

**FORM FDA 3638 (12/11)**  
**Guide for Filing Annual Reports for X-Ray  
Components and Systems**

---

**Public reporting burden for this collection of information** is estimated to average 26.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
1350 Piccard Drive, Room 400  
Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*

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.

More industry guidance and assistance can be found at the FDA homepage, see:  
<http://www.fda.gov/Radiation-EmittingProducts/>.

Send your completed report to:

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH  
DOCUMENT MAIL CENTER – WO66-G609  
ATTN: ELECTRONIC PRODUCT REPORTS  
10903 NEW HAMPSHIRE AVENUE  
SILVER SPRING, MD 20993-0002

Questions about reporting and suggestions for changes to this guide may be sent to the above address or may be discussed by calling (301) 796-5710.

# **Guide for Filing Annual Reports for X-Ray Components and Systems**

**Office of Compliance**

**July 1980  
(Reprinted April 1987)**

The reporting and/or recordkeeping requirements contained herein have been approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act.

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
Center for Devices and Radiological Health  
Silver Spring, MD 20993**

This page is deliberately blank.

## CONTENTS

	<b>Page</b>
<b>1.0 INTRODUCTION .....</b>	<b>1</b>
<b>1.1 PURPOSE .....</b>	<b>1</b>
<b>1.2 APPLICABILITY .....</b>	<b>1</b>
<b>1.3 REPORT DATE AND REPORT PERIOD .....</b>	<b>1</b>
<b>1.4 ADDITIONAL GUIDANCE .....</b>	<b>1</b>
<b>2.0 CURRENT PRODUCTION TABULATION .....</b>	<b>1</b>
<b>2.1 DISCONTINUED COMPONENTS .....</b>	<b>1</b>
<b>2.2 ADDED COMPONENTS .....</b>	<b>1</b>
<b>3.0 SUMMARY OF RECORDS TO BE MAINTAINED BY MANUFACTURERS .....</b>	<b>2</b>
<b>3.1 RESULTS OF TESTS .....</b>	<b>2</b>
<b>3.2 RESULTS OF LIFE (RELIABILITY) TESTS .....</b>	<b>4</b>
<b>3.3 CORRESPONDENCE AND OTHER WRITTEN COMMUNICATIONS .....</b>	<b>4</b>
<b>APPENDIX A. ADDITIONAL GUIDANCE FOR CABINET X-RAY SYSTEMS .....</b>	<b>5</b>

This page is deliberately blank.

# **GUIDE FOR FILING ANNUAL REPORTS FOR X-RAY COMPONENTS AND SYSTEMS**

## **1.0 INTRODUCTION**

### **1.1 PURPOSE**

This document will serve as a guide for all x-ray component manufacturers in complying with 21 CFR Subchapter J regarding Annual Reports.

### **1.2 APPLICABILITY**

This guide is applicable to every x-ray component manufacturer subject to the provisions of 21 CFR 1002.13, Annual Reports.

### **1.3 REPORT DATE AND REPORT PERIOD**

Annual Reports shall be submitted by September 1 of each year. Such reports should cover the 12-month period ending on June 30, preceding the date of the report.

### **1.4 ADDITIONAL GUIDANCE**

A response is required for each paragraph of the guide. If the paragraph does not apply, write "Not Applicable."

## **2.0 CURRENT PRODUCTION TABULATION**

### **2.1 DISCONTINUED COMPONENTS**

Please list all components discontinued during the reporting year. Include model number and date of discontinuation.

### **2.2 ADDED COMPONENTS**

Please list all certified components introduced during the reporting year. Include model number, place of manufacture, and the CDRH Accession Numbers assigned to the initial or supplemental reports in which the corresponding components were reported.

### 3.0 SUMMARY OF RECORDS TO BE MAINTAINED BY MANUFACTURERS

The following definitions apply to Section 3.0:

- (1) Direct Test – one that actually measures the compliance parameter of interest.
- (2) Indirect Test – one that measures a parameter that can be correlated to the compliance parameter of interest.
- (3) Go/No-Go Test – one in which no data are generated or recorded, and the tester makes the rejection/acceptance decision based on predetermined written criteria.
- (4) Name of Test – identification of the requirement in the Performance Standard being tested.

### 3.1 RESULTS OF TESTS

NOTE: Any corrections, changes, modifications or additions to those test procedures that were previously reported in Initial Report(s) should be submitted to the Center for Devices and Radiological Health as supplements to the appropriate Initial Report.

For each direct or indirect test described in your Initial Report(s) (and/or supplements) and performed to determine compliance of the components, provide a summary of the test data for each model (or group of models with similar design and testing) using one of the following two methods:

a. Go/No-Go

- (1) Name of Test: \_\_\_\_\_
- (2) Rejection Limit: \_\_\_\_\_
- (3) Component Model Number(s): \_\_\_\_\_
- (4) Percent of Components Tested: \_\_\_\_\_
- (5) Number of Components Rejected: \_\_\_\_\_



b. Histogram

For all test summaries other than those presented in Go/No-Go form, provide the following information and a histogram displaying the number of components tested versus the test parameter value.

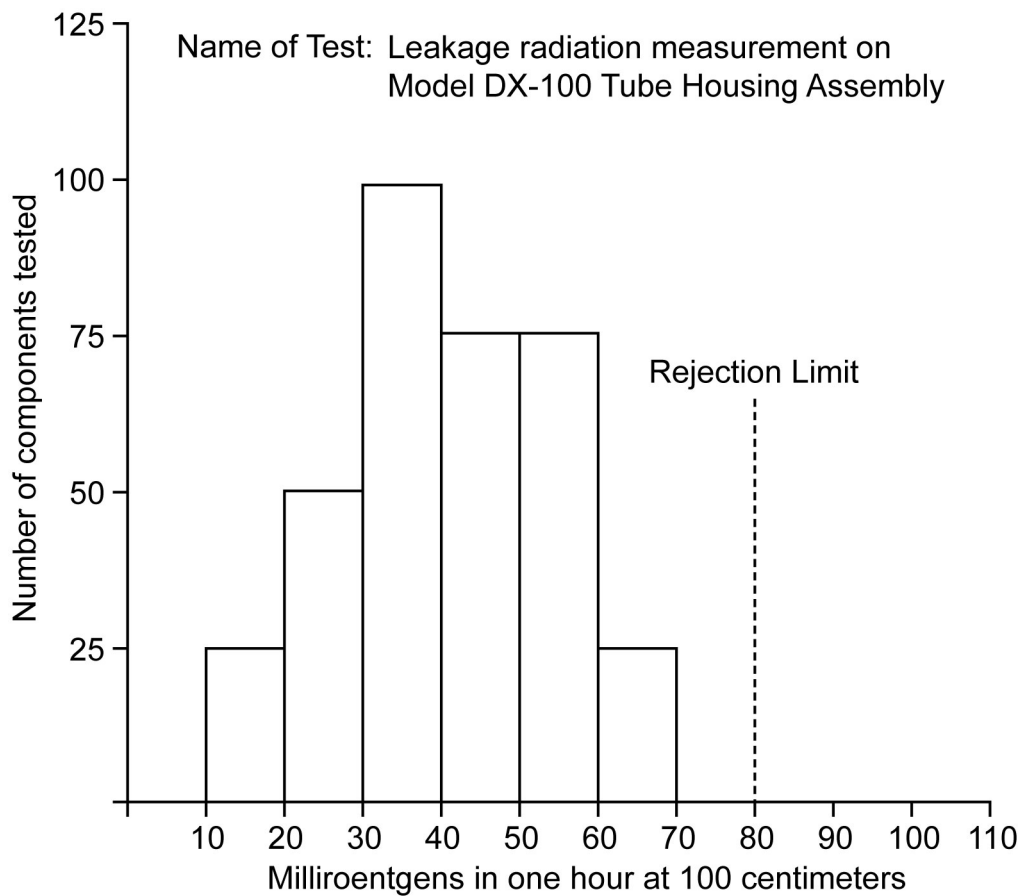
(1) Name of Test: \_\_\_\_\_

(2) Rejection Limit: \_\_\_\_\_

(3) Component Model Number(s): \_\_\_\_\_

(4) Percent of Production Tested: \_\_\_\_\_

Example of histogram:



### 3.2 RESULTS OF LIFE (RELIABILITY) TESTS

The Center for Devices and Radiological Health's concern with compliance-related reliability tests relates to the impact of these tests on maintenance schedules provided to the users.

For any compliance related life (reliability) tests performed (or monitored on an ongoing basis) during the reporting year, provide the following:

- a. Name of Test: \_\_\_\_\_
- b. Identification of component tested: \_\_\_\_\_
- c. Number of components tested: \_\_\_\_\_
- d. Time to failure or number of cycles to failure for each component tested: \_\_\_\_\_  
\_\_\_\_\_

(Note: "Failure" means the component tested is no longer in compliance.)

- e. Describe how the time to failure or cycles to failure information is factored into the maintenance schedules to users.

### 3.3 CORRESPONDENCE AND OTHER WRITTEN COMMUNICATIONS

Federal regulations require that files be maintained with copies of all written communications between the manufacturer and dealers, distributors, and purchasers concerning radiation safety complaints, investigations, instructions, or explanations affecting the use, repair, adjustment, maintenance, or testing of the listed component.

Additionally, a March 8, 1978 letter to all manufacturers urged each manufacturer to develop and utilize a system of obtaining and analyzing all causes of defects and failures to comply with the Standard.

Provide the following:

- a. A brief description of the system used to obtain and analyze all causes of defects and failures to comply with the Standard.
- b. A summary (or copies) of all written communications, both incoming and out-going, relating to these causes of defects and noncompliances.
- c. A summary or copies of any other written communications relating to electronic product radiation safety.

## **APPENDIX A**

### **ADDITIONAL GUIDANCE FOR CABINET X-RAY SYSTEMS**

The following guidance for cabinet x-ray systems is provided in addition to the general guidance in Paragraphs 1.0 - 3.0.

- A. Provide a summary of records pertaining to service and maintenance affecting radiation safety performance.
- B. Provide a summary of radiation surveys performed in the field.