



AUG. 23, 1985

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Exemption From Reporting Under 21 CFR 1002.10 and 21 CFR 1002.12 For Certain Low Power Laser Products

The majority of laser systems produce collimated beams whose irradiance varies little with distance from the source, so that retinal and skin hazards may be present near to and at considerable distance from the lasers. Reports on such products allow Center staff to evaluate compliance at the time the product is first introduced into commerce, and thus to respond to potential problems in a timely fashion.

Large numbers of laser products employing low power lasers with sharply converging/diverging beams are also introduced into U.S. commerce. Certain products, such as compact disc players, non-impact printers, and fiber optic transmission equipment, generally employ laser diodes which may themselves be Class I laser products when measured according to 21 CFR 1040.10(e). These lasers emit beams which either rapidly diverge or are of such low power that the Class I limits cannot be exceeded, limiting the potential for injury. However, these products are subject to the Radiation Control for Health and Safety Act of 1968 and to the regulations promulgated under the authority of the Act (21 CFR 1002-1010, 1040.10 and 1040.11).

As a step toward the reduction of the regulatory burden on the manufacturers of such products and the reduction of unnecessary use of Center staff time, the Center, under the authority of 21 CFR 1002.50, hereby grants exemption from the reporting requirements of 21 CFR 1002.12 (Model Change Reports) and from supplemental reports pursuant to 21 CFR 1002.10 (Initial Reports) and 1002.12 for those products which meet the conditions described below.


Conditions for use of the Exemption: The Center will not require submission of reports for laser products under 21 CFR 1002.12 or supplements to reports pursuant to 21 CFR 1002.10 and 1002.12 when the following conditions are met:

1. The maximum accessible laser radiation under any condition of operation, maintenance, or service does not exceed the Class I accessible emission limits (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 complied with including the annual reporting requirements (21 CFR 1002.11).

It should be noted that this exemption is not applicable to the requirements of 21 CFR 1002.10 (Initial Reports), 21 CFR 1002.11 (Annual Reports), 21 CFR 1002.20 (Reporting of Accidental Radiation Occurrences), 21 CFR 1002.30 and 1002.31 (Manufacturing Records), 21 CFR 1003 (Notification of Defects or Failure to Comply) and 21 CFR 1004 (Repurchase, Repair or Replacement of Electronics Products).

The Agency reserves the right to request information concerning these products or full reports 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.

  
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and Radiological Health

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