Submission Report

eRadHealth Menu

Introduction

Electronic Product Radiation Safety Reporting Form

This software application is intended to automate the hard copy product reporting forms in the effort of the Center for Devices and Radiological Health (CDRH) to become capable of accepting electronic submissions from industry and to improve our review process. This FDA Electronic Submission (eSub) software is the next version of the application developed to allow us to accept all Radiological Health reports and other submissions electronically and improve the ability of CDRH to accomplish its mandated product and industry evaluations in a timely and efficient manner.

All electronic reports and correspondence can either be transferred to CD and mailed to the address below, or can be sent via the FDA Electronic Submissions Gateway to CDRH. If you follow instructions to set up an account with the FDA Gateway, it currently may take several weeks,, but when you submit through it you will receive your acknowledgement email message with Accession Number within minutes! Or, in the interest of faster turn-around for a one-time urgent report of if you submit few reports, you may simply fill out this template creating the submission and then at 'Packaging' follow the instructions to transfer the files to a CD to mail in. This method of submitting your report will be acknowledged by an email with the Accession Number within several days.

Information about the FDA Electronic Submissions Gateway can be found at **www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm**. Please contact the Gateway Helpdesk with your questions about that system.

Electronic submissions on CD should be mailed directly to the Document Control Center at:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Attn: eSubmitter Team
Document Mail Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submissions received in the mail on CD will be processed within a few days of receipt.

Note about eSubmitter software:

Instructions provided in this software briefly summarize the requirements of the regulations under the Federal Food, Drug and Cosmetic Act (FFDCA), Chapter V, Subchapter C - Electronic Product

Radiation Control, that applies to manufacturers of electronic products that emit radiation. The software provides questions relevant to requirements in the performance standards and may include explanations or clarification about the performance, labeling, and informational requirements of the standard. It does not replace the regulations, however, and if there is any conflict between the software and the regulations, the regulations must prevail. Throughout this application, pertinent sections of Title 21, Code of Federal Regulations, Chapter I, Subchapter J, are cited in parentheses. Please consult them before making design or procedural decisions.

Regulatory requirements for radiological products can be found at **http://www.fda.gov/Radiation-EmittingProducts/default.htm** and for medical devices are located at **www.fda.gov/M/devaDvices/default.htm**. If you have specific questions about the regulations, please contact us at: **DSMICA@fda.hhs.gov**.

If you have specific questions regarding this software, please contact the eSub team by email at: **eSubmitter@fda.hhs.gov**.

Thank you for using our electronic product reporting software. Please communicate your comments and suggestions to the eSub team as often as you like.

Thank you for your continued support of the FDA Electronic Submission Program (eSub).

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. The OMB control number for this information collection is 0910-0025 (expires January 31, 2017).

Role

What is your role?	!*	Manufacturer

Information:	*The following screen provides several options for you to accurately define what type of eSubmission you intend to create for FDA. Below are explanations of your options. Please feel free to review this screen, advance to the next screen and view the picklists, but if you're confused, come back to read this screen again to be certain you are selecting the correct report or correspondence type you want to create.*

Submission Information

Step 1	**Use the radio buttons to identify the type of submission you are preparing. (Supplements should be prepared using the same document type as the original submission.)**

What Type of Submission is this? (Supplements should be submitted selecting the same document type as the original report.)	!*	(•) Radiation Safety Report (Product) Report (21 CFR 1002.10) ( ) Annual Report (21 CFR 1002.13) ( ) Laser Light Show Documents (all relevant documents) (21 CFR 1040.11(c)) ( ) Correspondence

	( ) Variance Request (General, not Laser Light Show) (21 CFR 1010.4) ( ) Laser Original Equipment/Component Manufacturer Registration (21 CFR 1040.10(a)(3)(ii)) ( ) Abbreviated Report (21 CFR 1002.12)

Step 2	**After answering the Submission Type question above, one of the questions below may become active and required (see the blue dot to the right of the question). If there is an active question, select the appropriate product area or document type from the question's pick list.**
What Type of Product is this Radiation Safety Report about? **!***	
Laser Products (Includes Projection Systems)	
What Type of Product is this Annual Report about?	
What Laser Light Show Document are you filing?	
What Type of Correspondence is this?	
What Type of Product is this Variance Request about?	

Manufacturer Data

Manufacturer Responsible for Product Compliance

Note:	*This is the firm that takes responsibility for certification that the product meets the performance standard. This firm develops and maintains the quality control and testing program that is the basis for the certification of this product. Additionally, this firm usually is the owner of the product design and manufacturing process design.* *Be sure to enter address information for each tab below:*

Select the Manufacturer's address from the Establishment Address book: *	
Establishment Information:	
Establishment Name	
Division Name	
Home Page	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Telephone Number	
Fax Number	

Responsible Individual

Note:	*The responsible individual is the highest level and most responsible individual affiliated with this establishment.*

Select the Responsible Individual from the Contact Address book: *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	

Mailing Location:	
Address	
Telephone Number	
Fax Number	

Manufacturer's Reporting Official

Note:	*This is the person at the manufacturing facility that is knowledgeable and responsible for addressing all aspects of the testing and quality control procedures for certification as reported to FDA in the product report. Documentation of changes intesting and quality control procedures submitted to FDA must be signed by this individual.*

Select the Reporting Official from Contact Address book: *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Telephone Number	
Fax Number	

Report Submitter

Note:	*The submitter may be a consulting individual or firm providing assistance in report preparation and maintenance. Documents or submissions such as this one that are prepared by the submitter must have an accompanying authorization letter from the manufacturer's reporting official for authenticity.*

Select the Submitter from the Contact Address book: *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	

Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Telephone Number	
Fax Number	
Comments:	

Internal Reference Number:	

Parent Establishment

Is there a parent establishment? *	

Select the Parent Establishment and Contact from the Contact Address book:	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Telephone Number	
Fax Number	

Manufacturer Designated United States Agent

Note:	*Manufacturers exporting to the U.S. must designate a U.S. agent, see 21 CFR 1005.25.*

Is there a United States agent that has been designated by the manufacturer? *	

Importer

Additional Manufacturing Locations

Product Data

Product and Model Identification

Attention - Information about this section

In this section you'll be asked to identify several required or optional things which will help FDA/CDRH staff to prioritize their reviews. You'll be asked to consider the following aspects:

(1) Identify your product's radiation type and the CDRH Product Code.

(2) Enter an Accession number if this will be a report supplment. If you are preparing a supplement, you'll see that after entering a valid 7-digit Accession number many questions will no longer be required (they will either be disabled or will be optional, meaning they will no longer have the blue dot).

(3) You will also have several questions that are of high significance for FDA/CDRH - why you might be submitting this report or correspondence. Please read these questions carefully, referring to the 21 CFR regulations on the website www.FDA.gov if you are unsure if the question is relevant to your firm's situation.

(4) If you find that you have more information that you want the FDA/CDRH to read but it doesn't seem to fit under other questions, we have a final "***Additional Information***" question in this section which invites you to add comments and/or attach a file that provides further information from your firm about this submission. This is the place to add that extra information.

Product Type Reported

What is the product code? *

To select the three letter product code,

- Click the plus sign. You will see a product code filter dialog box.
- Select the appropriate category name from the pick list. You will be provided a list of product codes from which to choose.
- Select the best match to your product.
- The remaining fields will be filled in for you when you select your product code.

Category	
Product Code	
Performance Standard	

If Other, provide a category name for this specific product.

Report Information

Is this the first time you've submitted a report on the particular type of product selected in the Product Type Reported section? *	
Since this is not the first time you've reported on this type of product, then is this a report supplement to a previously reported model family?	
Provide the Accession Number of the original report for which this is a supplement: (Note: Do not enter any Device Premarket Application or Notification document number here, such as PMAs, 510(k)s, IDEs, etc. See Accession number description below.)	

Are you requesting a new variance, a renewal, extension or amendment to a previous variance? *	
Stop:	*If you are requesting a new variance, renewal, extension, or amendment, you must file a Variance Request separate from this report. To do this, open a new report (File > New) and select either "Laser Light Show Variance Request" or "Variance Request (General, not Laser Light Show)" as your Type of Submission in the Submission Information Screen. If you select "Variance Request (General, not Laser Light Show)r" you must select the product for which you are requesting a variance with the pick list in the bottom section of the screen.*

Special Considerations

Information:	*If this product will require a formally approved Variance from a certain performance requirement, you will need to complete two Reports for FDA, both (1) this Radiation Safety Report (RSR) on this product, and (2) a Variance Request report. This eSubmitter software application package includes a general Variance Request form as well as the specific Laser Light Show Variance Request form. Both the Product RSR file and the appropriate Variance Request Correspondence file must be submitted to CDRH following the regular files packaging procedures in this application. Both may be transferred to the same CD or submitted via the FDA ESG to submit to the FDA/CDRH.* *In addition, any Variance Request form must be printed out and the signed hard-copy sent to FDA's Division of Dockets Management at:* *Division of Dockets Management (HFA-305)* *Food and Drug Administration* *5630 Fishers Lane* *Rockville, MD 20852* *NOTE: There is no need to send a copy of the CD to Division of Dockets Management.*

Noncompliances or Defects

Does this document or any of its attachments contain:	
A notification of noncompliance or defect? *	
You may provide an explanation and/or attach a document here:	
Details	

Responses to Noncompliances or Defects

Does this document or any of its attachments contain any of these responses concerning noncompliances or defects?	
A refutation of noncompliances or defects identified to your firm? *	
A request for an exemption from notification to purchasers (see 21 CFR 1003.21 and 1003.30)? *	
Corrective action plans you intend to implement to correct noncompliances or defects discovered in past or current production? *	
Note:	*If you are submitting a Corrective Action Plan (CAP) following 21 CFR 1004 and information on design changes for future production, the design change information must be submitted in a Radiation Safety (Product) Report or supplemental report. Both the proposed CAP and the design changes may be submitted in one document if you prepare a product report and choose to include the CAP in it as a file attachment. Alternatively, you may create a separate eSubmission for the CAP using the "Correspondence" type template and selecting "Follow-up correspondence to FDA."*
A description of any design changes that correct noncompliances for future production? *	
Note:	*If you are submitting information on product design changes for future production due to a discovery of noncompliances or defects in current production, you must use the Radiation Safety (Product) Report template to create the report . Correspondence templates may be used to submit other information such as a proposed corrective action plan pertaining to a noncompliance or defect.*
You may add an explanation and/or attach a document here:	
Details	

Exemption Requests

Does this document or any of its attachments contain:	
Exemption of a product for government use from a standard (21 CFR 1010.5)? *	
Exemption for products for government use from reporting and recordkeeping (21 CFR 1002.51)? *	
Special exemption of products from reporting and/or recordkeeping (21 CFR 1002.50)? *	
Request for approval of alternate labeling? *	
Application for alternate test procedures (21 CFR 1010.13)? *	
You may provide an explanation and/or attach any relevant documents here:	

Variance Requests

Information:	*Please note: in addition to responding to these questions below, a separate General Variance Request or Laser Light Show Variance Request form must be completed and submitted to CDRH, with a hard copy sent to FDA's Division of Dockets Management as instructed below for any variance request. The information requested on this screen does not constitute the full structured content of the variance request. The 2 types of Variance forms can be created in eSubmitter by selecting the appropriate Variance submission type under the eRad Health Menu section of this application.*

Message:	*Click the plus sign to list the requirements from which you are requesting a variance.*
This submission includes an application for a variance from certain requirements.	
Item	No Information Provided.
Provide an explanation and attach supporting files, if necessary. Click on the plus sign below to attach files.	
Details	
Stop:	*For all Variance requests, two submissions must be made to the FDA.* *The electronic version should be submitted following the Packaging Files for Submission instructions located under Output in the Menu bar, and explained in subsection 4.3 of the User Manual. If sending a CD & submittal letter, please mail to:* *U.S. Food and Drug Administration* *Center for Devices and Radiological Health* *Attn: eSubmitter Team* *Document Mail Center - WO66-0609* *10903 New Hampshire Avenue* *Silver Spring, MD 20993-0002* *Additionally, a paper version (hard-copy) of the signed Variance request document should be submitted to:* *Food and Drug Administration* *Division of Dockets Management (HFA-305)* *5630 Fishers Lane, Room 1061* *Rockville, MD 20857*

Responses to Communications from FDA

Does this document or any of its attachments contain:		
A response to an FDA inspection?	*	
What was the date of the inspection?		
A response to a Warning letter or a Notification of Noncompliance or Defect from the FDA?	*	
What was the date of the Warning Letter or other notification letter?		
A response to a report review inquiry from the CDRH (the inquiry may have been in the form of a letter, email, or phone call)?	*	
What was the date of the inquiry?		
A response to any other communication from FDA?	*	
What was the date of the communication?		
Provide an explanation:		

Additional Information

Here's your opportunity to add anything else to this submission that you want to tell the FDA!

Is there any other relevant information or additional comments that would help expedite the review of this submission? Click the plus sign below to attach any supporting files.	
Details	

Private Labeling

Is the product sold by other companies under different brand names? *	

Medical Devices

Provide the premarket 510(k), IDE, HDE, PDP, or PMA filing numbers related to this medical product, if one of these numbers has been assigned by FDA yet.

If it has not been submitted yet, or if your device is exempt from premarket clearance or approval, please provide an explanation. The device regulations can be found in 21 CFR 807 - device manufacturer registration and device listing.

Laser Product

PART 1: DEFINITIONS

GENERAL DEFINITIONS

This software application 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 CFR1040.10(b)(21)]. A separate form for reporting additional information concerning laser light shows is being published concurrently with this form and must be used in conjunction with this form when appropriate (Reporting Guide for Laser Light Shows and Displays).

Laser Reporting and Recordkeeping (21 CFR 1002)

Applicability of reporting and recordkeeping requirements for laser products:

Class I, IIa, II, and IIIa laser products and laser products containing such lasers will require: Product Report, Annual Report, test records,manufacturer's distribution records, and dealer/distributor distribution records.

Note that for Class I laser products containing lasers of Class I, IIa, II, or IIIa 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 require all of the above plus Supplemental Reports when the criteria requiring submission of Supplemental Reports are met.

The laser standard applies to all laser products manufactured after August 1, 1976 (1040.10(a)), unless the products are either: sold to a manufacturer for use as components (or replacements) in products that will be certified (1040.10(a)(l)); sold by or for a manufacturer as repair or replacement components if they are properly labeled as such and have installation instructions (1040.10)(a)(2)); or intended for export only, are labeled as such, and comply with the requirements of the importing country (1010.20). Manufacturers of laser products that are sold to other manufacturers for use as components in their products are required to register and list such products.

Laser Definitions from 21 CFR 1040.10(b)

Laser means any product that can be made to produce or amplify electromagnetic radiation at wavelengths greater than 250 nm but less than or equal to 13,000 nm or, after August 20, 1986, at wavelengths equal to or greater than 180 nm but less than or equal to 1.0 x 10 to the power of 6 nm primarily by the process of controlled stimulated emission.

Laser energy source means any product intended for use in conjunction with a laser to supply energy for the operation of the laser. General energy sources such as electrical supply mains or batteries shall not be considered to constitute laser energy sources.

Laser product means any manufactured product or assemblage of components which constitutes, incorporates, or is intended to incorporate a laser or laser system. A laser or laser system that is intended for use as a component of an electronic product shall itself be considered a laser product (1040.10(b)(21)).

Laser radiation means all electromagnetic radiation emitted by a laser product within the spectral range specified in paragraph1040.10(b)(19) that is produced as a result of controlled stimulated emission or that is detectable with radiation so produced through the appropriate aperture stop and within the appropriate solid angle of acceptance, as specified in 1040.10(e).

Laser system means a laser in combination with an appropriate laser energy source with or without additional incorporated components. See paragraph 1040.10(c)(2) of the laser product performance standard for an explanation of the term "removable laser system."

Specific-Purpose Products

Medical laser product means any laser product which is a medical device as defined in 21 U.S.C. 321(h) and is manufactured, designed, intended or promoted for in vivo laser irradiation of any part of the human body for the purpose of: (i) Diagnosis, surgery, or therapy; or (ii) relative positioning of the human body. Class IIIa, IIIb, and IV medical laser products must contain a means for measuring the delivered exposure or treatment level of radiation, accurate within plus or minus 20 percent. This requirement is not applicable to Class IIIa aiming devices except ophthalmic application.The instruction manual must include a procedure and schedule for recalibration of the measurement system. A modified aperture label is also specified (1040.11(a)).

Surveying, leveling, or alignment laser product means a laser product manufactured, designed, intended or promoted for one or more of the following uses:

(i) Determining and delineating the form, extent, or position of a point, body, or area by taking angular measurement.

(ii) Positioning or adjusting parts in proper relation to one another.

(iii) Defining a plane, level, elevation, or straight line.

Surveying, leveling, and alignment laser products are generally used in agriculture and in the construction industry. They are restricted to 5mW visible radiant power and to Class I for other wavelengths and pulses less than 3.8 x 10 to the power of negative 4 seconds (1040.11(b)).

Demonstration laser product means any laser product manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition. The term "demonstration laser product" does not apply to laser products which are not manufactured, designed, intended, or promoted for such purposes, even though they may be used for those purposes or are intended to demonstrate other applications. Demonstration laser products (1040.10(b)(13)) include:

laser products promoted for classroom demonstration of optical phenomena;

artistic displays and their associated apparatus;

laser light show projectors; and

laser light shows and displays themselves.

A general-purpose, scientific, medical or industrial laser product is not considered to be a demonstration laser product when it is demonstrated to a prospective purchaser. Demonstration laser products are restricted in their outputs to Class IIIa with its accompanying restrictions to Class I for short pulses and invisible wavelengths(1040.11(c)). Because these levels are too low for effective use in commercial theatrical lighting effects, CDRH may grant variances (1010.4) to manufacturers of laser light shows and display devices. As a condition of the variance, the manufacturer must agree to adhere to several safety conditions to provide a level of safety to the public equivalent to a fully compliant product. Consult the Compliance Guide for Laser Products, September 1985, Appendix B, Clarification of Certain Laser Light Show Requirements, for more information.

PART 2: PRODUCT AND MODEL IDENTIFICATION

! Attention !

In the following sections of the report template you will see references to "Laser Notice #NN" and the "Compliance Guide for Laser Products.'" You can find these documents and other information relating to laser products on the page *Laser Products and Instruments*.

On the Laser Products page you can click on the button link at the top, right side of the page *Notices to the Laser Industry* and you will be taken to the page which lists links to the Laser Notices and the Compliance Guide for Laser Products sorted in date order.

The Compliance Guide itself may be found at this link: *Compliance Guide for Laser Products (FDA 86-8260)*

2.1 Model Designation

Note:	*Report the model name and/or number, model family, brand name, or other designation of the product. If reporting a model family, provide the model designation of each model. If you do not use a model family or brand name, leave the field blank.*

Model Designation (Names and/or Numbers): *			
Item	Model Name	Family Name	Brand Name

2.2 Approval of Alternate Means

Does this document or any of its attachments contain:

An application for approval of alternate means of providing the equivalent or superior protection that a required performance feature or labeling would provide (this is applicable to the beam attenuator requirements and alternate labeling)? *	

What requirement are you requesting an approval of alternate means from?

Provide an explanation:

2.3 Product without a Laser

Is it a product that does not incorporate a laser but is intended to incorporate a laser? *	

If the product as introduced into commerce does not incorporate a laser, identify the manufacturer and models of the laser that you recommend:	
Item	No Information Provided.

Is it a product that is intended to be used with a laser? *	

If the product as introduced into commerce is intended to be used with a laser, identify the manufacturer and models of the laser that you recommend:	
Item	No Information Provided.

If your product does not incorporate a laser or you do not recommend a specific laser for use with the reported product, state the specifications of the laser or laser system which may beincorporated in or used with your product. This would include wavelengths, power or energy levels, etc.

2.4 Modification of a Laser Product

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).*

Is your laser product the result of the modification of a laser product certified by another manufacturer? *	

2.5 Incorporation of Unmodified, Certified Laser Product

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

2.6 Incorporation of Uncertified Laser Product

Does your laser product incorporate an uncertified laser product as a component or component subsystem? *	

2.7 Incorporation of Removable Laser System

Does your laser product incorporate a removable laser system or systems as defined by 21 CFR 1040.10(c)(2)? *	

Technical Data

PART 3: DESCRIPTION OF THE PRODUCT

Note:	*In this section, you are asked to provide descriptions of the product, its intended function, and the laser radiation fields or paths and collateral radiation that may be accessible in operation, maintenance, or service modes of the product. This section was previously Part 5 of the product reporting guide.*

3.1 Product Description and Function

Note:	*You may refer to brochures and manuals submitted as attachments to this report.*

Describe the product and its function: *	
Details	

3.2 External and Internal Laser Radiation Fields and Paths

Note:	*Include beam path diagrams indicating protective housing, beam attenuators, viewports, scanners, targets, etc. Indicate energy and power levels at locations inside and outside the product.*

Describe the external and internal laser radiation fields and paths: *

3.3 Operational Procedures and Accessible Radiation

Note:	*Describe here the procedures used during operation and the laser or collateral radiation that is accessible during these procedures.*

List the procedures performed during operation: *

Do these procedures provide human access to ANY laser or collateral radiation? *	

Do the levels of laser or collateral radiation exceed the limits of Class I or Table VI?	

Indicate those collateral and laser radiation fields to which human access is possible during those operation procedures. Include the locations and identifications of laser and collateral radiation made accessible by viewing optics, viewports, and display screens:

3.4 Maintenance Procedures and Accessible Radiation

Note:	*Describe here the procedures used during maintenance and the laser or collateral radiation that is accessible during these procedures.*

List the procedures performed during maintenance: *

Do these procedures provide human access to laser or collateral radiation levels in excess of Class I or Table VI? *

Indicate those collateral and laser radiation fields to which human access is possible during those maintenance procedures: *

3.5 Service Procedures and Accessible Radiation

Note:	*Describe here the procedures used during service and the laser or collateral radiation that is accessible during these procedures.*

List the procedures performed during service: *

Do these procedures provide human access to laser or collateral radiation levels in excess of Class I or Table VI? *

Indicate those collateral and laser radiation fields to which human access is possible during those service procedures: *

PART 4: CERTIFICATION, CLASSIFICATION, AND LEVELS OF RADIATION

Note:	*This section, covers the description of the certification and identification labels and the detailed explanation of your classification of the product.*

4.1 Performance Standard Identification

With which performance standard does your product comply? *

4.2 Certification Label

Note:	

	Required by the CDRH standard and Laser Notice #50 for all laser products regardless of whether the CDRH laser standard or the IEC laser standard is being used for other requirements..

Is a certification label present on your product? *	

Does your certification label state that the product complies with the FDA performance standards except for deviations pursuant to Laser Notice #50, dated July 24, 2007?	

Attach a copy of the certification label with an indication of its location on the product: *

4.3 Identification Label

Note:	*Required on all laser products.*

Attach a copy of the identification label with an indication of its location on the product:

4.4 Performance Standard Classification

Under which laser product performance standard are you classifying your product? *	

4.5 Laser Product Class

Indicate the Class of the Laser Product: *	

4.6 Operation

Note:	*For classification purposes describe the radiation levels accessible in any of the operational configurations of the product.*

4.7 Embedded Laser System

Note:	*Describe here laser radiation fields contained within the protective housing of the product which may exceed the class of the product. The classification of the contained laser radiation is pertinent to safety interlock and protective housing label requirements.*

4.7.1 Internal Radiation Levels

Does the protective housing contain radiation in excess of the Class of the product (such as in a product that has a higher class laser embedded inside, such as a laser printer or workstation)? *	

4.8 Maintenance

Note:	*Describe here the laser radiation fields accessible in maintenance configurations of the laser product.*

4.9 Service

Note:	*Describe here the laser radiation fields accessible in service configurations of the laser product.*

4.10 Collateral Radiation

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

Provide a diagram of yourmeasurement set-up or the analysis used in your calculations. Provide pertinent dimensions such as separation distances, source and detectoraperture size, etc. to show compliance with the standard under which you are classifying: *

PART 5: COMPLIANCE WITH PERFORMANCE REQUIREMENTS

Note:	*In this section, you will describe how your product complies with the performance requirements. This section was previously Part 7 of the product reports.*

5.1 Protective Housing

Note:	*Required for all classes of laser products (see 1040.10(f)(1) and Compliance Guide).*

Describe the product's protective housing and how it serves to prevent unnecessary human access to levels of laser radiation in excess of Class I: *

Describe how the protective housing prevents access to unnecessary collateral radiation in excess of Table VI: *

5.2 Safety Interlocks

Note:	*Applicable for all Classes of laser products (see 1040.10(f)(2)(i) and Compliance Guide).*

Does your product have portions of the protective housing that are intended to be opened or removed for:

Operation:	
Maintenance:	
Service:	

Does your laser product incorporate any safety interlocks?	

What types of interlocks (select all that apply):	
Item	No Information Provided.
If other, then please specify:	

Provide an electrical block diagram illustrating the logic of all interlock systems:

Provide a detailed mechanical diagram showing where they all are located on the product:

5.3 Remote Interlock Connector

Note:	*Applicable to Class IIIb or IV (and IEC:3B and 4) laser systems (see 1040.10(f)(3) and Compliance Guide).*

Does the product have a remote interlock connector that disables the laser radiation when the circuit is open? *	

Describe the electrical and mechanical construction and operation of the remote connector (give its circuit and physical location):

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

5.4 Security Master (Key) Control

Note:	*Required for Class IIIb or IV (and IEC:3B or 4) laser systems (see 1040.10(f)(4) and Compliance Guide).*

Does your product have a Security Master control? *	

What type of security control is it?	
If other, then please specify:	
Describe how it works,including how the key control prevents unauthorized use of the product:	

Is the key control removable in the "On" position?	

Describe the function of the key control and how it renders the laser inoperable when the "key" is removed:

5.5 Laser Radiation Emission Indicator

Note:	*Required for Class II, IIIa, IIIb, or IV (and IEC: 3R, 3B, and 4) laser systems (see 1040.10(f)(5) andCompliance Guide).*

Does the product incorporate any emission indicators? *	

Describe in detail the mechanical and electrical characteristicsof all emission indicators installed pursuant to Section 1040.10(f)(5)(i) or (ii) and give their locations:

What type of emission indicator is incorporated?	
If "other", please describe:	

How is your emission indicator warning fail-safe or redundant?

5.6 Beam Attenuator

Note:	*Required for Class II, IIIa, IIIb or IV (and IEC: 3B or 4) laser systems (see 1040.10(f)(6) and Compliance Guide).*

Note:	*You may be able to use currently approved alternate means or you may need to apply for approval of alternate means of providing this protection if this alternate means provides protection equivalent to a beam attenuator.*

Does your product have a beam attenuator? *	

Does your product have an alternative?	

Describe or attach request for approval of alternate means:

5.7 Location of Controls

Note:	*Applicable to Class II, IIIa, IIIb or IV laser products (see 1040.10(f)(7) and Compliance Guide).*

Are operational and adjustment controls located so that exposure to laser radiation, above the accessible emission limits of Class I and Table VI, is unnecessary? *	

Describe:

5.8 Viewing Optics

Note:	*Applicable to all laser products (see 1040.10(f)(8)and Compliance Guide).*

Does the product incorporate any of the following viewing optics: *	

If so, please further describe the viewing optic that is incorporated:

Is the laser and collateral radiation that is accessible by virtue of viewing optics, viewports, or display screens less than the accessible emission limits of Class I and Table VI during operation and maintenance?	

Provide calculations and/or measurements,including pertinent attenuation factors, window transmission characteristics, etc.:

5.9 Scanning Safeguard

Note:	*Required for certain laser products with scanned laser radiation (see 1040.10(f)(9) and Compliance Guide).*

Note:	*A safeguard is required when scan failure would cause the product to exceed the emission limits of its class.*

Does the product incorporate a scanning safeguard? *	

Describe the mechanical, electrical, and functional characteristics of any required scan failure safeguard:

Is the classification of the product based on the level of scanned radiation?	

What is the reaction time?	

Provide calculations to show that the safeguard's reaction time is adequate to prevent human access to laser radiation in excess of the product's class:

5.10 Manual Reset

Note:	*Applicable to Class IV laser systems manufactured after August 20, 1986. (see 1040.10(f)(10) and Compliance Guide).*

Does the product incorporate a manual reset mechanism or means that prevents automatic restart following interruptionof emission caused by power failure of at least 5 seconds or deactivationthrough the remote interlock connector? *	

Provide the circuit and physical description and location of the manual reset mechanism:

Does emission delay reactivate when power is resumed after an interruption of 5 seconds or more?	

Must the emission be manually restarted following interruption via the remote interlock connector?	

5.11 Medical Laser Product

Note:	*Applicable to Class III or IV (and IEC: 3B or 4) medical laser products intended for in-vivo surgical, therapeutic, or diagnostic irradiation of the human body (see 1040.11(a) and Compliance Guide).*

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.*

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:

5.11.1 Laser Radiation Levels

Is the radiation level continuously monitored?	

Explain how the radiation level is monitored:

Describe how the system can assure the accuracy of the displayed value to within 20%:

5.11.2 Measurement and Monitoring Uncertainties

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

Specify the uncertainty in the monitoring system and describe the method by which it was derived:

Describe how the displayed power/energy level is either measured at the point of delivery or measured earlier and then the actual output calculated:

If the displayed level is calculated, then provide calculations incorporating system constants, losses, attenuation factors, etc. to demonstrate accurate calibration of the delivered beam to +/-20%:

5.11.3 Calibration Procedures

Note:	*A procedure for calibration of the means for output measurement is required by the CDRH laser standard. However, if your medical laser product complies with IEC 60601-2-22 and you prefer to certify following Laser Notice #50, the IEC standard requires instructions for a calibration verification of the output beam.*
Are procedures and a schedule for recalibration of the measurement system included in the user instructions? If you are using the IEC 60601-2-22 standard for medical laser products in accordance with Laser Notice 50, do you provide instructions for doing a calibration verification of the output beam?	

Identify location in the user instructions:

5.12 Surveying, Leveling, or Alignment Laser Products

Note:	*As a surveying, leveling, or alignment laser product it is subject to the requirements of section 1040.11(b).*

Note:	*If the product's class exceeds CDRH Class IIIa or IEC Class 3R or is IEC Class 1M or 2M, then an approved variance from the performance requirements in this section would be necessary prior to introduction into commerce.*

Is a variance request being submitted with this report?	

5.13 Demonstration Laser Products

Note:	*As a demonstration laser product it is subject to the requirements of section1040.11(c).*

Note:	

	If the product's class exceeds CDRH Class IIIa or IEC Class 3R or is IEC Class 1M or 2M, then an approved variance from the performance requirements in this section would be necessary prior to introduction into commerce.

Note:	*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 for Class IIIb or IV shows or displays.*

Note:	*You may prepare all these reports and the variance request together using eSubmitter and transfer them all to a single CD to ship to CDRH, if that's the preferred method of submitting. If you do this you need to remember that during packaging of each submission you must print and sign each submittal letter, then send each letter (either scanned & attached following the packaging instructions or just inserted into the envelope with the CD).*

Is a Laser Light Show report being submitted along with this report?	
Is a variance application for a laser light show projector and laser light show being submitted along with this report?	
Does its user instructions include a warning not to direct the laser radiation at the audience?	

PART 6: COMPLIANCE WITH LABELING REQUIREMENTS

Note:	*In this section, you will describe how your product complies with the labeling requirements. This section was previously Part 3 of the product reporting guide.*

Note:	*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 allrequired labels. Submitting diagrams, photographs, blueprints, product literature, etc. is acceptable (see laser notices # 16, 17, 45, and 50).*

6.1 Performance Standard Identification

With which performance standard do your product's labels comply:	*	

6.2 Warning Logotype Label

Note:	*Required on Class II, III, and IV laser products. (see 1040.10(g)(1), (2),(3),(4),(8),(9),(10) and Compliance Guide).*

Attach a copy with an indication of its location on the product:

6.3 IEC Warning Label

Note:	*Required on all Class 1, 1M,2, 2M, 3R, 3B, and 4 laser products.*

Attach copies of both the warning label (hazard symbol) and the explanatory label with an indication of their locations on the product. If the radiation output and the standard used are not stated on the explanatory label, then a copy of the label giving this information and its location on the product must also be attached. *

6.4 Class IIa Warning Label

Note:	*Required on Class IIa laser products (see 1040.10(g)(1)(i) and Compliance Guide).*

Attach a copy with an indication of its location on the product:

6.5 Aperture Label

Note:	*Required on Class II, III and IV (IEC: 3R, 3B, and 4) laser products (for nonmedical laser products see 1040.10(g)(5),(8),(9),(10) or for medical laser products see 1040.11(a)(3) and Compliance Guide).*

Attach a copy with an indication of its location on the product:

6.6 Protective Housing Labels

Note:	*See 1040.10(g)(6),(7),(8),(9),(10), Compliance Guide, and Laser Notice 17.*

Does your product have any protective housing labels? *	

Does your product have any noninterlocked protective housing labels?	
Attach a copy with an indication of its location on the product:	
Indicate how the label(s) are visible both prior to and during opening or removal of housing:	

Does your product have any defeatably interlocked protective housing labels?	
Attach a copy with an indication of its location on the product:	
Indicate how the label(s) are visible both prior to and during interlock defeat:	

Does your product have any optionally interlocked protective housing labels?	
Attach a copy with an indication of its location on the product:	

Indicate how the labels are visible both prior to and during opening or removal of the housing:

PART 7: COMPLIANCE WITH INFORMATIONAL REQUIREMENTS

Note:	*In this section, you will describe how your product complies with the informational requirements. This section was previously Part 4 of the product reporting guide.*

7.1 User Information

Submit a copy of user information (operator's manuals) for your laser product. If the manual is very extensive, submit those portions that confirm compliance with Section 1040.10(h) [and 1040.11(a)(2), if a medical laser product]: *

Does the manual contain adequate instructions for assembly, operation, and maintenance? *	
Does it contain clear warnings to avoid exposure? *	
Does it contain a statement of output parameters? *	
Does it contain legiblereproductions of all labels, their locations on the product, and hazard warnings? *	
Does it contain a listing of controls, adjustments, and procedures for operation and maintenance? *	
Does it contain a schedule of maintenance? *	
Does it contain the "Caution - use of controls..." warning statement? *	
Does it include information to determine nominal hazard zone for users? *	
Does it contain a compatibility statement concerning recommended lasers or specifications? *	
Does it contain an additional warning stating that viewing the laser output with optical instruments may result in an eye hazard for Class 1M or an increased hazard for Class 2M? *	

Note:	*These materials may also have been used in the product description required by Part 3.*

7.2 Promotional Literature

Submit copies of any sales literature, including catalogs, specification sheets, and descriptive brochures for Class IIa, II, III, and IV laser products: *

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.

7.3 Servicing Information

Submit a copy of the relevant radiation safety sections of your product's servicing information (from your service manual): *

Quality Control

PART 8: PRODUCT DESIGN VERIFICATION

Note:	*In this section, any attached files must identify the manufacturing facility and name of the responsible Quality Assurance manager for the activity. This section waspreviously Part 9 of the laser product reporting guide.* *In this section, you will also describe those design considerations, verification activities, and controls implemented to ensure that the reported product will remain in compliance with the Federal laser product performance standard during its useful life.* *Quality control and product testing should be based on design considerations and factors that can affect product compliance with the Federal laser product performance standard.*

8.1 Critical Design Requirements

List the factors identified during design that may provide product compliance with the Federal laser product performance standard or performance as related to accessible or emitted laser radiation (e.g. performance specifications, component selection): *

8.2 Life Testing

Note:	*In this section you will describe those verification activities conducted to assure product compliance with the Federal laser product performance standard over its useful life.*

Note:	*Maintenance and/or service instructions must include schedules for maintenance and replacement of components that may be necessary for the compliance of the product during its useful life.*

Testing of features designed to meet Federal laser product performance requirements: *

Acceptance of electrical and electronic components: *

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

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

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

Provide an estimate of the useful life of the product (in years): *	

8.3 Change Controls

Describe the controls implemented to assure compliance with the Federal laser product performance standard (e.g. control of design changes, user and service information changes, labeling changes to assure that compliance of the product is not jeopardized.): *

PART 9: QUALITY CONTROL TESTS AND PROCEDURES

Note:	*In this section, any attached files must identifythe manufacturing facility and name of the responsible Quality Assurance manager for the activity. This section was previously Part 8 of the laser product reporting guide.* *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.*

9.1 Quality Control Documentation

Note:	*Attach 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.*

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:

Other(s), specify:

9.2 Alternate Quality Control Procedures

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:

PART 10: INSTRUMENTATION AND CALIBRATION

Note:	*In this section, you will describe the instrumentation used for compliance testing your product and the instrumentation calibration procedures.*

10.1 Component Testing

Do you purchase components or services from contractors or original equipment manufacturers in lieu of conducting your own in-house testing?

Provide certificates or sample test/inspection records from suppliers or original equipment manufacturers, etc. to assure that those entities are operating in a state of control.

Describe those tests and controls used to determine whether the reported product is producedto be in compliance with the Federal laser product performance standard:

Do you conduct in-house compliance testing for your product?

Do you have testing done by an outside contractor? *

10.2 Compliance Testing

Describe those tests and controls used to determine whether the reported product is produced to be in compliance with the Federal laser product performance standard: *

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. *

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

Provide a measurement error analysis (for all sources of error identified) and an uncertainty statement for all measurement data reported. (If it isclear 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 milliwattHeNe laser product classified in Class IIIa.):

10.3 Calibration

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) [If your laser product operates at a level closely approaching a specified limit, high accuracy and traceabilty to the National Institute of Standards and Technology (previously known as the National Bureau of Standards) are important]:

Stop:	*You have reached the end of this report. Please verify that all PDFs that are to be included in this submission are correctly attached to a specific file attachment question. Otherwise, they will not be packaged with your report. Check to make sure you have no missing data (select Missing Data Report from the Output menu). Once you have confirmed that there is no missing data and all your files are attached, click on the Package Submission icon on the tool bar.*