DoD Instruction 6055.15

DoD Laser Protection Program for Military Lasers

Originating Component:	Office of the Under Secretary of Defense for Personnel and Readiness
Effective:	August 25, 2023
Releasability:	Cleared for public release. Available on the Directives Division Website at https://www.esd.whs.mil/DD/.
Reissues and Cancels:	DoD Instruction 6055.15, "DoD Laser Protection Program," May 4, 2007, as amended
Incorporates and Cancels:	Directive-type Memorandum 19-013, "Managing Risk from Electromagnetic Field Radiation Emitters and Lasers," December 27, 2019, as amended
Approved by:	Gilbert R. Cisneros, Jr., Under Secretary of Defense for Personnel and Readiness

Purpose: In accordance with the authority in DoD Directive (DoDD) 5124.02 and the April 10, 2019 Deputy Secretary of Defense Memorandum, this issuance:

- Establishes policy, assigns responsibilities, and provides procedures in support of DoD Instruction (DoDI) 6055.01 to protect the health and safety of DoD personnel and the public from the operation of military lasers.
- Establishes the DoD Laser Systems Safety Working Group (LSSWG), the DoD Laser Safety Event Hotline, and the Laser Accident and Incident Registry.

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SECTION 1: GENERAL ISSUANCE INFORMATION

1.1. APPLICABILITY.

This issuance:

a. Applies to OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this issuance as the "DoD Components").

b. Applies to the acquisition, procurement, and use of DoD military-specific lasers that qualify for military exemption from the Food and Drug Administration (FDA) (i.e., FDA Exemption Number 76EL-01DOD, also known and referred to in this issuance as the "FDA military exemption," established in the FDA "Letter of Exemption from the Food and Drug Administration (FDA) for DoD Exemption from Provisions of 21 CFR 1040," referred to in this issuance as the "FDA military exemption letter.")

c. Does **not** apply to:

(1) Laser systems or personnel associated with lasers used for industrial, medical, or dental applications that do not qualify for exemptions specified in the FDA military exemption letter.

(2) Human effects from laser radiation exposure associated with the development of non-lethal weapons as described in DoDI 3200.19.

1.2. POLICY.

The DoD will:

a. Protect DoD personnel and the public from the risk of death, injury, or illness or property damage from the use of military lasers.

b. Safeguard defense systems, infrastructure, property, and the environment from accidental harm while executing its mission requirements in support of national defense.

1.3. INFORMATION COLLECTIONS.

The laser incident and mishap response report, referred to in Paragraph 3.6., does not require licensing with a report control symbol in accordance with Paragraphs 1.b.(4) and 1.b.(5) of Enclosure 3 in Volume 1 of DoD Manual (DoDM) 8910.01.

SECTION 2: RESPONSIBILITIES

2.1. ASSISTANT SECRETARY OF DEFENSE FOR READINESS (ASD(R)).

Under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, the ASD(R):

a. Oversees the implementation of this issuance and represents the Secretary of Defense on both internal and interagency laser safety and health matters.

b. Represents DoD safety and occupational health interests to Federal agencies. The ASD(R) is the sole interface with the FDA for DoD policy issues.

c. Establishes the DoD LSSWG to provide guidance and recommend policy on laser safety and health matters within the DoD. The functions of the DoD LSSWG are described in Section 4.

2.2. UNDER SECRETARY OF DEFENSE FOR ACQUISITION AND SUSTAINMENT.

The Under Secretary of Defense for Acquisition and Sustainment establishes DoD acquisition and sustainment policies for laser equipment and laser systems, including supply chain management.

2.3. UNDER SECRETARY OF DEFENSE FOR RESEARCH AND ENGINEERING.

The Under Secretary of Defense for Research and Engineering establishes DoD developmental testing and evaluation policies and capabilities across the Major Range and Test Facility Base (MRTFB) in accordance with DoDD 3200.11, including a risk management approach to address the uncertainties associated with developmental test and evaluation (T&E).

2.4. DOD COMPONENT HEADS.

The DoD Component heads:

a. Establish and maintain laser health and safety protection programs for their respective Components, in accordance with DoDI 6055.01 and Section 3 of this issuance.

b. Include laser injury prevention, collateral damage prevention, laser safety education, and laser incident and mishap reporting procedures during all routine laser safety training events.

c. Appoint functional area experts for laser health and safety issues to the DoD LSSWG.

d. Establish laser system-specific health and safety programs to protect personnel and equipment.

e. Conduct range safety reviews for laser use on DoD ranges.

f. Identify laser workers and perform occupational medical surveillance of these workers in accordance with DoDM 6055.05.

2.5. SECRETARIES OF THE MILITARY DEPARTMENTS.

In addition to the responsibilities in Paragraph 2.4., the Secretaries of the Military Departments:

a. Develop, test, and use laser systems to the extent practicable, that comply with Sections 1040.10 and 1040.11 and Part 1002 of Title 21, Code of Federal Regulations (CFR), collectively referred to in this issuance as the Federal Laser Product Performance Standards (FLPPS), consistent with the guidance in Paragraph 2.5.b.

b. Authorize use of the FDA military exemption and implement alternate control measures in accordance with Military Standard MIL-STD-1425A or other Military Service-specific requirements to mitigate risks of laser use for military-specific laser systems that cannot comply with all FLPPS due to operational mission requirements. Use of this exemption is limited to the exemption of the provisions in the FLPPS, excluding Section 1002.20 of Title 21, CFR.

c. Establish and maintain a records repository, to include copies of all DoD exemption notification letters (ENLs), as documentation of those DoD laser systems that qualify for the FDA military exemption as specified within the FDA military exemption letter. Additionally, include copies of all applicable FDA variances in this records repository.

d. Establish and maintain an inventory of all Class IIIb and Class IV lasers and all lasers covered by an FDA exemption or variance, regardless of class.

e. Establish Military Department-specific laser safety review processes to:

(1) Conduct laser safety reviews of all military-specific lasers, including those with an FDA-issued variance or exemption, that, when used as designed, could expose people to laser radiation in excess of established maximum permissible exposures (MPEs) or visual interference levels as defined in American National Standards Institute (ANSI) Z136.1 and ANSI Z136.6. The laser safety reviews will include considerations for safe use and an assessment of regulatory and policy compliance.

(2) Conduct a laser safety review in accordance with DoDI 5000.69, when two or more Military Departments plan to acquire the same laser system.

f. Designate laser safety review authorities (LSRAs), laser safety review coordinators (LSRCs), and laser safety range review assessors (LSRRAs).

2.6. SECRETARY OF THE AIR FORCE.

In addition to the responsibilities in Paragraphs 2.4. and 2.5., the Secretary of the Air Force establishes, administers, and maintains the DoD Laser Safety Event Hotline at commercial 800-473-3549 or Defense Switched Network (DSN) 312-798-3764 to:

a. Provide 24-hour consultation assistance on health effects and treatment in the event of an injury or suspected injury to DoD personnel from lasers.

b. Serve as a centralized repository for the recording of laser safety event reports. Section 5 describes functions of the DoD Laser Safety Event Hotline.

SECTION 3: DOD COMPONENT PROCEDURES

3.1. GENERAL.

The DoD Components implement these procedures within their Component, as appropriate. The Secretaries of the Military Departments will assign the following officials to assist in implementing these procedures.

a. Military Department LSRA.

The LSRA is the approval authority for use of the FDA military exemption for that Military Department. For prototype laser units delivered to an LSRC for the purposes of laser hazard evaluation (LHE) and standards compliance verification, the LSRC can act as the exemption approval authority.

(1) In accordance with the provisions of Title 10, United States Code, military acquisition program decision authority resides in the associated acquisition program office or superior acquisition authority. Being an LSRA creates no acquisition authority. The LSRA can provide laser safety advice and recommendations. The LSRA has authority for stipulating laser use requirements (how, where, and by whom lasers are used).

(2) The LSRA will:

(a) Make sure that any exemption request is processed and issued in accordance with Paragraph 3.3. of this issuance, the FLPPS, Military Standard MIL-STD-1425A, and applicable Military Department policy and guidance.

(b) Maintain the repository described in Paragraph 2.5.c.

(c) Maintain the inventory described in Paragraph 2.5.d. This inventory will include laser systems throughout the acquisition lifecycle.

(d) Determine the effectiveness of safety mitigations for the acquisition and use of laser products and use the subject matter expertise of the LSRC described in Paragraph 3.1.b. and LSRRA described in Paragraph 3.1.c. to provide or verify independent range and laser hazard parameters.

b. Military Department LSRC.

The LSRC provides independent subject matter expertise to the LSRA for the review and evaluation of laser hazard parameters as part of the LHE. Additionally, the Military Department LSRCs coordinate evaluations of laser systems to be used by more than one Military Department and share information in accordance with DoDI 5000.69.

c. Military Department LSRRA.

The LSRRA is the designated independent range review authority with the subject matter expertise to assess the safe use of lasers on ranges. The LSRRA will:

(1) Consider guidance from Military Handbook MIL-HDBK-828C and other appropriate laser range evaluation and assessment tools in accordance with Military Department-specific laser safety program policy and procedures.

(2) Use laser safety data provided by the LSRC when assessing ranges.

(3) Provide a laser range safety assessment report to the cognizant range certification authority. The assessment will include risks and possible remediation, including appropriate protections, mitigations, and precautions.

(4) Advise the LSRA on the safe use of lasers on ranges and recommend appropriate limitations and controls for such use.

3.2. REGULATORY REQUIREMENTS FOR LASERS AND FDA MILITARY EXEMPTION.

a. Background.

(1) The Electronic Product Radiation Control provisions of Chapter 9 of Title 21, United States Code, also known as the "Federal Food, Drug, and Cosmetic Act," gives the FDA the authority to regulate lasers in the United States, regardless of application. Part of this established regulatory process requires the manufacturer of the laser to report the laser product to the FDA and self-certify the laser product's compliance with the provisions of the FLPPS.

(2) The FDA issues variances to laser product manufacturers to permit them to deviate from certain regulatory requirements within the FLPPS. Any such variance includes conditions of applicability and alternate controls or limits of distribution. The DoD, either directly or via designated LSRAs, may add additional requirements, but cannot authorize alternate controls from those designated by the FDA within the variance.

(3) The FDA also has the authority to issue exemptions. As with FDA variances, exemptions contain conditions of applicability. In support of DoD military operations, the DoD may use laser devices that cannot meet all the requirements of the FLPPS due to mission requirements. For this reason, the FDA allows for the exemption from certain portions of the FLPPS for the DoD. This exemption, commonly referred to as the "FDA military exemption letter," was granted to the DoD for laser products procured for combat or combat training or that are classified for reasons of national security. Additional details are provided in FDA Laser Notice Number 52.

(4) The FDA military exemption letter specifies limitations on the use of the FDA military exemption. Additionally, any laser using the exemption must meet all requirements of

the FLPPS except for those specific requirements that would preclude DoD's mission requirements.

(a) The FDA military exemption letter requires that exempted lasers be labeled as exempted and that an inventory of exempted lasers be maintained and made available to the FDA upon request.

(b) As a condition of the FDA military exemption, the FDA directs the DoD to establish, maintain, and oversee the use of alternate control measures and their effectiveness to ensure an appropriate level of safety. This means that when the DoD plans to obtain a laser product from a vendor, the vendor cannot deliver the laser product under the FDA military exemption until they receive permission to do so by the DoD procuring agent in the form of an FDA military exemption notification. See Figures 1 or 2 for exemption notification templates available for use by procuring agents.

(5) The FDA military exemption letter provides a pathway for a laser to be delivered from a vendor to DoD. Use of the FDA military exemption notification described in Paragraph 3.2.a.(4) is limited only to vendors that deliver laser products to DoD. If the vendor is a system or device importer or reseller and not the laser product manufacturer as determined by the FDA, then that vendor is responsible to coordinate with the laser product manufacturer to verify that all FDA regulatory requirements are satisfied.

b. Lasers Complying with the Requirements of the FLLPS.

Those lasers registered and meeting the requirements of the FLPPS will be reviewed by the LSRA; however, the LSRA cannot approve or accept alternate control measures that would invalidate compliance with FLPPS. The LSRA may provide guidance, recommendations, or requirements appropriate for the safe use of the laser concerned.

c. Lasers Exempted under the FDA Military Exemption.

(1) The FDA military exemption is applied to laser products used exclusively by DoD Components for combat or combat training, or if the laser product's operational capabilities or vulnerabilities are classified in the interest of national security.

(2) The FDA military exemption cannot be used if the intended use for the laser does not require any deviations from the FLPPS.

(3) Common uses of the FDA military exemption include the need to use muted colored labels on laser products, the need to redact data on the laser product's label due to security classification, or a lack of a startup delay for high-powered, covert, tactical laser applications.

(4) The LSRA has the authority and responsibility to determine the appropriate circumstances where the use of the FDA military exemption is appropriate and to require appropriate control measures to enhance safety during laser use.

(5) Exempted laser products will:

(a) Comply with all provisions of the FLPPS, where practical, as determined by the LSRA.

(b) Meet the requirements of the Military Standard MIL-STD-1425A or alternate Military Department-specific requirements as approved by the LSRA.

(6) In the rare case where it is not possible to meet the standards described in Paragraphs 3.2.c.(5)(a) and 3.2.c.(5)(b) of this issuance, the LSRA will develop risk management procedures in accordance with DoDI 5000.02. The LSRA will apply and document controls and other hazard mitigations in accordance with Military Standard MIL-STD-882E and provide mitigation control recommendations to the acquisition program manager and user representative.

d. Lasers Operating with an FDA Variance.

(1) Those laser products that cannot meet all the requirements of the FLPPS, and do not qualify for the FDA military exemption, will only be accepted for use by the DoD after completion of one of the following actions:

(a) The laser product is made compliant with the FLPPS; or

(b) The laser product's manufacturer first obtains a variance from the FDA as described in Paragraph 3.2.a.(2).

(2) If the FDA issues a variance to a manufacturer for a laser product, that variance is contingent upon any restrictions or limitations determined by the FDA in that variance. The LSRA can require additional controls, restrictions, limitations, and safety mitigations as they deem necessary, but cannot authorize procurement or use of alternate controls from the requirements issued by the FDA in the variance.

(3) If the controls required by the FDA variance cannot be met due to operational mission needs, a new or updated variance or FDA military exemption would need to be obtained. The LSRC and LSRA can provide additional information for the appropriate use of an FDA variance for military use.

(4) Laser products with FDA variances will:

(a) Comply with all requirements of the FLPPS, where applicable, as determined by the LSRA.

(b) Meet the requirements and restrictions of the FDA variance and any additional requirements determined by the LSRA or Military Department-specific policy or authority, as applicable.

3.3. ACQUISITION.

a. All lasers acquired will have FDA registration, an FDA approved variance, or a military exemption. All lasers acquired within the scope of this issuance will be assessed for compliance with the provisions of the FLPPS by the LRSA or LSRC.

b. Requiring activities will work with supporting contracting activities to ensure solicitations and contracts clearly contain any necessary regulatory requirements for variance or exemption as described in Paragraph 3.2. to ensure offerors understand the requirement.

c. Any solicitation for a laser product will state if only FDA registered, or FDA variance approved laser products are acceptable or if the LSRA will entertain granting a military exemption. In the case of the later, the solicitation shall clearly state what additional documentation the offeror must provide to enable the LSRA to make a decision; the solicitation shall also state whether the offeror can be determined acceptable if the LSRA decides not to grant an exemption. The contracting activity will require any offeror proposing a laser product with either FDA registration of an FDA approved variance to provide, as part of the offeror's offer, the FDA accession number or FDA variance unique to the model of the laser product being offered.

d. For laser products having an FDA approved variance, the offeror will follow any of the FDA's restrictions or limitations as described within the variance.

(1) For lasers utilizing an FDA approved variance, the LSRC should perform an LHE to independently determine or verify laser hazard parameters before testing, fielding, training, operations, or other use by the DoD.

(2) LSRA involvement for lasers utilizing an FDA approved variance will be in accordance with Paragraph 3.9.f. of this issuance and Military Department-specific policy. Developmental T&E laser products that transition to operational or other non-developmental status will comply with Military Department-specific fielding approval processes and requirements.

e. Copies of accepted FDA military ENLs will be retained by the LSRA and the associated requiring activity.

(1) If the LSRA, with advice from the LSRC, approves of the use of the FDA military exemption, the LSRA will issue an exemption notification to the requiring activity who will provide that to the contracting office for transmittal to the offeror. The template formats in Figures 1 and 2 should be used in the exemption notification to the manufacturer.

(2) The scope of applicability for the exemption should be limited to the maximum extent practicable.

(3) The DoD exemption notification for fielding or fielding systems template, as shown in Figure 1, will be used for those laser systems to be fielded or delivered for operational testing or training. The following describes the assignment of the exemption notification identifier to include serializing the FDA military ENLs.

(a) Military ENLs are required to contain a unique 22-character exemption notification identifier code (ENIC) assigned by the LSRC (i.e., "ABBBBBBCCCCCCDDDDDDEEE"). The following defines the format required for this code and provides an example:

1. A, Notification Type: either "P" for provisional or "F" for fielded. Provisional ENLs are limited to prototype, demonstration, or test systems. The "Fielded" notification type can apply to laser systems that are farther along in their development process and are not expected to have significant changes in the future. For example, few changes that would affect the exemption would be expected for systems in low-rate initial production or operational T&E, even though they are not fielded systems.

2. "BBBBBB" is the date the ENL is issued (YYMMDD).

3. "CCCCCC" is the date the ENL expires (YYMMDD). If the ENL does not have an expiration date, this should be "000000". After this date, the manufacturer is no longer permitted to deliver laser products by reference of this ENL. This has no bearing on the user.

4. "DDDDDD" is the unit identification code for the unit of assignment of the person signing the ENL.

5. "EEE" is a three-character unique code (at the discretion of the issuer). This may be the organizational code, or any other code that ensures that the overall ENIC is truly unique.

6. For example, if Naval Surface Warfare Center Dahlgren, Unit Identification Code N00178, issued an ENIC for a laser system on March 18, 2021 that is valid for 3 years, and where this laser will be used for testing purposes only, the ENIC could be: ENIC: P210318240318N00178G73. In this example, the ENIC issuer decided to use an organizational code for the last three characters. If they issued another exemption notification on the same day, they would be required to use a different three-character code or to use a different date on the ENL.

(b) In accordance with Paragraph 3.3., FDA military ENLs to manufacturers or importers of T&E and fielded systems should be written using the templates in Figures 1 and 2. A template is available from the appropriate LSRC and LSRA.

Figure 1. DoD Exemption Notification for Fielding or Fielded Systems (Template)

DoD Exemption Notification for Fielding or Fielded Systems (Template)	
This electronic product has been exempted from FDA radiation safety performance standards prescribed in Part 1040 of Title 21, Code of Federal Regulations (CFR), Chapter 1, Subchapter J, under Exemption No. 76EL-01 DoD issued on 26 July 1976 and addendum(s) on 18 March 1986. To be declared as DoD exempt, a military laser product must be for use in combat, combat training, or classified in the interest of national security. This product should not be used without adequate protective devices or procedures. Food and Drug Administration (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 in this letter. Further, the appropriate Military Department Laser Safety Review Authority (LSRA) must perform a laser hazard analysis (LHA) on 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.	
1. Date:	
2. To: **Manufacturer Name** **Address** **Phone** **CAGE**	
3. From: **Procuring Office Name** **Address** **Phone**	
4. Laser System Nomenclature	
5. Exemption Notification Identifier Code (ENIC)	
6. Laser System Common Name(s)	
7. Military Specific Qualifier (Check all that apply.)	☐ COMBAT ☐ COMBAT TRAINING ☐ NATIONAL SECURITY
8. DoD Service(s) (Check all that apply.)	☐ U.S. AIR FORCE/SPACE FORCE ☐ U.S. ARMY ☐ U.S. NAVY/MARINE CORPS
9. Model/Part Number	
10. Serial Number(s)	
11. National Stock Number (NSN)	
12. Contract Number	
13. Quantity	

Figure 1. DoD Exemption Notification for Fielding or Fielded Systems (Template), Continued

13. Quantity	
14. Delivery Dates	
15. Other Limits (if any) to Authorization	

16. Conditions of Exemption

THE [LASER SYSTEM COMMON NAME(S)], BEING MANUFACTURED UNDER CONTRACT [CONTRACT NUMBER], IS EXEMPTED FROM REQUIREMENTS LISTED IN THIS FORM (BLOCK 17) OF THE FDA RADIATION SAFETY PERFORMANCE STANDARDS PRESCRIBED IN PARTS 1040.10 AND 1040.11 OF TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) IN ORDER TO MEET MILITARY OPERATIONAL REQUIREMENTS. THIS EXEMPTION IS BEING GRANTED BASED ON THE RECOMMENDATIONS OF LASER HAZARD ANALYSIS BY THE [LSRA].

ALTHOUGH THE USE OF THE DOD EXEMPTION HAS BEEN AUTHORIZED, THE SYSTEM DESIGN MUST STILL ADHERE TO THE REQUIREMENTS OF THE MILITARY STANDARD MIL-STD-1425, SAFETY DESIGN REQUIREMENTS FOR MILITARY LASERS AND ASSOCIATED SUPPORT EQUIPMENT, OR BY SPECIAL APPROVAL BY [LSRA] BASED ON LASER SAFETY REVIEW COORDINATOR (LSRC) RECOMMENDATIONS OF THE LASER BOARD.

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 LASER SAFETY REVIEW AUTHORITY).

CAUTION

THIS ELECTRONIC PRODUCT HAS BEEN EXEMPTED FROM FDA RADIATION SAFETY PERFORMANCE STANDARDS PRESCRIBED IN PARTS 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.

ENIC: XXXXXXXXXXXXXXXXXXXXXXXXXXXX

ANY MODIFICATION TO [LASER SYSTEM COMMON NAME(S)] (INCLUDING MATERIAL COMPONENTS, PHYSICAL DESIGN, OR LASER OUTPUT CHARACTERISTICS) OR CHANGES IN PART NUMBER, NOMENCLATURE, NSN, WILL REQUIRE SUBMISSION TO LSRA TO DETERMINE THE NECESSITY OF A NEW EXEMPTION LETTER. DEVIATION FROM THE PARAMETERS DEFINED IN SECTION 17 REQUIRES THE MANUFACTURER TO OBTAIN A NEW EXEMPTION AUTHORIZATION LETTER. CHANGES IN CONTRACT NUMBER, QUANTITY, OR DELIVERY DATES BUT NOT MODIFICATIONS [ABOVE] REQUIRE NOTIFICATION OF THE LSRA OR NEW EXEMPTION LETTER. SHIPMENTS FOR REPAIRS OF THE DEVICE ARE AUTHORIZED UNDER THE CONDITIONS OF THIS EXEMPTION. THE EXEMPTION IS FROM THE FEDERAL LASER PRODUCT PERFORMANCE STANDARD (FLPPS) FOR LASER PRODUCTS IN PARTS 1040.10 AND 1040.11 OF TITLE 21 CFR AND THE ASSOCIATED REPORTING AND RECORD KEEPING REQUIREMENTS OF PART 1002 OF TITLE 21 CFR, EXCEPT FOR PARAGRAPH 1002.20 RELATING TO ACCIDENTAL RADIATION OCCURRENCES.

Figure 1. DoD Exemption Notification for Fielding or Fielded Systems (Template), Continued

17. Deviations from Part 1040.10 of Title 21, CFR with Justification

APPROVED DEVIATIONS FROM THE REQUIREMENTS OF PART 1040 OF TITLE 21 CFR COMPLETE WITH JUSTIFICATION FOR EACH DEVIATION. OTHER DEVIATIONS ARE NOT AUTHORIZED UNDER THIS EXEMPTION NOTIFICATION. FOR EACH REQUIREMENT THAT CANNOT BE MET, PROVIDE RATIONALE FOR NONCOMPLIANCE AND ALTERNATE SAFETY MEASURES. SEE PART 1040 OF TITLE 21 CFR FOR DESIGN REQUIREMENT DETAILS.

Protective Housing (Part 1040.10(f)(1) of Title 21 CFR):

Safety Interlocks (Part 1040.10(f)(2) of Title 21 CFR):

Remote Interlock Connector (Part 1040.10(f)(3) of Title 21 CFR):

Key Control (Part 1040.10(f)(4) of Title 21 CFR):

Emission Indicator (Part 1040.10(f)(5) of Title 21 CFR):

Beam Attenuator (Part 1040.10(f)(6) of Title 21 CFR):

Location of Controls (Part 1040.10(f)(7) of Title 21 CFR):

Figure 1. DoD Exemption Notification for Fielding or Fielded Systems (Template), Continued

Viewing Optics (Part 1040.10(f)(8) of Title 21 CFR):

Scanning Safeguard (Part 1040.10(f)(9) of Title 21 CFR):

Manual Reset Mechanism (Part 1040.10(f)(10) of Title 21 CFR):

Labeling Requirements (such as no ENIC on label):

User/Purchasing/Servicing Information (Part 1040.10(h) of Title 21 CFR):

Modification of a Certified Product (Part 1040.10(i) of Title 21 CFR):

Other:

18. LSRA OFFICIAL

The above system has been recommended for approval for use by the service LSRA.

☐ **Yes** ☐ **No**

This exemption is being granted based on approval letter from the LSRA or the recommendations of laser hazard evaluation [Letter or Report Number], [Report Title], dated [Report Date] by the [LSRC].

A copy of this letter should be sent to the LSRA for all Services.

Figure 1. DoD Exemption Notification for Fielding or Fielded Systems (Template), Continued

Army LSRC and LSRA: U.S. Army Public Health Center (APHC), 5158 Blackhawk Road, Aberdeen Proving Ground, MD 21010-5403

Primary: APHC, Nonionizing Radiation Division, (MCHB-PH-NIR)
DSN: 584-3932
Commercial: 410-436-3932
E-mail: usarmy.apg.medcom-aphc.mbx.nonionizing@mail.mil
Alternate: DSN: 584-3353
Commercial: 410-436-3353

Navy or Marine Corps LSRA: Laser Safety Review Board, 17320 Dahlgren Road, Dahlgren, VA 22448-5100

Primary: DSN: 249-2442
Commercial: 540-653-2442
E-mail: Isrb@navylasersafety.com

Air Force LSRA: Headquarters Air Force Safety Center, Weapons Safety Division, 9700 G Avenue SE, Kirtland AFB, NM 87117-5670

Primary: DSN: 263-1203
Commercial: 505-853-1203
E-mail: HQAFSCSEW@us.af.mil
Alternate: DSN: 246-7031
Commercial: 505-846-7031

a. Typed or Printed Name
b. Title
c. Signature
d. Date Signed

19. Authorizing Official
a. Typed or Printed Name
b. Title
c. Signature
d. Date Signed

(4) For those laser prototypes or laser devices under development that do not have all the information required for the fielding systems, the template in Figure 2 should be used.

(a) This template will include as much information as is available.

(b) Military ENICs are required for use on this template. Developing and serializing the ENIC will follow the same procedure as described in Paragraph 3.3.e.(3)(a).

Figure 2. DoD Exemption Notification for T&E Systems (Template)

DOD COMPONENT LETTERHEAD

MILITARY EXEMPTION NOTIFICATION IDENTIFIER CODE:

[MONTH DAY, YEAR]

[NAME OF COMPANY]
ATTENTION: [ENTER NAME OR OFFICE SYMBOL]
[ADDRESS]
[CITY, STATE ZIP CODE]

Dear [ENTER NAME OR TITLE]:

This letter is the authorization to deliver [NAME OF T&E LASER PRODUCT OR SYSTEM] for fielding in accordance with Food and Drug Administration (FDA) Exemption No. 76EL-01DOD.

The prototype or experimental [NAME OF T&E LASER PRODUCT OR SYSTEM] is used exclusively by the DoD and designed for combat or combat training or classified in the interest of national security, manufactured under contract [CONTRACT NUMBER], and limited to the minimum number of units necessary for the T&E activity. The [NAME OF T&E LASER PRODUCT OR 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 LASER PRODUCT OR SYSTEM] (including material components, physical design, or laser output characteristics) or deviation from the parameters defined in the table below requires the manufacturer to obtain a new exemption authorization letter.

Parameter	Description
Contract #	[CONTRACT NUMBER]
Product Name	PROTOTYPE/EXPERIMENTAL XYZ LASER
Model #	[MODEL NUMBER]
Serial #(s)	SN1-SN5
Lot #(s)	
DoD Service(s)	[ENTER DOD SERVICE PROCURING LASERS FOR T&E]
Organization/Unit	ORGANIZATION/UNIT AND PROGRAM MANAGER NAME
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.

When the [NAME OF T&E LASER PRODUCT OR SYSTEM] is delivered to this office and before any T&E activities occur, a laser hazard assessment of the laser system(s) will be performed by the [ENTER THE APPROPRIATE DOD LSRC OR LSRA]. This assessment will include the classification of the laser and nominal ocular hazard distances and eye protection requirements if any exist.

The assessment 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 these Federal regulations and determination for how these requirements impact the military operational requirements of the [NAME OF T&E LASER PRODUCT OR

Figure 2. DoD Exemption Notification for T&E Systems (Template), Continued

SYSTEM] system.

In conjunction with the [ENTER THE APPROPRIATE DOD LSRC OR LSRA], 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 LASER PRODUCT OR SYSTEM]'s operational use.

The Federal performance requirements determined and verified by [ENTER THE APPROPRIATE DOD LSRC OR LSRA] that cannot be met by the [NAME OF T&E LASER PRODUCT OR 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 LASER PRODUCT OR SYSTEM] must meet all of the Federal requirements.

Before 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] 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 MIL-STD-1425 or as approved by the Department LSRA.

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 below (or alternate wording if approved by the applicable LSRA). An example of labeling could include the following: "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 (as amended). Use this product only with adequate protective devices or procedures. Do not sell or transfer outside the DoD. ENIC: XXXXXXXXXXXXXXXXXXXXX."

The point of contact for questions pertaining to this authorization is [NAME AND RANK OF POINT OF CONTACT, E-MAIL ADDRESS, PRODUCT MANAGER, PROGRAM, ATTENTION: OFFICE SYMBOL, ADDRESS, PHONE NUMBER].

Sincerely,

[AUTHORIZING OFFICIAL NAME]
[JOB TITLE]
[APPROVING OFFICE/DEPARTMENT LASER SAFETY AUTHORITY]

(5) For those laser systems and devices delivered to an LSRC for the purposes of LHE and standards compliance verification, notification for authorization to use the exemption will be temporary and limited.

f. Military-specific lasers within the Defense Logistics Agency supply system will additionally be reviewed for compliance with DoDI 5000.69 before assigning a national stock number as specified in Volume 2 of DoDM 4140.01 and DoDM 4100.39.

g. Military-specific laser systems that follow non-traditional acquisition processes (e.g., rapid acquisitions, middle-tier acquisitions) may apply Department-specific approval processes in accordance with Paragraph 3.3.f.(2) of this issuance.

h. DoD acquisition program offices will develop requirements and sources of supply and bring new items into the DoD inventory in accordance with the procedures in Volume 1 of DoDM 4140.01. The DoD acquisition program offices will not authorize deviations from an FDA variance. If additional capabilities are necessary beyond the variance, the program office may discuss with the LSRA the possibility of granting an exemption.

3.4. TRAINING.

a. Laser safety training will be provided for:

(1) Laser safety officers who are responsible for administrating laser safety programs.

(2) Personnel that may be exposed to laser hazards before operations that may result in exposure over the MPE. Training will include specific laser hazard information and operational and safety procedures commensurate with both duties and potential risk.

(3) Personnel who operate or maintain Class IIIb and Class IV lasers and others that may be at risk of being exposed to laser energy greater than the MPE. This training should be completed annually.

b. Laser safety training will include, at a minimum:

(1) Potential hazards associated with exposure to the laser beam.

(2) Laser product safety information to include laser classification, hazard distances, optical density requirements for laser eye protection, control measures to mitigate hazards, and laser incident reporting requirements and procedures.

c. The LSRA or LSRC may provide additional training and guidance that may include Military Department or Military Service-specific training policy, guidance, and commercial standards.

3.5. EXPOSURE AND MEDICAL SURVEILLANCE.

a. Workers who use lasers must be identified as required by DoDM 6055.05. All laser exposures and exposure controls will be documented in the DoD Occupational and Environmental Health Readiness System-Industrial Hygiene information management system in accordance with DoDI 6055.05.

b. Occupational medical surveillance for laser workers must be performed in accordance with DoDM 6055.05.

c. In addition to the reporting procedures described in Paragraph 3.6. of this issuance, DoD personnel who experience a laser exposure by way of laser misuse causing intentional or unintentional exposures (e.g., unknowing aircraft illumination) should follow the reporting procedures of DoDI 6055.07 for those exposures resulting in an occupational injury as determined by a licensed occupational medicine or other qualified health care provider.

3.6. LASER SAFETY EVENT REPORTING.

a. Laser events (e.g., incidents and mishaps) involving DoD personnel or air, ground, and naval assets must be reported in accordance with Chairman of the Joint Chiefs of Staff Manual 3320.02E.

b. If a suspected overexposure occurs, the DoD Laser Safety Event Hotline will be contacted immediately.

c. All laser events (i.e., mishaps and incidents) must be reported to the DoD Laser Safety Event Hotline. The DoD Component representative making the report will provide all information and comply with all response actions as directed by the operator of the DoD Laser Safety Event Hotline. These reports do not replace established safety investigation procedures conducted pursuant to DoDI 6055.07 or Component-specific notification procedures. Section 5 includes additional information for the DoD Laser Safety Event Hotline.

3.7. INVENTORY CONTROL.

a. All procedures for materiel management of lasers must be implemented in accordance with DoD supply chain policy and procedures as described in DoDIs 4140.01 and 4160.28; Volumes 1 and 10 of DoDM 4140.01; Volume 1 and 4 of DoDM 4160.21; and Volume 1 of DoDM 4160.28.

b. Inventory control provisions established in the FLPPS must be satisfied for non-exempted laser products.

c. DoD-exempted laser products must be properly accounted for, labeled, and ultimately disposed of in accordance with the FDA military exemption letter; DoDIs 4140.01 and 4160.28; Volume 6 of DoDM 4140.01; Volumes 1 and 4 of DoDM 4160.21; Volume 1 of DoDM 4160.28; and Military Standard MIL-STD-1425A.

d. Laser products with an FDA variance must be properly accounted for, labeled, and ultimately disposed of in accordance with the stipulations of the FDA variance.

e. DoD-exempted lasers must be reused or transferred in accordance with DoDIs 2030.08, 4140.01, and 4160.28; Volumes 6, 8, and 11 of DoDM 4140.01; Volumes 1 and 4 of DoDM 4160.21; Volume 1 of DoDM 4160.28; and Military Department-specific policy.

f. If the procurement activity, LSRA, or LSRC determines that a transfer of an FDA-exempted laser is outside the scope of the DoD exemption notification, a new DoD exemption

notification is required, and the source of the transfer is responsible to complete the exemption notification. The procurement activity will consult with the LSRA or LSRC if additional clarification is required.

g. The Military Departments will maintain inventory records indefinitely for lasers that are transferred, demilitarized by destruction, or brought into FLPPS compliance.

3.8. CONTROLLING EXPOSURES.

a. LSRAs will establish thresholds for acceptable risk of exposure to levels above MPE. In areas where the risk of laser radiation exposure exceeds the acceptable risk thresholds as established by the LSRA, control procedures will be established. This requirement excludes combat areas of operation. In combat areas of operation, laser product operators and those known to be in a potential overexposure situation will be trained to recognize the hazards and to employ appropriate protective measures.

b. Engineering controls will be used, where feasible, to mitigate risk posed by laser radiation. Administrative controls and, if necessary, personal protective equipment can be used in accordance with Military Standard MIL-STD-1425A with additional guidance available in Military Handbook MIL-HDBK-828C and ANSI Z136.6 when engineering controls result in remaining, unacceptable, residual risk.

c. Range safety policies and procedures will be established for the use of lasers and laser systems where testing, training, or operational use could expose non-participants to harmful emissions. The established policies and procedures following the guidance in Military Handbook MIL-HDBK-828C and ANSI Z136.6 will ensure proper control of laser emissions and use of barriers for limiting exposure to harmful laser radiation, such that the risk of harm to people, property, and infrastructure is maintained at or below the established acceptable risk thresholds.

3.9. LASER RISK MANAGEMENT FOR MILITARY-SPECIFIC LASERS.

a. The LSRA will perform a laser hazard analysis (LHA) for compliance with provisions of the FLPPS before laser use. For FDA-exempted lasers, the LSRA will conduct the LHA considering compliance with Military Standard MIL-STD-1425A.

b. T&E laser use includes experiments, tests, prototypes, and demonstrations of laser use involving DoD personnel or where the T&E activity is performed on DoD-controlled property (e.g., DoD training ranges). The proponents for T&E laser use will:

(1) Determine the scale and scope (i.e., operating conditions) of the laser activity.

(2) Use safety practices and follow guidance as described in ANSI Z136.6, Military Handbook MIL-HDBK-828C, and follow applicable policies of the Military Department with jurisdiction over the operation of the range.

c. Non-T&E laser use on DoD ranges includes training and operation of non-developmental, fielded laser equipment and laser systems involving DoD personnel. The proponent(s) for non-T&E laser use will:

(1) Determine the scale and scope of the laser activity.

(2) Use safety practices as described in ANSI Z136.6 and Military Handbook MIL-HDBK-828C in addition to the applicable policies and guidance of the Military Department with jurisdiction over the operation of the range.

d. If the laser use activity meets the definition of "outdoor," as defined in the Glossary:

(1) The procuring activity will submit the laser system to the LSRC for an LHE.

(2) The procuring activity will formally request a review by the LSRA.

(3) LSRA will perform an LHA utilizing the completed LHE provided by the LSRC and activity-specific laser use information provided by the proponent. Information from the LSRRA may be included, as needed.

(4) LSRA will approve or disapprove the activity based on the efficacy of laser risk mitigation to personnel, property, and the environment. The LSRA may include limiting parameters for use, as they deem appropriate.

(5) If the activity is not approved, the LSRA will provide justification for the disapproval; the proponent will alter the laser use or laser safety mitigations to satisfy the LSRA's objections; and the process will revert to Paragraph 3.9.b.(1).

(6) The procuring activity will formally request additional review(s) by the LSRA and/or the LSRC if any changes occur that extend beyond the scope of the LSRA's approval.

e. For laser use before operational use and fielding:

(1) The procuring activity will submit the laser system to the LSRC for an LHE.

(2) The procuring activity will formally request a review by the LSRA.

(3) The LSRA will perform an LHA utilizing the completed LHE provided by the LSRC and considering all potential operations provided by the proponent(s). This includes maintenance, operational use, and training.

(4) The LSRA will approve or disapprove operational use and fielding of the laser product based on the efficacy of laser risk mitigation to personnel, property, and the environment. If the LSRA does not approve the operational use and fielding of the laser product, they will provide to the procuring activity:

(a) Justification for the disapproval.

(b) Risk mitigation recommendations.

(5) The procuring activity, when practicable, implements LHA recommendations. When implementation of designated mitigations is not practicable due to established mission requirements, the procuring activity will provide the LSRA with a rationale. The rationale will be endorsed by the appropriate risk acceptance authority associated with the risk level pursuant to DoDI 5000.02.

(6) The procuring activity will request additional review(s) by the LSRA when all risk mitigation concerns have been addressed, whether by implementation or rationale.

(7) The LSRA will provide final concurrence or non-concurrence for operational use and fielding based on the controls implemented or rationale provided by the procuring activity. If the LSRA does not concur, they will provide justification for their non-concurrence and will provide additional or alternate risk mitigation recommendations to the procuring activity.

f. For Military Department-specific laser products within programs that utilize the adaptive acquisition framework (AAF) in accordance with DoDI 5000.02, the procuring activities:

(1) Solicit the LSRC for guidance and recommendations to support system safety in accordance with Military Standard MIL-STD-882E.

(2) Perform LHA throughout the AAF and document the findings.

(3) Minimize or eliminate safety risk associated with the use of the laser system.

g. For systems within the AAF when it is not possible to comply with the requirements in Paragraph 3.9. because of military operational necessity, these risk management procedures will be followed:

(1) For laser systems in research, development, test, and evaluation processes, follow the requirements of DoDIs 5000.02 and 5000.69, Military Standards MIL-STD-882E and MIL-STD- 1425A, and Paragraph 3.9.b. of this issuance, as applicable.

(2) For systems used in training, operations, and other activities not under the configuration control of an acquisition program office, the requirements of Paragraph 8.a.(3) of Enclosure 3 of DoDI 6055.01 for risk management under conditions of military necessity will be followed. When the design or operation of the system changes or when a change occurs in the decision-making authority, risk management for these systems will be reevaluated.

(3) For systems in development or use by multiple DoD Components, the lead Component will coordinate a joint risk assessment through the DoD LSSWG.

3.10. LASER RISK MANAGEMENT FOR LASERS COMPLIANT WITH THE FLPPS OR USING AN FDA VARIANCE.

a. The LSRA will perform an LHA to determine compliance with provisions of the FLPPS before use. For lasers with an FDA variance, the LHA will consider compliance with the requirements and limits of the variance and any additional designated DoD safety mitigations.

b. The proponents for T&E laser use will:

(1) Determine the scale and scope (i.e., operating conditions) of the laser activity.

(2) Use safety practices and follow guidance as described in ANSI Z136.6 and Military Handbook MIL-HDBK-828C, and follow applicable policies of the Military Department with jurisdiction over the operation of the range.

c. In addition to any requirements or limitations of an FDA variance (if applicable), the proponent(s) for non-T&E laser use will:

(1) Determine the scale and scope of the laser activity.

(2) Use safety practices as described in ANSI Z136.6 and Military Handbook MIL-HDBK-828C in addition to the applicable policies and guidance of the Military Department with jurisdiction over the operation of the range.

d. If the laser use activity meets the definition of "outdoor," as defined in the Glossary:

(1) The procuring activity will submit the laser system to the LSRC for an LHE.

(2) The procuring activity will formally request a review by the LSRA.

(3) The LSRA will perform an LHA utilizing the completed LHE provided by the LSRC and activity-specific laser use information provided by the proponent. Information from the LSRRA may be included, as needed.

(4) The LSRA will approve or disapprove the activity based on the efficacy of laser risk mitigation to personnel, property, and the environment and the restrictions of an FDA variance (if applicable). The LSRA may include additional limiting parameters for use, as they deem appropriate.

(5) If the activity is not approved, the LSRA will provide justification for the disapproval; the proponent will alter the laser or laser safety mitigations to satisfy the LSRA's objections; and the process reverts to Paragraph 3.10.b.(1).

(6) The procuring activity will formally request additional review(s) by the LSRA and/or the LSRC if any changes occur that extend beyond the scope of the LSRA's approval.

e. For laser use before operational use and fielding:

(1) The procuring activity will submit the laser system to the LSRC for an LHE. If the laser is using an FDA variance, the LHE will include verification of compliance of any requirements or limitations of that variance.

(2) The procuring activity will formally request an LSRA review.

(3) The LSRA will perform an LHA utilizing the completed LHE provided by the LSRC and considering all activity-specific laser use information provided by the proponent.

(4) The LSRA will approve or disapprove of the laser use activity based on the efficacy of laser risk mitigation to personnel, property, and the environment and consistent with any requirements of an FDA variance (if applicable). The LSRA may include additional limiting restrictions for use, as they deem necessary, but may not authorize deviations from requirements of any applicable FDA variance.

(5) If the activity is not approved, the LSRA will provide justification for the disapproval. The proponent will alter the laser or laser safety mitigations to satisfy the LSRA's objections and will request additional review(s) by the LSRA or the LSRC, if necessary, based on these modifications.

(6) The procuring activity will formally request additional review(s) by the LSRA or the LSRC if any changes are made that extend beyond scope of LSRA approval.

f. For systems in development or use by multiple DoD Components, the lead Component will coordinate a joint risk assessment through the DoD LSSWG.

SECTION 4: DOD LSSWG FUNCTIONS

The DoD LSSWG will:

a. Provide laser safety and health technical advice to the ASD(R).

b. Under the authority, direction, and control of the ASD(R), develop procedures to further define membership and operation.

c. Include representatives from the Office of the ASD(R) and the DoD Components. All members of the LSSWG will be full-time Federal civilian employees, permanent part-time federal civilian employees, or Service members on active duty.

d. Include subject matter experts for laser safety and health effects, risk management, laser use, acquisition, systems safety, laser range safety, and individuals representing the laser system review and approval processes.

e. Establish guidelines to govern the operation of the DoD LSSWG and procedures for selecting and rotating the chair.

f. Meet at the call of the chair to share information, discuss items of mutual interest, and recommend policies and guidance to the ASD(R).

g. Establish and maintain an evaluation subgroup from within the DoD LSSWG to:

(1) Recommend multi-Service laser safety review processes, in accordance with DoDI 5000.69, to conduct a safety review of all military-specific laser systems with potential for use by more than one DoD Component.

(2) Facilitate a forum for discussion and review of DoD Component measurement protocols and hazard assessment reporting.

(3) Share assessments with the affected DoD Components when an assessment may be used by more than one DoD Component.

h. Report on the DoD LSSWG work plan to the ASD(R), as directed.

SECTION 5: DOD LASER SAFETY EVENT HOTLINE FUNCTIONS

The DoD Laser Safety Event Hotline will:

a. Provide consultation assistance in the event of an injury or suspected injury to DoD personnel from lasers.

b. Coordinate the completion of incident and mishap event reports.

(1) Report forms may be completed using a web–based reporting form. The Laser Safety Event Hotline will provide the link to the form if requested.

(2) If the event reporter cannot complete the form online, they may e-mail the completed event report to the esoh.service.center@us.af.mil or call 1-800-473-3549 for assistance with completing the form.

c. Establish, administer, and maintain a laser event registry for DoD Components in accordance with Section 552a of Title 5, United States Code, also known as the "Privacy Act of 1974," as implemented through DoDI 5400.11 and DoD 5400.11-R.

d. Send event information to applicable LSRAs, removing any personally identifiable information and any protected health information.

e. Provide data and analysis to DoD entities for laser event prevention, safety, and treatments.

GLOSSARY

G.1. ACRONYMS.

ACRONYM	MEANING
AAF	adaptive acquisition framework
ANSI	American National Standards Institute
ASD(R)	Assistant Secretary of Defense for Readiness
CFR	Code of Federal Regulations
DoDD	DoD directive
DoDI	DoD instruction
DoDM	DoD manual
DSN	Defense Switched Network
ENIC	exemption notification identifier code
ENL	exemption notification letter
FDA	Food and Drug Administration
FLPPS	Federal Laser Product Performance Standard
LHA	laser hazard analysis
LHE	laser hazard evaluation
LSRA	laser safety review authority
LSRC	laser safety review coordinator
LSRRA	laser safety range review assessor
LSSWG	Laser Systems Safety Working Group
MPE	maximum permissible exposure
MRTFB	Major Range and Test Facility Base
T&E	test and evaluation

G.2. DEFINITIONS.

TERM	DEFINITION
acquisition	Defined in Subpart 2.1 of the Federal Acquisition Regulation.
Class IIIb laser	Defined in Section 1040.10 of Title 21, CFR.
Class IV laser	Defined in Section 1040.10 of Title 21, CFR.

TERM	DEFINITION
DoD-exempted lasers	Laser products specifically exempted from certain provisions of the FLPPS by appropriate DoD authorities in accordance with the FDA military exemption letter, due to incompatibility with mission requirements. To be eligible to use the exemption, the laser system must be a military-specific laser or a surveying, leveling, and alignment laser that meets the criteria as defined in FDA Laser Notice No. 58 or meets all three of these criteria: It is owned and used exclusively by DoD. It is designed for use in combat, combat training, or is classified in the interest of national security. It is unable to comply with all the provisions of the FLPPS due to mission requirements.
harm	An unwanted consequence to people, material, or the environment. Harm can be transient, temporary, or permanent.
incident	An undesired occurrence that happens unexpectedly or unintentionally, that does not result in harm.
injury	Bodily harm. Injury can lead to ancillary damage or additional injury.
laser safety review	An assessment of risk versus reward for use of a laser product performed by the procuring activity. The SLSRC and SLSRA can provide guidance when performing this assessment.
laser safety event	An occurrence of an incident or mishap that resulted in an injury or could have resulted in injury.
LHA	An independent analysis performed by a designated LSRA, or other designated organization such as the LSRC, of hazards and risks associated with the use of a laser system. An LHA typically includes parameters from an LHE along with consideration for where, when, and who will be using the laser and who could be exposed. The LHA also considers proposed control measures to determine the efficacy of the overall laser safety risk mitigation plan. Additionally, the LHA provides guidance for safe use of the laser.

TERM	DEFINITION
LHE	An independent evaluation of laser safety parameters, to include hazard classification, protection distances, and optical density requirements for laser eye protection.
LSRA	The Military Department agency, organization, committee, or board designated by appropriate authority to determine the efficacy of proposed safety mitigations for the acquisition or use of laser products. This determination considers safety and regulatory compliance as well as design, integration, and user interface of the laser or laser system. Military Department-specific policy may delegate this function as appropriate.
LSRC	The Military Department agency designated by the appropriate authority to independently perform laser hazard evaluation.
LSRRA	The Military Department agency designated by the appropriate authority to conduct range safety review for laser use on ranges.
military-specific laser	A laser or laser product developed for, delivered to, sold to, or used by a DoD Component for a function other than medical, industrial, or administrative purposes (e.g., classroom laser pointers, printers).
mishap	An unplanned event or series of events that results in: damage to DoD property; occupational illness to DoD personnel; injury to on- or off-duty DoD military personnel; injury to on-duty DoD civilian personnel; or damage to public or private property, or injury or illness to non-DoD personnel, caused by DoD activities.
MPE	The level of laser radiation to which a person may be exposed without known hazardous effects or adverse biological changes in the eye or skin in accordance with ANSI Z136.1.
outdoor	A location for a laser where the insertion of a mirror into the output beam path could create a specular reflection that extends indefinitely.
overexposure	An exposure that exceeds the applicable MPE or visual interference level.
variance	A formal document issued by the FDA to a laser product manufacturer that allows for non-compliance with certain portions of the FLPPS. Variances typically provide limitations and requirements for alternate control measures to effectuate a similar level of safety.

REFERENCES

American National Standards Institute Standard Z136.1, "American National Standard for Safe Use of Lasers," current edition[1]

American National Standards Institute Standard Z136.6, "American National Standard for Safe Use of Lasers Outdoors," current edition[1]

Chairman of the Joint Chiefs of Staff Manual 3320.02E, "Joint Spectrum Interference Resolution (JSIR) Procedures," current edition

Code of Federal Regulations, Title 21

Deputy Secretary of Defense Memorandum, "Safety and Occupational Health Policy Oversight Functions," April 10, 2019

DoD 5400.11-R, "Department of Defense Privacy Program," May 14, 2007

DoD Directive 3200.11, "Major Range and Test Facility Base (MRTFB)," December 27, 2007, as amended

DoD Directive 5124.02, "Under Secretary of Defense for Personnel and Readiness," June 23, 2008

DoD Instruction 2030.08, "Implementation of Trade Security Controls (TSCs) for Transfers of DoD Personal Property to Parties Outside DoD Control," February 19, 2015, as amended

DoD Instruction 3200.19, "Non-Lethal Weapons (NLW) Human Effects Characterization," May 17, 2012, as amended

DoD Instruction 4140.01, "DoD Supply Chain Materiel Management Policy," March 6, 2019

DoD Instruction 4160.28, "DoD Demilitarization Program," November 30, 2022

DoD Instruction 5000.02, "Operation of the Adaptive Acquisition Framework," January 23, 2020, as amended

DoD Instruction 5000.69, "Joint Services Weapon and Laser System Safety Review Processes," August 10, 2023

DoD Instruction 5400.11, "DoD Privacy and Civil Liberties Programs" January 29, 2019, as amended

DoD Instruction 6055.01, "DoD Safety and Occupational Health (SOH) Program," October 14, 2014, as amended

DoD Instruction 6055.05, "Occupational and Environmental Health (OEH)," November 11, 2008, as amended

DoD Instruction 6055.07, "Mishap Notification, Investigation, Reporting, and Record Keeping," June 6, 2011, as amended

DoD Manual 4100.39, "Federal Logistics Information System (FLIS) Procedures," March 8, 2017, as amended

DoD Manual 4140.01, Volume 1, "DoD Supply Chain Materiel Management Procedures: Operational Requirements," December 13, 2018

DoD Manual 4140.01, Volume 2, "DoD Supply Chain Materiel Management Procedures: Demand and Supply Planning," November 9, 2018

[1] Copies may be purchased from the Internet at https://www.ansi.org/

DoD Manual 4140.01, Volume 6, "DoD Supply Chain Materiel Management Procedures: Materiel Returns, Retention, and Disposition," March 8, 2017, as amended

DoD Manual 4140.01, Volume 8, "DoD Supply Chain Materiel Management Procedures: Materiel Data Management and Exchange," February 10, 2014, as amended

DoD Manual 4140.01, Volume 10, "DoD Supply Chain Materiel Management Procedures: Supply Chain Inventory Reporting and Metrics," March 9, 2017, as amended

DoD Manual 4140.01, Volume 11, "DoD Supply Chain Materiel Management Procedures: Inventory Accountability and Special Management and Handling," March 8, 2017, as amended

DoD Manual 4160.21, Volume 1, "Defense Materiel Disposition Manual: Disposal Guidance and Procedures," October 22, 2015, as amended

DoD Manual 4160.21, Volume 4, "Defense Materiel Disposition: Instructions for Hazardous Property and Other Special Processing Materiel," October 22, 2015, as amended

DoD Manual 4160.28, Volume 1, "Defense Demilitarization: Program Administration," August 9, 2017, as amended

DoD Manual 6055.05, "Occupational Medical Examinations: Medical Surveillance and Medical Qualification," July 27, 2022

DoD Manual 8910.01, Volume 1, "DoD Information Collections Manual: Procedures for DoD Internal Information Collections," June 30, 2014, as amended

Federal Acquisition Regulation, Subpart 2.1, current edition

Food and Drug Administration, "Letter of Exemption from the Food and Drug Administration (FDA) for DoD Exemption from Provisions of 21 CFR 1040," July 29, 1976[2]

Food and Drug Administration Laser Notice No. 52, "Guidance on the Department of Defense Exemption from the FDA Performance Standard for Laser Products; Guidance for Industry and FDA," July 12, 2002[3]

Food and Drug Administration Laser Notice No. 58, "Surveying, Leveling, and Alignment Laser Products: Guidance for Industry and Food and Drug Administration Staff," January 31, 2023[4]

Military Handbook MIL-HDBK-828C, "Department of Defense Handbook: Range Laser Safety," March 31, 2017, as amended

Military Standard MIL-STD-882E, "Department of Defense Standard Practice: System Safety," May 11, 2012

Military Standard MIL-STD-1425A, "Department of Defense Design Criteria Standard: Safety Design Requirements for Military Lasers and Associated Support Equipment," August 30, 1991, as amended

United States Code, Title 5, Section 552a (also known as the "Privacy Act of 1974")

[2] Copies may be obtained from the Internet at https://www.denix.osd.mil/soh/denix-files/sites/21/2016/03/19_FDA-Exemption-of-Certain-Military-Laser-Products-08-23-1976.pdf

[3] Copies may be obtained from the Internet at https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/guidance-department-defense-exemption-fda-performance-standard-laser-products-laser-notice-no-52

[4] Copies may be obtained from the Internet at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surveying-leveling-and-alignment-laser-products

United States Code, Title 10

United States Code, Title 21, Chapter 9 (also known as the "Federal Food, Drug, and Cosmetic Act")