This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

radiological health

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

CDRH PUBLICATIONS - RADIOLOGICAL HEALTH

Publications of the Center for Devices and Radiological Health (CDRH) are available as paper copies from either the U.S. Government Printing Office (GPO) or the National Technical Information Service (NTIS) as indicated by the GPO or PB prefix, respectively, on the ordering number. Publications are also available in microfiche from NTIS at $5.95 per copy. To receive all CDRH reports in microfiche, at $1.35 each, you may establish a deposit account with NTIS and request automatic distribution of "FDA/HFZ" reports under the "Selected Research in Microfiche" program. Publications without GPO or PB numbers are available only from the Center for Devices and Radiological Health.

Addresses for ordering are: Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402; National Technical Information Service, Springfield, VA 22161 (**outside North America, prices are double those listed**); and Center for Devices and Radiological Health, Food and Drug Administration (HFZ-265), 5600 Fishers Lane, Rockville, MD 20857. All prices are subject to change.

FDA 85-8243	Computer Program for Absorbed Dose to the Breast in Mammography (PB 86-114774/AS, $11.95).
FDA 85-8244	Evaluation of Radiation Exposure from Diagnostic Radiology Examinations - Technique/Exposure Guides for the Craniocaudal Projection in Mammography (PB 86-126075/AS, $9.95).
FDA 85-8245	Evaluation of Radiation Exposure from Diagnostic Radiology Examinations (Technique/Exposure Guides for the Dental Bitewing Projection) (flyer).
FDA 85-8246	Evaluation of Radiation Exposure from Diagnostic Radiology Examinations: General Recommendations (PB 86-125903/AS, $9.95).
FDA 85-8247	Recommendations for Evaluation of Radiation Exposure from Diagnostic Radiology Examinations (PB 86-125846/AS, $9.95).
FDA 85-8248	Measurement Techniques for Use with Technique/Exposure Guides (PB 86-123718/AS, $9.95).
FDA 85-8249	Basic Concepts in the Selection of Patients for Dental X-Ray Examinations (PB 86-126067/AS, $11.95, 92 pp.).
FDA 85-8250	Assessment and Modification of Clinical Utility in Diagnostic Radiology: The Oral Cholecystogram and the Upper Gastrointestinal Examinations (PB 85-246916/AS, $9.95).
FDA 85-8252	Reducing Patient Exposure During Scoliosis Radiography (pamphlet).
FDA 86-8253	Radiation Experience Data (RED): Documentation and Results of the 1980 Survey of U.S. Hospitals (PB 86-140944/AS, $16.95, 102 pp).
FDA 86-8254	Embryo, Fetus, Infant...Recommendations to Minimize Diagnostic Nuclear Medicine Exposure (flyer).
FDA 86-8255	CSU-FDA-NCI Collaborative Radiological Health Laboratory Annual Report 1984: Health Effects of Prenatal and Postnatal Whole-Body Exposure to Ionizing Radiation in the Beagle Dog (PB 86-132974/AS, $11.95, 88 pp.)
FDA 86-8256	Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products (PB 86-195674/AS, $9.95).
FDA 86-8257	MTF's and Wiener Spectra of Radiographic Screen-Film Systems: Volume II (Including Speeds of Screens, Films, and Screen-Film Systems) (PB 86-184934/AS, $16.95).

(Continued on inside back cover)

HHS Publication FDA 89-8221
Approved OMB No. 57 R 0068

Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment

Compiled by

Office of Compliance and Surveillance

WHO Collaborating Centers for:
- Standardization of Protection Against Nonionizing Radiations
- Training and General Tasks in Radiation Medicine
- Nuclear Medicine

March 1989

(Supersedes FDA 84-8221)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

FOREWORD

In October 1982, the Food and Drug Administration established the Center for Devices and Radiological Health (CDRH) by merging the Bureau of Medical Devices and the Bureau of Radiological Health.

The Center develops and implements national programs to protect the public health in the fields of medical devices and radiological health. These programs are intended to assure the safety, effectiveness and proper labeling of medical devices, to control unnecessary human exposure to potentially hazardous ionizing and nonionizing radiation, and to ensure the safe, efficacious use of such radiation.

The Center publishes the results of its work in scientific journals and in its own technical reports. These reports provide a mechanism for disseminating results of CDRH and contractor projects. They are sold by the Government Printing Office and/or the National Technical Information Service.

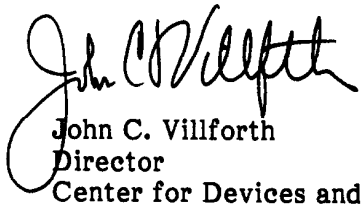
Also, CDRH technical reports in radiological health are made available to the World Health Organization (WHO) under a memorandum of agreement between WHO and the Department of Health and Human Services. Three WHO Collaborating Centers, established under the Bureau of Radiological Health, continue to function under CDRH:

WHO Collaborating Center for Standardization of Protection Against Nonionizing Radiations;

WHO Collaborating Center for Training and General Tasks in Radiation Medicine; and

WHO Collaborating Center for Nuclear Medicine.

We welcome your comments and requests for further information.



John C. Villforth
Director
Center for Devices and
Radiological Health

PREFACE

The Office of Compliance and Surveillance of the Center for Devices and Radiological Health (CDRH) has received numerous requests for interpretation of various sections of the Performance Standard for Diagnostic X-ray Equipment, 21 CFR Subchapter J, since its publication in the Federal Register on August 15, 1972. The Center compiles its responses to such queries, to the extent possible, in a composite document for distribution to the x-ray industry and other interested individuals or agencies.

This publication includes all current FDA Compliance Policy Guides pertaining to the Performance Standard, interpretations of the Performance Standard in either narrative or question-and-answer form, and interpretive letters that have been sent to the industry. Manufacturers are reminded that they must also meet pertinent requirements of the Medical Device Amendments, which are not addressed in this document. Guidance on Medical Device requirements may be obtained by contacting the Division of Small Manufacturers' Assistance (800-638-2041).

Placing this document in a binder will enable you to make revisions by adding or replacing pages. The Center will periodically prepare and distribute additional or replacement pages to provide clarifications, changes, or additions.

Specific questions or comments concerning this document should be addressed to the X-Ray Products Branch, Division of Standards Enforcement, Office of Compliance and Surveillance, Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, Maryland 20857 (301-427-7222).

Ann B. Holt

Ann B. Holt, D.V.M.
Acting Director
Office of Compliance and Surveillance

ABSTRACT

Prepared by the Office of Compliance and Surveillance, Center for Devices and Radiological Health. Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment. HHS Publication 89-8221 (March 1989) (106 pp.).

This report is a compilation of responses to requests for interpretation of the Federal radiation control regulations for diagnostic x-ray equipment. It includes all current FDA Compliance Policy Guides pertaining to diagnostic x-ray equipment, as well as answers to questions from individuals and industry regarding the regulations. The report consists of two sections: the General section, which discusses questions of a general nature, and the Specific section, which covers particular sections of the Standard.

NOTE

The Food and Drug Administration Compliance Policy Guides used in this document are taken from the Compliance Program Guidance Manual (CPGM). The manual and 1-year update service are available from the National Technical Information Service (NTIS), Springfield, Virginia 22161, which reproduces and distributes such information to the public.

Any questions regarding purchase of the Compliance Program Guidance Manual (or sections thereof) or the subscription service should be directed to NTIS.

CONTENTS

CLARIFICATION OF RADIATION CONTROL REGULATIONS FOR DIAGNOSTIC X-RAY EQUIPMENT

INTRODUCTION

The Office of Compliance and Surveillance of the Center for Devices and Radiological Health (CDRH) has received many requests for interpretation of the Federal regulations that relate to diagnostic x-ray equipment. Our responses to these requests were originally issued as FDA Compliance Policy Guides, industry-wide letters, and letters to individuals. This document is a compilation of those responses that remain applicable. Guides or opinions that have been withdrawn or are now obsolete because they have been incorporated into the regulations are not included in this document.

This document consists of two sections. The first is the General section, which contains information of a general nature. The second is the Specific section, which contains information specific to particular sections of the Federal Performance Standard for Diagnostic X-Ray Equipment (21 CFR 1020.30-32). When the term "Revised Language" appears in an item heading, it indicates English grammar correction; the term "Revised" indicates an updated version of the original clarification.

We recommend that this document be placed in a binder to permit insertion of additional issuances.

GENERAL CLARIFICATION

OF

THE RADIATION CONTROL REGULATIONS

FOR DIAGNOSTIC X-RAY EQUIPMENT

Product Identification

and

Certification

Insufficient Initial Report Documentation

QUESTION: Will you accept reports without the material called for in the guideline document for submitting of reports, pages 2 & 3, paragraph 102.7 (information to users) and 102.6 (assembler's instructions) with the understanding that this material will be sent as soon as available for attachment to the previously submitted reports?

ANSWER: We will accept such reports with the understanding that they are partial submission only. In addition, our acceptance of such reports does not relieve you, as manufacturer, of the responsibility of submitting the material as a supplement to your report nor of including the instruction manuals and assemblers' manuals with your equipment prior to its introduction into commerce.

Noncompliances of X-Ray Components

and

Defects

SUBJECT: Determination by Secretary that Product Fails to Comply or Has Defect - 21 CFR 1003.11

BACKGROUND:

Section 359(e) of the Radiation Control for Health and Safety Act (P.L. 90-602), and 1003.11 of the implementing regulations (21 VFR 1003.11) state that if the Food and Drug Administration determines that any electronic product either does not comply with an applicable Federal performance standard, or has a defect that relates to the safety of use of such product, the manufacturer shall immediately be notified in writing of the alleged defect or noncompliance, the findings of the FDA, and all information on which the findings are based. The notification shall also state a reasonable period of time during which the manufacturer may present his view and evidence to establish that there is no failure of compliance, or that the alleged defect does not exist. If the FDA alleges a defect or noncompliance which the manufacturer believws was caused by the user rather than through any fault in manufacture, the manufacturer will have an opportunity to present evidence in substantiation of his position.

POLICY:

As a general rule, a manufacturer is reponsible for defects or noncompliance. However, if it can be shown that a product no longer meets a performance standard because of modification of the equipment by unauthorized personnel, installation of improper replacement parts or materials, or unforeseeable abuse of the equipment by the owner or user, there may be a basis for a finding that certain of the notification requirements and the repair, replace and refund provisions (21 CFR 1003 and 1004) will not apply.

The manufacturer bears the burden of proof in establishing that a defect or noncompliance is due to a cause other than faulty manufacture. The FDA's mandate to protect the public health and safety under P.L. 90-602, together with the Act's specification that measures to enforce the control of electronic product radiation be directed against the manufacturer of a product, requires that the primary responsibility of a manufacturer for the safety of his product not be lifted unless the responsiblity can clearly be placed on another. FDA will refrain from requiring the manufacturer to repair, replace, or refund only in those situations where there is no

reasonable basis for believing that a violation of the Act resulted from a manufacturer's act or omission.

For example, a certain amount of normal wear will occur in electronic products. If such normal wear results in radiation emitted by the product exceeding the limit prescribed in an applicable standard, the manufacturer may be charged with noncompliance because of his failure to design the product to maintain an acceptable level of radiation leakage over its useful life. The distinction between normal wear and damage resulting from misuse of the equipment is something which the manufacturer would have to justify. Similarly, a manufacturer will be held responsible when he fails to act reasonably to inform users of the equipment and service personnel of the need for, and methods of proper servicing.

CHAPTER 33 - RADIOLOGICAL HEALTH

SUBJECT: Early Correction of Defects or Noncompliance - 21 CFR 1004.6

BACKGROUND:

If a product defect or noncompliance with the Federal standard is discovered by a manufacturer (or x-ray equipment assembler), he may wish to initiate repair simultaneously with notification to FDA so that down time is minimized. Part 1003 requires that FDA (and others) be notified of radiation safety defects or failure to comply with a performance standard, and Part 1004 requires that the manufacturer must repair, replace, or refund the purchase price of a defective or noncompliant product. The correction of the product must be performed pursuant to a plan approved by FDA (21 CFR 1004.6).

POLICY:

The Radiation Control for Health and Safety Act, and the regulations, do not preclude purchaser notification and correction of a defect or noncompliance prior to the approval of a plan; however, such corrective action would still be subject to a plan approved by FDA. To avoid the possibility of having to prepare and implement a second corrective action plan, a manufacturer or assembler should communicate with the Food and Drug Administration as early as possible after discovery of a defect or failure to comply.

Tube Housing Assembly Repair

QUESTION: In the case where a manufacturer repairs a tube housing assembly, including repairs that require the temporary removal of the insert, shall that repair constitute the manufacture of a new tube housing assembly?

ANSWER: Any repair done on any tube housing assembly that does not include the replacement of a tube insert in a previously certified tube housing shall not constitute the manufacture of a new tube housing assembly.

Definitions

Defects and Burned-Out X-Ray Tubes

QUESTION: In Section 1003.2(b)(3), a defect is defined as a product which "fails to accomplish the intended purpose." Does a burned-out x-ray tube fall under the definition of a defect?

ANSWER: As provided in the Act, the only defects for which the regulations apply are those which relate to the safety of use by reason of the emission of electronic product radiation. Thus, a burned-out x-ray tube would not be considered a "defect" but would be considered normal repair of the tube housing assembly. PBL systems or other beam-limiting devices which fail to accomplish their intended purpose may, on the other hand, be considered defective if they create a risk of injury, including genetic injury, as a result of such failure. Thus, a defect may be related to a product system as a whole, or a component of such system. However, it is important to recognize that the failure of a product to function and thereby produce no radiation would not be considered a radiation safety defect under the Act, since there can be no radiation safety problem.

Meaning of Numerical Limits

REVISED BRH:DOC:MA 337

The preamble to the final order establishing the Performance Standards for Diagnostic X-Ray Equipment, published in the Federal Register of August 15, 1972 (FR 16461), stated that normal roundoff procedures could be employed in measurements related to numerical values specified in the standard. However, the Commissioner has determined that such roundoff procedures may be misleading and not consistent with Section 360B(a)(5) (42 U.S.C. 263j) of the Public Health Service Act. The current policy prohibits the roundoff of measurements resulting in the certification of a product known to exceed any limit imposed by the standard. This means that numerical limits stated in the standard are to be treated as absolute limits, and the manufacturer must design his testing and quality control program in order to ensure that these limits are not exceeded.

April 2, 1987 Ref:MA:OC:DRP:390

TO: MANUFACTURERS OF DIAGNOSTIC X-RAY EQUIPMENT

SUBJECT: Definition of X-Ray Table, Tabletops, and Cradle

The following working definitions have been used by the Center for Devices and Radiological Health in the administration of the Performance Standard for Diagnostic X-Ray Systems and Their Major Components, 21 CFR 1020.30, 31, and 32. This letter is issued to restate the definitions, clarify that stretchers intended for diagnostic x-ray procedures are x-ray tables, and provide interim guidance regarding hospital stretcher x-ray tables.

X-ray table means a device with its patient support structure (tabletop) interposed between the patient and the image receptor during normal use. This includes but is not limited to any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or Bucky), cassette tunnel, image intensifier, or spot film device beneath the tabletop.

Mobile x-ray table means an x-ray table designed for patient transport.

Stationary tabletop means a tabletop which, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop. Mobile x-ray tables (stretchers) with a single radiolucent panel are considered equivalent to x-ray tables equipped with a stationary tabletop. (The maximum aluminum equivalent permitted for these tabletops is 1.0 mm Al.)

Movable tabletop means a tabletop which, when assembled for use, is capable of movement with respect to its supporting structure within the plane of the tabletop. Mobile x-ray tables (stretchers) with two hinged radiolucent panels are considered equivalent to x-ray tables equipped with a movable tabletop. (The maximum aluminum equivalent permitted for these tabletops is 1.5 mm Al.)

Cradle means a removable device which supports and may restrain a patient above an x-ray table; or a device with its patient support structure interposed between the patient and the image receptor during normal use, equipped with means for patient restraint, and capable of rotation about its long (longitudinal) axis. Mobile x-ray tables (stretchers) with three or more hinged radiolucent panels are considered equivalent to cradles. (The maximum aluminum equivalent for cradles and these tabletops is 2.0 mm Al.)

A hospital bed equipped with a standard hospital mattress and other operational features common to hospital beds is not considered an x-ray table unless the bed manufacturer represents the use of the bed as an x-ray table as defined elsewhere in this letter.

CHAPTER 33 - RADIOLOGICAL HEALTH

SUBJECT: Definition of "Commerce" - 21 CFR 1000.3(g)

BACKGROUND:

Section 360B(a)(1) of the Radiation Control for Health & Safety Act prohibits the introduction into commerce of any electronic product which does not conform to an applicable standard.

Questions have been raised as to whether a person who manufactures an electronic product for which a standard has been prescribed, for use solely in his own commercial activities or manufacturing process, has introduced the product into "commerce".

POLICY:

Such a person would not have introduced the product "into commerce" within the meaning of Section 360B(a)(1). However, Section 360B(a)(5) of the Act makes it a prohibited act for any person to fail to issue a certification as required by Section 358(h), regardless of whether the electronic product in question has itself been physically introduced into commerce. The assembly and use of an electronic product by a person "engaged in the business" of assembling that product (as defined in Section 355(3)) for commercial purposes in his own facility affects interstate commerce; thus Section 358(h) would require that the manufacturer certify that the product conforms to the relevant standard. However, if that person in no way receives compensation for the assembly and use of the product, he would not be "engaged in the business" and use of the product, he would not be "engaged in the business" and therefore would not be a "manufacturer" subject to Sections 358(h) and 360B(a)(5).

Reassembly and X-Ray System

QUESTION: Please define the meaning of "reassembly" and "x-ray system" as used in 21 CFR 1020.30(p).

ANSWER: "Reassembly" means the installation of a group of components (including upgraded components) that were previously assembled and used as an "x-ray system." An "x-ray system," as defined in the standard (21 CFR 1020.30(b)(47)), consists minimally of an x-ray control, high-voltage generator, tube housing assembly, beam-limiting device, and any necessary supporting structures. As stated in Section 1020.30(p)(1)(iv), an assembler may reassemble a previously existing (used) system for resale whether or not the system is comprised of all uncertified components.