DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Designation of a Class of Employees for Addition to the Special Exposure Cohort

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

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) gives notice of a decision to designate a class of employees at the Ames Laboratory, in Ames, Iowa as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On August 8, 2006, the Secretary of HHS designated the following class of employees as an addition to the SEC:

Department of Energy (DOE) employees or DOE contractor or subcontractor employees who worked at the Ames Laboratory in one or more of the following facilities/locations: Chemistry Annex 1 (also known as ''the old women's gymnasium'' and ''Little Ankeny''), Chemistry Annex 2, Chemistry Building (also known as ''Gilman Hall''), Research Building, or the Metallurgical Building (also known as ''Harley Wilhelm Hall'') from January 1, 1942 through December 31, 1954 for a number of work days aggregating at least 250 work days, or in combination with work days within the parameters (excluding aggregate work day requirements) established for one or more classes of employees in the SEC, and who were monitored or should have been monitored.

This designation will become effective on September 7, 2006, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV*.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 06–7485 Filed 9–6–06; 8:45 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Designation of a Class of Employees for Addition to the Special Exposure Cohort

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

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) gives notice of a decision to designate a class of employees at the Y–12 Plant, in Oak Ridge, Tennessee as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On August 8, 2006, the Secretary of HHS designated the following class of employees an addition to the SEC:

Department of Energy (DOE) employees or DOE contractor or subcontractor employees who were monitored or should have been monitored for:

(1) Thorium exposures while working in Building 9201–3, 9202, 9204–1, 9204–3, 9206, or 9212 at Y–12 for a number of work days aggregating at least 250 work days from January 1948 through December 1957 or in combination with work days within the parameters (excluding aggregate work day requirements) established for one or more classes of employees in the SEC; or

(2) Radionuclide exposures associated with cyclotron operations in Building 9201–2 at Y–12 for a number of work days aggregating at least 250 work days from January 1948 through December 1957 or in combination with work days within the parameters (excluding aggregate work day requirements) established for one or more classes of employees in the SEC.

This designation will become effective on September 7, 2006, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provisions by Congress regarding the decision by HHS to add the class to the SEC.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support; National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV*.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 06–7486 Filed 9–6–06; 8:45 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health (NIOSH); Advisory Board on Radiation and Worker Health

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

Name: Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health and Subcommittee for Dose Reconstruction and Site Profile Reviews (SDRSPR).

Subcommittee Meeting Time and Date: 9 a.m.–12 p.m., September 19, 2006.

Committee Meeting Times and Dates:

1 p.m.–4:45 p.m., September 19, 2006.
8:30 a.m.–5 p.m., September 20, 2006.
8:30 a.m.–5 p.m., September 21, 2006.

Public Comment Times and Dates:

5 p.m.–6 p.m., September 19, 2006.
7:30 p.m.–8:30 p.m., September 20, 2006.

Place: Westin Casuarina, 160 E. Flamingo Road, Las Vegas, Nevada 89169. Phone 702.836.5900, Fax 702.836.5990.

Status: Open to the public, limited only by the space available. The meeting space accommodates approximately 75 to 100 people.

Background: The Advisory 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 Advisory Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation

and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2007.

Purpose: This Advisory 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: The agenda for the Subcommittee meeting includes Individual Dose Reconstruction Reviews and Procedures Reviews; Subcommittee Operations and Future Plans. The agenda for the Advisory Board meeting includes Presentation of SEC Petitions for Oak Ridge Institute of Nuclear Studies (ORINS), Chapman Valve, S–50 Thermal, and Los Alamos National Laboratory (LANL) (Radioactive Lanthanum Exposure); Updates on SEC Petitions for Nevada Test Site (NTS), Pacific Proving Ground (PPG), Ames Laboratory, and Rocky Flats Plant; Working Group Reports on the Savannah River Site (SRS) Profile, NTS Site Profile, and SEC Petitions; Individual Dose Reconstruction Reviews; Procedures Review; NIOSH Conflict of Interest Policy; Board Conflict of Interest Policy; Status and Future Funding of Sanford Cohen & Associates (SC&A) Contract; Science Issues Updates; Charter for New Subcommittee; Working Group and Subcommittee Assignments; NIOSH, Office of Compensation Analysis and Support (OCAS) and Department of Labor (DOL) Status Reports; Board Correspondence; Board Future Plans, and Board Working Time. The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted. Any written comments should be submitted to the contact person below well in advance of the meeting, and the comments will be provided at the meeting.

For Further Information Contact: Dr. Lewis V. Wade, Executive Secretary, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, Telephone 513.533.6825, Fax 513.533.6826.

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: August 31, 2006.

Alvin Hall,

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

[FR Doc. E6–14787 Filed 9–6–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0336]

Draft Guidance for Industry and Food and Drug Administration Staff; Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions.'' This guidance document is intended to clarify the regulations regarding ASRs and the role and responsibilities of ASR manufacturers.

DATES: Submit written or electronic comments on this draft guidance by December 6, 2006.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label 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 this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Courtney C. Harper, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0490.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is providing this guidance in order to eliminate confusion regarding particular marketing practices among ASR manufacturers. ASRs are the building blocks of laboratory-developed tests and are defined and classified in a rule codified at § 864.4020 (21 CFR 864.4020). With this draft guidance document, FDA seeks to advise ASR manufacturers that it views certain practices as being inconsistent with the marketing of an ASR, as defined in § 864.4020. Some manufacturers have believed that when they combine a Class I ASR, which is exempt from premarket notification requirements under section 510(l) of the Federal Food, Drug, and Cosmetic Act (the act), (21 U.S.C. 360(l)), with other products, or with instructions for use in a specific test, the product remains exempt because of the presence of an ASR. However, as explained in this draft guidance, when an ASR is marketed in certain ways, FDA views the product as no longer being an ASR within the meaning of § 860.4020.

II. Significance of Guidance

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 commercially distributed ASRs. 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 requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using