Form Approved: OMB No. 0910-0025
Expiration Date: January 31, 2017

FORM FDA 3662 (12/15)

A Guide for the Submission of an Abbreviated Radiation Safety Report on Cephalometric Devices Intended for Diagnostic Use

---

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 RADIATION SAFETY REPORT ON CEPHALOMETRIC DEVICES INTENDED FOR DIAGNOSTIC USE

MARCH 1996

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

Foreword

The Office of Compliance, Center for Devices and Radiological Health (CDRH) developed this guide. This guide will assist manufacturers[1] of electronic products which emit radiation in providing adequate reporting of radiation safety testing and compliance with federal performance standards. Title 21 of the Code of Federal Regulations (CFR), Parts 1002 and 1003 specify Reporting and Notification requirements[2,3].

Reports submitted on radiation safety of electronic products must follow the appropriate guide (21 CFR 1002.7). If the report does not follow an applicable guide it must contain a sufficient justification for any deviations. The submitter of the report will receive an acknowledgment letter with the accession number we assign to the report. Please reference this accession number in the future when providing additional information about this model family in either a supplement or the annual report. If a report is incomplete or inadequate CDRH may reject it and return it for completion. CDRH will not enter a rejected report into our database. Also, a rejected report will not receive an accession number.

WE DO NOT APPROVE THESE REPORTS OR THE PRODUCTS BEING REPORTED. It is the manufacturer's responsibility to certify that their products comply with all applicable standards (21 CFR 1010 - 1050), based on a testing program in accordance with good manufacturing practices. Prior to the shipment of products in interstate commerce 21 CFR 1002 requires the manufacturer to submit the report and to comply with all applicable importation requirements (21 CFR 1005). If there are deficiencies, we may disapprove the firm's quality control and testing program, determine that the product contains a radiation defect, or determine that the product fails to comply with a standard. We will notify the manufacturer if we make such a determination. CDRH may require the manufacturer to cease introduction into U.S. commerce until deficiencies are corrected, and to initiate a corrective action program (21 CFR 1003 - 1004) for products already introduced into commerce.

Please mail your reports to the address below (FDA can not process electronic submissions at this time). Provide the original report with appropriate signature(s) (no facsimiles, please). Provide extra copies only if this guide specifically requires them. Submit the report written in the English language. Translate any text that appears in a language other than English into English in a complete and accurate manner. Keep a copy of the completed reports in your records.

We are making our reporting guides and other regulatory information available on the Internet under http://www.fda.gov/Radiation-EmittingProducts/. No copyright exists for these guides. Reproduce these guides as needed. If you would like to comment on the reporting guides, web site, or future electronic submissions, you may direct the comments to the address below. If you need additional regulations for electronic products or medical devices, you should contact the Division of Small Manufacturers, International and Consumer Assistance by telephone at 1-800-638-2041 or by facsimile at 301-847-8149.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance

E-MAIL ADDRESS: dsmica@fda.hhs.gov

MAILING ADDRESS (see 21 CFR 1002.7 for further information):

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

[1] **Manufacturer** (see 21) CFR § 1000.3 (n)) means any person engaged in the business of manufacturing, assembling, or importing electronic products.

[2] **Accidental Radiation Occurrences:** 21 CFR 1002.20 requires manufacturers to immediately report accidental radiation occurrences (see 21 CFR 1000.3(a) for the definition).

[3] **Notification:** Title 21 CFR Part 1003 requires manufacturers to provide Notification of Defects or Failure to Comply. Send these notifications to the above address.

INTRODUCTION

This guide presents an outline for a manufacturer to follow in preparing an abbreviated report, or abbreviated supplemental report, for cephalometric devices intended for use with diagnostic x-ray equipment. These certifiable components are subject to the Performance Standard, 21 CFR 1020.30 and 1020.31.

The focus of the guide is to identify the pertinent information required by the Food and Drug Administration for the certification of cephalometric devices. Information submitted will be considered toward fulfillment of the requirements of the Radiation Control for Health and Safety Act of 1968 (Public Law 90-602).

This reporting guide is to be used as a replacement for other previous guides that have been developed for presentation of product (initial) report and supplemental report data. This guide applies only to the manufacture and certification of cephalometric devices. It can not be used for other certifiable 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:

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

101.2 Name and address of the certifying manufacturer as it should appear on the product label

_____

_____

_____

101.3 Name, address and telephone number of submitter

_____

_____

_____

Email address of submitter

_____

Identification of corresponding official

_____

101.4 If the address listed in 101.2 above is not the manufacturing site where certification testing is documented, then provide the name and address (below) of the location where certification testing is documented, as it is identified on the product label.

_____

_____

_____

102.0 PRODUCT IDENTIFICATION

102.1 Provide the model designation as would appear on the component identification label, for each cephalometric component being certified in this report.

102.2 If the model designation(s) reported above is sold under a name other than your own, provide the model designation and name and address of each company under whose name the product is sold or labeled.

102.3 For each model designation listed under 102.1 and/or 102.2, provide an exact replica of all labeling completed with the following items filled in as would be found on the component when shipped:

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

102.4 Attach the following information as appendices:

(a) assembler's manual -- Appendix A
(b) user's manual -- Appendix B

PART 200 - COMPONENT DESCRIPTION FOR CEPHALOMETRIC DEVICES

This section should be completed for each cephalometric device listed in section 102.1 of PART 100 that includes a beam-limiting device (BLD) as an integral design feature.

200.1 For each model cephalometric device, indicate the design SID, and the image receptor size.

200.2 Describe the means for limiting and/or centering the x-ray field.

200.3 If a light field is used to define the perimeter of the x-ray field, then it must meet the requirements of 21 CFR 1020.31(d)(2).

PART 300 - QUALITY CONTROL TESTING
CEPHALOMETRIC DEVICES

This section requires documentation and test data to assure that cephalometric devices that include beam-limiting devices (BLDs) and which function at one SID and image receptor size, meet the requirement to limit the x-ray field at the plane of the image receptor to dimensions no greater than those of the image receptor, or the requirement to align the x-ray field such that at the plane of the image receptor, the x-ray field does not extend beyond any edge of the image receptor. When prototype and production testing are identical, refer to production testing.

300.1 Critical Parameters - 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.

300.2 Prototype Testing

a. Describe the test method used to insure that x-ray is properly aligned and centered with the image receptor.

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. If a light field is used to define the perimeter of the x-ray field, describe in detail the test method used to insure compliance with the light field requirements for light illuminance, edge contrast ratio, and alignment of visually defined field.

300.3 Production Testing

a. Describe the test method used to insure that x-ray is properly aligned and centered with the image receptor.

b. Identify all test instruments by manufacturer and model number.

c. Describe the procedure for periodic calibration of the test instruments.

d. Provide production test data and rejection limits.

e. If a light field is used to define the perimeter of the x-ray field, describe in detail the test method used to insure compliance with the light field requirements for light illuminance, edge contrast ratio, and alignment of visually defined field.