than current policy. This guidance document is appropriate because of the amendment of IEC 60825–1 and the intent of CDRH to harmonize its requirements with many of those of the IEC standards.

II. Significance of Guidance

This guidance document represents the agency's current thinking on appropriate interim relief for manufacturers from differences between the amendments of the IEC and CDRH radiation safety standards for laser products. It does not create or confer any rights for or on any person and does not operate to bind the FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations.

The agency has adopted good guidance practices (GGPs) regulation, and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document is issued as a level 1 guidance consistent with the GGPs.

III. Electronic Access

In order to receive ''Laser Products—Conformance with IEC 60825–1, Am. 2 and IEC 60601–2–22; (Laser Notice 50)'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1346) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. Guidance documents are also available on the Dockets Management Branch Web site at http://www.fda.gov/ohrms/dockets/default.htm. Laser Notice 45 may be accessed at www.fda.gov/cdrh/radhlth/index.html under the index heading for ''Lasers, Including Light Shows'' as a ''Notices to Industry.'' Scroll to number 92 in the list of notices.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this guidance by October 24, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 13, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: CMS–R–200]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Health Plan Employer Data and Information Set (HEDIS) and Health Outcome Survey (HOS) and Supporting Regulations in 42 CFR 422.152; *Form No.:* CMS–R–200 (OMB# 0938–0701); *Use:* The Centers for Medicare & Medicaid Services (formerly HCFA) collects quality performance measures in order to hold the Medicare managed care industry accountable for the care being delivered, to enable quality improvement, and to provide quality information to Medicare beneficiaries in order to promote an informed choice. It is critical to CMS's mission that we collect and disseminate information that will help beneficiaries chose among health plans, contribute to improved quality of care through identification of improvement opportunities, and assist CMS in carrying out its oversight and purchasing responsibilities; *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Individuals or households; *Number of Respondents:* 313,825; *Total Annual Responses:* 313,825; *Total Annual Hours:* 571,488.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Melissa Musotto, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 13, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–18662 Filed 7–25–01; 8:45 am]

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