

FORM FDA 3661 (6/15)

**A Guide for the Submission of an Abbreviated Report on
X-ray Tables, Cradles, Film Changers or Cassette Holders
Intended for Diagnostic Use**

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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.

A GUIDE FOR THE SUBMISSION OF AN
ABBREVIATED INITIAL REPORT ON X-RAY TABLES,
CRADLES, FILM CHANGERS OR CASSETTE
HOLDERS INTENDED FOR DIAGNOSTIC USE

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

INTRODUCTION

This guide presents an outline for a manufacturer to follow in preparing an abbreviated report, or abbreviated supplemental report, on x-ray tables, cradles, film changers or cassette holders intended for diagnostic use. These certifiable components are subject to the Performance Standard, 21 CFR 1020.30, 1020.31, and 1020.32.

The focus of the guide is to identify the pertinent information required by the Food and Drug Administration for the specified certifiable components. Information submitted will be considered toward fulfillment of the requirements of the Radiation Control for Health and Safety Act of 1968 (Public Law 90-601).

This reporting guide should be considered as a replacement for all previous guides that have been developed for presentation of initial report and supplemental report data. Manufacturers should discontinue usage of the earlier guides. This guide only applies to the above listed components.

NOTE: All reports submitted under this abbreviated guide must be in English.

PART 100 – IDENTIFICATION

101.0 REPORT IDENTIFICATION

Confirm that this report is submitted pursuant to paragraph (c)(1) of section 1002.61, and state the following:

Report type (initial report or supplement to CDRH Accession # _____)

Identification of manufacturer

Name, address and telephone number of submitter

Email address of submitter

Identification of corresponding official

102.0 PRODUCT IDENTIFICATION

102.1 Provide the model designation as would appear on the component identification label for all components being certified in this report. Applicable components are x-ray tables, cradles, film changers and/or cassette holders.

102.2 If any of the models reported above are sold under names other than your own, provide the model designation and name and address of each company under whose name the product is sold.

102.3 For every model listed under 102.1, provide an exact replica of all labels completed with the following items filled in as would be found on the component when shipped:

- (a) certification statement;
- (b) name and address of the manufacturer;
- (c) date and place of manufacture;
- (d) model designation and sample serial number; and
- (e) a drawing indicating the location of the labels.

102.4 Attach the following information as appendices:

- (a) assembler's manual – Appendix A;
- (b) user's manual (with product specifications) – Appendix B.

PART 200 – COMPONENT DESCRIPTION FOR X-RAY TABLES, CRADLES,
FILM CHANGERS OR CASSETTE HOLDERS

This section should be completed for each table, cradle, film changer or cassette holder listed in section 102.1 of Part 100, or any combination thereof.

- 200.1 For each model x-ray table, identify appropriate characteristics: stationary table, movable table, table designed for therapy simulation, table designed for computed tomography, cantilevered table, etc.
- 200.2 For each model cradle, identify the means for patient restraint and rotation about the long (longitudinal) axis. Indicate whether the model is a mobile stretcher design with three or more hinged radiolucent panels.
- 200.3 For each model film changer, explain the means whereby an exposure or a series of exposures lasting longer than one-half second is terminated.
- 200.4 For each vertical cassette holder equipped with size sensors, indicate the intended image receptor sizes.

PART 300 – QUALITY CONTROL TESTING ALUMINUM EQUIVALENCE

This section requires documentation and test data assuring that the aluminum equivalence of x-ray tables, cradles, and front panels of film changers and cassette holders, as may be used between the patient and image receptor, does not exceed the limits indicated in Table II of the performance standard (21 CFR 1020.30(n)).

300.1 Critical Parameters

- a. As a result of inherent inaccuracies of test procedures and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.
- b. Whereas peak tube potential is critical in determining aluminum equivalence, the test method(s) must include a procedure for the periodic calibration of tube potential.
- c. Compliance shall be measured at 100 kVp and 2.7 millimeters of aluminum half-value layer.

300.2 Prototype Testing

- a. Describe the direct test method that actually measures x radiation.
- b. Identify all test instruments by manufacturer and model number.
- c. Describe the procedure for periodic calibration of the test instruments.
- d. Provide prototype test data and rejection limits.
- e. Provide an analysis of the prototype test data.

300.3 Production Testing

- a. Describe the direct or indirect test method used to determine aluminum equivalence.
- b. Identify all test instruments by manufacturer and model number.
- c. Describe the procedure for periodic calibration of the test instruments.
- d. If sampling is used for production testing, give the basis for the selected sampling plan.
- e. Provide production test data and rejection limits.
- f. Provide an analysis of the production test data.