DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
WO 66/4649
10903 New Hampshire Avenue
Silver Spring, MD 20993

SEP 0 6 2012

VIA UNITED PARCEL SERVICE

Ref: Letter: 12000275

Mr. Dan Marsick, CIH, CSP
US Department of Energy
Office of Worker Safety and Health Policy
DOE-HQ-HS-11
19901 Germantown Road
Germantown, MD 20784

Dear Mr. Marsick:

This letter is in response to your March 28, 2012 letter on behalf of the Department of Energy (DOE) Laser Safety Subgroup (LSSG) of the Energy Facility Contractors Group (EFCOG). In your letter you requested a clarification of the circumstances under which a DOE Government-Owned Contractor Operated (GOCO) facility may be considered a laser manufacturer and subject to FDA laser manufacturer requirements and other points of interpretation of the FDA Exemption Letter, 78EL-01DOE (DOE exemption or exemption) by the LSSG for GOCG facilities:

1. GOCO facilities understand that Laser Notice 25 refers to noncompliant laser products procured by them or DOE from commercial laser manufactures under conditions specified by the DOE exemption.

2. GOCO facilities interpret Laser Notice 14 to mean that their facilities are not manufacturers of laser products for the purpose of entering them into US commerce, and do not consider themselves to be laser manufacturers when building lasers only for use at one of its facilities.

3. GOCO facilities may build or modify a laser that is then loaned, donated, or transferred to another facility. In these instances, the facilities will communicate directly with FDA for the purpose of making those laser products compliant with FDA regulations.

Laser Notice 25 and the DOE Exemption

Laser Notice 25 and the DOE exemption letter both refer to the procurement of non-compliant laser products by DOE from commercial laser manufacturers. However, be advised that Laser Notice 25 is a memorandum addressed to laser manufacturers and notifying them of the DOE and the National Oceanic and Atmospheric Administration, US Department of Commerce exemptions with regulatory information. While the DOE exemption letter and Laser Notice 25 share some of the same language, please refer to the exemption letter for specific exemption conditions and requirements, as it is the official FDA policy regarding the DOE exemption.

The DOE exemption states that laser products used by DOE under specified conditions are exempt from the laser performance standard found in 21 CFR 1040.10 and 21 CFR 1040.11 and reporting requirements found in 21 CFR 1002, except for 21 CFR 1002.20. The specified use conditions for this exemption include: 1) laser products ***used*** exclusively by DOE personnel at their respective facilities in unique research applications or as components in larger research and development systems and 2) laser products must not be of a model usually manufactured as certified laser products. Additionally, exemption Condition 2 requires DOE to establish monitoring procedures to assure that laser products are ***procured or used*** by DOE or its contractors pursuant to the conditional use limitations. The words, "used" and "procured or used" means that non-compliant laser products may be procured or manufactured by DOE, provided they are not available commercially as laser products which are compliant with FDA regulations.

Applicability of Laser Notice 14

According to Laser Notice 14, constructing a laser product at the place where it will be used on a one-time basis by the employees who built the laser product is not considered manufacturing. However, if the laser product is made on a continuing basis and used by employees other than those directly involved in the construction of the laser product, then company is considered to be engaged in the business of manufacturing or assembling laser products. In your letter, you stated that DOE has similar circumstances to those in Laser Notice 14 where a laser product may be built only for use at a DOE facility. If DOE and GOCO-facility (DOE) employees or contractors operate a DOE-manufactured and exempted laser product which they did not themselves manufacture, then DOE is considered to be a manufacturer and subject to the Federal Food, Drug, and Cosmetic Act (Act) for the protection of those personnel. Additionally, in granting the DOE exemption, FDA considered submitted examples of DOE safety and health policies and standards as evidence of a substantial laser safety and health program and required DOE to provide and enforce, to the extent practical for exempted laser products, the provisions of American National Standards Institute (ANSI) Standard Z136.1: Safe Use of Lasers and the FDA laser performance standard.

As per exemption Condition 1 and in keeping with Laser Notice 14 for exempted, DOE-manufactured laser products, FDA requires DOE to provide all personnel the radiation safety protections of the Act and ANSI Z1361.1 to the extent practical and provide the protections of the DOE laser safety and health standards and policies. However, DOE is not required to certify compliance with the laser performance standard and submit product reports for exempted DOE-manufactured laser products as per Laser Notice 14 because it is exempted from full compliance with 21 CFR 1040.10 and 1040.11 and the reporting requirements in 21 CFR 1002, except for 21 CFR 1002.20 *Reporting of accidental radiation occurrences.*

Disposal of Exempted Laser Products

CDRH concurs with the LSSG understanding that GOCO facilities may build or modify a laser that is then loaned, donated, or transferred to another facility, but only under the following conditions:

1. Pursuant to exemption Condition 4, disposal of exempted laser products through excess of surplus property channels, including to non-DOE purchasers requires authorization by FDA. Be advised that "purchaser" is defined in 21 CFR 1000(t), as the first person who, for ***value***, or as an award or prize, acquires an electronic (laser) product for purposes other than resale, and includes a person who leases an electronic product for purposes other than subleasing, even for no cost. Acquiring a laser product for value includes loaning, donating, or transferring. It is not required that money be exchanged for laser product to be purchased, according to FDA regulations. Laser products may only be purchased by non-DOE purchasers upon being made compliant with FDA regulations, which may include the granting of an exemption or variance.

2. There must be strict compliance with exemption's requirement that exempted laser products be used exclusively by DOE personnel at their respective facilities in unique research applications or as components in larger research and development systems. Transfer or loan of an exempted laser product between DOE facilities does not require that the exempted laser product be made compliant with FDA regulations, provided the loan or transfer is in keeping with the requirements of the exemption.

If you have any questions, please contact me at (301) 796 6927, or internet electronic mail at Patrick.Hintz@fda.hhs.gov.

Sincerely yours,

CAPT Patrick J. Hintz, USPHS
Electronic Products Branch
Office of Communication, Education,
and Radiation Programs
Center for Devices and
Radiological Health

Cc: Mr. Steve Singal
Office of Worker Safety
and Health Assistance
DOE-HQ-HS-12
19901 Germantown Road
Germantown, MD 20784

Cc: Barb O'Kane
EFCOG LSSG Chair
National Renewable Energy Laboratory
15013 Denver West Parkway
Golden, CO 80401

Cc: Michael Woods
EFCOG LSSG Vice Chair
SLAC Laser Safety Officer
SLAC National Accelerator Laboratory
M/S 84
2575 Sand Hill Rd.
Menlo Park, CA 94025