

TB MED 521

**TECHNICAL BULLETIN
OCCUPATIONAL AND
ENVIRONMENTAL HEALTH**

**MANAGEMENT AND CONTROL OF
DIAGNOSTIC X-RAY,
THERAPEUTIC X-RAY,
AND GAMMA-BEAM EQUIPMENT**

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**HEADQUARTERS DEPARTMENT OF THE ARMY
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 DEPARTMENT OF THE ARMY
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OCCUPATIONAL AND ENVIRONMENTAL HEALTH
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CHAPTER 1

GENERAL

Section I. INTRODUCTION

1-1. Purpose. This bulletin establishes Department of the Army (DA) policies, procedures, reporting requirements, and radiation protection practices related to the planning, acquisition, installation, calibration, maintenance, evaluation, and use of diagnostic and therapeutic x-ray and gamma-beam equipment having energies up to 10 million electron volts. This bulletin implements those provisions of:

a. Title 21, Code of Federal Regulations (CFR), chapter 1, subchapter J, Radiological Health, that apply to diagnostic medical and dental x-ray systems and their major components.

b. Presidential guidance to Federal agencies on radiation protection for diagnostic x-rays promulgated by the Environmental Protection Agency in 3 CFR subchapter B (Federal Register, Vol. 43, No. 22, 4377, 1 February 1978).

c. National Council on Radiation Protection and Measurements (NCRP) contained in NCRP Reports No. 33, 35, 36, and 49.

1-2. Scope. a. This bulletin is applicable to all

Active Army, US Army National Guard (ARNG), and US Army Reserve (USAR) elements worldwide, possessing, using, or maintaining diagnostic or therapeutic X-ray or gamma-beam equipment.

Note. The words "he," "his," and "him" as used in this bulletin are intended to include both the masculine and feminine genders and any exception to this will be so noted.

b. Policies and procedures for the acquisition of X-ray and gamma-beam equipment are contained in AR 40-61 and *SB 8-75-MEDCASE. These policies and procedures shall be followed for the acquisition of X-ray and gamma-beam equipment (AR 40-61).

1-3. References. A listing of references is contained in appendix A.

1-4. Definitions. Except as indicated in appendix B, terms used in this bulletin are defined in AR 310-25. Additional definitions are found in 21 CFR 1020.30. Where more specific definitions are required for quantities used in radiation protection, those provided in AR 40-14 shall be used.

Section II. RESPONSIBILITIES

1-5. Scope. This section establishes responsibilities and sets forth the DA implementation policies for 21 CFR subchapter J, as it applies to all diagnostic medical and dental X-rays systems worldwide under the jurisdiction of DA.

1-6. Responsibilities. a. The Surgeon General's (TSG) responsibilities are delineated in AR 10-5. Additionally, TSG will:

(1) Provide policy and advisory support to DA, ARNG, and USAR relevant to implementation of 21 CFR subchapter J.

(2) Maintain liaison with the Bureau of Radiological Health (BRH) in accordance with AR 40-5.

(3) Publish templates for X-ray equipment based on medical facility size, population supported, and mission.

b. All major Army commanders will insure that subordinate commands comply with this bulletin and 21 CFR subchapter J as applicable to diagnostic medical and dental X-ray systems. Additionally, major Army commands will:

(1) Review the Food and Drug Forms (ED) 2579 (Report of Assembly of a Diagnostic X-ray System) from subordinate activities and forward through command channels to the Commander, US Army Medical Materiel Agency (USAMMA), ATTN: SGMMA-MP, Frederick MD 21701.

(2) Forward a copy of the preacquisition technical survey through command channels to the Commander, US Army Environmental Hygiene Agency (USAEHA), ATTN: HSE-RH, Aberdeen Proving Ground, MD 21010, and to the Commander, USAMMA, ATTN: SGMMA-SDL,

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Frederick, MD 21701, for review and evaluation (see chap. 3).

(3) Forward one copy of all architectural design or modification plans, as well as all design or construction specifications for fixed radiologic facilities, through command channels to the Commander, USAEHA, ATTN: HSE-RH, Aberdeen Proving Ground, MD 21010, for review and evaluation prior to modification or construction of a new fixed radiologic facility (see chap. 4).

(4) Provide guidance and adequate resources to subordinate activities in support of the DA radiation protection and compliance programs.

c. The US Army Health Services Command (HSC) responsibilities are delineated in AR 10-43. In addition to *b* above, HSC will:

(1) Task the Academy of Health Sciences, in coordination with USAMMA, for staff advice and assistance, to develop training programs to insure that personnel are adequately trained to perform the applicable maintenance, assembly/reassembly, calibration, and acceptance inspection procedures for diagnostic medical and dental X-ray systems.

(2) Task the Academy of Health Sciences and USAEHA to develop training programs to insure that selected personnel are adequately trained to perform diagnostic X-ray protection, compliance, and quality assurance (QA) surveys.

d. USAMMA responsibilities are delineated in AR 10-71, AR 40-61, and AR 750-1. Additionally, USAMMA will:

(1) Insure that X-ray tube housing assemblies manufactured by USAMMA maintenance activities meet the standards in 21 CFR subchapter J.

(2) Receive and review Form FD 2579 for completeness and accuracy.

(a) Analyze Form FD 2579 to insure that the cited diagnostic medical or dental X-ray system is in compliance with 21 CFR subchapter J.

(b) Recommend corrective action for diagnostic medical and dental X-ray systems that are not in compliance with 21 CFR subchapter J.

(3) Forward completed copies of Form FD 2579 to BRH.

(4) Maintain a filing system of compliance data for the life of the system. Files shall include all Forms FD 2579 and the acceptance inspection information for each certified diagnostic medical and dental X-ray system used in the clinical care of human patients.

(5) Compile annual report(s) and provide copies to The Surgeon General (TSG) and BRH summarizing the compliance status of all diagnostic medical and dental X-ray systems in the Army as required by 21 CFR 1002.11.

(6) Coordinate with HSC in the development of training programs to insure personnel are adequately trained to perform the applicable assembly/reassembly, maintenance, calibration and acceptance test procedures for diagnostic medical and dental X-ray systems.

(7) Develop and publish a program for maintenance and calibration of diagnostic medical and dental X-ray systems, as required.

(8) Publish, update, and disseminate the details of the compliance program as required to include distribution of amendments to 21 CFR subchapter J as they appear in the Federal Register.

(9) Provide acquisition specifications to the procuring agency for diagnostic medical and dental X-ray systems, upon request.

(10) Act as a point of contact for reviewing questions, resolving problems, and interpretations relevant to 21 CFR subchapter J.

(11) Develop and perform acceptance testing for diagnostic medical and dental X-ray systems.

(12) Maintain a density listing of diagnostic medical and dental X-ray systems used in the clinical care of patients.

(13) Provide the Commander, USAEHA, ATTN: HSE-RH, Aberdeen Proving Ground, MD 21010, with an information copy of the Post calibration Radiation Inspection (PCRI) report for each newly installed diagnostic X-ray system in an Army medical treatment facility.

e. USAEHA responsibilities are delineated in AR 40-5. Additionally, USAEHA will:

(1) Conduct radiation protection, compliance, and QA surveys of diagnostic medical and dental X-ray systems and programs to determine status of compliance with the provisions of this bulletin and 21 CFR subchapter J.

(2) Review survey reports and records maintained at Medical Center/Medical Department Activity (MEDCEN/MEDDAC) with assigned qualified survey personnel.

(3) Coordinate with USAMMA and perform compliance inspections/surveys upon installation and acceptance of certified diagnostic medical and dental X-ray systems.

(4) Evaluate all diagnostic X-ray systems prior to type classification and acquisition for DA.

(5) Submit reports on trends of diagnostic medical and dental X-ray system deficiencies to OTSG, major Army commands, USAMMA, and US Army Medical Equipment and Optical School (USAMEOS).

(6) Develop and update the Diagnostic X-Ray Survey Procedures Manual and survey worksheets for use in the evaluation of radiologic facilities and equipment.

(7) Review preacquisition technical surveys for stationary (fixed) X-ray systems (see chap. 3).

(8) Review and evaluate architectural design or modification plans for fixed radiologic facilities (see chap. 4).

f. The United States Army, Europe (USAREUR) Medical Laboratory and the US Army Environmental Health Engineering Agency, Pacific, will:

(1) Conduct radiation protection, compliance, and QA surveys in accordance with this bulletin and the Diagnostic X-Ray Survey Procedures Manual prepared by USAEHA.

(2) Provide OTSG (HQDA (DASG-PSP), WASH DC 20310) with an information copy of each radiation protection survey report.

g. US Army Medical Materiel Center-Europe (USAMMCE) will perform X-ray acceptance inspections. Copies of the acceptance inspection report shall be forwarded directly to the Defense Personnel Support Center (DPSC) with an information copy to Commander, USAMMA, ATTN: SGMMA-MP, Frederick, MD 21701.

h. Acquisition activities at all levels shall procure only certified/compatible diagnostic medical and dental X-ray systems and specified components for the clinical care of human patients, in accordance with 21 CFR subchapter J and this bulletin.

(1) Acquisition activities should insure that contracts for diagnostic X-ray and therapeutic equipment include a provision requiring the equipment to comply with the design and performance standards in applicable Federal regulations and specifications, national standards, and this bulletin.

(2) While some field (tactical) diagnostic medical and dental X-ray systems design/performance requirements may not meet certification standards in accordance with 21 CFR subchapter J, systems may be procured if manufactured under a variance or an exemption granted under the provision of 21 CFR 1010. Those X-ray systems that cannot be fully certified shall not be procured without USAEHA and USAMMA evaluation and TSG approval.

Note. Field (tactical) diagnostic X-ray systems within Department of Defense inventories prior to 1 August 1974 are not affected by the requirements of the standard unless a certified component is added (21 CFR 1020.30).

i. Medical treatment facilities will:

(1) Insure that assembly, reassembly, and repair of diagnostic medical and dental X-ray systems and components are in accordance with the manufacturer's instructions and 21 CFR 1020.30. For contractor installed systems, the assem-

bler/installer shall complete Form FD 2579 and shall present completed Form FD 2579 to the local biomedical equipment maintenance activity. For systems installed by local biomedical equipment maintenance (in-house) activities, the assembler/installer shall complete Form FD 2579 (see para 10-4). In both instances, the local biomedical equipment maintenance activity shall file one copy of Form FD 2579 and submit two copies of Form FD 2579 through command channels to the Commander, USAMMA, ATTN: SGMMA-MP, Frederick, MD 21701, within 15 days following completion of the assembly (see 21 CFR 1020.30).

Note. For the purpose of filing the Form FD 2579, the date of installation of an X-ray system or component is considered to be the date the X-ray system is released by the assembler for use by the facility; however, the X-ray system shall not be used for the clinical care of patients prior to the completion of a radiation protection survey (see paras 2-4 and 3-6).

(2) Insure that all uncertified field (tactical) X-ray systems in fixed medical or dental treatment facilities are removed from routine use in the clinical care of human patients as soon as practical. X-ray systems that do not meet the radiation emission standards in this bulletin shall be disposed of in accordance with paragraph 1-16.

(3) Insure that all test, measurement, and diagnostic equipment (TMDE) and other equipment used in the calibration and maintenance of X-ray equipment and instruments are properly calibrated in accordance with the requirements of AR 750-25, TB 43-180, and TB 750-25.

(4) Insure that all information relating to the installation, repair, calibration, complaints/warranty actions, and compliance testing of X-ray and gamma-beam equipment are incorporated into the Army Medical Department Property Accounting System (AMEDDPAS) or into applicable historical data records (see chap. 10).

(5) Insure that radiation protection, compliance, and QA surveys are performed by a qualified expert (see paras 2-4 and 3-6).

(6) Perform acceptance inspections of diagnostic mobile and dental X-ray systems following coordination with USAMMA and with the concurrence of the major medical command (see para 3-6).

(7) Maintain diagnostic medical and dental X-ray systems in accordance with the instructions provided by the manufacturer and current Army directives.

(8) Report all accidental radiation occurrences as they relate to diagnostic medical and dental X-ray systems through command channels to OTSG (HQDA (DASG-PSP), WASH DC 20310) in accordance with 21 CFR 1002.20 (see para 6-17).

(9) Report all defects as they relate to unsafe conditions associated with the use of diagnostic medical and dental X-ray systems through command channels to the Commander, USAMMA, ATTN: SGMMA-MP, Frederick, MD 21701, in accordance with 21 CFR 1003 (see paras 1-12 and 6-17).

(10) Forward copy No. 2, DA Form 2407 (Maintenance Request), for all removal and/or condition coding relating to certified X-ray systems or specified components through command channels to the Commander, USAMMA, ATTN: SGMMA-MP, Frederick, MD 21701.

(11) Forward a **copy** of the preacquisition technical survey through command channels to the Commander, USAEHA, ATTN: HSE-RH, Aberdeen Proving Ground, MD 21010 and to the Commander, USAMMA, ATTN: SGMMA-SDL, Frederick, MD 21701, for review and evaluation (see

chap. 3).

(12) Forward one copy of all architectural design or modification plans as well as all design or construction specifications for fixed radiologic facilities through command channels to the Commander, USAEHA, ATTN: HSE-RH, Aberdeen Proving Ground, MD 21010, for review and evaluation prior to modification or construction of a new fixed radiologic facility (see chap. 4).

1-7. Supply of forms. a. Radiation protection survey worksheets are available from the Commander, USAEHA, ATTN: HSE-RH, Aberdeen Proving Ground, MD 21010.

b. Forms FD 2579 and other appropriate forms are available from Director, Bureau of Radiological Health (BRH), ATTN: HFX 420, Food and Drug Administration (FDA), Rockville, MD 20857 or one of the FDA Regional Offices.

Section III. GENERAL STANDARDS

1-8. Scope. This section provides general standards for the safe management and use of diagnostic and therapeutic X-ray and gamma-beam equipment.

1-9. Acquisition, design, construction and installation requirements. a. All diagnostic X-ray equipment acquired for use in medical and dental facilities shall meet the basic requirements for safe construction and performance as established by the Underwriters' Laboratories (UL), Inc., in UL-187 (this is not to be interpreted to mean that X-ray equipment must have a UL label or be UL listed) and by other appropriate Federal and consensus standards.

b. The design and installation of diagnostic and therapeutic X-ray equipment to be operated in an explosive atmosphere shall meet the requirements of the National Fire Protection Association (NFPA) in the National Fire Codes, and shall meet the UL safety standards for such use.

c. The design and installation of diagnostic and therapeutic X-ray and gamma-beam equipment shall meet the requirements of the NFPA as specified in the National Electrical Code and TB MED 286.

d. In addition to the shielding requirements contained in this bulletin and in NCRP Reports No. 35, 36, and 49, general guidance for the construction of X-ray facilities is ctm 5-838-2, and Corps of Engineers Guide Specification (CEGS)-13750.

1-10. Medical materiel complaints. Medical materiel complaints involving standard and non-standard X-ray, teletherapy, and ancillary equipment shall be reported on DD Form 1899 (Reporting and Processing Medical Materiel Complaints) in accordance with AR 40-61 when determined:

a. Harmful or defective to the extent use has caused or may cause death or injury.

b. Unsatisfactory because of malfunction, design, defects, or performance.

Defective or unsatisfactory medical materiel shall be classified as a Type I, II, or III complaint. When equipment is received in a nonoperational or unuseable condition, an SF 364 (Report of Item Discrepancy) shall be submitted in accordance with AR 40-61.

1-11. Equipment improvement recommendations. Equipment improvement recommendations shall be submitted on SF 368 (Quality Deficiency Report) to initiate early and effective corrective action because of faults/defects in design, operation and manufacture of X-ray and gamma-beam equipment in accordance with TM 38-750 and TB 38-750-2.

1-12. Food and Drug Administration (FDA) recalls/noncompliance. a. FDA recalls shall be monitored by the Chief, Biomedical Equipment Maintenance, at each MEDCEN/MEDDAC in accordance with direction from USAMMA.

b. Commanders of installations or activities who determine that a certified diagnostic medical or dental X-ray system or specified component is in non-compliance with 21 CFR subchapter J, shall submit DD Form 1899 in accordance with AR 40-61 (see para 6-17). An information copy shall be forwarded to the major medical command for review and evaluation.

c. If it has been determined that such non-compliance may be a defect injurious to personnel, the X-ray system/specified component shall be suspended from use and the major medical command shall be contacted. A copy of the compliance test/investigation report shall be attached to the DD Form 1899 and submitted through command channels in accordance with AR 40-61 (see para 6-17).

1-13. Maintenance and calibration policy. Maintenance and calibration of X-ray and ancillary equipment shall be performed by qualified biomedical equipment maintenance personnel in accordance with procedures established by the manufacturer, OMm0:1 9.hand this bulletin. Gamma-beam equipment shall be maintained in accordance with the recommendations of the manufacturer, American National Standards Institute (ANSI) Standards N449-1974 and N449.1-1978, and the Nuclear Regulatory Commission (NRC).

1-14. Training and qualification of operators of X-ray equipment. a. The duties performed by the medical X-ray specialists, and the skills and knowledge necessary to perform these duties are set forth in AR 611-201. TM 8-280 is a reference used in the training of the medical X-ray specialist and as a guide for performing his or her duties. Medical X-ray technologists shall have complete the X-Ray Specialist Course (313-91P10) or equivalent, as determined by competent medical authority, prior to performing independent medical diagnostic X-ray procedures in an Army medical treatment facility. The selected course shall be a program in radiologic technology approved by the Council on Medical Education of the American Medical Association and/or the American College of Radiology.

b. The duties performed by dental specialists and the skills and knowledge necessary to perform these duties are set forth in AR 611-201. TM 8-225 is a reference used in the training of the dental specialist and as a guide for performing his or her duties. Dental X-ray technologists shall have completed the Dental Specialist Course (330-91310) or equivalent, as determined by the Chief of Dental Activities, prior to performing independent dental diagnostic X-ray procedures in an Army dental facility.

Note. Independent operators of dental X-ray systems shall be individuals having adequate knowledge of radiation protection principles and practices. These individuals shall be qualified by didactic training and experience programs consistent with the Guidelines for Dental Hygienist and Dental Assistant Training Programs in Dental Radiology adopted by the Oral Radiology Section of the American Association of Dental Schools.

c. When student technologists are undergoing training, they shall be supervised by a qualified radiologic technologist at all times. They shall not be on duty or call alone until they are in the final phase of clinical training and have been approved by the education/training program director.

d. Limited privileged X-ray technologists are those individuals who do not meet the qualifications as stated above. Limited privileged X-ray technologists may perform single or limited X-ray examinations such as operating automatic chest X-ray systems. Paramedical personnel such as nurses and laboratory technologists should not operate diagnostic X-ray systems. Their use of such equipment could be warranted only in a life-saving situation during which qualified personnel as specified above are not available to perform the X-ray examination.

1-15. Access to X-ray equipment. All X-ray systems should be secured against unauthorized use. Unauthorized persons shall not operate X-ray equipment.

1-16. Disposal of X-ray equipment. X-ray equipment determined to be unserviceable, uneconomically repairable, or otherwise unsuitable for use on humans shall be condition coded S/H or X/H (AR 725-50 and DOD 4160.21M). Equipment shall be marked "CONDEMNED-NOT FOR PATIENT CARE" as required by AR 40-61 prior to turn-in for disposal through Defense Property Disposal Offices (DPDO). DPDO shall insure that no X-ray equipment condition coded S/H or X/H is sold, transferred or donated for the clinical care of human patients. Donations of certified or non-certified X-ray systems shall contain the "caution" statement cited in paragraph 104b, chapter VI, DOD Manual 4160.21M.

1-17. Disposition of high-voltage generators and dielectric oil. Requests for information concerning the handling, sampling, and disposal of high-voltage generators and dielectric oil should be submitted through command channels to the Commander, USAEHA. ATTN: HSE-ES, Aberdeen Proving Ground, MD 21010.

1-18. Recovery of silver from used hypo (fixer) solutions and silver-bearing scrap. In the processing

of radiographic films significant amounts of silver are generated. In addition, significant amount of silver are recoverable from unwanted/scrap radiographic film. Policies and procedures con-

forming with the requirements of AR 40-61 and **DOD 4160.21M** shall be established for the recovery of silver from hypo (fixer) solution and radiographic film.

CHAPTER 2

RADIATION PROTECTION

Section I. INTRODUCTION

2-1. Scope. This section outlines DA policies for the establishment and management of radiation protection and radiologic QA programs worldwide that are under the jurisdiction of DA.

2--2. General. a. *Commander, each MEDCEN/MEDDAC.*

(1) Designate a Radiation Protection Officer (RPO) and an alternate RPO in writing in accordance with AR 40-14. The MEDCEN/MEDDAC RPO's duties and responsibilities are outlined in AR 40-37. The RPO shall maintain a current registry of all diagnostic and therapeutic devices producing ionizing radiation for medical, veterinary, and dental purposes within the MEDCEN/MEDDAC/DENTAC. This registry shall include the location (building and room number); manufacturer (model and serial number(s) of the X-ray control and tube housing); type of equipment (accelerator, X-ray, etc.); use (general medical radiographic, dental panoramic, dental cephalometric, etc.); stationary or mobile; and the maximum tube potential (kV) and tube current (mA); or product of tube current (mA) and exposure time(s), milliamperere-seconds (mAs); and the date of the last radiation protection survey.

(2) Insure that an evaluation is made of each diagnostic X-ray procedure and technique for each X-ray system and publish a list of all diagnostic X-ray examinations for which testicular shielding should be routinely employed. However, based upon his professional judgment, a physician may omit testicular shielding on individual patients when its use would interfere with the clinical objectives of the examination. It is recommended that specific area testicular shielding (shadow or contact) be employed for those examinations of male patients in which the pubic symphysis may be visualized on the film and the clinical objectives will not be compromised by the use of specific area testicular shielding (see 21 CFR 1000.50).

Note. Specific area testicular shielding should always be used during those X-ray examinations in which the testes usually are in the useful (primary) beam, such as projections of the pelvis, hip and upper femur. Specific area testicular shielding is also warranted in projections of the abdominal, lumbar spine, and lumbosacral spine examinations; intravenous pyelograms; and abdominal scout film for barium enemas and upper GI

series. As with flat contact shielding, shadow shielding is not suited for gonad protection during fluoroscopic procedures.

(3) Insure that all physicians practicing diagnostic/therapeutic radiology are credentialed in accordance with AR 40-400 and that their credential files reflect the training, experience, and current competence required for all aspects of the radiologic service in which they are engaged. When privileges to perform specific limited interpretive diagnostic and monitoring radiologic studies have been granted to a physician who is not a radiologist, such studies shall be those of a highly specialized nature. The performance shall require special qualifications of training/experience in equipment use and in the interpretation of results, as well as medical practice in a field related to diagnostic/therapeutic radiologic activities.

Note. MEDCEN conducting a residency program in diagnostic and/or therapeutic radiology should be accredited by the Committee on Accreditation, Commission on Standards in Radiologic Practice of the American College of Radiology.

b. *Commander; each MEDCEN/MEDDAC/DENTAC.* Insure that all appropriate standing operating procedures required by Army directives and the Joint Commission on Accreditation of Hospitals are prepared and current.

c. *Commander, each Installation/Activity.*

(1) Insure that radiation sources under his/her jurisdiction are used only by persons competent in their use.

(2) Insure that annual instruction is conducted for subordinate personnel in radiation protection practices and in the biological effects and risks to employees and patients to ionizing radiation exposure. Employees will certify by a signed statement that they have received this instruction, and copies of each certificate shall be retained by the RPO for each individual during his duty assignment.

(3) Insure documentation is maintained indicating the participation by all appropriate personnel in inservice education, on-the-job training, and outside workshops.

(4) Establish and monitor a program to recover silver from silver-bearing scrap such as film and

spent hypo (fixer) solutions in accordance with AR 40-61 and DOD 4160.21-M.

(5) Insure that all such equipment is properly maintained and is calibrated/verified as prescribed in TM 8-605, in this bulletin, and by the X-ray equipment manufacturer.

(6) Implement an effective QA program in diagnostic radiology. This QA program should be consistent with the recommendations contained in 21 CFR 1000.55, TM 8-280, and the requirements in paragraph 2-10f.

d. Commander, Field Medical Unit. Insure that:

(1) A standing operating procedure (SOP) has been established to avoid needless exposure of the patient and other persons in the vicinity (paras 2-9 through 2-18).

(2) The X-ray system has been set up and operated in accordance with the manufacturer's instruction manual and unit SOP.

(3) The assigned operator has received appropriate training in radiation protection principles (see para 1-14).

Section II. RADIATION SURVEYS

2-3. Scope. This section establishes DA policy concerning surveys for radiation protection, compliance, Nationwide Evaluation of X-Ray Trends (NEXT), Breast Exposure: Nationwide Trends (BENT), and Dental Exposure Normalization Technique (DENT).

2-4. Radiation surveys. *a.* Radiation protection survey includes inspection of the equipment or X-ray system, an analysis of its location with references to controlled and noncontrolled areas in the immediate environment, and measurements of radiation exposure levels in the environment arising from operation of the equipment.

(1) Prior to using newly installed X-ray equipment or a new X-ray facility for clinical purposes, a radiation protection survey shall be performed by a qualified expert to insure compliance with this bulletin and 21 CFR subchapter J.

(2) All existing diagnostic X-ray facilities shall have a radiation protection survey performed by a qualified expert. A resurvey by a qualified expert shall be performed by a qualified expert. A resurvey by a qualified expert shall be performed at least once every 2 years for those Army medical facilities to be accredited by the Joint Commission on Accreditation of Hospitals and at least once every 3 years for all other diagnostic X-ray facilities.

(3) Field (tactical) X-ray systems that are components of TOE do not require periodic radiation protection surveys to be performed unless the X-ray system is to be used in conjunction with a fixed medical or dental facility for the clinical care of human patients.

(4) A resurvey should be performed and documented after every change in equipment, subsystem or component, workload, or operating conditions that might significantly increase the probability of persons receiving exposures in excess of the radiation exposure standards as specified in AR 40-14 or patients receiving unnecessary ex-

posure to ionizing radiation. The exposure of personnel to ionizing radiation shall be kept as low as is reasonably achievable (see AR 40-14).

(5) If, as a result of a radiation protection survey, supplementary shielding is installed or other corrections are made, another survey should be performed and documented to confirm the adequacy of the shielding or other recommended corrections.

h. Radiation protection and compliance surveys for the Army will be performed by the USAEHA, Aberdeen Proving Ground, MD 21010, on a scheduled basis, or upon written request through Commander, HSC, RTTN: HSPA-P, Fort Sam Houston, TX 78234, to the Commander, USAEHA, Aberdeen Proving Ground, MD 21010, in accordance with AR 40-5. Radiation protection, compliance, and QA surveys for the Army may also be performed by the Army medical activities having qualified Army Medical Department (AMEDD) personnel. MEDCEN/MEDDAC with assigned nuclear medical science officers, health physicists, or radiological physicists should perform annual radiation surveys and other surveys of diagnostic and therapeutic radiologic equipment as required by this bulletin. Requests for radiation protection and compliance surveys for the ARNG shall be forwarded through command channels to Chief, National Guard Bureau, ATTN: NGB-ARL-M, WASH DC 20310.

c. Radiation exposure measurements shall be made in the areas of interest (controlled and non-controlled) over appropriate time periods; or, alternatively, exposure rate measurements shall be made and appropriate workload, use, and occupancy factors shall be applied to calculate the cumulative exposure to occupants in these areas.

(1) Radiation exposure evaluations made to determine the adequacy of secondary protective barriers for X-ray or gamma-beam equipment shall be made under the following conditions: With a

phantom intercepting the useful (primary) beam; with the largest field size, the maximum peak tube potential (kVp) and tube current (mA) at which the equipment is capable of operating; and with the angle that will provide the greatest amount of scatter radiation at the point of interest. Radiation exposure measurements made to evaluate the adequacy of primary protective barriers shall be made without a phantom. It is not necessary for the mathematical evaluation of radiation exposure from radiographic facilities to operate the X-ray system at the maximum designed/rated tube current (mA) because survey results are normally expressed as milliroentgens per 100 milliampereseconds (mR/100 mAs) at the point/area of interest. For fluoroscopic and therapeutic facilities, the survey results are expressed as milliroentgens per hour (mR/hr); therefore, exposure rates for the maximum peak tube potential (kVp) and tube current (mA) shall be determined. (See NCRP Report No. 49.)

(2) In evaluating the results of the radiation protection survey for scatter radiation measurements, consideration shall be given to actual operating conditions including: Workload, use factor, occupancy factor, and attenuation of the useful (primary) beam by the patient and objects permanently in the useful (primary) beam. For useful (primary) beam radiation measurements no considerations shall be made for patient attenuation.

d. Whenever, in the opinion of the qualified expert, there is a reasonable probability that a person in a given noncontrolled area could receive more than 10 mrem to the whole-body dose equivalent in any week, or a radiation worker in a controlled area could receive more than 100 mrem to the whole-body dose equivalent in any week, then one or more of the following courses of action shall be taken to insure that no person will receive exposures in excess of the radiation exposure standard:

(1) Add supplementary shielding to the protective barriers to insure conformity with protective barrier requirements contained in TM 5-805-12 and this bulletin.

(2) Impose restrictions on the use of the equipment (workload or use factor).

(3) Impose restrictions on the occupancy of the area.

e. If the design or approved use of a fixed radiologic facility necessitates use factor restrictions of any primary protective barrier, it should be determined that these restrictions are actually observed. Restrictions shall be posted in full view of the operator.

f. The qualified expert shall report the findings

and recommendations in writing to the installation or activity commander. The report shall indicate if a resurvey is necessary after corrective action has been taken.

Note. When the design of an existing radiologic facility does not conform to all the design requirements specified in chapter 4, this bulletin, and NCRP Report No. 49, then the qualified expert shall determine the potential health hazards associated with the facility based upon observation, measurements, and professional judgment of the qualified expert.

g. All interlocks, "ON-OFF" beam control mechanisms, safety and warning devices shall be checked and serviced at least once every 6 months. For gamma-beam equipment, see ANSI Standards N449-1974 and N449.1-1978. Records of dates, findings, and changes shall be maintained on file.

h. The AMEDD is participating in the NEXT and BENT Programs. These are QA programs sponsored by BRH, FDA.

(1) The Commander, USAEHA, has been designated as project manager for the AMEDD NEXT and BENT Programs in accordance with DA policy. Commanders of all medical and dental facilities shall participate in the aforementioned programs, as appropriate.

(2) The NEXT Program provides for the collection and analysis of data from radiation surveys on a representative sample of diagnostic X-ray systems. This analysis is utilized to measure the effectiveness of the equipment, specific X-ray techniques, and radiation protection and compliance programs established for reducing radiation exposures to patients during diagnostic radiography.

(3) The NEXT Program calculates the exposure-at-skin entrance to a "reference" patient from measurements made onsite by the surveyor. The simulated patient exposures from individual diagnostic medical and dental X-ray systems should be determined by a NEXT survey and be reviewed in order to monitor patient exposures, to identify operating problems, and to reduce unnecessary patient exposure. When a simulated patient exposure measured on an individual diagnostic X-ray system for a specified examination is greater than the exposure-at-skin entrance index (EASEI) identified in table 20, appendix E, the X-ray system operation shall be analyzed and adjusted or restricted to reduce patient exposure, without loss of diagnostic quality of the radiograph. Radiation exposures that are less than the 10th percentile would likely result in poor image quality. The decision to exceed the EASEI should be based on the professional judgment of the X-ray diagnostician that the need for additional diagnostic information justifies the exception. NEXT surveys should be performed in conjunction with routine radiation

protection surveys of diagnostic medical and dental X-ray systems.

(4) The BENT Program is a QA program in mammography designed to minimize patient exposure and improve image quality. BENT surveys will be performed periodically by USAEHA.

(5) The DENT Program is a QA program in dentistry designed to minimize patient exposure and improve image quality.

i. Records of radiation protection, compliance, and NEXT/BENT/DENT surveys shall be maintained in accordance with AR 340-18-6 or AR 340-18-9, as applicable.

j. The applicable historical data received shall be annotated as specified in paragraph 10-3*b* or 10-3*c*.

2-5. Food and Drug Administration (FDA) surveillance inspections.

a. An agreement has been established between the Department of Defense (DOD) and BRH, FDA, permitting BRH personnel to conduct surveillance inspections on diagnostic medical and dental X-ray systems in Army medical treatment facilities; however, these surveillance inspections do not take the place of radiation protection, compliance, or QA surveys conducted by DA.

b. Previsit clearances shall be kept to a minimum. BRH or regional offices shall contact the MED-CEN/MEDDAC/DENTAC commander or the Chief, National Guard Bureau, ATTN: NGB-ARL-M, WASH DC 20310, as appropriate, prior to the visit to arrange for a convenient time and other items as may be appropriate.

c. Commanders possessing diagnostic medical and dental X-ray systems receiving BRH requests to conduct FDA surveillance inspection on diagnostic X-ray systems shall notify their major medical command or the Chief, National Guard Bureau, as appropriate, in accordance with command guidance. This notification shall be by such means as to reach the major medical command or the Chief, National Guard Bureau, as appropriate, prior to the accomplishment of the inspection.

d. Reports of these inspections shall be maintained in historical records located in the biomedical equipment maintenance activity in accordance with AR 340-18-6.

e. Only those copies of such inspection reports where equipment problems were revealed shall be submitted through command channels to the Commander, USAMMA, ATTN: SGMMA-MP, Frederick, MD 21701.

f. The commander of the medical or dental facility shall take appropriate action to correct all noted deficiencies.

2-6. Warning statements and signs. *a.* The X-ray control panel containing the main power switch or remote consoles of time sharing high-voltage generators of each diagnostic and therapeutic X-ray system shall bear a legible warning statement similar to the following: "WARNING: This X-ray system may be dangerous to patients and operator unless safe exposure factors and operating instructions are observed." If not provided, the marking shall be typed on self-adhesive paper approximately 3 1/2 inches (9 centimeters (cm)) in width and 1 inch (2.5 cm) in height, with letters 1/8 inch (0.3 cm) or more in height. This marking shall be located on the X-ray control panel readily visible to the operator when the X-ray system is being energized.

b. The X-ray control panel containing the main power switch or remote consoles of time sharing high-voltage generators of each diagnostic and therapeutic X-ray system that does not meet the minimum safe construction standards for use in an explosive atmosphere as established by the NFPA shall bear a legible warning statement similar to the following: "WARNING: This X-ray system shall not be used in the presence of an explosive atmosphere." If not provided, the marking shall be typed on self-adhesive paper approximately 3 1/2 inches (9 cm) in width and 1 inch (2.5 cm) in height, with letters 1/8 inch (0.3 cm) or more in height. This marking shall be located on the X-ray control panel readily visible to the operator when the X-ray system is being energized.

c. For radiologic facilities, "Radiation Area" warning signs shall be posted in each accessible area wherein a person could receive in a major portion of the body a dose equivalent in excess of 5 mrem in any 1 hour. "High Radiation Area" warning signs shall be posted in any accessible area wherein a person could receive in a major portion of the body a dose equivalent of 100 mrem in any 1 hour. Exceptions to the posting requirement of "Radiation Area" and "High Radiation Area" signs are permitted in locations visible to patients when such signs may be a source of apprehension. In these cases, sign posting requirements are relaxed only if personnel occupying the areas are otherwise informed of the radiation levels to which they may be exposed and entrance to the area is strictly controlled. For gamma-beam installations using byproduct material, posting shall be in accordance with 10 CFR 20.203, 10 CFR 20.204, and AR 385-30. Other warning/caution signs as recommended by a qualified expert shall be posted.

Section III. HEALTH PHYSICS PROVISIONS

2-7. Scope. This section establishes DA policy concerning the protection of the worker and the patient. It also establishes general standards for the clinical use of ionizing radiation in diagnosis and therapy.

2-8. Fundamental Objective. The fundamental objective of the medical, dental, or veterinary use of ionizing radiation is to obtain optimum diagnostic information or therapeutic effect with minimum exposure to the patient, the radiological personnel concerned, and the general public. To achieve this objective requires knowledge of the many technical factors and clinical considerations involved and an understanding of their relative importance. The exposure of individuals can be greatly reduced by the correct application of technical principles. The need for radiologic examination or treatment, the procedures to be employed, and the frequency of their repetition, are professional judgments to be made only by physicians, dentists, or veterinarians. Radiation exposure cannot be controlled merely by rules and regulations; however, protection of patients, radiation workers, and the general public, by the control of unproductive and unnecessary radiation exposure, can be reasonably assured by adhering to the provisions of this bulletin.

2-9. Standards for worker and patient protection. a. The physician, dentist, or veterinarian in charge is responsible for the working conditions and for the protection of patients and radiation workers from needless exposure to ionizing radiation. He shall ensure that written procedures are established to provide special health and safety rules for each activity, to include restrictions in operating techniques required to assure safe utilization of X-ray equipment (AR 40-5). The health and safety rules for X-ray systems in the departments of radiology, surgery, medicine, and other departments/clinics, as appropriate, shall include specific rules concerning the following: Radiation, electrical and mechanical hazards; prevention and containment of fire and explosion; the prevention and treatment of any untoward reaction to contrast media; the management of critically ill patients; and the administration of diagnostic agents by paramedical personnel. When paramedical personnel are permitted to administer diagnostic agents intravenously or parenterally, the health and safety rules should require that during any administration a physician be immediately available, should require that necessary sensitivity-testing is performed, and should specify in an appendix the individuals by name having such authority. The

health and safety rules should list those items on the emergency tray and establish a frequency for inspection and replacement of outdated or missing items. The health and safety rules should also relate to infection control for radiologic personnel, equipment, and patients.

Note. The health and safety rules shall be developed in cooperation with the MEDCEN/MEDDAC Radiation Control Committee and the MEDCEN/MEDDAC Safety and Health Committee. The infection control guidelines shall be developed in cooperation with the MEDCEN/MEDDAC Infection Control Committee.

b. When more than one X-ray system is located in a single X-ray room, only one patient shall be in the room when one of the X-ray systems is energized.

c. The deliberate exposure of an individual to the useful (primary) beam for training, research, or demonstration purposes shall not be permitted unless there is a medical or dental indication for the exposure and the exposure is prescribed by a physician or dentist, as appropriate.

d. All automatic equipment used to inject a bolus of contrast media shall be provided with both a mechanical and an electronic control mechanism.

e. Oxygen, airways, syringes, and needles shall be available in the department of radiology and other departments/clinics, as appropriate, at all times. Needles and syringes shall be controlled as required by TB MED 291.

f. All lead aprons, gloves, drapes, gonad shields, and other lead vinyl flexible shields should be checked/inspected semiannually and shall be checked/inspected at least annually for safety defects. Radiographic and/or other appropriate written records shall be maintained. Defective aprons, gloves, drapes, gonad shields, and other lead vinyl flexible shields shall be replaced as required. Appropriate devices shall be provided for the proper storage of lead aprons and gloves to minimize impairment by improper handling and storage (see NCRP No. 48).

2-10. General standards for the clinical use of ionizing radiation. As a general principle, the exposure to the patient shall be kept as low as is reasonably achievable and consistent with clinical objectives. The following are presented for the guidance of physicians, dentists, veterinarians, and other responsible for the exposure of patients:

a. The useful (primary) beam shall be limited to the smallest area practicable and consistent with the radiological examination or treatment.

b. The peak tube potential (kVp), filtration, and source-image receptor distance (SID) employed in radiological examinations shall be as great as is practical and consistent with the diagnostic objectives of the study. Low dose techniques should be employed whenever possible. The peak tube potential (kVp), grids, and filtration shall be consistent with the contrast requirements of the X-ray examination.

c. Appropriate and effective gonad shielding shall be utilized on patients who have a reasonable reproductive potential when the gonads will be within the useful (primary) beam or within 2 inches (5 cm) of the beam edge of an adjacent useful (primary) beam exposure area despite proper beam limitation, unless such devices interfere with the conditions or clinical objectives of the examination or treatment (see para 2-2b.).

Note. Specific area gonad shielding shall provide attenuation of X-rays at least equivalent to that afforded by 0.25 millimeter (mm) of lead. The gonad shield (NSN 6525-01-037-5182) is an acceptable device.

d. Protection of the embryo-fetus during radiologic examination or treatment of women known to be pregnant shall be given special consideration (see 21 CFR 1000.50):

(1) The X-ray referral slip should contain information indicating whether the patient is, is not, or may be pregnant. This information should be provided by the attending/referring physician for radiologic examinations of the abdominal area on women of childbearing age.

(2) Where possible, the attending/referring physician should consult with the radiologist concerning radiologic examination(s) on women known or suspected to be pregnant.

(3) Modification of a radiologic procedure for patient dose reduction is warranted only if it can be performed without significant jeopardy to the medical care of the patient and/or the embryo-fetus.

(4) No radiologic procedure for which there is a significant medical need should be denied a patient, even if she is pregnant. The risk to the patient of not having an indicated examination is also an indirect health risk to the embryo-fetus.

(5) NCRP Report No. 54 provides guidance concerning an action level for considering therapeutic abortion following a radiation exposure or when it is warranted to have radiographic procedures accomplished on women who are known to be pregnant and potentially pregnant women.

e. X-ray films, intensifying screens, and other image receptors shall be sensitive as is consistent with the requirements of the radiologic examination. The light emission spectrum from the

screen shall match the spectral sensitivity of the film. Intraoral image receptor radiography should be performed using dental film that meets the requirements of ANSI speed group rating "D" or faster.

f. To insure maximum information content of the developed X-ray film, a radiologic QA program shall be employed:

(1) A quality control program concerning materials and equipment specification, equipment calibration requirements, equipment performance requirements, and maintenance as established in TM 8-605, this bulletin, and other applicable documents shall be adhered to in order to assure that diagnostic quality radiographs are produced consistent with the facility mission and capabilities. The QA program shall be properly documented, monitored, reviewed regularly, revised, and appropriate action taken as necessary.

(2) Radiographic films shall be properly handled and stored in order to minimize fogging and other damage (TM S-280).

(3) The performance of diagnostic X-ray examinations shall be in accordance with procedures for patient preparation, instruction, positioning, and shielding; use of technique charts; and the monitoring of finished radiographs to minimize retakes due to operational deficiencies.

(4) Current technique charts, cooling curves for the anode and tube housing, and tube rating charts shall be posted near or on the X-ray control panel of each radiologic X-ray system.

(5) Daily records relating to retakes and reasons for rejection (i.e., the examination, projection, room, reason, technologist, X-ray system,) shall be maintained for each department, division, and clinic using X-ray equipment for the care of human patients. This information shall be reviewed weekly and appropriate recommendations made and corrective action taken to minimize retakes.

(6) Radiographic films shall be processed in properly designed and equipped rooms; both manual and automatic processing systems shall utilize developers, fixers, temperatures, and processing times that produce optimal diagnostic quality radiographs with minimum exposure to the patient (TM S-280). Film processing materials and techniques shall be those recommended by the X-ray film manufacturer or those otherwise tested.

(7) Applicable detailed film processing procedures shall be posted near each film processing area.

(8) When films are manually processed, an interval timer and thermometer shall be employed during development.

Note. Thermometers containing mercury should never be used in the darkroom/photographic laboratories.

(9) There shall be at least a daily evaluation of the index of speed, index of contrast, solution temperatures, and base plus fog. Also there shall be at least a weekly determination of replenishment rate for each film processor. The above data, except for replenishment rates, shall be plotted daily on a quality control chart for each film processor, reviewed weekly for trends, and appropriate action taken to produce diagnostic quality films.

(10) The base-plus-fog optical density should not exceed 0.1 and shall not exceed 0.2.

(11) There shall be at least a quarterly evaluation of dry-to-dry time, immersion time, and in-line filter screens for each film processor.

(12) There shall be at least a quarterly evaluation of film-screen contact, screen conditions, light leaks, and film-screen combinations used to assure optimal high quality radiographs with minimum patient exposure. Individual cassettes shall be radiographically identified.

Note. Intensifying screens that require more than ± 15 percent change in exposure factors to match a "reference" intensifying screen, as measured with a penetrometer, should be replaced.

(13) There shall be at least a quarterly evaluation of view boxes to determine consistency of light output with time and consistency of light, output and hue from one view box to another. There shall be a daily evaluation of view box surface conditions.

Note. Bulbs in view boxes should be replaced after 1500 hours of operation and as required to insure consistency of light output and hue.

(14) There shall be at least a semiannual evaluation of grid alignment, focal distance, and artifact identification.

(15) There shall be periodic evaluations of the integrity and safe light conditions in each darkroom.

n. When a chest X-ray examination is required, a 14 by 17 inch (36 by 43 cm) chest film should be used rather than a photofluorograph.

i. Dental X-ray examinations should not be taken until a dentist has established from clinical evaluation or pertinent history the need for the radiograph(s). Neither a full mouth series nor a bitewing series should be a routine part of the dental examination except for those made for forensic purposes.

j. Followup time or frequency of radiologic examinations should be limited to reasonable periods so that significant changes in clinical information are obtained to determine continuation or alteration of the management of the patient.

k. Routine or screening examinations that cannot be clinically justified should be eliminated. Examples of X-ray examinations that should not be routinely performed are:

(1) Chest and low-back X-ray examinations in routine physical examinations.

(2) Tuberculosis screening by chest radiography.

(3) Chest radiography in routine prenatal care.

(4) Chest radiography for routine hospital admission of patients under age 20 or lateral chest X-rays for patients under age 40 unless a clinical indication of chest disease exists.

(5) Mammography examinations for women under age 50.

l. Pelvimetry is not usually necessary nor helpful in making the decision to perform a caesarean section. Therefore, pelvimetry should be performed only when the physicians caring for the patient feel that pelvimetry will contribute to the decisions concerning diagnosis or treatment of the patient. The reason for requesting the pelvimetry study should be written on the patient's chart. This statement does not apply to X-ray examinations for purposes other than measurement of the pelvis.

m. The chief of the department, division/clinic shall outline the minimum number of views to be obtained for each requested radiological examination taking into account the X-ray systems available. The number, sequence, and types of "standard" views for a radiologic examination should be problem-oriented and kept to a minimum consistent with the clinical objectives. The necessity of additional views, such as comparison views, should only be authorized by the supervising radiologic diagnostician. Each department, division/clinic shall review the outline of "standard" views at least annually and revise as necessary.

n. The radiologic examinations obtained for the evaluation of cancer patients should be reviewed for their efficacy both for the initial evaluation and required followup care.

o. The use of self-referral radiologic examinations should be limited to unique studies required by the specialty of the physiciandentist performing them and be consistent with a medical review policy.

p. A request for a medical X-ray examination/study should be on the prescription of a physician. Exception for certain limited procedures may be made for dentists, podiatrists, or properly trained physician assistants, nurse practitioners, and physicians in post-graduate training status. The prescription of such X-ray examinations or studies should be considered to be a medical cor-

sultation between the clinician and the X-ray diagnostician, be based on prior clinical evaluation of the patient, and should state the diagnostic objective and detail relevant medical history.

q. A nonmilitary individual may not be furnished radiation therapy in any Army medical treatment facility without either the individual's consent or the express consent on the individual's behalf. Applicable local laws or the order of a court have jurisdiction over both the individual and the facility concerned. An express consent involves an interchange of language by which the patient or person authorized to act on his or her behalf specifically states that his or her consent is given to the proposed radiation therapy. A written consent shall be recorded on SF 522 (Clinical Record-Authorization for Administration of Anesthesia and for Performance of Operations and Other Procedures) when nonmilitary patients (either inpatient or outpatient) are involved in any procedure where therapeutic X-ray or gamma-beam radiation is used in their treatment (AR 40-3).

2-11. Personnel Monitoring and Radiation exposure standards. a. Personnel who are exposed to ionizing radiation during the normal course of their duties or occupation shall wear personnel monitoring devices to record occupational radiation

exposures as required by AR 40-14. Reports of overexposure to ionizing radiation shall be investigated in accordance with AR 40-14. Records shall be retained in accordance with AR 340-18-6.

b. Parents of infants and small children and owners of small animals who volunteer to hold subject patient/animal during radiographic procedures are not required to wear personnel monitoring devices unless they so request. However, they shall be provided with an appropriate protective apron and gloves during radiographic procedures as required by this chapter.

c. The occupational exposure to ionizing radiation shall be maintained as far below the standards in AR 40-14 as is reasonably achievable.

2-12. Recording of exposure. DD Form 1141 (Record of Occupational Exposure to Ionizing Radiation) shall be maintained for each person occupationally exposed to ionizing radiation in accordance with AR 40-14.

2-13. Unusual occurrence. Reports of unusual occurrences shall be prepared when a patient is involved as required by current Army directives.

2-14. Accidents/Incidents. Accidents/incidents shall be reported in accordance with AR 385-40.

Section IV. STANDARDS FOR THE USER

2-15. Scope. This section establishes DA policy concerning the acceptable standards for the user of diagnostic and therapy equipment in the diagnosis and treatment of disease.

2-16. Fluoroscopic X-ray systems. a. The fluoroscopist shall know the radiation characteristics of his X-ray system(s). Therefore, periodic measurements of patient exposure rate shall be made at the point where the center of the useful (primary) beam enters the patient. Records of such measurement shall be maintained. Image intensifiers may significantly reduce both observation time and exposure rate when properly used. In X-ray systems with automatic exposure control, the peak tube potential (kVp) and tube current (mA) may rise to high values without knowledge of the operator, particularly if the gain of the intensifier is diminished. It is important, therefore, for the fluoroscopist to monitor tube current (mA) and peak tube potential (kVp) on such X-ray systems.

b. The smallest practical field sizes and shortest exposure times shall be employed.

c. Fluoroscopy shall not be used as a substitute for radiography, but should be reserved for the study of dynamic or spatial relationships or for guidance in spot-film recording of critical details.

d. Medical fluoroscopy shall be performed only by or under the immediate supervision of physicians properly trained in fluoroscopic procedures. Fluoroscopic X-ray systems should be provided with image-intensification. When used by nonradiology specialists, the fluoroscopic X-ray systems should have image-intensification with electronic image-holding features.

e. The fluoroscopist's eyes should be sufficiently dark-adapted for the visual task required before commencing fluoroscopy. Under no circumstances shall the fluoroscopist attempt to compensate for inadequate adaptation by increasing the exposure factors employed or by prolonging the fluoroscopic examination. Dark adaptation normally is not necessary when using image intensifiers.

f. Extraneous light that interferes with the fluoroscopic examination shall be eliminated.

g. Special precautions, consistent with clinical needs, shall be taken to minimize the exposure of the gonads of potentially procreative patients and the exposure of the embryo or fetus in patients known to be or suspected of being pregnant (see para Z-10).

h. In serial fluorography and cinefluorography, special care should be taken to limit patient exposure where tube currents (mA) and peak tube potentials (kVp) employed may be higher than those normally used in fluoroscopy. The exposure rates to which patients are normally subjected shall be determined periodically and records of such measurements shall be maintained.

Note. The exposure for single film and serial fluorography should be within the range of 0.05 to 0.2 mR/frame at the image receptor or 5 to 20 mR/frame at the point where the center of the useful (primary) beam enters the patient; for cinefluorography, 0.01 to 0.04 mR/frame at the image receptor or 1 to 4 mR/frame at the point where the center of the useful (primary) beam enters the patient.

i. A protective skirt (drape) from the image receptor having a lead equivalent thickness of at least 0.01 inch (0.25 mm) shall be provided on fluoroscopic X-ray systems to minimize scatter radiation and to protect the hands of the fluoroscopist while inserting catheters.

j. Protective aprons of at least 0.01 inch (0.25 mm) lead equivalent shall be worn in the fluoroscopy room by each person (except the patient) whose trunk is exposed to scattered radiation fields of 2 mR/hr or more. The whole-body film badge shall be worn under the protective apron; however, an additional film badge should be worn on the collar outside the protective apron and thus nearer to the eyes (AR 40-14).

k. The hand of the fluoroscopist shall not be placed in the useful (primary) beam unless a protective glove of at least 0.01 inch (0.25 mm) lead equivalent is worn to attenuate the beam. A wrist badge or ring dosimeter shall be worn under the glove by the fluoroscopist during fluoroscopic procedures which involve putting the hand in the useful (primary) beam.

l. Only persons whose presence is required shall be in the fluoroscopy room during X-ray exposures. All such persons shall be protected by a protective apron of at least 0.01 inch (0.25 mm) lead equivalent or stand behind a protective barrier having the same lead equivalence.

m. All doors to the X-ray room that open into uncontrolled areas shall be closed during fluoroscopic procedures.

2-17. Stationary (fixed radiographic X-ray systems (except dental). a. Particular care shall be taken to

limit the useful (primary) beam to the smallest area consistent with clinical requirements and to align accurately the X-ray beam with the patient and film.

b. Special precautions, consistent with clinical needs, shall be taken to minimize the exposure of the gonads of potentially procreative patients and the exposure of the embryo-fetus in patients known to be or suspected of being pregnant (see para 2-10).

c. When a patient must be held in position for radiography, mechanical supporting or restraining devices should be used. If the patient must be held by an individual, that individual shall be protected with appropriate shielding devices such as protective gloves and apron having at least 0.01 inch (0.25 mm) lead equivalent. He shall also be positioned so that no part of his body will be exposed to the useful (primary) beam. No person occupationally exposed to ionizing radiation should be permitted to hold patients during exposures, nor shall any other person be regularly used for this service.

d. Only persons whose presence is necessary shall be in the radiographic room during exposure. All such persons shall be protected by a protective apron of at least 0.01 inch (0.25 mm) lead equivalent or stand behind a protective barrier having at least the same lead equivalence. The whole-body film badge shall be worn under the protective apron.

e. The radiographer shall stand behind the protective barrier provided for his protection and close all doors to the X-ray room that open into uncontrolled areas during radiographic procedures.

f. Special care shall be taken to insure adequate filtration in general purpose X-ray systems.

g. Particular care shall be taken to insure adequate filtration in any system equipped with a beryllium window tube or other lightly filtered beam.

2-18. Mobile X-ray systems. a. Recommendations in paragraph 2-17 for stationary radiographic X-ray systems apply also to mobile X-ray systems except for paragraph 2-17e; however, all doors to the room should be closed prior to the radiographic procedures.

b. The operator should use the maximum source to-skin distance or source-to-surface distance (SSD) consistent with the conditions of the radiographic examinations, which should be at least 15 inches (38 cm). An SSD of less than 12 inches (30 cm) shall not be used except for specific surgical applications where the SSD shall not be less than 8 inches (20 cm).

c. Mobile X-ray systems shall not be used for

fluoroscopy, unless they meet the design requirements and performance standards for mobile fluoroscopes.

d. The operator shall stand as far as practicable (at least 6 ft (1.8 m)) from the patient, the X-ray tube, and the useful (primary) beam. He shall wear a protective apron of at least 0.01 inch (0.25 mm) lead equivalent or stand behind a protective barrier having at least the same lead equivalence. The whole-body film badge shall be worn under the protective apron.

e. Mobile X-ray systems shall be used only for examinations when it is impractical to transfer patients to fixed radiologic facilities.

f. Mobile X-ray systems shall not be used in lieu of a stationary (fixed) X-ray system in a fixed radiologic facility except under emergency situations or for special procedures as determined by competent medical authority.

g. The responsible medical supervisor shall assure himself that operators of mobile equipment understand the proper use and limitations of the equipment so as to avoid needless exposure of the patient and other persons in the vicinity.

2-19. Urological X-ray systems. *a.* All provisions of paragraph 2-17 apply.

b. The urologist shall wear a protective apron of at least 0.01 inch (0.25 mm) lead equivalent. The whole-body film badge shall be worn under the protective apron.

c. The hand of the urologist should not be placed in the useful (primary) beam unless a protective glove of at least 0.01 inch (0.25 mm) lead equivalent is worn to attenuate the beam. A wrist badge or ring dosimeter shall be worn under the glove by the urologist during urological procedures which involve putting the hand in the useful (primary) beam.

d. All doors to the X-ray room that open into uncontrolled areas shall be closed during radiographic procedures.

2-20. Dental X-ray systems. *a.* Particular care shall be taken to align accurately the useful (primary) beam with patient and film.

b. In no case shall the film be held by the operator during exposures.

c. Only the patient shall be in the useful (primary) beam.

d. Neither the tube housing nor the position-indicating device (PID) shall be handled during exposures.

e. Gonad (lead apron) shielding should be used for

every patient. Thyroid shielding should be used for the patient when appropriate. The shielding shall not be a substitute for adequate beam collimation and alignment.

f. Only those persons whose presence is necessary for the radiographic procedure should be in the radiographic room during the exposure. All such persons shall be protected by a protective apron of at least 0.01 inch (0.25 mm) lead equivalent or stand behind a protective barrier having the same lead equivalence.

g. When a patient must be held in position for radiography, a mechanical supporting or restraining device should be used. If the patient must be held by an individual, that individual should be protected with appropriate shielding devices such as protective apron and gloves having at least 0.01 inch (0.25 mm) lead equivalent. He shall also be positioned so that no part of his body will be struck by the useful beam.

h. Fluoroscopy shall not be used in dental examinations.

i. The exposure of the patient shall be kept to the minimum consistent with clinical requirements. The peak tube potential used in routine dental radiography shall not be less than 65 kVp.

Note. Both bitewing and periapical dental projections should be performed at a peak tube potential of 80 kVp or higher to reduce the exposure-at-skin entrance, if the resulting image quality provides the required diagnostic information.

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

k. The operator shall stand as far as practicable (at least 6 ft (1.8 m)) from the patient, the X-ray tube, and the useful (primary) beam. He shall wear a protective apron of at least 0.01 inch (0.25 mm) lead equivalent or stand behind a protective barrier having at least the same lead equivalence. The whole-body film badge shall be worn under the protective apron.

1. All doors to the X-ray room that open into uncontrolled areas shall be closed during radiographic procedures.

2-21. Veterinary X-ray systems. *a.* The useful (primary) beam should be restricted to the minimum field size required for the study.

b. The lowest practical exposure technique factors (time and tube current (mA)) should be used to minimize the radiation output. The peak tube potential (kVp) shall be consistent with the contrast requirements of the examination.

c. A protective skirt (drape) from the image receptor having a lead equivalent thickness of at least 0.01 inch (0.25 mm) shall be provided on fluoroscopic X-ray systems to minimize scatter radiation and to protect the hands of the fluoroscopist while inserting catheters.

d. Sandbags, V-troughs, slings, or other appropriate ancillary devices should be used to assist in positioning animals for radiographic procedures. Mechanical devices should be used to hold/position cassettes during radiographic procedures of large animals. General anesthesia, sedation, or tranquilization should be used on animals if necessary to facilitate radiography or fluoroscopy with minimal human exposure.

e. No part of the animal handler's body shall be placed in the useful (primary) beam without adequate protection. Protective apron and gloves having a lead equivalent thickness of at least 0.01 inch (0.25 mm) shall be worn when holding the animal and during radiologic procedures. A whole-body film badge shall be worn under the protective apron and a wrist badge or ring dosimeter shall be worn under the glove during radiologic procedures that require holding the animal.

f. A log or equivalent record of the use of the X-ray systems shall be maintained to indicate the date of exposure, peak tube potential (kVp), tube current (mA), exposure time, operator, and identification of the animal and any persons used to hold the animal during the radiologic procedure.

g. All doors to the X-ray room that open into uncontrolled areas shall be closed during radiologic procedures.

2-22. X-ray therapy systems. a. An X-ray therapy system shall be calibrated by a qualified expert before use for the treatment of patients and at least annually thereafter (see para 9-4).

b. X-ray therapy systems capable of operating at a peak tube potential above 20 kVp shall not be operated routinely until the radiation safety of the facility has been established by a radiation protection survey. All X-ray therapy systems shall be operated in conformance with recommendations of the radiation protection survey.

c. Both the control panel and the patient shall be kept under observation during treatment.

d. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

e. No person other than the patient shall be in the treatment room when the tube is operated at peak

tube potentials exceeding 20 kVp. At operating peak tube potentials of 20 kVp or below, other persons may be permitted in the treatment room for good reason if they are adequately protected and their radiation exposure is monitored.

f. If the X-ray tube of a contact therapy system is hand-held during irradiation, the operator shall wear protective gloves and apron of not less than 0.02 inch (0.5 mm) lead equivalent. When practical, a cap of at least 0.02 inch (0.5 mm) lead equivalent shall cover the aperture window of the tube housing of such systems when the system is not being used. Because the exposure rate at the surface of the window of contact therapy machines may exceed 10,000 roentgens per minute (R/min), extreme precautions are necessary to prevent accidental exposure to the useful (primary) beam.

g. For X-ray therapy systems not meeting the recommendation of paragraph 9-2a(14), the "ON-OFF" switch at the control should always be turned "OFF" first, then the primary switch turned off or disconnect wall plug as appropriate. This sequence should never be reversed.

h. Lead, lead rubber, or lead foil used for limiting the field, should not transmit more than 5 percent of the useful (primary) beam. This does not pertain to shadow or contact shields.

i. Therapeutic X-ray systems (grenz-ray or contact) having an exposure rate of more than 500 R/min at any accessible location shall not be left unattended without the power being shut off at the primary disconnecting means. The power switch at the X-ray control should always be turned off first, then the primary main switch turned off or disconnect wall plug as appropriate. The sequence should never be reversed.

j. A whole-body film badge shall be worn during therapeutic procedures. A low-energy, self-reading, pocket dosimeter should also be worn during therapeutic procedures (AR 40-14).

k. All X-ray systems used for radiation therapy should be used by or under the supervision of a radiologist having had specialized training in radiation therapy. The users of X-ray therapy systems shall be approved by the Credentialing Committee in accordance with AR 40-400.

2-23. Gamma-beam equipment. a. Paragraphs 2-22c and 2-22h above, concerning the use of X-ray therapy equipment also apply.

b. The gamma-beam equipment shall be calibrated and documented by a qualified expert before use for the treatment of patients and at least annually thereafter (see para 9-4).

c. The gamma-beam therapy facility shall not be operated routinely until its radiation safeness has been established by a radiation protection survey. The equipment shall be operated in conformance with recommendations of the radiation protection survey. A resurvey shall be performed each time the equipment is loaded with a new radioactive source. A copy of the survey report shall be forwarded through command channels to the NRC in accordance with the NRC license conditions (AR 40-37).

d. Emergency procedures to be followed in the event of failure of the beam control mechanism shall be established and posted at the control panel. (See app C for a sample emergency procedure.)

e. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

f. No person other than the patient shall be in the treatment room while the source is in the "ON"

position.

g. The gamma-beam equipment shall be fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism. A permanent record of inspection and servicing shall be maintained (AR 340-18-6).

h. A whole-body film badge shall be worn during therapeutic procedures. A self-reading pocket dosimeter should also be worn during therapeutic procedures (AR 40-14).

i. The gamma-beam equipment, when used for the treatment of a patient, shall be used by or under the supervision of a radiologist. He shall have specialized training in radiation therapy and be approved (certified) by the Radiation Control Committee in accordance with AR 40-37 and by the Credentialing Committee in accordance with AR 40-400.

CHAPTER 3

ACQUISITION POLICIES

3-1. Scope. This chapter implements DA policies contained in AR 40-61 and SB 8-75-MEDCASE for the acquisition of diagnostic and therapeutic X-ray systems worldwide under the jurisdiction of DA.

3-2. Planning. a. Due to the high cost of acquisition and the degree of complexity involved in present day X-ray equipment, good planning is essential in all phases of the acquisition of X-ray equipment as outlined in SB 8-75-MEDCASE.

b. A preacquisition technical survey shall be accomplished in accordance with SB 8-75-MEDCASE (see para 3-5).

c. Receiving reports shall be submitted by the receiving medical activity in accordance with current directives. Reports shall include apparent condition of equipment upon receipt.

d. Upon receipt of the entire system the requesting medical activity shall coordinate for the installation of the equipment. MEDCEN/MEDDAC with capability of installing low capacity medical and dental X-ray systems should omit contract installation. Contract installations shall be monitored by the supporting biomedical equipment maintenance activity.

3-3. X-Ray System Development. X-ray requirements shall be completely identified at the time the requirements card and the letter of justification are submitted, and shall include complete information as required by SB 8-75-MEDCASE.

3-4. Acquisition of individual X-ray components. The addition of individual X-ray components to repair or augment an existing X-ray system does not normally require the extensive planning and coordination described in preceding paragraphs. Assembly of certified X-ray components into uncertified X-ray systems may result in a "non-compatible" installation in the sense that the term is used in 21 CFR 1020. This is only legal under certain circumstances. Additionally, two certified components which are noncompatible shall not be assembled into the same X-ray system. Necessary research concerning acceptable sources for add-on and replacement components shall be conducted before any purchase request for such items is released.

3-5. Preacquisition technical survey for stationary X-ray systems. a. A preacquisition technical survey shall be conducted for each planned acquisition of a stationary (fixed) X-ray system (see SB 8-75-MEDCASE).

b. The following are general areas which shall be considered:

(1) Professional requirements. The mission of a medical facility determines the capabilities and features required in a stationary medical X-ray system. Appendix D provides guidelines for determining the general types of X-ray systems and radiation capacities for most medical facilities. Additional specific features (e.g., table angulation and X-ray tube focal spot size) shall be identified by competent medical authority.

(2) General structural considerations. While SB 8-75-MEDCASE requires a detailed technical review of proposed installations, the medical supply officer and professional personnel who develop the preliminary system description should be aware of the following potential constraints governing radiologic facility plans.

(a) *Room size.* Rooms used for stationary (fixed) X-ray systems shall be large enough to accommodate all personnel and auxiliary equipment that will be present for anticipated X-ray procedures. Rooms (and their doors) shall be large enough to permit a wheeled litter or bed with fracture frame to be rolled adjacent to the table or cradle. In addition, the room, control booth and equipment layout must conform to appropriate radiation safety considerations contained in chapter 4 and TM 5-805-12.

(b) *Structural support.* A major X-ray installation shall not be attempted unless adequate structural support is already present or can be provided in the intended location.

(c) *Electrical power.* Title 21 CFR 1020.30 requires manufacturers to specify minimum electrical requirements necessary to ensure compliance of their X-ray high-voltage generators with the Standard. An assembler shall not connect a certified X-ray high-voltage generator to a power supply that fails to satisfy manufacturers' specifications. Overseas medical activities shall comply with the same power requirements as CONUS activities except where dependence on power supplied by host nations makes compliance impossible. A letter

report describing any deficient overseas power system, and all actions taken to correct the stated deficiencies, shall accompany the preacquisition technical survey when submitted through command channels to the Commander, USAMMA, ATTN: SGMMA-SDL, Frederick, MD 21701.

(d) *Shielding.* Protective barrier requirements for radiologic facilities are contained in chapter 4. When planning a fixed radiologic facility in a location that does not currently incorporate adequate shielding, allow for the additional construction time and costs involved.

3-6. Acceptance inspections. a. Acceptance inspections shall be performed on all new installations of diagnostic medical and dental X-ray systems as directed by USAMMA. In general, these procedures are to be followed:

(1) Acceptance inspections shall be performed by medical equipment maintenance depot personnel (i.e., Tobyhanna Army Depot, PA (SGMMA-MD-P) and Defense Depot Tracy, CA (SGMMA-MD-C) for CONUS, Alaska, Hawaii, and the Pacific; USAMMCE shall perform inspections for USAREUR).

(2) Diagnostic mobile and dental X-ray systems may be inspected by qualified biomedical equipment maintenance personnel assigned to the MEDCEN/MEDDAC following coordination with USAMMA and concurrence of the appropriate major medical command. Guidance on inspection policy for minor modifications or upgrading of existing X-ray systems shall be provided to the MEDCEN/MEDDAC based on the system components involved in the modification or upgrade.

(3) Acceptance inspection.

(a) Upon completion of the installation of a diagnostic medical X-ray system, the installer/assembler shall notify the Contractor's Government Representative, who shall notify DPSC of the installation completion date and that the equipment is ready for an acceptance inspection. DPSC shall notify USAMMA-MP who shall select and notify the acceptance team known as technical representative of the contracting officer (TRCO) that the inspection shall be accomplished within 30 days. The completed inspection report, to include the PCRI, shall be forwarded to DPSC within 10 working days after completion of travel. The contracting agency shall review and determine the acceptance or rejection of the X-ray system based on this report. Acceptance of the X-ray system shall cause DPSC to issue a "Warranty Start Date" to the contractor. Rejection of the X-ray system will activate a "Report of Defects" to the Contractor's Government Representative who has 14 days to

correct all cited defects and notify DPSC of his completion so that a reinspection can be set up by USAMMA-MP. The contractor is required to reimburse all travel, per diem, and personnel labor costs incurred by the TRCO for this reinspection. The TRCO's cost shall be identified and supported by traceable documents forwarded to DPSC with the address to which the reimbursement is to be sent. The X-ray equipment should not be utilized for clinical purposes prior to initial acceptance inspection; however, the equipment may be utilized for clinical use provided that a radiation protection survey has been performed by a qualified expert (see para 2-4).

(b) The medical facility shall advise the contracting agency when delays occur or are expected that will impact upon the installation schedule of the X-ray equipment. The contracting agency shall also be notified when problems occur during the installation impacting upon the successful completion of the installation in accordance with schedules included in the contract. All communications with the contracting agency are to be submitted to the Commander, USAMMA, ATTN: SGMMA-SDL, Frederick, MD 21701.

(c) The contracting agency shall advise the MEDCEN/MEDDAC medical supply officer when the installation has been accepted and specify the effective date the warranty period was initiated.

b. The commander of the installation or activity shall request a radiation protection and compliance survey upon notification of the acceptance inspection of certified diagnostic medical and dental X-ray systems in accordance with paragraph 2-4b. After the radiation protection and compliance survey has been conducted and the X-ray system is approved for routine use, approval may be contingent on correction of identified discrepancies that shall be accomplished by the contractor/assembler under warranty or by the Army assembler, as appropriate.

3-7. Reports. At least two sets of complete pictorial records (e.g., scope tracings, diagrams, electronic systems printout) and narrative description of acceptance inspection results shall be completed and distributed as follows:

a. One set of complete pictorial records and narrative description of findings shall be forwarded to the designated contracting agency at the completion of each acceptance inspection.

b. One set of complete pictorial records and narrative description of findings shall be retained in the local biomedical equipment maintenance activity's file for the life of the equipment (see para 10-5).

CHAPTER 4

DESIGN OR MODIFICATION OF RADIOLOGIC FACILITIES

4-1. **Scope.** This chapter establishes requirements for the design or modifications and the review of plans for radiologic facilities worldwide under the jurisdiction of DA. General guidance for the construction of fixed diagnostic X-ray facilities is contained in TM 5-805-12, TM 5-838-2, and CECS-13750.

4-2. **Qualification of Personnel.** The design or modification of diagnostic and therapeutic X-ray and gamma-beam therapy facilities shall be undertaken only by persons who have proven their competence in the field of radiation protection. Certification by the American Board of Health Physics or by the American Board of Radiology in Radiological Physics, Therapeutic Radiological Physics, Diagnostic Radiological Physics, or X-ray and Radium Physics may be considered as acceptable qualifications. All architectural design or modification plans as well as all design or construction specifications for fixed radiologic facilities shall be submitted through command channels for review by USABHA and approval by OTSG (HQDA (DASG-PSP), WASH DC 20310), prior to the modification or the construction of a new fixed radiologic facility.

4-3. **Review of design or modification plans for fixed radiologic facilities.** The following information is considered to be the minimum essential for the evaluation of a fixed radiologic facility to preclude the occurrence of radiation hazards and shall be submitted in accordance with paragraph 4-2.

a. Architectural blueprints showing locations of doors, windows, and information concerning occupancy in the areas adjacent to the X-ray room. This shall include occupancy above and below the X-ray room as well as type of occupied area (controlled or noncontrolled).

b. The type and thickness of proposed, or existing, floors, ceilings and walls, and their lead equivalence, if known.

c. The thickness of the lead to be installed on the walls and doors.

d. Which walls are to be leaded.

e. The locations and orientation of the X-ray table, diagnostic source assembly, and image receptor to include wall cassette, if used, as well as distances from diagnostic source assembly to occupied area(s).

f. The location and construction of the protective enclosure (control booth) to include dimension of the observation window, its height and placement in relation to the edge of the protective barrier.

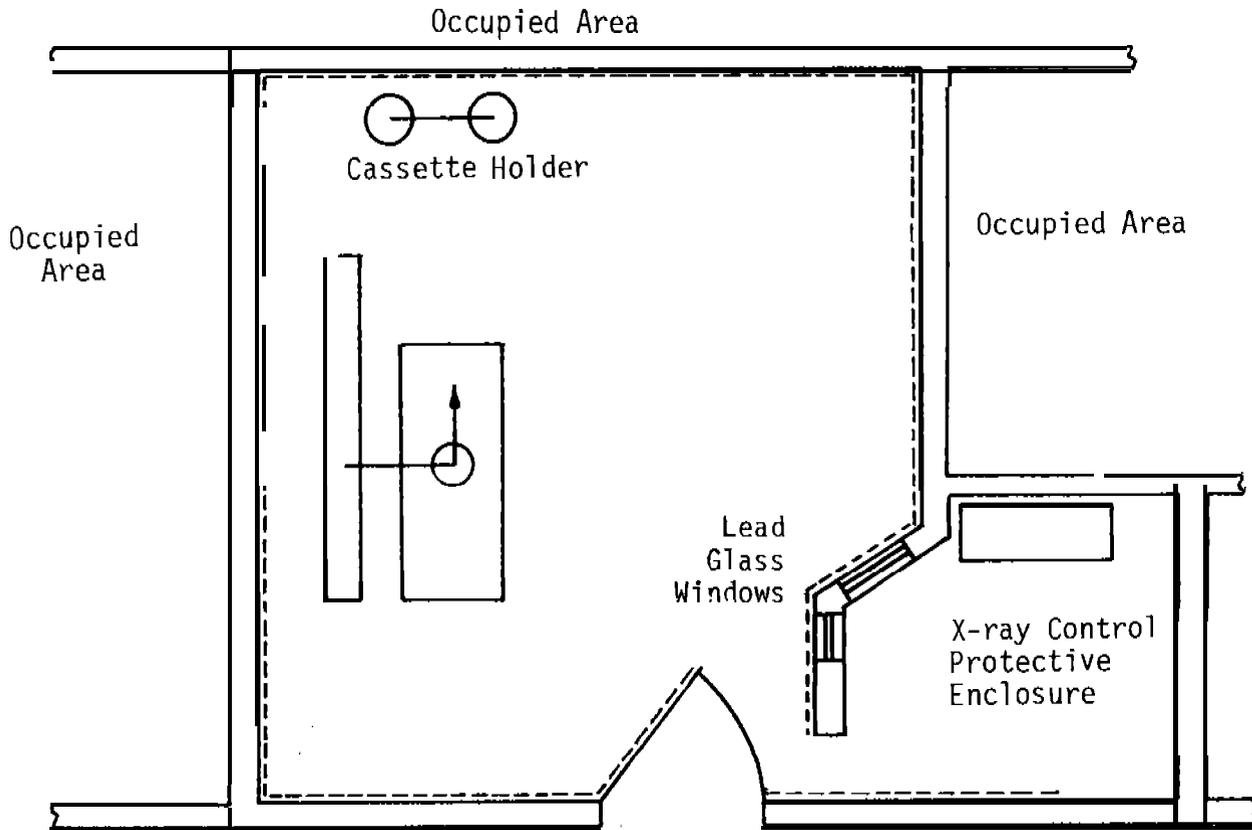
g. The orientation of the X-ray control panel in relation to the observation window.

h. The maximum peak tube potential (kVp), tube current (mA), weekly workload (mA-min/week), and calculations made to determine workload and required shielding.

4-4. **Design of diagnostic X-ray rooms and location of equipment.** Typical designs of fixed diagnostic X-ray facilities are shown in figures 4-1 through 4-4. The following comments illustrate basic considerations in the design of diagnostic X-ray facilities. Shielding requirements for diagnostic X-ray systems are given in appendix E.

a. The X-ray control panel for a fixed radiographic X-ray facility shall be located behind a fixed protective barrier (protective enclosure) or in a separate room, except for field radiography. The protective enclosure shall be located in the X-ray room so that the radiation has to be scattered twice before entering the protective enclosure. When a door is required to shield personnel, it shall have the same lead equivalent thickness required of the barrier in which it is located. Electrical interlocks shall be provided to insure that exposures cannot be made when the door is open. Provisions shall be made in the protective enclosure for the X-ray technician to observe and communicate with the patient at all diagnostic areas within the X-ray room. Precautionary measures shall be taken to prevent access to the X-ray control by unauthorized persons.

NOTE: For purposes of diagram orientation compass directions have been included. This is not to be construed as suggesting the specific compass orientation for all radiographic rooms.

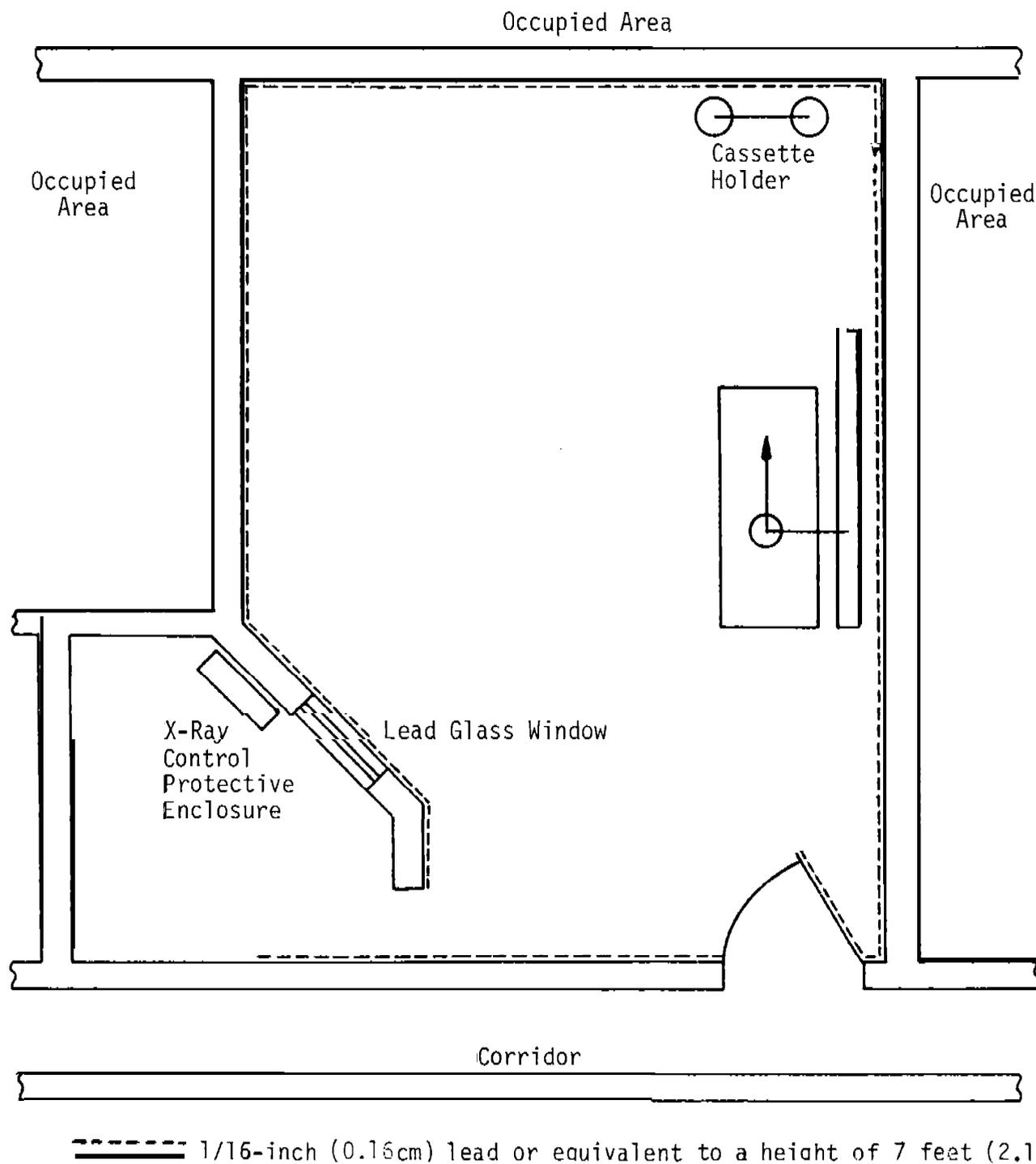


----- 1/16-inch (0.15 cm) lead or equivalent to a height of 7 feet (2.1 m)

There is an unobstructed view of both the table and the chest cassette from the protective enclosure. If the chest cassette holder had been placed on the south wall, the x-ray technician would be obliged to stand at the unprotected entrance to the enclosure so that he could observe and instruct the patient. If the radiographic table were re-positioned along an east-west axis, the chest cassette holder could be placed on either the east or west wall.

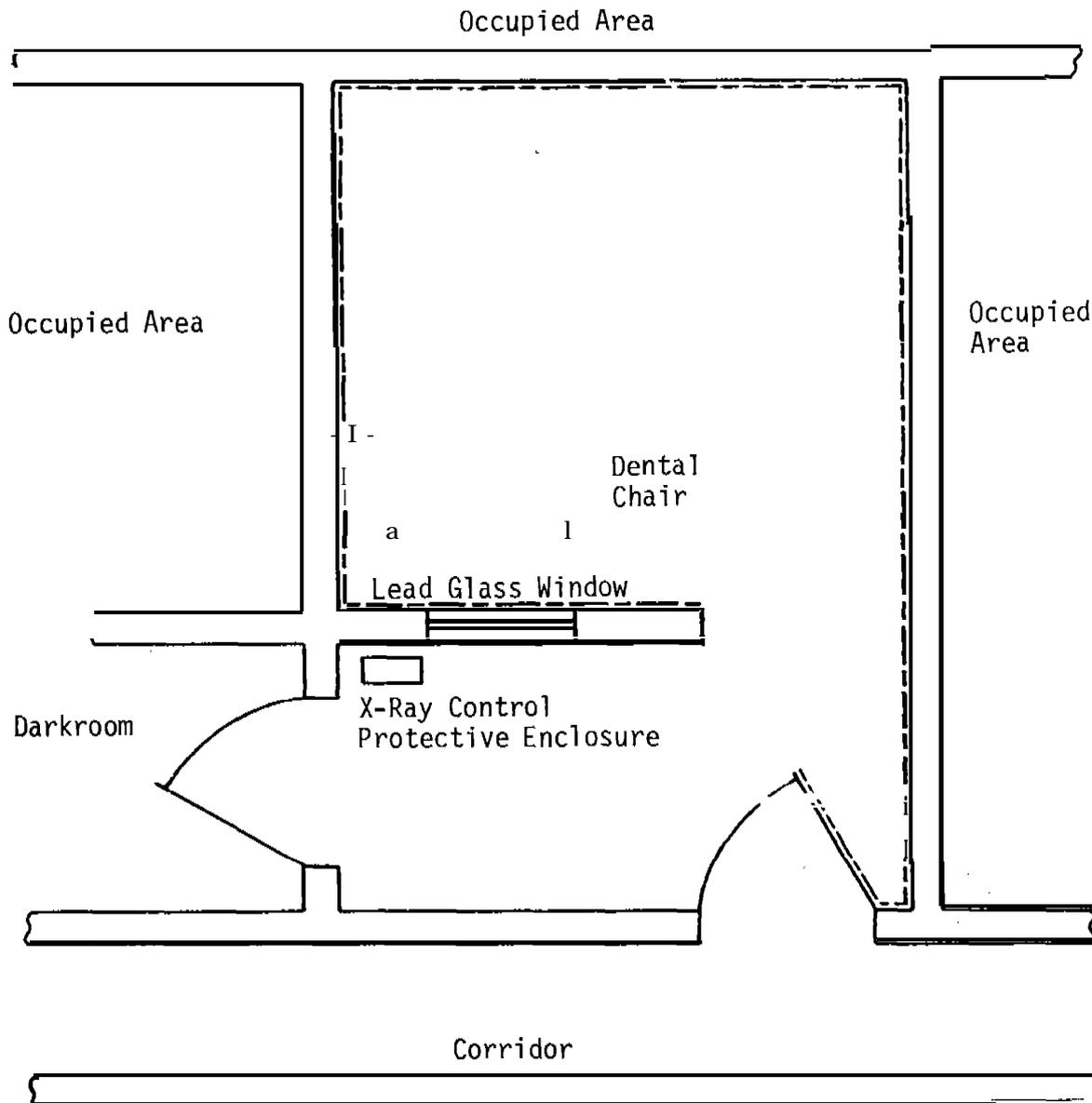
MED 521-1

Figure 4-1. A well-designed radiographic exposure room



MED 521-2

Figure 4-2. A well-designed radiographic-fluoroscopic exposure room.

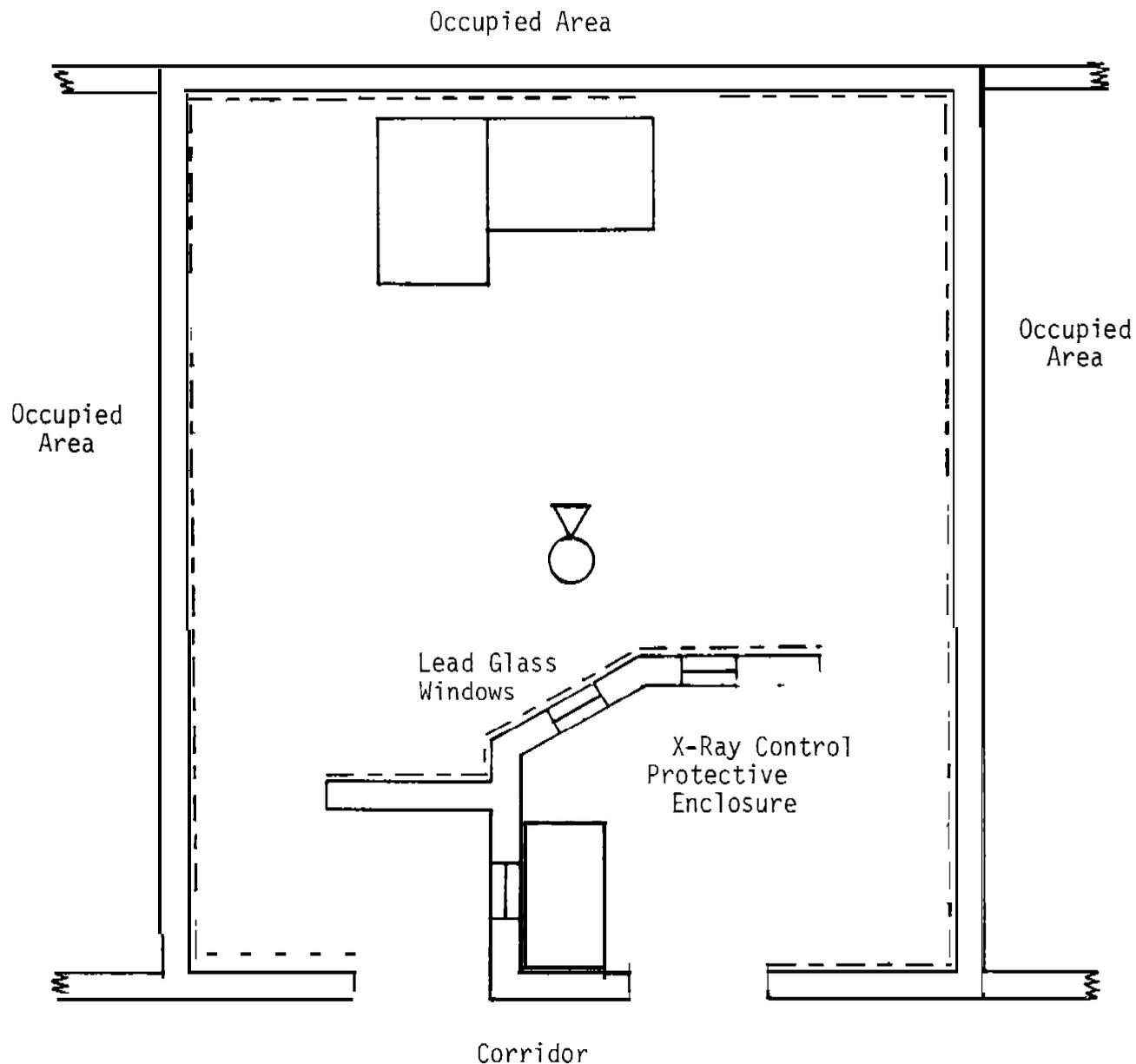


1/32-inch (0.08 cm) lead or equivalent to a height of 7 feet (2.1 m) for dental x-ray systems with tube potentials of 61 to 75 kVp;
 1/16-inch (0.16 cm) lead or equivalent to a height of 7 feet (2.1 m) for dental x-ray systems with tube potentials greater than 75 kVp.

Dental x-ray system either wall-mounted behind the dental chair or pedestal mounted.

MED 521-3

Figure 4-3. A well-designed fixed dental X-ray exposure room.



LEGEND:

-  1/32-inch (0.08 cm) lead or equivalent to a height of 7 feet (2.1 m)
-  1/16-inch (0.16 cm) lead or equivalent to a height of 7 feet (2.1 m)

MED 521-4

Figure 44. A well-designed automatic exposure controlled chest X-ray room with inline automatic film processor.

b. The protective enclosure shall be large enough to accommodate the X-ray control panel, unexposed X-ray film, and the X-ray technician. Normally 25 square feet (2.3 square meters) is adequate for stationary (fixed) X-ray facilities. The design shall provide a location for the X-ray control panel that does not deprive the X-ray technician of a suitable observation area in front of the observation window. The edge of the protective barrier (control booth) shall be at least 18 inches (45 cm) from the nearest edge of the observation window, as measured along the inside of the protective barrier (wall).

c. The observation window shall have the same lead equivalent thickness as that required of the protective barrier in which it is located. It should be at least 16 by 24 inches (41 by 61 cm). It shall be at least 10 by 12 inches (25 by 30 cm) to provide a convenient, unobstructed view of the patient and the X-ray room. For standing operations, the bottom of the observation window should be 53 inches (1.35 m) from the floor.

Note. If the protective enclosure (control booth) is designed in such a manner as to preclude a direct unobstructed view of the patient by the technologist during radiographic procedures, then other appropriate viewing methods shall be made available to assure an indirect unobstructed view of the patient (e.g., convex mirror or television).

d. When practical, doors into the X-ray room shall be so located that the X-ray technician has direct control of access to the room.

Note. When the X-ray technician does not have direct control of access to the room, then a fail-safe door interlock shall be installed, if recommended by a qualified expert. Prior to installation of the interlock, concurrence shall be obtained from the Commander, USAMMA, ATTN: SGMMA-MP. Frederick, MD 21701.

e. All walls, doors, floors, and ceiling areas of a fixed radiologic facility exposed to the useful (primary) beam shall be considered primary protective barriers. All walls considered to be protective barriers shall extend to a minimum height of 7 feet (2.1 m) above the floor.

f. For fluoroscopic rooms, the general room illumination should be through diffusing panels and should be controlled from within the room by means of a dimmer switch. Such devices should also be provided in radiographic rooms that utilize a light localizer.

g. For field (tactical) radiography, in tentage, the X-ray system should be located within the hospital area so that it is practicable to exclude all persons other than the patient and the X-ray technician or radiologist from the area described in tables 1 and 19, appendix E.

h. Combined fluoroscopic-radiographic X-ray

facilities shall be governed by the requirements for fixed radiographic X-ray facilities.

i. There shall be adequate ventilation in the film processing area, temperature control of the water supply, and light proofing and proper illumination (safelighting) of the film processing room (TM 8-280).

j. Where possible, the dressing room and patient toilet should connect directly with the medical diagnostic X-ray room. When this is not possible, a concerted effort should be made to insure patient privacy at all times, particularly for undressing and dressing, examination, waiting in the department/clinic, and evacuation of contrast media.

4-5. Structural detail of protective barriers for diagnostic X-ray facilities. a. General.

(1) For simplicity of planning and construction, 1/16-inch (0.16 cm) sheet lead is the most practical to use if the required lead equivalent thickness is not provided by the existing walls or floor structure. This thickness will provide adequate secondary barrier protection for diagnostic X-ray facilities and will, in all but the most unusual circumstances, provide a factor of safety.

(2) The principal disadvantages of sheet lead are that it is not self supporting and it is easily damaged; therefore, lead protective barriers shall be mounted in such a manner that they will not sag or cold-flow because of their own weight and be protected against mechanical damage. It is usually necessary to cover sheet lead with some form of wallboard, tile, or plaster (see TM 5-805-12 and CEGS-13750).

(3) Surfaces of lead sheets at joints in the protective barrier shall be in contact with an overlap of at least 0.5 inch (1.3 cm) or twice the thickness of the lead sheet, whichever is greater.

(4) Welded or burned lead seams are permissible, provided the lead equivalence of the seam is not less than the minimum requirement of the protective barrier.

(5) Windows, window frames, doors, and door frames shall have the same lead equivalent thickness as that required of the protective barrier in which they are located. Where thick concrete walls are tapered into openings, as is frequently the case with observation windows, it may be necessary to add lead protective flanges around the window frames to compensate for the reduced thickness of concrete.

(6) Holes in protective barriers shall be covered with an appropriate thickness of shielding material so that the overall attenuation is not impaired. The

shielding shall cover not only the back of the service boxes, but also the sides, or extend sufficiently to offer the same lead equivalent thickness as that required of the protective barrier in which it is located.

(7) Louvers and holes in protective barriers for pipes, conduits, service boxes, and air ducts may

require baffles to insure that the overall protection afforded by the protective barrier is not impaired. It is advisable to locate such penetrations outside the range of directions of the useful (primary) beam.

(8) The following are lead equivalent thickness of common building materials used in construction for various peak tube potentials:

Material	Equivalent primary barrier thicknesses* for various peak tube potentials							
	150kVp		125 kVp		100 kVp		70 kVp	
	(in)	(cm)	(in)	(cm)	(in)	(cm)	(in)	(cm)
Lead	0.06	0.16	0.06	0.16	0.06	0.16	0.03	0.08
Lead Glass	0.3	0.8	0.3	0.8	0.2	0.6	0.1	0.3
Marble	5.1	12.9	4.3	10.9	3.9	9.9	3.1	7.9
Granite	5.2	13.2	4.4	11.2	4.	10.2	3.1	7.9
Plate glass	5.3	13.5	4.5	11.4	4.1	10.4	3.2	8.1
Limestone	5.6	14.2	4.7	11.9	4.3	10.9	3.4	6.6
Siliceous concrete	5.9	15	4.9	12.5	4.5	11.5	3.5	9.0
Sandstone	6.3	16	5.3	13.5	4.6	12.2	3.8	9.7
Brick	7.3	18.5	6.0	15.2	5.6	14.2	4.4	11.2
Ceramic tile	7.3	18.5	6.0	15.2	5.6	14.2	4.4	11.2
Sand plaster	9.0	22.9	1.5	19.0	6.9	17.5	5.4	13.7

*The equivalent primary barrier thicknesses are related to lead, based on differences in the average density in table 16, appendix E, atomic weight, and atomic number for each specified peak tube potential (kVp).

b. Determining protective barrier requirements.
The following assumptions should be used in determining the shielding requirements for diagnostic X-ray facilities:

(1) That the X-ray system under consideration is operated at its maximum rated peak tube potential (kVp) and tube current (mA) and that the areas adjacent to the radiographic room are to be occupied by persons nonoccupationally exposed to ionizing radiation. The economic advantage which might be temporarily gained by determining the average workload of the X-ray system and the degree of occupancy in adjacent areas would in many instances not be justifiable should the workload of the system or the degree of occupancy of the adjacent areas increase at some future time. The probability of overexposure that might result from such an increase indicates the inadvisability of allowing standards for construction of new facilities to be based on reduced workload and occupancy under the current conditions in medical or dental treatment facilities.

(2) The minimum source-to-occupied-area distance is 5 feet (1.5 m).

(3) The minimum distance from an unshielded outside wall of a radiographic room to an occupied area is at least 50 feet (15.24 m).

(4) The following should be used as typical weekly workloads:

General radiographic-fluoroscopic	1500 milliamperes-minutes (mA-min)
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Radiographic	1000 mA-min
Fluoroscopic including spot fig	1500 mA-min
Dental	250 mA-min
Photofluorographic or automatic upright chest	250 mA-min (peacetime)
Cystoscopic	1250 mA-min (mobilization)
Special procedures	600 mA-min
Mammographic	700 mA-min
	2000 mA-min

(5) The individual is positioned at least 12 inches (30 cm) away from the protective barrier.

(6) The areas which are not part of the radiologic department or suite will not be declared controlled (restricted) areas for the purpose of permitting reduction in the degree of protection of occupants. The areas within the department or suite which are not directly related to the use of radiation sources will not be declared controlled (restricted) areas.

(7) The penetrability of scattered radiation for peak tube potentials of 500 kVp and below is the same as that of the useful (primary) beam. The exposure from leakage radiation is the same as that from scattered radiation. However, the leakage radiation is more penetrating than the scattered radiation; therefore, the exposure from leakage radiation is the determining factor for the secondary protective barrier.

c. Protective barrier shielding requirements.
When constructing a protective barrier to reduce the radiation exposure rate or exposure from an X-

ray system to a permissible level, the required thickness of the protective barrier depends upon the quality of the radiation, the quantity being produced in some chosen period of time, the distance from the tube to area of interest, the degree and nature of occupancy, the type of area, and the material of which the protective barrier is to be constructed. If the workload of an X-ray system is significantly greater than that stated in paragraph 4-5b(4) above, then the actual workload shall be used to determine the shielding requirements.

4-6. Special X-ray facilities. *a. Panoramic facilities.* These consist of a dental X-ray system having a tube housing with a collimator providing a narrow useful (primary) beam and an extraoral film carrier that are interlocked in their motion about the patient. While the narrow useful (primary) beam and shielding of the film carrier reduce the need for structural shielding and operator protection, such facilities shall have protective barriers of 1/32 inch (0.08 cm) or equivalent to a height of 7 feet (2.1 m).

b. Cephalometric facilities. Such facilities shall meet the general requirements recommended for conventional dental radiographic X-ray facilities. However, the extended SID requires a small collimator aperture to reduce the useful (primary) beam to that which will expose only the area of interest. The workload for this type of X-ray system is usually low.

c. Endodontic facilities. These consist of a dental X-ray system normally capable of operating at a peak tube potential of 50-70kVp. While the workload for this type of system is usually low, the shielding requirements are given in table 14, appendix E; however, unless a protective barrier or control booth is provided for the operator, the facility shall be so arranged that the operator, when making an exposure, can stand at least 6 feet (1.8 m) from the patient and well away from the useful (primary) beam.

d. Multiple tube facilities.

(1) Such facilities include two or more X-ray systems either in the same room or in adjacent rooms that are close enough to require consideration of their combined workloads in radiation protection design. These facilities may include two or more complete X-ray systems (single-tube systems) or a combination of two or more tube heads operable from a single X-ray control panel (multiple-tube systems). X-ray systems designed for multiple facilities shall conform to the general requirements recommended for conventional radiologic X-ray facilities.

(2) When there are two or more diagnostic or

therapeutic X-ray systems in the same room then means shall be provided to insure that only one X-ray system is operable at a time except for special procedure X-ray systems.

e. Mammography facilities. Such facilities consist of an X-ray system dedicated solely to mammography and normally operating at a peak tube potential of less than 50 kVp. The shielding requirements for these facilities shall be individually evaluated based upon workload, use, and occupancy. A protective barrier shall be provided for the operator. The protective barrier may be a component of the X-ray system. The operator shall have a clear and unobstructed view of the patient at all times during a mammographic examination.

f. Computed tomographic facilities.

(1) Such facilities consist of an X-ray system dedicated solely to computed tomography and operating at a peak tube potential of less than 150 kVp. The shielding requirements for these facilities shall be individually evaluated based upon workload, use, and occupancy of adjacent areas.

(2) Normally 1/32-inch (0.08 cm) lead is the most practical to use if the required 1/32-inch (0.08 cm) lead equivalent thickness is not provided by the existing walls, ceiling, doors, and floor structure. A protective enclosure (control booth) shall be provided for the operator. Provisions shall be made for the operator to have a clear and unobstructed view of the patient and communicate with the patient at all times during the examination.

4-7. Structural detail of protective barriers for therapeutic X-ray and gamma-beam facilities. Structural shielding requirements for therapy facilities have been omitted from this bulletin. The design or modification of such facilities requires the training and experience of a person qualified in radiological physics or health physics. (See NCRP Reports No. 49 and/or 51 for structural shielding design and evaluation and Planning Guide for Radiologic Installations, Radiation Therapy Installations, American College of Radiology.)

4-8. Therapeutic X-ray and gamma-beam facility design requirements. In addition to the shielding requirements contained in this bulletin and NCRP Reports No. 49 and/or 51, the following design requirements shall be met:

a. Warning lights shall be provided in a readily observable position near the outside of each access door to the treatment room containing a therapy system. It shall be capable of operating at a tube potential above 150 kV to indicate when the useful (primary) beam is "ON."

b. Fail-safe interlocks shall be provided for therapy systems capable of operating at a tube potential above 50 kV. When any door to the treatment room is opened, either the system will shut off automatically or the radiation level within the room will be reduced to an average of not more than 2 mR/hr, and a maximum of not more than 10 mR/hr, at a distance of 40 inches (100 cm) in any direction from the source. After such a shutoff or reduction in exposure rate, it shall be possible to restore the system to full operation only by closing the door and subsequently reinitiating the exposure from the control panel.

c. The technician shall have means for aural communication with the patient from the protective enclosure (e.g., voice, buzzer).

d. The technician shall have means to continuously observe the patient from the control panel during irradiation. When the viewing is by electrical means an alternate viewing system shall be provided.

e. When light localization of treatment portals is used, means should be provided to control the light intensity in the treatment room from within the room.

f. "Panic" or "Cut-off" buttons shall be at appropriate positions within a treatment room containing a therapy system capable of operating at energies above 500 keV, which, when pressed, will cause the irradiation to be terminated.

g. An independent area radiation monitor equipped with an alarm, capable of measuring exposure rates from 2 mR/hr to 10 R/hr, shall be installed in each gamma-beam room. It shall be possible to determine the status of the radioactive source from the protective enclosure.

h. Where possible, the dressing room and patient toilet should connect directly with the therapy room. When this is not possible, a concerted effort should be made to insure patient privacy at all times, particularly for undressing and dressing and while undergoing therapeutic procedures.

4-9. Veterinary X-ray facilities. Facilities designed and used for diagnostic studies and research activities with animals shall conform to the general shielding requirements recommended for corresponding medical facilities (appendix E).



CHAPTER 5

DIAGNOSTIC X-RAY SYSTEMS

5-1. Scope. This chapter establishes design requirements and performance standards for diagnostic X-ray systems to be used worldwide under the jurisdiction of DA.

5-2. Fluoroscopic X-ray systems. a. *Design requirements.*

(1) A diagnostic-type protective source assembly shall be provided, and shall have the apparent focal spot location clearly indicated on the tube housing.

(2) The minimum source-panel, source-tabletop or source-skin distance (SSD) for stationary undertable fluoroscopic X-ray systems shall be 15 inches (38 cm). The minimum source-panel or source-tabletop distance for stationary overtable fluoroscopic X-ray systems shall be at least 27 inches (68 cm) to insure that the minimum SSD is at least 15 inches (38 cm).

(3) Image intensification shall be provided on mobile fluoroscopic X-ray systems. It shall be impossible to operate a mobile fluoroscopic X-ray system unless the entire useful (primary) beam is intercepted by the image receptor. Inherent provisions shall be made so that the X-ray system is not operable at an SSD of less than 12 inches (30 cm).

(4) For image intensified fluoroscopic X-ray systems intended for specific surgical application that would be prohibited at an SSD specified in the paragraphs above, provisions shall be made for operations at an SSD of not less than 8 inches (20 cm).

(5) The total filtration permanently in the useful (primary) beam shall be at least 2.5 mm aluminum equivalent. When the tabletop or panel surface is interposed between the source and the patient, its aluminum equivalent may be included as part of the total filtration.

(6) The X-ray system shall be so constructed that, under conditions of normal use, the entire cross section of the useful (primary) beam is intercepted by the primary protective barrier permanently incorporated into the equipment at any SID for which the system is designed. The exposure shall automatically terminate when the primary protective barrier is not in a position to intercept the entire useful (primary) beam.

Note. There shall be an interlock(s) that prevents the fluoroscopic tube from producing X radiation unless the spot-film device, image intensifier, or fluoroscopic screen assembly are in position to intercept the entire useful (primary) beam.

(7) A beam-limiting device shall be provided to permit restriction of the size of the useful (primary) beam to less than the useable area of the image receptor. The X-ray tube and beam-limiting device shall be linked with the image receptor so that the useful (primary) beam at the image receptor is confined within the image receptor irrespective of the SID. For image intensifiers, the useful (primary) beam shall be centered on the input phosphor and during fluoroscopy or cine-recording it shall not exceed the dimensions of the entire visible area of the input phosphor. The minimum field size at the greatest SID shall be equal to 2 by 2 inches (5 by 5 cm) or less.

(8) The fluoroscopic exposure switch shall have a circuit closing contact (dead-man switch) that can be maintained only by continuous pressure on the switch.

(9) When recording serial fluoroscopic images, the operator shall be able to terminate the X-ray exposure(s) at any time, but means should be provided to permit completion of a single exposure of the series in progress.

(10) Provisions shall be made to intercept the scattered X-rays from the undersurface of the tabletop and other structures under the table. In most cases, this may be accomplished either by a cone extending from the tube housing to as near the tabletop as practical or by a shield around the fluoroscope understructure, or both. The cone shall provide the same degree of attenuation as is required of the tube housing assembly with the incident angle of the useful (primary) beam taken into consideration.

(11) A shielding device of at least 0.01 inch (0.25 mm) lead equivalent, at a peak tube potential of 100 kVp, for covering the Bucky slot during fluoroscopy shall be provided. This shielding device shall automatically cover the Bucky slot opening at the front of the table when the Bucky tray is in the parked position or means shall be provided to prevent the production of X-rays from the undertable tube until the shielding device has covered the Bucky slot opening.

(12) Shielding device(s) shall be provided for undertable fluoroscopic equipment of at least 0.01 inch (0.25 mm) lead equivalent, at a peak tube potential of 100 kVp. Such devices include overlapping protective drapes from the image receptor and a hinged or sliding panel at the front of the table to intercept scattered radiation that would otherwise reach the fluoroscopist and others near the X-ray system. The hinged or sliding panel shall project at least 5 inches (12 cm) above the tabletop when provided and shall not interfere with the use of the table.

(13) A cumulative timing device, activated by the fluoroscope exposure switch, shall be provided. The maximum cumulative time of the timing device shall, not exceed 5 minutes without resetting the timer. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while X-rays are produced until the timing device is reset. Radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which X-rays were produced and which is capable of being reset between X-ray examinations.

(14) Special means of activation of high level controls (HLC), such as additional pressure applied continuously by the operator, shall be required to avoid accidental use. The HLC shall only be operable when continuous manual activation is provided by the operator. The HLC shall be automatically deactivated at the termination of any exposure. A continuous signal audible to the fluoroscopist shall indicate that the HLC is being employed.

(15) Devices which continuously indicate the X-ray peak tube potential (kVp) and tube current (mA) shall be provided. On image intensified fluoroscopic equipment, such devices should also be located in such a manner that the fluoroscopist may monitor the peak tube potential (kVp) and tube current (mA) during fluoroscopy.

(16) A line voltage compensating device shall be operable from the X-ray control panel without the aid of tools, together with a meter for deter-

mining the proper adjustment of this device. It shall be mounted in all X-ray control panels not employing automatic voltage compensation or a prereading peak tube potential (kVp) meter that responds directly to line voltage variations.

(17) When the angle between the image receptor and the beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

(18) Each high-voltage generator assembly shall be supplied with a pair of shockproof cable receptacles for each X-ray tube assembly that the high-voltage generator is to energize. These shockproof cable receptacles shall be in accordance with Federal Standard No. 72, and the high-voltage generator shall be permanently marked "Equipped with Federal Standard Shockproof Cable Receptacles." Receptacles shall be covered when not in use.

(19) The cathode and anode cable receptacles shall be permanently identified (labeled).

(20) Each three-phase X-ray system having a tube current of 600 mA or greater shall be provided with an anode heat calculator.

(21) Each X-ray system shall have a tube protective circuit.

b. Performance standards. This paragraph is primarily for the guidance of those concerned with evaluating the radiation safety/compliance characteristics of fluoroscopic X-ray systems.

(i) New fluoroscopic X-ray systems, with or without automatic exposure control (AEC), shall not be operable at any combination of peak tube potential (kVp) and tube current (mA) that will result in entrance exposure rates (EER) in excess of the values shown below, at the point where the center of the useful (primary) beam enters the patient, except during recording of fluoroscopic images. Under normal technique factors, old X-ray systems should also comply with these EER limitations. Fluoroscopic radiation therapy simulation systems are exempt from the entrance exposure criteria. The applicable EER limit(s) shall be determined from the tables below.

Single Mode Fluoroscopic Equipment

	Without HLC	With HLC
With AEC	10 R/min	5 R/min*
Without AEC	5 R/min	5 R/min*

*Except when the HLC is activated. When the HLC is activated, the EER is not specified.

Dual Mode Fluoroscopic Equipment

	Without HLC	Manual mode with HLC	Automatic mode with HLC	Both modes with HLC
With AEC	10 R/min	10 R/min	5 R/min*	5 R/min*
Manual	10 R/min	5 R/min*	10 R/min	5 R/min*

*Except when the HLC is activated. When the HLC is activated, the EER is not specified.

(2) The measured half-value layer of the useful (primary) beam for a given single-peak tube potential (kVp) shall not be less than the values in tables 2 and 4, appendix E. For three-phase X-ray systems, the measured half-value layer of the useful (primary) beam at a peak tube potential of 90 kVp shall not be less than 3 mm aluminum equivalent (see table 4, appendix E). The homogeneity coefficient for a diagnostic X-ray system operating at a peak tube potential above 50 kVp should be greater than 0.6. The total filtration in the useful beam should not exceed 3.5 mm aluminum equivalent.

(3) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful (primary) beam combined with radiation from the image intensifier, if provided, shall not exceed 2 mR/hr at 4 inches (10 cm) from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor, for each roentgen per minute (R/min) of EER. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for, remote control operation.

(4) When the beam-limiting device, for nonimage-intensified fluoroscopic X-ray systems, is opened to its fullest extent, an unilluminated margin of at least 0.25 inch (0.64 cm) shall exist at all edges of the image receptor when it is 14 inches (35 cm) from the panel surface or tabletop, or at the fixed-screen position in equipment such as an orthodiascope. The X-ray field shall not exceed the dimensions of the fluorescent screen during its maximum vertical travel. For old image-intensified fluoroscopic equipment, the X-ray field:

(a) Should not exceed the dimensions of the visible area of the input phosphor over the entire range of image receptor's vertical travel.

(b) Shall not exceed the dimensions of the input phosphor's visible area when the input phosphor is positioned at the minimum SID.

(5) For new nonimage-intensified fluoroscopic X-ray systems, the X-ray field produced shall not extend beyond the entire visible area of the image receptor at any SID. Means shall be provided to permit further limitation of the X-ray field. The minimum X-ray field size at the greatest SID shall be equal to 2 by 2 inches (5 by 5 cm) or less. For

equipment manufactured after 25 February 1978, when the angle between the image receptor and the beam axis of the X-ray beam is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

(6) For new image-intensified fluoroscopic X-ray systems other than radiation therapy simulation systems, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall not exceed 4 percent of the SID. For a rectangular X-ray field used with a circular image receptor, the error in alignment shall be determined along the length and width dimensions of the X-ray field that pass through the center of the image receptor's visible area. For equipment manufactured after 25 February 1978, when the angle between the image receptor and the beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor. Means shall also be provided to permit further limitation of the X-ray field. Beam limiting devices manufactured after 22 May 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 47 square inches (300 cm²), shall be provided with means for stepless adjustment of the X-ray field. X-ray equipment with a fixed SID and a visible area of 47 square inches (300 cm²) or less shall be provided with either stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image to 19 square inches (125 cm²) or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 2X 2 inches (5 X 5 cm) or less.

(7) For new X-ray systems with a spot-film device, except when the spot-film device is provided for use with a radiation therapy simulation system, means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film that has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected

portion of the film. If the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the X-ray field size shall be only at the operator's option.

Note. If the overhead spot-film device has been specifically designed and manufactured to accept either English-sized cassettes or metric-sized cassettes, but not both, then compliance determination shall be based on the measurement system (English or metric) for which the device was designed and manufactured.

(8) The total misalignment of the edges of the X-ray field with the respective edges of the selected portion of the image receptor along the length or width dimension of the X-ray field in the plane of the image receptor, when adjusted for full coverage of the selected portion of the image receptor, shall not exceed 3 percent of the SID. The sum without regard to sign of the misalignment along any two orthogonal dimensions shall not exceed 4 percent of the SID. It shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. On spot-film devices, if the angle between the plane of the image receptor and the beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor. Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(9) The minimum field size, at the greatest SID, shall be equal to 2 by 2 inches (5 by 5 cm) or less. The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID.

(10) Deviation of technique factors from indicated/measured values shall not exceed the maximum deviation as specified by the manufacturer.

(11) The leakage radiation from the diagnostic source assembly when measured at 40 inches (100 cm) in any direction from the source shall not exceed 100 mR in 1 hour when the X-ray tube is operated at its leakage technique factors (see para 8-2). If the maximum rated peak tube potential (kVp) of the tube housing assembly is greater than the maximum rated peak tube potential (kVp) for the diagnostic source assembly, positive means shall be provided to limit the maximum X-ray peak tube potential (kVp) to that of the diagnostic source assembly.

5-3. Stationary (fixed) radiographic X-ray systems (except dental). a. Design requirements.

(1) A diagnostic-type protective source assembly shall be provided, and shall have the location of the apparent focal spot clearly indicated on the tube housing.

(2) Suitable beam-limiting devices (fixed-aperture, adjustable or automatic collimators), capable of restricting the useful (primary) beam to the area of clinical interest, shall be provided to define the X-ray field. Beam-limiting devices shall be calibrated in terms of the size of the projected useful (primary) beam at specified SID. For a fixed SID and a fixed image receptor size the beam-limiting device shall restrict the useful (primary) beam to dimensions no greater than those of the image receptor.

(3) All general-purpose radiographic X-ray systems shall be equipped with an adjustable rectangular beam-limiting device that contains a light localizer that visually defines the perimeter of the X-ray field. A light localizer shall not be used in an explosive atmosphere unless it is properly designed for such use. For new X-ray systems an optical viewfinder or properly designed light localizer shall be provided to visually define the perimeter of the X-ray field. New fixed general-purpose X-ray systems shall be provided with positive beam limitation. All general-purpose X-ray systems shall have a filter system that clearly indicates the amount of added filtration in place. For general-purpose X-ray systems, the beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted. Means shall be provided to produce a visible indication of adequate collimation and alignment on the developed X-ray film.

(4) The aluminum equivalent of the total filtration in the useful (primary) beam shall not be less than that shown below:

Maximum peak tube potential	Minimum total filtration (inherent plus added)
Below 50 kVp	0.5 mm aluminum
50-70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

For all new X-ray systems, positive means shall be provided to insure that at least the minimum filtration needed to achieve the beam quality as given in table 2, appendix E, for the technique used, is in the useful (primary) beam during each exposure.

(5) A timing device shall be provided that terminates the exposure at a preset time interval, preset product of tube current (mA) and exposure time(s), mAs, a preset number of pulses, or a preset radiation exposure to the image receptor.

(6) The exposure switch, except for those used in conjunction with spot-film devices in fluoroscopy, shall be so located that it cannot be conveniently operated outside a protective barrier (control booth).

(7) The radiographic exposure switch shall have a circuit closing contact (dead-man switch) that can be maintained only by continuous pressure on the switch.

(8) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Termination of the exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to zero or to the off position if either position is provided.

(9) When recording serial radiography, the operator shall be able to terminate the X-ray exposure(s) at any time, but means shall be provided to permit completion of any single exposure of the series in process.

(10) When automatic exposure control is provided, indication shall be made on the X-ray control panel when this mode of operation is selected.

(11) The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used. In this case, the technique factors that are set prior to the exposure shall be indicated. Indication of technique factors shall be visible on the

X-ray control panel. On X-ray systems with fixed technique factors, this requirement shall be met by permanent markings.

(12) A line voltage compensating device, operable from the X-ray control panel without the aid of tools, together with a meter for determining the proper adjustment of the device, shall be mounted in all X-ray control panels not employing automatic voltage compensation or a prereading peak tube potential (kVp) meter that responds directly to line voltage variations.

(13) X-ray systems equipped with beryllium window X-ray tubes shall contain keyed filter interlock switches in the tube housing and suitable indication on the X-ray control panel of the added filter in the useful (primary) beam. This applies if the total filtration permanently in the useful (primary) beam is less than 0.02 inch (0.5 mm) aluminum equivalent. The total filtration permanently in the useful (primary) beam shall be clearly indicated on the tube housing.

(14) Beryllium window X-ray tubes should not be used in general-purpose radiographic equipment.

(15) The aluminum equivalent of each item listed below shall not exceed the indicated limit.

Item	Aluminum Equivalent	
	(in)	(mm)
Front panel(s) of cassette holder	0.04	1.0
Front panel(s) of film changer	0.04	1.0
Stationary tabletop	0.04	1.0
Moveable tabletop (including stationary subtop)	0.06	1.5
Cradle	0.08	2.0
Radiation Therapy Simulator Tabletop		
a. Measured at peak tube potential of 100 kVp	0.20	5.0
b. Measured at half-value life	0.11	2.1

Note. All devices between the patient and the film should be made of the lowest atomic number material practicable and the minimum thickness required.

(16) Visual means shall be provided on the X-ray control panel of battery-powered X-ray systems to indicate whether the battery is in a state of charge that is adequate for proper operation. It shall not be possible to produce X-rays unless there is adequate charge for proper operation.

(17) Photofluorographic X-ray systems shall have a lens camera with an aperture of not less than $f/0.67$ or a mirror optics system and should have a high speed rare earth screen. The aluminum equivalent at the front panel of the camera hood shall not be more than 0.02 inch (0.5 mm) when measured at a peak tube potential of 100 kVp and a half-value layer of 0.11 inch (2.7 mm) aluminum.

(18) Each high-voltage generator assembly

shall be supplied with a pair of shockproof cable receptacles for each X-ray tube assembly that the high-voltage generator is to energize. These shockproof cable receptacles shall be in accordance with Federal Standard No. 72, and the high-voltage generator shall be permanently marked "Equipped with Federal Standard Shockproof Cable Receptacles." Receptacles shall be covered when not in use.

(19) The cathode and anode cable receptacles shall be permanently identified (labeled).

(20) Each three-phase X-ray system having a tube current of 600 mA or greater shall be provided with an anode heat calculator.

(21) Each X-ray system shall have a tube protective circuit.

b. Performance Standards. This paragraph is

primarily for the guidance of those concerned with evaluating the radiation safety/compliance characteristics of radiographic X-ray systems.

(1) If the filter in the X-ray system is not accessible for examination and the total filtration is unknown, the HVL of the useful (primary) beam shall be determined. The requirements in paragraph 5-3a(4) have been met for single-phase X-ray systems if the measured half-value layer of the useful (primary) beam for a given tube potential is not less than the value given in tables 2 and 3, appendix E. For three-phase X-ray systems, compliance in the range above a peak tube potential of 90 kVp may be assumed to have been met if the HVL at a peak tube potential of 90 kVp is not less than 3 mm aluminum equivalent (see table 4, appmE). The homogeneity coefficient for a diagnostic X-ray system operating at a peak tube potential above 50 kVp should be greater than 0.6. The total filtration in the useful (primary) beam should not exceed the values given in paragraph 5-3a(4) by more than 40 percent for a specified peak tube potential (kVp) except for special procedures X-ray systems.

(2) Deviation of technique factors from indicated values shall not exceed the maximum deviation as specified by the manufacturer. Additionally, the mAs or timer's estimated coefficient of variation shall be no greater than 0.05.

(3) When a certified X-ray system is operated on an adequate power supply and voltage regulation as specified by the manufacturer, for any specific combination of selected technique factors, the estimated coefficient of variation of the radiation exposures shall be no greater than 0.05. For old X-ray systems, the estimated coefficient of variation of the radiation exposures shall be no greater than 0.1.

(4) When an X-ray system allows a choice of tube current, (mA) settings and is operated with adequate power supply and voltage regulation, product (mR/mAs) obtained at any two consecutive tube current (mA) settings shall not differ by more than 0.10 times their sum for any fixed peak tube potential (kVp) within the range of 40 percent to 100 percent of the maximum rated peak tube potential (kVp). That is: $|\bar{X}_1 - \bar{X}_2| \leq 0.10 (\bar{X}_1 + \bar{X}_2)$; where \bar{X}_1 and \bar{X}_2 are the average mR/mAs values obtained at each of the two consecutive tube current (mA) settings.

Note. The linearity requirements do not apply to: a spot-film tube operated at only one tube current (mA) value, mammographic tube operation, or other X-ray systems where the X-ray system accuracy is specified at only one tube current (mA) value, or a tube used only with an image intensifier.

(5) The radiation output (mR/mAs) obtained

from the mean of the extremes over the entire range of exposure times and tube current (mA) settings designed into the X-ray control shall not vary by more than ± 10 percent when measurements are made at a specified peak tube potential (kVp) and distance.

Note. The product of tube current (mA) and exposure time shall be greater than 1 mAs when making the above measurements.

(6) The X-ray control shall provide visual indication whenever rays are produced. In addition, all X-ray systems shall have a signal audible to the operator that indicates when the exposure has terminated.

(7) Radiation emitted from capacitor energy storage X-ray systems when the exposure switch or timer is not activated shall not exceed 2 mR/hr at 2 inches (5 cm) from any accessible surface of the tube housing with the beam-limiting device fully open.

(8) For all new X-ray systems, the radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 mR in 1 hour at 2 inches (5 cm) from any accessible surface of the component when it is operated under any condition for which it was designed. For old X-ray systems, the radiation emitted by a component other than the diagnostic source assembly should not exceed 2 mR in 1 hour and shall not exceed 5 mR in 1 hour at 2 inches (5 cm) from any accessible surface of the component when it is operated under any condition for which it was designed.

(9) When two or more X-ray tube housing assemblies are operated from a single X-ray control, there shall be:

(a) Indication on the X-ray control panel identifying which tube is connected/energized.

(b) Indication at or near the tube housing assembly when it is connected/energized.

(c) Visible indication from the position of the exposure switch showing the peak tube potential (kVp), tube current (mA), and exposure time.

(d) Means to prevent energizing more than one tube housing assembly at the same time.

(10) The incident skin exposure to an average individual from a photofluorographic X-ray system shall not exceed 200 mR when the X-ray system is operated at the optimum technique factors for a posteroanterior (PA) chest examination. A photofluorographic X-ray system that gives an incident skin exposure in excess of 200 mR shall not be used until the value can be reduced to less than 200 mR.

(11) The incident skin exposure to an average individual from all other automatic exposure controlled chest X-ray systems shall not exceed 60 mR when the X-ray system is operated at the optimum

technique factors for a PA chest examination. An X-ray system that gives an incident skin exposure in excess of 60 mR shall not be used until the value can be reduced to less than 60 mR.

(12) For all new X-ray systems with automatic exposure control, there shall be a visible indication on the X-ray control panel when this mode of operation is selected. When the X-ray peak tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses. The minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver 5 mAs, whichever is greater. Either the product of peak tube potential (kVp), tube current (mA), and exposure time(s) shall be limited to not more than 60 kilowatt-seconds (kWs) per exposure, or the product of tube current (mA) and exposure time(s) shall be limited to not more than 600 mAs per exposure except when the peak tube potential is less than 50 kVp. In this case, the product of tube current (mA) and exposure time shall be limited to not more than 2000 mAs per exposure. A visible signal shall indicate when the exposure has been terminated at the limits described above. Manual resetting shall be required before further automatically timed exposures can be made.

(13) For general-purpose X-ray systems, except when spot-film devices or special attachments for mammography are used, means shall be provided for stepless adjustment of the size of the X-ray field. The minimum X-ray field size at an SID of 40 inches (100 cm) shall be equal to or less than 2 by 2 inches (5 by 5 cm). Means shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either linear dimension (length or width) shall not exceed 2 percent of the distance from the source to the center of the visually defined field, when the surface upon which it appears is perpendicular to the axis of the useful (primary) beam.

(14) For all new general-purpose X-ray systems, when a light localizer is used to define the perimeter of the X-ray field, it shall provide an average illumination of not less than 15 footcandles (160 lux) at 40 inches (100 cm) or at the maximum SID, whichever is less, when corrected for ambient light. For all old general-purpose X-ray systems, when a light localizer is used to define the perimeter of the X-ray field, it should provide an average illumination of at least 15 footcandles (160 lux) and shall provide an average illumination of not less than 8 footcandles (85 lux) at 40 inches (100 cm) or at the maximum SID, whichever is less, when

corrected for ambient light. Radiation therapy simulation systems are exempt from the above illumination requirements. For all general-purpose X-ray systems, the voltage and wattage of the light localizer light source shall not differ from the voltage and wattage specified by the manufacturer. The average illumination shall be based upon measurements made with a photometer in the approximate center of each quadrant of the light field.

Note. If the light field device is only a centering light and is not intended to visually define the perimeter of the X-ray field, then no specific illumination intensity or light field contrast requirements apply. The light intensity must be sufficient, however, to permit proper alignment in a normally illuminated room.

(15) For all new general-purpose X-ray systems, when a light localizer is used to define the perimeter of the X-ray field, the edge of the light field at 40 inches (100 cm) or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient light, of not less than 4 in the case of beam-limiting devices designated for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 0.12 inch (3 mm) from the edge of the light field toward the center of the field; and I_2 is the illumination 0.12 inch (3 mm) from the edge of the light field away from the center of the field. Compliance shall be determined with a photometer having a measuring aperture of 0.04 inch (1 mm).

(16) When positive beam limitation (e.g., field sizing or interlocking of the cassette tray and vertical cassette holder) is employed, the device shall, at the SID for which it was designed, either:

(a) Cause automatic adjustment of the X-ray field in the plane of the image receptor to the image receptor size within 5 seconds after insertion of the image receptor; or

(b) If adjustment is accomplished automatically in a time interval greater than 5 seconds of is manual, will prevent production of X-rays until the adjustment is completed.

At SID's for which the device is not intended to operate, the device shall prevent the production of X-rays. The X-ray field size in the plane of the image receptor, whether automatically or manually adjusted, shall be such that neither the length nor the width of the X-ray field differ from that of the image receptor by greater than 3 percent of the SID. The sum of the length and width differences without regard to sign shall be no greater than 4 percent of the SID when the beam indicates that the beam axis is perpendicular to the plane of the image receptor. The radiographic X-ray system shall be capable of

operation, at the discretion of the operator, in such a manner that the field size at the image receptor can be adjusted to a size smaller than the image receptor. The minimum X-ray field size at a distance of 40 inches (100 cm) shall be equal to 2 by 2 inches (5 by 5 cm) or less. Return to positive beam limitation shall occur upon a change in image receptor.

Note. The requirement for positive beam limitation shall apply to stationary, general-purpose X-ray systems containing a tube-housing assembly, an X-ray control, and for those systems so equipped, a table, all certified in accordance with 21 CFR 1020.30.

(17) Positive beam limitation may be bypassed when:

(u) Radiography is conducted that does **not** use the cassette tray or permanently mounted vertical cassette holder; or

(b) When either the beam axis or table angulation is not within 10 degrees of the horizontal or vertical during any part of the exposure, or during stereoscopic radiography.

If the bypass mode is provided, the return to positive beam limitation shall be automatic.

(18) A capability may be provided for overriding positive beam limitation in the event of system failure or to perform special procedures that cannot be performed in the positive mode. If so provided, a key shall be required to override the positive mode. It shall be impossible to remove the key while the positive mode is overridden.

(19) For all stationary general-purpose X-ray systems, except when spot-film devices or special attachments for mammography are used, means shall be provided to:

(a) Indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

(b) Align the center of the X-ray field with respect to the center of the image receptor to within 2 percent of the SID.

(c) Indicate the SID to within 2 percent.

(20) For all stationary general-purpose X-ray systems, except when spot-film devices or special attachments for mammography are used, the indication of field size dimensions and SID's shall be:

(a) Specified in inches/centimeters.

(b) Such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor. These correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(21) Radiographic X-ray systems designed for only one image receptor size at a fixed SID shall be:

(a) Provided with a means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to

align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID.

(b) Provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(22) The central ray of the X-ray beam, grid center, and image receptor center shall be aligned to within 0.5 inch (1.3 cm) when centered by means provided on the X-ray system.

(23) For new X-ray systems designed only for mammography, the transmission of the useful (primary) beam through any image receptor support provided with the system shall be limited such that the exposure 2 inches (5 cm) from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 mR for each activation of the X-ray tube. For X-ray systems, manufactured prior to 5 September 1978, designed only for mammography, the exposure through the image receptor support provided should not exceed 0.1 mR and shall not exceed 1 mR for each activation of the X-ray tube. The exposure shall be determined with the X-ray system operated at the minimum SXD for which it is designed.

(24) For all radiographic X-ray systems designed only for mammography and general-purpose radiographic X-ray systems with special attachments for mammography, means shall be provided to limit the useful (primary) beam so that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID, except the edge of the image receptor designed to be adjacent to the chest wall where the X-ray field shall not extend beyond this edge by more than 2 percent of the SID. Each image receptor support intended for installation on an X-ray system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(25) The leakage radiation from the diagnostic source assembly when measured at 40 inches (100 cm) in any direction from the source shall not exceed 100 mR in 1 hour when the X-ray tube is operated at its leakage technique factors (see para 8-2). If the maximum rated peak tube potential (kVp) of the tube housing assembly is greater than the maximum rated peak tube potential (kVp) for the diagnostic source assembly, positive means shall be provided to limit the maximum X-ray peak tube potential (kVp) to that of the diagnostic source assembly.

5-4. Mobile radiographic X-ray systems. a. Design requirements.

(1) Recommendations given in paragraph 5-3a for fixed radiographic X-ray systems are applicable to mobile equipment except for paragraphs 5-3a(6), 5-3a(15), and 5-3a(17).

(2) Inherent provisions shall be made so that the X-ray system is not operable at an SSD of less than 12 inches (30 cm).

(3) The exposure switch shall be so arranged that the operator can stand at least, 6 feet (1.8 m) from the patient, the X-ray tube, and the useful (primary) beam.

(4) Mobile X-ray systems shall have wheels and casters that are at least 4 inches (10 cm) in diameter and shall have wheel brakes capable of stopping and holding the system on a 5-degree incline.

(5) Mobile X-ray systems shall have a means other than the positioning locks to secure the diagnostic source assembly while the X-ray system is in motion.

(6) Mobile X-ray systems shall have a minimum turning radius no greater than the distance between the main support and the drive wheels.

(7) Self-propelled mobile X-ray systems shall have adequate power to climb an incline of at least 5 degrees and cross a worst-case elevator threshold consisting of a 1-inch (2.54 cm) step preceded by a 1.5-inch (3.8 cm) gap.

(8) If a mobile X-ray system is used routinely in one location, it shall be considered a fixed X-ray facility. Under these conditions the shielding requirements for fixed X-ray facilities apply (see chap. 4).

b. Performance standards. The performance standards in paragraph 5-3b for fixed radiographic X-ray systems are applicable to mobile X-ray system except for paragraphs 5-3b(9), 5-3b(10), 5-3b(11), 5-3b(16), 5-3b(17), 5-3b(18), 5-3b(19), 5-3b(20), 5-3b(21), and 5-3b(22).

5-5. Urological X-ray systems. a. Design requirements.

(1) All provisions of paragraphs 5-3a apply, except paragraphs 5-3a(3) and 5-3a(17).

(2) A beam-limiting device shall be provided. It may consist of an assortment of removable fixed-aperture diaphragms or of multiple fixed-apertures sufficient to meet the requirements for each combination of image receptor size and SID for which the unit is designed. Each device shall be clearly and permanently marked to indicate the image receptor size and SID for which it is designed.

b. Performance standards. The performance standards of paragraph 5-3b for fixed radiographic X-ray systems are applicable to urological X-ray system except for paragraphs 5-3b(10),

5-3b(11), 5-3b(13), 5-3b(14), 5-3b(15), 5-3b(16), 5-3b(17), 5-3b(18), 5-3b(19), 5-3b(23), and 5-3b(24).

5-6. Dental radiographic X-ray systems. a. Design requirements.

(1) A diagnostic type protection source assembly shall be provided, and shall have the location of the apparent focal spot clearly indicated on the tube housing.

(2) An open-ended position-indicating device (PID) shall be provided for an X-ray system using an intraoral image receptor. An open-ended PID should be designed so that the useful (primary) beam does not strike the inside wall of the PID or the PID shall be appropriately shielded to contain the radiation. The SSD shall not be less than 7 inches (18 cm) if the X-ray system is operable at a peak tube potential above 50 kVp, or 4 inches (10 cm) if not operable at a peak tube potential above 50 kVp.

(3) For dental X-ray systems designed for intraoral image receptor radiography, the useful (primary) beam at the minimum SSD shall be containable in a circle having a diameter of no more than 2.75 inches (7.0 cm) whenever the minimum SSD is 7 inches (18 cm) or more. If the minimum SSD is less than inches (18 cm), the useful (primary) beam shall be containable in a circle having a diameter of no more than 2.36 inches (6.0 cm).

(4) The aluminum equivalent of the total filtration in the useful (primary) beam shall be not less than that shown below:

Maximum peak tube potential	Minimum total filtration (inherent plus added)
≤ 70 kVp	1.5 mm aluminum
≥ 71 kVp	2.5 mm aluminum

(5) A timing device shall be provided to terminate the exposure after a preset time, preset product of tube current (mA) and exposure time (mAs) or a preset number of pulses. Termination of the exposure shall cause automatic resetting of the timer to its initial setting or to zero except for dental panoramic X-ray systems. It shall not be possible to make an exposure when timer is set to a zero or off position. The timing device should permit making reproducible exposures as short as 1/60 second.

(6) The exposure switch shall have a circuit-closing contact (dead-man switch) which can be maintained only by continuous pressure on the switch by the operator. The exposure switch shall be electrically connected into the primary circuit of the high-voltage generator except for a wireless switch, and shall be so located that it cannot be

conveniently operated outside the protective barrier when such a barrier is provided.

(7) Mechanical support of the tube head and beam-limiting device shall maintain the exposure position without drift, sag, or vibration.

(8) The X-ray control shall include means for indicating peak tube potential (kVp), tube current (mA), and exposure duration. For X-ray systems having fixed technique factors, this requirement shall be met by permanent markings. The X-ray control shall be so placed that these technique factors can be observed during the exposure procedure. The peak tube potential (kVp) and tube current (mA) shall be indicated by meters or by control settings, except for dental X-ray systems that operate at a present peak tube potential (kVp) and tube current (mA) or exposure duration. A milliammeter, light, or other device shall give visual indication when X-rays are being produced.

b. Performance standards. This paragraph is primarily for the guidance of those concerned with evaluating the radiation safety/compliance characteristics of dental X-ray systems.

(1) If the filter in the X-ray system is not accessible for examination and the total filtration is unknown, the HVL of the useful (primary) beam shall be determined, and the measured HVL compared to the HVL for the specific peak tube potential (kVp). For any dental X-ray system designed for use with intraoral image receptors, the HVL shall not be less than 1.5 mm aluminum up to and including peak tube potentials of 70 kVp. Above a peak tube potential of 70 kVp, the HVL shall not be less than the value given in table 2, appendix E, for the specific peak tube potential (kVp). The homogeneity coefficient for a diagnostic X-ray system operating at a peak tube potential above 50 kVp should be greater than 0.6. The total filtration in the useful (primary) beam:

(a) Should not exceed the values given in paragraph 5-6a(4) by more than 20 percent.

(b) Shall not exceed by more than 40 percent for a specified peak tube potential (kVp).

Note. The added aluminum filter acts as a source of scattered radiation when the X-rays pass through it. For this reason, the filter shall be located near the window of the tube housing and behind the diaphragm if possible.

(2) An appropriate open or closed-ended PID shall be provided in intraoral image receptor radiography.

(3) The exposure switch should be electrically connected into the primary circuit of the high-voltage generator. Exposure (telemetric) switches controlling the tube circuit by wireless means (radio or sound signal) should be used with caution. If two

or more telemetric timers are to be employed within the same dental clinic, no timers shall operate on the same frequency and the remote controls shall be labeled or controlled to assure that they do not become interchanged. In addition, all dental X-ray systems shall have a signal audible to the operator that indicates when the exposure has terminated.

(4) For dental X-ray systems designed for use with extraoral as well as intraoral image receptors, means shall be provided to limit the X-ray field in the plane of the image receptor/slot so that the X-ray field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the SID is variable and the axis of the X-ray beam is perpendicular to the image receptor. Means shall also be provided to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID. For dental panoramic X-ray systems that are designed with a fixed SID and one image receptor size, the size of the X-ray beam at the front plane of the film cassette holder shall be limited to the dimensions of the slot in the film cassette holder. For those dental panoramic X-rays systems in which the SID is variable, the X-ray beam dimensions at the front plane of the cassette holder shall not exceed the dimensions of the slit by more than 2 percent of the SID.

(5) Deviation of technique factors from indicated values shall not exceed the maximum deviation as specified by the manufacturer. Additionally, the mAs or timer's estimated coefficient of variation shall not exceed 0.05.

(6) When an X-ray system is operated with adequate power supply and voltage regulation as specified by the manufacturer, for any specific combination of selected technique factors, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05.

(7) When an X-ray system allows a choice of tube current (mA) settings and is operated on an adequate power supply and voltage regulation as specified by the manufacturer, for any fixed peak tube potential (kVp) within the range of 40 percent to 100 percent of the maximum peak tube potential (kVp), the average ratios of the radiation output to the indicated milliamper-second product (mR/mAs) obtained at any two consecutive tube current (mA) settings shall not differ by more than 0.10 times their sum. That is: $1X_1 - \bar{X}_2 \leq 0.10 (X_1 + \bar{X}_2)$; where \bar{X}_1 and \bar{X}_2 are the average mR/mAs values obtained at each of the two consecutive tube current (mA) settings.

(8) Radiation emitted from capacitor energy storage equipment when the exposure switch or timer is not activated shall not exceed 2 mR/hr at 2

inches (5 cm) from any accessible surface of the source assembly with the beam-limiting device fully opened.

(9) When two or more X-ray tube housing assemblies are operated from a single X-ray control, there shall be:

(a) Indication on the X-ray control panel identifying which tube is connected/energized.

(b) Indication at or near the tube housing assembly when it is connected/energized.

(c) Visible indication from the position of the exposure switch showing the peak tube potential (kVp), tube current (mA), and exposure time.

(d) Means to prevent energizing more than one tube housing assembly at the same time.

(10) For all new X-ray systems, the radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 mR in 1 hour at 2 inches (5 cm) from any accessible surface of the component when it is operated under any condition for which it was designed. For old X-ray systems, the radiation emitted by a component other than the diagnostic source assembly should not exceed 2 mR in 1 hour and shall not exceed 5 mR in 1 hour at 2 inches (5 cm) from any accessible surface of the component when it is operated under any condition for which it was designed.

(11) The leakage radiation from the diagnostic source assembly when measured at 40 inches (100 cm) in any direction from the source shall not exceed 100 mR in 1 hour when the X-ray tube is operated at its leakage technique factors (see para 8-2). If the maximum rated peak tube potential (kVp) of the tube housing assembly is greater than the maximum rated peak tube potential (kVp) for the diagnostic source assembly, positive means shall be provided to limit the maximum X-ray peak tube potential (kVp) to that of the diagnostic source assembly.

5-7. Veterinary X-ray systems, a. Design requirements. The X-ray systems shall meet the design requirements for the corresponding medical X-ray system and NCRP Report No. 36.

b. Performance standards. The X-ray system should meet the performance standards for the corresponding medical X-ray system; however, the X-ray system or the components do not require certification in accordance with 21 CFR subchapter J.

5-8. Other radiographic X-ray systems. All special purpose radiographic X-ray systems shall meet all provisions of paragraph 5-3a and 5-3 b except for field limitation and alignment or other variance granted under the provisions of 21 CFR 1010. For those special purpose radiographic X-ray systems that have not been granted a variance, means shall be provided to limit the X-ray field in the plane of the image receptor so that such a field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID (see 21 CFR 1020.31).

5-9. Time sharing high-voltage generators. a. When time sharing of a high-voltage generator is used, a means shall be provided to insure that only one X-ray control can be selected for continued use at a time by the employment of an appropriate type switching arrangement.

b. The switching arrangement of each X-ray control shall be readily accessible to the operator of each control and be capable of disconnecting primary electrical power to the time shared high-voltage generator (see National Fire Code).



CHAPTER 6

MANUFACTURE, MODIFICATION, REPAIR, ASSEMBLY, AND REASSEMBLY

6-1. Scope. This chapter establishes DA policies for the manufacture, modification, repair, assembly, and reassembly of diagnostic X-ray systems and specified components that are under the jurisdiction of DA. Specified components subject to the Standard are those specified components manufactured after 1 August 1974 (21 CFR 1020.30) or as indicated below:

a. Tube housing assemblies (tube housings with X-ray tube ins talled).

b. X-ray controls (includes exposure timers when housed separately).

c. X-ray high-voltage generators (transformers with other appropriate elements).

d. Tables.

e. Cradles.

f. Film Changers.

g. Cassette holders (Vertical frames and any cassette holder with a front panel, but excludes film trays within tables).

h. Beam-limiting devices (collimators, diaphragms, cones, etc.).

i. Fluoroscopic image assemblies (manufactured after 1 August 1974 and before 26 April 1977).

j. Spot-film devices (manufactured after 26 April 1977).

k. Image intensifiers (manufactured after 26 April 1977).

1. Cephalometric devices (manufactured after 25 February 1978).

m. Image receptor support devices (mam-mographic X-ray systems manufactured after 5 September 1978).

6-2. Applicability to manufacturers and assemblers. The requirements of 21 CFR 1020 for diagnostic X-ray systems and their major components differ from requirements for other electronic products in one important respect. The responsibility for product performance is divided between the "manufacturer" who designs and manufactures X-ray components, and the "assembler" who installs and adjusts them. Manufacturers and assemblers of X-ray systems are both

recognized as *manufacturers* in 21 CFR 1020 and each has different responsibilities under the provisions of 21 CFR subchapter J.

6-3. Responsibilities of component manufacturers. Commercial firms and military depots who manufacture X-ray components are subject to reporting and recordkeeping requirements (see 21 CFR subchapter J). The following responsibilities of component manufacturers are of particular interest to assemblers:

a. The component manufacturer shall certify that all specified components produced after 1 August 1974 will comply with the Federal performance standards of 21 CFR subchapter J when installed, adjusted, and tested in accordance with his instructions (21 CFR 1020).

b. Labels shall be permanently affixed to each separate component or group of components produced as a system. Labeling shall include identification of the manufacturer, model, serial number, date, and place of manufacture as well as a statement certifying that the component complies with the Standard. Labels shall be legible and readily accessible to view (21 CFR 1010 and 1020).

c. The manufacturer shall provide the assembler with adequate instructions for the assembly, installation, adjustment, and testing of each component to insure that it will comply with the performance standards of 21 CFR 1020 and the manufacturer's own specifications when those instructions are followed. These instructions shall include identification of those other components that are compatible with the component provided, when compliance of the completed system depends on their compatibility. Compatibility specifications may be made in terms of pertinent physical characteristics of the components and/or a list, by manufacturer's model number, of those components that may be assembled together.

d. The manufacturer shall provide to users of this equipment, and to others, at a cost not exceeding the cost of publication and distribution, a schedule of maintenance necessary to keep the equipment in compliance with the Standard as well as statements of required line voltage regulation and other significant data concerning X-ray generator operation (see 21 CFR 1020.30(h)).

6-4. DOD X-ray component manufacturers. a All manufacturers of diagnostic X-ray systems/specified components are required to submit to the BRH reports describing the components to be manufactured, specifications with respect to electronic production radiation safety, testing and quality control procedures, and labels to be used for identification, warnings, etc.

b. **USAMMA** is recognized by **BRH** to manufacture diagnostic X-ray tube housing assemblies. The manufacturing process may be performed by both **USAMMA** Medical Maintenance Divisions located at Defense Depot Tracy (SGMMA-MD-C) and Tobyhanna Army Depot (SGMMA-MD-P).

c. **Since USAMMA** is the only recognized manufacturer of diagnostic X-ray tube housing assemblies within the DOD, all certified X-ray tube housing assemblies within DOD shall be shipped to the appropriate **USAMMA** Medical Maintenance Division, or to a commercial manufacturer, should repairs be required.

6-5. X-ray tube housing assembly overhaul/manufacture. a. All X-ray tube housing assemblies manufactured by **USAMMA** shall be in full compliance with the Standard.

b. Overhaul of noncertified X-ray tube housing assemblies constitutes a repair, not a remanufacture. As such, provisions of the Standard do not apply.

c. Overhaul of certified X-ray tube housing assemblies constitutes a remanufacture and all certification and labeling requirements for the manufacture of these components shall apply (see 21 CFR 1020.0).

d. Medical and dental tube housing assemblies serviced/overhauled by **USAMMA** facilities should be scanned for leakage X-radiation. A certified X-ray tube housing assembly shall be rejected if leakage X-radiation exceeds original manufacturer leakage specifications when operated at its proper leakage technique factors.

e. Each tube housing assembly manufactured by **USAMMA** shall have a **USAMMA** compliance label affixed to the housing. This label shall be used for certified tube housings only.

f. **USAMMA** Medical Maintenance Divisions shall determine the dimensions of the effective focal spot after installing a new X-ray tube insert into a tube housing when so requested by the customer. This information shall be provided to the customer.

g. **USAMMA** Medical Maintenance Divisions shall determine the location of the focal spot after

installing a new tube insert into a certified tube housing and identify its location on the tube housing assembly.

h. **USAMMA** Medical Maintenance Divisions shall determine the amount of inherent filtration in the useful (primary) beam after installing a new X-ray tube insert into a tube housing when so requested by the customer. This information shall be provided to the customer.

6-6. Loan of X-ray components. a. **X-ray components** within the MEDCEN/MEDDAC and **USAMMA** Medical Standby Equipment Program (MEDSTEP) stock resources may be furnished to authorized customers under the following conditions:

(1) If the component being replaced by a loaned component is a certified component, then the loaned component shall also be certified.

(2) If the component being replaced by a loaned component is not certified, then the loaned component may be either certified or noncertified. When the original component, has been repaired and reinstalled, it may be noncertified since that was the condition when the loaned component was installed.

(3) Upon installation of a certified loaned component, BRH does not require the assembler to file Form FD 2579 provided the loaned component is clearly labeled as a temporarily installed component and it contains a label or other identification containing the assembler's signature, his company's name and address, and date of installation; and either of the following statements:

(a) **TEMPORARILY INSTALLED COMPATIBLE COMPONENT.** This certified component has been assembled, installed, adjusted, and tested according to the instructions provided by the manufacturer (see 21 CFR 1020.30).

(b) **TEMPORARILY INSTALLED NON-COMPATIBLE COMPONENT.** This certified component has been assembled or installed, but could not be assembled, installed, adjusted, and tested according to the instructions provided by the manufacturer because other already existing components of the system do not meet the compatibility specifications of the manufacturer of the certified component being installed, and there are no commercially available certified components of a similar type compatible with the system (see 21 CFR 1020.30).

b. Under no circumstances shall a noncertified loaned item be furnished when the defective component is a certified item.

6-7. Exchange of X-ray tube housing assemblies. a.

The exchange of X-ray tube housing assemblies from MEDSTEP stocks may be accomplished under the following conditions:

(1) Defective item is economically repairable, and

(2) Defective item is certified and MEDSTEP item is both certified and compatible; or,

(3) Defective item is not certified and MEDSTEP item is not certified.

b. The exchange of X-ray tube housing assembly shall not be accomplished when:

(1) Defective item is certified and MEDSTEP item is either not certified or not compatible.

(2) Defective item is not certified and MEDSTEP item is certified, unless a certified component has been previously installed in the X-ray system.

(3) Defective item is not economically repairable.

6-8. Responsibilities of assemblers. The following responsibilities of assemblers are those specified in 21 CFR 1020.30. Procedures for discharging these responsibilities are explained herein. Any DA active duty member or civilian employee who installs or maintains certified diagnostic medical or dental X-ray systems shall be familiar with these responsibilities and the DA procedures that apply to them. In addition he shall:

a. Install components of the type called for by the Standard.

b. Install components that are compatible with each other and with the certified components already in the X-ray system.

c. Follow the instructions of the manufacturer of the equipment installed.

d. Turn over to the purchaser those instructions that the component manufacturer is required to provide for the user.

e. Complete Form FD 2579 whenever finished with the installation of a certified X-ray component (see para 10-4).

f. Make required distribution of Forms FD 2579 within 15 days of completing an installation (see para 10-4).

g. Deviate from a through c above only in CFR 1010.4 or upon installation of a certified loaned component as provided for in paragraph 6-6.

h. Report all electronic product defects and accidental radiation occurrences in accordance with this bulletin (see para 6-17).

6-9. Meaning of "type called for by the Standard."

One of the statements an assembler certifies when

signing a Form FD 2579 is that all certified components installed by him were of the type called for by the Standard (21 CFR 1020). Signing this statement does not mean that an assembler personally tested the components to verify their compliance with every applicable requirement of the Standard. It does mean that he did not knowingly assemble any components which, by design, were inherently incapable of satisfying the Standard. For example, 21 CFR 1020.31 requires that beam-limiting devices on stationary, general purpose, medical X-ray systems be so designed as to provide positive beam limitation (PBL) when the X-ray system contains a tube housing assembly, an X-ray control, and, for those systems so equipped, a table, all certified in accordance with 21 CFR 1020.30. This means that the beam-limiting device shall be equipped with electronic circuitry to prevent the production of X-rays until the X-ray beam is aligned with the X-ray film PBL is not required for *mobile*, general purpose X-ray systems (21 CFR 1020.31), therefore, the beam-limiting devices for mobile X-ray systems lack PBL circuitry. An assembler who installs the certified beam-limiting device designed for a mobile X-ray system into a stationary, general purpose system, is not installing the type of component called for by the Standard. Assemblers shall be sufficiently familiar with 21 CFR 1020 so that errors of this type will not occur. Generally, determinations of noncompliance in the "type called for by the Standard" category are those that can be made without test equipment by a technically qualified individual who is knowledgeable about the Standard. While production and design defects may be discovered when using test equipment, and such discrepancies are to be reported, the assembler does not assume liability for the identification of defects that are not readily apparent at the time he signs Form FD 2579.

6-10. Compatibility of components. a. Two components are compatible, in the sense of 21 CFR 1020, if either is listed or described by its manufacturer as being compatible with the other and they can be assembled in accordance with manufacturer's instructions. Also, two components are considered compatible when their assembly into a system does not require interconnection of one with the other in a way that affects compliance with the Standard. In this case, manufacturers normally omit compatibility specifications. For example, it is important to assemble a beam-limiting device to an overtable X-ray tube housing assembly with which it is specified as being compatible, since the assembly of these two components determines the limitation of the X-ray beam. However, it would not

be necessary to specify compatibility of an overtable X-ray tube housing assembly with an overtable spot-film device, since the two never function simultaneously when installed in the same X-ray system.

b. Two components are noncompatible when at least, one's compliance with the Standard depends on the other, but neither is listed or described by its manufacturer as being compatible with the other and applicable instructions for their assembly and interconnection are, therefore, unavailable. Note that, from an operational viewpoint, two components might be considered compatible if they could be connected together and made functional. Even if such an assembly were to comply with the Standard, it would be noncompatible in the sense of 21 CFR 1020 if neither of the manufacturers declared the components to be compatible in their installation instructions.

6-11. When noncompatible installations are permitted. Two certified components that are noncompatible may only be assembled together if a variance has first been obtained. However, noncompatible installation of a single certified component into an X-ray system may be accomplished when both conditions *a* and *b* below are satisfied:

a. There is not commercially available component of a similar type that, is compatible with the X-ray system (a component is commercially available if it is offered for sale in the United States).

b. The component of the existing system not meeting the specifications is either:

(1) Not certified because it was manufactured before 1 August 1974.

(2) Not listed as subject to the Standard (an unspecified component) and purchased as new before 1 August 1974 (see 21 CFR 1020.30a).

6-12. Assembly and reassembly of diagnostic X-ray systems. The assembler is responsible for making compatibility determinations for the installations he performs. Determination of compatibility is only required when one or more certified components are installed. It does not apply when an uncertified component, manufactured before 1 August 1974, is installed after 1 August 1974; however, uncertified components may only be installed after that date under certain circumstances. Any specified components assembled after 1 August 1974 into an X-ray system that will be composed, upon completion of assembly, of one or more certified components, shall be only components that are themselves certified. The following examples illustrate this point:

a. An assembler who installs a new complete diagnostic X-ray system shall not install a system comprising both certified and uncertified components. If *all* components are certified, they shall all be compatible unless a variance has been obtained. If all components are uncertified, no Form FD 2579 is required and the question of compatibility is not applicable.

b. An assembler who installs components into an existing diagnostic X-ray system, containing one or more certified components prior to such installation, shall install only components that have been certified by the manufacturer, regardless of whether the certified components already in the system are themselves replaced.

c. An assembler who installs a group of components into an existing diagnostic X-ray system, containing no certified components prior to the assembly, shall not install a combination of certified and uncertified components, but shall install either all uncertified components or all certified components into such an X-ray system.

d. DA assemblers may reassemble previously existing (used) X-ray systems in DOD activities, regardless of whether they consist of all uncertified or a combination of certified and uncertified components, as long as the previous user was a DOD activity. However, any components added to or installed in place of the original components in an existing X-ray system composed of one or more certified components shall be certified. Propriety of the installation depends on the requirements of paragraph 6-1 1, above, when certified components are involved.

6-13. Exchange, repair, and replacement of X-ray components. The examples provided in paragraph 6-12, do not apply under either of the following circumstances (21 CFR 1020.30).

a. An assembler may reinstall an uncertified component into an X-ray system containing certified components, from which it was removed for the purpose of repair, whether this repair was accomplished onsite or at a commercial firm or military depot.

b. An assembler may install an uncertified component in exchange for another uncertified component in a system containing one or more certified components, so long as only *identical models* are exchanged. Exchange means permanent installation of the replacement component as distinguished from temporary replacement by a loaner.

c. The repair of X-ray systems shall be in accordance with the requirements of 21 CFR 1020.30.

6-14. Manufacturer's instructions. Assemblers installing certified components shall affirm on Form FD 2579 that they followed all applicable manufacturers' instructions except as specifically noted on the form when performing a noncompatible installation. When an assembler judges a manufacturers' instructions to be incomplete, incorrect, or ambiguous, he shall make every effort to resolve the problem with the manufacturer. If this fails, instructions should be followed to the extent possible in the assembler's best judgment, and a complete explanation of deviations included with each copy of the Form FD 2579. The assembler should be certain to "check his facts" carefully before forwarding the Form FD 2579, since all reports of inadequate installation instructions will be investigated by BRH.

6-15. Limits of responsibility. a. Manufacturer. The manufacturer of a certified component installed or assembled into an X-ray system or subsystem by another person shall not be liable for the non-compliance of such component which is attributable solely to the improper installation or assembly of the component into the system. He shall be held responsible for noncompliance if improper assembly was a result of inadequate instructions provided by such component manufacturer.

b. Assembler. The person who certified as to the assembly of an X-ray system or subsystem shall not be liable for noncompliance of a certified component if such assembly is in accordance with the instructions provided by the manufacturer of the component. He shall be held responsible for non-compliance of a component which is attributable solely to improper assembly or installation into the system or subsystem (see 21 CFR 1020.30).

6-16. Variances. A variance is required prior to assembling noncompatible certified components or assembling certified components in a manner that does not comply with all applicable instructions, except as provided in paragraph 6-11. It is also required prior to manufacturing a component or system which does not comply with the Standard. Variances are issued by BRH in accordance with the criteria and procedures contained in 21 CFR 1010.4. DA requirements for variances applicable to diagnostic X-ray systems should be rare and will normally be necessitated only by medical research programs at MEDCEN/MEDDAC or specialized medical laboratories. Applications for variance shall contain all information required by 21 CFR 1010.4. DA applications should be initiated by the commander as required. Applications shall be submitted in six copies through command channels to the Commander, USAMMA, ATTN: SGMMA-MP,

Frederick, MD 21701, for review and transmission to the Hearing Clerk, Food and Drug Administration. Requests lacking adequate justification may be disapproved by the major medical command or USAMMA without referral to BRH.

6-17. Reporting accidents, defects, and non-compliances. Pursuant to 21 CFR 1002 and 1003, manufacturers, *including assemblers*, shall report all accidental radiation occurrences to BRH and product defects or noncompliances in equipment manufactured after 1 October 1968 to the Director, Bureau of Radiological Health. To comply with these requirements, the commander shall submit such reports within 15 days through command channels to the Commander, USAMMA, ATTN: SGMMA-MP, Frederick, MD 21701, using DD Form 1899. USAMMA shall forward this information to BRH and OTSG HQDA (DASG-PSP), WASH DC 20310.

a. An accidental radiation occurrence is any radiation incident in which one or more individuals are suspected or known to have received exposure from a radiation source that was neither expected nor served the intended purpose of the equipment. A faulty timer or exposure control switch, for example, could cause an accidental radiation occurrence. Accidental radiation occurrence reports shall be filed regardless of the date of manufacture of the X-ray equipment concerned. Reports of accidental radiation occurrences shall include, at a minimum, the following information:

- (1) The nature of the accidental radiation occurrence.
- (2) The location at which the incident occurred.
- (3) The manufacturer, type, and model number of the component(s) of X-ray equipment involved.
- (4) The circumstances surrounding the accidental radiation occurrence, including causes.
- (5) The number of persons involved, adversely affected, or exposed during the accidental radiation occurrence, and the nature and magnitude of their exposure and/or injuries. (Do not include names in the initial report.)
- (6) Actions, if any, taken to control, correct or eliminate the causes and to prevent reoccurrence.
- (7) Any other information pertinent to the incident.

b. A diagnostic X-ray component or system manufactured after 1 October 1968 is considered to have a reportable defect if, as a result of design, production or assembly, it fails to conform to its design specifications relating to the emission of radiation; or, without regard to design specification,

emits electronic product radiation unnecessary to the accomplishment of its purpose which creates a risk of injury, including genetic injury to any person; or, fails to accomplish its intended purpose. Include the following information in defect or non-compliance reports:

(1) A complete description of the defect or manner in which the product fails to comply with the Standard. Include results of any test made to identify the defect or noncompliance as well as the manufacturer, model, serial number, and calibration data of any test equipment used to make the determination.

(2) A statement of any measures taken locally to correct the defect or noncompliance.

(3) The date and circumstances under which the defect was discovered.

c. A new diagnostic X-ray system or specified component that is determined to be in non-compliance with the Standard shall be described by the responsible biomedical equipment maintenance personnel using DD Form 1899 and submitted through command channels to the Commander, USAMMA, ATTN: SGMMA-MP, Frederick, MD

21701. USAMMA shall forward this information to BRH and OTSG HQDA (DASG-PSP), WASH DC 20310.

6-18. Modification of certified diagnostic X-ray systems and components. *a.* Diagnostic X-ray systems and components that are certified in accordance with 21 CFR 1010.2 shall not be modified such that the X-ray system or component fails to comply with applicable provisions of the Standard and this bulletin unless a variance or an exemption has been granted in accordance with 21 CFR 1010.

b. The X-ray system or component may be modified provided that the modification does not result in the failure of the X-ray system or component to comply with the applicable requirements of the Standard and this bulletin. The MED-CEN/MEDDAC that causes such modification need not submit reports required by 21 CFR 1002, provided the date and the details are documented on the DA Form 2409 (Equipment Maintenance Log) or automated equipment record by biomedical equipment maintenance personnel (see chap 10).

CHAPTER 7

MAINTENANCE CALIBRATION/VERIFICATION TECHNIQUES FOR DIAGNOSTIC X-RAY SYSTEMS

7-1. **Scope.** This chapter establishes DA policy for the maintenance calibration/verification techniques for diagnostic X-ray systems. These calibration/verification techniques will normally be performed by qualified biomedical equipment maintenance personnel in order to insure that the X-ray system is properly maintained in accordance with the manufacturer's maintenance instructions.

7-2. **Requirements.** a Calibration/verification of X-ray and ancillary equipment shall be performed by qualified biomedical equipment maintenance personnel at intervals not to exceed those recommended by the manufacturer, TM 8-605, and this bulletin. Where discrepancies are noted, appropriate corrective action shall be taken.

b. Technical inspections of X-ray and ancillary equipment shall be performed by qualified biomedical equipment maintenance personnel in accordance with AR 750-1, TM 8-605, TB 750-8-1, and the manufacturer's literature, as applicable.

c. Gamma-beam equipment shall be maintained in accordance with the recommendations of the manufacturer, ANSI Standards N449-1974 and N449.1-1978, and the NRC.

d. X-ray therapy equipment shall be maintained in accordance with the manufacturer's maintenance instructions. Recalibration or readjustments to X-ray therapy equipment by biomedical equipment maintenance personnel that could alter beam energy or tube current (mA) nullify the radiation calibration factor(s). When such adjustments are made, the equipment shall be recalibrated by a qualified expert as required by paragraph 9-4 prior to use for radiotherapy of human patients.

e. X-ray high-voltage generators are among the most potentially hazardous diagnostic equipment used in medicine and dentistry. Their continued safe and effective performance depends not only on the quality of the initial installation, but on the accomplishment of a thorough program of scheduled calibration/verification and preventive maintenance.

(1) The requirement to calibrate/verify and maintain certified X-ray components originates in 21 CFR 1020. It requires manufacturers of such

components to provide a schedule of maintenance necessary to maintain the system in compliance with the Standard for diagnostic medical and dental X-ray systems (21 CFR 1020.30(h)). Manufacturers are not responsible for performance discrepancies occurring in certified components not maintained according to their instructions and specifications. Uncertified X-ray system and components are not covered by the requirements of 21 CFR 1020, although they shall satisfy applicable requirements of this bulletin. Suitable instructions and standards for calibration/verification of uncertified components are not always available. To the extent possible, all X-ray systems shall be calibrated/verified to comply with the minimum standards contained in this chapter and with the manufacturer's specifications, whichever require greater accuracy. Calibration/verification of field (tactical) X-ray equipment, not in routine use, are exempt from these requirements; however, they are not exempt from the provisions of TM 8-605 and TB MED 1. Field (tactical) X-ray equipment shall be calibrated/verified prior to the clinical care of human patients.

Note. Calibration/verification at field unit level may be defined as following the operator's instructions which may be found in the manufacturer's equipment manual or the operator's instruction plate on the X-ray system.

(2) Personnel calibrating/verifying certified diagnostic X-ray components are only responsible, under provisions of 21 CFR 1020, for performing the calibration in accordance with manufacturer's instructions and specifications. The performance standards of 21 CFR 1020 are defined almost entirely in terms of quality, quantity, reproducibility, linearity, and beam limitation (collimation) of the useful (primary) beam.

(3) In addition to those maintenance actions which relate primarily to calibration/verification, there are a number of adjustments and inspection points which are necessary to insure safe (e.g., electrical and mechanical) functioning of the system. Examples of these are: Adjustment of variable aperture beam-limiting device, visual inspection of steel counterweight cable integrity, functional inspection of all interlock systems which limit, restrict, or prevent the production of X-rays, functional in-

spection of backup safety timers, etc. Manufacturer's instructions may not specify testing of all such items and certain safety features may not be required by 21 CFR 1020. The personnel conducting scheduled preventive maintenance on any X-ray system, whether certified or uncertified, are responsible for identifying and inspecting all critical safety features regardless of whether they are included in manufacturer's specifications, this bulletin, or 21 CFR 1020. While it is impossible to provide an exhaustive specification of such features applicable to all manufacturers and models of X-ray systems, this chapter includes a representative checklist for reference.

(4) Requirements for the calibration of **TMDE** and other equipment used in the calibration/verification and preventive maintenance of X-ray systems shall be as specified in AR 750-25, TB 750-25, and TB 43-180.

(5) Tube housing assembly heat storage capacity, anode cooling curves and tube rating charts, and specified tube warmup procedures shall be consulted prior to the beginning of the calibration/verification procedures and shall be strictly observed.

7-3. Responsibilities. Organization responsibilities for the calibration/verification and preventive maintenance of diagnostic X-ray systems as described below are in addition to the individual responsibilities of "assemblers" as defined in 21 CFR 1020.

a. The primary responsibility for scheduled preventive maintenance and calibration/verification of diagnostic X-ray systems rests with the **MED-CEN/MEDDAC** that has the responsibility for the geographic region in which the equipment is located.

b. Frequency of accomplishing **calibration/verification** and preventive maintenance procedures for diagnostic X-ray systems shall be as specified by the manufacturer, or after 25,000 exposures, or at least annually, whichever is more frequent. All X-ray systems used in the clinical care of patients shall be calibrated/verified so that tolerances meet the specifications of the manufacturer or this bulletin, whichever is the most restrictive.

c. In no case shall an effort be made to match the technique factors of systems with different power output modes (e.g., singlephase versus threephase, half-wave rectified versus full-wave rectified).

d. In some cases, it may not be feasible or safe to operate an X-ray high-voltage generator at technique factors capable of being selected on the X-ray control panel. For example, the power supply regulation may be insufficient to produce linearity of radiation output at specific peak tube potential (**kVp**) and tube current (**mA**) technique settings or the shielding of the X-ray tube housing assembly may be insufficient for the operation at the maximum peak tube potential (**kVp**) that the high-voltage generator is capable of producing. When such situations occur, the X-ray control shall be derated to prevent selection of undesirable or unsafe technique factors. Temporary derating (for periods of 3 months or less) may be accomplished by affixing an appropriate warning placard, dated and in plain sight, on the X-ray control panel. Permanent derating (for periods longer than 3 months) shall be accomplished by internal electronic or electromechanical modification, which disables the generator and prevents production of X-rays when a prohibited technique is selected, as well as affixing an appropriate warning placard, in plain sight, on the X-ray control panel. Accomplishments of such modifications shall be approved only by the Chief of Biomedical Equipment Maintenance. Written records of such modifications and the reasons for performing them shall be maintained.

e. Upon change of any X-ray component or repair part which may affect radiation output or specified tolerance (e.g., tube housing assembly, tube current (**mA**) stabilizer, printed circuit board), a partial or total recalibration shall be accomplished.

f. DD Form 2163, Medical Equipment Verification/Certification (label), shall be affixed to the master X-ray control panel of all X-ray systems upon completion of each scheduled calibration/verification as required by AR 40-61.

7-4. Schedule of annual maintenance for diagnostic medical and dental X-ray systems. a Tube housing assemblies and mounting system (para 7-5a).

	Paragraph reference	Medical X-ray systems	Denial X-ray systems
		Test/Verify	Test/Verify
Radiation leakage	7-5a(1)	X	X
Beam quality	7-5a(2)	X	X
Standby radiation (capacitor energy storage systems)	7-5a(3)	X	NA
Focal spot dimensions/size	7-5a(4)	X	X
Comparative film density	7-5a(5)	X	NA
Certification label	7-5a(6)	X	X
Indicator light(s)	7-5a(7)	X	X
Oil leaks	7-5a(8)	X	X
Physical damage or tampering	7-5a(9)	X	X
Mounting system stability and tubestand	7-5a(10)	X	X

b. Generators and controls (para 7-5b).

Line Voltage and Regulation	7-5b(1)	X	X
Calibration/Verification	7-5b(2)	X	X
Fluoroscopic-cinegraphic kVp and mA	7-5b(3)	X	NA
Fluoroscopic override and alarm	7-5b(4)	X	NA
Collimator filter interlock	7-5b(5)	X	NA
Visual exposure indicator	7-5b(6)	X	X
Audible exposure indicator	7-5b(7)	X	X
X-ray tube indicator	7-5b(8)	X	X
Automatic exposure control (AEC) devices	7-5b(9)	X	NA
AEC minimum exposure	7-5b(10)	X	NA
Fluoroscopic timer accuracy/alarm	7-5b(11)	X	NA
Dead-man exposure switch	7-5b(12)	X	X
Certification labels, warnings, and indicators	7-5b(13)	X	X
Reproducibility	7-5b(14)	X	X
Linearity	7-5b(15)	X	X
Overload protective circuit	7-5b(16)	X	NA
Main switch	7-5b(17)	X	X

c. Beam-limiting devices (para 7-5c).

Physical damage or tampering	7-5c(1)	X	X
Leakage radiation	7-5c(2)	X	X
Variable field	7-5c(3)	X	X
Visual definition, as appropriate	7-5c(4)	X	X
Field indication and alignment	7-5c(5)	X	X
Positive beam limitation	7-5c(6)	X	NA
Single image receptor size	7-5c(7)	X	X
Source-skin distance	7-5c(8)		
For fluoroscopic systems	7-5c(8)(a)	X	NA
For intraoral receptors	7-5c(8)(b)	NA	X
Certification labels	7-5c(9)	X	X

d. Fluoroscopic imaging assemblies (para 7-5d).

Radiation leakage	7-5d(1)	X	NA
Primary protective barrier	7-5d(2)	X	NA
Field limitation and alignment with spot film device	7-5d(3)	X	NA
Grid alignment	7-5d(4)	X	NA
Certification labels	7-5d(5)	X	NA

e. Nonimage intensified fluoroscopy (para 7-5e).

Test/Verify medical X-ray systems.

	Paragraph reference	Medical X-ray systems	Dental X-ray systems
		Test/Verify	Test/Verify

f. Image intensified fluoroscopy (para 7-5f).

Physical Alignment	7-5f(1)	X	NA
Misalignment	7-5f(2)	X	NA
Field Size Limitation	7-5f(3)	X	NA
Contrast	7-5f(4)	X	NA
Focusing	7-5f(5)	X	NA
Glare	7-5f(6)	X	NA
Entrance exposure rate	7-5f(7)	X	NA
Certification labels	7-5f(8)	X	NA

g. Tomography (para 7-5g).

Cut level	7-5g(1)	X	NA
Exposure angle	7-5g(2)	X	NA
Exposure uniformity and beam path	7-5g(3)	X	NA
Cut thickness	7-5g(4)	X	NA
Flatness of plane	7-5g(5)	X	NA
Resolution	7-5g(6)	X	NA
Certification labels	7-5g(7)	X	NA

h. Computerized tomography (para 7-5h).

Precision (noise)	7-5h(1)	X	NA
Control scale	7-5h(2)	X	NA
High and low contrast resolution	7-5h(3)	X	NA
Alignment	7-5h(4)	X	NA
scan increment	7-5h(5)	X	NA
Certification labels	7-5h(6)	X	NA

i. Table (para 7-5i).

Aluminum equivalent	7-5i(1)	X	NA
Grid alignment	7-5i(2)	X	NA
Bucky centering light	7-5i(3)	X	NA
Certification labels	7-5i(4)	X	NA

j. Cradles (para 7-5j).

Test/Verify medical and dental X-ray systems.

k. Film changers (para 7-5k).

Attenuation	7-5k(1)	X	NA
Interlocks (if applicable)	7-5k(2)	X	NA
Alignment in automatic mode (if applicable)	7-5k(3)	X	NA
Certification labels	7-5k(4)	X	NA

l. Cassette holders (para 7-5l).

Attenuation	7-5l(1)	X	NA
Interlocks (if applicable)	7-5l(2)	X	NA
Alignment indicators	7-5l(3)	X	NA
Alignment in automatic systems	7-5l(4)	X	NA
Certification labels	7-5l(5)	X	X

m. Counterweight and high tension Cables (para 7-5m).

Test/Verify medical and dental X-ray systems.

n. Electrical grounding and leakage current (para 7-5n).

Test/Verify medical and dental X-ray systems.

7-5. Details of annual maintenance schedule for diagnostic Medical and dental X-ray systems.

a. Tube housing assembly and mounting system.

(1) *Radiation leakage.* Look for obvious physical damage which would affect shielding integrity and proper beam-limiting device function. Measure tube housing assembly leakage (see para 8-2).

(2) Beam quality.

(a) Verify that all filtration elements, inherent and added, provided by the beam-limiting device and tube housing assembly, are present and show no evidence of physical damage or alteration which might alter attenuation of the useful (primary) beam. Measure the beam quality by determining the HVL (see para 8-3).

Note. For single-phase x-ray systems operated in the fluoroscopic mode, the voltage waveform closely approximates that of a three-phase high-voltage generator; therefore, table 4, appendix E, should be used for determining the total filtration from the measured half-value layer whereas table 3, appendix E, should be used for the spot-film mode. The measured beam quality (HVL) of the useful (primary) beam shall not exceed the values in table 2, appendix E, by more than 40 percent for a specified peak tube potential (kVp) except for special procedures X-ray systems.

(b) Verify the operation of the filter-peak tube potential (kVp) interlock in systems with more than one thickness of filtration.

(3) *Standby radiation* (capacitor energy storage systems). Verify that electronic (tube grid control) or mechanical devices (contractors, lead shutter, etc.) for standby radiation suppression are in proper operating condition. Measure the amount of radiation emitted when the exposure switch or timer is not activated (see para 8-14). Also measure the amount of radiation emitted when the peak tube potential (kVp) is reduced from the maximum setting and when electrical power is turned off after the peak tube potential (kVp) has been set at maximum.

(4) Focal spot dimensions/size.

(a) The tolerances for the dimensions of the focal spot as specified by National Electrical Manufacturers' Association (NEMA) and International Electrotechnical Commission (IEC) are as follows:

Nominal focal spot size (mm)	Tolerance in percent	
	Minus	Plus
< 0.8	0	50
0.8-1.5	0	40
> 1.5	0	30

(b) Measure dimensions of focal spot. The nominal focal spot size shall not exceed tolerances in the table above.

(c) Measure the resolution of the focal spot to determine the growth that occurs on the anode.

Note. The growth characteristics of the focal spot shall be such that the size of the focal spot does not increase by more than 50 percent over the entire range of peak tube potentials (kVp) and tube currents (mA) designed into the X-ray control.

(5) *Comparative film density.* Evaluate comparative film density for selected combinations of technique factors and distances using a penetrometer (step-wedge). These films should be compared to those previously obtained for the same combination of technique factors and distances (see table 2 1, appendix E).

Note. The comparison of film densities should be performed with caution, because the radiation output may vary by as much as 10 percent and the variability in film processing can not be controlled without appropriate quality control programs for film processing. Variations in peak tube potentials (kVp) that accompany changes in tube currents (mA) also can produce density differences and will produce variations in image contrast.

(6) *Certification label.* Verify that all certification labels are affixed and visible as required (see para 6-3).

(7) *Indicator light(s).* Verify that indicator lights operate properly.

(8) *Oil leaks.* Make visual inspection for oil leaks.

Note. An oil leak indicates mechanical damage to the tube housing and the possibility of leakage radiation increases. Oil leaks also affect the cooling of the X-ray tube as well as the high voltage insulation.

(9) *Physical damage or tampering.* Check for physical damage or tampering that might affect radiation safety.

(10) *Mounting system stability and tubestand.* Visual inspection for wear, sag, and drift. Perform a functional test of all locks intended to fix the position of moving mechanical components.

Note. The tubestand shall be free of binding, excessive noise, drift, and properly counterbalanced. All locks shall be quiet acting, positive stopping, easily operated, and within easy reach of the operator. The detent is positive acting in both longitudinal and lateral positions. The force required to position the tubestand of the X-ray system shall not be over 7 pounds (31 newtons). The tube hanger properly accommodates the diagnostic source assembly and associated components and the tube carriage is properly aligned both vertically and horizontally. Cables shall be properly dressed, protected by strain reliefs, and covered when required. Cable retractors shall be properly installed and operate properly. The tubehanger shall not interfere with table tilt when the tube is "parked."

b. Generators and controls.

(1) *Line voltage and voltage regulation.* Measure line voltage and voltage regulation to confirm that both are within manufacturer's specifications and that the supply line is connected to the proper line terminals, if applicable. Verify that the line voltage compensator is operable.

(2) *Calibration/verification.* Perform the manufacturer's calibration procedure, including but not necessarily limited to, testing and adjusting peak tube potential (kVp), tube current (mA), product of the tube current (mA) and exposure time(s), mAs, and other factors to specifications in the manufacturer's instructions.

(a) *Tube potential.* The peak tube potential (kVp) applied to the X-ray tube should be adjusted to within ± 3 percent and shall be adjusted within ± 5 percent of the measured value over the range of technique combinations for which operation is possible regardless of tube current (mA) or product of tube current (mA) and exposure time(s), mAs, selected.

Note. A decrease in actual peak tube potential (kVp) with an increase in nominal peak tube potential (kVp) may mean that the product of exposure time and tube current (mAs) is increasing with peak tube potential (kVp) and that the space charge compensation circuit is not properly adjusted.

(b) *Tube current.* For X-ray systems on which tube current (mA) and exposure time are independently selected at the X-ray control panel, tube current (mA) shall be adjusted throughout the rated range of peak tube potential (kVp) to within ± 5 percent of the nominal selected value.

(c) *Milliamperes-seconds.* For X-ray systems that do not have independently variable tube current (mA) and exposure time settings, the product of exposure time(s) and tube current (mA), mAs, must be calibrated or verified as appropriate. The measurement shall be within ± 5 percent of the value obtained by multiplying the indicated nominal values of exposure time and tube current (mA) or by

reading the value from the mAs/mA selector as appropriate.

Note. When mAs/mA is automatically selected by the selection of exposure time, then the deviation from linearity should not be greater than 0.10.

It may be necessary to readjust tube current (mA) or time settings to maintain a tolerance of ± 5 percent in product of tube current (mA) and exposure time(s), mAs.

(d) *Timer.* Verify that termination of exposure results in automatic resetting to the initial time setting or to zero, whichever is appropriate. Verify that an exposure can be made at all timer settings. Verify that an exposure cannot be made unless the timer is set on a specific time other than "zero."

Note. When evaluating timer accuracy, use the percentage of the voltage waveform peak pulse height as specified by the manufacturer. Normally, measurements are made at 75 percent of the peak pulse height.

Step starting of the X-ray contactor or core biasing circuits may generate an additional, low-amplitude pulse that should not be counted when determining time accuracy.

Verify that the indicated exposure times are accurate to within ± 5 percent of the measured value. Verify that successive exposures at the same timer setting are reproducible to within ± 5 percent (see para 8 - 1 1) .

(e) *Exposure rate.* Verify that the measured exposure rate produced by radiographic, dental, and panoramic dental X-ray systems does not differ from the value specified in tables 7, 8, or 9, appendix E, respectively, by more than ± 30 percent when the X-ray system is operated at specified techniques.

Note. High or low values may indicate too little or too much filtration, a defective tube anode, or improper calibration of the X-ray system.

Average Radiation Outputs (mR/mAs) for Medical and Veterinary Radiographic X-ray Systems •
(Measured at 24 inches (61 cm) from source-to-chamber distance)

Peak tube potential (kVp)	Single-phase full-wave	Three-phase (6-pulse)	Three-phase (12-pulse)
40	2.5	3.8	5.0
50	4.0	6.0	8.0
60	7.0	10.5	14.0
70	11.0	16.5	22.0
80	14.0	21.0	28.0
90	19.0	28.5	38.0
100	23.0	34.5	46.0
125	38.0	57.0	76.0

*See table 7, appendix E.

Note. If the radiation output (mR/mAs) of an X-ray system is found to be lower than the above values, it is likely that the beam quality ratio will be much less than 2 which indicates that the beam quality is greater than the required value in table 2, appendix E. When comparing the radiographic output (mR/mAs) for a given X-ray system over a long period of time, the radiation output (mR/mAs) will decrease. If after verification of beam

quality and X-ray system calibration the beam quality ratio continues to decrease, the most likely cause for this decrease is aging of the tube as a result of roughening of the tube anode and possibly tungsten deposition on the glass envelope of the X-ray tube. Should this phenomenon result in a reduction in radiation output (mR/mAs) in excess of 30 percent of the above value, the X-ray tube insert should be replaced.

(3) *Fluoroscopic-cinegraphic kVp and mA.* Test, and adjust if necessary, so that fluoroscopic cinegraphic peak tube potential (kVp) and tube current (mA) indicator are functioning within the manufacturer's specifications.

(4) *Fluoroscopic override and alarm.* Verify that high level fluoroscopic exposure rate switch, if provided, is operating properly and that the audible alarm is functioning during high level fluoroscopic operation.

(5) *Collimator filter interlock.* Verify, where applicable, that an exposure cannot be activated at a peak tube potential of 50 kVp and above, if the minimum required filtration is not in place.

(6) *Visual exposure indicator.* Verify that the means provided and specified by the manufacturer for visually indicating the occurrence of an X-ray exposure (e.g., mA meter, pilot light) are functioning properly to indicate when an exposure is made.

(7) *Audible exposure indicator.* Verify that the audible indicator provided by the manufacturer to indicate termination of X-ray exposure is functioning in the manner specified by the manufacturer.

(8) *X-ray tube indicator.* Verify that the indicator located on the X-ray control panel, provided for the purpose of indicating which of two or more tubes operating from the same switch is to be activated, correctly indicates the selected, and only the selected tube.

(9) *Automatic exposure control (AEC) devices.*

(a) Test, and adjust if necessary, the AEC (phototimer) backup timer and indicator to confirm that the backup circuit operates within the manufacturer's specification; the visible indication provided for indicating exposure termination by the backup timer is functioning; and an exposure cannot be activated until the backup circuit is manually reset.

(b) Verify field sensitivity and reproducibility of the various AEC field pickups to insure that the patient entrance exposure is within ± 10 percent regardless of the AEC field selected.

(c) Verify response capability of the AEC.

(d) Verify peak tube potential (kVp) compensation of the AEC to insure that the optical densities of the resultant radiographs do not vary by more than ± 10 percent.

(e) Verify AEC accuracy to insure that the patient entrance exposure rate is within ± 5 percent at different tube current (mA) settings at a fixed peak tube potential (kVp).

(f) Verify that the density control: provide the film optical density as specified by the manufacturer.

(10) *AEC minimum exposure.* For AEC

devices (phototimers), perform a functional test (and adjustments if necessary) to insure that either:

(a) The product of peak tube potential (kVp), tube current (mA), and exposure time(s) is limited to not more than 60 kW per exposure; or

(b) The produce of X-ray tube current (mA) and exposure time(s) is limited to not more than:

1. 600 mAs per exposure at or above a peak tube potential of 50 kVp and,

2. 2000 mAs per exposure below a peak tube potential of 50 kVp.

(11) *Fluoroscopic timer accuracy/alarm.* Verify that the fluoroscopic timer response time meets the manufacturer's specifications and that the required audible signal functions after expiration of the timer, if X-rays are still being produced.

(12) *Dead-man exposure switch.* Verify that the switch provided for activating an X-ray exposure requires continuous pressure to maintain the exposure and that release of the switch terminates the exposure.

(13) *Certification, warnings, and indicators.*

(a) Verify that all certification labels are affixed and visible as required (see para 6-3).

(b) Verify that all warning labels and embossed, painted, silk screened, or other technique factor indicators have not been defaced or worn so as to be illegible.

(14) *Reproducibility.* Verify that, for any specific combination of selected technique factors, the estimated coefficient of variation of radiation exposure is no greater than 0.05 for an X-ray system. For old X-ray systems, the estimated coefficient of variation of radiation exposure shall not be greater than 0.1. (See para 8-5.)

(15) *Linearity.* Verify that the ratios of radiation output (mR/mAs) obtained at a specified peak tube potential (kVp) and distance for all tube current (mA) settings are no greater than 0.10. (See para 8-6.)

$$\frac{(\text{mR/mAs}) \text{ max} - (\text{mR/mAs}) \text{ mm}}{(\text{mR/mAs}) \text{ max} + (\text{mR/mAs}) \text{ min}} \quad 0.10$$

Note. As a specified peak tube potential (kVp) the radiation output (mR/mAs) should be measured for all tube current (mA) settings by varying the tube current (mA) and exposure time(s) to maintain an approximate constant product of exposure time(s) and tube current (mA) which shall be greater than 1 mAs.

(16) *Overload protective circuit.* Verify that the exposure is prohibited when the overload light operates. The maximum system tube current shall not exceed the maximum rated tube current (mA). The measured values shall be compared to the tube rating charts and shall not exceed the tube rating or momentary generator rating. Single exposure tube

protection should range between 70 percent and 100 percent of the ratings. Series tube protection should range between 40 percent and 80 percent of the single exposure ratings.

Note: The exposure time at which the overload indicator activates shall not exceed the maximum allowable exposure time for all kVp/mA combinations as determined from the tube rating chart.

(17) *Main switch.* Verify that the main switch deenergizes the system when in the "OFF" position.

c. Beam-limiting devices.

(1) *Physical damage or tampering.* Check for physical damage or tampering that might affect proper operation or radiation safety.

(2) *Leakage radiation.* Inspect the beam-limiting device and its attachment to X-ray tube housing assembly (diagnostic source assembly) for physical damage, loosening or wear that might affect leakage radiation. Verify that the combination of the tube housing and beam-limiting device is listed as compatible.

(3) *Variable field.* Verify that an X-ray field size of 2 by 2 inches (5 X 5 cm) or less can be achieved at 40 inches (100 cm) SID.

(4) *Visual definition.* Verify that the average illumination is at least 15 footcandles (160 lux) at 40 inches (100 cm) from the source for a certified X-ray system and at least 8 footcandles (85 lux) at 40 inches (100 cm) from the source for an uncertified X-ray system and verify that the interval-timed beam-limiting light works properly. These illumination criteria are not applicable to radiation therapy simulation systems.

Note. A measurement of 30 footcandles (320 lux) or greater in any quadrant requires a voltage check of the lamp voltage under load.

(5) *Field indication and alignment.*

(a) Verify that the misalignment between visually defined field and the X-ray field does not exceed ± 2 percent of the SID.

(b) Verify the proper functioning of the means for alignment of the center of the X-ray field with the center of the image receptor to within 2 percent of the SID.

(c) Verify that the numerical indications of field size result in X-ray field dimensions in the plane of the image receptor within 2 percent of SID of the dimensions of the image receptor. Verify accuracy of field size and field-size indicators for both vertical and horizontal positions of the table, as appropriate.

(d) Verify that the central ray of the useful (primary) beam, grid center, and image receptor center are aligned to within ± 2 percent when centered by means provided on the equipment (see para 7-5d(4)).

(e) Verify that the tube housing assembly can be adjusted to be perpendicular to the plane of the image receptor by means provided on the equipment. Verify that the angulation indicators are functioning properly.

(6) *Positive beam limitation.*

(a) Verify automatic adjustment of X-ray field size to image receptor size within 5 seconds of insertion of image receptor, or inhibition of exposure until field congruency is obtained.

(b) Verify that the X-ray field size conforms to that of the image receptor within $+3$ percent of SID per axis and $+4$ percent of SID total.

(c) Verify operation of optional field size reduction and that the X-ray field can be reduced to 2 by 2 inches (5 by 5 cm) or less at 40 inches (100 cm) SID.

(d) Verify that the return to positive beam limitation occurs upon a change in image receptor.

(e) Verify that the bypass mode, where provided, functions when not using the cassette tray or permanently mounted vertical cassette holders, and when either beam axis or table angulation is not within ± 10 degrees of the horizontal or vertical during any part of the exposure. Verify automatic return to positive beam limitation when none of the above are applicable.

(f) Verify operation of the override key, where provided.

(7) *Single image receptor size.*

(a) Verify that certification and identification labels are visible as required.

(b) For intraoral X-ray systems, verify maximum field size at minimum SSD is 2.75 inches (7.0 cm) or 2.36 inches (6.0 cm), respectively if the minimum SSD is greater than or less than 7 inches (18 cm), respectively.

(c) Verify presence, integrity, and functioning of means provided to limit X-ray field size to not greater than the image receptor, and to align field and receptor center to within ± 2 percent of SID.

(8) *Source-skin distance.*

(a) Verify presence and integrity of SSD limiting device specified and provided for the certified component.

(b) Verify that the minimum SSD requirement is observed when used for intraoral image receptor radiography. The SSD shall not be less than 7 inches (18 cm) if the X-ray system is operable at a peak tube potential above 50 kVp, or 4 inches (10 cm) if not operable at a peak tube potential above 50 kVp.

(9) *Certification labels.* Verify that all certification labels are affixed and visible as required (see para 6-3).

d. *Fluoroscopic imaging assemblies.*

(1) *Radiation leakage.* Look for obvious physical damage that would affect shielding integrity.

(2) *Primary protective barrier.* Verify that the entire useful (primary) beam is intercepted by the primary protective barrier at any SID and that the fluoroscopic tube does not produce X-rays if the primary protective barrier is not in a fully-intercepting position.

(3) *Field limitation and alignment with spot-film device.* Verify that the automatic beam-limiting device provides an X-ray field in the film plane the size of that portion of the film that has been selected on the spot-film selector.

(4) *Grid alignment.* Verify the proper alignment of the grid used in conjunction with the image intensifier. The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within ± 2 percent of the SID.

(5) *Certification labels.* Verify that all certification labels are affixed and visible as required (see para 6-3).

e. *Nonimage intensified fluoroscopy.* Verify that the X-ray field cannot extend beyond the entire visible area of image receptor, that the means provided to further limit field size function properly, and that an X-ray field size of 2 by 2 inches (5 by 5

cm) or less at maximum SID can be provided.

f. *Image intensified fluoroscopy.*

(1) *Physical alignment.* Verify physical alignment of camera and collimating lens.

(2) *Misalignment.* Verify that the total misalignment of the edges of the X-ray field with the edges of the visible area of the image receptor do not exceed ± 3 percent of SID for any one dimension, and ± 4 percent of SID for the sum of magnitudes along orthogonal dimensions.

(3) *Field size limitation.* Verify functioning of means provided for further limiting the field, and that an X-ray field size of 2 by 2 inches (5 by 5 cm) or less can be achieved at the greatest SID (see para 5-2b(6)).

(4) *Contrast.* Verify high and low contrast performance of the image intensifier. The values listed below are considered to be minimum acceptable hole sizes.

(5) *Focusing.* Verify optimum focusing of optical system(s). The values listed below are considered to be minimum acceptable mesh values. Higher quality systems should resolve one higher mesh value except that TV systems are limited by the TV scanning process. Values given for "optical viewer" also refer to the use of the telescope or monocular to view the image intensifier through the collimator with the TV camera removed.

Minimum Resolvable Mesh Number (edge vs center) and Minimum Perceivable Hole Size for Image Intensified Fluoroscopic Image Systems for Various Viewing and Film Recording Modes

Image intensifier size**	Viewing mode		Film recording mode	
	Mirror optic	TV	Photospot	Cine
9-10 inch (23-25 cm)	30/40 0.13**	20/24 0.13	30/40 0.06	30/40 0.06
6-7 inch (15-18 cm)	40/50 0.06	30/40 0.13	40/50 0.06	40/50 0.06
4-6 inch (10-13 cm)	50/60 0.06	40/50 0.06	50/60 0.06	50/60 0.06

*For dual or tri field image intensifiers, the resolvable mesh should be the same for a reduced size mode as a single field image intensifier of the same size.

**Hole size is specified in decimal inches.

(6) *Glare.* Evaluate the effect of light scatter (veiling glare) in image intensifier tubes. A value 65 percent indicates inadequate low contrast.

(7) *Entrance exposure rate.* Measure the incident exposure rate to the patient. For any combination of technique factors selected, the incident exposure rate shall not exceed 10 R/min. If HLC is

provided, then for any combination of technique factors selected, the incident exposure rate shall not exceed 5 R/min unless the HLC is activated. (See para 5-2b(1).) When the HLC is activated, the limit on exposure rate (see para 8-8) is not specified. Entrance exposure criteria are not applicable to fluoroscopic radiation therapy simulation systems.

(8) *Certification labels.* Verify that all certification labels are affixed and visible as required (see **para** -3).

g. Tomography.

(1) *Cut level.* Verify the accuracy of depth and the cut level indicator. In tomographic systems the accuracy shall be within ± 0.02 inch (0.5 mm). The accuracy of the cut level shall be reproducible to within ± 0.5 mm.

(2) *Exposure angle.* Verify the accuracy of the exposure angle indicator. The measured exposure angle shall agree with the indicated exposure angle to within ± 4 percent and the symmetry of the exposure angle about the midline shall be within ± 2 percent unless the system is intended to operate in an asymmetrical manner.

(3) *Exposure uniformity and beam path.* Verify the uniformity of the tomographic exposure and completeness of tomographic motion. X-ray systems with linear, circular, elliptical, hypocycloidal, or **trispiral** scan capability shall have complete closures and not exceed 20 degrees overlap or as specified by the manufacturer.

(4) *Cut thickness.* Verify that the thickness of the cut meets the specifications of the manufacturer.

(5) *Flatness of plane.* Verify that the cut plane is flat to within ± 0.08 inch (2 mm).

(6) *Resolution.* Verify that the system is capable of resolving the 30-mesh pattern. Other systems should be capable of resolving the 50-mesh pattern. The mesh should be well resolved over its entire length in the plane of the cut.

(7) *Certification labels.* Verify that all certification labels are affixed and visible as required (see **para** 6-3).

h. Computerized tomography.

(1) *Precision (noise).* Verify that the precision (noise) level meets the specifications of the manufacturer.

(2) *Contrast scale.* Verify that the contrast scale meets the specifications of the manufacturer.

(3) *High and low level contrast.* Verify that the resolution capability for low and high contrast objects meets the specifications of the manufacturer.

(4) *Alignment.* Verify that the plane indication and **alignment** meet the specifications of the manufacturer. The total error in the indicated location of the tomographic or reference plane shall not exceed ± 0.2 inch (5 mm).

(5) *Scan increment.* Verify that the deviation of scan incrementation from the indicated values does not exceed ± 0.04 inch (1 mm).

(6) *Certification labels.* Verify that all cer-

tification labels are affixed and visible as required (see **para** 6-3).

i. Tables.

(1) *Aluminum equivalent.* Inspect tabletops for any physical damage, alterations, or **devcations** from the certified model that might alter the attenuation characteristics. The aluminum equivalent of stationary tabletops and **subtops** shall not exceed the values in paragraph 5-3b(15).

(2) *Grid alignment.* Verify that the radiographic grid is properly aligned with respect to the center of the image receptor and the center ray of the X-ray tube. The center of the X-ray field with respect to the center of the image receptor shall be within ± 2 percent of the SID.

Note. The table tilt indicator shall be accurate, moves freely, and readily visible to the operator.

The Bucky slot cover moves freely and closes.

(3) *Bucky centering light.* Verify operations of the Bucky centering light, when provided, and that it aligns properly on the table Bucky tray in both the vertical and horizontal position.

(4) *Certification labels.* Verify that all certification labels are affixed and visible as required (see **para** 6-3).

j. Cradles. Verify that the cradle has not been damaged, modified, or changed so that the **aluminum** equivalence exceeds 0.08 inch (2.0 mm) and that certification labels are affixed and visible as required (see **para** 6-3).

k. Film hangers.

(1) *Attenuation.* Inspect the front cover of the film changer for any physical damage or modifications that would alter the attenuation characteristics.

(2) *Interlocks.* Verify the proper operation of the alignment indicators, if provided, and alignment in the positive beam-limiting mode, if provided. Perform a functional test of all locks intended to fix the position of moving mechanical components.

(3) *Alignment.* Verify the proper operation of the alignment indicators, if provided, and alignment in the positive beam-limiting mode, if provided.

(4) *Certification labels.* Verify that all certification labels are affixed and visible as required (see **para** 6-3).

1. Cassette holders.

(1) *Attenuation.* Inspect the front cover of cassette holder, if provided, for any physical damage or modifications which would alter the attenuation characteristics.

(2) *Interlocks.* Verify the proper operation of interlocks, if provided, for the operation of positive beam limitation.

(3) *Alignment indicators.* Verify the proper operation and accurate indications of means provided to accomplish alignment between X-ray field and image receptor.

(4) *Alignment in automatic systems.* If provided for operation with positive beam limitation, verify the proper alignment between the X-ray field and image receptor.

Note. The requirements in paragraph l(1) through (4) apply to dental cassette holders when the use of such devices are required for the radiograph.

(5) *Certification labels.* Verify that all certification labels are affixed and visible as required (see para 6-3).

m. Counterweights and high tension cables.

(1) Visually inspect all steel counterweight cables for broken strands and evidence of crushing, kinking, or other damage. Replace any cable having a broken strand, kink, or crush mark. Verify that two cable clamps are installed at each end (anchor point) of each counterweight cable and that clamp screws bear on the tail end of the cable, not the loaded or weight bearing end.

(2) Visually inspect all shock-proof, **high-tension** cables for evidence for cracks, peeling, kinking, crushing, or other physical damage. High tension cables should not exceed the length recommended by the manufacturer.

n. Electrical grounding and leakage current.

Verify adequate ground connections to the system. The leakage current shall not exceed the limits specified in TB MED 286.

o. Note of Clarification. The following notes are provided to clarify paragraph 7-5.

Note. The Academy of Health Sciences. US Army, USAMEOS Text Pamphlet XE-300-026. provides an orderly and logical procedure for the tests and adjustments of mobile and stationary general-purpose X-ray systems to ensure compliance with this bulletin and should be readily available to biomedical equipment maintenance personnel.

Note. X-ray equipment that has been determined to be unserviceable, uneconomically repairable, or otherwise unsuitable for use on humans shall be marked "CONDEMNED-NOT FOR PATIENT CARE" as required by AR 40-61 prior to **turn-in** for disposal through Defense Property Disposal Offices. (See para 1-16.)

Note. X-ray equipment with safety related defects or with radiation emission characteristics that could cause injury to the patient or operator shall not be used until it is repaired or replaced.

Note. When making measurements in the field for the determination of reproducibility of exposure rates, linearity of radiation output at consecutive tube current (**mA**) settings or the accuracy and reproducibility of the timer, normally only four consecutive measurements are required. However, if there is a question as to whether the diagnostic X-ray system is in compliance with 21 CFR subchapter J. then measurements shall be made as specified in chapter 8, **this** bulletin. The determination of reproducibility and linearity may be verified by performing both tests at the same time (see USAEHA Diagnostic X-Ray Survey Procedures Manual and USAMEOS Technical Guide Test Pamphlet XE-300-026).



CHAPTER 8

COMPLIANCE MEASUREMENT TECHNIQUES FOR CERTIFIED DIAGNOSTIC X-RAY SYSTEMS

8-1. Scope. This chapter establishes DA policy for the compliance measurement techniques for certified diagnostic medical and dental X-ray systems. These measurement techniques will normally be performed by a healthradiological physicist in order to insure that the certified diagnostic X-ray system complies with the performance standards in chapter 5 and 21 CFR subchapter J.

8-2. Leakage radiation from the diagnostic source assembly. Component to which this requirement is applicable: Diagnostic source assembly.

a. Compliance shall be determined by measurements averaged over an area of 16 square inches (100 cm²) with no linear dimension greater than 8 inches (20 cm)

b. Leakage technique factors used in measuring leakage radiation are defined as follows:

(1) For capacitor energy storage system, the maximum rated peak tube potential (kVp) and the maximum rated number of exposures in 1 hour for operation at the maximum rated peak tube potential (kVp) with the quantity of charge per exposure being 10 millicoulombs (mC) or mAs or the minimum obtainable from the system, whichever is larger.

(2) For field emission X-ray systems rated for pulsed operation, the maximum rated peak tube potential (kVp) and the maximum rated number of X-ray pulses in 1 hour for operation at the maximum rated peak tube potential (kVp).

(3) For all other X-ray systems, the maximum rated peak tube potential (kVp) and the maximum rated continuous tube current (mA) for the maximum rated peak tube potential (kVp).

8-3. Beam quality. Components to which this requirement are applicable: Tube housing assembly, or the diagnostic source assembly if the beam-limiting device contains filtration. For capacitor energy storage X-ray systems, compliance shall be determined with the maximum mC or mAs per exposure.

8-4. Aluminum equivalent of material between patient and image receptor. Components to which this requirement are applicable: Cassette holders,

film changers, tabletops and subtops, and cradles. Measurement shall be made at a peak tube potential of 100 kVp and with an X-ray beam which has a half-value layer of 0.11 inch (2.7 mm) of aluminum. This applies to front panel(s) of cassette holder and film changers. It does not apply to such items as a screen and its associated mechanical support panel or grids.

8-5. Reproducibility. Components to which this requirement are applicable: X-ray control and high-voltage generator. When determining the coefficient of variation of exposure rates:

a. Determination shall be based on 10 consecutive radiation exposure (R or mR) measurements made within a time period of 1 hour when the X-ray system is operated with adequate power supply and voltage regulation as specified by the manufacturer.

b. For X-ray systems manufactured after 5 September 1978, all variable controls for technique factors shall be adjusted to alternate settings and then reset to the test setting after each radiation exposure (R and mR) measurement.

c. The percent line-voltage regulation (percent line-voltage regulation = $100 (V_n - V_1) / V_1$) shall be determined for each output measurement. All values for the percent line-voltage regulation shall be within ± 1 of the mean value for all measurements, where V_n is no-load line potential and V_1 is load potential.

d. For X-ray systems with automatic exposure control, measurements shall be made with an attenuation block of sufficient thickness placed in the useful (primary) beam so that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field emission systems rated for pulsed operation or no less than one-tenth of a second for all other systems.

e. Reproducibility should be determined for all combination of technique factors designed into the X-ray system.

8-6. Linearity. Components to which this requirement are applicable: X-ray control and high-voltage generator. When determining linearity of exposure rates:

a. Determination shall be based on 10 consecutive radiation output (mR/mAs) measurements taken at two consecutive (adjacent) tube current (mA) settings made within a time period of 1 hour when the X-ray systems is operated on an adequate power supply and voltage regulation as specified by the manufacturer.

b. All values for percent line-voltage regulation at any one combination of technique factors shall be within ± 1 percent of the mean value for all measurements at these technique factors (see para 8-5).

c. Where tube current (mA) selection is continuous, outputs $\bar{X}_1 - \bar{X}_2 \leq 0.10 (\bar{X}_1 + \bar{X}_2)$; where \bar{X}_1 and \bar{X}_2 are the average radiation output (mR/mAs) values obtained at each of the two consecutive tube current (mA) settings (see para 5-3b(4)).

d. For X-ray systems manufactured after 5 September 1978, all variable controls for technique factors shall be adjusted to alternate settings and then reset to the test setting after each radiation output (mR/mAs) measurement.

Note. When two or more diagnostic source assemblies are operated **from the same X-ray control**, each combination of source housing assembly and control shall be considered as a separate system **for the purpose of determining applicability of the linearity and reproducibility requirements.**

8-7. Field limitation and alignment on stationary general purpose radiographic X-ray systems. Component to which this requirement is applicable: Beam-limiting device. Measurements shall be made at discrete SID's and image-receptor dimensions in common clinical use (SID's 36, 40, 48, and 72 inches and nominal image receptor dimensions of 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches or metric equivalent) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic X-ray system is uniquely designed to operate.

8-8. Entrance exposure rate limits for fluoroscopic X-ray systems. Component to which this requirement is applicable: X-ray control.

a. If the source is below the table, the entrance exposure rate shall be measured at 0.4 inch (1 cm) above the **tabletop** or cradle.

b. If the source is above the table, the entrance exposure rate shall be measured at 12 inches (30 cm) above the **tabletop** with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

c. If the fluoroscope is of the C-arm type, the entrance exposure rate shall be measured at 12 inches (30 cm) from the input surface of the fluoroscopic

imaging assembly. The exposure rate should also be determined at 8 inches (20 cm) from the source or at the end of the beam-limiting device, whichever is less.

d. If the fluoroscope is of the lateral type (biplane), the entrance exposure rate shall be measured at 6 inches (15 cm) from the centerline of the table and in the direction of the source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the **tabletop** is movable, it shall be positioned as closely as possible to the lateral source, with the end of the beam-limiting device or spacer no closer than 6 inches (15 cm) to the centerline of the table.

8-9. Exposure rate due to transmission through the fluoroscopic primary protective barrier. Components to which this requirement are applicable: Fluoroscopic imaging assembly or components thereof, spot-film device, image intensifier, and fluoroscopic screen assembly.

a. If the source is below the tabletop, the measurement shall be made with input surface of the fluoroscopic imaging assembly positioned 12 inches (30 cm) above the tabletop.

b. If the source is above the **tabletop** and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the **tabletop** as it can be placed, provided that it shall not be closer than 12 inches (30 cm).

c. Movable grids and compression devices shall be removed from the useful (primary) beam during the measurement.

d. For all measurements, the attenuation block shall be positioned in the useful (primary) beam 4 inches (10 cm) from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

Note. When a 1.5-inches (3.8 cm) thick aluminum or 0.09-inch (0.23 cm) copper attenuation block is employed, the X-ray system shall be operated at a peak tube potential of 90 kVp.

8-10. Fluoroscopic X-ray field alignment. Components to which this requirement are applicable: Beam-limiting device and fluoroscopic imaging assembly.

a. General. When the angle between the image receptor and beam axis is variable, compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

b. *Image-intensified equipment+* For rectangular X-ray fields used with circular input phosphors, the error in alignment shall be determined along the length and width dimensions of the X-ray field that

pass through the center of the visible area of the input phosphor.

8-11. Timer reproducibility. Components to which this requirement are applicable: X-ray control and high-voltage generator. Determination shall be based on 10 consecutive measurements on at least two of the most commonly used timer settings at the same peak tube potential (kVp) within a time period of 1 hour when the X-ray system is operated on an adequate power supply and voltage regulation as specified by the manufacturer. For X-ray systems with automatic exposure control, the maximum exposure time selected shall be no greater than 0.5 seconds and for X-ray systems without automatic exposure control, the maximum exposure time selected shall not exceed 2 seconds.

8-12. Radiation from components other than the diagnostic source assembly. Components to which this requirement are applicable: X-ray controls and high-voltage generators that contain thermionic diode rectifiers (valve tubes) and image intensifiers.

a. Compliance shall be determined by measurements averaged over an area of 16 square inches (100 cm²) with no linear dimension greater than 8 inches (20 cm).

b. Measurements shall be made at any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed to operate.

8-13. Transmission limit for image receptor supporting devices for mammography. Components to which this requirement is applicable: Image receptor supporting devices for mammography.

a. Compliance shall be determined by measurements averaged over an area of 16 squares inches (100 cm²) with no linear dimension greater than 8 inches (20 cm).

b. Measurements shall be made at 2 inches (5 cm) from any accessible surface beyond the plane of the image receptor support devices when the X-ray system is operated at maximum rated peak tube potential (kVp) and at the maximum rated product of the tube current (mA) and exposure time (mAs) for the peak tube potential (kVp).

8-14. Standby radiation from capacitor energy storage equipment. Component to which this requirement is applicable: Diagnostic source assembly.

a. Compliance shall be determined by measurements averaged over on area of 16 square inches (100 cm²) with no linear dimension greater than 8 inches (20 cm).

b. Measurement shall be made at 2 inches (5 cm) from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open and the exposure switch or timer not activated.



CHAPTER 9

RADIATION THERAPY EQUIPMENT

9-1. Scope. This chapter establishes the design requirements and performance standards for X-ray therapy systems and gamma-beam therapy equipment. It also establishes therapy equipment calibration standards.

9-2. X-Ray therapy systems. a. Design Requirement.

(1) A therapeutic type protective housing shall be used. Contact therapy systems shall meet the additional requirement that the leakage radiation at 2 inches (5 cm) from the surface of the tube housing shall not exceed 0.1 R/hr.

(2) Permanent beam-limiting devices such as diaphragms or cones used for collimating the useful (primary) beam shall provide the same degree of attenuation as is required of the tube housing.

(3) Adjustable or removable beam-defining diaphragms or cones should not transmit more than 1 percent and shall not transmit more than 5 percent of the useful (primary) beam to be blocked/attenuated by these devices as determined at the maximum tube potential and with maximum treatment filter.

(4) The filter system shall be so arranged as to minimize the possibility of error in filter selection and alignment. The filter slot in a system capable of being operated at a tube potential above 150 kV shall be so constructed that the radiation escaping through it does not produce an exposure exceeding 1 R/hr at 40 inches (100 cm), or, if the patient is likely to be exposed to radiation escaping from the slot, 30 R/hr at 2 inches (5 cm) from the external opening. Each removable filter shall be marked with its material of construction and thickness or wedge angle. Filters shall be individual distinguishable and shall be secured in place to prevent their unintentional removal in any orientation of the tube housing assembly. This requirement does not apply to wedge or field-flattening filters or other filters that are often placed external to the beam-limiting device in radiotherapy.

(5) A filter indication system shall be used on all therapy systems using changeable filters. It shall indicate, from the control panel, the presence or absence of any filter and it shall be designed to permit easy recognition of the filter in place. Therapy systems provided with an automatic filter selection device connected to the technique selector are exempt from this requirement.

(6) The X-ray tube housing shall be so mounted that it cannot turn or slide with respect to the housing aperture. A mark on the tube housing shall show the location of the focal spot to within ± 0.2 inch (5 mm).

(7) Means shall be provided to secure the tube housing during stationary portal treatment.

(8) Easily discernible indicators which show whether electrical power is "ON" and whether rays are being produced shall be on the control panel. Means for indicating tube potential (kV) and tube current (mA) shall be provided.

(9) Beam monitoring devices shall be fixed in the useful (primary) beam of orthovoltage and supervoltage therapy machines to indicate any error due to incorrect filter, tube current (mA), or tube potential (kV).

(10) A suitable exposure control device (e.g., an automatic timer, exposure meter, or dose meter) shall be provided to terminate the exposure after a preset time interval, preset exposure, or dose limit. It should be designed to preserve its accumulated response in the event of equipment failure during patient treatment. If a timer is used, it should permit accurate presetting and determination of exposure times as short as 1 second and shall not permit an exposure if set at zero. Means shall be provided for the operator to terminate the exposure at any time.

(11) Unless it is possible to bring the X-ray exposure rate to the prescribed value within 5 seconds after the X-ray "ON" switch is energized, the tube housing on machines operating at a tube potential below 500 kV shall be fitted with an "ON-OFF" shutter electrically operated from the control panel and of lead equivalent not less than that of the tube housing. The "ON-OFF" positions of the shutter shall be indicated at the control panel.

(12) Mechanical/electrical stops shall be provided on X-ray systems capable of operating at a tube potential of 150 kV or above to insure that the useful (primary) beam is oriented only toward primary barriers.

(13) When the control panel may energize more than one tubehead:

(a) It shall be possible to activate only one tubehead during any one time interval.

(b) There shall be an indication at or near the tubehead assembly when it is connected/energized.

(c) There shall be an indication on the control panel identifying which tubehead is connected/energized.

(14) The X-ray control circuit shall be so designed that it is not possible to energize the X-ray tube to produce X-rays without resetting the X-ray "ON" switch at the control panel. For therapy systems not meeting this recommendation, see paragraphs 2-22g and 2-22i.

(15) X-ray therapy systems shall be provided with a locking device to prevent unauthorized use.

(16) When a high energy X-ray therapy system is mounted isocentrically, the counterweight frequently serves also as a beam interceptor in order to reduce the structural shielding requirements. When the counterweight is also used as a beam interceptor, it should transmit not more than 0.1 percent of the useful (primary) beam under any operating condition. It should also reduce by the same factor the radiation scattered from the central ray by the patient through an angle up to 30 degrees.

(17) A visible or audible indicator that shows whether or not X-rays are being produced shall be provided in the treatment room for X-ray systems capable of operating at a tube potential above 500 kV.

(18) Special considerations should be given to the safety design of X-ray systems with electron beam extraction capability (e.g., to insure that the electron mode cannot be employed inadvertently when the X-ray mode is intended).

(19) There shall be means of determining the SSD to within ± 0.4 inch (1 cm).

b. Performance standards. Compliance with some of the design requirements in paragraph 9-2a can be determined by visual inspection of the X-ray therapy system. In cases of doubt, however, appropriate measurements shall be made by or with the advice of a qualified expert responsible for calibrating X-ray therapy systems (see para 9-4). The leakage radiation through the X-ray tube housing for equipment operating at a tube potential below 500 kV may be tested as follows: With the housing window and filter slots blocked with at least 10 half-value layers of absorbing material (e.g., lead), the exposure rate should not exceed 1 R/hr at a distance of 40 inches (100 cm) from the source, with the tube X-ray tube operating at its maximum potential and at its maximum current for continuous operation at that potential. Small areas of reduced shielding are acceptable provided the average reading over any 16 square inches (100 cm²) of area at a 40-inch (10 cm) distance from the source does not exceed 1 R/hr (see NCRP Report No. 33).

c. Nonionizing radiation

(1) Leakage of microwave power from the waveguides is effectively precluded by the nature of the design of the medical linear accelerator (linac). A gap in any portion of the waveguide would result in the loss of waveguide pressure and shutdown of the linac would occur due to pressure interlock operation or arcing followed by highly reflected power interlock shutdown.

(2) The low-power, helium-neon lasers used as side or vertical light pointers could possibly be hazardous if directed into the patient's eyes. Permanent attenuation of the laser light beam by a neutral density filter should provide adequate protection (see TB MED 279).

9-3. Gamma-beam therapy equipment. *a. Sealed sources for teletherapy equipment.*

(1) *Sealed source capsules.* Radioactive sources used in gamma-beam therapy shall be sealed in capsules that are strongly resistant to breakage. Sources larger than a few curies have very high internal radiation intensities and are subject to decomposition of salts and minor contaminants, appreciable heat generation, and the potential production of gases, with a buildup of pressure within the source container. Such sources shall be sealed in a welded capsule that is contained in a second welded container and shall meet the requirements of the NRC for source capsule design.

(2) Replacement and servicing of gamma-beam sealed sources.

(a) All service operations performed with a teletherapy source, including the installation and replacement of radioactive source(s) and the installation of a teletherapy unit source housing containing a radioactive source or source handling system, shall be performed by an individual specifically licensed by the NRC to do so.

(b) Wipe tests of the protective source housing and leak tests of the radioactive source shall be conducted whenever a gamma-beam (sealed) source is replaced. Any removable radioactive contamination shall be removed prior to insertion of the new source. If the radiation survey of the source assembly housing reveals radioactive contamination, the used source shall not be reused until it has been determined that the source is not leaking (AR 40-37).

b. Design requirements.

(1) *Protective source housing: Beam "OFF" position.* The source housing shall be so constructed that at 40 inches (100 cm) from the source the maximum and the average exposure rates do not exceed 10 mR/hr and 2 mR/hr, respectively, when the beam control mechanism is in the "OFF" position.

In the design of the housing, consideration should also be given to reducing the surface exposure rate for small diameter housings.

(2) *Protective source housing: Beam "ON" position.* The leakage radiation measured at 40 inches (100 cm) from the source shall not exceed 0.1 percent of the useful (primary) beam exposure rate at that distance when the beam control mechanism is in the "ON" position, except for the portion of the source housing that includes the collimator zone (see para 9-3c(2)). This limit, however, does not apply to source housings where the leakage radiation at 40 inches (100 cm) is less than 1 R/hr, nor does it apply to apparatus used exclusively for whole-body irradiation.

(3) *Beam-limiting device.* The beam-limiting device comprising the collimator zone shall be constructed to attenuate the useful (primary) beam so that the transmitted exposure rate is not more than 5 percent of the unattenuated beam (see para 9-3c(2)). Auxiliary beam-limiting devices need not meet this requirement.

(4) *Beam control mechanism.* The beam-control mechanism shall meet the following specifications:

(a) In the "ON" position, the source and beam-limiting device shall be accurately aligned.

(b) The mechanism shall be capable of acting in any orientation of the housing.

(c) The mechanism shall be so constructed that in an emergency it can be returned manually to the "OFF" position with a minimum exposure to personnel.

(d) The moving parts shall be so constructed that it is highly improbable that the equipment will fail to return to the "OFF" position at the end of the preset exposure time.

(e) There shall be on the source housing and on the control panel a warning device that plainly indicates whether the beam is "ON" or "OFF."

(f) The control panel shall be provided with a timer that automatically terminates the exposure after a preset time and/or dose.

(g) The beam-control mechanism shall be so designed as to return automatically to the "OFF" position in the event of any breakdown or interruption of the activating force and shall stay in the "OFF" position until reactivated from the control panel.

(h) When the door to the treatment room is opened, the beam control mechanism shall automatically and rapidly return to the "OFF" position where it shall remain until the door is again closed and the machine is manually reactivated from the control panel.

(i) It shall not be possible to switch the beam-

control mechanism to the "ON" position from inside the treatment room.

(5) *Lock.* The equipment shall be provided with a key locking device to preclude unauthorized use.

(6) *Beam interceptor.* With gamma-beam equipment utilizing an isocentric mounting, the counterweight is frequently designed to serve also as a beam interceptor in order to reduce the structural shielding requirements. When the counterweight is also used as a beam interceptor, it should transmit not more than 0.1 percent of the useful (primary) beam. It should also reduce by the same factor the radiation scattered from the central ray by the patient through an angle of up to 30 degrees.

(7) *Beam orientation.* A beam interceptor is considered a primary barrier. When a beam interceptor is not present or when the relationship between the useful (primary) beam and the beam interceptor is not permanently fixed, mechanical, or electrical stops shall be provided to insure that the beam is oriented only toward barriers.

(8) *Resistance of source-housing to fire.* The source housing should be so constructed that the integrity of the shield is preserved in case of fire. The source capsule shall be constructed so as to minimize the probability of escape of radioactive material.

c. Performance standards. Compliance with some of the design specifications recommended in paragraph 9-3b can be checked by visual inspection of the gamma-beam equipment. In case of doubt, however, appropriate measurements shall be made by or with the advice of a qualified expert (see para 9-4). The following performance standards shall be used when indicated:

(1) *Leakage radiation: Beam "OFF" position.* The leakage radiation through the source housing with the beam in the "OFF" position shall be measured with a suitable, calibrated instrument. An acceptable method for obtaining the average exposure at 40 inches (100 cm) from the source is to tie measurements on the surface of an imaginary sphere 40 inches (100 cm) in radius centered on the source. The average of readings shall not exceed 2 mR/hr and no point shall exceed 10 mR/hr. Small areas of reduced protection, however, are acceptable in evaluating the maximum exposure rate providing the average over 16 square inches (100 cm²) at 40 inches (100 cm) from the source does not exceed 10 mR/hr (see NCRP Report No. 33).

(2) *Leakage radiation: Beam "ON" position.* The leakage radiation through the protective source housing with the beam in the "ON" position may be measured as follows: If the beam-limiting device has movable diaphragms, they should be closed as

far as possible. If the movable diaphragms do not completely block the useful (primary) beam aperture, or if the beam-limiting device does not have movable diaphragms, the entire collimating zone should then be covered with lead or other suitable material providing attenuation equal to that of the adjacent wall of the housing while making this measurement (see (2) above).

Note. The measurements in 9-3c(2), above, are not required on each source housing if results of measurements on an exact prototype are available.

(3) Leakage of radioactive material. The gamma-beam equipment shall be tested for possible leakage of radioactive material from the radioactive source after installation and at intervals not exceeding 6 months. If the amount of removable activity exceeds 0.05 microcurie (50 nanocuries), action shall be taken to prevent spread of contamination and appropriate authorities shall be notified (AR 40-37, AR 385-40 and appendix D, Title 10, Code of Federal Regulations, part 20).

(4) Alignment of source and beam-collimating device. The symmetry of the radiation field about the central axis of the useful (primary) beam shall be measured. This may be accomplished by the judicious exposure of X-ray films to the useful (primary) beam with the beam collimating device opened to its fullest extent, or by using any of a variety of appropriate small dosimeters distributed across the field or other suitable methods.

(5) The light field and the 50 percent penumbra line of the radiation field shall coincide at the appropriate SSD to within 0.12 inch (3 mm) on any side for a 4 by 4 inch (10 by 10 cm) field perpendicular to the central axis.

(6) The head movement and rotation shall be smooth and free. The angle-of-rotation indicator shall be accurate within \pm degree.

(7) The isocenter position shall be within a sphere not greater than ± 0.16 inch (4 mm) in diameter.

(8) The SSD indicator shall be accurate to within 0.12 inch (3 mm) over the range of distances used clinically.

(9) The timer shall be reproducible to within ± 3 percent over the range of times used clinically.

(10) The limit of movement of the central axis indicator from the central position should be no greater than ± 0.08 inch (2 mm) for all treatment distances and both vertical and horizontal head angulation.

(11) See ANSI Standard N449-1974 for other performance standards and ANSI Standard N449.1-1978 for procedures for periodic inspection of teletherapy equipment.

9-4. Therapy equipment calibration standards.

This paragraph is primarily for the guidance of physicians practicing radiation therapy and of medical physicists concerned with the calibration of X-ray and gamma-beam therapy equipment,

a. General. The exposure rate or dose rate of the useful (primary) beam and the geometry of the useful (primary) beam shall be known with reasonable certainty at all times during operation of the radiation therapy equipment for medical purposes.

b. Radiation calibration. A full calibration of the therapy equipment shall be performed by or under the direct supervision of a qualified expert (10 CFR 35.24) before the equipment is first used for treating humans.

(1) Radiation calibration shall be performed using a dosimetry system(s) that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system(s) shall be calibrated at least every 2 years and after each servicing which may affect system calibration. Each MEDCEN should have a primary and a secondary dosimetry system for the calibration of therapy equipment (see 10 CFR 35.23).

(2) Full radiation calibration of radiation therapy equipment shall be performed in accordance with accepted standards of practice, such as those recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine or by the Hospital Physicists' Association and the International Commission on Radiation Units and Measurements (see 10 CFR 35.21).

(3) The radiation calibration shall include at least the following determinations:

(a) The exposure rate or dose rate (output) for the range in field sizes routinely used, for each radiation quality and for each treatment distance (or for the axis distance) used in radiation therapy. The radiation output (exposure rate) shall be known to an accuracy within ± 3 percent and shall be reproducible to within ± 3 percent.

(b) The radiation quality (e.g., half-value layer when appropriate or effective energy) for all combinations of tube potentials and filters used for radiation therapy.

(c) The congruence between the radiation field and the field indicated by the light beam localizing device when light beam localizing devices are used for radiation therapy.

(d) The uniformity of the radiation field and

its dependence upon the orientation of the useful (primary) beam.

(e) Field-size dependence, backscatter factors for different techniques, inverse-square corrections, and effect of trimmer position.

(f) Time accuracy and reproducibility.

(g) The accuracy of all distance-measuring devices used for treating human patients.

c. Recalibration. The user shall make or shall have made appropriate determinations as described in *b* above in the following circumstances:

(1) Whenever the beam monitor or other meter related to exposure rate or dose rate shows a change of more than ± 3 percent in its normal reading or from the value obtained at the last full calibration when corrected mathematically for the physical decay of the radioactive source.

(2) Following major mechanical or electrical alterations of the radiation source, its housing, power supply or controls, or following reinstallation of the apparatus in a new location.

(3) After any servicing or repair of the beam-limiting device or source exposure assembly or removal/replacement of the source which might alter the characteristics of the useful (primary) beam.

(4) At least once every calendar year.

d. Spot-check measurements for teletherapy equipment. Spot-check measurements shall be per-

formed at intervals not exceed 1 month when the equipment is in routine use and shall include:

(1) Determination of timer accuracy and reproducibility.

(2) Determination of congruency of the useful (primary) beam with the light field.

(3) Determination of the exposure or dose rate or a quantity related in a known manner to these rates for one typical set of equipment operating conditions.

(4) Comparison of the measurements made in d(3), above, and the anticipated output (exposure rate) expressed as a percentage of the anticipated output (exposure rate) (i.e., the value (exposure rate) obtained at last full calibration corrected mathematically for the physical decay of the radioactive source).

(5) The accuracy of all distance-measuring devices used for treating humans.

e. Records.

(1) Records required by Federal and other applicable authorities as well as records consistent with the accepted standards of practice of radiation therapy and radiological physics shall be maintained.

(2) Leak test results of sealed sources shall be kept on a consecutive entry log and the removable activity shall be recorded in microcuries for each radioactive source being leak-tested (AR 40-37).



CHAPTER 10

RECORDS AND REPORTING REQUIREMENTS

10-1. Scope. This chapter establishes DA policy concerning records and reporting requirements for diagnostic medical and dental X-ray systems worldwide which are under the jurisdiction of DA.

10-2. General. Due to legal implications relating to exposure of humans to ionizing radiation, accurate record requirements are necessary to verify that all assemblies, services, adjustments, and calibrations of diagnostic X-ray equipment have been performed in such a manner as to minimize patient exposure. Records and reporting requirements may be determined at the local or command level.

10-3. Equipment log requirements. *a.* DA Forms 2409 and 2408-10 (Equipment Component Register) or automated equipment record (AMEDDPAS) shall be initiated immediately upon acceptance of any diagnostic X-ray system.

(1) Preparation procedures for these forms shall be as prescribed in TM 38-750 and TB 38-750-2.

(2) Disposition instructions for above forms are:

(a) Forms shall be maintained for the life of the system. (See AR 340-18-6).

(b) When the system is processed for disposal, all forms and historical data records shall be processed in accordance with TM 38-750 and TB 38-750-2.

b. Medical facilities shall take the following action whenever a radiation protection survey has been accomplished:

(1) Entries shall be made in section B, DA Form 2409, or automated equipment record by biomedical equipment maintenance personnel of the survey report number (e.g., 43984080). Note that the first two digits of the survey report number are to be dropped.

(2) Most recent radiation protection survey entry shall be transcribed to first line in section B when a new DA Form 2409 is required in accordance with TB 38-750-2.

(3) Radiation protection surveys and associated documents shall be maintained to support the above entries in accordance with AR 340-18-6.

c. DA Form 2407 (Maintenance Request) shall be:

(1) Completed in accordance with TM 38-750 and TB 38-750-2.

(2) Initiated for all services performed on

diagnostic X-ray equipment, to include commercial services.

Note. When contractual services are utilized, the contract shall include a requirement for the contractor to furnish the biomedical equipment maintenance activity with a detailed itemization of repairs each time repairs have been accomplished, and, when applicable, Form FD 2579, so that the necessary information can be recorded on the DA Form 2407 and subsequently posted to DA Form 2409 or automated equipment record.

(3) Disposition Instructions.

(a) Forward copy No. 2, DA Form 2407, for all removal and/or condition coding relating to certified X-ray systems or specified components through command channels to the Commander, USAMMA, ATTN: SGMMA-MP, Frederick, MD 21701.

(b) Remaining copies, DA Form 2407, shall be retained and disposed of in accordance with AR 340-18-6 and TM 38-750.

d. DA Form 2407 submitted to medical depots for X-ray equipment shall be annotated with one of the two following statements:

CERTIFIED COMPONENT-MUST BE CERTIFIED

NONCERTIFIED COMPONENT-DO NOT CERTIFY

10-4. Form Food and Drug (FD) 2579 (Report of Assembly of a Diagnostic X-Ray System). *a.* When to prepare Form FD 2579 (fig. 10-1). Whenever a specified component of a diagnostic X-ray system, which is certified to comply with the Standard, is installed at any DOD activity. In addition, any active or inactive military member or civilian employee of the DOD, who, in the course of authorized official duties, installs certified X-ray equipment in any activity of the Federal or State governments of the United States, regardless of location, shall report such assembly in accordance with this chapter. When the manufacturer's labeling contains a statement such as, "This component is certified to comply with the Standard in effect at the date of manufacture," prepare Form FD 2579 only if the date of manufacture is 1 August 1974 or later. The only authorized exceptions to the foregoing reporting requirements are for temporarily installed loaner components. The procedures of this bulletin do not apply to the off-duty activities of DOD personnel engaged in authorized self-employment or employment by another individual or corporation.

Such personnel are advised, however, that they are subject to 21 CFR subchapter J for all off-duty work performed as an assembler in the region of **applicability**.

b. Who must prepare Form FD 2579. When certified specified components are assembled by DA personnel under circumstances requiring a report of assembly, the Form FD 2579 shall be prepared by the individual who had direct supervisory control over the assembly. When the assembly is performed within territorial limits of the US by a contractor, or by government personnel under the supervision of a contractor, the contractor's representative who had direct supervisory responsibility for the assembly prepares the Form FD 2579. If the assembly is performed outside the territorial limits of the US, civilian contractors are not bound to prepare, or submit, Form FD 2579 for the assembly of any X-ray component. In this situation, the senior biomedical equipment maintenance repairer supervising the assembly shall be responsible for the preparation and forwarding of Form FD 2579.

c. Detailed instructions for preparing Form FD 2579.

(1) Item 1. Enter the official name of the medical or dental activity in which the specified component or X-ray system is installed.

(2) Item 2a. Enter the building number of the facility in which the component or X-ray system is installed.

(3) Item 2b. Enter the official name of the installation (if appropriate) where the assembly was accomplished.

(4) Item 2c. Use **two-letter** code from reverse side of form, otherwise leave blank.

(5) Item 2d. Enter local ZIP Code or APO.

(6) Item 3a. Whenever assembly/installation is performed by a military biomedical equipment maintenance activity, so indicate. If work was performed by contractor or civilian firm, items 3a through 3f shall be appropriately completed.

(7) Item 3b. Self explanatory.

(8) Item 3c. When work is performed by a military biomedical equipment maintenance activity, enter the building number of the maintenance activity.

(9) Item 3d. When work is performed by a military biomedical equipment maintenance activity, enter the official name of the installation (if appropriate) .

(10) Item 3e. Self explanatory.

(11) Item 3f. Self explanatory.

(12) Item 4. Use appropriate codes on reverse side of form.

(13) Item 5. Self explanatory: definitions are explained on reverse side of form.

(14) Item 6. Numeric entries required for month, day, and year.

(15) Item 7. Block 1, "new," shall be checked when a completed X-ray system is installed, even though it replaces a complete system that is being disposed of as uneconomically **repairable**. Block 2, "Addition or Replacement for Existing System," shall be checked whenever a component is added or replaced in an existing X-ray system.

Note. Certified X-ray tube housing are "manufactured" when the insert is replaced except for quick change tubes. This will be considered a "new" item and date of manufacture on certification label will be verified (see 21 CFR 1020.30).

(16) Item 8. In all cases block 1, "Yes," shall be checked.

(17) Items 9-11. Before completing, determine into which category each component falls. In item 9, enter only newly-installed certified components which were specified by the manufacturer as being compatible with all other components in the system on whose performance or design their compliance depends. For example, the positive beam limitation on a stationary general purpose X-ray system must be compatible with tube housing, the cassette holder(s), and the X-ray control. In item 10, enter the remaining newly-installed specified components not included in item 9 because of noncompatibility. In item 11, enter the components which were non-compatible with those listed in item 10. An entry in item 11 requires an explanation in "COMMENTS" section of the form, explaining the reasons for non-compatibility.

Note. Noncompatible certified and noncertified components cannot be added to a system containing one or more certified components without obtaining a variance from BRH (see para 6-16).

(18) Items 9a, 10a, 11a. Enter the correct component type codes from the reverse side of the form. Be sure to read through all codes and select the correct one. Remember that one system may have several "controls" (e.g., master control, phototimer, automatic brightness control). Every newly installed specified component which has a certification label on it shall be listed in item 9 or 10.

(19) Items 9b, 10b, 11b, and 12a. Enter the name of the manufacturer exactly as it appears on the name plate. Do not enter type of component.

(20) Item 9c, 10c, 11c and 12b (Model No.). Copy the model name **and/or** number exactly as provided on the label. In some cases manufacturers may not be properly labeling their equipment, so in addition to providing model information as required by 21 CFR 1010 and 1020 whenever the model

designation on the label is incomplete, assemblers should provide other identification available (e.g., catalog number, part number). This additional data, when furnished, should be entered in items 9b, 10b, 11b, and 12a. (In the section for "Model No." however, only include exactly what is specified on the label as the model number.)

(21) Items 9e and 10e. Mark the appropriate block. If instructions were inadequate, provide a specific explanation in item 12 (Comments) or item 13 (Comments), depending on the date of the Form FD 2579 being submitted.

(22) Items 9 and 10. Include the typewritten or legibly printed name and grade (if appropriate) of the individual signing either or both sections of the form. DA assembler/installers initiating Form FD 2579 need not comply with declaration 9e and 10g on the reverse side of the Form. Signatures shall be to the right of the typewritten or legibly printed name.

(23) Item 1 le. Numeric entries are required for month and year.

(24) Item 12. Manufacturer, model number, serial number, and location of the system master control panel shall be entered in item 12 (Comments) of Form FD 2579 dated 7/73, and item 13 of Form FD 2579 dated 6/74. If the X-ray system is of the mobile type, in place of room number, indicate the

hospital wing or floor or building number where it will be utilized, (e.g., third floor, Bldg 500).

(25) Item 13. Comments are required whenever assembly instructions are inadequate (items 9e or 10e), or when components already in the system (item 11) are noncompatible with those non-compatible components listed in item 10. Whenever Form FD 2579 dated 7/73 is used, the reasons for noncompatibility shall be entered in item 12 (Comments).

(26) Items 12 and 13. The 6/74 edition of Form FD 2579, item 12, requires **information** on the system master control panel item 13 is reserved for comments. On the 7/73 edition of the Form, item 12 was reserved for comments and item 13 was an overprint added for master control data. The earliest Forms FD 2579 lack the overprint and, therefore, master control panel information (manufacturer, model, serial number, and location/room number) shall be inserted under the comments section and **labelled** appropriately. Information required from the master control panel is self-explanatory and shall be included on all Forms FD 2579, including those which only report addition or replacement or components in an existing system. When reporting assembly work for a mobile X-ray system, enter "mobile" in the blank for master control location. The comments section of the form is reserved for explanatory information related to earlier entries.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BUREAU OF RADIOLOGICAL HEALTH				Form Approved OMB No. 57-R0077	
REPORT OF ASSEMBLY OF A DIAGNOSTIC X-RAY SYSTEM				A 611826	
(See statements and codes on reverse. If more space is needed use additional forms.)					
20	1. NAME OF PURCHASER OF X-RAY SYSTEM (Indicate name of hospital or name of doctor if for a private office.) (10-39) <i>Health Physics Division, US Army Environmental Hygiene Agency</i>				
21	2. STREET NO. AND NAME OF RURAL ROUTE NO. (10-39) <i>Building E-2100</i>			3. LOCATION OF X-RAY SYSTEM	
	4. CITY (50-68) <i>Aberdeen Proving Grd</i>		5. STATE (Use 2 letter codes on reverse) (69-70) <i>MD</i>	6. ZIP CODE (71-75) <i>21010</i>	
22	3. INSTALLER-ASSEMBLER			7. TELEPHONE NO. (Include Area Code) (50-59) <i>301-997-5000</i>	
	4. COMPANY NAME (10-49) <i>XXX Medical Corporation</i>			8. ZIP CODE (71-75) <i>21045</i>	
23	9. STREET NO. AND NAME OF RURAL ROUTE NO. (10-39) <i>8925 McCaw Court, Suite 1, Bldg. B</i>			10. CITY (50-68) <i>Columbia</i>	
	11. STATE (Use 2 letter codes on reverse) (69-70) <i>MD</i>		12. ZIP CODE (71-75) <i>21045</i>		
24	13. INTENDED USE OF SYSTEM (See codes on reverse)		14. X-RAY SYSTEM IS (Check one) (14)		15. DATE OF INSTALLATION (15-20)
	16. PRIMARY (10-71) <i>[0]</i>	17. SECONDARY (12-13) <i>[]</i>	18. <input type="checkbox"/> STATIONARY 2. <input checked="" type="checkbox"/> MOBILE		19. MO. DAY YR. <i>1 / 4 / 77</i>
25	20. X-RAY SYSTEM IS (Check one) (21)			21. X-RAY SYSTEM IS LOCATED IN FED GOV'T FACILITY (22)	
	22. <input checked="" type="checkbox"/> NEW 2. <input type="checkbox"/> AN ADDITION OR REPLACEMENT FOR EXISTING SYSTEM			23. <input checked="" type="checkbox"/> YES 2. <input type="checkbox"/> NO	
26. FDA USE ONLY (23)					
27. 1. <input type="checkbox"/> COMMENTS 2. <input type="checkbox"/> NO COMMENTS					
28. LIST ALL CERTIFIED COMPATIBLE COMPONENTS THAT YOU INSTALL (See reverse for Type Codes.)					
25	29. TYPE (10)	30. MANUFACTURER (Exactly as printed on name plate) (11-15)	31. MODEL NO. (16-50)	32. SERIAL NO. (51-79)	33. ASSEMBLY INSTRUCTIONS WERE ADEQUATE (Check one) (40)
	<i>A</i>	<i>XXX Medical Corporation</i>	<i>726B951G19</i>	<i>76-8-225</i>	1. <input checked="" type="checkbox"/> 2. <input type="checkbox"/>
26	<i>B</i>	<i>XXX Medical Corporation</i>	<i>Z42/J853</i>	<i>5402031</i>	1. <input checked="" type="checkbox"/> 2. <input type="checkbox"/>
27	<i>F</i>	<i>XXX Medical Corporation</i>	<i>726B024G03</i>	<i>76-6-347</i>	1. <input checked="" type="checkbox"/> 2. <input type="checkbox"/>
28	<i>H</i>	<i>XXX Medical Corporation</i>	<i>621B877G02</i>	<i>76-8-953</i>	1. <input checked="" type="checkbox"/> 2. <input type="checkbox"/>
29					1. <input type="checkbox"/> 2. <input type="checkbox"/>
30					1. <input type="checkbox"/> 2. <input type="checkbox"/>
31					1. <input type="checkbox"/> 2. <input type="checkbox"/>
32					1. <input type="checkbox"/> 2. <input type="checkbox"/>
34. SIGNATURE I affirm that the declarations 9 and 10 on the back of this form are true with respect to the certified components listed above.					
35. SIGNATURE <i>John A. Smith</i>					
36. LIST ALL CERTIFIED NONCOMPATIBLE COMPONENTS THAT YOU INSTALL (See reverse for Type Codes.)					
43	37. TYPE (10)	38. MANUFACTURER (Exactly as printed on name plate) (11-15)	39. MODEL NO. (16-50)	40. SERIAL NO. (51-79)	41. ASSEMBLY INSTRUCTIONS WERE ADEQUATE (Check one) (60)
44					1. <input type="checkbox"/> 2. <input type="checkbox"/>
42. SIGNATURE I affirm that the declarations 10 and 11 on the back of this form are true with respect to the certified components listed above.					
43. LIST ALL COMPONENTS ALREADY IN THE SYSTEM THAT ARE NONCOMPATIBLE WITH THOSE COMPONENTS LISTED IN ITEM 10. (See reverse for Type Codes. Briefly explain the reasons for incompatibility in item 13.)					
55	44. TYPE (10)	45. MANUFACTURER (11-15)	46. MODEL NO. (16-50)	47. SERIAL NO. (51-79)	48. APPROXIMATE DATE OF PURCHASE (68-71)
56					1. YES 2. NO MONTH/YEAR
49. SUPPLY THE FOLLOWING INFORMATION PERTAINING TO THE SYSTEM MASTER CONTROL PANEL.					
61	50. MANUFACTURER (11-15) <i>XXX Medical Corporation</i>		51. MODEL NO. (16-50) <i>726R024G03</i>	52. SERIAL NO. (51-79) <i>76-6-347</i>	
62	53. LOCATION (Room No.) (10-44) <i>Rm. 0402</i>				
54. COMMENTS					

A 611826

Figure 10-1. Sample Form FD 2579.

REPORT OF ASSEMBLY OF A DIAGNOSTIC X-RAY SYSTEM

Completion and filing of this form, which reports the assembly or installation of a diagnostic x-ray system or subsystem, is required by Federal Regulation 21 CFR 1020.30. Any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system is considered an assembler and is subject to this requirement. Public Law 90-602 provides that any person who fails to comply with this requirement is subject to a penalty of not more than \$1,000 for each violation.

This report MUST BE FILED WITHIN 15 DAYS following the date of completion of the assembly by an assembler who installs into an x-ray system or subsystem one or more components bearing a label or tag that certifies that such product conforms to 21 CFR 1020.30, the Diagnostic X-Ray Standard. The four copies of the completed report shall be distributed as follows: 1. (white copy) Bureau of Radiological Health, Division of Compliance (HFX-490) Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857; 2. (yellow copy) The appropriate State agency for radiation protection; 3. (pink copy) The purchaser or user; 4. (blue copy) Retained by the assembler for a period of five (5) years.

INSTRUCTIONS AND CODES

- | | |
|---|---|
| <p>NO. ITEM OR CODE</p> <p>4 Enter the two-digit code(s) which best describes the primary use, and, if applicable, the secondary use.</p> <p>Medical</p> <p>01 General Purpose Radiographic</p> <p>02 General Purpose Fluoroscopic</p> <p>03 Combination Radiographic and Fluoroscopic</p> <p>04 Tomographic</p> <p>05 Angiographic</p> <p>06 Podiatric</p> <p>07 Urologic</p> <p>08 Mammographic</p> <p>09 Chest</p> <p>10 Head-Neck</p> <p>11 Other (Specify in item 13)</p> <p>Dental</p> <p>12 Panoramic</p> <p>13 Intra-oral (General purpose)</p> <p>14 Cephalometric</p> <p>15 Other (Specify in item 13)</p> <p>5 "Stationary" equipment means equipment which through installation has been permanently affixed to a location such as a room or a van. If the equipment itself is intended to be transferred to different locations, it is considered "mobile".</p> <p>9-1 Codes for "Types" of Components</p> <p>A Beam Limiting Device</p> <p>B Tube Housing Assembly</p> <p>C Tube Housing Assembly with Beam Limiting Device</p> <p>D Tube Housing Assembly with Beam Limiting Device and High Voltage Generator</p> <p>E Tube Housing Assembly with High Voltage Generator</p> <p>F X-Ray Controls</p> <p>G X-Ray Controls with High Voltage Generator</p> <p>H High Voltage Generator</p> <p>I Fluoroscopic Imaging Assembly</p> <p>J Table</p> <p>K Cradle</p> <p>L Cassette Holders</p> <p>M Film Changer</p> <p>N Other (Specify in item 13)</p> <p>9 Compatibility - List all the components bearing a certification label that you install and for which you concur with the following four declarations:</p> <p>a. All certified components assembled or installed by me, as listed in item 9 and for which this report is being made, were of the type called for by 21 CFR 1020.30, and such components were assembled, installed, adjusted, and tested by me according to the instructions provided by their manufacturer(s).</p> | <p>NO. ITEM OR CODE</p> <p>b. All instructions manuals and other information required by 21 CFR 1020.30(h) and applicable to x-ray equipment assembled or installed by me have been furnished to the purchaser.</p> <p>c. No certified component has been modified by me in the course of this assembly so as to affect adversely its performance with respect to the requirements of 21,CFR 1020.30, 1020.31, 1020.32.</p> <p>d. A copy of this report has been delivered to the purchaser as required by 21 CFR 1020.30.</p> <p>e. A copy of this report will be transmitted to the state agency responsible for radiation protection.</p> <p>10 Noncompatibility - List all the components bearing a certification label that you install and for which you concur with the following seven declarations:</p> <p>a. The certified components assembled or installed by me, as listed in item 10 and for which this report is being made, were of the type called for by 21 CFR 1020.30, but could not be assembled, installed, adjusted, and tested according to the instructions provided by their manufacturer(s), because other already existing components of the system do not meet the compatibility specifications of the manufacturer(s) of the certified components being installed; and that there are no commercially available certified components of similar type which are compatible with the system.</p> <p>b. The noncompatible components already in the system that I could not assemble, install, adjust, or test according to the instructions provided by the manufacturers of certified components have been listed in item 11.</p> <p>c. Reasons for noncompatibility are stated in item 13.</p> <p>d. No certified component has been modified by me in the course of this assembly so as to affect adversely its performance with respect to the requirements of 21 CFR 1020.30, 1020.31, 1020.32.</p> <p>e. All instruction manuals and other information required by 21 CFR 1020.30(h) and applicable to x-ray equipment installed by me have been furnished to the purchaser.</p> <p>f. A copy of this report has been delivered to the purchaser as required by 21 CFR 1020.30(d).</p> <p>g. A copy of this report will be transmitted to the state agency responsible for radiation protection.</p> <p>11 Complete item 11 if and only if you have listed an entry in item 10.</p> |
|---|---|

TWO-LETTER STATE ABBREVIATIONS

Alabama AL	Kentucky KY	Ohio OH
Alaska AK	Louisiana LA	Oklahoma OK
Arizona AZ	Maine ME	Oregon OR
Arkansas AR	Maryland MD	Pennsylvania PA
California CA	Massachusetts MA	Puerto Rico PR
Canal Zone CZ	Michigan MI	Rhode Island RI
Colorado CO	Minnesota MN	South Carolina SC
Connecticut CT	Mississippi MS	South Dakota SD
Delaware DE	Missouri MO	Tennessee TN
District of Columbia DC	Montana MT	Texas TX
Florida FL	Nebraska NE	Utah UT
Georgia GA	Nevada NV	Vermont VT
Guam GU	New Hampshire NH	Virginia VA
Hawaii HI	New Jersey NJ	Virgin Islands VI
Idaho ID	New Mexico NM	Washington WA
Illinois IL	New York (State) NY	West Virginia WV
Indiana IN	New York City NX	Wisconsin WI
Iowa IA	North Carolina NC	Wyoming WY
Kansas KS	North Dakota ND	

MED 521-6

Figure 10-1—Continued.

d. Disposition of Forms FD 2579.

(1) Form FD 2579 shall be completed and two copies forwarded through command channels to the Commander, USAMMA, ATTN: SGMMA-MP, Frederick, MD 21701, within 15 days from date of installation. The installation of a certified component will not be considered complete until USAMMA has reviewed the Form FD 2579 and determined that the assembly/installation is in compliance with the Standard. At such time, USAMMA has 15 days to forward appropriate Form FD 2579 to BRH.

(2) When the assembly/installation of certified components is accomplished by DA personnel, the assembler/installer shall provide the purchaser's (pink) copy of completed Form FD 2579 to the Chief of Biomedical Equipment Maintenance or other agents as designated by the major medical command and forward all other copies through command channels to the Commander, USAMMA, ATTN: SGMMA-MP, Frederick, MD 21701.

(3) When the assembly/installation of certified components is accomplished by other than DA personnel, the Chief of Biomedical Equipment Maintenance, shall be furnished the purchaser's (pink) copy of the Form FD 2579. A certified reproduction of this copy shall be forwarded through command channels to the Commander, USAMMA, ATTN: SGMMA-MP, Frederick, MD 21701. Since it is not normally possible to obtain a legible reproduction (photocopy) of the purchaser's (pink) copy, Form FD 2579, the following is recommended: Prepare a certified ~~typewritten~~/**printed** copy of the original Form FD 2579. The above can be effected by following the procedure listed below:

(a) Type or legibly print *all* information from the original Form FD 2579, onto a new Form FD 2579.

(b) The installer's name must also be typed/printed in the certified copy of the installer's signature block.

(c) In the comment section, block 13, make the remark: Certified Copy of Form FD 2579 # (ENTER APPROPRIATE ORIGINAL FORM CONTROL NUMBER HERE) and have appropriate responsible personnel sign the above statement.

e. Retention of Form FD 2579. The following retention requirements are established for this form.

(1) USAMMA will retain one copy of each Form FD 2579 originated by or for DA activities until each specified component identified on the Form has been salvaged, transferred to float, reported in a new installation, or for 5 years, whichever comes last.

(2) The Chief of Biomedical Equipment Main-

tenance shall retain the purchaser's (pink) copy of every Form FD 2579 originated for his medical activity until each specified component identified on the Form has been salvaged, transferred to float, or installed on another X-ray system. To maintain consistency between USASMMMA and biomedical equipment maintenance activity records, the Chief of Biomedical Equipment Maintenance shall annotate disposition of each specified component on the Form and advise USAMMA within 15 days after salvaging, transferring, or relocating any certified X-ray component or X-ray system.

f. Supply of Form FD 2579. Manufacturers ordinarily include sufficient Forms FD 2579 with each shipment of certified X-ray components. (See para 1-7b.)

g. Suspenses for submitting Form FD 2579. Originals and copies of Form FD 2579 are required to be submitted through command channels to the Commander, USAMMA, ATTN: SGMMA-MP, Frederick, MD 21701, and received at USAMMA not later than 15 days after completion of the installation. USAMMA shall provide the original of each Form FD 2579 submitted by these activities to the BRH not later than 15 days after receipt (see paragraph 1-6h(1)).

10-5. Calibration/verification records. Records of calibration/verification of all diagnostic X-ray equipment used on human patients shall be prepared by the biomedical equipment maintenance activity performing the calibration by using DD Form 2164 (X-Ray Verification/Certification Worksheet). The local MEDCEN/MEDDAC shall retain one copy of each DD Form 2164 and all pictorial data as permanent records for the life of the system in accordance with AR 340-18-6.

a. Identification. Manufacturer, model, and serial number of all components of the X-ray system calibrated, together with the date of calibration and location of the system.

b. Personnel. Name, grade, and organization of personnel performing the calibration.

c. Test equipment. Manufacturer, model, serial number, and date of calibration expiration of all items of test and measurement equipment used to perform the calibration.

d. Numerical data. The types of data required depend on the type of system calibrated and the test equipment used. Maintain all DD Forms 2164 where data are recorded regarding the results of reproducibility, linearity, and exposure measurements.

e. Pictorial data. Label all radiographs, oscilloscope photographs, and data tapes to indicate X-ray system identification, date, and all appropriate parameters (e.g., kVp, mA, time; oscilloscope sweep speed, vertical deflection factor, channel 1, channel 2 connections; collimator indicated beam size, source to image receptor distance) depending on the type of test being documented. Use the minimum number of radiographs, oscilloscope photographs or data tapes needed to document overall calibration of the X-ray system.

(1) *Collimation.* Obtain radiographs using all beam-limiting devices to reflect proper alignment and beam limitation as appropriate. This includes collimators, spot film shutters, and dental PID.

(2) *Tube potential.* Obtain radiographs of modified A&an-Crooks penetrometer measurements utilized to determine the effective peak tube potential (kVp).

(3) *Timer accuracy.* Obtain oscilloscope photographs which indicate accuracy of the exposure timer at selected low, medium, and high settings. Use a high voltage divider/bleeder, photodiode transducer, or clip-on current probe (in the secondary high tension) to obtain these results.

f. Adjustment and safety inspection. Include written comments as appropriate concerning the results of the adjustment and safety checklist above as well as other significant findings.

g. Records of calibration. Contracts for service/repairs of Government-owned X-ray systems shall include provisions to insure that all records of calibration are generated and placed on file within the medical facility responsible for the performance of that maintenance.



APPENDIX A

REFERENCES

1. AR 10-5, Department of the Army.
2. AR 10-43, United States Army Health Services Command.
3. AR 10-71, United States Army Medical Materiel Agency.
4. AR 40-3, Medical, Dental, and Veterinary Care.
5. AR 40-5, Health and Environment.
6. AR 40-14, Control and Recording Procedures for Occupational Exposure to Ionizing Radiation.
7. AR 40-37, Licensing and Control of Radioactive Materials for Medical Purposes.
8. AR 40-61, Medical Logistics Policies and Procedures.
9. AR 40-400, Patient Administration.
10. AR 310-25, Dictionary of United States Army Terms.
11. AR 340-18-6, Maintenance and Disposition of General Personnel Management and Safety Functional Files.
12. AR 340-18-9, Maintenance and Disposition of Medical Functional Files.
13. AR 385-30, Safety Color Code Markings and Signs.
14. AR 385-40, Accident Reporting and **Records**.
15. AR 611-201, Enlisted Career Management Fields and Military Occupational Specialties.
16. AR 725-50, Requisitioning, Receipt, and Issue System.
17. AR 750-1, Army Materiel Maintenance Concepts and Policies.
18. AR 750-25, Army Metrology and Calibration System.
19. TM 5-805-12, X-Ray Shielding.
20. TM 5-838-2, Army Health Facility Design.
21. TM 8-225, Dental Specialist.
22. TM 8-280, Radiologic Technology.
23. TM 8-605, Preventive Maintenance Procedures and Serviceability Standards for Medical Equipment.
24. TM 38-750, The Army Maintenance Management System (TAMMS).
25. TB 38-750-2, Implementing Instructions for the Army Maintenance Management System (TAMMS) for Army Medical Department Units and Activities.
26. TB 43-180, Calibration Requirements for the Maintenance of Army Materiel.
27. TB 750-8-1, Maintenance Expenditure Limits for Medical Equipment.
28. TB 750-25, Maintenance of Supplies and Equipment Army Meteorology and Calibration System.
29. TB MED 1, Storage, Preservation, Packaging, Packing, Maintenance and Surveillance of Materiel; Medical Activities.
30. TB MED 279, Control of Hazards to Health from Laser Radiation.
31. TB MED 286, Prevention of Electrical **Shock** Hazards in Hospitals.
32. TB MED 291, Guidance for Inventory, Control and Accountability of Drugs and Injection Devices of Potential Abuse at Medical Treatment Facilities Worldwide.
33. SB 8-75-MEDCASE.*
34. DOD 4160.21-M, Defense Disposal Manual
35. CECS-13750, Corps of Engineers Guide Specification (CE)-X-Ray Shielding.
36. Federal Standard Number 72, Shockproof Cable Terminals and Receptacles for Use on X-Ray Equipment.
37. Title 3, Code of Federal Regulations (CFR), Subchapter B.
38. Title 10, CFR, Part 20, Standards for Protection Against Radiation.
39. Title 10, CFR, Part 35, Human Uses of Byproduct Material.
40. Title 21, CFR, Chapter 1, Subchapter J, Radiological Health.
41. Federal Register, Vol. 43, No. 22, **m4377**, 1 February 1978.

*This publication is not stocked by the Adjutant General. Copies may be obtained from Cdr, WSAMMA, ATTN: SGMMA-SDL, Frederick, MD 21701.

42. Bureau of Radiological Health (BRH), Publication DHEW Pub No (FDA) 77-8001, BRH Routine Compliance Testing for Diagnostic X-Ray Systems or Components of Diagnostic X-Ray Systems to which 21 CFR Subchapter J is applicable.
43. BRH, Publication DHEW Pub No. (FDA) 75-8029, BRH Regulatory Guidelines Applicable to Diagnostic X-Ray Systems and Their Major Components to which 21 CFR Subchapter J is applicable.
44. BRH, Publication DHEW Pub No. 76-8002, Assembler's Guide to Diagnostic X-Ray Equipment.
45. National Council on Radiation Protection and Measurements (NCRP) Report No. 33, Medical X-Ray and Gamma-Ray Protection for Energies up to 10 MeV (Equipment Design and Use).
46. NCRP Report No. 35, Dental X-Ray Protection-
47. NCRP Report No. 36, Radiation Protection in Veterinary Medicine.
48. NCRP Report No. 48, Radiation Protection for Medical and Allied Health Personnel.
49. NCRP Report No. 49, Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV.
50. NCRP Report No. 51, Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities.
51. NCRP Report No. 54, Medical Radiation Exposure of Pregnant and Potentially Pregnant Women.
52. International Commission on Radiological Protection (ICRP) Report No. 15, Protection Against Ionizing Radiation from External Sources.
53. ICRP Report No. 16, Protection of the Patient in X-Ray Diagnosis.
54. ICRP Report No. 21, Data for Protection Against Ionizing Radiation from External Sources: Supplement to ICRP No. 15.
55. International Electrotechnical Commission (IEC) 336-(1970), Measurement of the Dimensions of Focal spots of Diagnostic X-Ray Tubes Using a Pinhole Camera.
56. IEC 407-(1973), Radiation Protection in Medical X-Ray Equipment 10 kV to 400 kV.
57. IEC 407A-(1975), First Supplement to Publication 407-(1973), Radiation Protection in Medical X-Ray Equipment 10 kV to 400 kV.
58. IEC 522-(1976), Inherent Filtration of an X-Ray Tube Assembly.
59. American National Standards Institute (ANSI) Standard N449-1974, Guidelines for Maintaining Cobalt-60 and Cesium-137 Teletherapy Equipment.
60. ANSI Standard N449.1-1978, Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment.
61. ANSI Standard MD 156.26-1975, Dental X-Ray Equipment.
62. Underwriters' Laboratories, Inc. Report 187, Standard for Safety-X-Ray Equipment.
63. Federal Radiation Council Report No. 1, Background Material for the Development of Radiation Protection Standards.
64. Environmental Protection Agency (EPA) Report 520/4-76-002, Background Report- Recommendations on Guidance for Diagnostic X-Ray Studies in Federal Health Care Facilities.
65. EPA Report 520/4-76-012, Background Report-Recommendations on Guidance for Technic to Reduce Unnecessary Exposure From X-Ray Studies in Federal Health Care Facilities.
66. EPA Report 520/4-76-019, Radiation Protection Guidance for Diagnostic X-Rays, Federal Guidance Report No. 9.
67. National Electrical Manufacturers Association (NEMA), Publication No. XR-2-1974, X-Ray Cassettes, Fluoroscopic Diaphragms, and Minimum Power Supply Requirements.
68. NEMA, Publication No. XR5-1974, Measurement of Dimensions of Focal Spots of Diagnostic X-Ray Tubes.
69. NEMA Publication No. XR6-1979, Location of Primary Operating Controls for Spot-film Devices.
70. NEMA Publication No. XR7-1979, High-voltage X-Ray Cables and Receptacles.
71. NEMA Publication No. XR-1979, Test Methods for Diagnostic X-Ray Machines for Use During Initial Installation.
72. Academy of Health Sciences, United States Army, Text Pamphlet XE-300-025, Technical Guide for Performing Tests and Adjustments to Comply with TB MED 62 and 21 CFR Subchapter J of the Radiation Control for Health and Safety Act of 1968.
73. National Fire Protection Association, Publication NFPA No. 70, National Electric Code.
74. NFPA, Publication Vo14.
75. NFPA Publication Vo16.

76. Federal Specification, GG-X-635(-), X-Ray Apparatus Set, Radiographic and Fluoroscopic, Medical.
77. Accreditation Manual for Hospitals, Joint Commission on Accreditation of Hospitals.
78. World Health Organization (WHO), Manual on Radiation Protection in Hospitals and General Practice, Vo13, X-Ray Diagnosis.
79. WHO, Manual on Radiation Protection in Hospitals and General Practice, Vol 4, Radiation Protection in Dentistry.
- 80.** American Association of Physicists in Medicine (AAPM) Report No. 1, Phantoms for Performance Evaluation and Quality Assurance of CT Scanners.
81. AAPM Report No. 4, Basic Quality Control in Diagnostic Radiology.



APPENDIX B

DEFINITIONS

Absorbed dose: The energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The special unit of absorbed dose is the rad. One rad equals 0.01 joule per kilogram.

Acceptance test: Those tests and measurements that are performed by biomedical equipment maintenance personnel to insure that the diagnostic X-ray system complies with the manufacturer's stated specifications. This also includes a verification that all provisions of the contract have been fulfilled.

Accidental radiation occurrence: A single event or series of events occurring in the course of manufacturing, testing, or use of a diagnostic medical or dental X-ray system that results in injurious or potentially injurious exposure of any person to radiation as a direct result of the manufacturing, testing or use of a **diagnostic X-ray system**.

Accessible surface: The external surface of the enclosure or housing provided by the manufacturer.

Accessory Component: a. A component used with diagnostic X-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with this bulletin and the Standard; requires an initial determination of compatibility with the X-ray system.

b. Component necessary for compliance of the X-ray system with this bulletin and the Standard; may be interchanged with similar compatible components without affecting the X-ray system's compliance, such as one of a set of interchangeable beam-limiting devices.

c. Component compatible with all X-ray systems with which it may be used; does not require compatibility or installation instructions, such as a tabletop cassette holder.

Activity: The number of nuclear transformations occurring in a given quantity of material per unit time. See curie.

Actual focal spot: The location at which the anode of an X-ray tube intercepts the electron beam and X-rays are produced.

Added filter: (See filter.)

Aluminum equivalent: The thickness of aluminum (type 1100 alloy*) affording the same attenuation, under specified conditions, as the material in question.

Ancillary equipment: Any equipment that is not a major component of the X-ray system; used in support of radiologic procedures.

Assembler: Any person engaged in the business of assembling, replacing, or installing one or more components into an X-ray system or subsystem. The term includes the owner of an X-ray system or his employee or agent who

* The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper, "Aluminum Standards and Data," The Aluminum Association, New York, NY (1969).

assembles components into an X-ray system that is subsequently used to provide professional or commercial services.

Attenuation: The reduction of exposure rate upon passage of radiation through matter.

Attenuation block: A block or stack of sheets of type 1100 aluminum alloy having dimensions 7.9 by 7.9 by 1.5 inches (20 by 20 by 3.8 cm) or other material having equivalent attenuation used for radiation measurements (a 1.5-inch (3.8 cm) thick aluminum block or 0.09-inch (0.23 cm) copper attenuation block is equivalent to a 10-inch (26 cm) thick patient at a peak tube potential of 90 kVp).

Automatic exposure control: A device that automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.

Barrier: (See protective barrier.)

Beam-limiting device: A device that provides a means to restrict the dimensions of the X-ray or gamma-ray field, also called a collimator or beam defining device.

Calibration: a. Calibration, maintenance: Electrical, electronic and mechanical tests, measurements, and adjustments that are made to insure that the equipment (e.g., film processor, diagnostic X-ray system, etc.) meets the manufacturer's stated specification and the requirements of appropriate Army and Federal directives.

b. Calibration, radiation: The measurement and description of the quality, quantity, uniformity of the radiation field, radiation output (exposure rate or dose rate) for the range of field sizes, depths of field, treatment distances and various collimating devices and attenuators used to modify the useful (primary) beam.

Casset holder: A device, other than a spot film device, that supports and/or fixes the position of an X-ray film cassette during a radiographic exposure.

Cephalometric device: A device intended for the radiographic visualization and measurement of the dimensions of the human head.

Coefficient of variation: The ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{X}} = \frac{1}{n} \sqrt{\frac{\sum (X_i - \bar{X})^2}{n - 1}}$$

- where:
- C = Coefficient of variation
 - s = Estimated standard deviation of the population.
 - \bar{X} = Mean value of observation in sample.
 - X_i = ith observation sampled.
 - n = Number of observations sampled.

Collimation: The restriction of the useful (primary) beam to an appropriate size.

Collimator: A device used to restrict the area of the useful (primary) beam to an appropriate size. Also called a beam-limiting or beam-defining device.

Collimator zone: That portion of the source housing of a gamma-beam apparatus that includes the beam defining mechanism.

Compliance test: Those tests and measurements that are performed by health/radiological physicists in order to insure that the diagnostic X-ray system complies with the performance standards contained in this bulletin and 21 CFR subchapter J.

Concrete equivalent: The thickness of concrete based on the density of 2.35 g/cm^3 (147 lb/ft^3) affording the same attenuation under specified conditions as the material in question.

Cone: A device used to indicate beam direction and to establish a minimum source-surface or source-skin distance (SSD). It may or may not incorporate a collimator, also known as a position-indicating device (PID).

Cone cutting: Failure to cover the area of interest with the useful (primary) beam.

Constant potential: A potential difference (or voltage) that has little, or no, periodic variation in amplitude. The periodic component is called the ripple potential (or ripple voltage).

Contact therapy system: X-ray therapy system designed for very short treatment distances (SSD of 5 cm or less) usually employing peak tube potentials in the range of 20 to 50 kVp.

Contamination (radioactive): A radioactive substance dispersed in materials or places where it is undesirable.

Controlled area: A defined area in which the occupational exposure of personnel to radiation is under the supervision of the Radiation Protection Officer. (This definition implies that a controlled area is one that requires control of access, occupancy, working conditions, and egress for radiation protection purposes.) Controlled areas shall not include any areas used as living quarters. A separate room or rooms in a residential building may be set apart as a controlled area.

Coulomb: A unit of electrical charge that is equal to 1 ampere-second or that quantity of charge transferred in 1 second by a steady current of 1 ampere.

Curie (Ci): a. The special unit of activity equal to 3.7×10^{10} nuclear transformations per second.

b. By popular usage, the quantity of any radioactive material having an activity of one curie.

Dead-man switch: A switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch.

Defect: Any unsafe condition or any failure associated with the use of a X-ray system or component thereof which relates to the health and safety of use by reason of the emission of ionizing radiation for other than its intended purpose.

Diagnostic-type protective source assembly: An X-ray tube housing assembly with a beam-limiting device attached that is so constructed that the leakage radiation when measured at a distance of 40 inches (100 cm) from the source cannot exceed 100 mR in any 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance is determined by averaging

measurements over an area of 16 square inches (100 cm²) with no linear dimension greater than 8 inches (20 cm),

Diaphragm: A plate, usually of lead, with a central aperture so placed as to reduce the useful (primary) beam to an appropriate area (see collimation).

Dose equivalent (H): A quantity used for radiation protection purposes that expresses on a common scale for all radiations the biological effectiveness of absorbed dose. It is defined as the product of the absorbed dose in rads, the quality factor, and certain modifying factors. The unit of dose equivalent is the rem. (For radiation protection purposes in this publication, the dose equivalent in rems may be considered numerically equivalent to the absorbed dose in rads and the exposure in roentgens.)

Effective focal spot: The projection of the actual focal spot on a plane that is perpendicular to the central perpendicular line of the window of the X-ray tube housing or to an agreed specified direction (e.g., in stereoarrangements). It is also known as the projected focal spot.

Exposure (R): a A measure of the ionization produced in air by X-ray of gamma radiation. It is the sum of the electrical charges on all of the ions of one sign produced in air, when all electrons liberated by photons in a volume element of air are completely stopped in air, divided by the mass of the air in the volume element. The special unit of exposure is the "roentgen" (R). (For radiation protection purposes in this bulletin the number of roentgens may be considered to be numerically equivalent to the number of rads or rems.)

b. The act or state of being irradiated by ionizing radiation.

Exposure-at-skin entrance index (EASEI): That value derived from NEXT data below which 75 percent of the exposure/dose values are found. The exposure/dose values are based on a "reference" patient for nondental projections or the tip of the PID for dental **bitewing** and **periapical** projections.

Exposure rater The exposure per unit time.

Facility: Ionizing radiation source with associated equipment and space in which it is located, sometimes called an installation.

Fail-safe: A design in which all failures of indicators or safety components that can reasonably be anticipated cause the equipment/system to fail in a mode such that personnel are "safe" from exposure to radiation.

Federal performance standard: A performance standard issued pursuant to Section 359 of the Radiation Control for Health and Safety Act of 1968 (PL 90-602, 42 United States Code 263b et seq). **Same** as the Standard.

Field emission X-ray system: An X-ray system that uses an X-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Field medical facilities: **Facilities** in which permanent structural shielding is not installed due to the temporary nature of the mission.

Field radiography: Radiography of **fluoroscopy** performed in a field medical facility.

Field (tactical) X-ray system: A diagnostic X-ray system normally used in direct support military operations.

Film badge: A packet of special film(s) and its case used in radiation monitoring to estimate radiation exposure.

Filter or filtration: Material in the useful (primary) beam which usually absorbs preferentially the less penetrating radiation. This also includes wedge filters and field-flattening filters used in radiotherapy.

Added filter: Filter added to the inherent filter.

Inherent filter: The filter permanently in the useful (primary) beam; it includes the window of the X-ray tube and any permanent tube enclosure.

Total filter: The sum of the inherent and added filters.

Fluoroscopic imaging assembly: A subsystem in which X-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

General purpose radiographic X-ray system. Any radiographic X-ray system that, by design, it is not limited to radiographic examination by specific anatomical regions (e.g., extremities, head or head and neck, thoracic, and abdominal).

Half-value layer (HVL): The thickness of a specified substance that, when introduced into the path of a given beam of radiation, reduces the exposure rate by one-half. The **contribution** of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

High radiation area: Any area, accessible to personnel, in which there exists radiation, at such levels that a major portion of the body could receive in any 1 hour a dose equivalent in excess of 100 mrem.

High-voltage generator: A device that transforms electrical energy from the electrical potential supplied by the X-ray control to the X-ray tube operating electrical potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X-ray tube(s), high-voltage switches, electrical protective devices and other appropriate components/subsystems, also known as an X-ray high-voltage generator.

Homogeneity coefficient (h): The ratio of the first HVL to the second HVL, this value is unity for monoenergetic X-Rays. Sometimes referred to as homogeneity factor.

Image intensifier: A device installed in its housing which instantaneously converts an X-ray pattern into a corresponding light image of higher energy density.

Image receptor: Any device, such as a fluorescent screen or radiographic film, which transforms incident X-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect portions of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

Image receptor support: For mammographic X-ray systems it is that part of the X-ray system designed to support the image receptor in a horizontal plane during a mammographic examination-

Interlock: a. A limiting device to preclude activation or exposure of a radiation source unless some specific condition is met.

b. A device that terminates the exposure when some condition is met (e.g., current surge, high tube potential, collision during beam rotation).

Kilovolt (kV): A unit of electrical potential difference equal to 1000 volts.

Kilovolt constant potential (kVcp): The potential difference in kilovolts of a constant potential high-voltage generator.

Kilovolt Peak (kVp): The crest value in kilovolts of the potential difference of a pulsating potential high-voltage generator.

Lead equivalent: The thickness of lead affording the same attenuation under specified conditions, as the material in question.

Leakage radiation: (see radiation.)

Linearity: The ability of an X-ray system to maintain a near constant ratio of the radiation output to the measured product of tube current (mA) and exposure time (s), mAs, expressed as mR/mAs at various technique factors while maintaining a constant mAs.

Line-voltage regulation: The difference between no-load and the load line potential expressed as a percentage of the load line potential; that is:

$$\text{Percent linevoltage regulation} = 100 (V_n - V_l) / V_l$$

Where: V_n = No-load line potential.

V_l = Load potential.

Lux: A unit of illumination that is equal to one lumen per square meter. One lux is equal to 0.0929 footcandle or 10.764 lux equals 1 footcandle.

Manufacturer: Any person engaged in the business of manufacturing, assembling, or importing X-ray equipment which is subject to the Standard.

Maximum line current: The root mean square (rms) current in the supply line of an x-ray operating at its maximum rated values.

Measured percent error (MPE): The indicated value minus the measured value divided by the measured value, that quantity multiplied by 100. Thus:

$$\text{MPE} = \frac{\text{Indicated value} - \text{Measured value}}{\text{Measured Value}} \times 100$$

The indicated value is that value stated by the manufacturers for any combination of peak tube potential (kVp), tube current (mA), exposure time(s) or tube current-exposure time product (mAs) for which the system is designed to operate.

Milliroentgen (mR) and millirem (mrem): Equivalent to one-thousandth (1/1000 or 0.001) of a roentgen, or a rem, respectively.

Multiple tube facilities: A facility containing more than one X-ray system in the same room close enough to require consideration of their combined workloads in radiation protection design. Such a facility may include two or more complete X-ray systems (single-tube systems) or a combination of two or more tube heads operable from a single control panel (multiple tube systems).

Multipurpose (general purpose) X-ray system: An X-ray system designed or used for radiographic examinations of more than one part of the body, or one designed or used for both diagnosis and therapy.

New X-ray equipment/system: X-ray equipment/system that was manufactured and installed after 1 August 1974. Therefore, old equipment/system is that manufactured prior to 1 August 1974.

Nominal focal spot size: The numerical value, determined according to specific methods (e.g., pinhole or slit camera technique), significant for the dimensions of the effective focal spot with respect to a specified direction of the beam of X-ray radiation and technique factors.

Noncontrolled area: Any space or area not meeting the definition of a controlled area.

Occupancy factor (T): The factor by which the workload should be multiplied to correct for the degree of occupancy of the area in question.

Occupied area: An area that is or may be occupied by persons.

Operator: The person actually in control of the equipment when exposures are being made.

Panel, fluoroscopic: Surface of a vertical fluoroscope analogous to the tabletop of a tilting table fluoroscope.

Personnel monitor: An appropriately sensitive device used to estimate the radiation exposure of an individual (see AR 40-14).

Phantom: A **tissue-equivalent** object used to simulate the absorption and scatter characteristics of the patient's body.

Position indicating device (PID): A device on a dental radiographic X-ray system used to indicate the beam position and to establish a definite SSD. The devices may or may not incorporate or serve as a beam-limiting device.

Primary beam: (See useful beam.)

Primary protective barrier: (See protective barrier.)

Protective apron: Apron made of radiation absorbing materials, usually lead, used to reduce radiation exposure.

Protective barrier: A barrier of radiation absorbing materials used to reduce radiation exposure to the required value for radiation protection purposes.

Primary protective barrier: Barrier sufficient to attenuate the useful (primary) beam to the required value for radiation protection purposes.

Secondary protective barrier: Barrier sufficient to attenuate the stray radiation to the required value for radiation protection purposes.

Protective source housing: An enclosure for a gamma-beam therapy sealed source so constructed that the leakage radiation does not exceed specified limits with the source in the "ON" and "OFF" positions.

Protective tube housing: (See diagnostic and therapeutic type protective source assembly.)

Qualified expert: With reference to radiation protection, a person having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs (e.g., persons certified in this field by the American Board of Radiology, or the American Board of Health Physics, or those having equivalent qualifications as determined by The Surgeon General). With reference to the calibration of radiation

therapy equipment, a person having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy and meeting the requirements of 10 CFR 35.24 (for example, persons certified in Radiological Physics or Therapeutic **Radiological** Physics or X-Ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications).

Qualified biomedical equipment maintenance personnel- Individuals having knowledge and training necessary to maintain, repair, and calibrate (electrically, electronically, or mechanically) certain parameters of diagnostic and/or therapeutic x-ray systems.

Quality administration: Those management actions that guarantee monitoring techniques are properly performed and evaluated and that necessary corrective measures are taken in response to monitoring results.

Quality assurance: The planned and systematic actions that provide adequate confidence that a diagnostic x-ray facility will produce consistently high quality radiographs at minimum cost and exposure to the patient. Quality assurance actions include both quality control techniques and quality administration procedures. The nature and extent of the QA program at any medical facility will vary with the size, the type of examinations conducted, and other factors.

Quality control: The routine physical testing and calibration of the X-ray **high-voltage** generators, image receptors, image processors, and the ancillary equipment. Quality control techniques are concerned with equipment performance.

Quick change X-ray tube: An X-ray tube designed for use in its associated tube housing such that the X-ray tube cannot be inserted into its tube housing in such a manner that, after reloading, it would result in noncompliance of the X-ray system, because of focal spot position or misalignment of the **beam-limiting** devices with the requirements of this bulletin or 21 CFR 1020.30, 21 CFR 1020.31, 21 CFR 1020.32, and that the shielding within the tube housing cannot be displaced.

Rad: The special unit of absorbed dose equal to 0.01 joule per kilogram of material in question.

Radiation (ionizing): Any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, by interaction with matter.

Leakage radiation: All radiation coming from within the source housing except the useful **(primary)** beam. Leakage radiation includes the portion of the radiation coming directly from the source and not absorbed by the source housing as well as the scattered radiation produced within the source housing. Leakage radiation does not include radiation produced when the exposure switch or timer is not activated.

Scattered radiation.+ Radiation that, during passage through matter, has been deviated in direction. (It will also have been modified by a decrease in energy.)

Stray radiation: The sum of leakage and scattered radiation.

Useful beam: Radiation that passes through the window, aperture, cone or other beam-limiting device of the source housing when the exposure switch or timer is activated. Sometimes called "primary beam."

Radiation area: Any area, accessible to personnel, in which there exists ionizing radiation at such levels that a major portion of the body could receive in any 1 hour a dose equivalent of 5 mrem or in any 5 consecutive days a dose equivalent in excess of 100 mrem. For practical purposes, a radiation area shall be considered to be any area in which the radiation levels are greater than 2 mR/hr but less than 100 mR/hr.

Radiation exposure standards: Radiation dose equivalents that should not be exceeded without careful consideration of the reasons for doing so. Every effort should be made to encourage the maintenance of radiation doses as far below these limits as is reasonably achievable. There can be no single permissible or acceptable level of exposure without regard to the reason for permitting the exposure. It is basic that exposure should result from a specific determination of its necessity (see AR 40-14).

Radiation protection officer: A person designated by the commander to be directly responsible for the radiation protection program (see AR 40-14 and AR 40-37).

Radiation protection survey: An evaluation of existing or potential radiation hazards associated with the use of diagnostic and therapeutic X-ray and gamma-beam equipment under specified conditions.

Radiation therapy simulation device: A radiographic or fluoroscopic X-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiation worker: The term radiation worker is synonymous with an occupationally exposed individual as defined in AR 40-14. A radiation worker is an individual who is occupationally exposed to ionizing radiation as a result of his employment or duties. X-ray technicians and radiologists are examples of radiation workers. An occupational exposure shall not include the exposure of an individual to sources of ionizing radiation for the purpose of medical or dental diagnosis or therapy of that individual.

Rated line voltage: The range of potentials, in volts, of the supply line specified by the manufacturer at which the X-ray system is designed to operate.

Rated output current: The maximum allowable load current of the X-ray high-voltage generator.

Rated output voltage: The allowable peak tube potential, in volts, at the output terminals of the X-ray high-voltage generator.

Reassembly: The installation of one or more components or subsystems that were previously assembled and used as an X-ray system.

Rem: The special unit of dose equivalent. For radiation protection purposes, when the quality factor is 1, the number of rems may be considered equal to the number of rads or the number of roentgens (see AR 40-14).

Reproducibility: The ability of an X-ray system to maintain a near constant radiation exposure (mR) at specified techniques for repetitive exposures.

Resolution: A manifestation of sharpness and the minimum separation at which two adjacent objects can be distinguished as individual objects. The resolution capability of a focal spot is generally identified as the equivalent focal spot.

Roentgen (R): The special unit of radiation exposure. One roentgen is the exposure of X or gamma radiation such that the associated corpuscular emission per kilogram of air produces, in air, ions that carry 2.58×10^{-4} coulomb of electrical charge of either sign one electrostatic unit (esu) equals 0.333 nanocoulomb.

Scattered radiation: (See radiation.)

Sealed source: A radioactive source sealed in a container or having a bonded cover, in which the container or cover has sufficient mechanical strength to prevent contact with and dispersion of the radioactive material under the conditions of use for which it was designed.

Secondary protective barrier: (See protective barrier.)

Shall: Indicates a requirement that is necessary or essential to meet the currently accepted standards of protection of Federal rules and regulations.

Should: Indicates an advisory recommendation that is to be applied when practicable.

Shutter: a In beam therapy equipment, a device fixed to the X-ray or gamma-ray source housing to intercept the useful (primary) beam.

b. In diagnostic equipment, an adjustable device used to collimate the useful (primary) beam.

Source: a. The focal spot of the X-ray tube (also known as the tube target).

b. A discrete amount of radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

Source-film distance (SFD): The distance measured along the central ray from the center of the front surface of the source (X-ray focal spot or sealed radioactive source) to the surface of the X-ray film.

Source housing: (See protective source housing.)

Source-image receptor distance (SID): The distance from the source to the center of the input surface of the image receptor.

Source-surface distance (source-skin distance) SSD: The distance measured along the central ray from the center of the front surface of the source (X-ray focal spot or sealed radioactive source) to the surface of the irradiated object.

Spot-film device: A device intended to transport and/or position a radiographic image receptor between the X-ray source (tube) and the fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

Stationary (fixed) equipment: Equipment that is installed in a fixed location.

Stray radiation: (See radiation.)

Surface exposure integral ($R-cm^2$): The product of the exposure at skin entrance by the area of the beam at skin entrance for non-dental projections. For dental projections it is computed as the exposure at the tip of the PID times the beam area at the tip of the PID.

Survey: (See radiation protection survey.)

Technique factors: The conditions of **operation**. They are specified as follows:
 a For a capacitor energy storage X-ray system, the peak tube potential in **kVp** and the quantity of charge in **mAs**.

b. For a **field** emission X-ray system rated for pulsed operation, the peak tube **potential** in **kVp**, and the number of X-ray pulses.

c. For **all** other X-ray systems, the peak tube potential in **kVp**, and either the tube current in **mA** and exposure time in second, or the product of tube **current** (**mA**) and exposure time(s) in **mAs**.

Therapeutic type protective source assembly: a For X-ray therapy systems not capable of operating at 500 **kV** or above, the following definition applies: An X-ray tube housing so constructed that the leakage radiation at a distance of 40 inches (100 cm) from the source does not exceed 1 R in 1 hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential-

b. For X-ray therapy systems capable of operating at a peak tube potential of 500 **kVp** or above, the following definition applies: An X-ray tube housing so constructed that the leakage radiation at a distance of 40 inches (100 cm) from the source does not exceed 0.1 percent of the useful (primary) beam dose rate at 40 inches (100 cm) from the source, for any of its operating conditions.

c. In either case, small areas of reduced protection are acceptable **providing** the average reading over any 16 square inches (100 **cm²**) of area with no linear dimension greater than 8 inches (20 cm) at 40 inches (100 cm) distance from the source does not exceed the values given above.

Tube housing assembly: A device that includes the insert, high-voltage and/or filament transformers and other components/subsystems when they are contained within the tube housing.

Unspecified equipment: A component or equipment that is not certified (e.g., tube stand, cassette tray within tables, supporting structures) in accordance with 21 CFR subchapter J.

Use factor (beam direction factor) (U): Fraction of the workload during which the useful (primary) beam is directed at the barrier under consideration.

Useful beam: (See radiation.)

User: An individual(s) who has been delegated the responsibility for the use, operation, or storage of ionizing radiation sources. The user may be the operator.

Verification: Periodic performance of specified tests and measurements required to determine that diagnostic X-ray equipment functions and is maintained in accordance with the manufacturer's specifications and within guidelines established by the Standard.

Visible area: That portion of the input surface to the image receptor over which incident X-ray photons are producing a visible image.

Workload (W): The degree of use of an X-ray or gamma-ray source. For X-ray systems operable at a tube potential below 500 **kV**, the workload is usually expressed in **milliamperere-minutes** per week. For gamma-beam therapy sources and for X-ray systems operating at a tube potential of 500 **kV** or above, the workload is usually stated in terms of the weekly exposure of the useful (primary) beam at 40 inches (100 cm) from the source and is expressed in **roentgens** per week.

X-ray control: A device that controls input electrical power to the X-ray high-voltage generator/X-ray tube. It includes components/subsystems such as timers, phototimers, automatic brightness stabilizers, and similar devices which control and display technique factors of an X-ray exposure. Normally there are components/subsystems which permit line voltage compensation.

X-ray equipment: An X-ray system, subsystem, or component thereof.

X-ray high-voltage generator: A device that transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may include means for transforming alternating current to direct current, filament transformers for the X-ray tube(s), high-voltage switches, electrical protective devices, **and** other components.

X-ray subsystem: Any combination of two or more components of an X-ray system for which there are requirements specified in this bulletin.

X-ray system: An assemblage of components or subsystems for the controlled production of X-rays. This system includes as a minimum an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system, also called X-ray equipment.

X-ray tube: Any electron tube that is designed for the conversion of electrical energy into X-ray energy. Also called a tube.

APPENDIX C

EXAMPLE OF EMERGENCY PROCEDURES FOR FAILURE OF GAMMA-BEAM CONTROL MECHANISM

The emergency procedure to be used in case of failure of the gamma-beam control mechanism depends on the individual facility. The following is an example.

Emergency Procedure for Beam Control Failure

If the light signals indicate that the beam control mechanism has failed to terminate the exposure at the end of the preset time (for example if the red light stays on **and/or** the green signal does not light up), the source may still be in the "ON" position. In case of failure of the source shutter, the following steps are to be carried out.

FOR THE RADIATION THERAPY TECHNICIAN:

1. Press the "Emergency-Off" bar on the control console. Determine the status of the radioactive source by observation of the area monitor from the control console.
2. Open the door to the treatment room.
3. If the patient is ambulator, direct him to get off the table and leave the room.
4. If the patient is not ambulatory:
 - a. Enter the treatment room but avoid exposure to the useful (primary) beam.
 - b. Pull the treatment table as far away from the useful (primary) beam as possible.
 - c. Transfer the patient to a stretcher and remove him from the room.
5. Close and secure the door. Post a legible and clearly visible **sign** warning others of the existence of the emergency condition.
6. Turn off the main switch at the control console.
7. Notify the radiation therapist, radiation protection officer, and local biomedical equipment maintenance personnel at once.

FOR THE RADIATION PROTECTION OFFICER:

1. Secure a portable survey meter. Check to see that the survey meter is functioning properly.
2. Turn the power "ON" and open the door a few inches.
3. Stand behind the door and insert the survey meter into the door opening to determine whether, in fact, the source is still in the "ON" position.
4. If the source is still "ON," enter the room, observe and record readings obtained, then manually turn the source "OFF" as per manufacturer's instructions. Avoid intercepting the useful (primary) beam with any part of your body.

Note. Emergency procedures **shall** include specific instructions for locating and using the device for **manually** turning "OFF" the teletherapy unit's useful (primary) beam of radiation.

5. Adjust the limiting diaphragms to the smallest field size.
 6. Close the door to the treatment room. Turn off the power. Lock the control panel. Post a sign warning people not to enter, if not already posted.
- Source: *Medical X-ray and Gamma-Ray Protection for Energies up to 10 MeV* (NCRP Report No. 33, page 46-47).
- Source: Nuclear Regulatory Commission's Licensing Guide-Teletherapy Programs.

APPENDIX D

GENERAL CRITERIA FOR SELECTING X-RAY SYSTEM CAPABILITIES

Facility size	Application	Generator capacity
Health clinics, AFES , ARNG. and USAR medical facilities	Routine radiography	300 mA or 500-600 mA , single-phase radiographic generators are appropriate. Selection of the X-ray system should be based on availability of adequate power and type of patient load. A 500-600 mA X-ray system should be selected for most health clinics.
Health clinics	Radiography/fluoroscopy	500-600 mA single-phase radiographic/fluoroscopic X-ray systems are preferable. Higher capacity systems should not be considered without consultation with TSG radiology consultant. If the estimated equipment utilization rate for routine radiography is 75 percent or greater, then inclusion of fluoroscopic capability for routine daily use is not advisable.
MEDDAC	Radiography w/linear tomography attachment Radiography/fluoroscopy Angiography	Hospitals in this grouping should select at least 600 mA three phase X-ray systems. 800 mA three-phase X-ray systems are preferable. 800 to 1200 mA three-phase X-ray systems are preferable. 600 mA three-phase X-ray systems are preferable.
Medical centers	Routine radiography w/linear tomography attachment	
Medical centers	Radiography/fluoroscopy Angiography/neuroradiologic procedures Multidirectional	800 mA three-phase X-ray systems are preferable. 800 to 1600 mA three-phase X-ray systems are preferable. 800 to 1600 mA three-phase X-ray systems are preferable.

Note. Medical facilities performing more than 50 chest examinations per day should have at least one automatic film feed X-ray system with processor.

Note. Whenever possible, mobile X-ray systems should be battery operated. If battery operated, the X-ray system is not subject to electrical line voltage fluctuations that occur when there is inadequate electrical power.

Note. All MEDCEN/MEDDAC fixed medical X-ray systems should be three-phase for X-ray systems having a tube current of 600 **mA** or greater.

Note. All three-phase X-ray systems having a tube current of 600 **mA** or greater shall have an anode heat calculator device installed.

Note. The kilowatt (KW) output of an X-ray system is the product of the manufacturer's X-ray system's maximum rated tube current (**mA**) at its maximum rated peak tube potential (**kVp**) and the phase angle. For convenience, the **kW** rating of X-ray generators are determined by use of the following formulas:

single-phase:

$$\text{max (kVp)} \times \text{max (mA) at the kVp} \times 0.707 = \text{kW}$$

three-phase:

$$\text{max (kVp)} \times \text{max (mA) at that kVp} = \text{kW}$$

Generator **kW** ratings are determined under load which means that it may not be possible to simultaneously obtain the maximum rated **kVp** and **mA** capabilities of the generator. Do not depend entirely on **kW** ratings to compare generators; the application of the generator must also be taken into consideration.



APPENDIX E

TABLES FOR GENERAL INFORMATION

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Table 1. Protection Criteria for Field Radiography

Note. Circular area around the beam when perpendicular to the tabletop where occupancy is to be prevented. 100 mR/wk levels are given for radiation workers and 10 mR/wk levels are given for nonradiation workers.

Weekly workload (mA-min)	Radiation workers radius for 100 mR/wk		Nonradiation workers radius for 10 mR/wk	
	(ft)	(m)	(ft)	(m)
1500	10.0	3.0	30.0	9.1
1000	1.5	2.8	22.5	7.0
500	5.0	1.5	14.0	4.3

Note. Geometric selector of the beam for lateral radiography in which occupancy is to be prevented. 100 mR/wk levels are given for radiation workers and 10 mR/wk levels for nonradiation workers.

Weekly workload		Radiation workers radius for 100 mR/wk		Nonradiation workers radius for 10 mR/wk	
(mA-min)	(mAs)	(ft)	(m)	(ft)	(m)
150	9000	50	15.2	120	37.0
100	6000	44	13.4	1060	32.0
50	3000	32	10.0	70	21.3
25	1500			62	19.0
10	600	—	—	44	13.4
5	300		—	32	10.0

mAs—milliampere-seconds
mA-min—milliampere-minutes

Note: See table 19, this appendix.

Table 2. Half-Value Layer (HVL) as a Function of Measured Tube Potential for Diagnostic X-ray Systems*

X-ray design operating range (kVp)	Measured peak tube potential (kVp)	Minimum HVL (mm Al)	
		Specified dental systems	Other X-ray systems
Below 50	30	1.5	0.3
	40	1.5	0.4
	49	1.5	0.5
50-70	50	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.6
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

*If it is necessary to determine a half-value layer for an X-ray potential which is not listed above, then linear interpolation or extrapolation may be made.

Note. For three-phase X-ray systems operated at a peak tube potential of 90 kVp, the half-value layer shall not be less than 3.1 mm aluminum (see table 4, this appendix). For mammographic X-ray units using a molybdenum target tube, the half-value layer at a tube potential of 50 kVp shall not be less than 0.7 mm of aluminum; and at a tube potential of 60 kVp, it shall not be less than 0.8 mm of aluminum.

Source: Title 21, Code of Federal Regulations, Part 1020.

Table 3. Half-value Layers as a Function of Filtration and Tube Potential for Single-phase Diagnostic X-ray Systems*

Total filtration mm Al	Peak tube potential (kVp)									
	30	40	50	60	70	80	90	100	110	120
	Typical half-value layers in millimeters of aluminum									
0.5	0.36	0.47	0.58	0.67	0.76	0.84	0.92	1.00	1.08	1.16
1.0	0.55	0.78	0.95	1.08	1.21	1.33	1.46	1.58	1.70	1.82
1.5	0.78	1.04	1.25	1.42	1.59	1.75	1.90	2.08	2.25	2.42
2.0	0.92	1.22	1.49	1.70	1.90	2.10	2.28	2.48	2.70	2.90
2.5	1.02	1.38	1.69	1.95	2.16	2.37	2.58	2.82	3.06	3.30
3.0	—	1.49	1.87	2.16	2.40	2.62	2.86	3.12	3.38	3.65
3.5	—	1.58	2.00	2.34	2.60	2.86	3.12	3.40	3.68	3.95

*For single-phase full-wave rectified potential radiographic X-ray systems and spot-film devices.

Note. The total filtration (F) for a single-phase, full-wave, rectified potential X-ray system may be estimated by the following equation-

$$\ln(F) = 1.57 \ln(HVL) - 1.20 \ln(kVp) + 4.83, \text{ where } F \text{ and } HVL \text{ are in millimeters of aluminum.}$$

The peak tube potential (kVp) used in the above equation should be the actual measured value and not the indicated value.

Source: *Medical X-Ray and Gamma-Ray Protection for Energies up to 10 MeV* (NCRP Report No. 33, page 43).

Table 4. Half-value Layers as a Function of Filtration and Tube Potential for Three-phase Diagnostic X-Ray Systems

Total filtration mm Al	Peak tube potential (KVp)								
	60	70	80	90	100	110	120	130	140
	Typical half-value layers in millimeters of aluminum								
2.5	2.2	2.4	2.7	3.1	3.3	3.6	4.0	—	—
3.0	2.3	2.6	3.0	3.3	3.6	4.0	4.3	4.6	5.0
3.5	2.6	2.9	3.2	3.6	3.9	4.3	4.6	—	—

SOURCE: *Medical Radiation Exposure of Pregnant and Potentially Pregnant Women* (NCRP Report No. 54, page 17).

Tabk 5. Exposure Rate Through Fluoroscopic Screen Without Patient'

Total filtration: 3 mm aluminum equivalent
 Tabletop to screen distance: 14 inches (35.6 cm)
 Screen to chamber distance: 2 inches (5 cm)
 Medium length high tension cables

Peak tube potential (kVp)	Source to table-top distance		Lead equivalent of screen protective barrier		
			Lead equivalent of screen protective barrier		
	(in)	(cm)	1.5 mm	1.8 mm	2.0 mm
			Typical exposure rate: mR/hr per R/min at table top		
80	12	30	10.0	4.5	2.5
	15	38	13.0	6.0	3.5
	18	46	15.0	7.0	4.0
90	12	30	12.0	6.0	3.5
	15	38	16.0	7.5	4.5
	18	46	19.0	9.0	5.5
100	12	30	15.0	7.0	4.5
	15	38	20.0	9.0	5.5
	18	46	23.0	11.0	7.0
110	12	30	19.0	9.0	5.5
	16	36	24.0	12.0	7.0
	18	46	29.0	14.0	8.5
120	12	30	23.0	11.0	7.0
	15	38	30.0	14.0	9.0
	18	46	35.0	17.0	10.0
130	15	38	36.0	17.0	10.0
	18	46	42.0	20.0	12.0
140	15	38	41.0	19.0	12.0
	18	46	49.0	23.0	14.0
150	15	38	46.0	20.0	12.0
	18	46	55.0	24.0	16.0

• Actual exposure rate values may differ from the typical values given above by ± 15 percent depending upon length of high tension cables.

Source: Medical X-Ray and Gamma-Ray Protection for Energies up to 10 MeV (NCRP Report No. 33, page 43).

Table 6. Scattered Radiation Exposure Rate at Side of Fluoroscopic Table*

Phantom: 100 lb sack of flour
 15-inch (38 cm) source-panel distance
 4x4 inch (10x10 cm) field at tabletop
 Phantom edge 6 inches (15 cm) from side of table

Peak tube potential (kVp)	Exposure rate in mR per mA-hr	
	With no screen drape	With screen drape**
80	300	4.5
90	400	8.0
100	650	17.5
110	850	32.0
120	1050	42.0
130	1330	60.0
140	1550	77.0
150	1750	98.0

• After J. S. Krohmer (unpublished).
 • *0.3 mm lead equivalent.

Source: Medical X-Ray and Gamma-Ray Protection for Energies up to 10 MeV (NCRP Report No. 33, page 44).

Table 7. Average Exposure Rates Produced by Medical and Veterinary Radiographic X-Ray Systems*

Distance from source to point of measurement		Peak tube potential						
		50 kVp	60 kVp	70 kVp	80 kVp	90 kVp	100 kVp	125 kVp
(in)	(cm)	Roentgens per 100 milliamperere-seconds (R/100 mAs)						
12	30	1.8	2.8	4.2	5.8	8.0	9.8	15.2
18	46	0.8	1.3	1.8	2.5	3.4	4.2	6.7
24	61	0.4	0.7	1.1	1.4	1.9	2.3	3.8
39	100	0.2	0.3	0.4	0.5	0.7	0.9	1.4
54	137	0.1	0.1	0.2	0.3	0.4	0.5	0.7
72	183	0.1	0.1	0.1	0.2	0.2	0.3	0.4

*Measured with total filtration equivalent to 2.5 mm aluminum for single-phase full-wave rectified X-ray systems. (The output values from a three-phase X-ray system will be about 1.5 to 2.0 times the values given in this table depending on whether the X-ray system incorporates a 6- or 12-pulse circuit). The actual output should not differ from the average value by ± 30 percent.

Source: Medical X-Ray and Gamma-Ray Protection for Energies up to 10 MeV (NCRP Report No. 33, page 44).

Table 8. Average Exposure Rates Produced by Dental Radiographic X-Ray Systems

Peak tube potential (kVp)	Source-skin distance		Total filtration (mm Al)	output* (R/mA-min)	output* (R/mA-sec)
	(in)	(cm)			
50	4	10	1.5	12.0	0.20
70	8	20	1.5	8.3	0.14
70	12	30	1.5	3.7	0.06
70	16	41	1.5	2.1	0.04
90	8	20	2.5	8.4	0.14
90	12	30	2.5	3.7	0.06
90	16	41	2.5	2.1	0.04

* The actual output should not differ from the average value by ± 30 percent.

Source: Medical X-Ray Protection Up to Three Million Volts (NCRP Report No. 26, page 26).

Table 9. Average Exposure Rates Produced by Panoramic Dental X-Ray Systems*

Peak tube potential (kVp)	Source-film distance		Total filtration (mm Al)	output** (R/mA-sec)
	(in)	(cm)		
90	17	43	2.5	0.021
90	19	48	2.5	0.016
80	17	43	2.5	0.017
80	19	48	2.5	0.011

*The average exposure time is approximately 20 seconds for the SS White Panorex[®], and General Electric Panelipse[®] and 13 seconds for the Sieman's Orthopantomograph[®].

**The actual output should not differ from the average value by ± 30 percent.

Table 10. Occupancy Factors' for Nonoccupationally² Exposed Persons³

Note. For use as a guide in planning shielding where other occupancy data are not available.

Full Occupancy (T = 1)
Work areas such as offices, laboratories, shops, wards, nurses' stations, living quarters; children's play areas; and occupied space in nearby buildings.
Partial Occupancy (T = ¼)
Corridors, lounge and rest rooms, elevators using operators, unattended parking lots.
Occasional Occupancy (T = 1/16)
Waiting rooms, toilets, stairways, unattended elevators, janitors' closets, outside areas used only for pedestrians or vehicular traffic.

¹The use of occupancy factors for nonoccupationally exposed persons assumes that only a small portion of the total population is exposed and hence the genetically significant dose is small.

²The occupancy factor of occupationally exposed persons may be assumed to be one.

³It is advantageous in shielding design to take into account that the occupancy factor in areas adjacent to the radiation room usually is zero for any space more than 7 ft (2.1 m) above the floor as the height of most individuals is less. It is possible, therefore, to reduce the thickness of the wall shielding above this height provided the radiation source is below 7 ft (2.1 m). In determining the shielding requirements for wall areas above 7 ft (2.1 m), consideration must be given to the protection of any persons occupying the floor above the areas adjacent to the radiation room. The wall areas over 7 ft (2.1 m) from the floor of the radiation room must also have sufficient shielding to adequately reduce the scattering from the ceiling of adjacent rooms toward occupants.

It should be noted that the use of an occupancy factor of 1/16 may result in full-time exposure in noncontrolled areas greater than 2 mR in any 1 hour or 100 mR in any 7 consecutive days.

Source: Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 Me V (NCRP Report No. 49, page 65).

Table 11. Use Factors for Primary Protective Barriers¹

Note. For use as guides in planning shielding when complete data are not available.

	Radiographic ^a installations	Dental ^b installations	Therapy ^a installations	Veterinary ^c installations
Floor	1	1/16	1	1
Walls	114	1/16	114	114
Ceiling	2	2	3	1116

¹The use factor for secondary protective barriers is generally 1.

² The shielding requirements for the ceiling of a radiographic facility are determined by the secondary barrier requirements rather than by the use factor which is generally extremely low, usually not more than 1/16.

³The use factor for the ceiling of a therapeutic installation depends upon the type of equipment and techniques used, but usually is not more than 1/4.

Source a: Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV (NCRP Report No. 49, page 65).

Source b: Dental X-Ray Protection (NCRP Report No. 35, page 12).

Source c: Radiation Protection in Veterinary Medicine (NCRP Report No. 36, page 8).

Table 12. Minimum Shielding Requirements for Radiographic X-Ray Facilities

WUT ¹ in mA-min/week			Distance in feet (meters) from source (X-ray tube target) to occupied area												
100 kVp	125 kVp	150 kVp													
1000	400	200	5 (1.5)	7 (2.1)	10 (3.0)	14 (4.2)	20 (6.1)	28 (8.4)	40 (12.2)						
500	200	100		5 (1.5)	7 (2.1)	10 (3.0)	14 (4.2)	20 (6.1)	28 (8.4)	40 (12.2)					
250	100	50			5 (1.5)	7 (2.1)	10 (3.0)	14 (4.2)	20 (6.1)	28 (8.4)	40 (12.2)				
125	50	25				5 (1.5)	7 (2.1)	10 (3.0)	14 (4.2)	20 (6.1)	28 (8.4)	40 (12.2)			
62.5	25	12.5					5 (1.5)	7 (2.1)	10 (3.0)	14 (4.2)	20 (6.1)	28 (8.4)	40 (12.2)		
31	12	6						5 (1.5)	7 (2.1)	10 (3.0)	14 (4.2)	20 (6.1)	28 (8.4)	40 (12.2)	
15	6	3							5 (1.5)	7 (2.1)	10 (3.0)	14 (4.2)	20 (6.1)	28 (8.4)	40 (12.2)
Type of area	Material	Primary barrier thickness ^a													
Controlled	Lead, mm ²	1.96	1.65	1.4	1.15	0.9	0.65	0.45	0.3	0.2	0.1	0.1			
Noncontrolled	Lead, mm ²	2.9	2.6	2.3	2.65	1.75	1.5	1.2	0.95	0.75	0.55	0.35			
Controlled	Concrete, cm	18	15.5	13.5	11.5	9.5	7	5.5	4	2.5	1.5	0.5			
Noncontrolled	Concrete, cm	26	23	20.5	18.5	16.5	14	12	10	8	6	4			
		Secondary barrier thickness ^a													
Controlled	Lead, mm ²	0.55	0.45	0.35	0.3	0	0	0	0	0	0	0			
Noncontrolled	Lead, mm ²	1.3	1.05	0.75	0.55	0.45	0.35	0.3		0.05	0	0			
Controlled	Concrete, cm ³	5	3.5	2.5	2	0	0	0	0	0	0	0			
Noncontrolled	Concrete, cm ³	11.5	9.5	7.5	5.5	4	3	2	0.5	0	0	0			

¹ W-workload in mA-min/week, U-- use factor, F-- occupancy factor.

² See Table 16 for conversion of thickness in millimeters to inches or to surface density.

³ Thickness based on concrete density of 2.35 g/cm³ (147 lb/ft³).

⁴ Barrier thickness based on a peak tube potential of 150 kVp.

Source ^a: Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV (NCRP Report No. 49, page 66).

Source ^b: Radiation Protection in Veterinary Medicine (NCRP Report No. 36, page 34).

Table 13. Minimum Shielding Requirements for Fluoroscopic X-Ray Facilities

WT* in mA-min/week			Distance in feet (meters) from source X-ray tube target to occupied area											
100 kVp	125 kVp	150 kVp												
2000	800	400	5 (1.5)	7 (2.1)	10 (3.0)	14 (4.2)	20 (6.1)	28 (8.4)	40 (12.2)					
1000	400	200		5 (1.5)	7 (2.1)	10 (3.0)	14 (4.2)	20 (6.1)	28 (8.4)	40 (12.2)				
500	200	100			5 (1.5)	7 (2.1)	10 (3.0)	14 (4.2)	20 (6.1)	28 (8.4)	40 (12.2)			
250	100	50				5 (1.5)	7 (2.1)	10 (3.0)	14 (4.2)	20 (6.1)	28 (8.4)	40 (12.2)		
125	50	25					5 (1.5)	7 (2.1)	10 (3.0)	14 (4.2)	20 (6.1)	28 (8.4)	40 (12.2)	
62.5	25	12.5						5 (1.5)	7 (2.1)	10 (3.0)	14 (4.2)	20 (6.1)	28 (8.4)	40 (12.2)
31	12	6							5 (1.5)	7 (2.1)	10 (3.0)	14 (4.2)	20 (6.1)	28 (8.4)
										5 (1.5)	7 (2.1)	10 (3.0)	14 (4.2)	20 (6.1)
Type of Area	Material	Secondary Barrier Thickness												
Controlled	Lead, mm	0.75	0.6	0.45	0.35	0.3	0.05	0	0	0	0	0	0	0
Noncontrolled	Lead, mm	1.6	1.3	1.05	0.75	0.6	0.45	0.4	0.25	0.25	0	0	0	0
Controlled	Concrete, cm	7.6	5.5	4	3	2.5	0.5	0	0	0	0	0	0	0
Noncontrolled	Concrete, cm	14	12	10	8	6	4.5	3.5	2.6	2.5	0.6	0	0	0

* Work-workload in mA-min/week, T-occupancy factor.

Source 1: Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV (NCRP Report No. 49, page 68).

Source 2: Radiation Protection in Veterinary Medicine (NCRP Report No. 36, page 34).

Table 14. Summary of Shielding Requirements for Diagnostic X-Ray Facilities

Barrier*	Type of facility								
	Fluoroscopic only	Fixed radiographic and radiographic-fluoroscopic	Photofluorographic and upright chest*	Urologic Only	Dental				Veterinary
					Maximum tube potential (kV)				
					40-50	51-60	61-75	75	
Floor	1/16	1/16	1/32	1116	1/128	1164	1/32	1116	1116
Wall (primary barrier)	N/A	1116	1/16	1/32	1/128	1/64	1132	1116	1116
Wall (secondary barrier)	1/16	1132	1132	1132	1/128	1/64	1132	1/16	1/16
Ceiling	1132	1/16	1/32	1/32	11128	1/64	1/32	1/16	1/16
Control booth	1116	1/16	1/16	1/32	1/128	1/64	1/32	1/16	1/16
Observation window	1/16	1/16	1/32	1/32	1/128	1164	1/32	1/16	1/16
Door	1116	1/16	1/16	1/32	11128	1/64	1/32	1/16	1/16

* All shielding requirements are given in inches of lead or equivalent. Stated shielding requirements for wall, floors, and ceilings apply only if the area beyond the barrier is or could be occupied. Shielding for walls, doors, and control booths shall extend to a height of 7 feet (2.1 m) from the floor.

** Shielding of 1/16-inch lead or equivalent shall extend at least 1 foot (30 cm) on either side of the image receptor for photofluorographic and upright chest facilities. All other wall, floor and ceiling areas are secondary barriers and the shielding requirements are 1/32-inch lead or equivalent. For 350 kV chest X-ray facilities shielding of 1/4-inch lead or equivalent shall extend at least 1 foot (30 cm) on either side of the image receptor. All other wall, floor and ceiling areas are secondary barriers and the shielding requirements are 1/16-inch lead or equivalent. In new construction the saving obtained by limiting the primary protective barrier to only a section of the wall is insignificant when compared with the need for special care during construction and future restrictions on use of the room.

Note. Consideration should be given to actual workload, occupancy, and use factors when applying the above criteria.

Table 15. Shielding Requirements for Radiographic Film

Note. Indicated thickness required to reduce radiation to 0.2 mR for a weekly workload of 1000 mA-min at 100 kVp, 400 mA-min at 126 kVp, or 200 mA-min at 150 kVp.

Storage Period	Barrier Type	Distance from Source (X-ray tube target) to stored films							
		7 ft (2.13 m)		10 ft (3.05 m)		14 ft (4.26 m)		20 ft (6.10 m)	
		Lead mm	Concrete* cm	Lead mm	Concrete+ cm	Lead mm	Concrete+ cm	Lead mm	Concrete* cm
1 day	primary with use factor of 1/16	2.3	19.5	2.1	18.0	1.8	15.5	1.5	13.6
1 week		3.0	24.0	2.7	22.0	2.4	20.5	2.2	18.5
1 month		3.7	29.0	3.4	27.0	3.1	24.0	2.8	23.0
1 day	secondary with use factor of 1	1.7	15.0	1.5	13.0	1.2	11.0	1.0	9.0
1 week		2.4	19.5	2.1	17.5	1.8	16.00	1.5	13.5
1 month		3.0	24.0	2.8	22.0	2.5	20.0	2.2	18.5

* Thickness based on concrete density of 2.35 g/cm³ (147 lb/ft³).

Note. In the absence of specific information as to the length of film storage period to be expected, it is suggested that the shielding value for the 1 month's storage period be used.

Source: *Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV* (NCRP Report No. 49, page 67).

Table 16. Densities of Commercial Building Materials

Material	Density of Average Sample (gram/cubic centimeter)
Barium mortar	2.22
Brick	1.90
Ceramic tile (4"×4")	1.90
Cinder block	1.49
Granite	2.65
Gypsum plaster	1.63
Gypsum pyrobar	0.94
Lead glass	3.21
Limestone	2.46
Marble	2.70
Mosaic tile (1"×1")	2.35
Plate glass	2.60
Portland cement mortar (sand plaster)	1.54
Sandplaster	1.54
Sandstone	2.20
Siliceous concrete	2.35
Wood (hard)	0.75
wood (soft)	0.55

Note. One gram per cubic centimeter is equal to 62.428 pounds per cubic foot or 1 pound per cubic foot is equal to 0.016 gram per cubic centimeter.

Table 17. Lead Shielding

Thickness			Approximate weight
Millimeters	Inches	Inches decimals	lb/ft ²
0.20	1/128	0.0078	0.5
0.40	1/64	0.0156	1.0
0.60	3/128	0.0234	1.5
0.79	1/32	0.0313	2.0
1.00	5/128	0.0391	2.5
1.19	3/64	0.0469	3.0
1.39	7/128	0.0547	3.5
1.58	1/16	0.0625	4.0
1.98	5/64	0.0781	5.0
2.38	3/8	0.0938	6.0
3.17	1/8	0.1250	8.0
3.97	5/32	0.1563	10.0
4.76	3/16	0.1875	12.0
5.56	7/32	0.2187	14.0
6.35	1/4	0.2500	16.0
7.14	9/32	0.2813	16.5
7.94	5/16	0.3125	18.0
8.47	1/3	0.3333	20.0
8.73	11/32	0.3438	20.5
9.53	3/8	0.3750	22.0
10.76	2/5	0.4000	24.0
11.11	7/16	0.4375	26.0
12.70	1/2	0.5000	30.0
14.29	9/16	0.5625	33.0
15.88	5/8	0.6250	37.0
16.93	2/3	0.6667	40.0
17.46	11/16	0.6675	41.0
19.05	3/4	0.7500	45.0
20.64	13/16	0.8125	48.0
22.23	7/8	0.8750	52.0
23.81	15/16	0.9375	55.0
25.40	1	1.000	60.0

Note. The density of commercially rolled lead is 11.36 gm/cm³.

Note. The commercial tolerances are ±0.065 inches for lead up to 7/128 and ±0.0313 for heavier sheets.

Table 18. Half-value and Tenth-value Layers (TVL)

Note. Approximate values obtained at high attenuation for the indicated peak voltage values under broad-beam conditions; with low attenuation these values will be significantly less

Peak voltage kVp	Attenuating material					
	Lead (mm)		Concrete (cm)		Iron (cm)	
	HVL	TVL*	HVL	TVL	HVL	TVL
50	0.06	0.17	0.43	1.5		
70	0.17	0.52	0.84	2.8		
100	0.27	0.88	1.6	5.3		
125	0.28	0.93	2.0	6.6		
150	0.30	0.99	2.24	7.4		
200	0.52	1.7	2.5	8.4		
250	0.88	2.9	2.8	9.4		
300	1.47	4.8	3.1	10.4		
400	2.5	8.3	3.3	10.9		
500	3.6	11.9	3.6	11.7		
1000	7.9	26.0	4.4	14.7		
2000	12.5	42.0	6.4	21.0		
3000	14.5	46.5	7.4	24.5		
4000	16.0	53.0	8.8	29.2	2.7	9.1
6000	16.9	56.0	10.4	34.5	3.0	9.9
8000	16.9	56.0	11.4	37.8	3.1	10.3
10000	16.6	55.0	11.9	39.6	3.2	10.5
cs-137	6.5	21.6	4.8	15.7	11.6	5.3
Co-60	12.0	40.0	6.2	20.6	2.1	6.9
Radium	16.6	55.0	6.9	23.4	2.2	7.4

* One tenth-value layer is equivalent to 3.322 half-value layers

Source: Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV (NCRP Report No. 49, page 88.

Table 19. Distance Protection* (in Feet) Against Useful Beam in Controlled Areas and in Noncontrolled Areas**

WUT (mA-min/week)		Peak tube potential					
		50kVp	70 kVp	100 kVp	150 kVp	1000 kVp	2000kVp
Controlled area	Noncontrolled area	Output R/mA-min at 40 inches (100 cm)					
		0.05	0.1	0.4	2	20	280
		Distance in feet from source (X-ray tube target)					
10	1	7.5	11	21	44	127	380
20	2	10.5	15	30	50	165	480
40	4	14.0	20	40	76	210	580
60	6	17.0	24	46	91	250	660
80	8	19.0	27	54	100	272	720
100	10	21.0	30	58	110	300	780
200	20	28.0	40	75	140	370	950
400	40	36.0	52	96	182	410	1100
600	60	42.0	60	110	210	530	1200
800	80	46.0	67	120	230	575	1280
1000	100	50.0	72	130	245	600	1350
2000	200	62.0	92	165	310	750	1540
4000	400	71.0	120	205	365	850	1750
6000	600	90.0	140	230	420	980	1850
8000	800	100.0	152	255	460	1040	1900
10,000	1000	110.0	165	270	480	1100	2000
20,000	2000	135.0	205	330	570	1220	2150
40,000	4000	165.0	250	380	650	1400	2340
	6000	180.0	270	420	700	1450	2430
	3000	195.0	288	440	725	1500	2500
	10,000	210.0	300	460	750	1530	2600
	20,000	240.0	340	510	820	1630	2750
	40,000	280.0	390	580	900	1750	2850

*For design purposes only with maximum permissible exposure values assigned as follows:

Controlled areas: 100 mR/week

Noncontrolled areas: 10 mR/week

- * This table to be used only when there is no protective barrier between the source and the occupied areas.

Source: Medical X-Ray and Gamma-Ray Protection for Energies Up to 10 MeV (NCRP Report No. 34, page 82).

Table 20. Typical Patient Exposures During Diagnostic X-Ray Examinations

Examination (projection)	Body part	Body part thickness (cm)	Mean tub8 potential (kVp)	Mean tube current exposure time product (mAs)	Mean radiation output (mR/mAs)	Tenth percentile (mR)	Median* entrance skin exposure (mR)	Mean entrance skin exposure (mR)	Ninetieth percentile (mR)	Exposure at* skin entrance index (mR)	Surface exposure integral (Rx cm ²)
Chest (P/A)	Thorax	23	80	12	1.76	8	16	21	37	24	22
Skuli (lat)	Head	15	72	50	4.80	80	221	240	382	309	102
Abdomen (kub) scout	Abdomen	23	85		7.62	277	579	639	1097	772	434
Retrograde pyelogram (A/P)	Abdomen	23	77	91	1.96	334	615	725	1186	918	531
Thoracic spine (A/P)	Thorax	23	75	82	9.03	322	862	745	982	982	526
Cervical spine (A/P)	Neck	13	69	48	4.75	54	177	228	501	297	60
Lumbo-sacral spine (A/P)	Abdomen	23	77	112	7.12	335	687	796	1399	986	423
Full spine (A/P)	Chest & abdomen	23	79	173	1.79	122	283	310	421	325	412
Feet (DIP)	Foot	8	61	18	14.44	45	149	260	562	211	99
Dental bitewing (post)	Left bicuspid & molars	NA	71	7	66.14	154	326	463	903	539	11
Dental periapical (Maxillary)	Central incisor (Maxillary)	NA	71	7	73.43	159	334	514	1144	575	12
Dental cephalometric (lat)	Head	15	81	18	2.33	10	28	42	87	42	33

• The median value is the 50 percentile and exposure-at-skin entrance index is the third quartile or 75 percentile.

Source: Nationwide Evaluation of X-Ray Trends. This table demonstrates the weighted values for exposures at skin entrance over the five-year period from 1 Jan 73-31 Dec 77.

Table 21. Penetmmeter Techniques

Peak tube potential (kVp)	Tube current (mA)	Time (sec)	Tube current exposure time product (mAs)	Distance	
				(in)	(cm)
60	50	1	50.0	72	183
60	75	3/5	50.0	68	173
60	100	1/2	50.0		183
60	150	3/10	45.0	68	173
60	200	1/4	50.0	183	
60	300	3/20	45.0	68	173
60	500	1/10	50.0	72	183
60	600	1/12	50.0	72	183
60	800	1/15	53.3	74	188
100	50	1/5	10.0	93	236
100	75	2/15	10.0	93	236
100	100	1/10	10.0	93	236
100	150	1/15	10.0	93	236
100	200	1/20	10.0	93	236
100	300	1/30	10.0	93	236
100	500	1/60	8.3	84	213
100	600	1/60	10.0	93	236
100	800	1/120	6.6	75	191
150	50	1/30	1.7	100	254
150	75	1/30	2.5	124	315
150	100	1/60	1.7	100	254
150	150	1/60	2.5	124	315
150	200	1/120	1.7	100	254
150	300	1/120	2.5	124	315

- Penetmmeter techniques established using *standard penetrometer*, NSN 6635-00-875-8115, or equal.

Table 22. Pulse to Time Conversion

Decimal time	Fractional time	3-Phase	400 Hz FW	60 Hz FW	60 Hz HW	50 Hz FW	50 Hz HW
0.0083	1/120	8.33 ms	—	1		—	—
0.0167	1/60	16.67 ms		2	1	—	—
0.0250	1/40	25.00 ms	20	3			—
0.0333	1/30	33.33 ms		4	2		—
0.0416	1/24	41.67 ms		5	—		2
0.0500	1/20	50.00 ms	40	6	3		—
0.0667	11/15	66.67 ms		8	4	5	3
0.075	3/40	75.00 ms	60	9		—	3
0.0833	11/12	83.33 ms		10	5	—	4
0.1000	1/10	100.00 ms	80	12	6	—	5
0.1250	1/8	125.00 ms	100	16	a	—	6
0.1333	2/15	133.33 ma	—	16	—	10	—
0.1500	3/20	150.00 me	120	18	9	—	—
0.1667	1/6	166.67 ms		20	10		8
0.2000	1/5	200.00 ms	160	24	12	20	10
0.2500	1/4	250.00 ms	200	30	15	25	13
0.3000	3/10	300.00 ms	240	36	18	30	15
0.4000	2/5	400.00 ma	320	48	24	40	20
0.5000	1/2	500.00 ms	400	60	30	50	25
0.6000	3/5	600.00 ma	480	72	36	60	30
0.8000	4/5	800.00 ms	640	96	48	80	40
1	1	1.00 sec	800	120	60	100	50
1.5	1.5	1.50 sec	1200	180	90	150	75
2	2	2.00 sec	1600	240	120	200	100
3	3	3.00 sec	2400	360	180	300	150
4	4	4.00 sec	3200	480	240	400	200
5	5	5.00 sec	4000	600	300	500	250
6	6	6.00 sec	4800	720	360	600	300

Note. Full wave (FW), half wave (HW) pulsed single-phase X-ray systems.

The proponent agency of this regulation is the Office of The Surgeon General. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) direct to HQDA (DASG-PSP) WASH DC 20310.

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