GUIDE FOR SUBMISSION OF INFORMATION ON ACCELERATORS INTENDED TO EMIT X-RADIATION REQUIRED PURSUIANT TO 21 CFR 1002.10

Compiled by:
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GUIDE FOR SUBMISSION OF INFORMATION ON ACCELERATORS INTENDED TO EMIT X-RADIATION REQUIRED PURSUANT TO 21 CFR 1002.10

This Guide is intended to assist manufacturers in submitting initial reports on accelerators intended to emit x radiation required by 21 CFR 1002.10. It also serves as a basis for review of such reports by the Division of Standards Enforcement. All questions apply to the medical and nonmedical use of accelerators unless otherwise noted. 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 Division of Standards Enforcement 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) of Section 1002.61

2.0 21 CFR 1002.10(b) Identify each model of the listed product together 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 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 model of the listed product.

3.1 Describe the intended use of each model and include product data sheets such as material used for promotional sales, specification sheets, etc.

3.2 What type of high voltage generator is employed in the accelerator?

3.3 Describe the timing mechanism or other means for selecting or measuring the irradiation time.

3.4 If the unit has a shutter mechanism, indicate whether it is manual or automatic, the source of the force for closing, the position indicators and the interlocks and method(s) for failsafe operation.

3.5 Describe the rated x-ray beam parameters. Include for each target material available, the maximum energy, the continuous current, the repetition rate and pulse duration for pulsed units, the exposure rate at specific distances, the spatial distribution for various modes of operation, and other beam quality information.

For medical accelerators only:

3.6 For the timing mechanism, what is the minimum and maximum elapsed time, and the accuracy and reproducibility under each available timing mode?

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 are the specific design parameters which cause interlock operation, and are there any failsafe devices incorporated with these?

4.2 What limits do you place on unnecessary leakage, secondary and scatter radiation such as may be found from the target housing collimator, power supply, the RF section, or dark current, where applicable.

For medical accelerators only:

4.3 What are the exposure reproducibility design standards and timer mechanism accuracy in this model?

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 specification reported pursuant to paragraph (d) of this section are met.

5.1 Is there a conspicuously marked switch which can be used to terminate exposure? How is exposure restored after this switch is used?

5.2 What features insure that operation of the unit does not cause emission of either primary or any secondary radiation at levels exceeding design specifications?

5.3 What control panel security is provided?

5.4 What control panel indicators exist which specify the status of the unit's various active components?

5.5 What warning systems are utilized in this model?

5.6 What switches, meters, lights, etc., are incorporated in this model which assure the operator of the present operating mode of this unit?

5.7 What methods are used to limit the useful beam and to control unnecessary leakage, secondary and scatter radiation?

5.8 What shielding is provided (when applicable) for klystrons, magnetron tubes, or other components capable of emitting radiation, outside the useful beam?

5.9 What arrangements are available for connecting interlock switches into the control panel?

5.10 In what portion of the circuitry do the interlocks function? Provide diagrams.

5.11 Describe the interlock position indicators provided.

5.12 Is it necessary to bypass the interlocks for any operating procedure that you recommend? What indicators are there to caution the operator that the interlocks have been bypassed? What procedure is required to operate unit when interlocks fail or are bypassed?

5.13 After an interlock operation, how is exposure restored?

<u>For medical accelerators only:</u>

5.14 If a particle beam can be extracted from the unit, what methods are used to insure that it is contained within the unit when only x rays are desired? How completely is it contained? How is the type of external beam indicated to the operator?

5.15 What means are used to attain the exposure reproducibility and timer accuracy standards or design specifications?

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 procedures 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 incoming component parts. Include any applicable specifications for 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 radiation control or emission characteristics.

6.3 Specifically provide the requested description and information for testing and measuring:

6.3.1 The maximum energy x-ray beam
6.3.2 The continuous current
6.3.3 The repetition rate and pulse duration
6.3.4 The exposure rate
6.3.5 The spatial distribution
6.3.6 Timer accuracy and exposure reproducibility

6.4 Provide details of all test procedures to measure, evaluate, or control electronic product radiation including unnecessary, secondary, scatter, or leakage radiation. This should include:

6.4.1 Types of tests conducted
6.4.2 Parameters monitored
6.4.3 Electrical conditions under which tests are conducted
6.4.4 Adjustments, if any, made during tests and how these adjustments are made
6.4.5 Locations and distances at which radiation measurements are made
6.4.6 Scanning speed, scanning pattern and time allowed for each measurement made for quantitative purposes

6.5 Do the methods of survey used conform to any published reference?

6.6 What are the test methods and results of testing timing devices, interlocks and shutters.

6.7 Describe the instruments that are used to make measurements. Give manufacturer and model if commercially available. If not, include the following parameters:

6.7.1 Accuracy
6.7.2 Ranges
6.7.3 Response
6.7.4 Response pattern
6.7.5 Effective measurement area
6.7.6 Type of detector
6.7.7 Energy and/or frequency dependence of detector (if applicable)

6.8 Indicate procedures used for calibration of measuring instruments. Include:

6.8.1 Intervals of time between calibration
6.8.2 Name and location of calibration laboratory
6.8.3 Accuracy of calibration
6.8.4 Method(s) of calibration

6.9 What are the procedures used to check instruments for proper operation prior to making measurements (daily check procedure)?

6.10 What are the methods used to interpret measurements and the basis for using these methods?

6.11 Summarize the results of testing program to date? This should include:

6.11.1 Time period represented in results presented
6.11.2 Total number of units tested
6.11.3 Proportion of total production
6.11.4 Mean, range, and standard deviation of measurements

6.12 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.

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 Specifically, describe the methods and results of testing for induced radioactivity of accelerator components following prolonged high energy bombardment.

7.2 Provide details of any other life testing procedures to measure, evaluate, or control radiation, including unnecessary, secondary, scatter, leakage radiation, and exposure reproducibility. This should include:

7.2.1 Type of tests conducted
7.2.2 Parameters monitored
7.2.3 Electrical conditions under which tests are conducted
7.2.4 Adjustments, if any, made during tests and how these adjustments are made
7.2.5 Locations and distances at which radiation measurements are made
7.2.6 Scanning speed, scanning pattern, and time allowed for each measurement made for quantitative purposes
7.2.7 Time duration of the testing program including equivalent years of use

7.3 Summarize the results of the life testing program to date. This should include:

7.3.1 Time period represented in results presented
7.3.2 Total number of units tested
7.3.3 Proportion of total production tested
7.3.4 Mean, range, and standard deviation measurements
7.3.5 Component failures, time of failure, and means of correction, effect of correction on radiation emission, if any

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 instructions for installation, operation, and use which relate to electronic product radiation safety.

9.1 Does your instruction manual present to your purchasers specific guidelines for use in relation to radiation safety? Please provide a copy of the instruction manual or the reference to these guidelines.

9.2 What recommendations are made to service personnel or users to insure the continued proper performance and safety of the units?

9.3 What material in the form of signs, labels, or instructions are supplied for post-production safeguarding against improper installation, misalignment, or removal of safety devices and shields.

9.4 Where do you affix all labels and other certifications required by published recommendations related to radiation safety.

9.5 What consultation or service do you offer to the purchaser?