

efforts performed for this Program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Background: The Advisory Board on Radiation and Worker Health met on January 8, 2003, in closed session to discuss the Proposed Independent Government Cost Estimate (IGCE) for a contract. This contract, once awarded, will provide technical support to assist the Board in fulfilling its statutory duty to advise the Secretary of Health and Human Services regarding the dose reconstruction efforts under the Energy Employees Occupational Illness Compensation Program Act. A Determination to Close the meeting was approved and published, as required by the Federal Advisory Committee Act.

Summary of the Meeting: Attendance was as follows:

Board Members:

Paul L. Ziemer, Ph.D., Chair
 Larry J. Elliott, Executive Secretary
 Henry A. Anderson, M.D., Member
 Antonio Andrade, Ph.D., Member
 Roy L. DeHart, M.D., M.P.H., Member
 Richard L. Espinosa, Member
 Michael H. Gibson, Member
 Mark A. Griffon, Member
 James M. Melius, M.D., Dr.P.H., Member
 Robert W. Presley, Member
 Genevieve S. Roessler, Ph.D., Member

NIOSH Staff:

Jim Neton
 David Naimon
 Liz Homoki-Titus
 Martha DiMuzio
 Cori Homer

Ray S. Green, Court Recorder.

Summary/Minutes

Dr. Ziemer called to order the Advisory Board on Radiation and Worker Health (ABRWH) in closed session on January 8, 2003 at 9:45 a.m. The purpose of the closed meeting was to develop the Independent Government Cost Estimate for a contract to provide technical support to the ABRWH review of completed dose reconstructions.

Dr. Ziemer noted that Ms. Wanda Munn and Mr. Leon Owens were not available to attend and could not be connected via conference call due to telephone line security issues.

General topics discussed:

- Closed session procedures.
- Independent Government Cost Estimate.

- Member of Board to be appointed to the Technical Review Panel for this procurement.

Dr. Paul Ziemer adjourned the closed session of the ABRWH meeting at 11:18 a.m. with no further business being conducted by the ABRWH.

SUPPLEMENTARY INFORMATION: The Advisory Board on Radiation and Worker Health ("the Board") was established under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) of 2000 to advise the President, through the Secretary of Health and Human Services (HHS), on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Board include providing advice on the development of probability of causation guidelines which have been promulgated by HHS as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, evaluation of the scientific validity and quality of dose reconstructions conducted by the National Institute for Occupational Safety and Health (NIOSH) for qualified cancer claimants, and advice on the addition of classes of workers to the Special Exposure Cohort.

In December 2000 the President delegated responsibility for funding, staffing, and operating the Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was signed on August 3, 2001 and in November, 2001, the President completed the appointment of an initial roster of 10 Board members. In April, and again in August 2002, the President appointed additional members to ensure more balanced representation on the Board.

FOR FURTHER INFORMATION CONTACT:

Larry Elliott, Executive Secretary, ABRWH, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/841-4498, fax 513/458-7125.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 30, 2003.

Joseph E. Slater,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS-10083]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as 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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with the Trade Act of 2002. We cannot reasonably comply with the normal clearance procedures because President of an unanticipated event and public harm.

We are requesting emergency clearance of a pilot study designed to elicit information from discharged patients concerning their hospital/acute care experience. Given the current momentum, enthusiasm and support expressed by hospitals and the hospital associations for public reporting of hospital quality information, it is important to provide the tools needed for reliable and valid data collection as soon as possible. CMS would like to take advantage of the opportunity of testing the H-CAHPS instrument in the Hospital State Pilots that has just started. It is important to provide hospitals a standard tool and data collection methodology by July/August 2003 to support this joint initiative. We are interested in receiving comments on the pilot during the course of the pilot, as well as during the comment period mentioned below. However, those received after the close of the comment period will not be included in the materials that OMB reviews in determining whether to approve the collection.

CMS is requesting OMB review and approval of this collection by February 21, 2003, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by February 20, 2003. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection Request: New collection; *Title of Information Collection:* Pilot Test of Hospital CAHPS Survey; *Form No.:* CMS-10083 (OMB #0938-XXXX); *Use:* CMS has requested a hospital survey as a way of providing comparison information for consumers who need to select a hospital and as a way of encouraging accountability of hospitals for the care they provide. With a standardized instrument consumers will be able to make "apples to apples" comparisons among hospitals, allow hospitals and hospital chains to self compare, and provide state oversight officials with useful data. A standardized instrument, developed under the CAHPS umbrella, will produce a reliable and valid instrument that any organization can use at no cost to obtain patient data about hospital experiences. This tool will be adopted by the National Hospital Voluntary Initiative; *Frequency:* Once; *Affected Public:* Individuals or households;

Number of Respondents: 16,500; *Total Annual Responses:* 16,500; *Total Annual Hours:* 5,500.

We have submitted a copy of this notice to OMB for its review of these information collections. A notice will be published in the **Federal Register** when approval is obtained.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://cms.hhs.gov/regulations/prd/default.asp> or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcfra.gov, or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, in order to be considered in the OMB approval process, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, by February 20, 2003.

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attn: Reports Clearance Officer, Room C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244-1850. Fax Number: (410) 786-3064. Attn: Julie Brown; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395-6974 or (202) 395-5167, Attn: Brenda Aguilar, CMS Desk Officer.

Dated: January 30, 2003.

John P. Burke, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-0109]

Medical Devices: Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test Systems; Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA." This guidance document was developed as a special control guidance to support the reclassification of the fully automated short-term incubation cycle antimicrobial susceptibility device from class III to class II. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying the fully automated short-term incubation cycle antimicrobial susceptibility device from class III to class II.

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

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance entitled "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), 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. Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

Freddie M. Poole, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2096.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document was developed as a special control guidance to support the reclassification of the fully automated short-term incubation cycle antimicrobial susceptibility device from class III to class II. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to reclassify