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.

A GUIDE FOR THE SUBMISSION OF ABBREVIATED INITIAL REPORTS ON IMAGE RECEPTOR SUPPORT DEVICES FOR MAMMOGRAPHIC X-RAY SYSTEMS

INTRODUCTION

This guide presents an outline for a manufacturer to follow in preparing an abbreviated report, or abbreviated supplemental report for image receptor support devices contained in mammographic x-ray systems. 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 these 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 90-602).

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 of mammographic image receptor support devices reporting under this guide should discontinue use of the earlier guides. This guide applies only to the manufacture and certification of image receptor support devices.

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

Identification of corresponding official

102.0 PRODUCT IDENTIFICATION

102.1 Provide the model designation for each mammographic image receptor support device 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.

102.3 For each model designation listed under 102.1, provide an exact replica of all labeling complete with the following:

(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 MAMMOGRAPHIC IMAGE RECEPTOR SUPPORT DEVICES

This section should be completed for each image receptor support device listed in section 102.1 of PART 100.

200.1 For each model image receptor support device that includes a cassette holder with a front panel as an integral part, state the aluminum equivalence of the front panel with respect to the limits indicated in Table II of the diagnostic x-ray performance standard.

200.2 Describe the means for limiting the transmission of the primary beam through an image receptor support device such that any exposure 5 centimeters from an accessible surface beyond the plane of the image receptor support device will not exceed 0.1 milliroentgen for each activation of the x-ray tube.

PART 300 - QUALITY CONTROL TESTING
MAMMOGRAPHIC IMAGE RECEPTOR SUPPORT DEVICES

This section requires documentation and test data to assure that: (a) the aluminum equivalence of the front panel of a cassette holder in a mammographic image receptor support device does not exceed the limits specified in Table II of the diagnostic x-ray performance standard (21 CFR 1020.30(n)0; and (b) the transmission of the primary beam through the support device is limited such that exposure 5 centimeters from any accessible surface beyond the plane of the support device does not exceed 0.1 milliroentgen for each activation of the x-ray tube (21 CFR 1020.31(1)). When production testing and prototype 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 in detail the test methodology used to insure that the front panel of the cassette holder is compliant and that transmission through the IRSD is compliant. Use set-up diagram as needed to assist in explanation.

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. Identify all test instruments by manufacturer and model number.

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

c. Provide production test data and rejection limits.

d. Provide an analysis of the production test data.