on harm arising from an implanted medical device.

V. Comments

Interested persons may submit to Dockets Management Branch (address above) written comments regarding this draft guidance by July 2, 2001. Submit two copies of any comments, 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. Written comments concerning the information collection requirements must be received by Dockets Management Branch by June 1, 2001. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 26, 2001.

Linda S. Kahan,

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

[FR Doc. 01–7956 Filed 3–30–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4130]

Medical Devices; Information Disclosure by Manufacturers to Assemblers for Diagnostic X–Ray Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; availability of guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance entitled ''Information Disclosure by Manufacturers to Assemblers for Diagnostic X–Ray Systems; Final Guidance for Industry and FDA.'' This guidance document is intended to provide guidance to the industry about meeting requirements for disclosure to assemblers, and to others upon request, of certain types of information at a cost not to exceed the cost of publication and distribution to ensure that x-ray systems will meet Federal performance standards.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Information Disclosure by Manufacturers to Assemblers for Diagnostic X–Ray Systems; Final Guidance for Industry and FDA'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Thomas M. Jakub, Center for Devices and Radiological Health (HFZ–322), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4591.

SUPPLEMENTARY INFORMATION:

I. Background

This final Level 1 guidance document entitled ''Information Disclosure by Manufacturers to Assemblers for Diagnostic X–Ray Systems; Final Guidance for Industry and FDA'' is intended to provide guidance to diagnostic x-ray system manufacturers, users, assemblers, and others concerning the requirement to disclose information about the assembly, installation, adjustment, and testing (AIAT) of x-ray components for diagnostic x-ray systems. (See § 1020.30(g) (21 CFR 1020.30(g))). With the advancement of technology and the use of computers with corresponding software, manufacturers need clarification about what information must be disclosed to satisfy the requirements of AIAT disclosure. This final Level 1 guidance document supersedes the corresponding draft guidance entitled ''Draft Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X–Ray Systems,'' which was announced in the **Federal Register** on October 8, 1999 (64 FR 54901). The comment period closed on January 6, 2000. The agency received several comments and recommendations concerning the draft guidance. A number of comments received by the agency addressed issues that do not fall within the scope of the guidance and § 1020.30(g). The final guidance contains only minor changes from the draft guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents the agency's current thinking on information disclosure by manufacturers to assemblers for diagnostic x-ray systems, as required by § 1020.30(g). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

III. Electronic Access

In order to receive ''Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X–Ray Systems; Final Guidance for Industry and FDA'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number (2619) followed by the pound sign (#). Then 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 access to the Internet. Updated on a regular basis, the CDRH home page includes ''Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X–Ray Systems; Final Guidance for Industry and FDA,'' 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 on Information Disclosure by Manufacturers to Assemblers for Diagnostic X–Ray Systems; Final Guidance for Industry and FDA'' is also available at http://www.fda.gov/cdrh/comp/2619.html. Guidance documents are also available on the Dockets Management Branch website at http://www.fda.gov/ohrms/dockets/default.htm.

IV. Comments

Interested persons may, at any time, submit written comments regarding the guidance to the Dockets Management

Branch (address above). 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 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: March 26, 2001.

Linda S. Kahan,

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

[FR Doc. 01–8058 Filed 3–28–01; 3:43 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-day Proposed Collection; Indian Health Service Contract Health Service Report

AGENCY: Indian Health Service, HHS.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, to provide a 60-day advance opportunity for public comment on proposed data collection projects, the Indian Health Service (IHS) is publishing for comment a summary of a proposed information collection project to be submitted to the Office of Management and Budget for review.

Proposed Collection: Title: 09–17–0002, ''IHS Contract Health Service Report''. *Type of Information Collection Request:* 3-year reinstatement, without change, of previously approved information collection, 0917–0002, ''IHS Contract Health Service Report'' which expires 07/31/01. *Form Number:* IHS–843–1A, ''Purchase-Delivery Order for Health Services.'' *Need and Use of Information Collection:* The Contract Health Service health care providers complete form IHS–843–1A to certify that they have performed the health services authorized by the IHS. The information is used to manage, administer, and plan for the provision of health services to eligible American Indian patients, process payments to providers, obtain program data, provide program statistics, and serve as a legal document for health care services rendered. *Affected Public:* Businesses or other for-profit, Individuals, not-for-profit institutions and State, local or Tribal Government. *Type of Respondents:* Health care providers. The table below provides: Type(s) of Data Collection Instruments, Estimated Number of Respondents, Number of Responses per Respondent, Annual Number of Responses, Average Burden Hour per Response, and Total Annual Burden Hour.

Data collection instrument	Estimated number of respondents	Number of responses per respondent	Annual number of responses	Average burden hour per response (3 mins)*	Total annual burden hours
IHS–843–1A	7,399	42	310,758	0.05	15,538
IDS**	16,356	1	16,356	0.05	818

* For ease of understanding, burden hours are also provided in actual minutes.
** Inpatient Discharge Summary (IDS)

There are no Capital Costs, Operating Costs or Maintenance Costs to report.

Request for Comments: Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments and Requests for Further Information: Send your written comments, requests for more information on the proposed project, or requests to obtain a copy of the data collection instrument and instructions to: Mr. Lance Hodahkwen, Sr., M.P.H., IHS Reports Clearance Officer, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852.1601, call non-toll free (301) 443–1116, fax (301) 443–2316, or send your E-mail requests, comments, and return address to: lhodahkw@.hqe.ihs.gov.

Comment Due Date: Your comments are best assured of having their full effect if received on or before June 1, 2001.

Dated: March 23, 2001.

Michael H. Trujillo,

Assistant Surgeon General, Director, Indian Health Service.

[FR Doc. 01–7998 Filed 3–30–01; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2001 Funding Opportunities

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of Funding Availability.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Prevention (CSAP),Center for Substance Abuse Treatment (CSAT), and Center for Mental Health Services (CMHS) announce the availability of FY 2001 funds for a cooperative agreement for the following activity: Competing Continuation of the Starting Early Starting Smart Data Coordinating Center (DCC).

Eligibility: Only the currently funded SESS Data Coordinating Center, operated by the Evaluation, Management & Training (EMT), Associates may apply. Only EMT may