DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

AUG - 9 1988

TO: ALL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Exemption from Certain Reporting and Recordkeeping Requirements for Certain Low Power Laser Products.

BACKGROUND

Every manufacturer of laser products to be introduced into commerce in the United States is required to submit initial and model change reports pursuant to 21 CFR 1002.10 and 1002.12. However, the Center for Devices and Radiological Health (Center) has exempted manufacturers of certain low power laser products from some reporting requirements provided the exempted models meet the criteria stated in its August 23, 1985, notice to laser product manufacturers. The Center has been requested to expand its approval to include exemption from certain recordkeeping requirements.

EXEMPTION

As a step toward further reduction of the regulatory burden on manufacturers of certain laser products meeting the criteria given below, and to reduce the cost associated with administering the regulation, the Center, under authority of 21 CFR 1002.50 hereby grants exemption from the recordkeeping requirements of 21 CFR 1002.30(b), 1002.40 and 1002.41 in addition to the exemption previously granted from the reporting requirements of 21 CFR 1002.12 and from supplemental reports pursuant to 21 CFR 1002.10 and 1002.12 for those products meeting the criteria described below.

CONDITIONS FOR USE OF THE EXEMPTION

The Center will not require the submission of reports for laser products under 21 CFR 1002.12 or supplements to reports pursuant to 21 CFR 1002.10 or 1002.12 or the keeping of record required by 21 CFR 1002.3(b), 1002.40 and 1002.41 when the following conditions are met:

1. The maximum accessible laser radiation emitted by the product under any condition of operation, maintenance, service or failure does not exceed the Class I accessible emission limits given in 21 CFR 1040.10(d) when determined in accordance with 21 CFR 1040.10(e).

2. Such laser products are tested and certified by the manufacturer to comply with the Federal performance standard, 21 CFR 1040.10 and 1040.11.

3. All other applicable requirements are met including the annual reporting requirements of 21 CFR 1002.11.

It should be noted that exemption is not granted from the requirements of 21 CFR 1002.10 (Initial Reports), 21 CFR 1002.11 (Annual Reports), 21 CFR 1002.30(a) and 1002.31 (Manufacturer's Records), 21 CFR 1003 (Notification of Defects or Failure to Comply) and 21 CFR 1004 (Repurchase, Repair or Replacement of Electronic Products).

The Center reserves the right to request information concerning these products or full reports and recordkeeping if it determines this to be necessary in keeping with the intent of the Radiation Control for Health and Safety Act of 1968.

Comments on this notice are invited.

Sincerely yours,

Kshitij Mohan

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