MILITARY LASER EXEMPTION FROM U.S. FOOD AND DRUG ADMINISTRATION REQUIREMENTS

TIP No. 24-108-0420

INTRODUCTION

Laser systems manufactured or marketed in the United States must meet the requirements set forth in the U.S. Food and Drug Administration (FDA) Federal Laser Product Performance Standard (FLPPS).[1] The FDA, which regulates lasers in the United States, has granted an exemption to specific requirements for military-specific laser systems when a design requirement could compromise mission performance. A military-specific laser is one used for combat, combat training, or one that is classified in the interest of national security. This is often referred to as the "military exemption." Misunderstandings about the exemption process by both laser manufacturers and Department of Defense (DOD) offices that procure military-specific lasers have led to instances of the military exemption being misused.

The use of the military exemption to the FDA's requirements is granted to the DOD by FDA Exemption No. 76EL-01DOD[2] and further clarified in FDA Laser Notice No. 52.[3] The DOD policy for issuing the exemption is explained in Department of Defense Instruction 6055.15[4] and Military Standard (MIL-STD) 1425A.[5] The Army's policy on military laser exemptions is detailed in Army Regulation (AR) 385-10, (*The Army Safety Program*, 2017) paragraph 7-8e.

BACKGROUND

Laser systems manufactured or marketed in the United States for the Army are required to comply with all provisions of the FDA FLPPS unless an exemption from specific control measure(s) has been granted. The Nonionizing Radiation Division (NRD) of the U.S. Army Public Health Center (APHC) performs laser hazard assessments of laser systems being procured by the Army. These assessments address the hazards of the laser system and the system's safety control measures that are required by the FDA FLPPS. A general overview of the performance requirements in the FDA FLPPS is included in Table 1. The FDA Laser Notice 56[6] allows manufacturers to meet comparable clauses in International Electrotechnical Commission (IEC) Standard 60825-1, Edition 3,[7] in lieu of those in the FDA FLPPS and still be considered FDA compliant. More detailed information can be found in the referenced paragraph. These control measures were developed with commercial, laboratory, and medical applications in mind and some are not conducive to military applications.

ELIGIBILITY REQUIREMENTS

To be eligible to use the military exemption, the laser system must meet all of the criteria below:

1. **The laser system is owned and used exclusively by the DOD (Army, Navy/Marine Corps, and Air Force).** All other Federal offices/agencies (Coast Guard, Department of Homeland Security, Border Patrol, Federal Bureau of Investigation, and so forth) do not qualify. Manufacturers developing laser systems for sale to other Federal agencies that cannot comply fully with the FDA FLPSS must seek guidance from the Federal

entity prior to the sale of these devices. Systems delivered to other offices will have different exemption or variance procedures to follow.

2. **The laser system being acquired/purchased is designed for actual combat or combat training or is classified in the interest of national security.** Laser systems purchased by the DOD for other purposes (e.g., a laser cutter in a welding shop, laser system purchased for a research lab, medical laser, and so forth) are not eligible for the exemption. Selling/delivering a laser system to the Army does not singularly qualify the laser for exemption from the FDA FLPPS requirements. The military exemption can only apply to combat systems, combat training systems, and systems that are classified in the interest of national security.

3. **The laser system is unable to comply with the FDA FLPPS due to mission requirements.** The FDA recognizes that certain required engineering control measures for commercial laser systems may be incompatible with the intended mission of a DOD laser system. For example, an illuminated emission indicator could compromise camouflage, or the key for a master key control could be lost in combat and render a system inoperable. Creative and innovative designs should be used as much as possible to comply with FDA FLPPS requirements without compromising mission performance. For example, some systems use recessed light-emitting diodes or indicators inside viewing optics to satisfy the emission indicator requirement without compromising camouflage.

If all three eligibility requirements above are satisfied for a laser system, then the system is eligible for the military exemption. FDA FLPPS requirements that **could not** be met must be justified, and alternate control measures are required according to MIL-STD 1425A.[5] All FDA FLPPS requirements that will not have a negative impact on the mission must be met by the laser system prior to sale to the DOD.

PROCESS

The laser system manufacturer must receive an exemption notification letter from the DOD procuring office granting the use of the military exemption for the product in order for a laser system to be sold/delivered. This signed exemption letter allows the manufacturer to deliver exempt lasers.

Table 1. Food and Drug Administration Performance Requirements

Requirement	Reference		Discussion	Required for Class*:
	21 CFR 1040.10	Comparable clause in IEC 60825-1		
Protective Housing	(F)(1)	6.2	Prevents access to hazardous collateral laser radiation.	All
Safety Interlocks	(F)(2)	6.3	Designed to prevent removal of access panels until accessible emission values are below hazardous levels.	All

Requirement	Reference		Discussion	Required for Class*:
	21 CFR 1040.10	Comparable clause in IEC 60825-1		
Remote Interlock Connector	(F)(3)	6.4	Permits easy addition of external interlock (e.g., door sensor) in laser installations.	3B, 4
Key Control	(F)(4)	6.6	Renders laser inoperative when key is removed to limit access to only authorized users.	3B, 4
Emission Indicator	(F)(5)	6.7	Gives audible/visible warning when laser is switched on.	3R (Invisible wavelengths), 3B, 4
Beam Attenuator	(F)(6)	6.8	Allows user to temporarily block beam to safe levels. This may be an opaque cover that completely blocks the beam or a filter that reduces the transmitted power to safe levels.	3B, 4
Location of Controls	(F)(7)	6.9	Controls so located that there is no danger of exposure to hazardous radiation when adjusting controls.	All
Viewing Optics	(F)(8)	6.10	Viewing optics that are incorporated into the laser system must allow safe viewing of direct or reflected laser radiation emitted by the system.	All
Scanning Safeguard	(F)(9)	6.11	For scanning laser systems (e.g., lidar [Light Detection and Ranging]), a scan failure shall not cause product to exceed its designated class.	All
Manual Reset Mechanism	(F)(10)		Requires manual reset if power interrupted or remote interlock is actuated.	4
Laser Warning Label	(G)	7.2-7.9	Required information depends on the hazard class and laser product standard used to classify the laser. Label must be clearly visible, permanent, and legible.	All
Aperture Label	(G)(5)	7.8	Location of laser emission must be marked by a label. See referenced paragraph for specific text or symbol.	3R, 3B, 4
User Information	(H)	8.1	Required information to instruct users of all relevant safety information.	All
Modification of a Certified Product	(H)(3)		Reporting required if a certified laser is modified.	All
Identification Label	21 CFR 1010.2		Required information to identify the laser product standard used to classify the laser.	All
Compliance Label	21 CFR 1010.3		Specific wording required information to identify compliance with regulatory requirements.	All
Note: *The name and nomenclature of the hazard classes varies between standards. IEC class 3R is equivalent to FDA class IIIa and IEC class 3B is equivalent to FDA class IIIb.				

Two letters have been developed by the DOD's Laser System Safety Working Group (LSSWG) in conjunction with the FDA: one for sale/delivery of a small number of devices for test and

evaluation (T&E) and one for sale/delivery of any fielding systems. Detailed information about the two different types of exemption letters is in Appendices A and B. Assistance in writing an exemption letter is available by contacting the APHC NRD.

The DOD exemption letters are authored and signed by an appropriate person in the procuring office and delivered to the manufacturer prior to sale/delivery of any laser system to the DOD office. AR 385-10 paragraph 7-8.e requires that "PEOs [Program Executive Offices] and/or program managers or contract officers" issue the DOD military exemption letter. By issuing the exemption letter, the signatory is responsible for knowing the location of laser systems on that contract from delivery to disposal. The military laser exemption process is designed to keep lasers that are lacking necessary safety features from falling into the hands of Civilians.

By law, a laser must be labeled stating compliance with the FDA FLPPS or that it is exempt. Sample labels are shown in Figures 1 and 2 below.

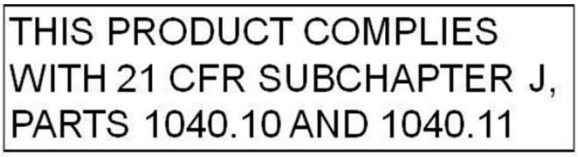

Figure 1. Sample Compliance Label

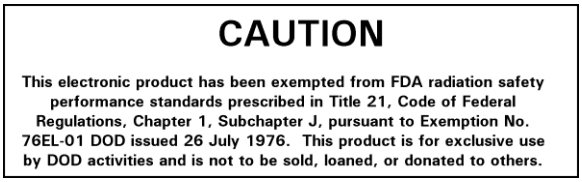

Figure 2. Sample Military Exemption Label

It is a violation of Federal law for a manufacturer to sell/deliver a laser system labeled as "military exempt" without receiving written permission to use the exemption from the DOD. MIL-STD-1425A paragraph 1.3.3[5] states that the military exemption letter is provided to the contractor by the government contracting officer. Army offices issuing exemption letters must provide a copy to the APHC NRD.

RESTRICTIONS

An exemption notification letter is written specifically for a particular contract and is limited by the number of units or sale/delivery date. There is **no such thing as a "blanket" exemption**. Most importantly, **exempted laser systems cannot be resold by the DOD** to any other office or person(s) unless they are brought into full compliance with the FDA FLPPS, labeled as such, and registered with the FDA. Typically, DOD exempt laser systems are destroyed after their useful life has ended.

COMPONENTS

Electronic laser products that are sold from one manufacturer to another for use as a component in a laser system, are considered laser components. Once the component is integrated into a laser system, the system must comply with the FDA FLPPS or be issued a military exemption before being sold or delivered to the DOD.

By definition, a component is a laser subsystem, incorporated into a laser product that is incapable, without modification, of producing laser radiation when removed from a laser product. In other words, if a laser subsystem can be removed from the end product and connected to the electrical mains and operated without needing the use of tools for connection, then the laser system is a "removable laser system" that must comply with the FDA FLPPS. Laser components must be labeled, as in Figure 3, and registered as components with the FDA by the manufacturer. Laser components require adequate instructions for safe installation in the laser system service manual. Guidance is provided in paragraph 10.40.10(a) of the FDA FLPPS[1] and the FDA Compliance Guide for Laser Products[8].

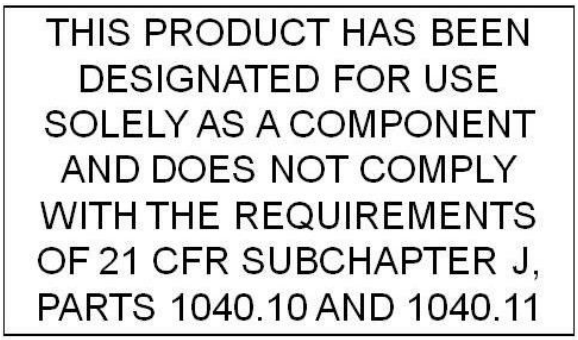

Figure 3. Sample Component Label

TEST AND EVALUATION MILITARY EXEMPTION

Deficiencies in laser systems are sometimes unknown before the DOD takes ownership, such as systems delivered to DOD in limited quantities for T&E early in the acquisition cycle, demonstrations, proof of concept tests, and so forth. Laser systems in this category are expected to undergo design changes before entering full-rate production or fielding. The DOD has worked with the FDA to develop a template for a military exemption notification letter to allow delivery of laser systems so that evaluation of the T&E system will influence design changes on the next iteration of the system. A template of a T&E laser military exemption letter is included in Appendix A. It is recommended that APHC NRD be notified of intended design specifications early in the development process in order to assist in safety design considerations for current and later developmental stages.

Upon delivery of T&E laser systems to the procuring office and prior to any T&E activities, APHC NRD will perform a laser-hazard assessment of the laser system(s). This assessment will

include classification of the laser, hazard distances, and eye protection requirements. This will also include a review of the performance requirements of FDA FLPPS to determine system compliance with Federal regulations.

FIELDING MILITARY EXEMPTION

The designs of laser systems that are being fielded or are entering full-rate production are not expected to change. The design requirements of the FDA FLPPS that cannot be met due to mission requirements have been confirmed through previous T&E and are known before the systems are delivered to the DOD. Alternate control measures to mitigate these deficiencies have been implemented according to MIL STD 1425A. The DOD has worked with the FDA to develop a template for a military exemption notification letter for such systems. A template of a fielding laser military exemption letter is included in Appendix B.

A form is included that lists all of the design requirements included in the FDA FLPPS. Requirements that cannot be met should be noted on this form with justification and mitigation procedures noted in the text box. For example, the emission indicator box could be checked and the text box filled out with, “A visible emission indicator would hinder mission performance by compromising camouflage. Operators will be trained to treat all armed lasers as live weapons to avoid exposure to operator and bystanders.”

POINT OF CONTACT

For more information, contact the APHC NRD at: usarmy.apg.medcom-aphc.mbx.nonionizing@mail.mil, 410-436-3932, DSN 584-3932, or https://phc.amedd.army.mil/topics/workplacehealth/lor/Pages/default.aspx.

REFERENCES

1. *Code of Federal Regulations*. Title 21, Part 1040, Performance Standards for Light-Emitting Products.

2. FDA. 1976. Exemption No. 76EL-01DOD, Letter of Exemption from the FDA for DoD Exemption from Provisions of Title 21 CFR, Part 1040, July 29, 1976.

3. FDA. 2002. Laser Notice 52. Guidance on the Department of Defense Exemption from the FDA Performance Standard for Laser Products; Guidance for Industry and FDA, FDA Center for Devices and Radiological Health, 12 July 2002.

4. Department of Defense. 2007. Instruction No. 6055.15, *DOD Laser Protection Program*.

5. Department of Defense. 1991. Military Standard-1425A, *Safety Design Requirements for Military Lasers and Associated Support Equipment*.

6. FDA. 2019. Laser Notice 56. Laser Products—Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1, 8 May 2019.

7. IEC. 2014. International Standard 60825-1 Edition 3.0, Safety of Laser Products—Part 1: Equipment Classification and Requirements.

8. Department of Health and Human Services. 2008. Compliance Guide for Laser Products, HHS Publication FDA 86-8260.

APPENDIX A

DOD MILITARY LASER EXEMPTION NOTIFICATION FOR T&E SYSTEMS TEMPLATE

According to Department of Defense Instruction 6055.15 and MIL-STD 1425A, paragraph 1.4.4.4, a DOD military laser exemption notification letter for T&E systems should be developed using the template provided in this appendix.

TIP No. 24-108-0420

OFFICE SYMBOL Month day, year

Military Exemption Authorization Number (Contact APHC)

Name of Company
Attention [Enter Name or OFFICE SYMBOL]
Address
City State ZIP + 4

Dear [Enter Name or Title]:

This letter is the authorization to deliver [Name of T&E System] for test and evaluation activities according to the U.S Food and Drug Administration (FDA) Exemption No. 76EL-01DOD.

The prototype/experimental [Name of T&E System] is used exclusively by the DOD and designed for combat/combat training or classified in the interest of national security, manufactured under contract XXX-XXX-XXXXX, and limited to the minimum number of units necessary for test and evaluation (T&E) activity. The [Name of T&E System] is exempted from requirements of the FDA radiation safety performance standards prescribed in sections 1040. 10 and 1040.11 of Title 21 Code of Federal Regulations (CFR) in order to meet military T&E requirements.

Any modification to the [Name of T&E System] (including material components, physical design, or laser output characteristics) or deviation from the parameters defined in the table requires the manufacturer to obtain a new exemption authorization letter.

Parameter	Description
Contract #	XXX-XXX-XXXXX
Product Name	Prototype/Experimental XYZ ILRFTD
Model #	XYZ-ABC
Serial #(s)	00001-00005
Lot #(s)	
DOD Service(s)	Enter DOD Service procuring lasers for T&E
Organization/Unit	PM XYZ
Quantity	Minimum number of units necessary for T&E activity
Delivery Dates	mm/dd/yyyy - mm/dd/yyyy
Other Limits to Authorization	Systems delivered under this contract are limited to T&E activities on an approved [enter appropriate DOD Service] laser range only.

Upon delivery of the [Name of T&E System] to this office and prior to any T&E activities, a laser hazard evaluation of the laser system(s) will be performed by the [enter the appropriate DOD Service laser safety review coordinator from paragraph 1.4.1.1. This evaluation will include classification of the laser and nominal ocular hazard distances and eye protection requirements if any exist.

The evaluation will also include a review of the performance requirements of sections 1040.10 and 1040.11 of Title 21 CFR to determine system compliance with this Federal regulation and how these requirements impact the military operational requirements of the [Name of T&E System] system.

In conjunction with the [enter the appropriate Department of Defense Service laser safety review coordinator or authority from paragraph 1.4.1.1, this office will verify and determine which of the Federal performance requirements must be met and those which cannot be met due to the [Name of T&E System]'s operational use.

The Federal performance requirements verified and determined by [enter the appropriate DOD Service laser safety review coordinator or authority from paragraph 1.4.1.1 that cannot be met by the [Name of T&E System] due to its operational use are exempt, and those exempt Federal performance requirements will be reported by this office to [Name of Company]. If none are reported, the [Name of T&E System] must meet all of the Federal requirements.

Prior to delivery of any laser devices outside the scope of this notification, such laser(s) must either comply with all Federal requirements and be registered by [Name of Company] as such with the FDA. If exempt from specific performance requirements, a letter listing these exempted requirements and rationale for noncompliance will be authored by this office to [Name of Company]. The manufacturer is then required to meet all of the design requirements for exempt lasers as outlined in Military Standard-1425A or as approved by this Service laser safety authority.

In addition to any other labeling requirements, an exempted laser product is required to have labeling permanently affixed to the device housing with the information shown in the sample label (or alternate wording if approved by the applicable Service laser safety authority).

CAUTION
This electronic product has been exempted from FDA radiation safety performance standards prescribed in sections 1040.10 and 1040.11 of Title 21, Code of Federal Regulations under Exemption No. 76EL-01DoD issued on July 26, 1976. Use this product only with adequate protective devices or procedures. Do not sell or transfer outside the DOD.

The point of contact for questions pertaining to this authorization is [POC name, title, and contact information].

Sincerely,

Authorizing Official Name
Job Title
Approving Office

cc:
For Army exemption notifications include: APHC (MCHB-PH-NRD)

APPENDIX B

DOD MILITARY LASER EXEMPTION NOTIFICATION FOR FIELDING SYSTEMS TEMPLATE

According to Department of Defense Instruction 6055.15 and MIL-STD-1425A paragraphs 1.4.4.4, a Department of Defense military laser exemption notification letter for fielding systems should be developed using the template provided in this appendix.

TIP No. 24-108-0420

OFFICE SYMBOL Month day, year
Military Exemption Authorization Number (Contact APHC)

Name of Company
Attention [Enter Name or OFFICE SYMBOL]
Address
City State ZIP + 4

Dear [Enter Name or Title]:

This letter is the authorization to deliver [Name of Fielding System] for fielding according to the U.S. Food and Drug Administration (FDA) Exemption No. 76EL-01DOD.

The [Name of Fielding System], being manufactured under contract XXXXXX, is exempted from requirements listed in the attached form (Block 16) of the FDA radiation safety performance standards prescribed in sections 1040.10 and 1040.11 of Title 21 Code of Federal Regulations (CFR) in order to meet military operational requirements.

Any modification to [Name of Fielding System] (including material components, physical design, or laser output characteristics) or deviation from the parameters defined in the table requires the manufacturer to obtain a new exemption authorization letter.

Parameter	Description
Contract #	XXXXXX
Product Name	XYZ ILRFTD
Model #	XYZ-ABC
Serial #(s)	00006-01006 (If known)
Lot #(s)	
Department of Defense Service(s)	Enter DOD Service procuring lasers for Fielding
Organization/Unit	PM XYZ
Quantity	1000
Delivery Dates	Mm/dd/yyyy - mm/dd/yyyy
Other Limits to Authorization	

FDA Laser Notice 52 states that a manufacturer violates Federal law if it delivers a laser system to the DOD not in compliance with the FDA standard unless it first receives a written authorization by the applicable DOD authority to apply the exemption discussed herein. Further, an appropriate DOD laser safety review coordinator must evaluate all military exempt laser products to determine compliance with relevant military or Federal requirements. Finally, the manufacturer must maintain a copy of this authorization for use of the military exemption.

Although the use of the DOD exemption has been authorized, the system design must still adhere to the requirements of MIL-STD-1425, “Safety Design Requirements for Military Lasers

and Associated Support Equipment," or by special approval by [enter the appropriate DOD Service laser safety review coordinator or authority from paragraph 1.4.1.1.] In addition to any other labeling requirements, this laser product is required to have labeling permanently affixed to the device housing with the information shown in the sample label (or alternate wording if approved by the applicable Service laser safety authority).

CAUTION
This electronic product has been exempted from FDA radiation safety performance standards prescribed in sections 1040.10 and 1040.11 of Title 21, Code of Federal Regulations under Exemption No. 76EL-01DoD issued on July 26, 1976. Use this product only with adequate protective devices or procedures. Do not sell or transfer outside the DOD.

Approved deviations from the requirements of Title 21 CFR, Part 1040, complete with justification for each deviation, are listed in the attached form (Block 16). Other deviations are not authorized under this exemption notification.

The point of contact for questions pertaining to this authorization is [POC name, title, and contact information].

Sincerely,

Encl

Authorizing Official Name
Job Title
Approving Office

cc:
For Army exemption notifications include: AIPH (MCHB-PH-NRD)

DOD LASER EXEMPTION FROM FEDERAL STANDARDS	1. DATE

EXEMPTION STATEMENT

In accordance with an interagency agreement between DOD and FDA, 29 July 1976, the following electronic product(s) are exempted from FDA radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter 1, Subchapter J, pursuant to Exemption No. 76 EL-01 DOD, issued 26 July 1976.

2. TO:	3. FROM:

4. LASER SYSTEM NOMENCLATURE	5. NATIONAL STOCK NUMBER *(if Known)*

6. MODEL/PART #	7. SERIAL #(S)

8. MANUFACTURER	9. DOD SERVICE(S)
	☐ US Army ☐ US Air Force ☐ US Navy/Marine Corps ☐ Joint Office

10. MILITARY SPECIFIC QUALIFIER (Check all that apply)

☐ COMBAT ☐ COMBAT TRAINING ☐ NATIONAL SECURITY (Security Classification of Secret or above)

11. CONTRACT NUMBER	12. QUANTITY	13. DELIVERY DATES

14. OTHER LIMITS (IF ANY) TO AUTHORIZATION

15. REMARKS

This exemption is required in order to allow the _____ to be procured by the _____ for _____ operational requirements. The _____ is unable to comply with all of the requirements of the Federal Performance Standard for Laser Products issued by the FDA, CDRH, in Title 21, CFR, Subchapter J, Parts 1040.10 and 1040.11. The _____ will incorporate all of the design requirements for exempted lasers as required in MIL-STD-1425A, Safety Design Requirements for Military Lasers and Associated Support Equipment. The _____ is unable to comply with the following performance, labeling, and/or informational requirements of 21 CFR 1040. For each requirement that cannot be met, provide rationale for noncompliance. See 21 CFR 1040 for design requirement details.

16. DEVIATIONS FROM 21CFR1040 WITH JUSTIFICATION

☐ Protective Housing

☐ Safety Interlocks

☐ Remote Interlock Connector

☐ Key Control

16. DEVIATIONS FROM 21CFR1040 WITH JUSTIFICATION (cont)

☐ Emission Indicator

☐ Beam Attenuator

☐ Location of Controls

☐ Viewing Optics

☐ Scanning Safeguard

☐ Manual Reset Mechanism

☐ Labeling Requirements

☐ User/Purchasing/Servicing Information

☐ Modification of a Certified Product

☐ Other

17. AUTHORIZING OFFICIAL

a. TYPED OR PRINTED NAME (First, Middle Initial, Last)	b. TITLE
c. SIGNATURE	d. DATE SIGNED