Short Course On:

# Importation Requirements of Laser Products

## ICALEO – 2006

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# Course Topics

- Discuss the penalties associated with improperly or illegally importing a laser product.
- Review laser product performance standards.
- Provide an overview of the U.S. performance standards and reporting requirements for domestic and imported laser products.
- Discuss the key procedures for importing a laser product into the U.S.
- Give an overview of U.S. export requirements and the basic documentation requirements for select countries

# PENALTIES

All imported products are required to meet the same standards as domestic goods.

- **National Safety Requirements**
  - Performance Standards
  - Documentation
- **Customs Requirements**
  - Restrictions on product type or manufacturer may exist.
  - Documentation

# What is the chance of a non-compliant laser product being identified by a customs agent?

## What are the penalties?

- **Improper customs documentation or shipping non-compliant laser products can create unexpected costs, delays, and liabilities.**
  - **Entry into a country can be refused or product can be detained while verifying compliance.**
  - **Non-compliant product may be returned, destroyed, or brought into compliance under an approved corrective action plan.**

**Effects on Manufacturer**

- **Delays in schedule or payment.**
- **Credibility with customer and customs.**
- **Costs associated with Recall, repair, or replacement of every unit under a corrective action plan.**
- **Fines**

**Effects on Purchaser**

- **Production delays**
- **Costs for supplying additional safety controls**
- **Loss of purchase price**
- **Liability**
- **Cannot offer for resale a non-compliant product.**

- **Many illegal laser products are not properly identified and pass through customs. Penalties are not incurred until after the purchaser has taken ownership.**

# Laser Product Performance Standards

## Laser Safety Standards Can Be Placed Into Two Categories

- Product
  - Applies to the manufacture of laser products
- User
  - Applies to the use of lasers and laser systems

# National Product Safety Performance Requirements

- Countries with national product safety requirements applicable to lasers normally adopt or refer to the following performance standards.

## U.S. Federal Laser Product Performance Standard (FLPPS)

And/ Or

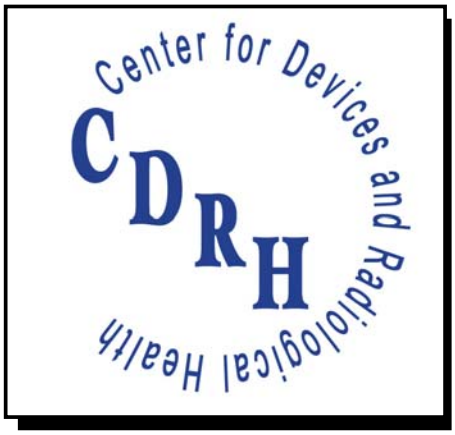
## International IEC 60825 Series of standards

- National requirements and deviations may have additional regulations or restrictions based on the intended use of the laser product. For example; toys, medical devices, alignment and entertainment devices, etc.
- Reporting, testing, and technical documentation requirements vary between countries.

# U.S. Federal Laser Product Performance Standard (FLPPS)

Code of Federal Regulations (CFR), Title 21, Subchapter J (Parts 1000 – 1050)

- General Requirements for all electronic products which Emit Radiation (1000 – 1005)
  - Reports, Records, Import and Export Requirements
- General Performance Standard (1010)
  - Certification to Standards, Identification, and Variances
- Specific Performance Standards for Electronic Products which Emit Radiation (1020 – 1050)
  - Laser Products 1040.10 and 1040.11



| Part | IEC 60825 Series | Type |
|---|---|---|
| **1** | **Equipment classification, requirements and user's guide** | IS |
| **2** | **Safety of optical fibre communication systems** | IS |
| 3 | Guidance for laser displays and shows | TR |
| **4** | **Laser guards** | IS |
| 5 | Manufacturer's checklist for IEC 60825-1 | TR |
| 6 | Safety of products with optical sources, exclusively used for visible information transmission to the human eye | TS |
| 7 | Safety of products emitting infrared optical radiation, exclusively used for wireless 'free air' data transmission and surveillance | TS |
| 8 | Guidelines for the safe use of medical laser equipment | TR |
| 9 | Compilation of maximum permissible exposure to incoherent optical radiation | TR |
| 10 | Application guidelines and explanatory notes to IEC 60825-1 | TR |
| **12** | **Safety of free space optical communication systems used for transmission of information** | IS |
| 13 | Measurements for classification of laser products | TR |
| 14 | A user's guide | TR |

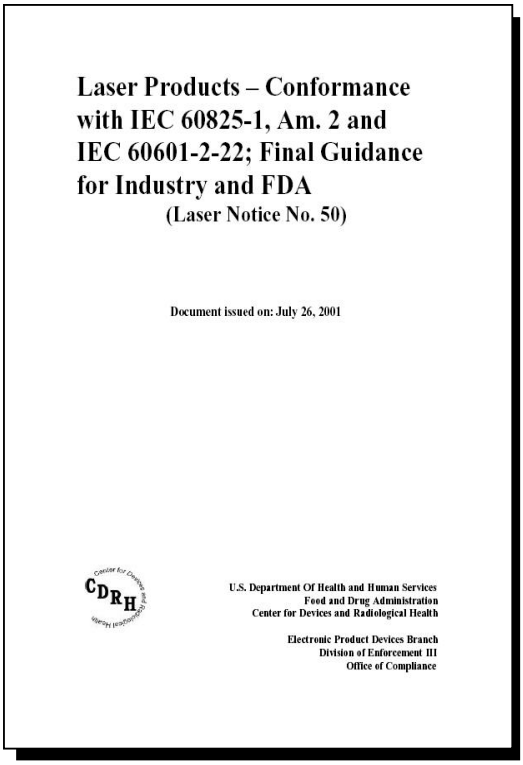
# Key Differences Between 21 CFR 1040 and IEC 60825-1

- Hazard Classification Schemes
- Measurement Criteria
- Emission Duration
- Apparent Source Size
- Repetitively Pulsed Outputs
- Human Access Definitions
- Tests Conditions
- Engineering Requirements
- Specific Use Requirement
- Label Requirements
- User Information
- Servicing and Purchasing information

# U.S. Performance and Reporting Requirements for Lasers

# Laser Notice #50 - Harmonization

- Laser notices are periodically issued to provide clarification and/ or relaxation on the interpretation and enforcement of the Federal Laser Product Performance Standard.
- Laser Notice #50 provides guidance on the conditions under which laser product manufacturers may introduce into United States that comply with the:
  - IEC standards 60825-1 and
  - IEC 60601-2-22.



**Laser Products – Conformance with IEC 60825-1, Am. 2 and IEC 60601-2-22; Final Guidance for Industry and FDA**

**(Laser Notice No. 50)**

**Document issued on: July 26, 2001**

**U.S. Department Of Health and Human Services**
**Food and Drug Administration**
**Center for Devices and Radiological Health**

**Electronic Product Devices Branch**
**Division of Enforcement III**
**Office of Compliance**

# Three Product Performance Schemes

1. **FLPPS/CDRH 21 CFR 1010 and 1040**
   - For countries that recognize U.S. FLPPS. This should be considered if the laser product is only sold in the U.S.

2. **IEC 60825 – 1**
   - For countries that only recognize IEC. For example Europe normally only accepts this format.

3. **FLPPS/CDRH + Laser Notice # 50** ***– Recommended Scheme***
   - Recommended for selling to an international market. With the exception of language translation requirements this method should meet requirements for all countries that have national standards. For example selling both into Europe and the U.S. this option should be used.

Note: Laser products used for Optical Fiber Communications Systems, Free Air-Space Communications Telecommunications, and Class 3B and Class 4 medical laser systems may have additional requirements.

## Who has authority in the U.S. over the manufacture of laser products?

CDRH is an organizational component of FDA

**Center for**
**Devices and**
**Radiological**
**Health**

- Authority granted under the Electronic Product Radiation Control Provisions Of The Federal Food, Drug, And Cosmetic Act.
- Requires compliance to 21 CFR Part 1000 – 1050, except for deviations pursuant to published Laser Notices, granted exemptions, and variances.
- All products with an applicable standard must comply with the U.S. FDA's standard before entering the U.S. or its territories.
- FDA does not recognize regulatory approvals from other countries or other organizations such as test houses.

# When am I allowed to sell my laser product in the United States?

1. Your product must comply with 1040.10 and 1040.11 except for deviations pursuant to laser notices, approved variances and exemptions;
2. You must establish a testing and quality control program sufficient to prove your product is completely compliant with its applicable standard (Title 21 CFR 1020 through 1050);
3. Your product must have certification and identification information permanently affixed or inscribed as required in the general performance standard (Title 21 CFR 1010).
4. You must have submitted any applicable Laser Product Report, Supplemental Report, or Component Registration.

# Summary of CDRH Required Reports and Documentation For Laser Products

Required Reports:

- Certified Laser Products - Require a Product Report (1002)
- OEM laser products sold only to or for integrators to be used as a component or replacement part for a complete laser product (1040.10) - Requires a laser product registration
- Annual Reports or quarterly updates.

- Records to be maintained:
  - Radiation Testing, Quality Control, and Complaints (Title 21 CFR § 1002.30)
  - Product Distribution (Title 21 CFR § 1002.40)

- Variance and Exemptions
  - Requests and approvals

- Reports of problems and hazards:
  - Accidental Radiation Occurrences and Radiation Incidents (Title 21 CFR § 1002.20)
  - Reporting a Radiation Safety Defect in an Electronic Product or a Failure to Comply with a Federal Performance Standard (Title 21 CFR § 1003)
  - Corrective Action Plans for Noncompliant or Defective Products (Repair, Repurchase, or Replace) (Title 21 CFR § 1004)

Additional Requirements

- Required by other regulations. For example pre-market approval is required for medical products.

# U.S. Importation Procedures

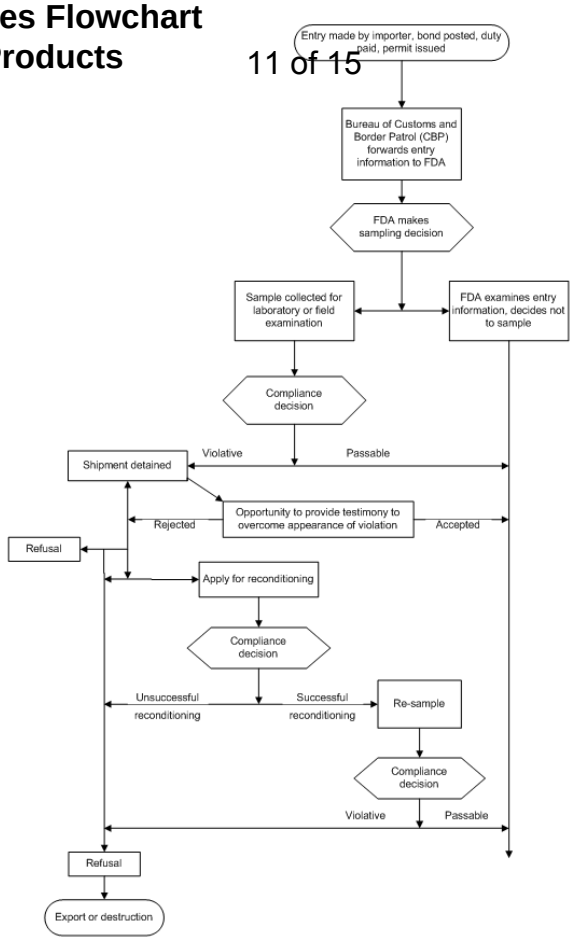
## Ref: CDRH Import/ Export Web References

**Electronic Products Radiation Control - Imports and Exports**

1. New Product Codes for Radiation-Emitting Electronic Products - Now Available
2. Electronic Products Subject to Import Review by FDA (Title 21 CFR 1005.1)
3. Designation of U.S. Agent ( Title 21 CFR 1005.25 )
4. Procedures for Importing Electronic Products which Emit Radiation
   - Form FDA-2877 *Declaration for Products Subject to Radiation Control Standards*
5. Detention and Product Sampling ( Title 21 CFR 1005.3 )
6. Bringing Products Into Compliance ( Title 21 CFR 1005.21 )
7. Bonds and Fees ( Title 21 CFR 1005.23 )
8. FDA Import Program Overview
9. Use of FDA-assigned Manufacturer Report's Accession Numbers
10. Importation of Radiation-Emitting Consumer Electronics for Investigation and Evaluation
11. Exports ( Title 21 CFR 1010.20 )

**http://www.fda.gov/cdrh/radhlth/eprc_imports_and_exports.html**

**Import Procedures Flowchart For Laser Products**

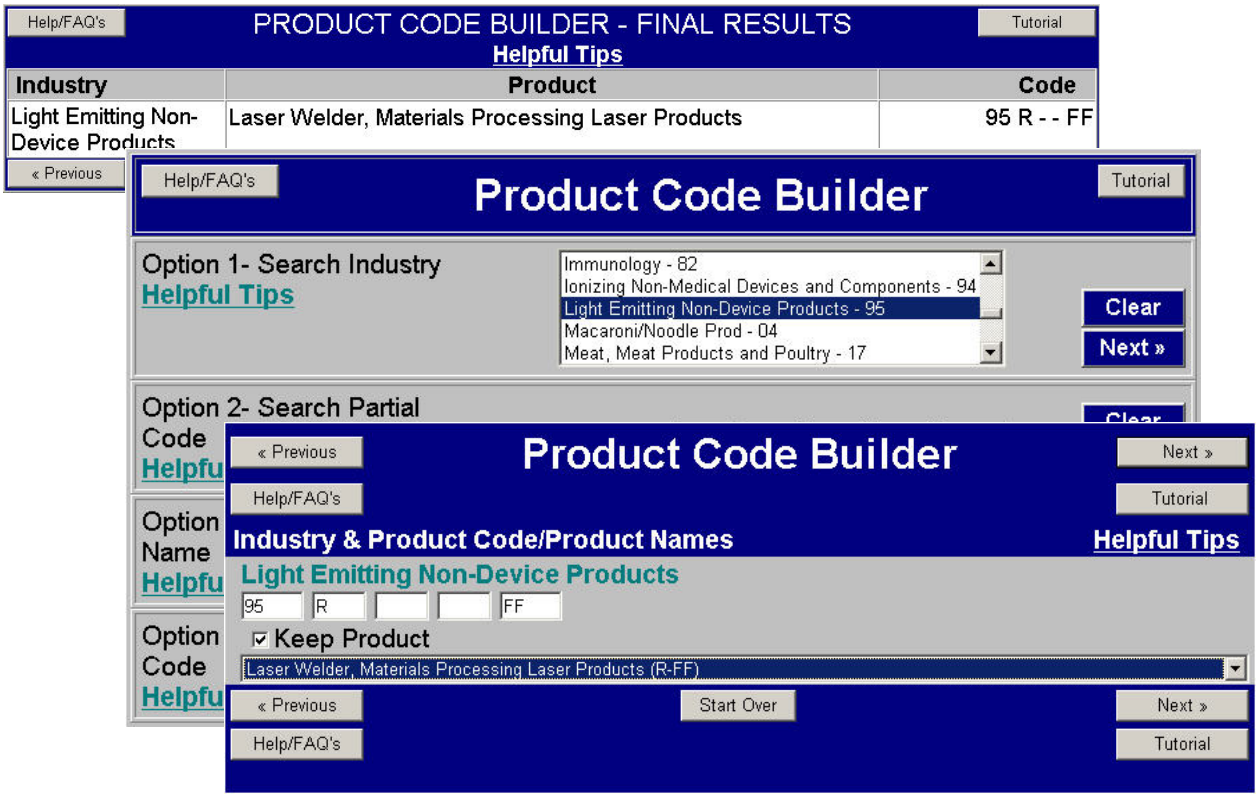



# Steps for Importing Laser Products in to the U.S.A.

1. **Comply with FDA/CDRH Federal Laser Product Performance Standard.**
   - If applicable submit a Laser Product Report or OEM component registration.
   - Medical products must comply with additional FDA device reporting requirements.
2. **Foreign manufacturers must designate a U.S. agent:**
   - Prior to importing a permanent resident of the United States must be designated as the manufacturer's importing Agent. This is normally identified to the FDA/CDRH in a laser product report.
3. **Prepare the following items to include with the standard shipping information and/or with the product:**
   - Form FDA 2877- "Declaration of Products Subject to Radiation Control Standards".
   - If applicable affix certification label to the laser product (21 CFR 1010.2) Product name as reported to the FDA/CDRH
   - FDA Product Code – Use Product Code Builder
   - Include documentation to assist in verifying the product is compliant. Items can include; copies of the Laser Product Report, OEM Registration, response letter from the FDA/CDRH, or CDRH Accession No. supplied by the FDA/CDRH.
4. **Use a domestic customs broker (or filer) to submit paper work to the U.S. Bureau of Customs and Border Protection:**
   - They can supply standard importation and shipping forms.
   - If possible have them submit documents electronically.
   - For time critical shipments ask about pre-approvals.

# Product Code Builder






## DECLARATION FOR IMPORTED ELECTRONIC PRODUCTS SUBJECT TO RADIATION CONTROL STANDARDS

**DECLARATION: I / WE DECLARE THAT THE PRODUCTS IDENTIFIED ABOVE:** *(Mark X applicable statements, fill in blanks, & sign)*

☐ **A. ARE NOT SUBJECT TO RADIATION PERFORMANCE STANDARDS BECAUSE THEY:**

- ☐ 1. Were manufactured prior to the effective date of any applicable standard; Date of Manufacture _____ .
- ☐ 2. Are excluded by the applicability clause or definition in the standard or by FDA written guidance.
  Specify reason for exclusion _____.
- ☐ 3. Are personal household goods of an individual entering the U.S. or being returned to a U.S. resident. (Limit: 3 of each product type).
- ☐ 4. Are property of a party residing outside the U.S. and will be returned to the owner after repair or servicing.
- ☐ 5. Are components or subassemblies to be used in manufacturing or as replacement parts (NOT APPLICABLE to diagnostic x-ray parts).
- ☐ 6. Are prototypes intended for on going product development by the importing firm, are labeled "FOR TEST/EVALUATION ONLY," and will be exported, destroyed, or held for future testing (i.e., not distributed). (Quantities Limited - see reverse.)
- ☐ 7. Are being reprocessed in accordance with P.L. 104-134 or other FDA guidance, are labeled "FOR EXPORT ONLY," and will not be sold, distributed, or transferred without FDA approval.

☐ **B. COMPLY WITH THE PERFORMANCE STANDARDS** WHICH ARE APPLICABLE AT DATE OF MANUFACTURE AND THAT A CERTIFICATION LABEL OR TAG TO THIS EFFECT IS AFFIXED TO EACH PRODUCT. COMPLIANCE DOCUMENTED IN:

- ☐ 1. Last annual report or Product/Initial report
  _____ ACCESSION NUMBER of Report
  _____ Name of MANUFACTURER OF RECORD *(Filed report with FDA/CDRH)*
- ☐ 2. Unknown manufacturer or report number; State reason: _____

☐ **C. DO NOT COMPLY WITH PERFORMANCE STANDARDS;** ARE BEING HELD UNDER A TEMPORARY IMPORT BOND; WILL NOT BE INTRODUCED INTO COMMERCE; WILL BE USED UNDER A RADIATION PROTECTION PLAN; AND WILL BE DESTROYED OR EXPORTED UNDER U.S. CUSTOMS SUPERVISION WHEN THE FOLLOWING MISSION IS COMPLETE:

- ☐ 1. Research, Investigations/Studies, or Training (attach Form FDA 766)
- ☐ 2. Trade Show/Demonstration; List dates & use restrictions _____

☐ **D. DO NOT COMPLY WITH PERFORMANCE STANDARDS;** ARE HELD AND WILL REMAIN UNDER BOND; AND WILL NOT BE INTRODUCED INTO COMMERCE UNTIL NOTIFICATION IS RECEIVED FROM FDA THAT PRODUCTS HAVE BEEN BROUGHT INTO COMPLIANCE IN ACCORDANCE WITH AN FDA APPROVED PETITION. *(See Form FDA 766.)*

☐ 1. Approved Petition is attached. ☐ 2. Petition Request is attached. ☐ 3. Request will be submitted within 60 days.

# U.S. Export Requirements

## 1010.20 Electronic products intended for export

The U.S. Federal Laser Product Performance Standard (FLPPS) shall not apply to any electronic product which is intended solely for export if:

(a) Such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export, and

(b) Such product meets all the applicable requirements of the country to which such product is intended for export.

# Importing into other countries

## European Laser Product Requirements

- Unlike the U.S.A. it is not necessary in Europe for laser products to be registered or reported, but it is a legal requirement that such products meet the Essential Safety Requirements of the applicable European Directives.

- All laser products, should conform to the requirements of relevant safety standards. In Europe, this standard is EN 60825-1 (*Safety of laser products – Part 1: Equipment classification & requirements*), which is identical to the international standard IEC 60825-1.

- This standard is used to demonstrate conformance with various EU Directives, including the Low Voltage Directive and the Machinery Directive.

- Note: In addition, further safety requirements apply to certain types of laser equipment, including medical lasers, materials-processing lasers and optical communication systems.

# Selling a Laser Product into Europe



1. Affix a CE mark to the product.
2. Ship product with a:
   - Declaration of conformity or
   - Declaration of incorporation,
3. Create a technical file with information that documents compliance of the laser product with the applicable standards.

# Questions?

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