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5. De Angelis C., J.M. Drazen, F.A. Frizelle, et al., "Clinical Trial Registration: A Statement From the International Committee of Medical Journal Editors," *Annals of Internal Medicine*, 2004;141:477-8, electronically published on September 8, 2004.

6. De Angelis, C., J.M. Drazen, et al., "Is This Clinical Trial Fully Registered?: A Statement From the International Committee of Medical Journal Editors," *International Committee of Medical Journal Editors*, available at [http://www.icmje.org/clin\\_trialup.htm](http://www.icmje.org/clin_trialup.htm), accessed on July 30, 2009.

7. Sim, I., A. Chan, A. Gülmezoglu, T. Evans, et al., "Clinical Trial Registration: Transparency Is the Watchword," *The Lancet*, Vol. 367, Issue 9523, pp. 1631-33, May 2006.

#### List of Subjects in 21 CFR Part 50

Human research subjects, Prisoners, Reporting and recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 50 be amended as follows:

#### PART 50—PROTECTION OF HUMAN SUBJECTS

1. The authority citation for 21 CFR part 50 continues to read as follows:

**Authority:** 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 352, 353, 355, 360, 360c-360f, 360h-360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b-263n.

2. Section 50.25 is amended by adding paragraph (a)(9) to read as follows:

#### § 50.25 Elements of informed consent.

(a) \* \* \*  
\* \* \* \* \*

(9) For applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement, notifying the subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act: Information, that does not include personally identifiable information, concerning this clinical trial has been or will be submitted, at the appropriate and required time, to the government-operated clinical trial registry data bank, which contains registration, results, and other information about registered clinical trials. This data bank can be accessed by you and the general public at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov). Federal law requires clinical trial information for

certain clinical trials to be submitted to the data bank.

\* \* \* \* \*

Dated: December 23, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9-30751 Filed 12-28-09; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF STATE

### 22 CFR Part 62

[Public Notice: 6858]

#### Exchange Visitor Program—Secondary School Students

**AGENCY:** Department of State.

**ACTION:** Proposed rule; withdrawal.

**SUMMARY:** On December 23, 2009 the State Department published in the **Federal Register** a proposed rule titled Exchange Visitor Program—Secondary School Students. The Department revised existing regulations to provide greater specificity and clarity to sponsors of the Secondary School Student category with respect to the execution of sponsor oversight responsibilities under the exchange visitor program. This rule is being withdrawn because it was submitted prior to OMB completing review. The proposed rule is withdrawn in its entirety.

**DATES:** The proposed rule published at 74 FR, Number 245, December 23, 2009 is withdrawn effective December 28, 2009.

**FOR FURTHER INFORMATION CONTACT:** Michael Cheman, U.S. Department of State, Washington, DC 20547, (202) 312-9605.

#### SUPPLEMENTARY INFORMATION:

##### Background

On December 23, 2009 the State Department published a final rule at 74 FR, Number 245. The rule was intended to revise existing regulations to provide greater specificity and clarity to sponsors of the Secondary School Student category with respect to the execution of sponsor oversight responsibilities under the exchange visitor program.

##### Reason for Withdrawal

This rule is being withdrawn because it was submitted prior to OMB completing review. The proposed rule is withdrawn in its entirety. Accordingly, the Department withdraws the rule "Exchange Visitor Program—Secondary School Students", RIN 1400-AC56. This

Proposed Rule was submitted on Friday, 18 December and was published Wednesday, 23 December, 2009 in Volume 74, Number 245 on pages 68200-68208.

Withdrawal of the rule does not preclude the Department from issuing another rule on the subject matter in the future or committing the agency to any future course of action.

Issued in Washington, DC, on December 23, 2009.

Dated: December 20, 2009.

**Thelma Furlong,**

*Director, Office of Directives Management, Department of State.*

[FR Doc. E9-30837 Filed 12-28-09; 8:45 am]

**BILLING CODE 4710-24-P**

## DEPARTMENT OF LABOR

### Occupational Safety and Health Administration

#### 29 CFR Parts 1910, 1915, and 1926

[Docket No. OSHA-H022K-2006-0062 (formerly OSHA Docket No. H022K)]

RIN 1218-AC20

#### Hazard Communication

**AGENCY:** Occupational Safety and Health Administration (OSHA), Department of Labor.

**ACTION:** Proposed rule; notice of informal public hearings.

**SUMMARY:** OSHA is scheduling informal public hearings on its proposal to revise the Hazard Communication Standard. OSHA anticipates receiving several hearing requests, and this document describes the procedures the public must use to participate in the hearings.

**DATES:** *Informal public hearing.* The hearing will begin at 9:30 a.m., local time, on the following dates:

- March 2, 2010, in Washington, DC;
  - March 31, 2010, in Pittsburgh, PA;
- and

- April 13, 2010, in Los Angeles, CA.

If necessary, the hearing will continue at the same time on subsequent days at each location.

*Notice of intention to appear at the hearing.* Interested persons who intend to present testimony or question witnesses at any of these locations must submit (transmit, send, postmark, deliver) a notice of their intention to do so by January 18, 2010.

*Hearing testimony and documentary evidence.* Interested persons who request more than 10 minutes to present testimony or who intend to submit documentary evidence at the hearing

must submit (transmit, send, postmark, deliver) the full text of their testimony and all documentary evidence by February 1, 2010.

**ADDRESSES:** *Informal public hearing.* The Washington, DC, hearing will be held in the auditorium of the U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. OSHA will announce the address of the Pittsburgh, PA, and Los Angeles, CA, hearings in a later **Federal Register** document.

*Notice of intention to appear, hearing testimony and documentary evidence:* You may submit (transmit, send, postmark, deliver) your notice of intention to appear, hearing testimony, and documentary evidence, identified by docket number OSHA-H022K-2006-0062, by any of the following methods:

*Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions online for electronically submitting materials, including attachments;

*Fax:* If your written submission does not exceed 10 pages, including attachments, you may fax it to the OSHA Docket Office at (202) 693-1648; or

*Regular mail, express delivery, hand delivery, and messenger and courier service:* Submit your materials to the OSHA Docket Office, Docket No. OSHA-H022K-2006-0062, U.S. Department of Labor, Room N-2625, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693-2350 (TTY number (877) 889-5627). Deliveries (express mail, hand delivery, and messenger and courier service) are accepted during the Department of Labor's and OSHA Docket Office's normal hours of operation, 8:15 a.m. to 4:45 p.m., e.t.

*Instructions:* All submissions must include the Agency name and docket number for this rulemaking (Docket No. OSHA-H022K-2006-0062). All submissions, including any personal information, are placed in the public docket without change and may be available online at <http://www.regulations.gov>. Therefore, OSHA cautions you about submitting certain personal information such as social security numbers and birthdates. Because of security-related procedures, the use of regular mail may cause a significant delay in the receipt of your submissions. For information about security-related procedures for submitting materials by express delivery, hand delivery, messenger, or courier service, please contact the OSHA Docket Office. For additional information on submitting notices of

intention to appear, hearing testimony or documentary evidence, see the **SUPPLEMENTARY INFORMATION** section of this notice.

*Docket:* To read or download comments, notices of intention to appear, and other material in the docket, go to Docket No. OSHA-H022K-2006-0062 at <http://www.regulations.gov>. All documents in the docket are listed in the <http://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the Web site. All submissions and other material in the docket are available for public inspection and copying in the OSHA Docket Office. For information on reading or downloading materials in the docket and obtaining materials not available through the Web site, please contact the OSHA Docket Office.

Electronic copies of this **Federal Register** notice are available at <http://www.regulations.gov>. This notice as well as news releases and other relevant information also are available at OSHA's Web page at <http://www.osha.gov>.

**FOR FURTHER INFORMATION CONTACT:**

*Press inquiries:* Jennifer Ashley, OSHA, Office of Communications, Room N-3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693-1999.

*Technical information:* Maureen Ruskin, OSHA, Office of Chemical Hazards-Metals, Room N-3718, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693-1950.

*Hearings:* Ms. Veneta Chatmon, OSHA, Office of Communications, Room N-3647; 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693-1999; e-mail [chatmon.veneta@dol.gov](mailto:chatmon.veneta@dol.gov).

**SUPPLEMENTARY INFORMATION:** On September 30, 2009, OSHA published a proposed rule to revise the Hazard Communication Standard (HCS) to conform with the United Nations' (UN) Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (74 FR 50280). OSHA published a correction notice for the NPRM on November 5, 2009 (74 FR 57278). The deadline for submitting written comments and hearing requests is December 29, 2009. OSHA anticipates receiving several hearing requests and is scheduling hearings to begin on March 2, 2010, in Washington, DC; March 31, 2010, in Pittsburgh, PA; and April 13, 2010, in Los Angeles, CA. This document describes the procedures the public must use to participate in the hearings.

*Informal public hearings—purpose, rules and procedures.* OSHA invites interested persons to participate in this rulemaking by providing oral testimony and documentary evidence at the informal public hearing. In particular, OSHA invites interested persons who have knowledge of or experience with hazard communication and the issues the proposed rule raises to participate in the hearings. OSHA also welcomes presentation of data and documentary evidence that will provide the Agency with the best available evidence to use in developing the final rule.

Pursuant to section 6(b)(3) of the Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 655(b)(3)), members of the public have an opportunity at the informal public hearing to provide oral testimony and evidence on issues raised by the proposal. An administrative law judge (ALJ) will preside over the hearing and will resolve any procedural matters relating to the hearing.

The legislative history of section 6 of the OSH Act, as well as OSHA's regulation governing public hearings (29 CFR 1911.15), establish the purpose and procedures of informal public hearings. Although the presiding officer of the hearing is an ALJ and questioning of witnesses is allowed on crucial issues, the proceeding is largely informal and essentially legislative in purpose. Therefore, the hearing provides interested persons with an opportunity to make oral presentations in the absence of procedural restraints or rigid procedures that could impede or protract the rulemaking process. The hearing is not an adjudicative proceeding subject to the technical rules of evidence. Instead, it is an informal administrative proceeding convened for the purpose of gathering and clarifying information. The regulations that govern the hearings and the prehearing guidelines issued for the hearing will ensure that participants are treated fairly and provided due process. This approach will facilitate the development of a clear, accurate, and complete record. Accordingly, application of these rules and guidelines will be such that questions of relevance, procedure, and participation generally will be resolved in favor of developing a clear, accurate, and complete record.

Conduct of the hearing will conform to 29 CFR 1911.15. In addition, the Assistant Secretary may, on reasonable notice, issue additional or alternative procedures to expedite the proceedings, to provide greater procedural protections to interested persons or to further any other good cause consistent with applicable law (29 CFR 1911.4).

Although the ALJ presiding over the hearing makes no decision or recommendation on the merits of the proposal, the ALJ has the responsibility and authority necessary to ensure that the hearing progresses at a reasonable pace and in an orderly manner. To ensure that interested persons receive a full and fair hearing, the ALJ has the power to regulate the course of the proceedings; dispose of procedural requests, objections, and comparable matters; confine presentations to matters pertinent to the issues the proposed rule raises; use appropriate means to regulate the conduct of persons present at the hearing; question witnesses and permit others to do so; limit the time for such questioning; and leave the record open for a reasonable time after the hearing for the submission of additional data, evidence, comments and arguments (29 CFR 1911.16).

At the close of the hearing the ALJ will establish a post-hearing comment period for interested persons who filed a timely notice of intention to appear at the hearing. During the first part of the post-hearing period, those persons may submit additional data and information to OSHA. During the second part they may submit final briefs, arguments, and summations.

*Notice of intention to appear at the hearing.* Interested persons who intend to participate in and provide oral testimony or documentary evidence at the hearing must file a written notice of intention to appear prior to the hearing. To testify or question witnesses at one of the hearing locations, interested persons must submit (transmit, send, postmark, deliver) their notice by January 18, 2010. The notice must provide the following information:

- Name, address, e-mail address, and telephone number of each individual who will give oral testimony;
- Name of the establishment or organization each individual represents, if any;
- Occupational title and position of each individual testifying;
- Hearing location at which each individual wishes to appear and testify and/or question witnesses;
- Approximate amount of time required for each individual's testimony;
- A brief statement of the position each individual will take with respect to the issues raised by the proposed rule; and
- A brief summary of documentary evidence each individual intends to present.

Participants who need projectors and other special equipment for their testimony must contact Ms. Veneta

Chatmon at OSHA's Office of Communications, telephone (202) 693-1999, no later than a week before the hearing begins.

OSHA emphasizes that the hearings are open to the public; however, only individuals who file a notice of intention to appear may question witnesses and participate fully at the hearing. If time permits, and at the discretion of the ALJ, an individual who did not file a notice of intention to appear may be allowed to testify at the hearing, but for no more than 10 minutes.

*Hearing testimony and documentary evidence.* Individuals who request more than 10 minutes to present their oral testimony at the hearing or who will submit documentary evidence at the hearing must submit (transmit, send, postmark, deliver) the full text of their testimony and all documentary evidence no later than February 1, 2010.

The Agency will review each submission and determine if the information it contains warrants the amount of time the individual requested for the presentation. If OSHA believes the requested time is excessive, the Agency will allocate an appropriate amount of time for the presentation. The Agency also may limit to 10 minutes the presentation of any participant who fails to comply substantially with these procedural requirements, and may request that the participant return for questioning at a later time. Before the hearing, OSHA will notify participants of the time the Agency will allow for their presentation and, if less than requested, the reasons for its decision. In addition, before the hearing OSHA will provide the pre-hearing guidelines and hearing schedule to each participant.

*Certification of the hearing record and Agency final determination.* Following the close of the hearing and the post-hearing comment periods, the ALJ will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health. The record will consist of all of the written comments, oral testimony and documentary evidence received during the proceeding. The ALJ, however, will not make or recommend any decisions as to the content of the final standard. Following certification of the record, OSHA will review all the evidence received into the record and will issue the final rule based on the record as a whole.

#### Authority and Signature

David Michaels, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this

notice under the authority granted by section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(b)), Secretary of Labor's Order 5-2007 (72 FR 31160), and 29 CFR part 1911.

Signed at Washington, DC, on this 18th day of December 2009.

**David Michaels,**

*Assistant Secretary of Labor for Occupational Safety and Health.*

[FR Doc. E9-30713 Filed 12-28-09; 8:45 am]

**BILLING CODE 4510-26-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R07-OAR-2008-0787; FRL-9096-3]

#### Approval and Promulgation of Implementation Plans; State of Missouri

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to approve a revision to the State Implementation Plan (SIP) submitted by the state of Missouri. This revision applies to Missouri's rule relating to restriction of emission of visible air contaminants and removes redundant definitions, removes an outdated exemption for incinerators used to burn refuse in the outstate area of Missouri, and clarifies that the test methods stated in the rule shall be used to determine the opacity of visible emissions. EPA is not taking action on the state submitted revisions relating to open burning, as these provisions revise a rule that has not been adopted into the SIP. This revision will ensure consistency between the state and the federally-approved rules.

**DATES:** Comments on this proposed action must be received in writing by January 28, 2010.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R07-OAR-2008-0787, by mail to Lachala Kemp, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Lachala Kemp at (913) 551-7214, or by e-mail at [kemp.lachala@epa.gov](mailto:kemp.lachala@epa.gov).