

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Health Protection Research Initiative Institutional Research Training Grant, Request for Applications (RFA) CD-04-003

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 meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Health Protection Research Initiative Institutional Research Training Grant, Request for Applications (RFA) CD-04-003.

Times and Dates: 8 a.m.–8:30 a.m., August 13, 2004 (Open). 8:30 a.m.–5 p.m., August 13, 2004 (Closed).

Place: Westin Peachtree Plaza Hotel, 210 Peachtree Street, NW., Atlanta, GA 30303, Telephone 404-659-1400.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to: Health Protection Research Initiative Institutional Research Training Grant, Request for Applications (RFA) CD-04-003.

Contact Person for More Information: Elizabeth Skillen, PhD., Scientific Review Administrator, Public Health Practice Program Office, CDC, 4770 Buford Highway, MS-K38, Atlanta, GA 30314, 770-488-2592.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 15, 2004.

Joseph E. Salter,

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

[FR Doc. 04-16671 Filed 7-21-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Study Team for the Los Alamos Historical Document Retrieval and Assessment (LAHDRA) Project

The Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Public Meeting of The Study Team for the Los Alamos Historical Document Retrieval and Assessment Project.

Time and Date: 5 p.m.–7 p.m. (mountain time), July 27, 2004.

Place: Cities of Gold Hotel in Pojoaque (15 miles north of Santa Fe on U.S. 84/285), 10-B Cities of Gold Road, Santa Fe, New Mexico 87506, telephone 505-455-0515.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Background: Under a Memorandum of Understanding (MOU) signed in December 1990 with the Department of Energy (DOE) and replaced by MOUs signed in 1996 and 2000, the Department of Health and Human Services (HHS) was given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS delegated program responsibility to CDC.

In addition, a memo was signed in October 1990 and renewed in November 1992, 1996, and in 2000, between the Agency for Toxic Substances and Disease Registry (ATSDR) and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or "Superfund"). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This study group is charged with locating, evaluating, cataloguing, and copying documents that contain information about historical chemical or radionuclide releases from facilities at the Los Alamos National Laboratory since its inception. The purpose of this meeting is to review the goals, methods, and schedule of the project, discuss progress to date, provide a forum for community interaction, and serve as a vehicle for members of the public to express concerns and provide advice to CDC.

Matters To Be Discussed: Agenda items include: CDC release of the Final Interim Report of the LAHDRA Project; discussion of

document access at Los Alamos and information gathering that remains to be done; and an update on the outlook for continuation of information gathering at Los Alamos. All agenda items are subject to change as priorities dictate.

Contact Person for Additional Information: Phillip R. Green, Public Health Advisor, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 1600 Clifton Road, NE. (MS-E39), Atlanta, GA 30333, telephone 404/498-1717, fax 404/498-1811.

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 CDC and ATSDR.

Dated: July 16, 2004.

Alvin Hall,

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

[FR Doc. 04-16665 Filed 7-21-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Operations and Construction Meeting

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Vessel Sanitation Program (VSP) Operations Manual and Construction Guidelines Review.

Time and Date: 9 a.m. to 4 p.m., August 23-26, 2004.

Place: Auditorium, Port Everglades Administration Building, 1850 Eller Drive, Fort Lauderdale, Florida 33316.

Status: Open to the public, limited by the space available. The meeting room accommodates approximately 100 people.

Purpose: From August 23-26, the Vessel Sanitation Program staff and cruise ship industry will review revisions to both the Vessel Sanitation Operations Manual 2000 (August 23-24) and the Recommended Ship Building Guidelines for Cruise Vessels Destined To Call on U.S. Ports (August 24-26).

Matters to be discussed:

- Revisions to the Vessel Sanitation Operations Manual 2000.
- Revisions to the Recommended Ship Building Guidelines for Cruise Vessels Destined To Call on U.S. Ports.

The official record of this meeting will remain open for a period of 15 days following the meeting (through September 10, 2004) so that additional materials or comments may be submitted to be made part of the record of the meeting.

Advanced registration is encouraged. Please provide the following information: Name, title, company name, mailing address, telephone number, facsimile number, and e-mail address to Lisa Beaumier at 770-488-7138, FAX 770-488-4127, or lbeaumier@cdc.gov.

If you need additional information, please contact Lisa Beaumier (contact information provided above).

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 CDC and ATSDR.

Dated: July 16, 2004.

Alvin Hall,

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

[FR Doc. 04-16672 Filed 7-21-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Idaho National Engineering and Environmental Laboratory Health Effects Subcommittee (INEELHES)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

Name: Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Idaho National Engineering and Environmental Laboratory Health Effects Subcommittee (INEELHES).

Times and Dates: 1:30 p.m.—4:45 p.m., August 10, 2004. 8:30 a.m.—2:45 p.m., August 11, 2004.

Place: The Shilo Inn, 780 Lindsay Boulevard, Idaho Falls, Idaho 83402, telephone 208-523-0088 Ext. 100, fax 208-522-7420.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Background: Under a Memorandum of Understanding (MOU) signed in December 1990 with DOE, and replaced by MOUs signed in 1996 and 2000, the Department of Health and Human Services (HHS) was given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use.

HHS delegated program responsibility to CDC.

In addition, a memo was signed in October 1990 and renewed in November 1992, 1996, and in 2000, between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or "Superfund"). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This subcommittee is charged with providing advice and recommendations to the Director of CDC and the Administrator of ATSDR pertaining to CDC's and ATSDR's public health activities and research at this DOE site. The purpose of this meeting is to provide a forum for community, American Indian Tribal, and labor interaction, and to serve as a vehicle for communities, American Indian Tribes, and labor to express concerns and provide advice and recommendations to CDC and ATSDR.

Matters To Be Discussed: Agenda items include a presentation of the Sanford Cohen & Associates Report; a report on the Final INEEL Public Health Assessment; the INEEL Worker Cohort Mortality Study; and a Historical Review of the INEEL Dose Reconstruction Project: CDC's Perspective. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Ms. Natasha Friday, Executive Secretary, INEELHES, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, CDC, 1600 Clifton Road, NE. (E-39), Atlanta, Georgia 30333, telephone (404) 498-1800, fax (404) 498-1811.

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 CDC and ATSDR.

Dated: July 16, 2004.

Alvin Hall,

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

[FR Doc. 04-16669 Filed 7-21-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0114]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 23, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Institutional Review Boards—(OMB Control Number 0910-0130)—Extension

When reviewing clinical research studies regulated by FDA, institutional review boards (IRBs) are required to create and maintain records describing their operations, and make the records available for FDA inspection when requested. These records include: Written procedures describing the structure and membership of the IRB and the methods that the IRB will use in performing its functions; the research protocols, informed consent documents, progress reports, and reports of injuries to subjects submitted by investigators to the IRB; minutes of meetings showing attendance, votes and decisions made by the IRB, the number of votes on each decision for, against, and abstaining, the