Guidance for Industry and FDA Staff

Radiation Safety Considerations for X-Ray Equipment Designed for Hand-Held Use

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Food and Drug Administration
Center for Devices and Radiological Health
Diagnostic Devices Branch
Division of Mammography Quality and Radiation Programs
Office of Communication, Education, and Radiation Programs

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Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

The intent of this guidance is to advise manufacturers and FDA staff about safety procedures and recommendations that should be provided to the end user to promote safe use of hand-held x-ray equipment. In general, there are a number of regulations, consensus safety standards, and radiation protection guidelines governing the performance and use of diagnostic x-ray equipment. Diagnostic x-ray equipment manufactured for the US market must meet the performance requirements described in Title 21 of the Code of Federal Regulations, sections 1020.30 through 1020.33, which require manufacturers to provide users with operational and safety information as well as to meet standards for equipment performance.[(1)]

Internationally, radiation safety standards are provided by the International Electrotechnical Commission (IEC) in its collateral standard 60601-1-3.[(2)] Voluntary guidelines, particularly relevant to handheld equipment, have been provided by the National Council on Radiation Protection and Measurement (NCRP) for radiation protection in dentistry.[(3)] Many states regulate the use of x-ray equipment under their own regulations based on the *Suggested State Regulations for the Control of Radiation*, published by the Conference of Radiation Control Program Directors (CRCPD).[(4)]

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory

requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device and electronic product regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/.

1. Issue

There are two basic sources of potential x-ray exposure to operators that should be addressed during the use of hand-held diagnostic x-ray equipment:

- Leakage radiation transmitted through the equipment housing and shielding that surrounds the source assembly
- Backscatter radiation from the patient and nearby structures.

2. Guidance

A primary consideration in any radiographic procedure is to reduce the dose to the patient as well as to the operator as much as possible while still achieving the diagnostic goals. This guidance briefly discusses the hazards unique to hand-held medical x-ray equipment, clarifies applicable requirements, and makes recommendations for safe use of the equipment.

What are the exposure concerns with handheld x-ray systems?

The federal performance standard for diagnostic x-ray systems and their major components did not anticipate hand-held x-ray systems at the time it was written. It therefore does not address system performance attributes or protective measures in light of the operator’s proximity to the source assembly and the patient. Because of such proximity, hand-held x-ray systems pose increased operator exposure concerns due to leakage radiation and backscatter radiation. The radiation exposure to the operator will be the sum of any radiation leaking from the x-ray tube source assembly (leakage radiation) and any radiation that scatters from the patient or any objects in the room that are in the x-ray field (backscattered radiation.)

What limits are placed on leakage and backscatter radiation?

The applicable performance standard for a diagnostic source assembly, under 21 CFR 1020.30(k), limits radiation leakage from the x-ray source assembly to an air kerma of 0.88 mGy (corresponding to an exposure of 100 mR) in one hour at a distance of one meter from the x-ray source when measured as specified in the standard.

How can leakage and backscatter radiation to the operator be reduced?

- ***Shield the unit housing as required by the federal standard.***
  Leakage radiation is of particular concern because the operator may be holding the x-ray source assembly. Increasing the distance from the source may not be possible. Hand-held x-ray equipment must incorporate into its design physical means to protect the operator from leakage radiation with sufficient shielding surrounding the source assembly to ensure compliance with 21 CFR 1020.30(k).

- ***Provide external shielding or a means to increase distance between the operator and the unit.***
  To reduce operator exposure to backscatter radiation, manufacturers of hand-held x-ray equipment should incorporate physical means to provide operator shielding or allow operation of the unit at a distance. For example, an external, physical shield may be supplied with the equipment to be placed between the operator and the patient to attenuate backscatter radiation. Additionally, you may provide a means to initiate x-ray exposure using an equipment stand and remote switch from a distance to increase distance between the operator and the unit during exposure.

  Any product features designed into the equipment to protect the operator from radiation exposure should be described in user information with instructions for their proper use.

- ***Measure typical exposures near and around the unit.***
  Because operators will typically be closer than 1 m to the unit, exposure measurements at distances closer than those required by the Federal standard become important. Manufacturers of hand-held x-ray units should make and report exposure measurements at distances near the unit, especially representative of positioning where the operator will actually be in contact with or in close proximity to the unit during use. For example, exposures at the location of handgrips and control devices are of particular interest to the operator of the unit.

  These data may be used to estimate an operator's whole-body or partial-body radiation dose for a single exposure or over an extended period of typical use. The data may be compared to occupational exposure limits to ensure limits are not exceeded and allow users to implement appropriate control measures based on an actual exposure assessment.

- ***Identify necessary safety precautions as required by the Federal standard.***
  Under 21 CFR 1020.30(h)(1)(i) manufacturers must provide "adequate instructions concerning radiological safety procedures and precautions which may be necessary

because of unique features of the equipment." A unit that is hand-held constitutes a unique feature that requires manufacturers to describe any safety procedures and precautions necessary to reduce operator exposure. Safety precautions may include designating a significant zone of occupancy and providing exposure information near the unit as described in the IEC standard.[2]

Information on exposure levels near and around a hand-held unit should be included with operator instructions to identify the unique exposure hazards posed by the equipment. Providing exposure information will support any manufacturer's precautions and allow the operator to develop additional safe working practices to limit unnecessary exposure during equipment use. Precautions may include wearing appropriate personnel monitoring and protective equipment, such as a personnel exposure monitoring device or lead-lined gloves and gowns. Procedural controls may be recommended to limit the number of exposures initiated by a single operator over a period or time, or to limit use of the hand-held unit without an equipment stand or remote switch in such circumstances only as necessary.

Manufacturers may also include information describing exposure hazards and radiation safety precautions appropriate for patients and other individuals present in the area during examination (e.g., a person holding a child or other personnel assisting with procedures).

3. Getting More Information

For additional information on state requirements applicable to hand-held x-ray systems, refer to your state's radiation control program regulations. The CRCPD website has a list of contacts for each state (http://www.crcpd.org/links.asp). Please contact your state officials on this subject. Another resource to consider is the *Suggested State Regulations for the Control of Radiation*. Some state programs do not allow the use of hand-held x-ray equipment.

If you have any questions about this guidance, contact CDR Sean Boyd in the Division of Mammography Quality and Radiation Programs, Office of Communication, Education and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993 at 301-796-5895 or sean.boyd@fda.hhs.gov.

4. References

1. *Code of Federal Regulations*, Title 21 (Food and Drugs), Part 1020 (Performance Standards for Ionizing Radiation Emitting Products), Sections 1020.30-1020.33.

2. *International Standard IEC 60601-1-3, Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment,* Edition 2.0, (International Electrotechnical Commission, Geneva, 2008).
3. *Radiation Protection in Dentistry,* NCRP Report no. 145, (National Council on Radiation Protection and Measurements, Bethesda, MD, 2003).
4. *Suggested State Regulations for the Control of Radiation,* http://www.crcpd.org/publications.asp#ssrcr,(Conference of Radiation Control Program Directors, 2008).