of examinations and to provide appropriate medical assistance.

Variances to the above qualification requirements should occur only for emergency or life-threatening situations. Non-peacetime operations in the field and aboard ship could require such variances. Equipment designed for field use might need to be operated by those personnel available to assist in the performance of necessary medical services.

Any requests in specialized radiography and fluoroscopy, such as angiography, pneumoencephalography, computerized axial tomography, or other complex studies requiring many exposures should be made by persons having special training or expertise to evaluate the indications of the examinations. In recognition of this consideration, privileges to request such specialized examinations should be restricted to physicians and dentists meeting recommendations of Federal facility committees established to credential those who may prescribe general radiographic procedures and who have had advanced training in the medical specialty involved.

#### Screening and Administrative Programs

Many x-ray examinations are the result of screening programs or administrative decisions, the reasons for which may no longer be justifiable. In general, such examinations are not preceded by clinical evaluation by a physician to determine their need. All screening programs should be under the auspices of an appropriate medical staff committee which annually reviews and affirms the need to continue the program. This annual review should eliminate all routine or screening examinations which are not clinically justified. Other routine or screening x-ray examinations which should be carefully evaluated are pre-employment lower back studies and routine physical examinations which involve routine upper GI, barium enema, gall bladder, and IVP examinations (11). Examinations required by legislation for certain high risk populations in order to establish worker disability compensation should be evaluated carefully to determine their continuing necessity.

#### Chest X rays

Chest x-ray examinations to screen for tuberculosis in the general population are not justified except for certain high risk population groups (12,13). The U.S. Public Health Service, the National Tuberculosis and Respiratory Disease Association (now the American Lung Association), the American College of Chest Physicians, and the American College of Radiology have publicly opposed such screening programs. A

review board should establish that the expected incidence of tuberculosis is sufficiently high in a population before a screening program is started. The radiation exposure and economic considerations suggest that the primary screening examination for tuberculosis should be a tine or tuberculin test even in populations exhibiting a higher than average incidence of the disease (14); radiological examinations should be used only to follow-up clinical indications derived from such methods.

Where chest x-ray screening has involved large numbers of persons, it has been common practice to employ a photofluorographic technic to save time and expense. This technic uses a fluoroscope to produce an image of the chest which is then photographed on 70 mm film. Whereas the procedure is relatively fast and adaptable to examining patients quickly at mobile stations, the exposure per examination is often considerably higher than an x-ray examination performed on general purpose equipment which uses standard-sized films and screens. Also, the size and quality of the 70 mm film is such that only gross abnormalities can be diagnosed. Although the technic was perhaps justified a few decades ago when there was a high incidence of tuberculosis in the United States, the relatively higher exposure and lower diagnostic yield of this technic make its use generally impracticable even when chest x-ray screening may be justified. Whenever avoidable, Federal agencies should not use photofluorographic equipment to perform chest x-ray examinations.

A routine chest examination for hospital admission is not suggested nor presently required by the guidelines of the Joint Commission on Accreditation of Hospitals. A chest examination is currently not justified as a routine requirement for hospital admission due to the low yield of abnormalities diagnosed. A recent study of routine screening in a hospital population indicated that routine chest examinations, obtained solely because of hospital admission or scheduled surgery, are not warranted in patients under the age of 20 and the lateral projection can generally be eliminated in patients under age 40 (15). Careful evaluations should be made of the need for existing admission x-ray examinations and, of course, should precede the institution of new ones.

#### X-ray Examination of Pregnant Women

X-ray examinations which result in exposure of a fetus should be avoided whenever possible (16). In prescribing x-ray examinations for women who are or may be pregnant, clinicians should determine if a patient is or may be pregnant and whether the diagnostic information sought outweighs the potential risk to the fetus. This finding should be communicated to the x-ray facility so that it may conduct the examination in a way that the information is obtained at minimum risk to the fetus. Examples of exposures which may not be justified include routine prenatal chest and routine pelvimetry examinations for pregnant women who have otherwise received adequate prenatal care.

#### Mammography

Breast cancer in women is recognized as one of the significant causes of cancer death in the United States. Because of the importance of early detection in control and survival, an increased emphasis on the use of mammography has occurred. This technic has improved considerably, especially with respect to lowering exposure per examination with the development of low-dose mammography and xeroradiography; however, even at the current state of the art, these techniques often result in a dose of several rads to each

breast for a typical examination. Whereas the procedure is justified to examine symptomatic women at any age, the use of mammography to screen asymptomatic women is still being seriously examined by several groups, in particular, the National Cancer Institute and the American Cancer Society. A committee of the American College of Radiology has evaluated mammography data accumulated from the Health Insurance Plan (HIP) in New York and the National Cancer Institute. On the basis of this evaluation, the Committee recently presented interim recommendations on mammography screening to the U.S. Food and Drug Administration's Medical Radiation Advisory Committee (17).

Almost all groups which have issued recommendations about mammography agree that it should not be used routinely to screen asymptomatic women under the age of 35 for breast cancer. Likewise, most groups generally agree that above age 50 routine screening appears to be indicated. Data on the effectiveness of mammography screening of asymptomatic women between the ages of 35 and 50 has been uncertain for establishing firmly whether such screening was justified as part of routine programs to detect breast cancer. There has been no controversy over its recommended use as part of the evaluation of women of any age who have symptoms of the disease.

Asymptomatic women are defined as those without complaint, without history, without physical findings, and without a strong family history of breast cancer. Symptomatic women are those who exhibit clinical findings, including cysts or lumps, repeated pain, enlargement of the lymph nodes, fluid discharges or other abnormalities of the nipples or any change in the shape of the breast. Other risk factors include previous breast cancer, a family history of breast disease, an unusually early menopause and first pregnancies after the age of 30.

The American Cancer Society and the National Cancer Institute undertook a joint demonstration project in 1972 to evaluate the efficacy of routine mammographic examinations for 270,000 women in various age groups above age 35. Even though the efficacy of mammographic screening of women under age 50 was questionable at the time the project was started, it was believed that newer x-ray technic would result in lower radiation exposures such that younger women could be expected to derive an overall benefit from annual screening examinations which included mammography. Recent studies have questioned the efficacy of mammography as part of a screening program for early detection of breast cancer for women under age 50 (79). Because of recent controversy over mammography screening of asymptomatic women, the National Cancer Institute established three committees to evaluate all relevant data on risks and benefits. The first committee, which reevaluated the HIP data, has reported that mammography does not appear to be efficacious for asymptomatic women under the age of 50. The second committee reviewed radiation risk data and concluded that even with lower dose mammography the risk for each film appeared to provide an additional one percent to the current lifetime risk of breast cancer; thus, the benefit to screening large groups of women under age 50 would be questionable. The third committee, which is reviewing the pathological tissue of women in the HIP study, has not yet reported its findings. On the basis of these committee evaluations, the National Cancer Institute recently informed the directors of the 27 breast cancer detection centers that routine mammography should not be performed on asymptomatic women under age 50 (80). This communique also emphasized the need to continue providing mammography to women under age 50 who exhibit clinical symptoms or a strong family history as determined by their physicians and

recommended continued screening of asymptomatic women above age 50. This policy is also recommended for Federal agencies; however, because of the continuing development of new information on mammography, Federal agencies should periodically evaluate available data in order to reaffirm screening policies for asymptomatic women. Any change in this policy should be based on current data on yield, radiation risks, and economic and social factors. It is also recommended that mammographic procedures continue to be evaluated to develop technic that represents an appropriate balancing between low exposures and diagnostic accuracy.

#### **Cancer Patient Evaluations**

In many health care facilities it is common practice for cancer patients to receive extensive x-ray studies as part of their treatment planning and follow-up. Bagley, et al., have reported the effectiveness of several studies in managing the treatment of cancer patients admitted to the National Institutes of Health (18). Their findings indicate that once the primary diagnosis was made and confirmed for some cancers, the results of routine xray studies, such as a barium enema and an upper GI series, were found to have little influence in the treatment of the patient. These findings also suggest that the yield of certain x-ray examinations is too low to justify their use as a general screening tool for cancer evaluation. Although any study that would assist in the control of cancer in a patient can be justified, such examinations should be generally productive in the care and follow-up of a patient. For this reason, Federal facilities should periodically evaluate existing protocol studies to establish those that are appropriate for the initial evaluation of patients with carcinomas and any required follow-up care. It is particularly important to establish the appropriate studies for evaluating the various types of malignancy and its metastatic spread. In this respect, the American College of Surgeons recently recommended that tumor committees be established to periodically review cancer evaluations and management (19). Such requirements have also been established by the Joint Commission on Accreditation of Hospitals.

#### Self-referral Examinations

A 1970 study indicates that approximately 30% of the medical x-ray examinations in the U.S. were performed by non-radiologic clinicians (7). Some examinations performed by non-radiologists may occur because of the convenience of having the x-ray unit and the patient in the same location, or, in the case of civilian contract services, need to justify the equipment purchased or maintenance costs. Self-referral examinations are frequently performed by equipment operators lacking adequate training and having supervision by clinicians with inadequate radiologic experience.

Unnecessary radiation exposure caused by self-referral practices generally need not occur in Federal health care installations where facilities staffed by radiologists are normally provided. Exceptions could be small operational units, such as ships, field units, or isolated stations where the normal workload does not justify a staff radiologist. Thus, the conduct of self-referral x-ray examinations should be permitted only for a physician whose qualifications to supervise, perform, and interpret diagnostic radiologic procedures have been demonstrated to the appropriate authorities.

It is recognized that limited self-referral type examinations are performed in Federal medical centers in certain clinical specialties. The use of such self-referral x-ray examinations should, however, be limited to studies unique to and required by the specialty of the physician performing them and be consistent with a peer review policy.

Self-referral practices in contract civilian facilities should be prohibited. It has been shown that self-referral practices have led to overutilization (21). Exception may be made in remote areas where no practicable alternative exists.

#### Procedure and Review

Although the largest reduction in radiation exposure is to prevent the ordering of an unproductive x-ray examination, patient exposure can also be reduced by the diagnostician by careful consideration of the numbers and types of radiographs to be taken during the examination (22). These considerations can also be classified as prescription decisions. In conducting x-ray examinations, therefore, the diagnostician should be capable of making the best diagnosis possible and be aware of the quantity and potential risk of the radiation he is administering.

Each x-ray examination should be as objective-related as possible to accomplish the diagnosis with the minimum amount of exposure. Most x-ray facilities establish a set of standard examination procedures which specify the number and types of radiographic views to be taken when the procedure is performed. A periodic review of all standard examination procedures should be performed to determine if the established routine is achieving the objectives and whether modifications are warranted. Continuation of a standardized examination procedure should be predicated on satisfying the following criteria: a) the efficacy of the examination is sufficiently high to assure that the diagnosis could not have been made with less risk by other non-radiological means or a lower number of views, b) consideration of previous similar examinations performed with multiple views established that in a significant number of the cases all views were necessary for the diagnoses rendered, and c) the yield of the examinations offsets the radiation exposure delivered.

A periodic review of standard operating procedures should be made at least annually by the appropriate medical or dental staff committee with the advice of referring physicians. Such reviews should consider the consensus and advice of professional societies concerning the efficacy of radiologic examinations.

#### Minimum Number of Examinations and Views

A written outline containing the minimum number of views to be obtained for each requested examination should be made available to each clinician and equipment operator in every radiology facility. Beyond the specified minimum views, the examination should be individualized according to a patient's needs.

All examinations should be tailored to the individual department taking into account the equipment available. In some instances, certain examinations should be done only on certain types of equipment.

The outline of procedures should indicate who may authorize deviations from the standard set of views for any examination. Every effort should be made to reduce to a minimum the number of standard views for any examination. The necessity of additional views, such as comparison views, should be determined by the radiological diagnostician. In order to effect this important procedural aspect of the prescription of x-ray studies, it is recommended that the standard views for defined examinations be provided in a current document and that the number, sequence, and types of standard views for an examination be problem-oriented and kept to a minimum.

Follow-up for examinations are commonly done so that significant changes in clinical information are obtained for making proper decisions on continuation or alteration of the management of the patient. Such examinations may result in unnecessary patient exposure if repeated before significant changes in clinical information occur; therefore, it is recommended that they be done only at time intervals long enough to make proper decisions concerning continuation or alteration of treatment.

#### **Patient History and Physical Condition**

Important considerations in providing optimal diagnostic information at minimum patient exposure, are the role of radiologic diagnosticians and the information provided. Requests for x-ray examinations should be considered as medical consultations between the clinician and the diagnostician and should state the diagnostic objective of the examination and detail relevant medical history including results of previous diagnostic x-ray examinations and other relevant tests.

Whenever possible a radiologist should review all examination requests requiring fluoroscopy or multiple film studies, especially those associated with tomography or scanning techniques, before the examination is given and preferably before it is scheduled (23). For this reason, it is important that a thorough and accurate patient history be included with each examination request. Based upon a review of the history and previously documented studies, the radiologic diagnostician should direct the examination to obtain the diagnostic objective stated by the referring clinician through the addition, substitution or deletion of views. It is preferable that changes in the examination be done in consultation with the requesting clinician.

Patients are sometimes referred to another health care facility for medical care and previous x-ray examinations conducted at the first facility will be repeated. Only the studies needed for proper referral should be performed in the first facility. When examinations have been conducted prior to referral, these x-ray films should accompany the patient to minimize the need for additional diagnostic x-ray examinations and the added patient exposure (20). Films from such studies should also be put in the patients record or given to the patient for transfer to further reduce this kind of unnecessary exposure.

Another means by which the radiologic diagnostician may reduce patient exposure is to avoid any repeat examinations due to improper patient preparation for contrast media studies. Miller has reported that poor bowel preparation is a frequent cause of marginal or repeated contrast media studies of the lower GI tract (24). The radiology department can minimize the number of marginal studies of the lower GI tract by instituting pre-examination procedures to assure that patients have had the necessary

laxatives and enemas (20). It may also be advantageous to place bedridden, elderly, or constipation-prone patients on low-residue diets several days before scheduling the studies. Determination that a patient has had previous surgery before GI tract examinations could also help minimize the number of marginal studies. Similarly, the prior determination that a patient had taken any prescribed oral contrast media would prevent unnecessary retakes of such studies.

13

#### **EQUIPMENT**

Once the physician or dentist determines that the prescription of an x-ray examination is warranted for diagnostic purposes, other factors become important in limiting patient exposure. One of the more important factors is the design of x-ray equipment to be used in performing the examination. Minimization of patient exposure may not be accomplished even with well designed equipment unless appropriate quality assurance programs exist to keep it functioning properly and those who operate it are properly qualified to use the features of the equipment. These latter considerations are discussed in the chapter on Technic.

#### General Radiographic Equipment

The Nationwide Evaluation of X-ray Trends survey has 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 Subchapter J) requires that x-ray equipment manufactured after August 1, 1974, be certified by manufacturers to comply with performance standards issued by the U.S. Department of Health, Education, and Welfare pursuant to the Radiation Control for Health and Safety Act of 1968 (PL 90–602). All Federal health care facilities which perform diagnostic x-ray examinations should meet this standard sooner than required if practicable. Although it is possible to obtain variances for special medical and dental x-ray equipment purchased after August 1, 1974, Federal use of this variance should be minimized.

All existing, non-certified equipment being used is not necessarily substandard. In order to preclude substantial economic costs involved with large-scale replacement or retrofit of all non-certified equipment, while still providing for the elimination of equipment which is determined to be sub-standard with reference to currently accepted radiation safety standards, it is recommended that all non-certified medical and dental x-ray equipment meet the criteria in parts F.4, F.5, F.6, and F.7 of "Suggested State Regulations for Control of Radiation" (25). Whereas the above criteria do not meet the rigid requirements for certification according to the Federal performance standard, they provide adequate conformance with those parameters which affect radiation protection of the patient and operator. Assurance that the x-ray generator meets the "Suggested State Regulations for Control of Radiation" can be demonstrated with test equipment considerably less complex than that required to demonstrate compliance with the equipment performance standards for x-ray equipment required by 21 CFR Subchapter J.

Certain sections of the x-ray equipment performance standard provide for planned obsolescence, such as the provision which permits the use of non-certified components as replacement items in equipment manufactured before August 1, 1974. Although such use of non-certified replacement components is permitted until August 1, 1979, their use should be justified. Stockpiling of either x-ray equipment or components should also be minimized, since the technological advances in x-ray equipment tends to preclude its use.

To insure that x-ray equipment used is justifiably representative of present day technological advances, authorities should develop and periodically review a planned replacement schedule for all types of diagnostic x-ray equipment used in their programs.

#### Fluoroscopic Equipment

Although the aggregate population dose is larger from the use of general purpose diagnostic equipment, the highest exposures to individuals are generally associated with fluoroscopic examinations. Fluoroscopic examinations require large exposure rates for periods of time long enough to observe dynamic changes; thus, it is of utmost importance that Federal health care facilities give particular attention to minimization of fluoroscopic examinations. X-ray equipment should not exceed the medical mission of the facilities, i.e., fluoroscopy should not be available in facilities where qualified medical personnel are not assigned.

Because the reduction of patient exposure is considerable and the additional cost of image-intensified units is justifiable, fluoroscopic units which do not contain image-intensification systems should not be used. The retention of older non-image intensified units for the reason that they may not be used with great frequency should not be permitted because the patient exposure rates are an order of magnitude greater than intensified units. If the medical mission requires fluoroscopy, only image-intensified units operated by those with demonstrated competence should be permitted.

Specialized procedures (hip replacements, transphenoid hypophysectomy, biopsy and cannulizations via fibro optic scopes) may require fluoroscopic assistance. In order to provide fluoroscopic assistance for such special procedures and to minimize patient exposure, non-radiological specialists such as orthopedists, neurosurgeons, gastroenterologists, cardiologists, chest surgeons, etc. should where practicable only use equipment with electronic image holding features such as pulsed video-hold or equipment with similar low-exposure features. The advantage of such units is that the radiation exposure is about one-twentieth of that from continuous fluoroscopy and yet the image is adequate.

Non-radiologists who operate a special fluoroscopic unit should take a course of instruction in radiation safety which meets guidelines established by responsible authority and demonstrate competence in the use of this equipment. Such courses of instruction should be considered as a standard part of the training program for physicians who may have occasion to use such equipment in their practice. Use of pulsed video-hold or similar dose-saving special equipment should be approved by a senior radiologist in order to prevent use of such units for studies other than those for which they were designed. This consideration should be generally given to all special purpose equipment such as computer assisted tomography.

#### **TECHNIC**

The fundamental objective in performing an x-ray examination is to obtain optimum diagnostic information with minimum patient exposure. Achievement of this objective requires: 1) assurance that equipment is functioning properly and calibrated as required, 2) operation of equipment is only by competent personnel, 3) the patient is appropriately prepared, and 4) technic factors which will minimize exposure are selected.

The Subcommittee on Technic of Exposure Prevention considered each of these areas in developing recommendations to assure that good technic is employed in Federal health care facilities. Recommendations were made by the Subcommittee on quality assurance, radiographic technic, operator qualifications, and exposure guidance in the form of broad principles to be achieved by qualified professionals (81). The discussion that follows broadly summarizes the areas addressed in the Subcommittee's report, which was made available to the public on July 8, 1976, and takes into account appropriate comments and information received.

#### **Quality Assurance**

The production of consistent and high quality radiographs concurrent with minimal patient exposure depends on two important factors: quality performance of equipment and materials and optimal performance of the operator. Because of the complex interrelationship of equipment, technic, and procedural factors, each of which could affect radiographic quality and exposure, a functional quality assurance program to monitor the significant elements is desirable. Such a program is important to provide the diagnostician with consistent quality radiographs regardless of which operator or x-ray generator is involved in performing the examinations. There is considerable recognition of the need for quality assurance programs in diagnostic radiology. A Subcommittee of the Food and Drug Administration's Medical Radiation Advisory Committee views the existing lack of quality assurance programs in hospitals and outpatient facilities as a major source of unnecessary patient exposure and radiographs of poor diagnostic quality (26).

The benefits of consistently high quality radiographs and increased production efficiency would in themselves seem to provide compelling support for implementation of quality assurance programs in Federal health care facilities. In addition, it appears that a substantial portion of costs associated with a quality assurance program could be justified by savings of resources such as film, processing chemicals, and labor. Meeting the objectives of quality assurance requires periodic monitoring of equipment performance and standards of procedure. The design and scope of quality assurance programs are expected to vary. The program should be consistent with the clinical specialty and available resources.

#### **Equipment and Materials**

The quality performance of equipment and materials is determined by such factors as: 1) initial verification of equipment performance per specifications, 2) ongoing testing and calibrations of equipment, 3) periodic cleaning, adjustment, and preventive maintenance for equipment, and 4) verification of material performance. The level of

emphasis of each will vary according to the needs of each Federal health care facility. Therefore, the details for implementing each of these factors should be established by the responsible authority.

Quality assurance of equipment begins with assuring that upon completion of installation and calibration of newly purchased equipment, and prior to its clinical use, that it meets Federal regulations (27) and any additional performance requirements. Once equipment has been placed into service, periodic performance and preventive maintenance surveys should be conducted to provide prompt remedial action and continuing assurance of desired operation. It is important to monitor such parameters as x-ray tube potential, tube current, timer, beam quality, filtration, and focal spot size, especially when equipment is calibrated or receives preventive maintenance (27,28,29). Another factor which often affects the optimum use of x-ray equipment is the beam alignment and beam-limiting device.

Because of the importance of equipment and materials in producing high quality radiographs, equipment quality assurance programs should be established. These programs should contain equipment specifications, equipment calibration requirements, materials and equipment performance requirements, and preventive maintenance schedules. For equipment manufactured after August 1, 1974, the manufacturer is required by the Federal Equipment Performance Standard (21 CFR Subchapter J) to provide recommended preventive maintenance schedules which should be followed.

The quality of the finished radiograph depends upon the condition of the film prior to its use; thus, it is desirable to evaluate periodically the quality of unused film. Considerations of time, cost, and traumatized patients associated with repeat examinations also suggests the need for a program to ensure adequate evaluation and handling of films (30,31,32). All films should be handled and stored under carefully controlled light, temperature, humidity, and background radiation conditions so that fogging can be minimized (27,33,34). Use of "safe lights" to minimize film fogging requires the selection of proper filters for the particular wave length sensitivities of the films. Dark rooms should be designed and operated to eliminate light leaks.

A periodic review of film and film-screen combinations used and their performance is suggested to assure optimal high quality radiography with minimum patient exposure. Image receptors should be as sensitive as is practicable consistent with the requirements of examinations since the use of faster speed receptors generally reduces patient exposure (3,4,5). On the other hand, cursory acceptance of advanced speed films or screens should not occur at the expense of compromising necessary diagnostic information.

It is apparent that patient exposures can vary significantly just on the basis of film/screen considerations. Image receptor combinations recommended in the summary report of the First Image Receptor Conference on Film-Screen Combinations can be used as a current guide in this regard (35). The image receptor combinations discussed in this report represent a recent consensus of an assembled group of radiology experts. For most cases, the typically preferred receptors ranged from par-speed film/par-speed screen to par-speed film/high-speed screen combinations. Recent studies have shown that some of the newer film/screen combinations can achieve a reduction in exposure for the majority of diagnostic x-ray examinations by factors of two to four without a reduction

in quality of the image (36,37). Reductions in exposure can be achieved with certain technic factors by the use of rare earth intensifying screens together with suitable films which match the light emission characteristics of the screens. When their use is consistent with image quality requirements, the highest-speed film and film-screen combinations should be used.

The concurrent objectives of consistently high quality radiographs and minimized patient exposure also require quality film processing. Whether processing is accomplished manually or by machine, the quality of the equipment, materials, calibrations, housekeeping, and preventive maintenance are important.

Automatic processing machines can, with proper maintenance and monitoring, be used to obtain consistent high quality processing. Selection of processors should assure that the processing achieved provides an image commensurate with the level of resolution and consistency of the other components of the radiology system (31,38,39). A preventive maintenance protocol for automatic processors is particularly important because of the many moving parts susceptible to failure. The scheduled cleaning and maintenance recommendations of the equipment manufacturers or an equivalent should be followed.

The concentration and replenishment of chemical solutions, proper functioning of temperature, process speed, and other controllers are significant considerations of film processing equipment. One method of assuring quality of film processing is to use control films periodically, especially upon the introduction of new preparations of processing chemicals. Sensitometric strip techniques have been shown to be of value in monitoring the quality of film processing (27,40,41). In addition to these considerations, radiographic films should be stored, handled, and processed in appropriately equipped rooms. Periodic quality control inspections should be made for each aspect of film storage, handling, and processing that may affect radiographic quality or patient exposure.

#### **Operational Procedures**

Monitoring of operator performance is important to assuring that high quality radiographs are produced with minimized patient exposure. A procedural quality assurance program for the performance of x-ray examinations is important to this goal.

Upon receipt of an examination request, the x-ray equipment operator determines a patient's measurements, and in accordance with facility protocol, selects the film-screengrid combination, the kV, and the mAs. Some facilities have both single and three-phase x-ray generators and use several film-screen-grid combinations. In such situations, an upto-date technic chart which gives optimum values for each generator is especially important. The chart can be particularly important for unusual situations and when the usual operator is not available.

Reduction of the number of radiographic retakes is generally agreed to be important in eliminating unnecessary exposure. Common causes for retakes are patient motion, errors in exposure, collimation, or positioning. Values of reported retake rates have ranged from approximately two to ten percent (42,43,44,45,46). Some variation in retake rates is reflective of the medical specialty and whether the x-ray facility is in a clinic,

hospital, or teaching facility. Every reasonable effort should be made to eliminate retake examinations.

Unnecessary duplicate examinations result in costs and patient exposure that should be eliminated. Use of examinations on file is basic to this concern. This consideration has been addressed in a large-scale pilot project to automate scheduling and file room functions, which has shown a reduction in the number of duplicate examinations (47).

Monitoring by qualified technologists of the final processed radiograph for diagnostic quality before the diagnostician views it appears to be of value in identifying problem areas. Prompt monitoring provides for timely repeat examinations with minimum inconvenience and anxiety to the patient and provides notice of poor performance of equipment or operators (22). The recording of information related to retakes (e.g., the examination, projection, reason, technologist, x-ray generator, etc.) can assist in determining patterns of retakes and in decreasing their frequency.

#### **Equipment Operator Performance**

It is possible to obtain a range of radiographs considered diagnostically acceptable and have entrance skin exposure vary by a factor of six to ten because of the choice of the various technic factors (48,49,50). Operators should be cognizant of those technic interrelationships which accomplish minimized exposure. Federal agencies should assure that equipment operators involved in Federal health care delivery: 1) are adequately trained to produce a diagnostic quality radiograph, 2) know how to produce the prescribed radiograph with the lowest possible exposure, and 3) periodically demonstrate continuing occupational competence.

#### **Operator Qualification**

Responsible use of medical and dental x-ray equipment involves restricting its operation to properly qualified and supervised individuals. Such a policy should be established for each x-ray facility by the responsible authority upon the recommendations of medical and dental staff. Medical personnel eligible for utilization of x-ray equipment are physicians and radiologic technologists. Eligible physicians include radiologists and other physicians granted privileges in radiology on the basis of the needs of patients served by the facility. Such privileges might include the use of x-ray equipment by cardiologists for cardiac catheterizations and by dentists or podiatrists as part of their practice. Before physicians and dentists are granted radiology privileges they should have received adequate training in equipment use and radiation protection. However, specific protocols establishing the limit of radiology privileges to specified types of physicians or dentists should be part of the written policy statement.

Available evidence indicates that x-ray technologists who are trained and credentialed (registered, licensed, or certified by a state or voluntary credentialing organization) more often produce radiographs with lower average patient exposures than nontrained or noncredentialed operators (49,51). Such results should not be unexpected since many noncredentialed operators have little or no formal training in anatomy, patient positioning, or radiation protection practices. The analyses of Nationwide Evaluation of X-

ray Trends (NEXT) program (52) data and recent proficiency test results indicate that inadequately trained operators are likely to expose patients and themselves unnecessarily (49,53). Personnel responsible for patient preparation and positioning, selection of technic factors, radiation protection measures, and film processing should be trained to produce quality radiographs. They should also be able to optimize various technic factors of the x-ray equipment to produce the radiograph at the lowest practicable patient exposure and to use optimal procedures in working with patients and ancillary equipment to reduce to a minimum the number of repeat examinations (3,48,54,55). Performance of x-ray examinations by untrained personnel does not appear justified except for unusual circumstances.

Operator competence is normally achieved through the successful completion of a professionally approved training program which provides both a didactic base and sufficient practical experience. Such competence should be developed in accordance with training programs identical to or equivalent to those approved by the Council on Medical Education of the American Medical Association or the American Registry of Clinical Radiography Technologists.

Even though both didactic and practical training are necessary, the primary criterion is for each operator to accomplish and maintain a capability to perform optimal examinations. The American Society of Radiologic Technologists has advocated such a criterion (56). Continuing competence and professional growth should be encouraged with specific opportunities to further the person's knowledge and skills through attendance at workshops or by other means of training.

Other medical personnel such as nurses and laboratory technologists should not be eligible to operate x-ray equipment. Their use of such equipment could be warranted only in a life-saving or life-threatening situation during which qualified personnel as specified above are not available to perform the examination.

The above considerations for operators of x-ray equipment should be implemented by the responsibile authority in a protocol which details: 1) who may operate diagnostic x-ray equipment and the supervision required, 2) the education-training and/or proficiency requirements for x-ray equipment operators, and 3) requirements for continuing education and demonstration of proficiency. This policy should be reviewed periodically and revised as appropriate.

#### **Operator Responsibility**

The responsibility of operators in performing x-ray examinations should be discharged through adherence to prescribed protocol. The operator should not perform any examination which has not been prescribed by an authorized person. In performing an examination, he should prepare the patient on the basis of the requesting prescription and facility protocol. Patients should be attired suitably with all objects removed that might cause artifacts and be positioned properly. They should also be instructed when to hold their breath and on the position required in each view to prevent blurring of the radiograph due to motion.

Collimation of the x-ray beam and shielding of body areas not being examined minimizes unnecessary exposure. It is especially important to confine the useful beam to

the clinical area of interest (4,5,57,58). The beam size should be generally limited to the image receptor size or smaller. The operator has a responsibility to properly collimate the x-ray beam and to use shielding where appropriate and practicable to further limit the exposure of body tissues (3,22,48,59,60). Special effort should be made to protect the blood forming organs of children (58,61,62).

Particular care should be exercised when a fetus may be irradiated. It is important, therefore, that facility protocol concerning x-ray examinations of pregnant or possibly pregnant patients verifies that medical consideration has been given to possible fetal exposure prior to exposing the patient so that additional precautions may be taken. Such a procedure would provide a mechanism for the diagnostician to consult the referring clinician before conducting the examination or to alter the examination. If the examination could result in exposure of the fetus, operators have a responsibility to use shielding to minimize such exposure.

Minimization of the Genetically Significant Dose (GSD) has been a major goal of radiological protection for many years in order to provide protection for future generations. In an effort to reduce the GSD to the population, the U.S. Food and Drug Administration, in cooperation with its Medical Radiation Advisory Committee and the American College of Radiology, has developed a voluntary guideline (21 CFR 1000, Subpart C), which recommends the use of gonadal protection for those procedures in which the gonads lie within or are in close proximity to the x-ray field and where their exclusion would not compromise the clinical objectives of the examination (63). Specially designed shields for males were field tested during the course of developing the proposed guidelines and were found to be a desirable action for minimizing the GSD. This consideration is particularly important for those examinations which result in gonadal exposure of persons of reproductive potential due to the increasing use of x-rays in medical care (4,5,57,58,61).

#### **Patient Exposure Considerations**

Production of a radiograph results in two determinants: the qualitative evaluation by the diagnostician of the required diagnostic quality of the radiograph and the amount of radiation exposure required to produce it. Each radiograph is evaluated for acceptable quality by a technologist or the diagnostician. An explicit evaluation of exposure is not usually made for each radiograph, although a change in radiographic quality generally provides an indication of exposure variation. A periodic evaluation of exposures in accordance with appropriate guidelines for routine examinations would appear to provide a mechanism to indicate levels above which good technic was probably not used and appropriate actions are warranted to reduce such exposures.

The development of exposure guides necessitates consideration of those technic factors which most affect the exposure. Data from the Nationwide Evaluation of X-ray Trends (NEXT) were considered extensively by the Subcommittee on Technic of Exposure Prevention for this purpose (81). The NEXT data probably provide a representative profile of the practice of diagnostic radiology in the United States at the present time because they reflect the myriad of combinations of x-ray generator types, films and screens, film processing technic, contrast requirements, and a range of skills of equipment operators. Therefore, regardless of the specific details or combinations of all

these factors, the frequency distributions of entrance skin exposures (ESE) derived from the NEXT data were assumed to be sufficiently representative of the complex system of diagnostician preference, operator technic, and x-ray equipment performance for each of the selected standard examinations.

The distributions of ESE from the NEXT data are widely varying and generally cannot be described in terms of conventional distributions. However, for each distribution, there is a point above which the exposure is likely to be unnecessary due to poor equipment or less than optimal technic factors. The choice of the point in the distribution where exposures become unnecessarily high is difficult since it is necessary to allow for a normal range of diagnostician preference and state-of-the-art variations in x-ray generating equipment, ancillary equipment, and technic factors. Careful consideration of these factors and the ESE data from the NEXT program suggests that exposures above the third quartile (i.e., those in the fourth quartile) probably represent unnecessary exposure. In order to determine whether exposures in the fourth quartile were unnecessary, the military services reviewed such surveys to determine whether adjustments in equipment and technic factors could be made to reduce the ESE below the fourth quartile without significantly affecting image quality. For these surveys, it was found that minor adjustments in technic could reasonably be made to reduce values of ESE below the fourth quartile. The measured ESE values for selected standard examinations above which it was determined that practicable measures should be taken to evaluate and reduce exposures are as follows:

Examination (Projection)	ESEG (milliroentgens)*					
Chest (P/A)	30					
Skull (Lateral)	300					
Abdomen (A/P)	750					
Cervical Spine (A/P)	250					
Thoracic Spine (A/P)	900					
Full Spine (A/P)	300					
Lumbo-Sacral Spine (A/P)	1000					
Retrograde Pyelogram (A/P)	900					
Feet (D/P)	270					
Dental (Bitewing or Periapical)	700					

<sup>\*</sup>Entrance skin exposure determined by the NEXT program for a patient with the following body part/thickness: head/15 cm, neck/13 cm, thorax/23 cm, abdomen/23 cm, and foot/8 cm.

There are several examples for the use of the third quartile as the level above which patient exposures could be considered excessive. In the consideration of the range of exposures utilized for chest examinations as represented by NEXT survey data, a Bureau of Radiological Health staff report noted that "exposures falling above the third quartile can be considered as overexposures to patients" (49). The Illinois Division of Radiological Health, Department of Public Health, reasoned that if 75% of the existing facilities could obtain a clinically acceptable radiograph by exposing patients below that level, then the other 25% of facilities should be able to alter their technic to reduce unnecessarily high radiation exposure (64).

22

The decision that exposure guides should be at the third quartile of the NEXT data accommodates these considerations. It is important, however, to emphasize that good technic can be selected which will generally produce practicable levels of exposure well below these guides. For each type of x-ray examination there exists, within available technology, an optimal combination of type of x-ray generator, technic factors and ancillary equipment to produce a diagnostic radiograph at optimal exposure. Hence, it is important to evaluate each system to determine what exposure is as low as reasonably achievable and to establish procedures that routinely assure that exposures are consistently near that exposure level. Such determinations require an evaluation of the diagnostic requirements, generators, films, screens, technic factors, etc. of each facility. In certain instances, it may be reasonable to exceed the exposure guide for the purpose of specified diagnostic information. The decision to exceed a guide should be based on an evaluation that the need for the diagnostic information justifies the additional exposure.

It is emphasized that these proposed guides apply to exposures for routine or non-specialty examinations and their implementation could be done with a reasonable expenditure of resources without restricting the diagnostician's preference for image receptor combinations and radiographic technic.

#### **DENTAL RADIOGRAPHY**

One of the most common radiographic procedures an individual is likely to receive as a part of health care is a dental x ray. A large portion of the U.S. population visits a dentist one or more times each year for routine checkups and associated dental care. The 1970 study of population exposure to x rays estimated that 661 million radiographic films were produced in 1970 and of this number 279 million were dental films (7).

A dental patient has a good chance of receiving a dental x ray even though he may have no immediate dental problems. A study of dental radiography in Nashville, Tennessee indicated that 57 percent of the facilities surveyed routinely do interproximal examinations each year on regular patients and 21 percent do a full-mouth series every one to three years; on new patients 58 percent routinely do interproximal examinations and 64 percent selectively do a full-mouth series (65). The mean exposure per film in the Nashville study was 542 mR in 1972; after an educational program the mean dropped to 340 mR per film, indicating the value of carefully controlled procedures in reducing patient exposure due to dental radiography. Because of the increased use of dental radiography in the United States, it appears reasonable to optimize the exposure per film and the number of films per examination.

#### Prescription of Dental X rays

The proper decision to use x-ray studies in dental examinations should be based on a requirement for proper diagnosis or definition of disease and the number of radiographs should be the minimum necessary to obtain the essential diagnostic information (6). It is recommended that dental radiographs be taken only after a dentist has examined the patient and established by clinical indication the need for the x-ray examination; neither a full mouth series nor a bitewing series is justified as part of periodic preventive dental care. This recommendation is consistent with those of the American Dental Association which also decidely disagrees with any requirement to provide post-operative radiographs as proof of services rendered (67). A full mouth radiograph of the teeth and jaw structure may be justified for forensic purposes for military personnel.

As in general medical radiology, the qualifications of those who order dental x rays are important to eliminating unproductive radiation exposure in dentistry; thus, privileges to request dental x-ray examinations should be limited to Doctors of Dental Surgery or Dental Medicine who are eligible for licensure in the United States or one of its territories or commonwealths. Exception may be granted only for persons in post graduate training status under the supervision of a person meeting such requirements.

#### **Dental Operator Qualification**

Dental equipment operators should receive appropriate education and training in the areas of anatomy, physics, technic principles of radiographic exposure, radiation protection, radiographic positioning, and film processing that are relevant to dental radiography. Such proficiency can be met by satisfying the Guidelines for Dental Hygienist and Dental Assistants Training Programs in Dental Radiography adopted by the Oral Radiology Section of the American Association of Dental Schools. These guidelines were developed to assure the protection of the public and improve the diagnostic yield of dental radiographs. Primary objectives of the guidelines are that "...upon completion of a dental radiology training program the dental hygienist and dental assistant should be able to:

- 1. Express and practice radiological health measures that are required by legal and/or ethical considerations;
- 2. Describe and demonstrate competency in theoretical considerations underlying radiation hygiene and radiological practice;
- 3. Expose, process, evaluate for quality, mount and file radiographic projections usually involved in dental practice; and
- 4. Produce films with density, definition, contrast and other attributes of sufficient diagnostic value to the dentist" (68).

#### **Dental Technic**

Important factors in dental technic for reducing patient exposure are the accurate positioning and the use of the smallest practicable x-ray beam to the clinical area of interest. Collimation for dental x-ray systems to limit the beam should be in accordance with the beam diameter at skin entrance requirement of the Federal Diagnostic X-ray Equipment Performance Standards [21 CFR 1020.31(f)]. Significant advances in exposure reduction have been shown by the use of open-ended shielded positionindicating devices and a number of voluntary standard-setting organizations have recommended their use (54,69,70,71). In 1968, the Council on Dental Research of the American Dental Association (ADA) developed a set of recommendations which includes the use of shielded open-ended cylinders (72). The Department of Health, Education and Welfare has also concluded that dental practitioners should be encouraged through increased educational and training activities to adopt the paralleling, long-cylinder (source-to-cylinder tip distance greater than 30 cm) technic which uses the long openended shielded position indicating device in order to obtain the optimum balance between film quality and minimized exposure (73). Regardless of other technic considerations, the useful beam should be limited insofar as practicable to the clinical area of interest through the use of definitive beam collimation and body shields.

In addition to the essential considerations of collimation, the general recommendation to use the fastest speed image receptor consistent with diagnostic requirements is again most important and appropriate. In 1968 the ADA Council on Dental Research recommended that dental clinics "...use the fastest speed film available" and that they "...request film of ANSI group rating of "D" or faster" (72,73). Because patient exposure can be reduced with adequate film quality, it is recommended that such films be used for intra-oral radiography when they are consistent with image quality requirements.

It is recognized that the technic and technology of dental radiography are continually evolving and that new methodologies will be refined to provide practicable alternatives to current ones. The desirability of limiting the x-ray beam size to that of the image receptor has been accomplished only recently, for example, by rectangular

collimation (74,75,76,77). Another approach which involves placing a new focused radiation source within the mouth to reduce patient exposure is currently being investigated at the National Institute of Dental Research (78). Therefore, recommendations for dental radiography will, of necessity, need periodic review and appropriate revision.

26

#### **SUMMARY AND RECOMMENDATIONS**

This report has examined the elements of good radiography, the fundamental objective of which is to obtain optimal diagnostic information with minimum patient exposure. Achievement of this objective requires elimination of clinically unproductive examinations, the use of appropriate and properly functioning equipment, and the use of optimal technic by qualified operators. Satisfactory accomplishment of each of these requirements depends on sound judgment applied to a wide range of individual situations; thus, the recommendations developed for Federal agencies are directed towards the achievement of broad principles by qualified professionals. The programs of various Federal agencies should continue to develop basic information and optimal procedures for meeting these broad principles.

Recommendations for guidance to Federal agencies for prescribing and performing medical and dental radiographic procedures in order to minimize unnecessary exposure without loss of requisite diagnostic benefits are as follows:

- 1. General radiographic or fluoroscopic examinations should be prescribed only by licensable Doctors of Medicine or Osteopathy; specialized studies should be prescribed only by those physicians with advanced training in the particular specialty. Exception for certain limited procedures may be made for dentists and podiatrists or properly-trained physician assistants, nurse practitioners, and physicians in postgraduate training status.
- 2. Prescription of an x-ray study should be a medical consultation between the clinician and the x-ray diagnostician, be based on clinical evaluation of the patient, and should state the diagnostic objective and detail relevant medical history.
- 3. Routine or screening examinations in which no clinical evaluation is made should not be performed; exception may be made for high risk groups on the basis of careful consideration of diagnostic yield, radiation risk, and economic and social factors. Examinations which should not be routinely performed are:
  - a) chest and lower back x-ray examinations in routine physical examinations or as a Federal requirement for employment,
  - b) tuberculosis screening by chest radiography,
  - c) chest x rays for hospital admission of patients under the age of 40 unless a clinical indication of chest disease exists,
  - d) chest radiography in routine prenatal care,
  - e) mammography examinations for women under the age of 50 who do not exhibit symptoms or have a strong family history of disease.
- 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 problem-oriented and kept to a minimum. Diagnosticians should closely monitor the performance of x-ray examinations, and, where practicable, direct examinations to obtain diagnostic objectives stated by clinicians by appropriate addition, substitution, or deletion of prescribed views. Technic protocols for performing medical and dental x-ray examinations should detail the operational procedures for all standard radiographic projections, patient preparation requirements, use of technic charts, and image receptor specifications.
- 6. X-ray equipment used in Federal programs should meet, where practicable, Federal performance standards (21 CFR Subchapter J) sooner than required, or in the interim, the 1974 "Suggested State Regulations for Control of Radiation." General purpose fluoroscopy units should provide image-intensification; fluoroscopy units for non-radiology specialty use should, when practicable, have electronic image-holding features. 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 materials 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; these individuals should be qualified by didactic training and practical experience identical to or equivalent to those programs approved by the Council on Medical Education of the American Medical Association or the American Registry of Clinical Radiography Technologists for medical x-ray equipment operators, or for dental equipment operators, the guidelines of the Oral Radiology Section of the American Association of Dental Schools.
- 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 when such exclusion does not interfere with the examination being conducted.

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

Examination (Projection)	ESEG (milliroentgens)*					
Chest (P/A)	30					
Skull (Lateral)	300					
Abdomen (A/P)	750					
Cervical Spine (A/P)	250					
Thoracic Spine (A/P)	900					
Full Spine (A/P)	300					
Lumbo-Sacral Spine (A/P)	1000					
Retrograde Pyelogram (A/P)	900					
Feet (D/P)	270					
Dental (Bitewing or Periapical)	700					

<sup>\*</sup>Entrance skin exposure determined by the NEXT program for a patient with the following body part/thickness: head/15 cm, neck/13 cm, thorax/23 cm, abdomen/23 cm, and foot/8 cm.

- 11. Dental x-ray examinations should be prescribed only by licensable Doctors of Dental Surgery or Dental Medicine or properly supervised postgraduate dentists on the basis of clinical evaluation or pertinent history; neither a full-mouth series nor bitewing radiographs should be part of routine preventive dental care. Exceptions may be made for certain forensic purposes.
- 12. Intra-oral radiography should be performed with open-ended, shielded, position indicating devices having a source-to-cylinder tip distance greater than 30 cm and dental film which meets the requirements of ANSI speed group rating "D" or faster; the x-ray beam should be as near the size of the image receptor as practicable.

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