ADVISORY OPINION

SUBJECT: RELATIONSHIP OF INTEGRATED RADIANCE TO SCANNED LASER RADIATION, RESPONSE TO 21 CFR 1040.10(d) and (e)

BACKGROUND: A manufacturer of a laser universal product code reader for supermarkets desires the accessible scanned laser radiation from the product to be within the limits of Class I. The manufacturer acknowledges that the product could exceed the Class I accessible emission limits for radiant energy given in Table I-A of Section 1040.10(d) of the standard. Therefore, pursuant to the dual Class I limits of Section 1040(d)(4), he has tried to design the product to be below the integrated radiance limits of Table I-A. In order to reduce the integrated radiance below the Class I limits, the manufacturer would like to incorporate an optical device which varies the apparent origin from which the scanned pattern is emitted. Thus, if the integrated radiance of the product is measured with an instrument in which the detector's aperture and acceptance angle are fixed in position and orientation relative to the product there would be an apparent reduction in the integrated radiance. The manufacturer asks whether this approach of reducing the integrated radiance is appropriate to use when designing a laser product to conform to the provisions of Class I and to the other provisions of the standard (21 CFR 1040.10 and 1040.11).

ADVISORY OPINION: Based upon the following rationale the above approach for reducing the integrated radiance, including the measurement protocol, would not be appropriate to use to ascertain compliance with the performance standard. The standard is specific in requiring that any device used for determination of integrated radiance must be positioned and oriented as to maximize the detectable radiation.

The intent of the integrated radiance alternative of the standard as stated in Comment 14 of the preamble to the standard, is to accommodate extended sources (real or virtual) such as holographic images, diffuse reflections, transmissions through diffusers, or diffuse collateral radiation (Federal Register 40, 32254 (July 31, 1975)). If the concept of integrated radiance is considered for the output from a stationary laser, either the source area or the intrinsic divergence (or both) is small, yielding a radiance level in excess of the radiance portion of the dual limits for Class I of Section 1040.10(d)(4). If sources of radiation are stationary, classification of both the extended source and the stationary laser source would be based upon measurements, pursuant to Section 1040.10(e)(2)(iv), in which the detector generally would remain fixed both in position and orientation so as to result in the maximum detection of radiation required by that section.

The performance standard for laser products provides that the measurement of accessible emission levels of scanned laser radiation shall be determined from the measurement of radiation detectable within a stationary circular aperture stop having a 7-millimeter diameter. The resulting temporal

variation of detected radiation shall be considered as a pulse or series of pulses (Section 1040.10(e)(4)). Thus, radiant energy, radiant exposure and integrated radiance may be used as measures of the level of scanned laser radiation for the purpose of classification. The measurement of integrated radiance would also involve, under Section 1040.10(e)(3)(iii), a solid angle of acceptance of 0.00001 steradian. However, pursuant to Section 1040.10(e)(2)(iv) the acceptance angle of the instrument for measuring integrated radiance would have to be instantaneously so positioned and so oriented with respect to the laser product as to result in the maximum detection of radiation by the instrument. Conceptually the orientation of the instrument would have to track the source, but its aperture stop would remain stationary. As noted in Section 1040.10(e)(3), techniques, including computations, that provide results equivalent to the above are permitted.

DATED: 1/26/76

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