

Procurement of Outdoor Laser Systems for use on Military Facilities





- ♦ Exemption
- ♦ Compliance
- ◆ Laser Safety

1. **PROBLEM.** Several laser system manufacturers market off-the-shelf laser products that they declare either to be compliant with 21CFR1040 or are labeled as "military exempt" from this safety regulation. Many of these systems have not been formerly certified as exempt by the government contracting office and have not been evaluated for compliance with military or federal requirements by the appropriate DOD laser safety representatives.

2. BACKGROUND.

- a. **FDA Requirements.** Laser products normally must comply with the Radiation Safety Performance Standards issued by the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), in Title 21, Code of Federal Regulations, Subchapter J, Part 1040. 10 and 1040.11. The FDA does not certify laser product compliance with these laws. This standard requires laser system manufacturers to include certain safety design features in laser products sold in the United States. Such products may be required to incorporate safety features such as warning lights, warning labels, housing interlocks, etc.
- b. **Military Laser Exemption.** In 1976, the FDA Commissioner exempted certain military laser products from the provisions of the FDA Standard (FDA Exemption No. 76 EL-01DOD), e.g., where warning indications would compromise camouflage. This exemption is only for military lasers used for actual combat or combat training or those classified in the interest of national security. Government contracting officials must certify that these laser products can employ this exemption by preparing a letter to the manufacturer for a specific product. MIL-STD-1425A, Safety Design Requirements for Military Lasers and Associated Support Equipment, provides alternative requirements for the safe design of military exempt laser products. The military exemption issued to the DOD requires manufacturers to meet all requirements of 21CFR1040 for these systems except where compliance would hinder mission fulfillment during actual combat or combat training operations or when the laser product is classified in the interest of national security. MIL-HDBK-828, Laser Range Safety, lists several military laser systems which have been exempted.

Laser/Optical Radiation Program
U.S. Army Center for Health Promotion and Preventive Medicine
Aberdeen Proving Groun4 MD 21010-5422
DSN 584-3932 or Commercial (410) 671-3932

- 3. **RECOMMENDATIONS.** Government purchasers of laser products and systems should:
- a. Ensure that-all laser systems intended for actual combat or combat training or that are classified in the interest of national security have been evaluated by the appropriate DOD laser safety representatives and/or the DOD Laser Safety Review Board.
- b. Procurement and safety personnel should not assume that a laser product has been reviewed by the appropriate DOD laser safety representatives and/or the DOD Laser Safety Review Board unless it is in MIL-HDBK-828.
- c. Manufacturers of government law equipment should not assume that the DOD exemption applies to their product unless the government purchaser has provided such certification in writing.

4. REFERENCES.

- a. Title 21, Code of Federal Regulations, Subchapter J, Part 1040, Laser Products.
- b. DODI 6055.11, Protection of DOD Personnel from Exposure to Radiofrequency Radiation and Military Exempt Lasers, 21 February 1995, with enclosure, FDA Exemption 76EL-01DOD, 29 July 1976.
 - c. MIL-STD-1425A, Safety Design Requirements for Military Lasers and Associated Support Equipment.
 - d. MIL-NDBK-828, Military Handbook, Laser Range Safety.
- e. Memorandum, DACS-SF, LSSWG Chairman, Subject: Formation of DOD Laser Safety Review Board (LSRB), 15 September 1995.
- 5. **DOD REPRESENTATIVES**. The following organizations are responsible for laser safety issues:

Commander, USA Center for Health Promotion and Preventive Medicine ATTN: MCHB-DC-OLO APG, MD 21010-5422 Com (410) 671-3932, or DSN 584-3932

Commander, Naval Surface Warfare Center Dahlgren Division 17320 Dahlgren Road Dahlgren, VA 22448-5100 Com (540) 653-1149 or DSN 249-1149

Commander, U.S. Air Force
Optical Radiation Division
Armstrong Laboratories
8111 Eighteenth Street
Brooks Air Force Base, Texas 78235-5215
Com (210) 536-3622

This Fact Sheet was prepared for the DOD Laser System Safety Working Group by the Information Subgroup led by Mr. Terry Lyon, USACHPPM. This information was intended for laser system manufacturers, Radiation Protection Officers, Laser Safety Officers, Range Safety Personnel, and Procurement Activities.