

Inspection Document (SID),” Volume I, Revision 6, dated July 2005, are acceptable for compliance with the corresponding requirements of this AD.

#### Alternative Methods of Compliance (AMOCs)

(p)(1) The Manager, Los Angeles ACO, FAA, ATTN: Dara Albouyeh, Aerospace Engineer, Airframe Branch, ANM-120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712-4137; telephone (562) 627-5222; fax (562) 627-5210; has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Los Angeles ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and 14 CFR 25.571, Amendment 45, and the approval must specifically refer to this AD.

(4) AMOCs approved previously in accordance with AD 93-01-15 are approved as AMOCs for the corresponding provisions of this AD.

Issued in Renton, Washington, on August 21, 2008.

**Kevin Hull,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

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## DEPARTMENT OF LABOR

### Office of the Secretary

#### 29 CFR Part 2

#### RIN 1290-AA23

#### Requirements for DOL Agencies' Assessment of Occupational Health Risks

**AGENCY:** Office of the Assistant Secretary for Policy, Office of the Secretary, Department of Labor.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** Pursuant to the Secretary of Labor's authority at 5 U.S.C. section 301, the Department of Labor (Department or DOL) is proposing to compile its existing best practices related to risk assessment into a single,

easy to reference regulation, and to include two requirements to establish consistent procedures for conducting risk assessments that promote greater public input and awareness of the Department's health rulemakings. DOL proposes to issue an Advanced Notice of Proposed Rulemaking soliciting public information on relevant data when developing risk assessments for health standards regulating occupational exposure to toxic substances and hazardous chemicals, and to electronically post rulemaking documents and underlying studies used in a risk assessment. The proposed regulation implements recommendations of the 1997 Presidential/Congressional Commission on Risk Assessment and Risk Management Report,<sup>1</sup> and is consistent with Government-wide Office of Management and Budget's (OMB) Information Quality Guidelines,<sup>2</sup> current internal DOL Information Quality Guidelines,<sup>3</sup> and the OMB/Office of Science and Technology Policy 2007 Memorandum on Updated Principles for Risk Analysis.<sup>4</sup>

**DATES:** Comments must be submitted on or before September 29, 2008.

**ADDRESSES:** You may submit comments, identified by RIN, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail/Hand Delivery/Courier:* Submit comments to Office of the Assistant Secretary for Policy, 200 Constitution Avenue, NW., S-2312, Washington, DC 20210, *Attention:* Risk Assessment Policy. Because of security-related concerns, there may be a significant delay in the receipt of submissions by United States Mail. You must take this into consideration when preparing to meet the deadline for submitting comments.

*Instructions:* All submissions received must include the agency name and Regulatory Information Number (RIN) for this rulemaking. Comments received will be posted without change to

<sup>1</sup> Presidential/Congressional Commission on Risk Assessment and Risk Management, *Framework for Environmental Health Risk Management*, 2 Final Report 131-36 (1997).

<sup>2</sup> [http://www.whitehouse.gov/omb/fedreg/2005/011405\\_peer.pdf](http://www.whitehouse.gov/omb/fedreg/2005/011405_peer.pdf).

<sup>3</sup> U.S. Dept. of Labor, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Department of Labor* (2002) (Appendix II), available at <http://www.dol.gov/informationquality.htm>.

<sup>4</sup> OMB/OSTP Memorandum for the Heads of Executive Departments and Agencies, *Updated Principles for Risk Analysis* (2007) M-07-24, available at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf>.

<http://www.regulations.gov>, and available for public inspection in the Office of the Assistant Secretary for Policy, 200 Constitution Avenue, NW., S-2312, Washington, DC 20210, including any personal information provided. Persons submitting comments electronically are encouraged not to submit paper copies.

*Docket:* All comments will be available for public inspection and copying during normal business hours by contacting OASP at (202) 693-5959 (VOICE) (this is not a toll free number) or 1-877-889-5627 (TTY/TDD). You may also contact OASP at the address listed above. As noted above, the Department also will post all comments it receives on <http://www.regulations.gov>.

Copies of the proposed rule are available in alternative formats of large print and electronic file on computer disk, which may be obtained at the above-stated address.

**FOR FURTHER INFORMATION CONTACT:** Kathleen Franks, Office of Regulatory and Programmatic Policy, Office of the Assistant Secretary for Policy, U.S. Department of Labor, (202) 693-5959. This is not a toll-free number.

Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1-800-877-8339.

#### SUPPLEMENTARY INFORMATION:

##### A. Background

*The Department's Mission Under the Occupational Safety and Health Act and Federal Mine Safety and Health Act*

The Secretary of Labor (Secretary) is charged with ensuring safe and healthful working conditions for every working man and woman in the Nation. To that end, the Secretary has broad authority to promulgate health standards. In Section 6(b)(5) of the Occupational Safety and Health Act of 1970 (OSH Act)<sup>5</sup> and Section 101(a)(6) (A) of the Federal Mine Safety and Health Act of 1977 (Mine Act),<sup>6</sup> Congress required the Secretary to set health standards “on the basis of the best available evidence.”<sup>7</sup> The Acts also state that, “in addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field.”<sup>8</sup> In sum, the OSH Act and Mine Act

<sup>5</sup> 29 U.S.C. 655 (2000).

<sup>6</sup> 30 U.S.C. 811 (2000).

<sup>7</sup> 29 U.S.C. 655(b)(5) (2000), 30 U.S.C. 811(a)(6) (2000).

<sup>8</sup> *Id.*

reflect a basic principle that agency actions should be based on the best scientific information available at the time of the agency action. The Government-wide Office of Management and Budget (OMB) Information Quality Guidelines,<sup>9</sup> existing internal U.S. Department of Labor (Department or DOL) Information Quality Guidelines,<sup>10</sup> and the OMB/ Office of Science and Technology Policy (OSTP) 2007 Memorandum on Updated Principles for Risk Analysis further reflect this principle.<sup>11</sup>

This proposed regulation compiles in one easy-to-reference regulation, all of the Department's existing best practices related to risk assessment, and includes two requirements to establish consistent procedures that promote greater public input and awareness of the Department's health rulemakings. The Department is proposing this rulemaking pursuant to the Secretary's authority at 5 U.S.C. section 301 to prescribe regulations related to the performance of the agency's business and the conduct of its employees. Because the Department is not required to seek public comment on its internal procedures under the Administrative Procedure Act (APA),<sup>12</sup> the Regulatory Flexibility Act does not apply to this rulemaking.<sup>13</sup> Although the Department is not required to seek public comment on this proposal, it has chosen to do so in order to gain valuable public input and in the interests of full transparency and accountability. In addition, because this rulemaking merely communicates to the public how the Department will regulate itself, and does not require the regulated community to provide conditions or adopt practices to provide safe or healthful employment, it does not constitute an "occupational safety and health standard" for the purposes of the public hearing requirements of the OSH Act<sup>14</sup> and Mine Act.<sup>15</sup>

#### *Public Accountability and the Need for Consistency, Reliability and Transparency in the Department's Risk Assessment Procedures*

Federal risk assessment and management policies were thoroughly studied by the Presidential/

Congressional Commission on Risk Assessment and Risk Management (Commission on Risk), which was created by the 1990 Clean Air Act Amendments, "to make a full investigation of the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various Federal laws to prevent cancer and other chronic human health effects which may result from exposure to hazardous substances."<sup>16</sup> In its 1997 final report, the Commission on Risk made specific findings with respect to the Occupational Safety and Health Administration (OSHA). In particular, it found that, "OSHA seems to have relied upon a case-by-case approach for performing risk assessment and risk characterization," and recommended that the agency publish guidelines laying out its scientific and policy defaults with regard to risk assessment and risk characterization in support of risk management.<sup>17</sup> This NPRM implements the Commission on Risk's recommendation by explaining the agency's existing best practices related to risk assessment in one easy-to-reference regulation, and including two requirements to establish consistent procedures that promote greater public input into and awareness of the Department's health rulemakings. This proposed regulation is a compilation of basic principles and practices related to risk assessment. As such, it ensures that DOL's scientists have the necessary latitude to exercise their professional discretion and to modify their assessments as science evolves, while assuring that the Department's process is fully accountable to the public.

This proposal is drawn from the agency's historical experience promulgating rules under the OSH Act<sup>18</sup> and the Mine Act,<sup>19</sup> and technical expertise on the American workforce and occupational health standards in general. It is also consistent with OMB/OSTP's September 19, 2007, Memorandum to the Heads of Executive Departments and Agencies on Updated Principles for Risk Analysis,<sup>20</sup> the OMB Government-wide Information Quality

Guidelines,<sup>21</sup> and existing internal DOL Information Quality Guidelines.<sup>22</sup>

The core principles underlying this rulemaking are:

- *Transparency:* The reasoning, assumptions, calculations, methods and data on which risk assessment findings and risk management decisions are made should be presented in an open and readily accessible format to enable members of the public to review, critique, and replicate the process leading to the Department's findings and decisions. Where results embody uncertainty, the degree of uncertainty should be clearly stated and quantified in probabilistic terms if adequate data are available, and the analysis adds value to the risk management decision process.

- *Consistency:* The approaches used to assess risk should conform to accepted scientific practice and strive to be consistent with approaches used in previous occupational standards that address similar hazards and agents. A justification should be provided when alternate approaches are employed. The choice of methods, procedures and approaches should be based on objective criteria and adhere to basic principles that have achieved general scientific acceptance. While consistency is a key objective, risk analysis is an evolving scientific process and agencies must retain sufficient flexibility to incorporate methodological and analytical advances. In addition, to the extent risk analyses must be tailored for particular projects, the Department's agencies should clearly articulate the reasons for selecting the methodologies used.

- *Reliability:* Analyses and calculations must be based on the best available scientific data and practices consistent with the Federal Government's directives on information quality and peer review.

The underlying principles of this proposed rulemaking are not new, but rather reflect existing agency best practices and broad scientific consensus. This proposed rulemaking will reinforce those existing best practices and by compiling DOL's procedures into a single, easy to reference, policy statement reflects the agency's historical commitment to public accountability.

<sup>21</sup> [http://www.whitehouse.gov/omb/fedreg/2005/011405\\_peer.pdf](http://www.whitehouse.gov/omb/fedreg/2005/011405_peer.pdf).

<sup>22</sup> <http://www.dol.gov/informationquality.htm>.

<sup>9</sup> [http://www.whitehouse.gov/omb/fedreg/2005/011405\\_peer.pdf](http://www.whitehouse.gov/omb/fedreg/2005/011405_peer.pdf).

<sup>10</sup> <http://www.dol.gov/informationquality.htm>.

<sup>11</sup> OMB/OSTP Memorandum for the Heads of Executive Departments and Agencies, *Updated Principles for Risk Analysis (2007) M-07-24*, available at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf>.

<sup>12</sup> 5 U.S.C. 553(b)(A).

<sup>13</sup> See, 5 U.S.C. 601 (2000).

<sup>14</sup> See, 29 U.S.C. 652(8) (2000) and § 655(b)(3) (2000).

<sup>15</sup> See, 30 U.S.C. 811(a)(3) (2000).

<sup>16</sup> 42 U.S.C. 7412 note, Pub. L. 101-549, § 303, Nov. 15, 1990.

<sup>17</sup> Presidential/Congressional Commission on Risk Assessment and Risk Management, *Framework for Environmental Health Risk Management*, 2 Final Report 131-36 (1997) (Commission on Risk Report).

<sup>18</sup> 29 U.S.C. 655 (2000).

<sup>19</sup> 30 U.S.C. 811 (2000).

<sup>20</sup> OMB/OSTP Memorandum for the Heads of Executive Departments and Agencies, *Updated Principles for Risk Analysis (2007) M-07-24*, available at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf>.

### *Compilation of the Department's Existing Best Practices Related to Risk Assessment*

Currently, the Department does not have comprehensive regulations or internal guidance laying out its scientific and policy defaults with regard to risk assessment and characterization. The Department has, however, developed best practices related to risk assessment. It also follows internal DOL guidelines governing the information quality aspects of risk assessments, and conducts peer review of important scientific information in accordance with OMB's Government-wide Information Quality Bulletin for Peer Review.<sup>23</sup>

### **B. The Department's Risk Assessment Paradigm**

Within the Department, risk assessments related to the regulation of occupational exposure to toxic substances and hazardous chemicals are performed primarily by OSHA and the Mine Safety and Health Administration (MSHA). This section provides a summary of the Department's risk assessment paradigm and existing best practices. For the purposes of this rulemaking, "risk assessment" is defined as the overall process of evaluating the risk associated with a health hazard from a toxic substance or hazardous chemical. A "hazard" is an intrinsic property of a substance or event, which has the potential to cause harm. "Risk" is the probability of the occurrence of harm given exposure to the hazard.

DOL's risk assessment paradigm incorporates the following steps:

- a. Hazard identification. The hazard identification step examines whether a substance or chemical is a health hazard;
- b. Dose-response assessment. The dose response assessment step examines the relationship between exposure to a hazardous substance and an adverse health outcome.
- c. Exposure assessment. The exposure assessment step estimates exposure to the hazardous substance in the workplace.
- d. Risk characterization. The risk characterization step provides estimates of risk to workers from occupational exposure scenarios of interest. The risk characterization also summarizes the key findings and discusses the limitations of the data, the choice of assumptions, the inherent uncertainties associated with the estimates of risk,

limitations of the database, and how these factors impact the risk assessment.

Under the Department's existing current Information Quality Guidelines,<sup>24</sup> OSHA and MSHA are required to use the best available scientific methodologies, information and health and exposure data when conducting the analyses for each of the four steps in the risk assessment paradigm. In addition, to assure that a consistent and scientifically defensible approach is used throughout the process, DOL agencies describe key assumptions that are made in the risk assessment and discuss their impacts on the outcome and proper interpretation of the risk assessment in both the presentation of dose-response models to DOL risk managers and all public risk assessment documents.

#### *1. Hazard Identification*

The foundation for every risk assessment is a thorough compilation of relevant studies and information. Currently, the Department's agencies start the process of risk assessment by reviewing applicable scientific information to determine whether a toxic substance or hazardous chemical is a health hazard. Risk assessors gather applicable information directly from the National Institute for Occupational Safety and Health (NIOSH), the Environmental Protection Agency (EPA), other Federal agencies, academic researchers, stakeholders, petitioners, and other experts. Also, relevant studies may be provided to the DOL's agencies as part of a petition for rulemaking. Supplementary searches may be performed using scientific literature databases to obtain a complete profile of the chemical of interest.

An important component of hazard identification is the selection of health endpoints, which are the outcomes that result from exposure to a hazard. Endpoints can be selected for chemicals based on observational studies (epidemiologic studies), industrial hygiene assessments, medical assessments, experimental studies (toxicological studies), surveillance data, and toxicological screening batteries. The hazard identification discussion includes an explanation of the basis for selecting the particular health endpoints and an analysis of the overall reliability of studies relied upon. Given that there are many different designs for studies, simple rules for their evaluation do not exist. However, key factors that affect the reliability of the epidemiological studies include: the power of the study to detect the

endpoint, biases that may make the study data not representative of the whole population, and confounders (e.g., age, smoking, or drug use). For animal studies, key considerations include quality of the study design, number of dose groups, number of animals per dose group, range of dose levels employed, route of exposure, and human relevance of health outcomes found in the studies.

The hazard identification phase of a risk assessment is currently published by DOL in the "Health Effects" chapter of the preamble to proposed and final rules. The discussion includes a summary of the database and an opinion as to the confidence with which conclusions can be drawn from this database, any alternative conclusions that are supported by the database, and any significant data gaps.

#### *2. Dose-Response Assessment*

A dose-response assessment examines the relationship between exposure to the toxin or chemical agent in question and the health effects of concern. Under the Department's current procedures, the quantitative estimation of health risk may involve the use of dose-response mathematical models which extrapolate scientifically observable data in humans or animals to a variety of exposure scenarios. The dose-response assessment ultimately strives to quantitatively estimate health risk in the range of occupational exposures of interest, e.g. the current exposure limit or exposure levels being considered for new or revised limits. The process generally involves: Selection of suitable study data, exposure metrics, and health endpoints; selection and application of appropriate risk models to the data; characterization of the uncertainties and limitations in the assessment; and a discussion of how the results compare to other published dose-response assessments for the same agent under similar exposure conditions.

While many studies may add to the overall weight of evidence, the Department often finds that only select data are suitable for making quantitative estimates of risk. Dose-response assessments must be conducted with complete scientific objectivity and transparency. The criteria and rationale for the selection of studies and health endpoints used in the analysis should be fully explained. The assessment should explore a range of plausible risk models and exposure metrics consistent with scientific understanding about the agent and its mode of action. If physiologically based models are applied to the data, the chosen input parameters should be well supported

<sup>23</sup> [http://www.whitehouse.gov/omb/fedreg/2005/011405\\_peer.pdf](http://www.whitehouse.gov/omb/fedreg/2005/011405_peer.pdf).

<sup>24</sup> <http://www.dol.gov/informationquality.htm>.

and the model sufficiently documented and validated. The quantitative dose response assessment should give preference to those risk models that have previously undergone scientific peer review, if such models are appropriate and compatible with the available data. Risk descriptors should be presented as estimates of central tendency along with the appropriate upper and lower bounds. The assessment should strive to determine whether the quantitative estimates are consistent with other risk assessments and with positive and negative animal or epidemiological studies of the hazard in question. Any assumptions and other judgments used in the absence of data are stated and the rationale articulated.

The risk assessment should characterize strengths, limitations and uncertainties in the data sets and models employed in the dose-response assessment, as well as important sources of variability in risk from occupational exposures. The assessment should discuss the impact of key assumptions, uncertainties, and factors that interact with the agent of concern. Quantitative uncertainty and sensitivity analyses should be considered if adequate information is available and its use would add value to the risk management decision. Population variability in risk should be characterized when appropriate, given adequate information and analytical approaches. The assessment should address vulnerable and/or susceptible workers populations where there is scientific evidence to support potential differences in risk. The dose-response assessment is currently published by the Department in the "Risk Assessment" chapter of the preamble to proposed and final rules.

### 3. Exposure Assessment

In the exposure assessment phase of risk assessment, the Department identifies all industry sectors where employees may be potentially exposed to the substance of interest, and estimates current exposures by industry and job title. Exposure parameters include the level, duration, route, and frequency of exposure. In past rulemakings, OSHA and MSHA have found relatively few peer-reviewed studies from which they could reliably construct exposure profiles for all or most affected industry sectors. Instead, the agencies have typically relied on exposure data generated by enforcement activity, data obtained by the agencies or their contractors during site visits, exposure data submitted to the record by industry or labor organizations, and industry studies conducted by NIOSH.

To develop a profile of the population at risk, the Department usually relies on statistics published by the Bureau of Labor Statistics (BLS) or the U.S. Bureau of the Census.

There should be included adequate characterization of relevant information in determining exposure to an agent. Where there are known differences in exposure for different individuals or subpopulations, the Department's agencies characterize this variability. Risk managers are better informed when an understanding of variability and the key contributors to the cause of this variability are presented in the exposure analysis.<sup>25</sup> The exposure assessment analysis is currently provided by the Department in the "Industry Profile" chapter of the Economic Analysis that accompanies proposed and final rules.

### 4. Risk Characterization

Finally, the risk characterization phase of a risk assessment summarizes the findings of the hazard identification, dose-response assessment, and the exposure assessment steps, and ultimately serves as a bridge between the risk assessment and risk management processes. Risk characterization conveys to agency risk managers, stakeholders, and the public, the key findings that risk assessors have derived about the nature and magnitude of the health risks from occupational exposure to a particular toxin or hazardous chemical. It also includes a discussion of the empirical strengths and weaknesses of the risk assessment. With this knowledge, a risk manager is prepared to make policy decisions about how to best manage the particular risk.

The Department's risk characterizations indicate the range of risks posed to workers. Specifically, the occupational exposure profiles and the quantitative estimates of risk are used to estimate the adverse health impacts, e.g., number of lung cancers, associated with current exposure conditions, and to analyze the benefits in terms of health risk avoided, e.g., lung cancers prevented, that are expected to arise from compliance with the proposed occupational standard. In the case of OSHA, the risk characterization also shows how those risks pertain to the legal requirement that the agency determine whether a significant risk exists that can be eliminated or lessened by a change in practices, and the

<sup>25</sup> U.S. Office of Management and Budget (OMB) and Office of Science and Technology Policy (OSTP), Memorandum for the Heads of Executive Departments and Agencies, *Updated Principles for Risk Analysis* (2007) M-07-24, available at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf>.

reduction of risk that is necessary to eliminate significant risk.

OSHA and MSHA historically report their "best estimate" of the risk to workers exposed to a health hazard. This is typically an estimate that the agencies refer to as a "maximum likelihood" estimate (MLE) derived from using the statistical method of maximum likelihood estimation to fit a mathematical exposure-response curve to dose-response data. The agencies also typically report statistical upper and lower limits of their estimates of the MLE of risk.<sup>26</sup> Risk characterizations identify inherent uncertainties associated with estimates of risk. When a quantitative characterization of risk is provided, a range of plausible risk estimates is provided. Quantitative uncertainty analysis, sensitivity analysis, and a discussion of model uncertainty are utilized when possible. In addition, the Department is usually faced with a range of choices on assumptions and inputs used in dose-response models because risk assessments are typically conducted with limited amounts of data. Thus, some assumptions must be made to predict the effects of exposure to toxins or hazardous chemicals. The Supreme Court has confirmed that OSHA, "is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection."<sup>27</sup> The decision to adopt a particular assumption over another must always be rational, transparent and fully articulated to both risk managers and the public. The risk characterization is currently published by the Department in the "Significance of Risk" section of the preamble and the "Benefits" chapter of the Economic Analysis that accompanies proposed and final rules.

Once a risk assessment is complete, the agencies then turn to reduction of the identified risk through risk management. For the purposes of this rulemaking, "risk management" is defined as policy decision-making that applies the findings of risk assessment within statutory and other legal parameters to reduce, control or mitigate health hazards. The Supreme Court has interpreted the OSH Act to require that the Department find there is a "significant risk" that can be eliminated or lessened by a change in practices before promulgating any health

<sup>26</sup> See for example, Hexavalent Chromium rule 39 FR 10195 (February 28, 2006).

<sup>27</sup> *Industrial Union Dept. v. American Petroleum Inst.*, 448 U.S. 607, 656, 100 S.Ct. 2844, 2871 (1980).

standard.<sup>28</sup> “Significant risk” was not, however, defined by the Court. Instead the Court deemed it to be the agency’s, “responsibility to determine, in the first instance, what it considers to be a ‘significant’ risk.”<sup>29</sup> In a later case, the Supreme Court held that a cost-benefit analysis by OSHA is not required by the statute because a feasibility analysis is instead.<sup>30</sup> The Court explained that, “Congress itself defined the basic relationship between costs and benefits, by placing the ‘benefit’ of worker health above all other considerations save those making attainment of this ‘benefit’ unachievable.”<sup>31</sup>

Risk management integrates risk characterization results with Department policies and directives, and other information to assess policy options and recommend regulatory action. This may include consideration of both positive and negative studies, in light of each study’s technical quality. The scientific community continues to develop techniques for weight of evidence evaluations, and DOL risk assessors and managers should make every effort to keep apprised of developments and recommended best practices.

### C. Best Available Evidence: DOL’s Internal Guidance on Information Quality

As mentioned previously, the Department currently has internal guidance on information quality that seeks to assure that the best available evidence and most up to date scientific information is used in setting health standards to protect American workers. In the 1996 Amendments to the Safe Drinking Water Act (SDWA Amendments), Congress emphasized that risk analyses under the SDWA should be based upon the best available scientific methodologies, information, data, and weight of the available scientific evidence.<sup>32</sup> The Department later adopted those principles for its health and safety risk analyses in accordance with the requirements of OMB’s Government-wide Information Quality Guidelines.

The Department’s internal Information Quality Guidelines mandate that:

1. In taking agency actions that are based on the use of science in the analysis of health risks, the agency shall use:

a. The best available peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and

b. Data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justify use of the data), including:

i. Exposure data such as that generated by enforcement activity, contained in published literature, and submitted to the rulemaking record; and

ii. Testimony and comment from experts familiar with the underlying scientific information related to the risk analysis and other relevant information in the rulemaking record.

2. In the dissemination of public information about risks, the agency shall ensure that the presentation of information about risk effects is comprehensive, informative, and understandable, within the context of its intended purpose.

3. In a quantitative analysis of health risks made available to the public, the agency shall specify, to the extent practicable:

a. Each population addressed by any estimate of public health effects;

b. The expected risk or central estimate of risk for the specific populations;

c. Each appropriate upper-bound or lower-bound estimate of risk;

d. Each significant uncertainty identified in the assessment of public health effects and studies that would assist in resolving the uncertainty; and

e. Information, data, or studies, peer-reviewed where available, known to the agency that support, are directly relevant to, or fail to support any estimate of risk effects and a discussion that reconciles inconsistencies in the data or information, and explains the rationale used by the agency to rely on the data or information used for the risk analysis.

During the course of rulemaking, OSHA and MSHA consider and address data, expert testimony, and public comments pointing out uncertainties in the risk assessment and conflicting scientific evidence. The agencies present their reasons for accepting certain studies or data, rejecting others, and reconcile apparent discrepancies or conflicts in the available data to the extent possible. The Department strives to obtain the best available evidence in all key assumptions and defaults underlying its risk assessments, but the use of assumptions is invariably necessary if information is lacking. For example, the Department identifies all industry sectors where employees may be potentially exposed to the substance

of interest and uses the best available data, combined with reasonable assumptions to fill data gaps, to characterize current exposures by industry and job title, and the frequency, intensity and duration of exposure to workers.<sup>33</sup>

The Department’s internal Information Quality Guidelines are consistent with the principles of the OMB/OSTP 2007 Memorandum on Updated Principles for Risk Analysis. The agency also complies with OMB’s Government-wide Information Quality Bulletin for Peer Review, which requires the peer review of important scientific information before dissemination or use by qualified, independent specialists or scientists who were not involved in producing the product under review. The Department posts on its Web site a public agenda of peer review plans for all planned and ongoing influential scientific information,<sup>34</sup> and submits an annual report to OMB summarizing the peer reviews conducted by the agency during the previous fiscal year.

### D. The Department’s Proposals for Comment

The Department requests public comment on the following proposals:

ANPRM: Casting a Wide Net for the Best Available Data

The Department believes that any health rulemaking should involve the open and vigorous exchange of information and ideas among technical experts in the relevant disciplines, policy makers, and the public. In light of the OSH Act’s and Mine Act’s mandates that the Secretary set health standards based on the best scientific information available at the time of the agency action, it is particularly important that the Department seek out and receive all relevant data before proposing a health standard. Therefore, the Department is proposing that when developing a health standard regulating occupational exposure to a toxic substance or hazardous chemical, its agencies shall issue an Advance Notice of Proposed Rulemaking (ANPRM) soliciting public input on studies,

<sup>33</sup> DOL has previously solicited information regarding the duration of employment in various occupational groups when proposing to regulate occupational exposure to tuberculosis. See 62 FR 54,160, 54,193 (October 17, 1997). (Later withdrawn for unrelated reasons. 68 FR 75767 (December 31, 2003)). In the Hexavalent Chromium rulemaking, a 20 year working life was selected as another reasonable assumption to illustrate the effect of exposure duration on risk, 71 FR 10,100, 10,224 (February 28, 2006), and the Asbestos rule presented risk estimates for 1, 20 and 45 year durations. 51 FR 22,612, 22,644 (June 20, 1986).

<sup>34</sup> <http://www.dol.gov/asp/peer-review/index.htm>.

<sup>28</sup> *Id.* at 614–15.

<sup>29</sup> *Id.* at 655.

<sup>30</sup> See, *American Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 509, 101 S.Ct. 2478, 2490–91 (1981).

<sup>31</sup> *Id.*

<sup>32</sup> 42 U.S.C. 300g–1(b)(3)(A) and (B) (2000).

scientific information, data describing the frequency, intensity and duration of exposure of workers in the affected industries and occupations, key default factors and assumptions, and other relevant information, prior to issuing a Notice of Proposed Rulemaking (NPRM) or other regulatory action in that health rulemaking. The Department's agencies shall publish an ANPRM except when issuing emergency temporary standards under section 6(c) of the OSH Act, 29 U.S.C. 655(c) or section 101(b)(1) of the Mine Act, 30 U.S.C. 811(b)(1).

Any public comments received in response to the ANPRM shall be reviewed by the agencies, and the strength or weakness of any data received shall be carefully evaluated by agency scientists and experts in the same manner that comments in response to an NPRM are reviewed. The Department expects that the publication of the ANPRM, collection of public comments, and review will occur simultaneously with the ordinary development of the standard in order to ensure that the rulemaking process is not delayed or slowed. For instance, publication of the ANPRM could occur soon after the proposed standard is placed on the regulatory agenda which is the period of time when the agency would typically be gathering information related to the proposed rulemaking, or concurrently with the Small Business Regulatory Enforcement Fairness Act (SBREFA)<sup>35</sup> process. Finally, it should be noted that using an ANPRM to gather public information at the beginning of the development of a health standard is not a new procedure for the Department. DOL has issued an ANPRM in at least half of the health standards regulating exposure to toxins that have been promulgated over the last two Administrations, including the last three standards issued, Hexavalent Chromium in 2006,<sup>36</sup> Methylene Chloride in 1997,<sup>37</sup> and Butadiene in 1996.<sup>38</sup> The Department believes the risk assessment and rulemaking process will be strengthened by consistent opportunities for public input through an ANPRM.

#### Electronic Posting of Rulemaking Information

Transparency and easy public access to all rulemaking information is a key principle of this rulemaking and also consistent with the existing DOL and OMB guidelines. Accordingly, the Department proposes to electronically

post together in an easily accessible and well-organized format on <http://www.regulations.gov> and/or <http://www.dol.gov>, all relevant documents related to a rulemaking addressing occupational exposure to toxic substances and hazardous chemicals no later than fourteen days after the conclusion of the relevant rulemaking step that relied upon or utilized those documents. Those rulemaking steps would include but are not limited to: publication of the ANPRM, conclusion of the SBREFA process, publication of the NPRM, conclusion of any public hearing under the OSH Act and Mine Act, and the publication of the Final Rule. The documents to be posted would include but are not limited to: any underlying scientific studies relied upon in the rulemaking, to the extent possible given copyright limitations; all risk assessment analyses underlying the NPRM and Final Rule; the text of the ANPRM; SBREFA process documents; the text of the NPRM; all public hearing transcripts and briefs; all public comments; the final docket of the rulemaking; and the text of the Final Rule. This transparency requirement will move the Department closer to the EPA approach of providing all applicable documents in the rulemaking docket, and enhance public access to agency information.

#### Conclusion

The Department invites comment from the public on two proposed procedural requirements: (1) To issue an ANPRM seeking public input on key data and assumptions when developing a health standard; and (2) to electronically post all relevant documents after each regulatory step in a health rulemaking.

We encourage the submission of comments and other relevant information to the Federal eRulemaking Portal at <http://www.regulations.gov> or to the Office of the Assistant Secretary for Policy in accordance with the instructions provided above.

#### Executive Order 12866

This rule has been drafted and reviewed in accordance with Executive Order 12866, section 1(b), Principles of Regulations. The agency has determined that this rule is not a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review. Accordingly, there is no requirement for an assessment of potential costs and benefits under section 6(a)(3) of that order.

#### Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule under section 553(b) of the Administrative Procedure Act (APA), the requirements of the Regulatory Flexibility Act (5 U.S.C. 601) pertaining to regulatory flexibility do not apply to this rule. See 5 U.S.C. 601(2).

#### Paperwork Reduction Act

This rule is not subject to section 350(h) of the Paperwork Reduction Act (44 U.S.C. 3501) since it does not contain any new collection of information requirements.

#### Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not classified as a "rule" under Chapter 8 of the Small Business Regulatory Enforcement Fairness Act of 1996, because it is a rule pertaining to agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties. See 5 U.S.C. 804(3)(C).

#### List of Subjects in 29 CFR Part 2

Administrative practice and procedure, Claims, Courts, Government employees.

For the reasons outlined in the preamble, the Department of Labor proposes to amend 29 CFR part 2 as follows:

#### PART 2—GENERAL REGULATIONS

1. The authority citation for part 2 continues to read as follows:

**Authority:** 5 U.S.C. 301; Executive Order 13198, 66 FR 8497, 3 CFR 2001 Comp., p. 750; Executive Order 13279, 67 FR 77141, 3 CFR 2002 Comp., p. 258.

2. Add § 2.9 to subpart A to read as follows:

#### § 2.9 Assessment of Occupational Health Risks.

(a) *Purpose.* These provisions apply to risk assessments prepared by DOL agencies and to risk assessments prepared by others, for use by DOL, in relation to the development of health standards. Risk assessments for the development of health standards addressing toxic substances and hazardous chemicals shall be prepared in the following manner.

(b) *Definition. Significant risk.* The Department shall find, as a threshold matter, that there is a significant risk that can be eliminated or lessened by a change in practices before promulgating a health standard pursuant to the Occupational Safety and Health Act.

(c) *Risk assessments overview.*

<sup>35</sup> 5 U.S.C. 609(b).

<sup>36</sup> 71 FR 10,100 (February 28, 2006).

<sup>37</sup> 62 FR 1,493 (January 10, 1997).

<sup>38</sup> 61 FR 56,746 (November 4, 1996).

(1) Department agencies shall issue an Advance Notice of Proposed Rulemaking (ANPRM) soliciting public input on relevant studies and scientific information, data regarding the frequency, intensity, duration and other parameters of worker exposure in the affected industries, occupations and activities, key default factors and assumptions, and other relevant information related to the development of a health standard regulating occupational exposure to a particular toxic substance or hazardous chemical prior to issuing a Notice of Proposed Rulemaking (NPRM) or other regulatory action in that health rulemaking, except when promulgating an emergency temporary standard under section 6(c) of the OSH Act, 29 U.S.C. 655(c) (2000) or section 101(b)(1) of the Mine Act, 30 U.S.C. 811(b)(1) (2000).

(2) In its risk assessments, the Department's agencies shall identify and discuss key issues including, but not limited to, the reliability of data, significant uncertainties, choice of assumptions and default factors, and shall address all related comments from the public and peer reviewers in the subsequent Notice of Proposed Rulemaking (NPRM) and Final Rule.

(3) Risk assessments shall utilize the best available evidence, and the latest available scientific data in the field, including industry-by-industry evidence relating to working life exposures.

(4) Department risk assessments shall include and identify the following four components:

(i) *Hazard identification.* The hazard identification step examines whether a substance or chemical is a health hazard;

(ii) *Dose-response assessment.* The dose response assessment step examines the relationship between exposure to a hazardous substance and an adverse health outcome;

(iii) *Exposure assessment.* The exposure assessment step estimates exposure to the hazardous substance in the workplace;

(iv) *Risk characterization.* The risk characterization step provides estimates of risk to workers from occupational exposure scenarios of interest. The risk characterization also summarizes the key findings and discusses the limitations of the data, the choice of assumptions, the inherent uncertainties associated with the estimates of risk, limitations of the database, and how these factors impact the risk assessment.

(5) *Information quality and peer review.* Risk assessments shall be performed in accordance with Office of Management and Budget's (OMB) and

the Department's information quality and peer review guidelines.

(d) *Public access to rulemaking information.*

(1) The Department shall post together in an easily accessible and well organized format on <http://www.regulations.gov>, all relevant documents related to any rulemaking addressing occupational exposure to toxic substances and hazardous chemicals no later than fourteen days after the conclusion of the relevant step in the rulemaking process, including but not limited to publication of the ANPRM, conclusion of the Small Business Regulatory Fairness Act (SBREFA) process, publication of the NPRM, conclusion of any public hearing and the publication of the Final Rule.

(2) The documents posted shall include but are not limited to any underlying scientific studies relied upon in the rulemaking, to the extent possible given copyright limitations; all risk assessment analyses underlying the NPRM and Final Rule; the text of the ANPRM; SBREFA process documents; the text of the NPRM; all public hearing transcripts and briefs; all public comments; the final docket of the rulemaking; and the text of the Final Rule.

Signed at Washington, DC, this 26th day of August 2008.

**Leon R. Sequeira,**

*Assistant Secretary for Policy.*

[FR Doc. E8-20179 Filed 8-28-08; 8:45 am]

**BILLING CODE 4510-23-P**

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## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

#### 30 CFR Part 946

[VA-126-FOR; Docket ID OSM-2008-0012]

#### Virginia Regulatory Program

**AGENCY:** Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

**ACTION:** Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

**SUMMARY:** We are announcing receipt of a proposed amendment to the Virginia regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The amendment revises the Virginia Coal Surface Mining Reclamation Regulations pertaining to ownership and control, valid existing rights, self-bonding, and availability of records.

Virginia intends to revise its program to be consistent with the corresponding Federal regulations and SMCRA and is responding, in part, to 30 CFR Part 732 letters.

This document gives the times and locations that the Virginia program and this submittal are available for your inspection, the comment period during which you may submit written comments, and the procedures that we will follow for the public hearing, if one is requested.

**DATES:** We will accept written comments until 4 p.m., local time, September 29, 2008. If requested, we will hold a public hearing on September 23, 2008. We will accept requests to speak until 4 p.m., e.s.t., on September 15, 2008.

**ADDRESSES:** You may submit comments, identified by "VA-126-FOR/OSM-2008-0012" by any of the following methods:

- *E-mail:* [ebandy@osmre.gov](mailto:ebandy@osmre.gov).
- *Mail/Hand Delivery:* Earl Bandy, Knoxville Field Office, Office of Surface Mining Reclamation and Enforcement, 710 Locust Street, 2nd Floor, Knoxville, Tennessee 37902, Telephone: (865) 545-4103.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. The proposed rule has been assigned Docket ID OSM-2008-0012. If you would like to submit comments through the Federal eRulemaking Portal, go to <http://www.regulations.gov> and do the following. Click on the "Advanced Docket Search" button on the right side of the screen. Type in the Docket ID OSM-2008-0012 and click the "Submit" button at the bottom of the page. The next screen will display the Docket Search Results for the rulemaking. If you click on OSM-2008-0012, you can view the proposed rule and submit a comment. You can also view supporting material and any comments submitted by others.

*Instructions:* All submissions received must include the agency docket number "OSM-2008-0012/VA-126-FOR" for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Comment Procedures" section in this document. You may also request to speak at a public hearing by any of the methods listed above or by contacting the individual listed under **FOR FURTHER INFORMATION CONTACT**.

*Docket:* You may review copies of the Virginia program, this submission, a listing of any scheduled public hearings, and all written comments received in response to this document at OSM's