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FORM FDA 3641 (04/23)

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

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 1-800-638-2041.

HHS Publication FDA 890-8123

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

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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 1002.11, 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.