Form Approved: OMB No. 0910-0025
Expiration Date: May 31, 2029

FORM FDA 3639 (09/26)

Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21 CFR 1020.40

Public reporting burden for this collection of information is estimated to average 24 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
Paper Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please do NOT send your completed document to this PRA Staff email address.

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/.

Email your completed, signed report to: RadHealthCustomerService@fda.hhs.gov
or 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.

GUIDANCE FOR THE SUBMISSION OF CABINET X-RAY SYSTEM REPORTS PURSUANT TO 21 CFR 1020.40

Compiled by:
Division of Compliance
X-Ray Products Branch

FEBRUARY 1975

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.

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 Industry and Consumer Education by telephone at 1-800-638-2041 or by facsimile at 301-847-8149.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance

Email your completed, signed report to: RadHealthCustomerService@fda.hhs.gov
or 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

[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.

This page is deliberately blank.

FOREWORD

This document is intended to serve as a guide to assist manufacturers in the submission of initial and supplements to initial reports for cabinet x-ray systems (21 CFR 1020.40). The format selected for this guidance is that of report form. It may be used directly or it may serve as a model for developing a reporting form. However, if a manufacturer develops his own report form he must be sure that all information requested by the "model" form is included and keyed to this format since this information has been interpreted by the Division of Compliance as being necessary to satisfy, in whole or in part, the initial and supplemental reporting requirements. In order to standardize reports and facilitate their review the order and organization of the model form should be followed as closely as possible.

CONTENTS

Page

FOREWORD i
GENERAL INSTRUCTIONS iii
CABINET X-RAY SYSTEM REPORTING FORM 1
Part I - Manufacturer and Report Identification 1
Part II - Product Identification and Technical Information 2
A - Model Identification 2
B - Technical Information 3
Part III - Basic Sampling and Testing Information 15
ATTACHMENT LIST 22
APPENDIX A - DEFINITIONS 23

GENERAL INSTRUCTIONS

The attached model form is to be used when submitting initial reports and supplements to initial reports. Definitions of these types of reports and of several other items necessary to properly complete the form are given in Appendix A. Part I of the form covers manufacturer and report identification, Part II covers product identification and technical information, and Part III covers the basic sampling and testing program. The form contains specific instructions for the completion of each part. General instructions for the preparation and submission of the various types of reports are given below.

1. One copy of Part I of the form is to accompany each report submission.

2. Initial Reports - Information being submitted to meet the requirements of an initial report will require completion of all parts of the form. A copy of Part II (A), Part II (B) and Part III is to be completed for each model cabinet x-ray system.

3. Supplemental Reports - Any changes in information previously submitted in Part II (A), Part II (B) or Part III of this form is to be submitted as a supplement to an initial report. Only the portions of each part undergoing change need be submitted. The date and accession number of the initial report to which the supplement applies is to be listed in item 3 of Part I.

4. Attachments - Throughout the guide reference is made to attachments. These attachments should be clearly marked according to the alphabetical letter indicated in the guide. All attachments should be placed in order at the end of the guide and the accompanying attachment list filled in. The manufacturers may reference their own data identification numbers on this list.

5. Email your completed, signed report to: RadHealthCustomerService@fda.hhs.gov or 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

This page is deliberately blank.

Center for Devices and Radiological Health
Document Mail Center - WO66-G609
Electronic Product Reports
10903 New Hampshire Avenue
Silver Spring, MD 20933-0002

Cabinet X-ray System Reporting Form

Part I - Manufacturer and Report Identification

This part of the form is to accompany each submission. Only one copy of this part need be completed even though more than one copy of other parts of this form may be required to provide all the information being reported.

1. Manufacturer:

   Name _____

   Address _____

   _____

   Corresponding Official: (May not be applicable for imports)

   Signature _____

   Name _____

   Title _____

   Telephone _____ Email _____

2. Importer: (Complete if applicable)

   Name _____

   Address _____

   _____

   Corresponding Official:

   Signature _____

   Name _____

   Title _____

   Telephone _____ Email _____

3. Report Type:

   _____ ☐ Initial

   _____ ☐ Supplement to initial report, CDRH Accession No. _____ submitted on _____ (dates)

4. Report Date: _____

Part II - Product Identification and Technical Information

Complete Sections A and B for each new cabinet x-ray system being reported. A copy of Section A and B is to be completed for each new cabinet x-ray system being reported. Only Section A need be completed to report additional brand and/or selling model numbers of a system when all other manufacturing and testing information is the same as previously submitted. Any information covered in Part II (B) and/or Part III of the form that has not been previously reported should be provided in the applicable portions of Part II (B) and/or Part III.

A. Model Identification

1.0 Product Type:

☐ Reported pursuant to paragraph c of 1002.61

- check as applicable -

Product Type	
Radiographic, conventional source	☐
Radiographic, pulsed or flash source	☐
Fluoroscopic	☐
Radiographic and fluoroscopic	☐
Screening device used in public facilities (such as baggage inspection devices)	☐
Other than specified types (describe below)	☐

Description of other product types:

_____

_____

2.0 List the name and model number of the product manufactured or imported to which the cabinet x-ray standard is applicable. Do not report if the item is intended solely for export to countries whose applicable requirements are met.

Name of Product _____

Model Number _____

3.0 If the reported model is sold under brand names, other than those of the manufacturer, please provide the brand name, model number, and name and address of each company under whose name the model is sold.

Brand Name _____

Model Number _____

Company _____

Address _____

_____

_____

4.0 List all uses or applications for which the model is intended.

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

5.0 Reference Verification (check one)

☐ 5.1 All information previously reported in CDRH Accession No. _____ on _____ (date) is applicable to the models listed under item 2, Part II (A) of this report. The models will be manufactured and tested in accordance with the procedures reported in the reference document.

☐ 5.2 Except as specifically indicated in Section B of Part II and/or Part III, all information previously reported in CDRH Accession No. _____ on _____ (date) is applicable to the models listed under item 2, Part II (A) of this report. These models will be manufactured and tested in accordance with the procedures reported in the referenced document(s).

☐ 5.3 This is the initial submission of information required for cabinet x-ray system(s).

B. Technical Information

1.0 X-ray Emission

1.1 Is the system designed to limit x-ray emission from the cabinet x-ray system to an exposure of 0.5 milliroentgen in any one hour at a point of five centimeters outside the external surface?

Yes ☐ No ☐

1.2 List the following characteristics of the x-ray system:

range of kVp adjustment _____

range of mA adjustment _____

duty cycle (see definition) _____

range of timer adjustment _____

total filtration _____

beam divergence _____

beam orientation _____

1.3 Describe the type, thickness, and location of shielding incorporated into the product to limit x-ray emission at the external surface. Provide illustrative drawings as attachment A.

_____

_____

_____

_____

1.4 Describe all service adjustments and procedures that affect radiation leakage.

_____

_____

_____

_____

_____

1.5 Are any doors included as part of the cabinet x-ray system?

Yes ☐ No ☐

If no, proceed to section 1.6. If yes, complete the following.

1.5.1 Describe the intended purpose of each door.

Describe: _____

_____

_____

_____

_____

1.6 Are any access panels included as part of the cabinet x-ray system?

Yes ☐ No ☐

If no, proceed to section 2.0. If yes, complete the following.

1.6.1 Describe the intended purpose of each access panel.

Describe: _____

_____

_____

_____

_____

_____

_____

2.0 X-ray Controls and Indicators (Provide a circuit diagram as attachment B).

2.1 Describe the control device(s) for initiating and terminating x-ray generation and the physical location(s). Include the method by which x-ray exposure interruption is accomplished (e.g., release of exposure switch, termination of preset time, etc.) and the method of resuming operation following x-ray generation interruption by the control device(s).

Describe: _____

_____

_____

_____

_____

_____

_____

2.2 Describe the characteristics, operation, and location of the main power control.

_____

_____

_____

_____

2.3 Describe the characteristics, operation, and location of the key activated control. Include a statement of the key capture condition.

_____

_____

_____

_____

2.4 Can an x-ray exposure greater than a period of one-half second be made with this cabinet x-ray system?

Yes ☐ No ☐

2.4.1 If yes, are means provided to enable the operator to terminate the exposure prior to completion of the preset exposure period? Yes ☐ No ☐

2.4.2 If no, are means provided to prevent an additional x-ray exposure to be made? Yes ☐ No ☐

2.5 Describe all devices that indicate when and only when x-rays are being generated and that can be viewed from any location where x-ray generation can be initiated. Include dimensions, location, and labeling.

Describe: _____

_____

_____

_____

_____

_____

_____

2.6 How long are indicators actuated when the x-ray generation period is less than one-half second? _____

2.7 Does failure of any single component of the cabinet x-ray system cause failure of more than one x-ray production indicator?

Yes ☐ No ☐

2.8 Describe all other means which indicate when x-rays are being generated that can be viewed from any door, access panel, and port. Include dimensions, location, and labeling.

Describe: _____

_____

2.9 Is the cabinet x-ray system designed to admit humans?

Yes ☐ No ☐

If no, proceed to section 3.0. If yes, complete the following.

2.9.1 Describe all exposure controls within the cabinet and include them in the diagram provided as attachment B.

Describe:

2.9.2 Is a method provided to reset, override, or bypass the controls described in 2.9.1 from outside the cabinet?

Yes ☐ No ☐

2.9.3 Describe the audible and visible warning signals provided in the cabinet.

Describe:

2.9.4 How long are the warning signals activated prior to the first initiation of x-ray generation after closing any door or access panel designed to admit humans?

_____ .

2.9.5 If any single component of the cabinet x-ray system fails, can x-rays be produced without either the audible or visible warning systems indicating x-ray production?

Yes ☐ No ☐

2.9.6 Does a visible signal within the cabinet remain activated for the entire period of x-ray generation?

Yes ☐ No ☐

2.9.7 Provide copies (or replicas) of all signs that are illuminated within the cabinet which explain the meanings of the warning devices. Indicate the sign location with pictures and/or drawings. Label these as attachment C.

3.0 Safety Interlocks.

3.1 Describe the interlock system and provide circuit diagrams showing interlocks and safety systems for each door and each access panel.

The circuit diagrams may be included in attachment B or provided separately as attachment D. Include the electrical and mechanical characteristics of each interlock device in the description.

Description: _____

_____

_____

_____

_____

_____

_____

3.2 Describe any provisions for adjustment of the interlocks.

_____

_____

_____

_____

3.3 Indicate the amount of door or access panel movement that is possible prior to actuation of the interlock.

_____

_____

3.4 Is any part of the circuit physically removed from the energy supply circuit to the high-voltage generator when a door is opened.

Yes ☐ No ☐

3.5 Is such disconnect dependent upon any moving part other than the door. Yes ☐ No ☐
Provide drawings, sketches or engineering drawings to clearly illustrate operation as attachment E.

3.6 Describe how x-ray production can be resumed after any safety interlock has been activated.

Describe: _____

_____

_____

_____

_____

_____

3.7 Are the required interlock circuits designed to ensure that the failure of one component does not result in the failure of more than one required safety interlock?

Yes ☐ No ☐

3.8 Provide a circuit analysis describing the effects of critical component failure on the interlock system. Label the analysis Attachment F.

4.0 Warning, Certification, and Identification Labels.

4.1 Provide an exact replica of all labels which show any of the following.

(a) The certification statement,

(b) the name and address of the manufacturer (or individual or company under whose name it is sold),

(c) the date and place of manufacturer (these should be spelled out in full), and

(d) the model number and serial number.

Label the replicas as attachment G.

4.1.1 Is this labeling permanently affixed to or inscribed on the system and legible and accessible to view when the system is fully assembled for use?

Yes ☐ No ☐

4.2 Is a warning label affixed at the location of any control which can be used to initiate x-ray generation?

Yes ☐ No ☐

4.2.1 Is this warning label permanently affixed to or inscribed at the location of the control, legible and accessible to view?

Yes ☐ No ☐

4.2.2 Provide a copy of the warning label affixed at the control(s) and label it attachment H.

4.3 Describe all other warning labels and their locations and include copies of the labels as attachment I.

Describe: _____

_____

_____

_____

_____

_____

5.0 Ports and Apertures

5.1 What are the shapes and dimensions of all entrance and exit ports?

	Shape	Dimensions
1.	_____	_____
2.	_____	_____
3.	_____	_____
4.	_____	_____
5.	_____	_____
6.	_____	_____

5.2 What is the shortest distance from the primary beam to any location in the plane or perimeter of any entrance or exit port? (Numbers indicate same ports as in 5.1)

	Distance
1.	_____
2.	_____
3.	_____
4.	_____
5.	_____
6.	_____

5.3 Describe all means specifically provided as part of the cabinet x-ray system to prevent insertion of any part of the body through a port into primary beam.

Describe: _____

_____

_____

_____

_____

_____

5.4 What are the shapes and dimensions of all apertures?

	Shape	Dimensions
1.	_____	_____
2.	_____	_____
3.	_____	_____
4.	_____	_____
5.	_____	_____
6.	_____	_____

5.5 What is the purpose of each of these apertures? (Numbers indicate same apertures as in 5.4)

1. _____

_____

_____

2. _____

_____

_____

3. _____

_____

_____

4. _____

_____

_____

5. _____

_____

_____

6. _____

_____

_____

5.6 Describe the means provided to prevent the insertion of any part of the human body through these apertures. (Numbers indicate the same apertures as in 5.4)

Means:

1. _____

_____

_____

2. _____

_____

_____

3. _____

_____

_____

4. _____

_____

_____

5. _____

_____

_____

6. _____

_____

_____

6.0 Floors of the Cabinet X-ray Systems.

6.1 Does the design of the cabinet x-ray system depend upon the purchaser providing a support surface that becomes the floor of the system when installed?

Yes ☐ No ☐

6.2 If the answer to 6.1 is yes, describe these installation requirements.

Describe: _____

_____

_____

_____

_____

_____

_____

6.3 Does the installation described in 6.2 constitute a permanent installation?

Yes ☐ No ☐

7.0 Ground Fault.

7.1 Can a ground fault result in generation of x-rays?

Yes ☐ No ☐

7.2 Provide a ground fault analysis as attachment J.

8.0 Include a copy of the information packet on safety, installation, and maintenance procedures, which is supplied to users as required by 1020.40 (c) (9) of the standard for each model, as attachment K.

9.0 Provide copies of any additional operating instructions, published product technical data sheets, specifications sheets, applications notes, or other published material relating to product specifications, applications, radiation emission or radiation safety, as attachment L. A picture or drawing of each product should also be included. Promotional sales literature may be included, if appropriate.

10.0 Systems designed primarily for screening of hand-carried items in public facilities.

10.1 Describe means provided to require operator presence at the control area during generation of x-radiation.

Describe: _____

_____

_____

_____

_____

10.2 Do the means described in 10.1 permit surveillance of all ports and doors?

Yes ☐ No ☐

10.2.1 If no, explain _____

_____

_____

10.3 Do the means described in 10.1 permit the operator to terminate x-ray generation at any time?

Yes ☐ No ☐

10.3.1 If no, explain _____

_____

_____

Part III - Basic Sampling and Testing Information

A. Direct Testing

1.0 Briefly explain the concept of each direct x-ray measurement test that is done to verify compliance with the emission limit of the standard. Include in this explanation a copy of the test method(s). Label the explanation and test methods as attachment M.

The test described shall include, but not be limited to:

a. Testing to evaluate effects of scattering object and placement,

b. Testing to evaluate x-ray emission prior to interruption of x-ray generation through operation of any required safety interlock,

c. Testing to evaluate the effects on shielding from shipping, transporting or moving the cabinet system,

d. Testing to evaluate line voltage fluctuations and critical component deterioration,

e. Testing to evaluate effects of service adjustments and procedures, and

f. Final acceptance testing.

2.0 At what stage(s) (i.e., engineering prototype, initial production lot run, production run installation, etc.) in the design, production, or installation of the cabinet x-ray system is a direct test made to verify compliance with the standard?

	Test	Stage
1.	_____	_____
2.	_____	_____
3.	_____	_____
4.	_____	_____
5.	_____	_____
6.	_____	_____
7.	_____	_____
8.	_____	_____
9.		

3.0 State the limit(s) at which the unit would be rejected for each final acceptance test.

Limit: _____

_____

_____

_____

_____

_____

4.0 Describe the procedure used to determine the location(s) of maximum radiation intensity.

Describe: _____

_____

_____

_____

_____

_____

5.0 If the direct test utilizes a radiation measurement instrument that scans the cabinet x-ray system, what is the rate of scan (in cm/sec)?

Rate: _____

6.0 State the tube potential, current, beam orientation, duty cycle, and scatter conditions that will produce the maximum external surface x-ray exposure.

tube potential _____

current _____

beam orientation _____

_____

_____

duty cycle _____

scatter object _____

scatter object position _____

7.0 State the distance (in centimeters) between the external surface and the radiation measurement instrument _____.

8.0 In each stage, described in 2.0, list the percentage or number of items tested.

	Stage	Percentage or Number
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		

B. Radiation Instrumentation Used for Testing

1.0 Instruments used for radiation measurement.

	Instruments		
	#1	#2	#3
Manufacturer			
Model Number			
Type of Instrument			
Precision of Instrument			
Accuracy of Instrument			
Response Time			
Energy Dependence			
Angular Response			
Exposure Rate Dependence			
Range			
Effective Measurement Area			

2.0 Calibration of Instruments

2.1 Interval of time between calibration _____

2.2 Method of calibration, including accuracy and source of calibration _____

_____

_____

2.3 Verification procedure used to assure proper day-to-day operation of instrumentation _____

_____

_____

C. Indirect Testing

1.0 If the test method used to monitor compliance with the emission limit performance requirement is other than the direct measurement described above, describe the method and attach a copy of the test procedure labeled as attachment N. In addition, provide the basis for the indirect method (any method other than a radiation exposure measurement); explain why it is an accurate indication of compliance with the emission requirements, and submit the technical data which supports this conclusion.

2.0 Specify the primary purpose of each indirect test.

	Test	Purpose
1.	_____	_____
2.	_____	_____
3.	_____	_____
4.	_____	_____
5.	_____	_____
6.	_____	_____
7.	_____	_____
8.	_____	_____
9.	_____	_____
10.	_____	_____

3.0 Specify the stage(s) in the design, production, or installation of the system that the indirect test is made.

	Test	Stage
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

4.0 For any test whose purpose is acceptance or rejection of the system, specify the rejection limit of the product.

	Test	Rejection Limit
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

5.0 Specify who has the responsibility for conducting these tests.

Specify: _____

_____

_____

_____

6.0 For each test conducted for the purpose of acceptance, specify the actual number of units tested and the proportion of production output which that number represents.

Test	# Tested	Proportion of Production

D. Sampling

For each production line test performed for the purpose of determining product acceptability on less than 100 percent of the output, as attachment O, answer the following:

1. Specify the sampling plan used and provide the parameters of the plan (i.e., lot size, sample size, acceptance criteria, etc.). If the sampling plan is obtained from a set of standard sampling tables, indicate the source and type of plan. If the sampling plan was designed specifically for this application, indicate the requirements which were established for the plan and the assumptions used, and whether acceptance criteria is based upon attributes or variables.

2. Describe the procedure used for selecting the sample and indicate how randomness is assured.

3. For each test or inspection specify the quality characteristics and the specification limit(s) by which acceptable quality is distinguished from unacceptable.

4. Provide the operating characteristic (O.C.) curve of the sampling plan.

5. Specify the distribution assumed and the procedures used for computing acceptance probabilities for the O.C. curve of the sampling plan.

6. Specify the producer's and consumer's risk of the sampling plan and indicate at what quality level each applies.

7. Describe the action taken if the sampling plan leads to a rejection decision.

E. Critical Component Testing

As attachment P, answer the following:

1. Describe all applicable quality control and testing procedures for critical components conducted prior to installation of the components into your product which you consider a necessary and vital part of your testing program to assure compliance with the Federal Performance Standard. This shall include, but not be limited to, incoming inspection and/or sub-assembly testing of such items as x-ray sources, pressure pads, interlock switches, relays and shielding components. Where applicable, the description shall include:

a. Vendor qualification requirements.

b. Incoming inspection procedures, accept/reject criteria, and lot and sample size if not 100 percent tested. If 100 percent tested, so state.

c. Corrective action following unit or lot rejection.

2. Describe all applicable life testing procedures on the x-ray system or on those critical components incorporated into the x-ray system which you consider a necessary and vital part of your testing program to assure compliance with the Federal Performance Standard for the life of the product. This description shall include, but not be limited to, the following information:

a. The state(s) in the development or production of a specific model or design when life testing is conducted on the system or critical component.

b. A copy of the life testing protocol, including the test method used. If previously addressed, reference may be made to your response to other appropriate sections of your report.

c. The period of time (e.g., years) relative to use of the unit at an installed site which the life testing represents.

F. Test Results: As appendix Q, provide:

1.0 The results of Quality Control testing to date as follows:

1.1 The numerical results of the direct radiation tests upon which you base your certification, including: a) date of the test, b) state of development, production or installation at which the test was made.

1.2 A summary of the numerical results of direct and/or indirect quality control tests of production line units.

1.3 Where sufficient data are available, the mean, range, and standard deviation of each type of measurement. If these values are unavailable, other representative statistics or expressions or results may be reported.

2.0 Summary results of tests performed to determine "worst case" conditions for x-ray emission at the external surface of the cabinet x-ray system.

3.0 Summary of results of critical component testing.

4.0 Summary of results of critical component or system life testing.

5.0 Describe changes in critical components occurring with time that affect the performance of the unit with respect to applicable performance requirements.

ATTACHMENT LIST

(check all that are attached including any added to provide information not specifically identified below)

			Manufacturer's Own Data Identification Number
☐	A.	Shielding Drawings	
☐	B.	Circuit Diagrams	
☐	C.	Signs Within the Cabinet	
☐	D.	Interlock System-Circuit Diagram	
☐	E.	Drawings of Disconnect Interlock	
☐	F.	Analysis of Interlock System Component Failure	
☐	G.	Certification and Identification Labels	
☐	H.	Control Warning Labels	
☐	I.	Other Warning Labels	
☐	J.	Ground Fault Analysis	
☐	K.	User Information	
☐	L.	Other Information and Data	
☐	M.	Direct Test Methods	
☐	N.	Indirect Testing	
☐	O.	Sampling	
☐	P.	Critical Component Testing	
☐	Q.	Test Results	

Note: This sheet, completed as applicable, is to accompany each report.

Appendix A - Definitions

The definitions of report types and several other terms given below are provided for use with the general guidance to assure proper completion of the attached model form and satisfaction of reporting requirements.

1. Initial Report - The first report from a manufacturer to CDRH on a particular model of product. It must provide complete information on the manufacturing and testing program that a manufacturer is employing.

2. Supplemental Report - A report that provides details of any additions, deletions, corrections, or changes to information previously submitted in an initial report. Reports of this type are to be designated as supplements to the report (referenced by CDRH Accession Number and submission data) where the information being changed was previously submitted.

3. "Access panel" means any barrier or panel which is designed to be removed or opened for maintenance or service purposes, requires tools to open, and permits access to the interior of the cabinet.

4. "Aperture" means any opening in the outside surface of the cabinet, other than a port, which remains open during generation of x-radiation.

5. "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure (hereinafter termed "cabinet") which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated; provide radiation attenuation, and exclude personnel from its interior during generation of x-radiation. It would include all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

6. "Door" means any barrier which is designed to be movable or opened for routine operation purposes, does not generally require tools to open, and permits access to the interior of the cabinet. For the purposes of paragraph (c) (4) (i) of this section, inflexible hardware rigidly affixed to the door shall be considered part of the door.

7. "Duty cycle" means the amount of time x-rays can be generated or the number of x-ray pulses that can be generated in any hour, the limit of which is determined by the design of the x-ray system.

8. "Exposure" means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air.

9. "External surface" means the outside surface of the cabinet x-ray system, including the high voltage generator, doors, access panels, latches, controls knobs, and other permanently mounted hardware and including the plane across any aperture or port.

10. "Floor" means the underside external surface of the cabinet.

11. "Ground fault" means an accidental electrical grounding of an electrical conductor.

12. "Port" means any opening in the outside surface of the cabinet which is designed to remain open, during generation of x-rays, for the purpose of conveying material to be irradiated into and out of the cabinet, or for partial insertion for irradiation of an object whose dimensions do not permit complete insertion into the cabinet.

13. "Primary beam" means the x-radiation emitted directly from the target and passing through the window of the x-ray tube.

14. "Safety interlock" means a device which is intended to prevent the generation of x-radiation when access by any part of the human body to the interior of the cabinet x-ray system through a door or access panel is possible.

15. "X-ray system" means an assemblage of components for the controlled generation of x-rays.

16. "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.