

FOR FURTHER INFORMATION CONTACT: Gina Kiang, Office of the Chief Information Officer, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-255-6702

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the IT Assessment entitled "Prescription Drug User Fee Act (PDUFA) IV Information Technology Assessment." This Assessment is intended to provide regulated industry and other stakeholders with information on FDA's progress toward the goals set out in the PDUFA IV IT Plan. As referenced in that plan published in May 2008, Section 7.2, B. Communications and Technical Interactions, 3.b., "FDA will conduct an annual assessment of progress against the IT plan and publish on the FDA Web site a summary of the assessment within 2 months after the close of each fiscal year."

II. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov> and at <http://www.fda.gov/oc/pdufa>.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>

Dated: August 12, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH-174]

Recent Coal Dust Particle Size Surveys and the Implications for Mine Explosions

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of draft publication available for public comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following draft Publication available for public comment entitled "Recent Coal Dust Particle Size Surveys and the Implications for Mine Explosions." The document and instructions for submitting comments can be found at <http://www.cdc.gov/niosh/review/public/174/default.html>.

Public Comment Period: Comment period from August 31, 2009 to September 30, 2009.

ADDRESSES: Written comments may be submitted to the NIOSH Docket Office, Robert A. Taft Laboratories, 4676 Columbia Parkway, MS-C34, Cincinnati, Ohio 45226. All material submitted to the NIOSH should reference docket number NIOSH-174 and must be submitted by September 30, 2009 to be considered by the Agency. All electronic comments should be formatted as Microsoft Word. In addition, comments may be sent via e-mail to nioshdocket@cdc.gov or by facsimile to (513) 533-8285. A complete electronic docket containing all comments submitted will be available on the NIOSH Web page at <http://www.cdc.gov/niosh/docket>, and comments will be available in writing by request. NIOSH includes all comments received without change in the electronic docket, including any personal information. All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, Room 111, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone (513) 533-8611.

Background: Spreading rock dust in bituminous coal mines is the primary means of reducing the explosion potential of coal dust that collects

during the normal workings of an active coal mine. Accordingly, guidelines have been established by the Mine Safety and Health Administration (MSHA) about the relative proportion of rock dust that needs to be present in both intake and return airways. Specifically, current MSHA regulations require that intake airways contain at least 65% incombustible content and return airways contain at least 80%. The higher limit for return airways was set in large part because fine "float" coal dust (100% < 200 mesh or 75 μ m) tends to collect in these airways. MSHA inspectors routinely monitor rock dust inerting efforts by collecting dust samples and measuring the percentage of total incombustible content (TIC). These regulations were based on two important findings: a survey of coal dust particle size that was performed in the 1920s and large-scale explosion tests conducted in the U.S. Bureau of Mines' Bruceton Experimental Mine (BEM) using dust particles of that size range to determine the amount of inerting material required to prevent explosion propagation.

Mining technology and practices have changed considerably since the 1920s when the original coal dust particle survey was performed. Also, it has been shown conclusively that as the average size of coal dust particles decreases, the explosion hazard increases. Given these factors, the National Institute for Occupational Safety and Health (NIOSH) and MSHA conducted a joint survey to determine the range of coal particle sizes found in dust samples collected from intake and return airways of U.S. coal mines. Results from this survey show that the coal dust found in mines today is much finer than in mines of the 1920s, presumably due to increased automation and a greater reliance on mining machinery.

In light of this recent comprehensive dust survey, NIOSH conducted additional large-scale explosion tests at the Lake Lynn Experimental Mine (LLEM) to determine the degree of rock dusting necessary to abate explosions using Pittsburgh seam coal dust blended as 38% < 200 mesh and referred to as medium-sized dust. Explosion tests indicate that medium-sized coal dust required 76.4% TIC to prevent explosion propagation. Even the coarse coal dust (20% < 200 mesh or 75 μ m) representative of samples obtained from mines in the 1920s required approximately 68% TIC to be rendered inert, a level higher than the current regulation of 65% TIC. In return airways, the particle size survey revealed that the average dust particle size is roughly the same as float coal

dust as defined in the Coal Mine Health and Safety Act of 1969.

Given the results of the recent coal dust particle size survey and large-scale explosion tests, NIOSH recommends a new standard of 80% TIC be required in the intake airways of bituminous coal mines. The survey results indicate that the current requirement of 80% TIC in return airways is still sufficient and appropriate. In addition, NIOSH agrees with and endorses an earlier recommendation that new rock dusting standards should be based on a worst-case scenario (using high volatile coals) with no relaxation for lower volatile coals.

FOR FURTHER INFORMATION CONTACT: Dr. Jeff Kohler, NIOSH Associate Director for Mining and Construction, 626 Cochran Mill Road, Pittsburgh, PA 15236, (412) 386-6544, E-mail jkohler@cdc.gov.

Reference: Web address for this publication: <http://www.cdc.gov/niosh/review/public/174/pdfs/RD-inertingOutToExtReview.pdf>.

Dated: August 14, 2009.

Christine M. Branche,

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

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DEPARTMENT OF HOMELAND SECURITY

Science and Technology (S&T) Directorate

[Docket No. DHS-2009-0107]

Submission for Review; Information Collection Request for the DHS S&T SAFETY Act Program

AGENCY: Science and Technology Directorate, DHS.

ACTION: 30-day Notice and request for comment.

SUMMARY: The Department of Homeland Security (DHS) invites the general public to comment on the following data collection forms for the DHS Science and Technology Directorate's Support Anti-Terrorism by Fostering Effective Technologies (SAFETY) Act Program: Registration of a Seller of an Anti-Terrorism Technology (DHS Form 10010), Request for a Pre-Application Consultation (DHS Form 10009), Notice of License of Qualified Anti-Terrorism Technology (DHS Form 10003), Application for Modification of SAFETY Act Benefits (DHS Form 10002), Request for Transfer of SAFETY

Act Benefits (DHS Form 10001), Application for SAFETY Act Renewal (DHS FORM 10057), Application for SAFETY Act Developmental Testing and Evaluation (DT&E) Designation (DHS Form 10006), Application for SAFETY Act Designation (DHS Form 10008), Application for SAFETY Act Certification (DHS Form 10007), Application for SAFETY Act Block Designation (DHS Form 10005), and Application for SAFETY Act Block Certification (DHS Form 10004).

In 2002, The Support Anti-Terrorism by Fostering Effective Technologies (SAFETY) Act (6 CFR part 25) was enacted as part of the Homeland Security Act of 2002, Public Law 107-296. The SAFETY Act program promotes the development and use of anti-terrorism technologies that will enhance the protection of the nation and provides risk management and litigation management protections for sellers of Qualified Anti-Terrorism Technology (QATT) and others in the supply and distribution chain.

The Department of Homeland Security, Science & Technology Directorate (DHS S&T) currently has approval to collect information for the implementation of the SAFETY Act program until January 31, 2010. With this notice, DHS S&T seeks approval to renew this information collection for continued use after this date. The SAFETY Act program requires the collection of this information in order to evaluate and qualify Anti-Terrorism Technologies, based on the economic and technical criteria contained in the SAFETY Act Final Rule, for protection in accordance with the Act, and therefore encourage the development and deployment of new and innovative anti-terrorism products and services.

This notice and request for comments is required by the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. chapter 35).

DATES: Comments are encouraged and will be accepted until October 20, 2009.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to Desk Officer for the Department of Homeland Security, Science & Technology Directorate, and sent via electronic mail to oir_submission@omb.eop.gov or faxed to 202-395-5806. Please include docket number [DHS-2009-0107] in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Michael Bowerbank, 202-254-6895.

SUPPLEMENTARY INFORMATION: DHS S&T provides a secure Web site, accessible through <http://www.SAFETYAct.gov>, through which the public can learn about the program, submit applications for SAFETY Act protections, submit questions to the Office of SAFETY Act Implementation (OSAI), and provide feedback. The data collection forms have standardized the collection of information that is both necessary and essential for the DHS OSAI.

Overview of Information Collection:

(1) *Type of Information Collection:* Existing information collection.

(2) *Title of the Form/Collection:* SAFETY Act Program.

(3) *Agency Form Number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* DHS Science & Technology Directorate, DHS Forms 10001, 10002, 10003, 10004, 10005, 10006, 10007, 10008, 10009, 10010, and 10057.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Business entities, Associations, and State, Local and Tribal Government entities. Applications are reviewed for benefits, technology/program evaluations, and regulatory compliance.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

a. *Estimate of the total number of respondents:* 950.

b. *An estimate of the time for an average respondent to respond:* 18.2 burden hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 17,300 burden hours.

Dated: August 15, 2009.

Gregg Piermarini,

Acting Chief Information Officer, Science and Technology Directorate, Department of Homeland Security.

[FR Doc. E9-20077 Filed 8-20-09; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2009-0100]

The National Infrastructure Advisory Council

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: Committee Management; Notice of Federal Advisory Council Meeting.

SUMMARY: The National Infrastructure Advisory Council (NIAC) will meet on Tuesday, September 8, 2009, at the J.W.