MELLES GRIOT
LASER DIVISION

4 June, 1993

Dockets Management Branch (HFA-305)
Food and Drug Administration, Rm. 1-23
12420 Parkland Drive
Rockville, MD 20857

Subject: Intent to Amend Laser Performance Standard, Docket 93N-0044

Dear Sir/Madam

93 JUN 10 PM 3:40
DOCKETS MANAGEMENT BRANCH

The suggested amendments will aid in achieving the goal of attaining a common set of laser safety requirements that apply world wide. These changes will also allow us to operate with greater flexibility in the European market. Your commitment to integrate the standards and the dedication of those involved in this effort are greatly appreciated.

There are a few items that require clarification. The following comments are provided to match the item numbers in the Notice of Intent:

2. Clarification of the last sentence of the first paragraph as follows: "However, the products for which long-term viewing or exposure is" . . . . . [to differentiate between products in which viewing or exposure would only occur for short periods].

   It is assumed that products that emit in the near-IR range that are classified on the basis of 100s would continue to be so classified, even if they are general purpose products.

   Surveying lasers should not be included in the category with laboratory laser systems for a 10,000s classification since they are not intended to be viewed for long durations. It would also help to clarify the proposal by adding "general construction" to the applications listed for use with the 100 s classification time.

4. This change should be included only if the change to reduce the time period for classification in item 2 is also made. If this change was made without reducing the time period for classification, the result would be lowering the allowable power for some products and an inconsistency with the IEC 825 standard.

   Suggest to revise the first sentence: " . . . .AEL of class I for products with scanning or repetitively pulsed outputs. " [to clarify that this would apply also to scanning products].

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8. It would be helpful to clarify that condition 1) refer only to Class IIIa radiation that is emitted out, not just any radiation level. Please note that this condition goes beyond the interlock requirements in Amendment 2 to IEC-825.

10. This would appear to require the indicator to be on only when an aperture is actually emitting energy. We are concern that an indicator that is lit only when there is energy being emitted out of an aperture would be difficult to implement and may not provide additional safety for the user.

12. The acceptance of the IEC labels will ease our burden as a manufacturer. We hope this can be addressed in your next amendments to the IEC standard.

13. This is a great suggestion. In order to provide consistency, it should also be apply to the labels in 1040.10 g(7).

14. Excellent suggestion. We hope this will be incorporated into the CDRH laser performance standard.

In conclusion, we would like to reiterate our support for these changes. We encourage an expeditious review and approval process. This will minimize the conflicting set of requirements we are faced with.

Please don't hesitate to contact me if additional information is required.

Sincerely,

MELLES GRIOT LASER DIVISION
Cheem S. Ang, Quality Assurance Engineer

Enclosed

cc: Orest Baransky

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