INTRODUCTION
Laser systems manufactured or marketed in the United States must meet the requirements set forth in the Federal Laser Product Performance Standard (FLPPS). The Food and Drug Administration (FDA), which regulates lasers in the United States, has granted an exemption to specific requirements for military-specific laser systems when a design requirement could compromise mission performance. This is often referred to as the “military exemption.” Misunderstandings by both laser manufacturers and Department of Defense (DOD) offices procuring military-specific lasers about the exemption process have led to the military exemption being misused.

BACKGROUND
All laser systems manufactured or marketed in the United States for the Army are required to comply with all provisions of the FLPPS unless an exemption from specific control measure(s) has been granted. The Nonionizing Radiation Division (NRD) of the U.S. Army Public Health Center (APHC) performs laser safety evaluations of laser systems being procured by the Army. These evaluations address the hazards of the laser system and the system’s safety control measures that are required by the FLPPS.

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

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

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

3. **The laser system is unable to comply with the FLPPS due to mission requirements (e.g., an illuminated emission indicator could compromise camouflage).**

If all three eligibility requirements are true for a laser system, then the manufacturer is responsible for requesting the use of the military exemption from the DOD-procuring agency. FLPPS requirements that could not be met must be justified, and alternate controls are required according to Military Standard (MIL-STD)-1425A. All FLPPS requirements that will not have a negative impact on the mission must be met by the laser system prior to sale to the U.S. Army.
PROCESS
For a laser system to be sold/delivered using the military exemption, the laser system manufacturer must receive an exemption notification letter from the DOD-procuring office granting the use of the military exemption for the product. This signed exemption letter allows the manufacturer to deliver exempt lasers. The DOD’s Laser System Safety Working Group developed two letters: one for sale/delivery of a small number of devices for test and evaluation and one for sale/delivery of systems for fielding. Samples of these letters and assistance in writing an exemption letter are available by contacting the APHC NRD or visiting https://phc.amedd.army.mil/topics/workplacehealth/lor/Pages/default.aspx.”.

DOD exemption letters are authored and signed by an appropriate person in the procuring office and delivered to the manufacturer prior to sale/delivery of any laser system to the DOD office. By issuing the exemption letter, the procuring office is responsible for knowing the location of laser systems on that contract from delivery to disposal. The military laser exemption process is designed to keep lasers lacking in necessary safety features from falling into the hands of civilians.

By law, a laser must be labeled with either a label stating it is compliant with the FLPPS or is exempt, with a label similar to Figures 1 or 2 below.

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<table>
<thead>
<tr>
<th>THIS PRODUCT COMPLIES</th>
<th>CAUTION</th>
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<tr>
<td>WITH 21 CFR SUBCHAPTER J,</td>
<td>This electronic product has been exempted from FDA radiation safety performance standards prescribed in Title 21, Code of Federal Regulations, Chapter 1, Subchapter J, pursuant to Exemption No. 76EL-01 DOD issued 26 July 1976. This product is for exclusive use by DOD activities and is not to be sold, leased, or donated to others.</td>
</tr>
<tr>
<td>PARTS 1040.10 AND 1040.11</td>
<td></td>
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</tbody>
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Figure 1. Sample Compliance Label

Figure 2. A Military Exemption Label

It is a violation of Federal law for a manufacturer to sell/deliver a laser system labeled as military exempt without receiving written permission to use the exemption from the DOD. MIL-STD-1425A, paragraph 1.3.3, states that the military exemption letter is provided to the contractor by the government contracting officer.

REstrictions
An exemption notification letter is written specifically for a particular contract and is limited by number of units or sale/delivery date. There is no such thing as a blanket exemption.

Most importantly, exempted laser systems cannot be resold by the DOD to any other office or person(s) unless they are brought into full compliance with the FLPPS, labeled as such, and registered with the FDA. Typically, DOD-exempt laser systems are destroyed after their useful life has ended.

Contact
For more information, contact the APHC NRD at: 410-436-3932, or DSN 584-3932; usarmy.apg.medcom-aphc.mbx.nonionizing@mail.mil.

References