GUIDE FOR SUBMISSION OF INFORMATION

ON INDUSTRIAL X-RAY EQUIPMENT

REQUIRED PURSUANT

TO 21 CFR 1002.10

Compiled by:

Office of Compliance

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GUIDE FOR SUBMISSION OF INFORMATION ON INDUSTRIAL X-RAY EQUIPMENT REQUIRED PURSUANT TO 21 CFR 1002.10

This Guide is intended to assist manufacturers in submitting initial reports on industrial x-ray equipment required by 21 CFR 1002.10. It also serves as a basis for review of such reports by the Office of Compliance. Items 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, and 9.0 of the Guide are paragraphs (a) through (i) of 21 CFR 1002.10 respectively. Subparts of these items represent specific information which the Office of Compliance has interpreted as being necessary for the purpose of satisfying, in whole or in part, the reporting requirements of 21 CFR 1002.10.

1.0 21 CFR 1002.10(a) Please confirm that the report is submitted pursuant to paragraph (c)(2) of Section 1002.61.

2.0 21 CFR 1002.10(b) Identify each model of the listed product with sufficient information concerning the manufacturer's code or other system of labeling sufficient to enable the Secretary to determine the date and place of manufacture.

2.1 Please provide the model number of each product covered by your report.

2.2 Identify any system or systems of labeling which can allow the date and place of manufacture to be determined by this office. If this information is coded, please provide the key to the code.

3.0 21 CFR 1002.10(c) Describe the function, operational characteristics affecting radiation emissions, and intended and known uses of each model of the listed product.

3.1 What is the intended use of each model, such as radiography, fluoroscopy, or thickness gauge? Include a statement on portability and include any appropriate equipment literature and a picture or drawing of the product.

3.2 What is the range of the x-ray potential?

3.3 What is the range of the x-ray tube current adjustments?

3.4 What is the maximum rated x-ray tube potential and maximum rated continuous tube current for that potential? For units not rated for continous operation, describe the duty cycle at the maximum rated tube potential.

3.5 Describe the beam divergence and method provided for altering the divergence.

3.6 Describe the material and thickness of the x-ray window.

4.0 21 CFR 1002.10(d) State the standards or design specifications, if any, for each model with respect to electronic product radiation safety.

4.1 What is the design specification for radiation leakage through the tube housing, shutters, collimators, and enclosures. State the electrical operating characteristics, distance and cross-sectional area on which the leakage rate is based?

4.2 Maximum leakage from or around an interlocked component in any position which allows the machine to operate (i.e. door opening) under conditions of any possible service adjustment.

4.3 What are the design specifications with regard to the control system? (i.e on-off, exposure control, control panel security, etc.)

4.4 Describe all service adjustments and procedures that affect radiation leakage and interlock operation.

5.0 21 CFR 1002.10(e) For each model, describe the physical or electrical characteristics such as shielding, or electronic circuitry, etc., incorporated into the product in order that the standards or specifications reported pursuant to paragraph (d) of this section are met.

5.1 Describe the type, thickness, and location of shielding incorporated to reduce radiation levels to the specification described under paragraph (d) of Section 1002.10.

5.2 Describe the mechanism for initiating and terminating x-ray production.

5.3 Is primary beam interruption accomplished by shutter mechanism or by termination of x-ray production?

5.4 Describe the method for resuming operation following primary beam interruption.

5.5 Describe the timing mechanism. Include answers to the following questions:

5.5.1 What is the timer range?

5.5.2 Does the timer indicate elapsed time?

5.5.3 How does timer operation interrupt the primary beam?

5.6 Describe the interlock system and provide circuit diagrams showing interlocks and safety systems. Include answers to the following questions:

5.6.1 What components are interlocked?

5.6.2 What are the electrical and mechanical characteristics?

5.6.3 Are interlock circuits designed to insure that the failure of one component does not result in the failure of the entire system?

5.6.4 Is manual reset at the control panel required following interlock interruption?

5.7 Are warning lights or audible alarms provided to indicate the true status of x-ray generation and shutter position? If so, provide the answers to the following questions:

5.7.1 Do those devices provided fail in such a manner as to render x-ray production impossible?

5.7.2 What are the dimensions, color, and location of warning lights?

5.7.3 Are labels provided to indicate the meaning of the warning lights or audible signals?

5.8 For gaging devices:

5.8.1 What attenuation is provided by the primary beam stop?

5.8.2 Describe the scatter shields if provided.

5.9 Describe the shutter mechanism including:

5.9.1 Automatic or manual operation.

5.9.2 Nature of the closing force.

5.9.3 Fail safe characteristics.

5.9.4 Status indicators (open and closed)

5.9.4.1 Type (lights, mechanical flags, etc.)

5.9.4.2 Fail safe characteristics

6.0 21 CFR 1002.10(f)Describe the methods and procedures employed, if any, in testing and measuring each model with respect to electronic product radiation safety including the control of unnecessary, secondary, or leakage electronic product radiation, the applicable quality control procedure used for each model, and the basis for selecting such testing and quality control procedures.

6.1 Describe any applicable tests or testing procedures used during prototype design and testing to assure electronic product radiation safety.

6.2 Describe any applicable quality control and testing procedures used with regard to in-coming component parts. Include any applicable specifications for x-radiation control which you require your material and/or component suppliers to meet, the nature of these requirements and the degree of control which you exercise over the quality of these products with regard to their x-radiation control or emission characteristics.

6.3 Describe any applicable quality control and testing procedures used during production and assembly of the product to assure the proper assembly and operation of its product with regard to x-radiation safety; eg. shield placement, accuracy of controls, operation of interlocks and other safety features, etc.

6.4 Describe any applicable quality control and testing procedures used after final product assembly to assure that the product meets the design standards or specifications for radiation safety including requirements for leakage radiation and accuracy and proper operation of controls, interlocks, shutters, warning indicators and other product safety features.

6.5 If you install or have any control over the installation of the product including its check-out for proper operation and function, please describe any applicable tests and testing procedures to assure the radiation safety of the product as installed.

6.6 In describing any quality control and testing procedure for leakage radiation include:

6.6.1 Electrical conditions under which the tests are conducted.

6.6.2 Locations and distances at which radiation measurements are made.

6.6.3 Time allowed for each measurement made for quantitative purposes.

6.6.4 Primary beam limitations under which tests are conducted.

6.6.5 Method for determining area of small beams and means of correcting readings for area less than the cross-sectional area of the detector used.

6.6.6 Statement of references if survey method conforms to any published plan.

6.6.7 Summary of results of testing program to date including:

6.6.7.1 Total number of units tested,

6.6.7.2 Proportion of total production tested, and

6.6.7.3 mean, range, and standard deviation of each type of measurement.

6.7 In describing any tests performed on interlocks, shutters, and timers provide a summary of the testing program to date including

6.7.1 Total number tested

6.7.2 Proportion tested

6.7.3 Frequency of rejection

6.8 For any quality control and testing procedures involving sampling or auditing please provide a description of the sampling or auditing procedures including:

6.8.1 Reference to any published acceptance sampling plans.

6.8.2 Description of sampling or auditing schemes used, methods of sample selection, sample size, and lot size from which sample is taken.

6.8.3 Lot and unit rejection criteria.

6.8.4 Corrective actions taken after lot and/or unit rejection.

6.8.5 Proportion of total production inspected.

6.9 For each model, specify instruments by manufacturer and model that are used to make measurements.

6.10 Describe parameters of instruments used to make measurements. Include:

6.10.1 Accuracy

6.10.2 Range

6.10.3 Response time (0-90%)(if applicable)

6.10.4 Effective measurement area (if applicable)

6.10.5 Type of detector (if applicable)

6.10.6 Energy dependence characteristics (if applicable)

6.11 Describe calibration procedures for each measuring instrument including:

6.11.1 Intervals of time between calibration

6.11.2 Name and location of calibration laboratory

6.11.3 Method of calibration including energy of source

6.12 Describe procedures to check measuring instruments for proper operation prior to making measurements (daily check procedures).

6.13 List all corrections made to instrument readings.

7.0 21 CFR 1002.10(g) For those products which may produce increased radiation with aging describe the methods and procedures used, and frequency of testing each model for durability and stability with respect to electronic product radiation safety. Include the basis for selecting such methods and procedures, or for determining that such testing and quality control procedures are not necessary.

7.1 Describe the details of all life testing procedures to:

7.1.1 Measure or evaluate leakage radiation after extended use.

7.1.2 Evaluate the effects of extended use on the operation of mechanical and/or electrical components (shutter, timer, interlock, warning devices, and relays).

7.2 Reference any published plan for life testing procedure used.

7.3 Summarize the results of the life testing program, including these points:

7.3.1 Number of life test cycles or approximate equivalent years of use represented by present data.

7.3.2 Total number of units tested.

7.3.3 Proportion of total production tested.

7.3.4 Component failures, time of failures (or number of life test cycles) and means of correction.

7.4 If durability and stability tests are not conducted, provide documentation of the basis for determining that such testing and quality control procedures are not necessary.

8.0 21 CFR 1002.10 (h) Provide sufficient results of the testing and measuring of electronic product radiation safety and of the quality control procedures described in accordance with paragraphs (f) and (g) of this section to enable the Secretary to determine the effectiveness of the methods and procedures used to accomplish the stated purposes.

9.0 21 CFR 1002.10 (i) Report for each model, all warning signs, labels and instruction, for installation, operation, and use which relate to electronic product radiation safety.

9.1 Please provide a copy or picture of all warning signs or labels applied to or supplied with each model.

9.2 Provide a copy of all instructions for installation, operation and use which relate to x-radiation safety. If only a portion or portions of a supplied document relate to x-radiation safety, please specify the appropriate portions.