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

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TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Applicability of the Performance Standard to Products Manufactured by a Company For Use in its Manufacturing Process

BACKGROUND AND QUESTION: A company manufactures a variety of products that are not necessarily laser products but which require that rigid product specifications be met. The company has developed a laser product for exclusive use in their own plants to monitor product quality during manufacturing, inspection or service. The company desires to know if their laser product is subject to the Federal Performance Standard for Laser Products and other regulations.

RESPONSE: The central question revolves around whether the company is "engaged in the business" of manufacturing or assembling these laser products within the meaning of Section 355(3) of the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (the Act), and is therefore a "manufacturer" required by Sections 358(h) and 360B(a)(5) of the Act to certify compliance of these laser products with the standard.

The Bureau of Radiological Health has been advised previously by General Counsel that an electronic product, including laser products, constructed on a one-time basis by a particular company for use by that company in its manufacturing process at the place where constructed is not considered "manufacturing". If, however, the products are made on a continuing basis in the course of a commercial enterprise and used by employees other than those directly involved in the manufacture of the electronic product, the company is considered to be "engaged in the business" of manufacturing products subject to the Act.

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Policy Statement #14