GUIDE FOR PREPARING PRODUCT REPORTS FOR LASERS AND PRODUCTS CONTAINING LASERS

September 1995

(Address corrections Aug. 2008)

U.S. Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

FOREWORD

This guide was developed by the Office of Compliance, Center for Devices and Radiological Health (CDRH), to assist electronic product manufacturers in providing adequate reporting of radiation safety testing and compliance with performance standards. Reporting requirements are specified in Title 21 of the Code of Federal Regulations (CFR), Part 1002.

Reports submitted on radiation safety of electronic products must follow the appropriate guide (21 CFR 1002.7), or contain a justification why it was not followed. CDRH may reject an incomplete report and return it for completion. When the report is adequate for filing, it will be logged into the CDRH computer system and assigned an accession number. 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.

WE DO NOT APPROVE THESE REPORTS OR THE PRODUCTS BEING REPORTED. It is the manufacturer's responsibility to certify that their products comply with the applicable standard (21 CFR 1010 - 1050), based on a testing program in accordance with good manufacturing practices. The manufacturer is required to submit the report (21 CFR 1002) and to comply with all applicable importation requirements (21 CFR 1005) prior to the shipment of products in interstate commerce. If there are deficiencies, we may disapprove the firm's quality control and testing program or determine that the product contains a radiation defect or fails to comply with a standard. We will notify the manufacturer if we make such a determination. Then the manufacturer may be required 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.

We are making our reporting guides available on the CDRH web site at http://www.fda.gov/cdrh/comp/eprc.html, for downloading and reproduction. They are not copyrighted and may be reproduced as needed.

Please mail your reports to the address below (electronic submissions cannot be processed yet). Provide one original IN ENGLISH (no facsimile, please) unless specified otherwise in the guide. Make a copy of the completed report for your records. If you would like to comment on the reporting guides or the electronic docket or future electronic submissions, you may direct the comments to the same

address. If you need additional regulations for electronic products or medical devices, contact the Division of Small Manufacturers, International, and Consumer Assistance by telephone at 1-800-638-2041 or 301-443-6597, or by facsimile at 301-443-8818.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance

MAILING ADDRESS:

Center for Devices and Radiological Health
Attn: Electronic Product Reports
Electronic Product Document Control (HFZ-309)
Office of Communication, Education, and Radiation Programs
9200 Corporate Blvd.
Rockville MD 20850

PREFACE

Manufacturers of products subject to performance standards under the Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C - Electronic Product Radiation Control are required to furnish various reports to the Center for Devices and Radiological Health (CDRH). This guide is for use by manufacturers of lasers and products containing lasers in preparing Product Reports as required by paragraph 1002.10 and 1002.11 of Title 21 CFR (Code of Federal Regulations).

This reporting guide incorporates all current changes and should be used in conjunction with the companion publication, "Compliance Guide for Laser Products." You should read and understand that guide and determine how your product complies with the regulations before completing this report. To further assist you, relevant Sections of Title 21 CFR are cited in parentheses throughout this guide.

If you have specific questions, write to the Electronic Products Branch, Office of Communication, Education and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, or call (240) 276-3332.

I. Paul Leggett, Chief
Electronic Products Branch
Division of Enforcement III
Office of Compliance

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GENERAL INSTRUCTIONS

Product Reports, Supplemental Reports, and Abbreviated Reports must be submitted to the Center for Devices and Radiological Health (CDRH) at the address on the following page prior to introduction of the reported products into commerce. (This includes products imported into the U.S.)

This guide should be followed for all lasers and products containing, incorporating, or intended to incorporate, a laser or laser system [see the definition of "laser product" in section 21 CFR 1040.10(b)(21)]. A separate guide for reporting additional information concerning laser light shows is being published concurrently with this guide and must be used in conjunction with this guide when appropriate (Reporting Guide for Laser Light Shows and Displays).

A complete Product Report is required for each laser product model or model family. Product Reports were formerly called Initial or Model Change Reports. Since these reports contain essentially the same information, the single term, Product Report, is now used. CDRH suggests that a complete report on one model of a family be submitted, with a separate Supplemental Report for each of the other models in the family. The Supplemental Report should respond in detail to the parts of the guide where there are differences to report, referencing the number of the affected item. Items that are unchanged need only be referenced to the original report.

A new or modified model belonging to a previously reported model family must be reported in a Supplemental Report on that model family prior to its introduction into commerce.

If an individual item or requirement of the standard is not appropriate for the laser product, so indicate. In general, any aspect of the product that pertains to radiation safety should be reported, including aspects not covered by the guide, such as special use conditions; other controls, indicators or warnings; and aspects for which there are no applicable provisions in sections 1040.10 and 1040.11.

Much of the information requested in this guide can be given in the space provided. Where attachments are required, so indicate in the space provided in the body of the guide. Attachments should be clearly numbered the same as the specific part of the guide to which they are addressed. For example, an attachment responding to Part 3.2 should be labeled "Attachment 3.2."

The report for each laser product model family should be complete and separable from the reports for other model families. However, certain information to be reported may be the same for two or more model families, such as quality control and testing programs, instrumentation, and calibration procedures. Such information may be fully reported in one model family report and referenced in another.

If this is done, the reference must be clear and unambiguous, including the CDRH accession number, date, and item number.

The manufacturer must be sure that referenced information is accurate, current, and applicable to the reported models. Information that is applicable to more than one model family, but cannot be referenced in accordance with the above guidance, should be duplicated and included in each report.

When new models of a laser product are introduced, if the models satisfy the criteria for an established reporting exemption or if the new models do not involve changes in radiation emission or performance requirements, then the manufacturer need not report the models prior to introduction into commerce. Rather, the manufacturer is only required to identify them in the annual report, or in quarterly updates to the annual report. Quarterly updates to annual reports should be clearly marked as such and be submitted prior to October 1, December 1, March 1, and/or June 1 when required. [See 21 CFR 1002.13(c).]

All symbols, units, and unusual terms in the report must be adequately defined and consistently used. Please use the terms as defined in Section 1040.10(b) and in the IEEE Standard Dictionary of Electrical and Electronic Terms (IEEE Std. 1001972 and ANSI C42.1001972).

All reports and correspondence must be addressed to:

Center for Devices and Radiological Health
ATTN: Electronic Product Reports
Electronic Product Document Control (HFZ-309)
9200 Corporate Blvd.
Rockville, MD 20850

When a report is received at CDRH, a unique accession number will be assigned for future reference. The submitter will be informed of the accession number in a letter of acknowledgment, which should not be construed as a technical review of the report. The report will be reviewed by CDRH technical staff as soon as possible and the submitter will be advised of the results. Clearly identify Supplemental Reports with the accession number of the relevant Product Report.

The Product Reporting Guides and Annual Reporting Guides are available from the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) in Rockville, Maryland at 1-800-638-2041. DSMICA should be contacted for requests of any current documents, including information on medical device approval procedures, registration & listing of medical devices, and the reporting guides mentioned here. If you have specific questions regarding regulations or filling out these reports, call the Electronic Products Branch at (240) 276-3332.

DEFINITIONS

NOTE: These definitions have been revised.

PRODUCT REPORT (21 CFR 1002.10) - A Product Report is a report submitted by a manufacturer of a regulated product, e.g., laser products, sunlamps, TV. The Product Report describes the product, details how the product complies with the standard, and explains the quality control program to assure compliance. A Product Report can be used for families of products as well as for individual products.

SUPPLEMENTAL REPORT (21 CFR 1002.11) - A Supplemental Report provides information supplementary to a previously submitted Product Report. It is used to report a new model in a previously reported model family, a modification of a previously reported model, or other changes to a previous report (e.g., changes in testing programs, additions or changes in user or service manuals, responses to CDRH report review letters).

Supplemental Reports are also required for changes that:

a. affect actual or potential radiation emission,

b. affect the manner of compliance with a standard or affect the manner of testing for radiation safety.

Supplemental Reports should clearly reference the CDRH accession number of the Product Report and the appropriate sections of this guide.

ANNUAL REPORT (21 CFR 1002.13) - An Annual Report summarizing the required records must be submitted by September 1 for the 12 months ending on June 30 of the same year. In addition, the Annual Report is the appropriate vehicle for identifying new models for which Supplemental Reports are not required. If the new models do not involve changes in radiation emission or performance requirements, then the manufacturer need only identify them in their annual report, or in quarterly updates to the annual report. Copies of the annual report form to be followed are available from DSMA by calling 1-800-638-2041.

MODEL FAMILY - A model family is a group of two or more laser product models with basically similar design, performance features and intended function, manufactured under the same or very similar quality control and testing procedures. Models within the same family may have different outputs and different laser media and, in some cases, may belong to different classes.

Applicability of reporting and recordkeeping requirements for laser products:

Class I, IIa, II, and IIIa lasers and laser products containing such

lasers will require: Product Report, Annual Report, test records, and (for all except Class I lasers) manufacturer's distribution records.

Note that for these classes no Supplemental Reports are required. Furthermore, some Class I laser products have already been exempted from the requirement for distribution records (see Notice to Industry dated August 9, 1988, Laser Notice # 41).

Class IIIb and IV laser products, and products containing such lasers, require all of the above plus Supplemental Reports when the criteria requiring submission of Supplemental Reports are met.

LASER PRODUCT REPORT

PART 1: MANUFACTURER AND REPORT IDENTIFICATION

1.1 Manufacturer:

Manufacturing Firm:

Address:

Corresponding official:

Signature:

Name & title:

Telephone number:

Firm's Prime Contact or Responsible Person if different from above:

Name & title:

Telephone number:

1.2Importing agent (For manufacturers exporting to the U.S., see 21 CFR 1005.25.):

Signature:
(Or attach copy of written agreement with agent)

Name & title:

Address:

Telephone number:

1.3 Report type: ( ) Laser Product Report, or

( ) Supplement to CDRH Accession No.:

submitted on (date):

1.4 Date of this report:

PART 2: PRODUCT AND MODEL IDENTIFICATION

2.1 List all names, brand names, model numbers and model family designations of the laser product being reported. If the product is sold by other companies under different brand names, also give the names and addresses of the companies, the brand names, and the model numbers, and indicate how the brand names and model numbers correspond with your own brand names and model numbers.

2.2 Is your laser product the result of the modification of a laser product certified by another manufacturer? [see 1040.10(i)]

( ) Yes ( ) No

If yes, identify the manufacturer(s), brand(s), and model number(s).

NOTE: MODIFICATION INVOLVES ANY CHANGES TO THE PRODUCT THAT AFFECT ITS CLASSIFICATION, PERFORMANCE OR LABELING REQUIREMENTS (as required by the standard or an approved variance).

2.3 Does your laser product incorporate an unmodified, certified laser product?

( ) Yes ( ) No

If yes, identify the manufacturer(s), brand(s), and model number(s).

2.4 Does your product incorporate a noncertified laser product?

( ) Yes ( ) No

If yes, identify the manufacturer(s), brand(s), model(s), and describe the type of product.

2.5 Does your laser product incorporate a removable laser system or systems as defined in 1040.10(c)(2)?

( ) Yes ( ) No

If yes, identify the manufacturer(s), brand(s), and model number(s).

2.6 If the laser product, as introduced into commerce, is not supplied with a laser or laser system or the product does not incorporate a laser or laser system, report by manufacturer and model number which laser or laser system, if any, is recommended by you for use with the product.

2.7 If you do not recommend a specific laser or laser system for use with the reported product, state the specifications of the laser or laser system to be incorporated.

PART 3: COMPLIANCE WITH THE LABELING REQUIREMENTS

For each of the following labels required for the product being reported, provide a sample or a facsimile of each label. Clearly indicate the locations on the product of all required labels in your response to this Part or to Part 5. Reference to diagrams, photographs, blueprints, product literature, etc., is acceptable. See Compliance Guide, page 7, for assistance.

3.1Certification label - Required on all laser products (1010.2).

Is the label (or a copy) submitted with this report?

( ) Yes ( ) No

Location on product:

3.2Identification label - Required on all laser products (1010.3).

Is the label (or a copy) submitted with this report?

( ) Yes ( ) No

Location on product:

3.3Warning logotype - Required on Class II, III, and IV laser products. [1040.10(g)(1), (2),(3),(4),(8),(9),(10)].

Is the label (or a copy) submitted with this report?

( ) Yes ( ) No

Location on product:

3.4Warning label - Required on Class IIa laser products [1040.10(g)(1)(i)].

Is the label (or a copy) submitted with this report?

( ) Yes ( ) No

Location on product:

3.5Aperture label(s) - Required on Class II, III and IV laser products [1040.10(g)(5),(8),(9),(10) or 1040.11(a)(3)].

Are the label(s) (or copies) submitted with this report?

( ) Yes ( ) No

Location on product:

3.6Label(s) for noninterlocked protective housings [1040.10(g)(6),(8),(9),(10)].

Are the label(s) (or copies) submitted with this report?

( ) Yes ( ) No

Location on product:

Are the label(s) visible both prior to and during opening or removal of housing? ( ) Yes ( ) No

3.7Label(s) for defeatably interlocked protective housings [1040.10(g)(7),(8),(9),(10)].

Are the label(s) (or copies) submitted with this report?

( ) Yes ( ) No

Location on product:

Are the label(s) visible both prior to and during interlock defeat? ( ) Yes ( ) No

3.8Label(s) for optionally interlocked protective housings. (See Laser Notice of March 2, 1977, dealing with optional interlocks.)

Is the label (or a copy) submitted with this report?

( ) Yes ( ) No

Location on product:

Are labels visible both prior to and during opening or removal of the housing? ( ) Yes ( ) No

NOTE: IF THE LABELING REQUIREMENTS ARE INAPPROPRIATE TO YOUR PRODUCT, YOU MAY APPLY FOR APPROVAL OF ALTERNATE LABELING. See sections 1010.2, 1010.3, and 1040.10(g)(10).

PART 4: COMPLIANCE WITH THE INFORMATIONAL REQUIREMENTS

4.1 Submit copies of user and servicing information (operator and service manuals) for your laser product. If the manuals are very extensive, submit those portions that confirm compliance with Section 1040.10(h) [and 1040.11(a)(2), if a medical laser product] and that permit understanding how your laser product functions. See Compliance Guide, page 8, for assistance.

Are copies of user and service information attached to this report?
( ) Yes ( ) No

If "Yes," please identify attachment:

If "No," explain why:

NOTE: THESE MATERIALS MAY ALSO BE USED IN THE PRODUCT DESCRIPTION required by Part 5.

4.2 Submit copies of any catalogs, specification sheets, and descriptive brochures for Class IIa, II, III, and IV laser products.

Are copies of catalogs, specification sheets, or brochures attached to this report?
( ) Yes ( ) No

If "Yes," please identify attachment:

If "No," explain why:

NOTE: THIS MATERIAL IS NEEDED TO DEMONSTRATE COMPLIANCE WITH Section 1040.10(h)(2), which states that a reproduction of the warning logotype is required in all catalogs, specification sheets, and descriptive brochures.

PART 5: DESCRIPTION OF THE PRODUCT

5.1 Describe the product and its function. You may refer to brochures and manuals submitted with this report. Please include drawings or photographs adequate to document compliance of the product with the performance and labeling requirements.

Is a product description attached to this report?

( ) Yes ( ) No

Please identify attachment:

5.2 Describe the external and internal laser radiation fields and paths. Beam path diagrams indicating protective housing, beam attenuators, viewports, scanners, targets, etc. would be helpful. Please identify external and internal laser power or energy levels where applicable.

Are description and diagrams of the laser radiation fields and paths attached?

( ) Yes ( ) No

Please identify attachment:

5.3 List the procedures performed during OPERATION and indicate those collateral and laser radiation fields specified in Part 6 to which human access is possible when those procedures are being performed. [See definition of human access - Section 1040.10(b)(15)].

Operational procedures and accessible radiation:

5.4 List the procedures performed during MAINTENANCE and indicate those collateral and laser radiation fields specified in Part 6 to which human access is possible when those procedures are being performed. See the definition of maintenance in section 1040.10(b)(24) and Compliance Guide, page 5.

Maintenance procedures and accessible radiation:

5.5 List the procedures performed during SERVICE and indicate those collateral and laser radiation fields specified in Part 6 to which human access is possible when those procedures are being performed.

Service procedures and accessible radiation:

PART 6: LEVELS OF ACCESSIBLE LASER RADIATION AND CLASSIFICATION OF THE LASER PRODUCT

6.1Give the specifications of all laser radiation fields described in Part 5 to which human access is possible during OPERATION. See Section 1040.10(e) for measurement parameters. Indicate whether the values are measured or based on calculations. Whether measured or calculated, please provide a diagram of your measurement/calculation set-up, and pertinent dimensions such as separation distances, source and detector aperture size, etc. in order to show how your measurements or calculations are in accordance with 1040.10(e).

Please provide as much of the following as is appropriate to your product:

wavelength(s): nm

maximum average radiant power: W

beam divergence: degrees/radians

beam diameter at laser aperture: mm

IF PULSED: pulse energy: J

peak power: W

pulse duration: sec

repetition rate:

IF APPLICABLE:

maximum irradiance or radiant exposure: W or J cm-2

max. radiance or integrated radiance: W or J cm-2 sr-1

Are measurement parameters, diagrams, calculations, and/or specifications submitted as an attachment to this report?

( ) Yes - Please identify attachment:

( ) No

6.2 Indicate the Class of the laser product, based on your response to Part 6.1.

( ) Class I ( ) Class IIa ( ) Class II

( ) Class IIIa ( ) Class IIIb ( ) Class IV

6.3 Give the specifications of all possible laser radiation fields described in Part 5 to which human access is possible during MAINTENANCE.

Are specifications attached? ( ) Yes ( ) No

6.4 Give the specifications of all possible laser radiation fields described in Part 5 to which human access is possible during SERVICE.

Are specifications attached? ( ) Yes ( ) No

6.5 Describe all collateral radiation associated with the product. Report the source(s) and levels and describe where and under what circumstances such radiation is accessible.

Is description attached? ( ) Yes ( ) No

PART 7: COMPLIANCE WITH THE PERFORMANCE REQUIREMENTS

7.1 Protective housing - Required for all laser products [1040.10(f)(1)]

7.1.1 Describe the product's protective housing and how it serves to prevent unnecessary human access to laser radiation.

Is additional information attached? ( ) Yes ( ) No

7.1.2 Describe how the protective housing prevents access to unnecessary collateral radiation.

Is additional information attached? ( ) Yes ( ) No

7.2 Safety interlocks - Applicable for all laser products [1040.10(f)(2)(i)]

7.2.1 Provide a detailed mechanical diagram showing the location of each interlock incorporated into the laser product for radiation safety.

Is a mechanical diagram attached? ( )Yes ( )No

Describe each interlock and explain how each such interlock prevents access to laser and/or collateral radiation when each portion of the protective housing is opened.

Is additional information attached? ( ) Yes ( ) No

7.2.2 Provide an electrical block diagram illustrating the logic of the interlock system.

Is an electrical diagram attached? ( ) Yes ( ) No

7.2.3 For each safety interlock, state whether actuation is intended during operation, maintenance, service, or any combination thereof.

Is additional information attached? ( ) Yes ( ) No

7.2.4 For each safety interlock, state the highest level of laser radiation and collateral radiation to which access is prevented.

7.3 Defeatable safety interlocks - Applicable to all laser products [1040.10(f)(2)(ii) and (iii)]

7.3.1 Identify which safety interlocks are designed to allow defeat and describe how they operate.

Is additional description attached? ( ) Yes ( ) No

7.3.2 For each safety interlock designed to allow defeat, state whether defeat is intended during operation, maintenance, service, or any combination thereof.

7.3.3 For each safety interlock designed to allow defeat, describe how replacement of a removed or displaced portion of the protective housing is not possible while the safety interlocks are defeated.

7.3.4 For each safety interlock designed to allow defeat, describe the means of providing a visible or audible indication of defeat.

7.4 Safety interlock failure - Applicable to all required safety interlocks [1040.10(f)(2)(iii)] that prevent access to Class IIIb or IV levels of laser radiation.

7.4.1 Describe how each safety interlock is "fail-safe," i.e., precludes removal or displacement of the interlocked portion of the protective housing upon failure of the safety interlock or is redundant.

Are electrical/mechanical diagrams or additional information attached?
( ) Yes ( )No

7.4.2 Describe the possible modes of failure of each safety interlock and the resultant effect upon the radiation safety of the laser product.

Is additional information attached? ( ) Yes ( ) No

7.4.3 State the rating of each safety interlock, including the number of operational cycles before failure.

7.5 Remote interlock connector - Applicable to Class IIIb or IV laser systems [1040.10(f)(3)]

7.5.1 Describe the electrical and mechanical construction and operation of the remote interlock connector. Give its circuit and physical location.

Are electrical/mechanical diagrams or additional information attached?
( ) Yes ( ) No

7.5.2 Record the open-circuit electrical potential difference between the terminals of the remote interlock connector.

Volts

7.6 Key control - Required for Class IIIb or IV laser systems [1040.10(f)(4)]

7.6.1 Describe the electrical and mechanical construction of the key-actuated master control.

Are electrical/mechanical diagrams or additional information attached?
( ) Yes ( ) No

7.6.2 Describe the function of the key-actuated master control and how it renders the laser inoperable when the key is removed.

Are electrical/mechanical diagrams or additional information attached?
( ) Yes ( ) No

7.6.3 Is the key removable in the "On" position?
( ) Yes ( ) No

7.7 Laser radiation emission indicator - Required for Class II, IIIa, IIIb, or IV laser systems [1040.10(f)(5)]

7.7.1 Describe in detail the mechanical and electrical characteristics of all emission indicators installed pursuant to Section 1040.10(f)(5)(i) or (ii) and give their locations. Note that if the energy source and remote controller(s) are separable by more than 2 meters, then each control must have an emission indicator.

Are electrical/mechanical diagrams or additional information attached?
( ) Yes ( ) No

7.7.2 Record the length of time each emission indicator of Class IIIb and IV laser systems is actuated prior to the emission of accessible laser radiation.

Emission indicator delay: sec

7.8 Protective eyewear - Applicable to Class II, IIIa, IIIb or IV laser systems [1040.10(f)(5)(iv)]

State whether protective eyewear is supplied or recommended for use with the laser system. If so, confirm that any visible emission indicator can be clearly seen through the protective eyewear.

Is protective eyewear supplied? ( ) Yes ( ) No

Is it recommended? ( ) Yes ( ) No

Can visible emission indicators be seen through eyewear?

( ) Yes ( ) No

7.9 Beam attenuator - Required for Class II, IIIa, IIIb or IV laser systems [1040.10(f)(6)]

7.9.1 For each beam attenuator, describe the mechanical and electrical characteristics and how, when actuated, the attenuator prevents access by any part of the human body to all laser and collateral radiation in excess of the accessible emission limits of Class I and Table VI.

Are electrical/mechanical diagrams or additional information attached?
( ) Yes ( ) No

7.9.2 Describe the permanency of attachment of each beam attenuator.

NOTE: YOU MAY APPLY FOR APPROVAL OF ALTERNATE MEANS of providing this protection if a beam attenuator is inappropriate to the product.

7.10 Location of controls - Applicable to Class II, IIIa, IIIb or IV laser products [1040.10(f)(7)]

Explain how the location of each of the operation and adjustment controls of the laser product is such that human exposure to laser or collateral radiation in excess of the accessible emission limits of Class I and Table VI is prevented during operation or adjustment of such controls.

7.11Viewing optics - Applicable to all laser products [1040.10(f)(8)]

7.11.1State whether all laser and collateral radiation accessible by virtue of viewing optics, viewports, and display screens incorporated into the reported model of laser product is less than the accessible emission limits of Class I and Table VI during operation and maintenance. Include with your calculations pertinent attenuation factors, window transmission characteristics, etc.

Are electrical/mechanical diagrams or additional information attached?
( ) Yes ( ) No

REMINDER: Report in Part 5 the location and identification of laser and collateral radiation made accessible by viewing optics, viewports, and display screens. In Part 6, report the highest levels.

7.11.2Describe in detail, using diagrams or photographs and radiation transmission or reflection spectra, each shutter or variable attenuator incorporated into viewing optics, viewport, or display screen. Describe how exposure of the eye to laser or collateral radiation in excess of the accessible emission limits of Class I and Table VI is prevented whenever the shutter is opened or the attenuator is varied.

Are diagrams/photographs or additional information attached?
( ) Yes ( ) No

7.11.3 Describe how exposure of the eye to laser or collateral radiation in excess of the accessible emission limits of Class I and Table VI is prevented in the event of failure of the shutter or variable attenuator, as required by Section 1040.10(f)(8)(ii).

Are diagrams or additional information attached?

( ) Yes ( ) No

7.12 Scanning safeguard - Required for certain laser products with scanned laser radiation [1040.10(f)(9)].

Describe the mechanical, electrical, and functional characteristics of any required scan failure safeguard. Include calculations to show that the safeguard's reaction time is adequate for compliance with this section.

Are electrical/mechanical diagrams, calculations, or additional information attached?

( ) Yes ( ) No

NOTE: A SAFEGUARD IS REQUIRED WHEN SCAN FAILURE WOULD CAUSE THE PRODUCT TO EXCEED THE EMISSION LIMITS OF THE CLASS OF THE PRODUCT, OR in the case of Class IIIb or IV laser products WOULD CAUSE THE ACCESSIBLE EMISSION LIMITS OF Class IIIa TO BE EXCEEDED.

7.13 Manual reset - Applicable to Class IV laser systems manufactured after August 20, 1986.

Provide the circuit and physical description and location of the means provided to require manual restart following interruption of emission caused by power failure of at least 5 seconds or deactivation through the remote interlock connector.

7.14 Medical laser product - Applicable to Class III or IV medical laser products intended for in-vivo surgical, therapeutic, or diagnostic irradiation of the human body.

NOTE: THE REQUIREMENT IN Section 1040.11(a) DOES NOT APPLY TO VISIBLE AIMING BEAMS LESS THAN THE ACCESSIBLE EMISSION LIMITS OF Class IIIa except for ophthalmic indications.

If your product is a Class III or IV medical laser product, provide the following information:

7.14.1 Describe the means incorporated into the product to measure the level of laser radiation intended for irradiating the human body; include circuit diagrams and/or optical system diagrams.

Are electrical/mechanical diagrams, calculations, or additional information attached?

( ) Yes ( ) No

7.14.2 Specify the uncertainty in the measurement system and describe the method by which it was derived.

Are calculations or additional information attached?

( ) Yes ( ) No

7.14.3 Is the displayed power/energy level measured at the point of delivery or earlier and then calculated? If the displayed level is calculated incorporating system constants, losses, attenuation factors, etc. please provide calculations to demonstrate accurate calibration of the delivered beam to within + or - 20%, as required by 1040.11(a)(1).

Are calculations or additional information attached?

( ) Yes ( ) No

7.14.4 Are procedures and a schedule for recalibration of the measurement system included in the user instructions?

( ) Yes ( ) No

If yes, please identify location in the user instructions:

7.15 Surveying, leveling, or alignment laser products - Is the product a surveying, leveling, or alignment laser product?

( ) Yes ( ) No

If yes, then it is subject to the requirements of section 1040.11(b). If the product's class exceeds Class IIIa then an approved variance from the performance requirements in this section would be necessary prior to introduction into commerce. Procedures for applying for a variance are given in section 1010.4, and described in the Compliance Guide, page 13.

7.16 Demonstration laser products - Is the product a demonstration laser product? ( ) Yes ( ) No

If yes, then it is subject to the requirements of section 1040.11(c). If the product's class exceeds Class IIIa then an approved variance from the performance requirements in this section would be necessary prior to introduction into commerce. Procedures for applying for a variance are given in the Compliance Guide, pages 13 and 16-22.

An Application for a Variance from 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device (form FDA 3147) must be submitted, following the instructions on the form. A Laser Light Show report may also be required if you intend to produce shows or displays with Class IIIb or Class IV demonstration laser products. The Reporting Guide for Laser Light Shows and Displays should be filled out and submitted along with this report and the variance application, following the instructions in each document.

7.16.1 Is a Variance application being submitted along with this report?

( ) Yes - date of submission: ( ) No

7.16.2 Is a Laser Light Show report being submitted along with this report?

( ) Yes - date of submission: ( ) No

PART 8: QUALITY CONTROL TESTS AND TESTING PROCEDURES

8.1 Attach, and identify as attachments to Part 8, samples of documents that describe, specify, or relate to procedures or tests used to ensure compliance of your reported product with the standard, including compliance with all performance, labeling, and informational requirements. These may include:

( ) specification controls for critical components,

( ) manufacturing and assembly control procedures,

( ) inspection and test control procedures,

( ) assembly and test traveler forms,

( ) inspection and test reports and checklists, and/or

( ) other(s) (specify):

8.2 If formal quality control and testing procedures have not been implemented or are not sufficient to assure that your product(s) will comply with the standard, explain how you assure that your products comply and submit supporting documentation.

NOTE: Section 1010.2(c) REQUIRES THAT CERTIFICATION BE BASED ON A TEST, IN ACCORDANCE WITH THE STANDARD, OF EACH UNIT OR ON A PROGRAM IN ACCORDANCE WITH GOOD MANUFACTURING PRACTICES. Failure to maintain an adequate testing program may result in disapproval of the program by CDRH.

PART 9: LIFE AND ENDURANCE TESTING

Describe those tests and controls used to ensure that the reported product will remain in compliance with the Federal laser product performance standard during its useful life. Items to be addressed include:

9.1 Dimensional stability and rigidity of mechanical parts and assemblies such as housings and mounts

Is additional information/documentation attached?

( ) Yes ( ) No

9.2 Design and ratings of electrical and electronic components

Is additional information/documentation attached?

( ) Yes ( ) No

9.3 Environmental stability of components such as filter materials, coatings, and adhesives

Is additional information/documentation attached?

( ) Yes ( ) No

9.4 Design and testing of features designed to meet Federal laser product performance requirements

Is additional information/documentation attached?

( ) Yes ( ) No

9.5 Other factors that might affect your product's radiation safety

Is additional information/documentation attached?

( ) Yes ( ) No

NOTE: MAINTENANCE AND/OR SERVICE INSTRUCTIONS MUST INCLUDE SCHEDULES FOR MAINTENANCE AND REPLACEMENT OF THOSE COMPONENTS RELATED TO THE COMPLIANCE OF THE PRODUCT that may be expected to be replenished or replaced during the life of the product.

PART 10: INSTRUMENTATION AND CALIBRATION

Describe those tests and controls used to ensure that the reported product will remain in compliance with the Federal laser product performance standard during its useful life. Items to be addressed include:

10.1 List the instruments you use to determine compliance of the reported product with the standard. Describe these instruments or provide copies of specification sheets. Identify each detector's aperture size, if applicable.

Is additional information attached? ( ) Yes ( ) No

10.2 Indicate how the measurement system collects or accounts for the total radiant energy or power specified in Section 1040.10(e).

Is additional information attached? ( ) Yes ( ) No

10.3 Provide a measurement error analysis (for all sources of error identified) and an uncertainty statement for all measurement data reported.

Is additional information attached? ( ) Yes ( ) No

NOTE: IF IT IS CLEAR FROM THE MEASUREMENT DATA, INCLUDING THE TOTAL ESTIMATED UNCERTAINTY, THAT THE LEVELS ARE WELL BELOW THE APPLICABLE CLASS LIMIT, THEN AN ERROR ANALYSIS AND UNCERTAINTY STATEMENT ARE NOT REQUIRED. For example, an error analysis and uncertainty statement would not be required for a 1.5 milliwatt HeNe laser product classified in Class IIIa.

10.4 Provide instrument calibration schedules and indicate how your instruments are calibrated (e.g., calibrated by your company against a working standard, returned to the manufacturer of the instrument, sent to an independent calibration laboratory).

Is additional information attached? ( ) Yes ( ) No

NOTE: IF YOUR LASER PRODUCT OPERATES AT A LEVEL CLOSELY APPROACHING A SPECIFIED LIMIT, HIGH ACCURACY AND TRACEABILITY TO THE NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY (previously known as the National Bureau of Standards) ARE IMPORTANT.