

e. The budget request is clearly explained, adequately justified, reasonable, and consistent with the intended use of grant funds.

## VI. Award Administration Information

1. *Award Notices:* If your application is to be funded, you will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

2. *Administrative and National Policy Requirements:* 45 CFR parts 74 and 92.

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-3 Animal Subjects Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-13 Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR-20 Conference Support
- AR-21 Small, Minority, and Women-Owned Business
- AR-22 Research Integrity
- AR-25 Release and Sharing of Data

Starting with the December 1, 2003 receipt date, all NCIPC funded investigators seeking more than \$250,000 in total costs in a single year are expected to include a plan describing how the final research data will be shared/released or explain why data sharing is not possible. Details on data sharing/release, including the timeliness and name of the project data steward, should be included in a brief paragraph immediately following the Research Plan Section of the PHS 398 form. References to data sharing/release may also be appropriate in other sections of the application (e.g. background and significance, human subjects requirements, etc.) The content of the data sharing/release plan will vary, depending on the data being collected and how the investigator is planning to share the data. The data

sharing/release plan will not count towards the application page limit and will not factor into the determination of scientific merit or priority scores. Investigators should seek guidance from their institutions, on issues related to institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule.

Further detail on the requirements for addressing data sharing in applications for NCIPC funding may be obtained by contacting NCIPC program staff or visiting the NCIPC Internet Web site: at [http://www.cdc.gov/ncipc/osp/sharing\\_policy.htm](http://www.cdc.gov/ncipc/osp/sharing_policy.htm).

Additional information on these requirements can be found on the CDC web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

### 3. Reporting:

You must provide CDC with an original, plus two copies of the following reports:

1. Interim progress report, (PHS 2590, OMB Number 0925-0001, rev. 5/2001) no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:
  - a. Current Budget Period Activities Objectives.
  - b. Current Budget Period Financial Progress.
  - c. New Budget Period Program Proposed Activity Objectives.
  - d. Detailed Line-Item Budget and Justification.
  - e. Additional Requested Information.
2. Financial status report, no more than 90 days after the end of the budget period.
3. Final financial and performance reports, no more than 90 days after the end of the project period.

## VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, PA #04057, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2700.

For scientific/research program technical assistance, contact:

Tom Voglesonger, Program Manager, Office of the Associate Director for Science, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, (K02), Atlanta, GA 30341-3724, Telephone: (770) 488-4823, Email: [tdv1@cdc.gov](mailto:tdv1@cdc.gov).

For questions about peer review, contact: Gwendolyn Cattledge, PhD,

Scientific Review Administrator, Office of the Associate Director for Science, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, (K02), Atlanta, GA 30341-3724, Telephone: (770) 488-1430, E-mail: [gxc8@cdc.gov](mailto:gxc8@cdc.gov).

For financial, grants management, or budget assistance, contact: Van King, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488-2751, E-mail: [vbk5@cdc.gov](mailto:vbk5@cdc.gov).

Dated: November 20, 2003.

**Edward Schultz,**

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### National Institute for Occupational Safety and Health Meeting

The National Institute for Occupational Safety and Health (NIOSH) announces the following meeting:

*Name:* NIOSH B Reader Certification Program: Looking to the Future.

*Date and Time:* 1-5 p.m., March 4, 2004.

*Place:* Fairfax Ballroom, Courtyard Marriott, 1960-A Chain Bridge Road, McLean, Virginia.

*Status:* This meeting is hosted by NIOSH and will be open to the public, limited only by the space available. The meeting room will accommodate approximately 100 people. An opportunity to provide comments regarding the NIOSH B Reader Program will be given.

Requests to make comments at this public meeting must be made by completing the online registration form or by sending the completed form by fax to (304) 285-6058. The registration form may also be obtained on the NIOSH homepage at <http://www.cdc.gov/niosh> by selecting Conferences and then the event, or by calling (304) 285-5724. All requests to speak should include the name, mailing and e-mail addresses, telephone number, relevant business affiliations of the speaker, and a brief outline of the content of the comments. No audio-visual aids (other than a microphone) will be available, however,

speakers may wish to provide printed copies of their presentations for distribution. Presentations will be strictly limited to a maximum of 5 minutes. After reviewing all requests, NIOSH will notify each speaker of the order and approximate timing of the presentations. Speakers who are not ready when the preceding speaker has finished will be skipped, and the remaining speakers will be heard in order. At the conclusion of the meeting, as time permits, an attempt will be made to include presentations by scheduled speakers who missed their assigned slot. Attendees who wish to speak but did not submit a prior request also may be given this opportunity at the conclusion of the meeting, at the discretion of the presiding officer.

Interested parties may make hotel reservations directly with the Courtyard Marriott, 1960-A Chain Bridge Road, McLean, VA, 22102, telephone, (703) 790-0207, before the cut-off date of February 1, 2004. A special rate has been negotiated for meeting guests of \$150.00 per night. The NIOSH B Reader Meeting must be referenced to receive these special rates.

Comments on the topics presented in this notice and at the meeting should be mailed to the NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone: (513) 533-8303, fax: (513) 533-8285. Comments may also be submitted by e-mail to [niocindocket@cdc.gov](mailto:niocindocket@cdc.gov). E-mail attachments should be formatted as WordPerfect 6/7/8/9 or Microsoft Word. Comments should be submitted no later than April 5, 2004, and should reference Docket Number NIOSH-015, B Reader Program, in the subject heading.

**Purpose:** Chest radiographic imaging is a widely applied and important tool for assessing lung health in clinical medicine, research investigations, hazard evaluations, and medical monitoring of workers exposed to silica, asbestos, coal, beryllium, and other dusts capable of producing occupational pneumoconiosis. Valid reproducible categorization of chest radiographic images requires close adherence to standard methods of radiograph classification and adoption of procedures for quality assurance. The International Labour Office (ILO) (Geneva) has for many years provided a standardized system for classification of chest radiographs for pneumoconiosis, including specification of procedures for obtaining images. The ILO system has been widely used by physicians and epidemiologic researchers in the investigation of work-related respiratory hazards.

Under the U.S. Code of Federal Regulations [42 CFR part 37], since 1970, chest radiographic examinations have been provided to underground coal miners at approximate five year intervals. As part of this mandated Coal Workers' Health Surveillance Program (CWHSP), NIOSH arranges for the determination of the presence and degree of dust-related changes on those films by physicians who have demonstrated proficiency in the ILO system. NIOSH developed and currently administers the B Reader Certification Program, a unique quality assurance program for training and certifying physicians who classify chest radiographs of pneumoconiosis. Under this Program, physicians who wish to obtain B Reader Certification must successfully complete an extensive initial examination. To demonstrate ongoing competence and maintain certification, every four years each individual who passed the initial examination must complete a recertification examination. Because the B Reader Certification Program objectively documents proficiency in the evaluation of lung images for occupational disease, it has attained high visibility in the U.S. and throughout the world. The Program continues to have important impacts on occupational lung disease research, surveillance, clinical practice, regulation, and litigation. Numerous research studies and hazard evaluations have relied upon the classification of chest radiographs by certified B Readers as a useful health outcome in the investigation and assessment of occupational health risks. State-based surveillance programs have utilized B Reader classifications as a criterion for identifying silicosis cases. The Occupational Safety and Health Administration (OSHA) asbestos standard (§ 1910.1001, App. E) requires that roentgenograms be interpreted and classified only by a B Reader, a board eligible/certified radiologist, or an experienced physician with known expertise in pneumoconioses. OSHA also specifies B Readers and the ILO classification in its safety and health standards for general industry (§ 1910.1001, App. E), construction (§ 1926.1101, App. E), and shipyard employment (§ 1915.1001, App. E).

The ILO, with NIOSH involvement and support, has recently completed a revision of the classification system (ILO 2000). Additionally, in the years since the development of the B Reader Certification process, the field of professional competency testing, as well as the field of radiology, have

experienced considerable advances in knowledge, techniques, and methodology. The B Reader Certification Program has not been substantially revised since its first development, and would benefit from critical evaluation and modification in order to assure optimal test validity, reliability, and efficiency, and overall effectiveness of the Program. In order for NIOSH to maintain the B Reader Program as a contemporary, relevant, and effective quality assurance program for the classification of chest radiographs for occupational lung disease research and prevention, and to assure the Program is adherent to the ILO 2000 system, ongoing refinements and modifications are required to the B Reader examinations and related training activities and materials. This open meeting is intended to serve as an important additional step in the continuing evolution and improvement of the NIOSH B Reader Program.

**FOR FURTHER INFORMATION CONTACT:** CWHSP, 1095 Willowdale Road, Morgantown, West Virginia 26505-2888, *Telephone:* (304) 285-6263/5724, *Fax:* (304) 285-6058, *E-mail:* [CWHSP@cdc.gov](mailto:CWHSP@cdc.gov).

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: November 21, 2003.

**Alvin Hall,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003N-0513]

#### Electronic Submissions of Food Contact Notifications; Notice of Pilot Project

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is seeking volunteers to participate in the Food Contact Notification (FCN) Electronic Submissions Pilot Project developed by