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. 06–7486 Filed 9–6–06; 8:45 am]
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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.

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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 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.

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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. An individual cannot attend, written comments may be submitted. Any written comments should be submitted to the contact person below 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.


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

**BILLING CODE** 4165–18–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(i)), 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