



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

MAY 5 1977

REF:DOC:4036:MA

To: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Response To Question Concerning An Aiming Beam For The Therapeutic Beam Of A Medical Laser Product, 21 CFR 1040.11(a) (1)

BACKGROUND AND QUESTION: A company manufactures a medical laser product that uses pulses of laser energy at Class IV levels for treatment. The product also uses a low level (Class II) laser beam for aiming the treatment beam. A meter on the product indicates what the level of laser radiation in the treatment mode is or will be within ± 20 percent. Does the manufacturer also have to provide a means of measuring the level of laser radiation in the aiming beam within ± 20 percent.

RESPONSE: The intent of the measurement requirement of 21 CFR 1040.11(a) (1) is to ensure accurate knowledge of the Class III or Class IV levels of laser radiation intended for in vivo diagnostic, surgical or therapeutic laser irradiation of patients. Without such knowledge, day-to-day reproducibility in patient irradiations would not be possible. However, if the laser radiation is at Class I or Class II levels, the means for this type measurement is not required by the standard. The product must, of course, comply with the applicable requirements of Section 1040.10.

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