



Military Laser Exemption from FDA Requirements

FACT SHEET 25-025-0212

Introduction: Laser systems entering commerce in the United States must comply with the Federal Laser Product Performance Standard (FLPPS). The Food and Drug Administration (FDA), which regulates lasers in the U.S., has granted an exemption to these requirements for military specific laser systems when a design requirement could compromise mission performance. This is often referred to as the “military exemption.” Misunderstandings about the exemption process by both laser manufacturers and Department of Defense (DOD) offices procuring military-specific lasers led to the military exemption being misused.

Background: Laser systems manufactured or marketed in the U.S. for the Army are required to comply with all provisions of the FLPPS unless the laser system is exempt. This applies to all laser systems sold/delivered to the Army, whether it is a single experimental prototype for demonstration or test and evaluation (T&E) or hundreds of thousands procured for fielding. The Laser/Optical Radiation Program of this Command performs laser hazard evaluations of laser systems being procured by the Army. These evaluations address the hazards of the laser system and if the performance requirements of the FLPPS were met.

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, Dept of Homeland Security, Border Patrol, FBI, etc.) do not qualify. Manufacturers developing laser systems for sale to other Federal agencies that cannot comply fully with the FLPPS must seek a variance through the FDA prior to the sale of these devices.

2. **The laser system being acquired/purchased is designed for actual combat or combat training, or is classified in the interest of national security.** Laser systems purchased by the DOD for other purposes (e.g., a laser cutter in a welding shop, laser system purchased for a research lab, medical laser, etc.) 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 firing 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 may be required. 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.

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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.

Two letters have been developed by the DOD's Laser System Safety Working Group (LSSWG); one for sale/delivery of a small number of T&E devices and one for sale/delivery of any systems after T&E models. Samples of these letters and assistance in writing an exemption letter are available by contacting this Command's L/ORP.

DOD exemption letters are authored and signed by 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 sale/delivery to disposal.

By law, a laser must be labeled with either a label stating it is compliant with the FLPPS or is exempt under the military exemption.

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 for that particular system.

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, **these 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.

For more information, contact the Army Institute of Public Health, Laser/Optical Radiation Program at army.laser.safety@us.army.mil, 410-436-3932, or DSN 584-3932.

References

[FLPPS](#), Food and Drug Administration, Title 21, Code of Federal Regulations, Part 1040, Performance Standards for Light-Emitting Products

[Department of Defense Instruction Number 6055.15](#), 4 May 2007, DOD Laser Protection Program.