PICKER

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July 16, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Reference: Docket No. 93N-0044
Laser Products: Proposed Amendments to Performance Standard

Gentlemen:

Picker International, Inc. ("Picker") provides innovative products and services to the medical imaging and healthcare information systems marketplace worldwide. Picker welcomes and acknowledges the Food and Drug Administration's (FDA) request to comment on the "Laser Products: Proposed Amendment to Performance Standard, Docket No. 93N-0044."

Picker commends the FDA for recognizing the need to harmonize the current Laser Products Performance Standards with the International Electrotechnical Commission's (IEC) standard for laser products and medical laser products. In addition, the FDA has clarified the parts of the Performance Standard that needed revision.

Picker's comments address the Proposed Amendment area of interest, which is then followed by the suggested revision (new text underlined for ease of understanding and the deleted text is strikethrough). A rational for the revision is also provided.

Proposed Amendment

§ 1040.10(h)(2) Purchasing and servicing information. Manufacturers of laser products shall provide or cause to be provided:

§ 1040.10(h)(2)(ii) To servicing dealers and distributors and to others upon request, at a cost not to exceed the cost of preparation and distribution, adequate instructions for servicing and adjustments and service procedures for each laser model, including clear warnings and precautions to be taken to avoid possible exposure to laser and collateral radiation in excess of the accessible limits in Table 1, 2, 3, 4, and 7 of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and, if applicable §1040.11.

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Suggested Revision

§1040.10(h)(2)(ii) To assemblers ~~servicing dealers and distributors~~ and to others upon request, at a cost not to exceed the cost of preparation and distribution, instructions ~~adequate instructions for servicing and adjustments and service procedures~~ for assembly, installation, adjustment, and testing of ~~for~~ each laser product model adequate to assure that the product will comply with applicable provisions of §1040, ~~including clear warnings and precautions to be taken to avoid possible exposure to laser and collateral radiation in excess of the limits in Tables 1, 2, 3, 4, and 7 of paragraph (d) of this section,~~ and a schedule of maintenance to keep the product in compliance with this section and, if applicable §1040.11.

Rational:

Harmonization of IEC 825-1 and IEC 601-2-22 with 21 CFR 1040 is one of the stated reasons for the FDA actions with the Laser Performance Standard. Consistency within the FDA regulation development is paramount if the "Re-engineering Efforts" are to be maximized. Therefore, harmonization of FDA Performance Standards, specifically with 21 CFR Subchapter J - Radiological Health, §1020.30(g) and §1040.10(h)(2)(ii) is necessary for consistency of the FDA Performance Standards. In addition, specifying that "the product will comply with §1040" eliminates the reference to Tables, etc.

Picker thanks the FDA for the opportunity to comment on the Proposed Amendments to the Laser Performance Standard.

Should you have any questions concerning the above, then please contact me at the above letterhead address or telephone 440 473 3528.

Sincerely yours,

Robert L. Turocy
Regulatory Affairs and Compliance Manager

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