ROUTINE COMPLIANCE TESTING PROCEDURES
FOR

DIAGNOSTIC X-RAY SYSTEMS
or
Components of Diagnostic X-Ray Systems to which 21 CFR Subchapter J is applicable

Office of Compliance

Center for Devices and Radiological Health
CDRH

WHO Collaborating Centers for:

- **Standardization of Protection Against Nonionizing Radiation**
- **Training and General Task in Radiation Medicine**
- **Nuclear Medicine**

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Rockville, Maryland

FDA ROUTINE COMPLIANCE TESTING PROCEDURES FOR DIAGNOSTIC X-RAY SYSTEMS

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FOREWORD

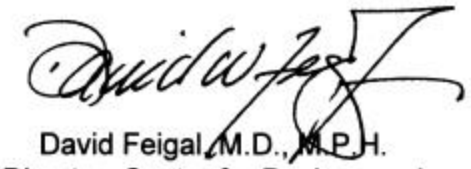
The Center for Devices and Radiological Health, FDA, develops and implements national programs to protect the public health in the fields of medical devices and radiological health. These programs are intended to assure the safety, effectiveness and proper labeling of medical devices, to control unnecessary 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.



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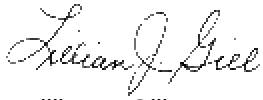
PREFACE

This manual has been developed by the Center for Devices and Radiological Health (formerly the Bureau of Radiological Health), Food and Drug Administration (FDA), to establish procedures for routine testing of diagnostic x-ray systems for compliance with Federal Performance Standard 21 CFR 1020.30-1020.32. It has been prepared to instruct FDA personnel and State officials who assist FDA in its functions in the use of the various devices that FDA may procure. The procedures and routine test equipment will be used for screening diagnostic x-ray systems for evidence of noncompliance with the Performance Standard. More rigorous follow-up testing will be performed as required.

The manual has two major subject areas: (1) testing procedures, and (2) test equipment. The first section presently contains procedures that provide efficient means of testing against many performance requirements and are applicable to many different types of x-ray systems. The second section describes each component of the routine compliance test system. It includes detailed drawings of the routine compliance test stand, operating manuals for the x-ray exposure monitor and the photometer, and descriptions of how to use the direct-print paper.

Manufacturers of diagnostic x-ray equipment can adopt such test formats and select such test equipment, as they deem appropriate. It must be realized, however, that any equipment used in a testing program upon which a product certification is based must demonstrate fully that the products will comply with the applicable standard. The Center has the authority to disapprove a testing program pursuant to Section 534(h) of Subchapter C - Electronics Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968) of Chapter V of the Federal Food, Drug and Cosmetic Act.



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