

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
58.120	300	15.38	4,614	32.7	150,878
58.195	300	251.5	75,450	3.9	294,255
Total					793,308

¹There are no capital costs or operating maintenance costs associated with this collection of information.

Dated: December 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0554]

Agency Information Collection Activities; Proposed Collection; Comment Request; Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information from manufacturers of monoenergetic neutron sources in order to comply with an amendment to FDA's food additive regulations.

DATES: Submit written or electronic comments on the collection of information by March 7, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the

docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Irradiation in the Production, Processing, and Handling of Food—21 CFR 179.21 (OMB Control Number 0910-0549)—Extension

In the **Federal Register** of December 21, 2004 (69 FR 76401), FDA announced OMB's approval of this collection of information (OMB control number 0910-0549). Since this was an emergency approval that expires on January 31, 2005, FDA is following the normal PRA clearance procedures by issuing this document.

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless it conforms to the terms of a regulation prescribing its use, or to an exemption for investigational use, or in the case of a food additive that is a food contact substance, there is in effect a regulation prescribing the conditions under which such additive may be safely used or a notification that is effective. In response to a petition that is submitted under section 409 of the act to establish that a food additive is safe, the agency may either: (1) By order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or (2) by order deny the petition and notify the petitioner of such order and of the reasons for such action.

In response to a petition filed by Science Applications International Corp., who subsequently transferred

their rights to the petition to Ancore Corp., FDA published in the **Federal Register** of December 21, 2004, a document that amended 21 CFR 179.21 to provide for the use of sources of monoenergetic neutrons to inspect cargo containers that may contain food. Under this regulation, monoenergetic neutron sources producing neutrons at energies not less than 1 million electron volts

(MeV) but no greater than 14 MeV may be used for inspection of cargo containers that may contain food, providing that the neutron source bears a label stating the minimum and maximum energy of radiation emitted by the source. The regulation also requires that the label or accompanying labeling bear adequate directions for safe use and a statement that no food

shall be exposed to this radiation source so as to receive a dose in excess of 0.01 gray. FDA has determined that this information is needed to assure safe use of the source of radiation.

FDA estimates the total annual burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Operating & Maintenance Costs	Total Hours
179.21(a)(5), (b)(1)(iv), and (b)(2)(v)	1	1	1	1	\$100	1

¹ There are no capital costs associated with this collection of information.

FDA estimates that the burden will be insignificant because the reporting requirement reflects customary business practice. Based on discussions with an industry representative, the burden hours estimated for this collection of information is 1 hour. The operating and maintenance cost associated with this collection is \$100 for preparation of labels.

Dated: December 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

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

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at <http://workplace.samhsa.gov> and <http://www.drugfreeworkplace.gov>.
FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, SAMHSA/CSAP, Room 2-1035, 1 Choke Cherry Road, Rockville, Maryland 20857; 240-276-2600 (voice), 240-276-2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Public Law 100-71. Subpart C of the Mandatory Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to

be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Mandatory Guidelines dated April 13, 2004 (69 FR 19644), the following laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414-328-7840/800-877-7016 (Formerly: Bayshore Clinical Laboratory);

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585-429-2264;

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901-794-5770/888-290-1150;

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615-255-2400;

Baptist Medical Center-Toxicology Laboratory, 9601 I-630, Exit 7, Little Rock, AR 72205-7299, 501-202-2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center);

Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215-2802, 800-445-6917;

Diagnostic Services Inc., dba DSI, 12700 Westlinks Dr., Fort Myers, FL 33913, 239-561-8200/800-735-5416;

Doctors Laboratory, Inc., 2906 Julia Drive, Valdosta, GA 31602, 229-671-2281;

DrugProof, Division of Dynacare Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 206-386-2661/800-898-0180 (Formerly: Laboratory of Pathology of