

## Specific Instructions for Laser Product Inspections and Tests

### Background

The Laser Products Performance Standard (the standard), promulgated in August 1976, was designed to protect the public from unnecessary radiation hazards associated with the use of these products. The radiation emitted from these laser products can pose varying degrees of hazards depending upon the type, magnitude, and accessibility of the radiation and upon the particular functions or operations they perform. The standard was last amended in 1985. Since then, the CDRH has intended to harmonize the requirements of the standard with those of the international standard IEC 60825-1: 2001. As an interim step the CDRH published its Laser Notice 50 in 2001 stating that it would not object to compliance with specified requirements of the international standards in lieu of comparable requirements of the CDRH standard.

### Specific Instructions

High-risk laser products and their manufacturers should be inspected or tested as a priority. Examples of high-risk laser products and manufacturers include:

- Class IIIb and IV medical lasers (e.g. surgical)
- Class IIIb and IV industrial lasers used in material processing
- Class IIIb and IV lasers used in law enforcement or military applications
- Manufacturers with known or suspected problems based on previous inspection, field tests or complaints
- New manufacturers not yet inspected
- Manufacturers introducing new technology to the US market
- Manufacturers with a large portion of the US market share for any laser product. Class I low risk laser products, such as optical disk drives or laser printers, should not be inspected or tested.

Electro-optics specialists have been specifically trained in general EPRC requirements and also have specialized training in the laser product performance standards. EOS's should perform these inspections and field tests, and may train additional field staff or accompany a medical device investigator to conduct joint EPRC/medical device inspections. If an EOS has training in both EPRC and QSIT inspections, a single EOS may conduct both portions of the inspection.

CDRH is responsible for review of laser manufacturer inspection and product field test observations and initiating administrative or regulatory follow-up.

### References

Frequently Asked Questions about Lasers.

<http://www.fda.gov/cdrh/radhealth/products/laserfaq.html>

Performance Standard-Lasers and Products Incorporating Lasers

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?FR=1040.10>

Performance Standard-Specific Laser Products (Includes Display, Survey, and Medical Laser Products)

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?FR=1040.11>

Laser Compliance Guide

<http://www.fda.gov/cdrh/radhlth/pdf/lasgde01.pdf>

Reporting Guide-Radiation Safety Product Report for Laser Products

<http://www.fda.gov/cdrh/radhlth/pdf/lasrpt0p.pdf>

Reporting Guide-Radiation Safety Product Report for Laser Light Shows/Displays

<http://www.fda.gov/cdrh/radhlth/pdf/lasrpt01.pdf>

Laser Quality Control Guide

<http://www.fda.gov/cdrh/radhlth/pdf/lasgdeqc.pdf>

**Refer to the laser products main page for guidance documents and additional information:**

<http://www.fda.gov/cdrh/radhealth/products/lasers.html>.

**Laser Product Codes**

<b>Translation of 2-Digit Code</b>	<b>Product Name</b>	<b>Product Code</b>		<b>CFR</b>	<b>Definition</b>
Other Laser Products	Automotive Accessory, Automobile or Transport Vehicle, Laser	95	RDV	1040.10	A laser product or product containing a laser that is an automotive or other transport vehicle accessory.
Other Laser Products	General Purpose Laser Products, Non-Medical	95	RDW	1040.10	Product, laser, general, emit beam; A laser or product containing a laser that is intended for general purpose use with no medical claims.
Other Laser Products	Other	95	RZZ	Unk	A laser or product containing a laser for which its intended use is not previously defined.
Laser Light Show/Display Products	Low-Power Laser Light Show Projector	95	RDZ	1040.10; 1040.11	Product, laser, demo, projector, laser light show/display, Class IIIa/3R and lower; Laser projection system that incorporates a laser having a maximum radiation output of less than 5mw.
Laser Light Show/Display Products	High-Power Laser Light Show Projector (Output > 5mW)	95	REA	1040.10; 1040.11	Product, laser, demo, projector, laser light show/display, Class IIIb/IV/3B/4; Laser projection system that incorporates a laser having a maximum radiation output power greater than 5mw.
Laser Light Show/Display Products	High-Power Laser Light Show	95	REB	1040.10; 1040.11	Product, laser, demo, laser light show/display, Class IIIb/IV/3B/4; Laser light show or demonstration using laser projection equipment having an output that exceeds 5mW
Laser Light Show/Display Products	Laser Video Projector	95	REC	1040.10; 1040.11	Product, laser, demo, projector, display, video; A laser used in conjunction or incorporated in a video display system or projector.
Laser Light Show/Display Products	Laser Advertising Display System	95	RED	1040.10; 1040.11	Product, laser, demo, system, display, advertising
Laser Light Show/Display Products	Laser Visual Display - Display Retinal Image, Non-Medical Display Product	95	REE	1040.10; 1040.11	Product, laser, display, system, images, direct to retina
Laser Light Show/Display Products	Other	95	RZZ	Unk	Other laser products used in light shows or demonstrations that are not otherwise defined.
Medical Laser Products	Laser, Ophthalmic	86	HQF	1040.10; 1040.11	
Medical Laser Products	Laser Instrument, Surgical, Powered	79	GEX	1040.10; 1040.11	
Medical Laser Products	Laser, Surgical, Gynecologic	85	HHR	1040.10; 1040.11	
Medical Laser Products	Laser, ENT Microsurgical Carbon-Dioxide	77	EWG	1040.10; 1040.11	
Medical Laser Products	Photocoagulator and Accessories	86	HQB	1040.10; 1040.11	
Medical Laser Products	Lens, Surgical, Laser, Accessory, Ophthalmic Laser	86	LQJ	1040.10; 1040.11	

Medical Laser Products	Laser, Neurosurgical	84	LKW	1040.10; 1040.11	
Medical Laser Products	Laser, Neurosurgical, Argon	84	LLF	1040.10; 1040.11	
Medical Laser Products	Laser, Neodymium: YAG, Pulmonary Surgery	73	LLO	1040.10; 1040.11	
Medical Laser Products	Laser, Neodymium: YAG, for Gynecologic Use	85	LLW	1040.10; 1040.11	
Medical Laser Products	Laser, Neodymium: YAG, Ophthalmic for Uses Other than Posterior Capsulotomy and Cutting Pupil	86	LXS	1040.10; 1040.11	
Medical Laser Products	Laser, Neodymium: YAG, Ophthalmic for Uses Other than Posterior Capsulotomy	86	LOI	1040.10; 1040.11	
Medical Laser Products	Laser, Neodymium: YAG, Optical, Pumped Parametric Oscillator	86	MVQ	1040.10; 1040.11	
Medical Laser Products	Laser, Microsurgical Argon, for Use in Otolaryngology	77	LXR	1040.10; 1040.11	
Medical Laser Products	Laser, Microsurgical Argon, for Uses Other Than Otolaryngology	77	LMS	1040.10; 1040.11	
Medical Laser Products	Laser for Gastro-Urology Use	78	LNK	1040.10; 1040.11	
Medical Laser Products	Device, Angioplasty, Laser, Coronary	74	LPC	1040.10; 1040.11	
Medical Laser Products	Device, Laser Peripheral Angioplasty	74	LWX	1040.10; 1040.11	
Medical Laser Products	Catheter, Coronary Laser Myoplasty	74	MGC	1040.10; 1040.11	
Medical Laser Products	System, Laser, Transmyocardial	74	MNO	1040.10; 1040.11	

	Revascularization				
Medical Laser Products	Instrument, Visual Field, Laser	86	HPJ	1040.10; 1040.11	
Medical Laser Products	Laser for Pain Therapy	84	LLP	1040.10; 1040.11	
Medical Laser Products	Laser, System, Excimer	86	LZS	1040.10; 1040.11	
Medical Laser Products	Laser, Dental	76	LYB	1040.10; 1040.11	
Medical Laser Products	Photodynamic Therapy (PDT)	79	MVF	1040.10; 1040.11	
Medical Laser Products	Photodynamic Therapy (PDT), Fiber Optic	79	MVG	1040.10; 1040.11	
Medical Laser Products	Laser, Fluorescence Caries Detection	76	NBL	1040.10; 1040.11	
Medical Laser Products	Laser for Wound Healing	79	LXU	1040.10; 1040.11	
Medical Laser Products	Ophthalmoscope, Laser Scanner	86	MYC	1040.10; 1040.11	
Medical Laser Products	Laser, Phacolysis	86	MXO	1040.10; 1040.11	
Medical Laser Products	Caries Detector, Laser, Light, Transmission	76	NTK	1040.10; 1040.11	
Medical Laser Products	Other	95	RZZ	Unk	A laser or laser product intended for medical treatment or other uses on humans, not previously defined.
Other Demonstration Laser Products	Laser Science Education Products	95	REI	1040.10; 1040.11	Product, laser, demo, education, illustrate science principles
Other Demonstration Laser Products	Other	95	RZZ	Unk	Laser products used for demonstrations that are not otherwise defined.
Toy, Novelty, Play Laser Products	Toy, Novelty, Play Laser Product	95	REJ	1040.10; 1040.11	Product, laser, toy/novelty
Research, Scientific, Laboratory Laser Products	Research Laser, Scientific, Laboratory Laser Products	95	REK	1040.10	Product, laser, research/laboratory; A laser under development in and of itself. A laser used for conducting research during development of new data or to improve a process would not be considered a research laser although it is being used in research.
Research, Scientific, Laboratory Laser Products	Guide-Star Laser System, Research, Scientific, Laboratory Laser Products	95	REL	1040.10	Product, laser, adaptive-optics telescope focusing accessory, generate artificial star; A laser used for alignment of optical telescopes.
Research, Scientific, Laboratory Laser Products	Spectroscopy Instrument, Laser, Research, Scientific,	95	REM	1040.10	Product, laser, instrument, spectroscopy; An instrument incorporating a laser for spectroscopic testing or examination with no medical claims.

	Laboratory Laser Products				
Research, Scientific, Laboratory Laser Products	Particle-Size Measuring Instrument, Laser, Scientific, Laboratory Laser Products	95	REN	1040.10	Product, laser, instrument, particle size measurement; An instrument or system incorporating a laser for determining the size or number of particles of particles a test sample.
Research, Scientific, Laboratory Laser Products	Analytical Measuring and Detection, Research, Scientific, Laboratory Laser Products	95	REO	1040.10	Product, laser, instrument, analyze/detect chemical species
Research, Scientific, Laboratory Laser Products	Other	95	RZZ	Unk	Laser products used in scientific and laboratory applications that are not otherwise defined.
Surveying, Leveling, Alignment Laser Products	Surveying Laser Product, Leveling, Alignment Laser Products	95	REP	1040.10	Product, laser, surveying, instrument, determine position by measurement of angles
Surveying, Leveling, Alignment Laser Products	Ranging (Geodimeter) Laser Products	95	REQ	1040.10	Product, laser, ranging, instrument, measure distance by time-of-flight
Surveying, Leveling, Alignment Laser Products	Alignment Laser Product, Surveying, Leveling, Alignment Laser Products	95	RER	1040.10; 1040.11	Product, laser, alignment, aid positioning or adjusting parts in relation to each other
Surveying, Leveling, Alignment Laser Products	Laser Pointer, Surveying, Leveling, Alignment Laser Products	95	RES	1040.10; 1040.11	Product, laser, pointer, indicate point of interest; A laser product intended specifically to define a spot or surface for drawing attention to a viewer.
Surveying, Leveling, Alignment Laser Products	Laser Target Designator, Surveying, Leveling, Alignment Laser Products	95	RET	1040.10	Product, laser, target designator; An optical devices, using a visible beam of laser light that permits the alignment of a gun, cannon or rocket system with its target.
Surveying, Leveling, Alignment Laser Products	Laser Aiming Product, Visible, Surveying, Leveling, Alignment Laser Products	95	REU	1040.10; 1040.11	Product, laser, aiming, visible, attached to weapon; An optical devices, using a visible beam of laser light that permits the alignment of a gun, cannon or rocket system with its target

Surveying, Leveling, Alignment Laser Products	Laser Aiming Product, Non-Visible, Surveying, Leveling, Alignment Laser Products	95	REV	1040.10; 1040.11	Product, laser, aiming, infrared, attached to weapon, viewed with night-vision equipment; An optical devices, using an invisible beam of laser light that permits the alignment of a gun, cannon or rocket system with its target.
Surveying, Leveling, Alignment Laser Products	Other	95	RZZ	Unk	Other laser products used for surveying, leveling and alignment that are not otherwise defined.
Safety, Security, Surveillance Laser Products	IR Laser Illuminator with Alignment Aid/Night Vision System, Safety, Security, Surveillance Laser Products	95	REW	1040.10; 1040.11	Product, laser, infrared, illuminator with alignment aid, viewed through night-vision equipment
Safety, Security, Surveillance Laser Products	IR Laser Illuminator Only/Night Vision System, Safety, Security, Surveillance Laser Products	95	REX	1040.10	Product, laser, infrared, illuminator only, viewed through night-vision equipment
Safety, Security, Surveillance Laser Products	Collision-Avoidance Laser System, Safety, Security, Surveillance Laser Products	95	REY	1040.10	Product, laser, infrared, collision-avoidance system
Safety, Security, Surveillance Laser Products	Laser Traffic Signal, Safety, Security, Surveillance Laser Products	95	REZ	1040.10	Product, laser, traffic signal/control
Safety, Security, Surveillance Laser Products	Laser Automotive Lighting & Signals, Safety, Security, Surveillance Laser Products	95	RFA	1040.10	Product, laser, automotive, lighting/signals
Safety, Security, Surveillance Laser Products	IR Laser Intrusion Detection/Security System, Safety, Security, Surveillance Laser Products	95	RFB	1040.10	Product, laser, infrared, intrusion detecting, security system
Safety, Security, Surveillance Laser Products	Laser Radar (Lidar) or Speed Measurement, Safety, Security, Surveillance Laser Products	95	RFC	1040.10	Product, laser, infrared, Doppler or time-of-flight speed measurement

Safety, Security, Surveillance Laser Products	Other	95	RZZ	Unk	Laser products used in safety, security, surveillance applications not otherwise defined
Safety, Security, Surveillance Laser Products	Laser Weapon (Military or Police), Safety, Security, Surveillance Laser Products	95	RFD	1040.10	Product, laser, weapon (military/police)
Material Processing Laser Products	Laser Cutter, Material Processing Laser Products	95	RFE	1040.10	A high power laser intended to cut or drill a variety of materials in an industrial or commercial environment.
Material Processing Laser Products	Laser Welder, Material Processing Laser Products	95	RFF	1040.10	A high power laser intended to weld (join) materials in an industrial or commercial environment.
Material Processing Laser Products	Microelectronic Mask or Chip Checking/Repair, Material Processing Laser Products	95	RFG	1040.10	A laser intended to inspect and/or repair microelectronic components in an industrial or commercial environment.
Material Processing Laser Products	UV Curing, Material Processing Laser Products	95	RFH	1040.10	An ultraviolet wavelength laser used to illuminate a material of a certain composition such that the laser "cures" or causes a chemical reaction to change the material in a desired fashion with no medical claims. Typical materials are adhesives, plastics, potting compounds, etc.
Material Processing Laser Products	Print Industry Plate Maker, Material Processing Laser Products	95	RFI	1040.10	A laser intended to etch, engrave or otherwise create printer's plates used in an industrial or commercial environment.
Material Processing Laser Products	Process Control, Material Processing Laser Products	95	RFJ	1040.10	A laser used for inspection, counting, or other application intended to monitor a part of the manufacturing process in an industrial or commercial environment. Often incorporated in an automated process system.
Material Processing Laser Products	Laser Vision, Material Processing	95	RFK	1040.10	A laser used for positioning, focusing, inspection, counting, or other application in an industrial or commercial environment. Often incorporated in an automated assembly line system.
Material Processing Laser Products	Laser Micrometer, Material Processing	95	RFL	1040.10	A laser used in high precision dimensional measurements in materials processing.
Material Processing Laser Products	Laser-Based Material Positioning System	95	RFM	1040.10	A laser used in precision positioning of materials in manufacturing in an industrial or commercial environment.
Material Processing Laser Products	Other	95	RZZ	Unk	A laser used in materials processing not otherwise defined.



Material Processing Laser Products	General Industrial Use Material Processing Laser Products	95	RZN	1040.10	A laser used in industrial manufacturing or materials processing not otherwise defined.
Data Measurement, Transmit, Control Laser Products	Fiber Optic Communication and Data Transfer, Laser	95	RFN	1040.10	A laser used in fiber optic communications to transmit data and information.
Data Measurement, Transmit, Control Laser Products	IR Free-Space Data Transmit/Control, Laser	95	RFO	1040.10	A laser used in free space (open air) communications to transmit data and information.
Data Measurement, Transmit, Control Laser Products	Remote Controller, Laser, Data Measurement, Transmit	95	RFP	1040.10	A laser used to transmit signals and/or information in order to operate equipment or machinery remotely.
Data Measurement, Transmit, Control Laser Products	Interferometric Position Measuring Product, Laser	95	RFQ	1040.10	A laser used as an interferometer for high precision positioning and/or measurements.
Data Measurement, Transmit, Control Laser Products	Product Incorporating Certified Class 1 Laser Data Measurement, Transmit, Control	95	RFR	1040.10	A data measurement, data transmission, or remote control product that incorporates a certified Class 1 laser.
Data Measurement, Transmit, Control Laser Products	Other	95	RZZ	Unk	A data measurement, data transmission, or remote control product that incorporates a laser other than a certified Class 1 laser.
Utility/Peripheral Laser Products	Reprographics, Laser, Utility/Peripheral Laser Products	95	RFS	1040.10	A reprographics machine that incorporates a laser utilized to expose internal sensitive components or materials for photocopying text and graphics.
Utility/Peripheral Laser Products	Laser Printer, Utility/Peripheral Laser Products	95	RFT	1040.10	A printing machine that incorporates a laser utilized in printing images on paper with no medical claims.
Utility/Peripheral Laser Products	Laser FAX Machine, Utility/Peripheral Laser Products	95	RFU	1040.10	A printing machine that incorporates a laser utilized in printing facsimiles of images on paper.
Utility/Peripheral Laser Products	CD, CD-ROM Player, Laser Utility/Peripheral Laser Products	95	RFV	1040.10	A CD or CD-ROM player that utilizes a laser to read data on the compact disc.
Utility/Peripheral Laser Products	DVD, DVD-ROM Player, Laser Utility/Peripheral Laser Products	95	RFW	1040.10	A DVD or DVD-ROM player that utilizes a laser to read data on the digitally recorded video disc.

Utility/Peripheral Laser Products	CD-R, CD-RW Recorder, Utility/Peripheral Laser Products	95	RFX	1040.10	A CD-R or CD-RW recorder machine that utilizes a laser to read and/or write data on the compact disc.
Utility/Peripheral Laser Products	DVD-R, DVD+R, DVD-RAM, DVD+RW, DVD-RW Recorder, Utility/Peripheral Laser Products	95	RFY	1040.10	A DVD recorder machine that utilizes a laser to read and write or read, write, and erase data on a digitally recorded video disc in any of the data formats: DVD-R, DVD+R, DVD-RAM, DVD-RW, or DVD+RW.
Utility/Peripheral Laser Products	UPC Reader (Bar Code Reader), Utility/Peripheral Laser Products	95	RFZ	1040.10	A laser used to scan across a bar code to identify the product. Bar code readers can be hand-held accessories, under-counter components incorporated in store check-out systems, or laser scanner systems incorporated in assembly lines used for identification and inventory purposes in manufacturing facilities, warehouses and storage facilities, or other consumer, industrial, health care, or commercial locations.
Utility/Peripheral Laser Products	Home/Office Machine Incorporating Utility/Peripheral Laser	95	RZP	1040.10	A laser utilized in the home or office environment not otherwise defined.
Utility/Peripheral Laser Products	Product Incorporating Certified Class 1 Data Utility/Peripheral Laser Products	95	RGA	1040.10	A utility/peripheral laser product that incorporates a certified Class 1 laser.
Utility/Peripheral Laser Products	Other	95	RZZ	Unk	A utility/peripheral laser product that incorporates a laser other than a certified Class 1 laser.
In Vitro and Other Medical Laser Products	Veterinary Laser, In Vitro and Other Medical Laser Products	95	RGB	1040.10; 1040.11	A laser used for treatment of animals other than human
In Vitro and Other Medical Laser Products	Separator, Automated, Blood Cell, Diagnostic	81	GKT	1040.10	
In Vitro and Other Medical Laser Products	Automated Differential Cell Counter	81	GKZ	1040.10	
In Vitro and Other Medical Laser Products	Cell Particle Counter (Automated)	81	GKL	1040.10	
In Vitro and Other Medical Laser Products	Urine Particle Counter	88	LKM	1040.10	
In Vitro and Other Medical Laser Products	System, Separation, Hematopoietic Stem Cell	81	MZK	1040.10	
In Vitro and Other Medical Laser Products	Test, Urea (Breath or Blood) for H. Pylori Test	83	MSQ	1040.10	

In Vitro and Other Medical Laser Products	Multipurpose System for In-vitro Coagulation	81	JPA	1040.10	
In Vitro and Other Medical Laser Products	System, Laser Assisted Hatching	85	MRX	1040.10; 1040.11	
In Vitro and Other Medical Laser Products	Sorter, Cell	81	KEX	1040.10	
In Vitro and Other Medical Laser Products	Separator, Semi-Automated, Blood Component	81	MYY	1040.10	
In Vitro and Other Medical Laser Products	Other	95	RZZ	Unk	A laser used for in vitro applications or other medical applications that do not expose patients to the laser radiation.
Positioning Medical Laser Products	X-Ray Field Indicator Light (Laser), Positioning Medical Laser Products	95	RGC	1020.30; 1040.10; 1040.11	A laser incorporated in a diagnostic x-ray system that is irradiated onto the film screen area indicating the x-radiation area. The beam is usually scanned to show a rectangular region for patient placement.
Positioning Medical Laser Products	Monitor, Patient Position, Light Beam	90	IWE	1040.10; 1040.11	
Positioning Medical Laser Products	Positioning Medical Laser Product	95	RZS	1040.10; 1040.11	A laser used for positioning in medical applications not otherwise defined.

### Classification of Non-compliant Items

Performance requirements			
1040.10(d)	Classified in higher class	Minor, Concern	Class B, C
1040.10(d)	Classified in lower class	Major	Class A
1040.10(f)(1)	Protective housing allows unnecessary body access to Class IV or high IIIb radiation	Major	Class A
1040.10(f)(1)	Protective housing allows unnecessary straight line access to interior Class IV or high IIIb radiation With high risk of exposure (IV or IIIb product) With low risk of exposure (IV or IIIb product) With any risk of exposure (I, IIa, II, or IIIa product)	Major Minor Major	Class A Class B Class A
1040.10(f)(1)	Protective housing allows unnecessary body access to low Class IIIb or IIIa radiation In a Class IV or IIIb product In a Class I, IIa, II, or IIIa product	Minor Major	Class B Class A
1040.10(f)(1)	Protective housing allows necessary body access to Class IIIa or IIIa radiation In a Class IV or IIIb product In a Class I, IIa, II, or IIIa product	Concern Minor	Class C Class B
1040.10(f)(1)	Protective housing allows unnecessary body access to Class II radiation In a Class II product In a Class I product	Concern Minor	Class C Class B
1040.10(f)(2)	Safety interlocks absent when required	Major	Class A
1040.10(f)(2)	Single safety interlock when redundant required	Major	Class A
1040.10(f)(2)	Single component with multiple contacts when redundant required	Minor	Class B
1040.10(f)(2)	Defeatable safety interlocks lacks indication	Minor	Class B
1040.10(f)(2)	Defeatable safety interlocks fails to prevent replacement of protective housing during defeat	Minor	Class B
1040.10(f)(3)	No remote interlock connector	Major	Class A
1040.10(f)(4)	No key control	Major	Class A
1040.10(f)(4)	Key control removable when on	Major	Class A
1040.10(f)(5)	No emission indicator	Major	Class A
1040.10(f)(5)	No delay preceding radiation emission	Minor	Class B
1040.10(f)(5)	Shorter delay than required	Minor	Class B
1040.10(f)(5)	Remote control lacks emission indicator	Major	Class A
1040.10(f)(6)	Beam attenuator without approvable alternate	Major	Class A
1040.10(f)(6)	Beam attenuator with approvable alternate	Concern	Class C
1040.10(f)(8)	Viewing optics Hazardous Non-hazardous for viewing period	Major Concern	Class A Class C
1040.10(f)(9)	No scanning guards	Major	Class A
1040.10(f)(10)	No manual reset	Major	Class A
1040.10(g)(1), (2), and (3)	Warning logotype None Classification too low Classification too high	Major Major Minor, Concern	Class B Class B Class B

1040.10(g)(4)	Warning logotype output information	Minor	Class B
1040.10(g)(5)	No aperture label	Minor	Class B
1040.10(g)(5)	Aperture label not in close proximity to aperture	Minor	Class B
1040.10(g)(5)	Aperture label wording incorrect	Concern	Class C
1040.10(g)(6), (7)	No protective housing labels	Minor	Class B
1040.10(g)(6), (7)	Protective housing placement inappropriate	Minor	Class B
1040.10(g)(6), (7)	Protective housing wording wrong	Concern	Class C
1040.10(g)(8)	Invisible radiation warning on labels	Minor	Class B
1040.10(g)(9), (10)	Label positioning and legibility	Minor	Class B
1040.10(h)(1)	User instructions (i) Promoting unsafe practices Inadequate instructions to avoid exposure (ii) Inadequate radiometric specifications (iii) Inadequate reproductions and locations (iv) Inadequate listing of controls Inadequate caution statement	Major Minor Minor Minor Minor Concern	Class A Class B Class B Class B Class B Class C
1040.10(h)(2)(i)	Reproduction of warning logotype not in catalogs	Minor	Class B
1040.10(h)(2)(ii)	Service information inadequate	Minor	Class B
<b>Specific product requirements</b>			
1040.11(a)(1)	Means to measure medical laser output None Inaccurate	Major Major	Class A Class A
1040.11(a)(2)	Inadequate calibration procedure/schedule	Major	Class A
1040.11(a)(3)	Aperture label	Minor	Class B
1040.11(b)	Excessive output on surveying lasers	Major	Class A
1040.11(c)	No variance for demonstration Class IIIb or Class IV lasers	Major	Class A

**Sample Laser Product Inspection and Field Test Checklist**LASER PRODUCT TEST RECORD

MANUFACTURER \_\_\_\_\_ CLASS \_\_\_\_\_

MODEL \_\_\_\_\_ SERIAL NUMBER \_\_\_\_\_

Status of Unit Examined (Circle one): Prototype/Production unit

Status of Assembly (circle one): Complete/Incomplete

Manufactured Date: \_\_\_\_\_

A. Product Description: (Include basic configuration and size of product, reference to photos and/or diagrams, basic functions to be performed during operation and during maintenance.)

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Product Report: Has the product been reported to CDRH?

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, what is the Accession Number? \_\_\_\_\_



C. Certification/Identification Requirements. If possible, obtain a sample of each required label and attach it to this report. Otherwise, quote pertinent information, especially any noncompliant items.

1. Certification label (1010.2)

a. Is the label permanently affixed? Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

b. Is the Label readily viewable? Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

Location: \_\_\_\_\_

c. Is the label properly stated? Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

(Note: Products under variance require modified certification labels 1010.4(d))

d. Remarks: \_\_\_\_\_  
\_\_\_\_\_

2. Identification label (1010.3)

a. Is the label permanently affixed? Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

b. Is the label readily viewable? Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

Location: \_\_\_\_\_

c. Does the label contain the full name and address?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

d. Does the label contain the place of manufacture (in full or in code)?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

e. If coded, has CDRH been provided the code?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

f. Are the month and year of manufacture stated in full?\*

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

Month and year: \_\_\_\_\_

g. Remarks: \_\_\_\_\_  
\_\_\_\_\_



\*Note: Serialization is acceptable in lieu of month and year for consumer electronic products.

D. Special Purpose Products (1040.11)

1. Is the product a medical laser product?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

Note: In inspecting manufacturers of not only medical laser products but also laser products that are medical devices, verify compliance with other applicable requirements including but not limited to current registration and listing, 510k market clearances, device master record or quality system, current complaint and service records, etc.

a. Does the product include a means of measurement of levels of radiation intended for irradiation of the human body?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

b. How is this accomplished? Measure beam prior to delivery system and determine output levels via calibration constant \_\_\_\_\_;  
Measure output of delivery system \_\_\_\_\_;  
Other \_\_\_\_\_.

c. Indication: power \_\_\_\_\_; energy \_\_\_\_\_; time \_\_\_\_\_.

d. Type of indicator: energy/power select switch \_\_\_; "Test shot" display (remains constant until next best shot) \_\_\_; Real time display (displays level at all times) \_\_\_;  
Other \_\_\_\_\_.

e. If test shot is available only at initiation of procedure or if a select switch is used, does the product have an internal monitoring system capable of maintaining output levels to within  $\pm 20\%$  of displayed value?

Yes \_\_\_ No \_\_\_

f. Is display analog \_\_\_; or digital \_\_\_? If digital, are there sufficient significant digits to allow  $\pm 20\%$  accuracy?

Yes \_\_\_ No \_\_\_

g. Is the total measurement error within  $\pm 20\%$  (see Attachment G)

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

h. Is there a laser aiming beam? Yes \_\_\_ No \_\_\_. Is there a means to measure the level of the aiming beam if the product is ophthalmic and the aiming beam may exceed 1 mW or if the product is not ophthalmic but the aiming beam may exceed 5 mW?

Yes \_\_\_ No \_\_\_

i. Remarks: \_\_\_\_\_  
\_\_\_\_\_

2. Is the product a surveying, leveling, and alignment product?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

a. Is access prevented for wavelengths of 400 nm to 710 nm to radiation power in excess of 5.0 mW for any duration greater than  $3.8 \times 10^{-4}$  seconds?

b. Is access prevented to radiation levels in excess of Class I limits for any other combination of emission Duration and wave length range?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

c. Remarks: \_\_\_\_\_  
\_\_\_\_\_

3. Is the product a demonstration laser product?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

a. Does the product prevent human access to radiation in excess of the Class IIIa (3R) limit?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

b. Remarks: \_\_\_\_\_  
\_\_\_\_\_

E. Label Requirements. See instruction in paragraph B.

1. Warning logotypes\* (1040.10(g)(1),(2),(3),(4),(5),(9), and (10))

a. Is the logotype the correct logotype?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

b. Is the label properly worded for its class designation?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

c. Does the label have the proper color?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

d. Is the output information present and correct?

(Maximum output stated \_\_\_\_\_.) Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

e. Is the media or wavelength information present and correct?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

f. Is the label permanently affixed and clearly visible during operation, maintenance, and service?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

g. Is the label positioned so as to make exposure unnecessary during reading?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

Location: \_\_\_\_\_

h. Does the label include a warning for "invisible" or "invisible and/or visible" radiation?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

i. Remarks: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Note: Warning labels in accordance with IEC 60825-1 including product classification are acceptable.

2. Aperture label (for Classes II, IIIa, IIIb, IV, 3R, 3B and 4) 1040.10(g)(5),(8),(9), and (10)

a. Is a label present and in proximity to each aperture?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

b. Is the label properly worded? Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

c. Is the label permanently affixed and clearly visible?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

d. Is the label positioned so as to make exposure unnecessary during reading?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

(Location: \_\_\_\_\_)

e. Does the label include a warning for "invisible" or "invisible and/or visible" radiation?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

f. Remarks: \_\_\_\_\_

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3. Noninterlocked protective housing label (1040.10(g)(6),(8),(9), and (10))

a. Are the labels on or near all appropriate panels or covers which are removed for operation, maintenance, or service?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

b. Are all labels visible prior to removal of such portions of the protective housing?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

c. Are all labels visible after opening?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

d. Are all labels correctly worded? Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

e. Are all labels permanently affixed and clearly visible?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

f. Do all labels contain a warning for "invisible" or "invisible and/or visible" radiation?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

g. Remarks: \_\_\_\_\_

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4. Defeatably interlocked housing labels 1040.10(g)(7),(8),(9), and (10)

a. Are labels provided for each defeatably interlocked panel or cover which is removed for operation, maintenance, or service?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

b. Are all labels visible prior to interlock defeat?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

c. Are all labels visible during interlock defeat?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

d. Are all labels correctly worded?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

e. Are all labels permanently affixed and clearly visible?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

f. Do all labels contain a warning for "invisible" or invisible and/or visible" radiation?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

g. Remarks: \_\_\_\_\_  
\_\_\_\_\_

F. Performance Requirements (1040.10(f)):

1. Protective Housing (1040.10(f)(1))

a. Does the housing prevent access at all times to laser radiation above Class I not necessary for operation of the product?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

b. Does the housing prevent access at all times to collateral optical radiation above Class I not necessary for operation of the product?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

c. Has x-radiation been evaluated?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

d. Does the housing prevent access to x-radiation levels in excess of 0.5 mR/hr at all times during operation of the product?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

e. Remarks: \_\_\_\_\_  
\_\_\_\_\_

2. Safety Interlocks (1040.10(f)(2)) (Complete for each interlock. Identify the portion of removable or displaceable housing and interlock described.)

a. Do operation or maintenance functions require moving portions of the housing which could allow access to radiation?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

Describe: \_\_\_\_\_

\_\_\_\_\_

b. Class of radiation to which access could be gained?

Class \_\_\_\_\_.

c. Is a fail safe or multiple interlock required (including 1040.1(f)(2)(iii))?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

Where? \_\_\_\_\_

\_\_\_\_\_

d. Are safety interlock(s) present? where? \_\_\_\_\_

1. TYPE: Microswitch \_\_\_; Mercury switch \_\_\_;  
male-female plug \_\_\_; mechanical shutter \_\_\_; other \_\_\_\_\_.

Describe: \_\_\_\_\_

e. Method of limiting access: directly interrupts primary laser power \_\_\_; interrupts primary laser power through relay, contactor, switching tube or transistor \_\_\_; spoils the cavity \_\_\_; shutter beam via solenoid \_\_\_; other \_\_\_\_\_.

f. Is there a multiple or fail safe interlock on each housing for which an interlock is required?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

g. Is the interlock defeatable? Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

h. Is there an indication of defeat? Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

Describe: \_\_\_\_\_

i. Does the interlock preclude replacement of the housing while the interlock is defeated?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

j. Are non-safety interlocks present? Where? \_\_\_\_\_

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

k. Remarks: \_\_\_\_\_

\_\_\_\_\_

3. Remote Interlock Connector (1040.10(f)(3), Class IIIb or IV systems only)

a. Is a remote control connector present?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

b. Type? Describe: \_\_\_\_\_

c. Is the voltage across the connector less than 130 volts RMS?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

d. Is the access to laser and collateral radiation prevented when the terminals are not joined?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

e. Method of operation: Directly interrupts laser power\_\_\_; interrupts laser power through relay, etc.\_\_\_\_; shuts beam or interrupts cavity\_\_\_\_\_.

f. Does the emission delay reactivate when the remote control circuit is interrupted?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

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

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

h. Remarks: \_\_\_\_\_

\_\_\_\_\_

4. Key Control (1040.10(f)(4), Class IIIb, IV, 3B, or 4 systems only)

a. Is a key control present? Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

Describe: \_\_\_\_\_

- 
- b. Is a key removable in the "on" position?  
Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_
- c. Is operation prevented when the key is removed?  
Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_
- d. How? \_\_\_\_\_  
\_\_\_\_\_
- e. Remarks: \_\_\_\_\_  
\_\_\_\_\_
5. Beam Attenuator (1040.10(f)(6), Class IIIb, IV, 3B or 4 systems only)
- a. Is a beam attenuator present? Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_
- b. Type: mechanically operated shutter\_\_\_; electrically operated\_\_\_; aperture cap or cover\_\_\_; other\_\_\_.
- Describe: \_\_\_\_\_  
\_\_\_\_\_
- c. Is the attenuator permanently attached?  
Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_
- d. Does the attenuator prevent access by any part of the body to radiation in excess of Class I limits?  
Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_
- e. If there is no beam attenuator, has the manufacturer requested and obtained approval of an alternate means of safety?  
Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_
- f. Remarks: \_\_\_\_\_



- 
6. Emission Indicator (1040.10(f)(5), Class, IIIb, IV, 3B or 4 Systems only)
- a. Is an emission indicator present on the laser product?
- Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_
- Where? \_\_\_\_\_
- b. Type: tungsten lamp(s)\_\_\_\_; neon lamp(s)\_\_\_\_; LED(s)\_\_\_\_; other\_\_\_\_.
- Describe: \_\_\_\_\_
- \_\_\_\_\_
- c. If the indicator is visible, is it visible through the protective eyewear that is normally supplied or recommended?
- Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_
- d. Can the indicator be viewed without exposure to radiation in excess of Class I limits?
- Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_
- e. Is there a delay between an indication of emission and the beginning of emission?
- Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_
- f. How is emission delay achieved? Thermal relay\_\_\_\_; inherent in the lasing process\_\_\_\_; delay circuit\_\_\_\_; other\_\_\_\_.
- Describe: \_\_\_\_\_
- \_\_\_\_\_
- g. Length of delay? \_\_\_\_\_
- h. Is the power source or operation control separable from the laser by greater than 2 meters when assembled for use?
- Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_
- i. If separated greater than 2 meters, is an emission indicator present on the energy source or controller?
- Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

Where? \_\_\_\_\_

j. Type: Tungsten lamp(s)\_\_\_; neon lamp(s)\_\_\_; LED(s)\_\_\_; bell or buzzer\_\_\_; meter or display\_\_\_; mechanical flag\_\_\_; other\_\_\_.

Describe: \_\_\_\_\_

\_\_\_\_\_

k. Is there a delay between an indication of emission and the beginning of emission?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

l. How is emission delay achieved? Thermal relay\_\_\_; inherent in the lasing process\_\_\_; delay circuit\_\_\_; other\_\_\_.

Describe: \_\_\_\_\_

\_\_\_\_\_

m. Length of delay? \_\_\_\_\_

n. Remarks: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

6. Location of Controls (1040.10(f)(7))

a. Are the controls located so that exposure is unnecessary for operation or adjustments?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

b. Remarks: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

7. Viewing optics (1040.10(f)(8))

a. Are viewing optics or viewports present?

Yes\_\_\_ No\_\_\_ ND\_\_\_ NA\_\_\_

b. Type: microscope \_\_\_; telescope \_\_\_; viewport \_\_\_; display screen \_\_\_; other \_\_\_.

Describe: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

c. Where? \_\_\_\_\_

\_\_\_\_\_

d. Do the viewing optics attenuate radiation at all times during operation or maintenance to levels less than Class I limits?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

e. Do the viewing optics employ a shutter or variable attenuator?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

f. Upon failure of the shutter of the variable attenuator is access to radiation levels greater than the Class I limits prevented?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

g. Remarks: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

8. Scanning Safeguard (1040.10(f)(9))

a. Is the radiation emitted by the product scanned?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

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

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

c. In the event of scan failure, is human access to laser radiation in excess of the product class prevented?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

d. Remarks: \_\_\_\_\_

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9. Manual Reset Mechanism (1040.10(f)(10) Class IV laser systems)

Describe the operation of the Manual Reset. \_\_\_\_\_

How is it achieved? (latching relay, etc.) \_\_\_\_\_

10. Removable laser system (1040.10(c)(2))

a. Does the product incorporate a laser system?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

b. Is the laser system removable?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

c. If removable, is the laser system independently certified?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

d. If not removable, specify how removability is prevented: hard wiring \_\_\_; modified connector \_\_\_; assembled internally from components \_\_\_; other (specify).

\_\_\_\_\_

e. Remarks: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

G. Laser Product Measurements

Model # \_\_\_\_\_ Serial # \_\_\_\_\_

Manufacturer's Claimed Classification: \_\_\_\_\_

Brief description of product: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Test Instrument(s) Used: \_\_\_\_\_

\_\_\_\_\_

Circle radiometric quantity tested and specify units below (Radiance ( $\text{W cm}^{-2} \text{sr}^{-1}$ ), Radiant Energy (J), Power (W), etc.)

Measurement No.	Wavelength (nm)	Instrument reading, R (units _____)	Calibration factor, K (units _____)	Corrected value, R*K (units _____)

Calculations (as needed):

\_\_\_\_\_

\_\_\_\_\_



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J. Information requirements (Directions: Complete this section only if the information and requirements are reviewed during the inspection).

1. User Information (1040.10(h)(1))

a. Does the manual contain adequate instructions for assembly, operation, and maintenance? Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

b. Does it contain clear warnings to avoid exposure?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

c. Does it contain a statement of output parameters?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

d. Does it contain legible reproductions of all labels and hazard warnings?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

e. Does it include the corresponding position of each label on the product?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

f. Does it contain listing of controls, adjustments, and procedures for operation and maintenance?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

g. Does it contain a schedule of maintenance?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

h. Does it contain the "Caution - use of controls..." warning?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

i. Does it contain a compatibility statement (laser source or laser system not supplied with the product)?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

j. Does it contain a calibration schedule (medical laser product)?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

k. Does it include a warning not to point the laser radiation at the audience (especially Class IIIa demonstration laser products)?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

l. Does it include information to determine nominal hazard zone(class IV multi-axis workstations)?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

m. Remarks: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

2. Purchasing Information (1040.10(h)(2))

a. Are legible reproductions of the logotype required to be affixed to the product (including information required for positions 1, 2, and 3) contained in catalogues, specification sheets, and descriptive brochures?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

3. Servicing Information (1040.10(h)(2))

a. Are adequate instructions for service adjustments and service procedures available?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

b. Are clear warnings and precautions to avoid possible exposure included?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

c. Is a schedule of maintenance necessary to keep the product in compliance included?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

d. Are controls and procedures which would be used by reasons other than the manufacturer or his agent to increase accessible emission levels listed?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

e. Is a clear description of the locations of displaceable portions of the protective housing provided?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

f. Do these instructions provide legible reproductions of required labels and hazard warnings?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_



g. Do these instructions include protective procedures for service personnel?

Yes \_\_\_ No \_\_\_ ND \_\_\_ NA \_\_\_

h. Remarks: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_