SECNAV INSTRUCTION 5100.14E

From: Secretary of the Navy

Subj: DEPARTMENT OF THE NAVY LASER PROTECTION PROGRAM

(b) 21 CFR 1040
(c) DoD Instruction 6055.15 of 4 May 2007
(d) FDA Exemption 76EL-01 of 26 July 1976
(e) SECNAVINST 5000.2E
(g) SECNAVINST 5100.10K
(h) DoD Instruction 5000.02 of 7 January 2015
(i) MIL-STD 1425A, Safety Design Requirements for Military Lasers and Associated Support Equipment of 30 August 1991
(k) DoD Instruction 5000.69 of 9 November 2011

Encl: (1) Definitions
(2) Responsibilities
(3) Sample Military Exemption Notification: Authorization to Deliver Prototype/Experimental XYZ Infrared Range Finder Target Designator (ILRFTD) Per FDA Exemption No. 76EL-01DOD
(4) Sample Format: Transfer/Disposal of Exempt Laser Products

1. Purpose. Establish policy and assign responsibility to implement the requirements in references (a) through (l) and enclosure (1) through (4). This instruction has been revised and should be reviewed in its entirety.
2. **Cancellation.** SECNAVINST 5100.14D.

3. **Definitions.** See enclosure (1).

4. **Applicability**

   a. This instruction applies to the Offices of the Secretary of the Navy, the Chief of Naval Operations (CNO), and the Commandant of the Marine Corps (CMC), and all U.S. Navy and U.S. Marine Corps installations, commands, activities, field offices, and other organizational entities within the Department of the Navy (DON) that procure, fabricate, possess, use, store or dispose of laser products.

   b. This instruction incorporates all:

      (1) Military exempt lasers regardless of laser classification;

      (2) Laser products that may be capable of emitting accessible laser radiation in excess of Class 3R limits (Class 1M, 2M, 3B, and 4) as defined in reference (a) and used by the Department of the Navy;

      (3) Those laser products planned solely for industrial, construction, medical, or indoor experimental laboratory use shall comply with reference (b).

5. **Policy.** The design and use of laser products within DON shall comply to the maximum extent practicable with all applicable Department of Defense (DOD) and DON requirements and the standards set forth in reference (b).

6. **Responsibilities.** See enclosure (2).

7. **Background.** Reference (c) provides policy for lasers, to include those described in paragraph 4b above. Laser products manufactured or marketed in the U.S. for DON are required to comply with all provisions of reference (b) unless the laser system is designated as a military exempt laser, or as permitted by the FDA via variance, or other FDA granted exemption. This applies to all laser systems transferred into the custody of the DON, whether it is a single experimental prototype for demonstration or test and evaluation, or any one of the myriad of systems procured within DON for fielding each year.
8. Records Management

a. Records created as a result of this instruction, regardless of format or media, must be maintained and dispositioned according to the records disposition schedules found on the Directives and Records Management Division (DRMD) portal page:

b. For questions concerning the management of records related to this instruction or the records disposition schedules, please contact your local Records Manager or the DRMD program office.

9. Forms. DoD Laser Exemption From Federal Standard Form included in enclosure (3) can be obtained at

Distribution:
Electronic only, via Department of the Navy Issuances Web site
DEFINITIONS

1. Laser. An acronym for Light Amplification by Stimulated Emission of Radiation. Any device that can produce or amplify electromagnetic radiation in the x-ray, ultraviolet, visible, infrared or other portions of the spectrum by the process of controlled stimulated emission of photons.

2. Laser Product. Any manufactured product or assemblage of components which constitutes, incorporates, or is intended to incorporate a laser product. A laser product that is intended for use as a component of an electronic product shall itself be considered a laser product.

3. Military Exempt Laser. A laser product, regardless of laser hazard classification, designated by the Program Office as eligible according to reference (d) based upon the system meeting all of the criteria listed below:

   a. The laser product is procured and used exclusively by the DOD;

   b. The laser product is designed for actual combat or combat training, or is classified in the interest of national security;

   c. The laser product cannot comply with the Performance Standards for Light-Emitting Products, as expressed in reference (b), due to mission requirements (e.g., an illuminated firing indication could compromise camouflage);

   d. Laser products meeting the above criteria are exempted from requirements of reference (b), which interfere with mission requirements. Laser products used in research, development, test or evaluation which meet the above criteria can be military exempt lasers.

4. Applicable Lasers. All laser products, regardless of laser classification, capable of emitting accessible laser radiation in excess of Class 3R limits with the exception of those lasers and laser systems planned solely for industrial, construction, medical, or indoor experimental laboratory use.
5. The DON Laser Safety Review Board (LSRB). The LSRB is a Naval advisory review authority on laser safety as established by this instruction. The LSRB provides laser systems safety reviews of all Applicable Lasers. The LSRB provides an advisory concur or non-concur position and findings on utilization of Military Exempt lasers. The position and findings shall be incorporated into the Procuring Activities Safety Assessment Report for all phases of use.

6. **Outdoor Laser Range.**
A designated land or water area that is set aside, managed, and used for laser range activities of the Department of Defense. Such term includes the following:

   a. Firing lines and positions, maneuver areas, firing lanes, test pads, detonation pads, impact areas, electronic scoring sites, buffer zones with restricted access, and exclusionary areas.

   b. Airspace areas designated for military use in accordance with regulations and procedures prescribed by the Administrator of the Federal Aviation Administration.

7. **Laser Use Area.** An area where laser use is expected. Typically, this area has been reviewed to identify outstanding hazards and appropriate mitigations, and subsequently approved for laser use. Laser use areas can include ranges certified for laser use, as well as areas that have not been certified. Areas that are not certified ranges for laser use require a through hazard analysis on a case-by-case basis. These laser use areas are best suited for short term laser use for laser systems that have relatively short hazard distances (where the laser operator is likely able to ensure safe use).
RESPONSIBILITIES

1. The Deputy Assistant Secretary of the Navy for Safety (DASN(Safety)) shall: Provide Policy and Oversight for the implementation of the Naval Laser Protection Program. DASN(Safety) approves and endorses the Laser Safety Review Board Chair.

2. The Assistant Secretary of the Navy for Research, Development, and Acquisition (ASN(RDA)) is the DON Component Acquisition Executive (CAE) and Service Acquisition Executive (SAE) responsible for DON acquisition.
   a. ASN(RDA) provides overall guidance and direction for the DON acquisition community’s participation in the laser safety policy, per reference (e).
   b. Per reference (f), the CAE is responsible for development and implementation of plans that ensure DON has provided the appropriate personnel and funding resources for developmental testing and systems engineering, to include laser systems.
   c. Per reference (g), ASN (RDA) is responsible for informing ASN (EI&E) on the status of High Risk Acceptance decisions and associated user concurrence, to include decisions on high risk acceptance of hazards related to the operation of laser systems.

3. The CNO and CMC shall:
   a. Implement the DON Laser Safety Program within the Navy and Marine Corps respectively;
   b. Ensure Applicable laser products procured by the DON are evaluated through the laser hazard evaluation (LHE) process, by the Lead Naval Technical Laboratory (LNTL). These evaluations address the hazards of the lasers and laser systems and determine if the performance requirements of references (b and d) FDA Exemption No. 76EL-01 DOD are met;
   c. Hold the manufacturer responsible for requesting from DON the use of the military exemption when the three eligibility criteria in the Military Exempt Laser definition are met.
Reference (b) requirements that could not be met must be justified and alternative controls may be required. All reference (b) requirements that will not have a negative impact on the mission must be met by the laser product prior to transfer of custody to DON;

d. CNO shall manage, or delegate management to appropriate Executive Schedule/Senior Executive Service civilian or flag/general officer, the oversight of the Laser Safety Review Board (LSRB);

e. Designate a resource sponsor to fund the LNTL manpower, core activities, management, and administrative requirements.

f. Provide three voting members each to the Laser System Safety Working Group (LSSWG).

4. CNO N09F shall:

a. Include laser safety policy as part of the Navy non-ionizing safety policy ashore and afloat;

b. Coordinate with the Marine Corps on laser safety policy;

c. In conjunction with the Director, CMC Safety Division (SD), recommend in writing the LSRB Chair as elected by the LSRB membership to DASN(Safety) for approval.

5. CMC SD shall:

a. Act as the designated laser protection program manager for the Marine Corps;

b. Maintain membership in the DOD LSSWG;

c. In conjunction with the CNO N09F, recommend in writing the LSRB Chair as elected by LSRB membership to DASN(Safety) for approval.

6. Marine Corps Combat Development Command (C465) shall establish and maintain a laser range safety program as a component of the Marine Corps’ institutional Range Safety Program and Range Certification Program to include:
a. Policies and procedures for the use of airborne and ground tactical lasers on Marine Corps ranges;

b. Laser range safety training for operating forces and applicable range personnel. Leverage laser safety capabilities of Naval Sea Systems Command for laser safety course curriculum development as necessary;

c. Development and fielding of laser range safety tools;

d. Oversight and certification of all Marine Corps ranges to ensure safe and efficient training use of approved tactical lasers.

7. Chief, Bureau of Medicine and Surgery, as the DON designated Medical Lead Agent (MLA) for Laser Safety shall:

a. Act as liaison to the Deputy Under Secretary of Defense (Installations and Environment) (DUSD (I&E)) on behalf of Assistant Secretary of the Navy (Energy, Installations and Environment) (ASN (EI&E)) with regards to matters concerning medical effects of laser radiation;

b. Establish and update laser medical surveillance requirements, set medical training requirements for personnel working with laser radiation sources, prescribe treatment process for Laser radiation injuries, and conducting research on biological effects of laser radiation;

c. Maintain membership in the DOD LSSWG and pertinent national and international standards committees.

8. Commander, Naval Sea Systems Command, as the DON designated Technical Lead Agent (TLA) for Laser Safety, shall:

a. Designate the LNTL and ensure it participates in design reviews and evaluates compliance with the references. The LNTL shall evaluate applicable lasers to determine laser safety parameters and compliance with applicable safety standards in support of the LSRB;

b. Designate and ensure that the Lead Naval Range Laser Safety Group (LNRLSG) at NSWC Corona, under the direction of and with technical assistance from the LNTL, independently surveys
and evaluates all Navy ranges where Applicable Lasers are used. Outdoor Ranges should not be confused with outdoor laser use areas;

c. In conjunction with the Chair of the LSRB, provide laser safety survey assistance to DON activities;

d. Assign lasers and laser systems that are unable to meet FDA requirements specified in reference (b) for review by the DON LSRB for military exemption status consideration during each phase of development as appropriate;

e. Maintain a repository of LSRB and Joint Service Laser Safety Board meeting minutes;

f. Maintain archives of military exemption notification letters;

g. Maintain a repository of Navy Certified LSSOs;

h. Maintain and update the inventory of all Applicable Laser types military exempt and laser products capable of emitting accessible laser radiation in excess of Class 3R limits in the DON.

9. All commands, contracting and supply activities, research and development activities and acquisition program managers shall:

   a. Identify lasers and laser systems that are unable to meet FDA requirements specified in reference (b) and establish procedures to ensure that authorizations to use the military exemption are granted only to lasers and laser systems that meet the criteria for military exempt laser as defined in enclosure (1)

   b. Prior to accepting delivery of the laser product, provide written notification on Command letterhead to the manufacturer of each laser product that is covered by the military exemption. A copy shall be provided to the TLA. The notification letter format is provided in enclosure (3) and includes the required caution label verbiage. The notification letter format and wording should not be changed without LSRB approval. The letter shall include the justification for the
military exemption, list each specific deviation from reference (b), and explain why the deviations are required;

c. By issuing the exemption notification letter, the procuring activity assumes responsibility for tracking the location of the laser product specified in the letter throughout the life cycle of the laser product;

d. It is a violation of federal law for a laser manufacturer to sell, deliver, or otherwise transfer custody of a laser product labeled as military exempt without receiving written authorization from the particular DOD Procuring activity to apply the military exemption on that particular laser product;

e. Restrictions: An exemption notification letter is written specifically for a particular laser product and contract and is limited by number of units or sale/delivery date. Authorizations to use the military exemption may be limited to a specific DoD component. New procurements shall not use previously issued exemption notification letters; Exemption letters will be reviewed by the LSRB prior to issuance by the command.

f. Include system safety provisions in all Applicable Laser procurement documentation. This includes prototype and experimental laser systems. As a minimum, the following shall be specified:

(1) Per reference (h) a systems safety program shall be established in accordance with reference (j). The program shall include a system safety program plan, LHE, in-depth system hazard analysis and risk assessment of the equipment during each phase of its life cycle, hazard analyses of training and testing sites, routine surveys of equipment located aboard ship, on aircraft and ashore, and operator training in the safe use of the laser system;

(2) Safety controls and procedures of reference (i) and analysis and reporting of those portions of reference (b) that cannot be met. In the military exemption notification, justification for noncompliance with reference (b) shall be documented along with all specific areas of noncompliance. Planned mitigations for the hazards resulting from noncompliance
shall be documented and submitted to the LSRB for review. Highlight those significant hazards that cannot be corrected or for which a solution has not been identified and implemented;

(3) Establish a safety review procedure to determine whether adequate hazard analyses and corrective actions have been completed and that Applicable Laser system under their cognizance is designed and will be operated under the applicable requirements of references cited;

(4) During each phase of development, modifications, to include platform changes and employment methods (tactics, techniques, and procedures), not previously reviewed by the LSRB, submit documentation concerning each Applicable Laser to the LSRB for review;

(5) Complete risk acceptance as mandated by Reference (j) at the appropriate level in accordance with authorities designated in reference (e);

(6) Notify the LSRB if the laser is a joint procurement and implement the joint review process per reference (k);

(7) Plan, budget, and provide funding to the LNTL to perform an independent LHE of the laser system in support of the LSRB. Planning for development or acquisition of Applicable Lasers should also include sufficient schedule time for completion of the independent LHE and LSRB prior to the acquisition or field testing event taking place.

9. All DON activities that procure, fabricate, possess, use, store or dispose of Applicable Lasers shall:

   a. Prohibit the use of all Applicable Lasers that have not been reviewed for use by the LSRB;

   b. Ensure that all laser-operating procedures are in accordance with the references cited;

   c. Maintain inventory control and permanent record of the status of all Applicable Laser products, including their ultimate disposition;
d. Report excess lasers to the Defense Reutilization and Marketing Service for screening within DoD and maintain accountability during the reporting period. Transfer of excess lasers shall be made directly between the gaining and losing organization but only after notification and approval by the TLA;

e. Develop an appropriate demilitarization and disposal plan for all military exempt lasers;

f. Dispose of Applicable Lasers per reference (l). No potentially usable laser or laser parts shall be demilitarized, disposed of, donated, or sold to entities outside the DoD without prior approval of the TLA. The demilitarization, disposal, donation or sale of any other Applicable Laser shall require notification to the TLA.
SAMPLE MILITARY EXEMPTION NOTIFICATION: AUTHORIZATION TO DELIVER PROTOTYPE/EXPERIMENTAL XYZ INFRARED RANGEFINDER TARGET DESIGNATOR (ILRFTD) PER FDA EXEMPTION NO. 76EL-01DOD

(Format per correspondence regulations using command letterhead)

TO    ABC Lasers, Incorporated
       ATTN:
       Main Street
       Anytown, State Zip Code

SUBJECT: AUTHORIZATION TO DELIVER PROTOTYPE/EXPERIMENTAL XYZ INFRARED RANGEFINDER TARGET DESIGNATOR (ILRFTD) PER FDA EXEMPTION No. 76EL-01DOD

1. In accordance with reference (d) the XYZ ILRFTD, being used exclusively by the DOD, and designed for combat, combat training, or classified in the interest of national security, manufactured under contract DAAB08-03-C-H006, is exempted from requirements of the FDA performance standards for light emitting products prescribed in the reference (a) in order to meet military requirements.

2. Any modification to the XYZ ILRFTD (including material components, physical design, or laser output characteristics), or deviation from the scope defined in the table below or attached form, require the manufacturer to obtain a new military exemption authorization letter.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contract #</td>
<td>DAAB08-03-C-H006</td>
</tr>
<tr>
<td>Product Name</td>
<td>Prototype/Experimental XYZ Infrared Laser Rangefinder Target Designator (ILRFTD)</td>
</tr>
<tr>
<td>Model #</td>
<td>428-AST-34S-EXP</td>
</tr>
<tr>
<td>Serial #(s)</td>
<td>00001-00005</td>
</tr>
<tr>
<td>Lot #(s)</td>
<td></td>
</tr>
<tr>
<td>DOD Service(s)</td>
<td>Enter DOD Service procuring lasers</td>
</tr>
<tr>
<td>Org./Unit</td>
<td>Unit acquiring laser product and responsible for inventory</td>
</tr>
</tbody>
</table>
3. FDA Laser Notice 52, Guidance on the DOD Exemption from the FDA Performance Standard for Laser Products, states that a manufacturer violates Federal law if it delivers a laser system not in compliance with the FDA standard to the DOD unless it first receives a written authorization by the applicable DOD authority to apply the exemption discussed herein. Further, it states that an appropriate DOD laser safety representative must evaluate all military exempt laser products to determine compliance with relevant military and/or Federal requirements. Finally, it requires that the manufacturer maintain evidence of this authorization for use of the military exemption.

4. Although the use of the DOD exemption has been authorized, the system design must still adhere to the requirements of the current version of reference (i) or by special approval by the applicable military laser safety authority. In addition to any other labeling requirements, this laser product is required to have labeling permanently affixed to the device housing with the information provided below (or alternative 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 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 DOD.

5. Approved deviations from the requirements of reference (a), complete with justification for each deviation must be provided. Other deviations are not authorized under this exemption notification.
6. The point of contact for questions pertaining to this authorization is Mr. John Q. Doe, (123) 555-1234, john.q.doe@navy.mil, Program Manager, Naval Air Systems Command, Building 1234, Patuxent River, MD 12345-5000.

Sincerely,

John Doe
Manager
PM Aviation

Copy to: (w/encl)
NAVSEA (Technical Lead Agent for Laser Safety).
SAMPLE FORMAT: TRANSFER/DISPOSAL OF EXEMPT LASER PRODUCTS

(Use letter head)

From:

To: Commander, Naval Sea Systems Command, Technical Lead Agent for Laser Safety

Subj: REQUEST FOR APPROVAL OF TRANSFER/DISPOSAL OF MILITARY EXEMPT LASER(S)

1. It is requested that approval be granted to transfer/dispose (select one) the following military exempt laser(s).

<table>
<thead>
<tr>
<th>Laser Type</th>
<th>List laser medium, emitted wavelength, maximum output radiation (power or energy, as applicable) and laser hazard classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td></td>
</tr>
<tr>
<td>Contract Number</td>
<td></td>
</tr>
<tr>
<td>Serial Number(s)</td>
<td></td>
</tr>
<tr>
<td>National Stock Number</td>
<td>if assigned</td>
</tr>
<tr>
<td>Military Specific Qualifier</td>
<td>☐ Combat ☐ Combat Training ☐ Classified in Interest of National Security</td>
</tr>
<tr>
<td>To be transferred to:</td>
<td></td>
</tr>
<tr>
<td>To be donated or sold to:</td>
<td></td>
</tr>
</tbody>
</table>

2. (For disposal, describe methods for demilitarization or re-modification that have been or will be accomplished to bring the laser in compliance with reference (b) prior to disposal outside DOD.)

3. Point of contact is XXXXX.

I. N. CHARGE

Enclosure (4)