animals. The public is invited to attend and will have the opportunity to provide comments.

Contact Person for General Information: Judy Curless, Education and Information Division, NIOSH, CDC, 4676 Columbia Parkway, MS C–32, Cincinnati, Ohio 45226, telephone 513/533–8314, fax 513/533–8230, e-mail *jcc4@cdc.gov.*

Contact Person for Technical Information: Thomas Lentz, Education and Information Division, NIOSH, CDC, 4676 Columbia Parkway, MS C–32, Cincinnati, Ohio 45226, telephone 513/533–8260, fax 513/533–8230, e-mail *tbl7@cdc.gov.*

Written research, data, or supporting materials to be considered in support of the information gathering effort should be submitted to the NIOSH Docket Office, ATTN: Diane Miller, Robert A. Taft Laboratories, M/S C–34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/533–8450, fax 513/533–8285. Comments may also be submitted by e-mail to: *NIOCINDOCKET@CDC.GOV.* E-mail attachments should be formatted as WordPerfect 6/7/8/9, or Microsoft Word. Comments should be submitted to NIOSH no later than November 15, 2002, and should reference docket number NIOSH–007 in the subject heading.

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: August 15, 2002.

Joseph E. Salter,

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

[FR Doc. 02–21252 Filed 8–20–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Board on Radiation and Worker Health (ABRWH).

Time and Date: 1 p.m.–2 p.m., August 22, 2002.

Place: Teleconference call will originate at the Centers for Disease Control and Prevention, National Institutes for Occupational Safety and Health, Atlanta, Georgia. Please *see* **SUPPLEMENTARY INFORMATION** for details on accessing the teleconference.

Status: Open to the public, teleconference access limited only by ports available.

Background: The Advisory Board on Radiation and Worker Health (''the Board'') was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President 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 Department of Health and Human Services (HHS), advice on methods of dose reconstruction which have been promulgated as an interim final rule, evaluation of the 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 Centers for Disease Control and Prevention (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. The initial tasks of the Board have been to review and provide advice on the proposed and interim rules of HHS.

Purpose: This board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction 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.

Matters To Be Discussed: Agenda for this meeting will focus on the Board finalizing comments on the Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000; proposed rule 42 CFR part 83. The period for comment closes on August 26, 2002, and the Advisory Board on Radiation and Worker Health is required to comment as mandated by the Energy Employees Occupational Illness Compensation Program Act of 2000.

Agenda items are subject to change as priorities dictate.

This request has been submitted late as this conference call was scheduled on August 15, 2002. This conference call cannot be delayed as the open comment period closes on August 26, 2002; two business days after this conference call takes place.

SUPPLEMENTARY INFORMATION: This conference call is scheduled for 1:00 p.m. Eastern Standard Time. To access the teleconference you must dial 1/800–311–3437. To be automatically connected to the call, you will need to provide the operator with the participant code ''984100'' and you will be connected to the call.

Contact Person for More Information: 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: August 16, 2002.

Joseph E. Salter,

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

[FR Doc. 02–21400 Filed 8–20–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Fees for Sanitation Inspections of Cruise Ships

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces fees for vessel sanitation inspections for fiscal year 2003 (October 1, 2002, through September 30, 2003).

EFFECTIVE DATE: October 1, 2002.

FOR FURTHER INFORMATION CONTACT: David L. Forney, Chief, Vessel Sanitation Program, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mailstop F–16, Atlanta, Georgia 30341–3724, telephone (770) 488–7333, e-mail: *Dforney@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose and Background

The fee schedule for sanitation inspections of passenger cruise ships currently inspected under the Vessel Sanitation Program (VSP) was first published in the **Federal Register** on November 24, 1987 (52 FR 45019), and CDC began collecting fees on March 1, 1988. Since then, CDC has published the fee schedule annually. This notice announces fees effective October 1, 2002.

The formula used to determine the fees is as follows:

$$\text{Average cost per inspection} = \frac{\text{Total cost of VSP}}{\text{Weighted Number of annual inspections}}$$

The average cost per inspection is multiplied by a size/cost factor to determine the fee for vessels in each size category. The size/cost factor was established in the proposed fee schedule published in the **Federal Register** on July 17, 1987 (52 FR 27060), and revised in a schedule published in the **Federal Register** on November 28, 1989 (54 FR 48942). The revised size/cost factor is presented in Appendix A.

Fee

The fee schedule is presented in Appendix A and will be effective October 1, 2002, through September 30, 2003. This fee schedule represents a 4.2 percent decrease over the current fee schedule, which became effective October 1, 2001. If travel expenses continue to increase, it may be necessary to readjust the fees before September 30, 2003, because travel comprises a sizable portion of the program's costs. If such a readjustment in the fee schedule is necessary, a notice will be published in the **Federal Register** 30 days before the effective date.

Applicability

The fees will be applicable to all passenger cruise vessels for which inspections are conducted as part of CDC's VSP.

Dated: August 15, 2002.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention.

APPENDIX

Appendix A

SIZE/COST FACTOR

Vessel size	GRT [1]	Average cost
Extra Small	<3,001	0.25
Small	3,001–15,001	0.50
Medium	15,000–30,000	1.00
Large	30,001–60,000	1.50
Extra Large	>60,000	2.00

[1] GRT—Gross register tonnage in cubic feet, as shown in *Lloyd's Register of Shipping.*

FEE SCHEDULE OCTOBER 1, 2002–SEPTEMBER 30, 2003

Vessel size	GRT [1]	Fee ($U.S.)
Extra small	<3,001	1,150
Small	3,001–15,000	2,300
Medium	15,001–30,000	4,600
Large	30,001–60,000	6,900
Extra large	>60,000	9,200

Note: Inspections and reinspections involve the same procedure, require the same amount of time, and are, therefore, charged at the same rate.

[FR Doc. 02–21249 Filed 8–20–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0350]

Draft Guidance for Industry on Handling and Retention of Bioavailability and Bioequivalence Testing Samples; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Handling and Retention of Bioavailability and Bioequivalence Testing Samples.'' Inspection of clinical and analytical sites that perform bioavailability (BA) and bioequivalence (BE) studies frequently reveals the absence of reserve samples at the testing facilities where the studies are conducted. The draft guidance is intended to clarify how to distribute test articles and reference standards to testing facilities, how to randomly select reserve samples, and how to retain reserve samples.

EFFECTIVE DATE: Submit written or electronic comments on the draft guidance by September 20, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Martin Yau, Center for Drug Evaluation and Research (HFD–45), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5458.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Handling and Retention of Bioavailability and Bioequivalence Testing Samples.'' Following the generic drug crisis in the 1980s, FDA issued regulations to deter possible bias and fraud in BA and BE testing by study sponsors and/or drug manufacturers (58 FR 25918, April 28, 1993). In the preamble of the final rule, the agency stated that the study sponsor should not separate out the reserve samples of the test article and reference standard prior to sending the drug product to the testing facility. This is to ensure that the reserve samples are in fact representative of the same batches provided by the study sponsor for the testing. FDA's Division of Scientific Investigations and field investigators from the Office of Regulatory Affairs conduct inspections of clinical and analytical sites that perform BA and BE studies for sponsors and/or drug manufacturers seeking approval of generic and new drug products. A frequent finding from these inspections is the absence of reserve samples at the testing facility. This draft guidance clarifies the responsibilities of the involved parties for retention of samples used in BA and BE studies. It includes recommendations for sampling techniques and responsibilities in various study settings.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on retention of BA and BE testing samples. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An