

# Department of Defense **INSTRUCTION**

NUMBER 6055.15 May 4, 2007

USD(AT&L)

SUBJECT: DoD Laser Protection Program

- References: (a) DoD Instruction 6055.1, "DoD Safety and Occupational Health (SOH) Program," August 19, 1998
  - (b) DoD Directive 4715.1E, "Environment, Safety, and Occupational Health (ESOH)," March 19, 2005
  - (c) Exemption No. 76EL-01DOD, Letter of Exemption from the Food and Drug Administration (FDA) for DoD Exemption from Provisions of 21 CFR 1040, July 29, 1976<sup>1</sup>
  - (d) Title 21, Code of Federal Regulations (CFR), Parts 1040, 1040.10, and 1040.11
  - (e) through (m), see Enclosure 1

## 1. PURPOSE

This Instruction:

1.1. Implements policy, assigns responsibilities, and describes procedures in support of References (a) and (b) for DoD laser protection.

1.2. Establishes the DoD Laser Systems Safety Working Group (LSSWG), the Tri-Service Laser Injury Hotline, and the Laser Accident and Incident Registry.

## 2. APPLICABILITY AND SCOPE

2.1. This Instruction applies to the Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the Department of Defense (hereafter referred to collectively as the "DoD Components").

<sup>&</sup>lt;sup>1</sup> Available at https://www.denix.osd.mil/denix/Public/ES-Programs/ERS/references.html

2.2. This Instruction does not apply to personnel who, as patients, are exposed to laser radiation as part of diagnostic or therapeutic procedures for medical and dental treatment.

# 3. <u>DEFINITIONS</u>

3.1. <u>DoD Exempt Lasers</u>. Laser products specifically exempted by the FDA (Exemption No. 76EL-01DOD (Reference (c)) from the DoD-specified elements of part 1040 of title 21 CFR (Reference (d)) due to mission need. 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.

3.2. <u>Maximum Permissible Exposure</u> (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 per American National Standards Institute (ANSI) Standard Z136.1 (Reference (e)). The MPEs may be obtained from each Service's functional area expert identified in paragraph 4 of Enclosure 2.

# 4. <u>POLICY</u>

In accordance with Reference (b), it is DoD policy to:

4.1. Protect DoD personnel from accidental death, injury, or occupational illness.

4.2. Protect the public from risk of death, injury, illness, or property damage because of DoD activities.

# 5. <u>RESPONSIBLITIES</u>

5.1. The <u>Under Secretary of Defense for Acquisition, Technology, and Logistics</u> (USD(AT&L)) shall implement this Instruction during all phases of the acquisition of laser equipment or the laser system life cycle, including planning, design, procurement, testing, installation, operation, maintenance, training, and reuse or disposal.

5.2. The <u>Deputy Under Secretary of Defense for Installations and Environment</u> (DUSD(I&E)), under the USD(AT&L), shall:

5.2.1. Establish, as an integral element of the Safety and Occupational Health (SOH) Committee (Reference (a)), the DoD LSSWG to provide guidance and recommend policy on laser safety and health matters within the Department of Defense.

5.2.2. Oversee the implementation of this Instruction and represent the Secretary of Defense on both internal and interagency laser safety and health matters.

5.3. The <u>Heads of the DoD Components</u> that own and operate lasers shall:

5.3.1. Establish and maintain a laser protection program that conforms to the requirements and procedures in this Instruction.

5.3.2. Ensure that particular emphasis is placed on laser injury prevention education and reporting incidents/accidents.

5.3.3. Appoint functional area experts on laser health and safety issues to the DoD LSSWG.

5.3.4. Establish unique health, safety, and surveillance programs for directed energy systems to protect personnel and equipment.

5.3.5. Establish a Service-specific laser safety review process to provide a systems safety review of all lasers used in combat, combat training or classified in the interest of national security, and all Class 1M, 2M, 3B or 4 lasers.

5.3.6. Provide an update of the laser protection program to DUSD(I&E) as part of the SOH Program in-progress review requirements of Reference (a).

5.4. The <u>Secretary of the Air Force</u> shall establish, administer and maintain the Tri-Service Laser Injury Hotline (1-800-473-3549 or DSN 240-4784) to provide immediate expert medical advice in the event of an injury or suspected injury to DoD personnel from lasers.

5.5. The <u>Secretary of the Army</u> shall establish, administer and maintain the Laser Accident and Incident Registry for DoD Components and analyze data for use in laser safety, protection, and treatment programs.

5.6. The <u>DoD LSSWG</u> shall:

5.6.1. Provide laser safety and health technical advice to the Assistant Deputy Under Secretary of Defense for Environment, Safety, and Occupational Health (ADUSD(ESOH)), under the DUSD(I&E).

5.6.2. Include representatives from the Office of the DUSD(I&E) and the Military Departments.

5.6.3. Establish guidelines to govern the operation of the LSSWG and procedures for selecting and rotating the Chair.

5.6.4. Meet at the call of the Chair to share information, discuss items of mutual interest, and recommend policies through the Director for Environmental Readiness and Safety (ER&S) to the ADUSD(ESOH).

5.6.5. Act as a technical liaison body to interact with international, Federal, and state regulatory and advisory agencies on issues related to occupational and environmental exposure to lasers.

5.6.6. Coordinate with NATO Standardization Agencies involved in laser safety and health issues.

5.6.7. Appoint a Joint Services Evaluation Subgroup (JSES) from within the LSSWG to:

5.6.7.1. Facilitate a forum for joint DoD agency measurement protocols and hazard evaluation reporting.

5.6.7.2. Evaluate laser systems and share evaluations with the DoD Components when an evaluation may be used by more than one DoD Component.

5.6.8. Submit an annual report with a work plan to the Director for ER&S.

## 6. <u>PROCEDURES</u>

## 6.1. Standards

6.1.1. <u>Non-Exempt Laser Systems</u>. Comply with parts 1040.10 and 1040.11 of Reference (d) when using non-exempt laser systems.

## 6.1.2. DoD Exempt Lasers

6.1.2.1. Prior to procurement of DoD Exempt Lasers, ensure the laser manufacturers understand they are responsible for requesting the exemption from the DoD Component in accordance with Reference (c), FDA Laser Notice 52, and the amendment to exemption (References (f) and (g)).

6.1.2.2. Provide notice of DoD exemption to the laser manufacturers. A sample exemption notice is provided as Enclosure 2.

6.1.2.3. Ensure that DoD Exempt Lasers comply with part 1040 of Reference (d) except when it is in conflict with the intended mission. Specify alternate controls to eliminate or control hazards by applying the system safety order of precedence for hazard control as defined in Military Standard 882D (Reference (h)).

6.2. <u>Education</u>. Train personnel in laser hazards and specific operational and safety procedures commensurate with their duties prior to operations where exposure over the MPE could occur.

6.3. <u>Medical Surveillance</u>. Maintain an occupational medical surveillance program for laser personnel in accordance with DoD 6055.5-M (Reference (i)).

#### 6.4. Accident and Incident Response

6.4.1. Develop procedures to report incidents involving suspected or known exposures to laser radiation above the MPE.

6.4.1.1. Include measurements or analysis to determine exposure levels and appropriate medical service, medical surveillance, and a description of circumstances surrounding the event.

6.4.1.2. Call the Tri-Service Laser Injury Hotline (1-800-473-3549 or DSN 240-4784) for immediate expert medical advice.

6.4.2. Submit incident and accident reports through DoD Component channels to the Laser Accident and Incident Registry (U.S. Army Medical Research Detachment, Walter Reed Army Institute of Research). These reports do not replace established safety investigation procedures or other Service-specific notification procedures.

#### 6.5. Inventory Control

6.5.1. For non-exempt laser products, ensure that the labeling requirements of part 1040 of Reference (d) are met.

6.5.2. Account for, appropriately label, and properly dispose of DoD exempt lasers in accordance with References (c), (g), and ANSI Standard Z136.6 (Reference (j)).

## 6.6. Controls

6.6.1. Establish and maintain control over areas where laser exposures above the MPE could occur. Comply with Major Range and Test Facility Base policies and procedures in accordance with DoD Directive 3200.11 (Reference (k)), where applicable, throughout the life of the laser system. Combat areas of operation are excluded from this requirement; however, laser operators and those known to be in a potential overexposure situation must be trained to recognize the hazards, and if practical, when to take protective measures.

6.6.2. Mitigate the risk from laser radiation to an acceptable level using engineering design, protective equipment, administrative controls, or a combination thereof, pursuant to References (e) and (j) and ANSI Standard Z136.4 (Reference (l)).

6.6.3. Implement engineering controls whenever possible and supplement with additional administrative controls.

## 6.7. Hazard Evaluation

6.7.1. Maintain a Service capability to conduct evaluations to assess the hazards from laser systems.

6.7.2. Maintain a repository consisting of surveys, reports, and theoretical calculations for each system evaluated.

6.7.3. Incorporate procedures into each Service laser review process to notify the DoD LSSWG JSES of any laser system being considered for procurement or development that is intended for joint Service use.

6.7.4. Use product performance standards in Reference (e) for commercially procured common use lasers (e.g., laboratory lasers, classroom laser pointers, lasers embedded in equipment, and other lasers not procured for military-specific uses).

# 7. INFORMATION REQUIREMENTS

The reporting requirements in this Instruction are exempt from licensing in accordance with paragraphs C4.4.2., C4.4.3., and C4.4.4. of DoD 8910.1-M (Reference (m)).

## 8. EFFECTIVE DATE

This Instruction is effective immediately.

Kenneth J. Krieg Under Secretary of Defense for Acquisition, Technology and Logistics

Enclosures - 2

E1. References, continued

E2. Sample DoD Military Laser Exemption Notice

# E1. ENCLOSURE 1

# **<u>REFERENCES</u>**, continued

- (e) American National Standards Institute Standard Z136.1, "American National Standards for Safe Use of Lasers," current edition<sup>2</sup>
- (f) 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<sup>1</sup>
- (g) Amendment to Letter of Exemption from the FDA for DoD Exemption from Provisions of 21 CFR 1040, March 18, 1986<sup>1</sup>
- (h) Military Standard 882D, "Standard Practice for System Safety," February 10, 2000
- DoD 6055.05-M, "Occupational Medical Examinations and Surveillance Manual," May 2, 2007
- (j) American National Standards Institute Standard Z136.6, "American National Standard for Safe Use of Lasers Outdoors," current edition<sup>2</sup>
- (k) DoD Directive 3200-11, "Major Range and Test Facility Base (MRTFB)," May 1, 2002
- American National Standards Institute Standard Z136.4, "American National Standard Recommended Practice for Laser Safety Measurements for Hazard Evaluation," current edition<sup>2</sup>
- (m) DoD 8910.1-M, "DoD Procedures for Management of Information Requirements," June 30, 1998

<sup>&</sup>lt;sup>1</sup>Available at https://www.denix.osd.mil/denix/Public/ES-Programs/ERS/references.html

<sup>&</sup>lt;sup>2</sup> Available for purchase from http://www.ansi.org/

# E2. ENCLOSURE 2

# SAMPLE FORMAT FOR DoD MILITARY LASER EXEMPTION NOTICE

1. In accordance with Exemption No. 76EL-01DoD issued to the Department of Defense on July 26, 1976, by the Commissioner of Food and Drugs, the following electronic product is exempted from Food and Drug Administration (FDA) radiation safety performance standards prescribed in Title 21, Code of Federal Regulations, Chapter 1, Subchapter J, Parts 1040.10 and 1040.11.

DoD Component(s) Granting Military Exemption
Laser Type/Medium
Manufacturer
Number of Lasers
National Stock Number
Local Stock Number
Reason for exemption: (Check all that apply)
Combat
Combat Training
Classified

2. The manufacturer shall label laser products exempted under 76EL-01DoD as follows:

## CAUTION

This electronic product is exempt from FDA radiation safety performance standards prescribed in the Code of Federal Regulations, title 21, Chapter 1, Subchapter J, 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 Department of Defense.

[Or with other wording approved by the DoD Component. In special circumstances, other wording approved by the DoD Component may be used to notify personnel that the laser shall not be sold or distributed to the public without demilitarization or disposal of the laser system.]

3. The contractor must comply with each DoD Component authority's requirements and recommendations as stipulated in the contract, identify those design requirements of 21 CFR Part 1040, which cannot be incorporated in the system, and provide rationale for noncompliance with each requirement. Exemptions are Service specific, and procurement or use of lasers and laser systems must be approved by the DoD Component's laser safety authority.

4. For further information on this process, contact the appropriate DoD laser safety representative.

Commander, US Army Center for Health Promotion and Preventive Medicine ATTN: MCHB-TS-OLO 5158 Blackhawk Road Aberdeen Proving Ground, MD 21010-5403 (410) 436-3932

Commander, Naval Surface Warfare Center Dahlgren Division 17320 Dahlgren Road Dahlgren, VA 22448-5100 (540) 653-1149

Chief, Optical Radiation Safety Team Air Force Research Laboratory Optical Radiation Branch 2624 Louis Bauer Drive Brooks City-Base, TX 78235-5218 (800) 473-3549