

JUN 23 1976

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TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Response to Question Concerning Component Lasers and Laser Systems for Repair of Laser Products, 21 CFR 1040.10(a)

BACKGROUND AND QUESTION: A manufacturer notes that there are many laser products in use that were manufactured before the effective date of the standard. These products will need to be repaired in order to be kept in operable condition. Occasionally the laser or laser system will need to be replaced. The manufacturer asks how the standard will affect the repair of these products.

RESPONSE:

The repair of certified or uncertified laser products to their original condition, whether performed in a factory or at the site of use, is not considered to be manufacturing or assembly under the Radiation Control for Health and Safety Act of 1968. Therefore, persons who engage in this activity will not be required to certify such products. However, certified laser products, when repaired according to the instructions provided by the manufacturer pursuant to 21 CFR 1040.10(h), must continue to meet the applicable provisions of 21 CFR 1040.10 and 1040.11 as when manufactured.

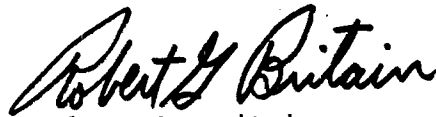
A laser or laser system for use as a replacement component in an (uncertified) electronic product manufactured before the effective date of the standard, would not be subject to the standard, if it were sold either to, for, or by the manufacturer of the electronic product. The replacement laser or laser system, in this case, would not be subject to the standard even if manufactured after the effective date of the standard. Also, removable laser systems replaced in laser products manufactured before the effective date would not be subject to the standard, if sold to, for, or by the manufacturer of the old product since 21 CFR 1040.10(c)(2) applies only to those removable laser systems used as components of products subject to the standard.

All lasers and laser systems manufactured after the effective date of the standard for use as components of an electronic product would be subject to the standard if not sold by, to, or for the manufacturer of such electronic product because they would be laser products under 21 CFR 1040.10(b)(17) which are not excluded by 21 CFR 1040.10(a) (Ref: 40 FR 32253).

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Although the above is generally true, laser products manufactured before August 2, 1976, may become subject to the standard upon repair or refurbishment after the effective date of the standard, if the repaired product is incorporated as a removable laser system component into a laser product subject to the standard (21 CFR 1040.10(c)(2)).

The modification of a previously certified laser product by any person engaged in the business of manufacturing, assembling or modifying laser products shall be construed as manufacturing under the Act if the modification affects any aspect of the product's performance or intended function(s) for which 21 CFR 1040.10 and 1040.11 have an applicable requirement. The manufacturer who performs such modification shall recertify and reindentify the product in accordance with the provisions of 21 CFR 1010.2 and 1010.3 (21 CFR 1040.10(i)).



Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health