Policy and Procedures for ADSO* Review of NIOSH Publications

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*Office of the Associate Director for Science

Department of Health and Human Services
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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Replaces:

Policy and Procedures for Document Review by the Office of the Director: A Manual for NIOSH Document Development (NIOSH OD Document Review Manual); Issued: 06/01/06; Updated: 04/16/07, 06/08/07

NIOSH Good Guidance Practices: Interim Supplemental Procedures for Document Review by the Office of the Director; Issued: 02/12/08

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Acronyms and Abbreviations

ADS	Associate Director for Science
ADSO	Office of the Associate Director for Science
CDC	Centers for Disease Control and Prevention
DART	Division of Applied Research and Technology
DLO	Division, Laboratory, and Office
EID	Education and Information Division
FACE	Fatality Assessment and Control Evaluation
FRN	Federal Register Notice
GGP	Good Guidance Practices
HHE	Health Hazard Evaluation
HHS	Department of Health and Human Services
HISA	Highly Influential Scientific Assessment
ISI	Influential Scientific Information
MMWR	Morbidity and Mortality Weekly Report
NIOSH	National Institute for Occupational Safety and Health
NORA	National Occupational Research Agenda
OD	Office of the Director
OHC	Office of Health Communications
OMB	Office of Management and Budget
PEERA	Peer Review Agenda
REL	Recommended Exposure Limit
TCM	Topic Concept Memo

Table of Contents

I. Introduction

Purpose

This document[1] provides guidance on policies and procedures for scientific review of NIOSH publications by the Office of the Associate Director for Science (ADSO), Office of the Director (OD), NIOSH. The terms *NIOSH document, NIOSH publication,* and *NIOSH scientific information product* are used interchangeably in this document to refer to any scientific information product, regardless of format, that is officially distributed by NIOSH and is not exempt from OD review.

Audience

This document is intended to be a resource primarily for authors and others in the NIOSH Divisions, Laboratories, and Offices (DLOs) who are developing publications that require review by the ADSO. It also may be useful as a best practices resource for NIOSH authors developing other scientific information products.

Role of the Office of the Associate Director for Science[2]

Procedures to review the quality, objectivity, utility, and integrity of scientific information disseminated by NIOSH are the responsibility of the Director, NIOSH, and have been delegated to the ADSO.

When reviewing NIOSH publications, the Associate Director for Science (ADS) is responsible for ensuring they meet scientific information quality standards as required by the Office of Management and Budget (OMB), the Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), and NIOSH. Senior Scientists in the ADSO are charged with conducting these scientific information quality reviews, an instrumental part of achieving a larger NIOSH goal of scientific quality.

Content

This document includes information on the types of publications the OD reviews and the criteria and process used for the ADSO review during document development. The content of this document is organized into the following sections:

- Section II: Publications Reviewed by the Office of the Director. This section provides information on which publications require and which are exempted from OD review.
- Section III: Planning for Peer, Stakeholder, and Public Review. This section provides information to assist authors with anticipating review issues affecting publication development, such as required levels of peer, stakeholder, and public review.
- Section IV: Internal and External Review of NIOSH Publications. This section explains what to expect during internal and external review of NIOSH publications, documenting responses to reviewer comments, and making revisions to address reviewer comments.

[1] Supersedes and merges Policy and Procedures for Document Review by the Office of the Director and NIOSH Good Guidance Practices: Interim Supplemental Procedures for Document Review by the Office of the Director.

[2] Director's Memorandum on NIOSH Scientific Information Quality Review, March 18, 2005 (see Appendix A).

II. Publications Reviewed by the Office of the Director

Publications Exempted From OD Review and Clearance

The OD reviews all scientific information products by NIOSH authors, except those on the following list:

1. Fire fighter fatality investigation reports.

2. Fatality Assessment and Control Evaluation (FACE) investigation reports.

3. Individual worker notification products for epidemiologic studies.

4. Health Hazard Evaluation (HHE) reports (42 CFR Part 85) and site visit reports (42 CFR Part 85A), unless they contain policy positions or raise national media interest.

5. Division of Applied Research and Technology (DART) engineering survey reports, unless they contain policy positions or raise national media interest.

6. Journal articles, book chapters, articles in conference proceedings, unless they contain policy positions, raise national media interest, are authored by a DLO Director, or raise concerns of dual use research (note that journal articles are subject to DLO approval processes) [3,4].

7. Individual presentations, (e.g. speeches, PowerPoint, or talking points) and abstracts unless they involve terrorism related topics, contain policy positions, raise national media interest, or raise concerns of dual use research (note that presentations and abstracts are subject to DLO approval processes) [3,4].

All other scientific information products must be submitted for NIOSH OD review and clearance. All publications sent to the OD for review and clearance should be submitted through Documentum (see Scientific Information Products).

Publications Requiring OD Review

Examples of NIOSH publications that require review and clearance by the OD include:

- Any product that recommends a new Recommended Exposure Limit (REL)
- Criteria Documents
- Alerts
- Current Intelligence Bulletins
- Manual of Analytical Methods
- Pocket Guide to Chemical Hazards
- Bibliographies, Anthologies, and Research Compendia
- Conference Proceedings (entire volume)
- Fact Sheets, Brochures, Pamphlets, and Newsletters
- Mining Information Circulars
- Morbidity and Mortality Weekly Report (MMWR) articles
- National Occupational Research Agenda (NORA) Reports
- Mining Reports of Investigation
- Statistical Reports (e.g. surveillance)
- Technical Reports
- Training Materials
- Web Pages
- Workplace Solutions

No Change in Policy for Publications Reviewed by DLOs

A large number of publications, such as most journal articles, book chapters, articles in conference proceedings, presentations, and abstracts, currently are reviewed and cleared at the DLO level. DLOs have the primary responsibility to conduct scientific review of publications exempted from OD review, according to the list above, to ensure scientific quality. DLOs continue to be responsible for determining whether publications in these categories require interagency cross-clearance or cross-clearance from other Coordinating

[3] Disseminating scientific information that is not an official agency position, sharing draft scientific information confidentially with colleagues, or disseminating scientific information for the purposes of peer review may require the use of a disclaimer (see NIOSH Policy on the Use of Disclaimers for Scientific Information Products).

[4] The ADSO coordinates the review of dual use research for NIOSH, in order to meet CDC requirements (see Oversight and Clearance of Dual Use Research of Concern).

Centers, Coordinating Offices, or National Centers within CDC. There also is no change in DLO responsibility to determine whether publications require OD review and clearance because they contain policy positions or sensitive issues such as those that generate Congressional and media interest or raise concerns about dual use research.

III. Planning for Peer, Stakeholder, and Public Review

The terms *peer review, stakeholder review,* and *public review* refer to distinct processes that serve different purposes.

Peer reviewers assess the scientific and technical quality of publications, make recommendations for improvement, or identify areas where scientific uncertainties should be addressed more fully. Choose peer reviewers for their technical and scientific expertise, independence, and freedom from conflicts of interest.

Stakeholder reviewers provide crucial feedback on how the document will be accepted by the parties impacted by its publication. Choose stakeholder reviewers for their vested interest in the publication as NIOSH customers, including employers, employees, and others such as product manufacturers or impacted government agencies. Stakeholder reviewers may or may not be technical experts.

Peer review frequently is conducted in parallel with stakeholder review. In some cases, it may be desirable to conduct peer review prior to stakeholder review so that stakeholders receive the most accurate technical information possible.

Public review allows an opportunity for the general public to provide comments and suggestions on NIOSH publications of interest to them. This process often captures additional stakeholder viewpoints and ensures transparency in the development of NIOSH publications.

Initial Review Plan

Prior to initiating publication development, a Topic Concept Memo (TCM) must be written and approved by the NIOSH Leadership Team (see Policy and Guidance for Developing the Topic Concept Memo). The TCM provides an opportunity for authors to develop an initial plan for peer, stakeholder, and public review of their publication. The TCM requires a brief description of the anticipated internal and external review process and the names and affiliations of proposed peer and stakeholder reviewers. If specific individuals cannot be named, list the organizations from which peer and stakeholder reviewers will be drawn (e.g. academia, employer groups, or labor organizations). The plan may be updated when the publication is submitted for OD review prior to external review.

Internal Peer Reviewers

Identify NIOSH staff knowledgeable about the subject to review the draft publication prior to first submission to the OD for ADSO review. Internal reviewers assess technical accuracy, content format, comprehensibility, completeness of references, and scientific interpretation of data. Policies for internal review are established by each DLO. The ADSO relies on comments by internal reviewers, and the responses to those comments by the authors, to certify the scientific and technical quality of the publication.

External Peer and Stakeholder Reviewers

Choose external peer and stakeholder reviewers according to the level of sensitivity and complexity of the publication. Anyone outside of NIOSH is considered an external reviewer, including staff from another CDC center or office. *External peer review and stakeholder review are required for most publications reviewed by the NIOSH OD.* The ADSO relies on comments by external reviewers and the authors' responses to those comments to certify the scientific and technical quality of the publication, as well as the soundness of any scientific policy statements.

An exception to external peer review may be made if the scientific information and conclusions have been peer reviewed previously (for an example, see Clearance of Workplace Solutions Documents). In this case the publication only requires stakeholder review to ensure that the material is appropriate for its intended audience.

External Peer Review Process

Determine the appropriate level of peer review based on the complexity and sensitivity of the science. Publications undergo more extensive review if they are complex, include novel or controversial methods or interpretations, or are likely to have a significant impact on stakeholders. The OMB *Peer Review Bulletin*

and *Good Guidance Practices Bulletin* contain specific requirements for external peer review.

All NIOSH publications classified as *Influential Scientific Information (ISI)* must meet OMB requirements described in the Final Information Quality Bulletin for Peer Review or *Peer Review Bulletin* (see page 11 and Appendices B and C). There are additional public participation requirements for documents classified as *Highly Influential Scientific Assessments* (HISAs) (see pages 13-18 and Appendix B and C). During review, the ADSO will assess whether NIOSH publications classified as ISI or HISA meet the requirements of the *Peer Review Bulletin*.

Peer Reviewer Criteria

Select peer reviewers for their scientific expertise but give additional consideration to conflicts of interest and impartiality. At a minimum, two peer reviewers are used. Additional peer reviewers are selected for HISAs and other complex or high-profile publications. The National Academies criteria for selection of committee members provide a useful guide for selecting external peer reviewers (www.nationalacademies.org/coi/index.html).

- ***Expertise***: Choose peer reviewers to ensure that the full range of scientific disciplines related to the publication is represented. For publications containing potentially controversial scientific approaches, multiple reviewers are selected with expertise in the controversial areas. For publications containing detailed statistical analyses, at least one reviewer is selected with expertise in statistical methodology.
- ***Balance***: Select reviewers to represent a balanced range of scientific opinions. This is especially important for publications containing potentially controversial scientific conclusions.
- ***Independence***: Select reviewers with no prior involvement with the publication being reviewed who are outside of CDC and HHS, if possible. Avoid reviewers who currently are NIOSH contractors or recipients of funding through cooperative agreement mechanisms. NIOSH grantees, who receive funding through a competitive extramural process, are not precluded from being reviewers and often are excellent choices.
- ***Conflict of Interest***: Avoid reviewers who have financial or other conflicts that might affect their judgment. Avoid both real and perceived conflict of interest.

Stakeholder Review Process

Determine the appropriate level of stakeholder review by the likely influence of the publication on workers and industry. A minimum requirement is one stakeholder representing workers and one representing industry. For HISAs or other publications that are especially important or controversial, include more stakeholder reviewers and plan to receive public comments in an open meeting and through posting of a draft publication on the NIOSH Internet website.

Public participation is part of the external review procedures. It also satisfies the public comment requirement for publications that are revised in response to external review and contain *significant guidance* as defined by the Final Bulletin for Agency Good Guidance Practices, or *Good Guidance Practices Bulletin* (see pages 13-18 and Appendices B and D). During review, the ADSO will assess whether NIOSH publications classified as containing significant guidance meet the requirements of the *Good Guidance Practices Bulletin*.

Stakeholder Reviewer Criteria

Choose stakeholder reviewers to represent the range of individuals or organizations affected by the publication. Stakeholder reviewers are always external to NIOSH and, if possible, include representatives of affected industries, impacted workers, interested government agencies, and other end-users.

IV. Internal and External Review

NIOSH publications, along with supporting materials, are reviewed by the ADSO subsequent to submission to the Documentum electronic content management system. One to three OD submissions for ADSO review may be required to meet all scientific, policy, and administrative review requirements, and to provide opportunities for public comment. MMWR articles, journal articles needing policy review, journal articles needing cross-clearance, and miscellaneous reports, pamphlets, and fact sheets may require only one submission to the OD for ADSO review. Criteria Documents, Current Intelligence Bulletins, Alerts, and other major NIOSH publications require multiple submissions.

Review requirements and review process for typical publications are outlined in Table 1. As shown in Columns D and E of Table 1, there are two options for timing the solicitation of public comment for documents requiring it, either before or after external peer and stakeholder review. See Appendix E for advantages and disadvantages of each option. Subsections A through E of this Section IV (pages 8-18) describe the review sequence in detail for each document type.

The ADSO coordinates cross-clearance within CDC (see Clearance of Information Products Disseminated Outside CDC for Public Use) and cross-clearance with other federal agencies.

The ADSO also coordinates review of materials classified as Dual Use Research of Concern. Depending on the publication type, materials containing dual use research may require multiple levels of review to resolve issues of concern.

The ADSO review sequence usually is the same for each submission:

1. The ADS or Deputy ADS accepts the submission and assigns the document to a Senior Scientist.
2. The Senior Scientist performs a review for science quality, policy, and communication according to the ADSO Review Worksheet (see Appendices F and G). The Senior Scientist then recommends approval, with or without changes, or revision and resubmission.
3. The Senior Scientist may work directly with the author or lead DLO on revisions.
4. Following Senior Scientist review, the ADS or Deputy ADS provides a similar review, highlighting points raised by the Senior Scientist, and makes the final ADSO recommendation.
5. The ADS may provide additional recommendations for NIOSH publications that contain complex or controversial scientific policy statements or highly influential scientific information.

Table 1: NIOSH OD Review Requirements At-A-Glance

	Clearance for External Review[1] Not Required by NIOSH OD	Clearance for External Review[1] Required by NIOSH OD			
		No Public Comment		Public Comment	
	A	**B**	**C**	**D**	**E**
Comments	DLOs may require external review even when the OD does not assess it.		Covered by OMB Peer Review Bulletin	• Covered by OMB Peer Review Bulletin & Good Guidance Practices Bulletin • Public Comment Before Peer / Stakeholder Review (Option 1)[2]	• Covered by OMB Peer Review Bulletin & Good Guidance Practices Bulletin • Public Comment After Peer / Stakeholder Review (Option 2)[2]
Document Examples	• Announcements • Fact sheets • Journal articles needing policy review and/or cross clearance • Manuscripts • MMWR • NORA Council Reports • Novelty Items • Pocket Guide Updates • Pamphlets • Posters • Postcards • Slide presentations • Testimony • Web pages Others on case by case basis	• Revisions to NMAM methods • Statistical Reports • Technical Reports • Workplace Solutions Others on case by case basis	• New NMAM methods Others on case by case basis	• Alerts • Criteria Documents • Current Intelligence Bulletins • Publications with a new REL Others on case by case basis	• Alerts • Criteria Documents • Current Intelligence Bulletins • Publications with a new REL Others on case by case basis
Review Process	Initial Submission ADSO Review Cross-Clearance, if required OD Clearance External Review conducted outside of NIOSH, if required Publish	Initial Submission ADSO Review Cross-Clearance, if required OD Clearance Peer / Stakeholder Review ADSO Review OD Clearance Publish	Initial Submission ADSO Review Cross-Clearance, if required OD Clearance Peer / Stakeholder Review ADSO Review OD Clearance Publish	Initial Submission ADSO Review Cross-Clearance, if required OD Clearance Public Comment / Public Meeting Peer / Stakeholder Review ADSO Review OD Clearance Publish	Initial Submission ADSO Review Cross-Clearance, if required OD Clearance Peer / Stakeholder Review ADSO Review OD Clearance Public Comment ADSO Review OD Clearance Publish
	See Subsection A	**See Subsection B**	**See Subsection C**	**See Subsection D**	**See Subsection E**

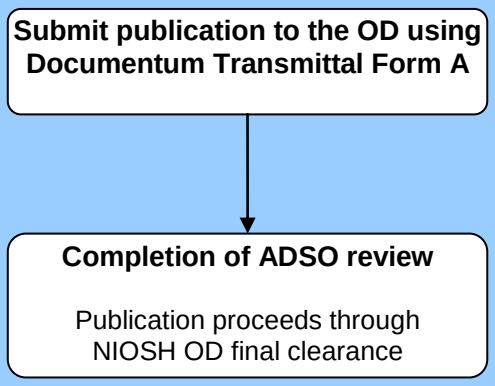
1. External review may consist of any combination of peer review, stakeholder review, and/or public comment
2. There are two options for timing the solicitation of public comment, either before or after external peer and stakeholder review. See Appendix G for advantages and disadvantages of each option.

A. Clearance for External Review is Not Required by NIOSH OD

This category of NIOSH publications generally includes:

- **MMWR articles**
- **Journal articles needing policy review**
- **Journal articles needing cross-clearance**
- **NORA Council Reports**
- **Pamphlets and fact sheets**
- **Other publications on a case-by-case basis**

Note that DLOs may require external review for certain documents even when the OD does not require it.



Submission Procedure

1. Submit Publication to the OD Using Documentum Transmittal Form A. Include:

- Cover memo from the lead author's DLO Director describing the purpose and type of review (e.g. policy, cross-clearance) and highlighting potential areas of concern.
- Documentation of internal reviewer comments and how they were addressed.
- Other items listed in Transmittal Form A.

2. Completion of ADSO Review

- After review of the materials and resolution of all science-related issues, the ADSO review is complete and the document proceeds through the OD for final clearance for publication.

B. External Review Required of *Scientific Information*

This category of NIOSH publications generally includes:

- ***Scientific Information*,** defined by the Peer Review Bulletin as any communication or representation of scientific knowledge containing factual inputs, data, models, analyses, technical information, or scientific assessments based on physical, biological, behavioral, or social sciences.

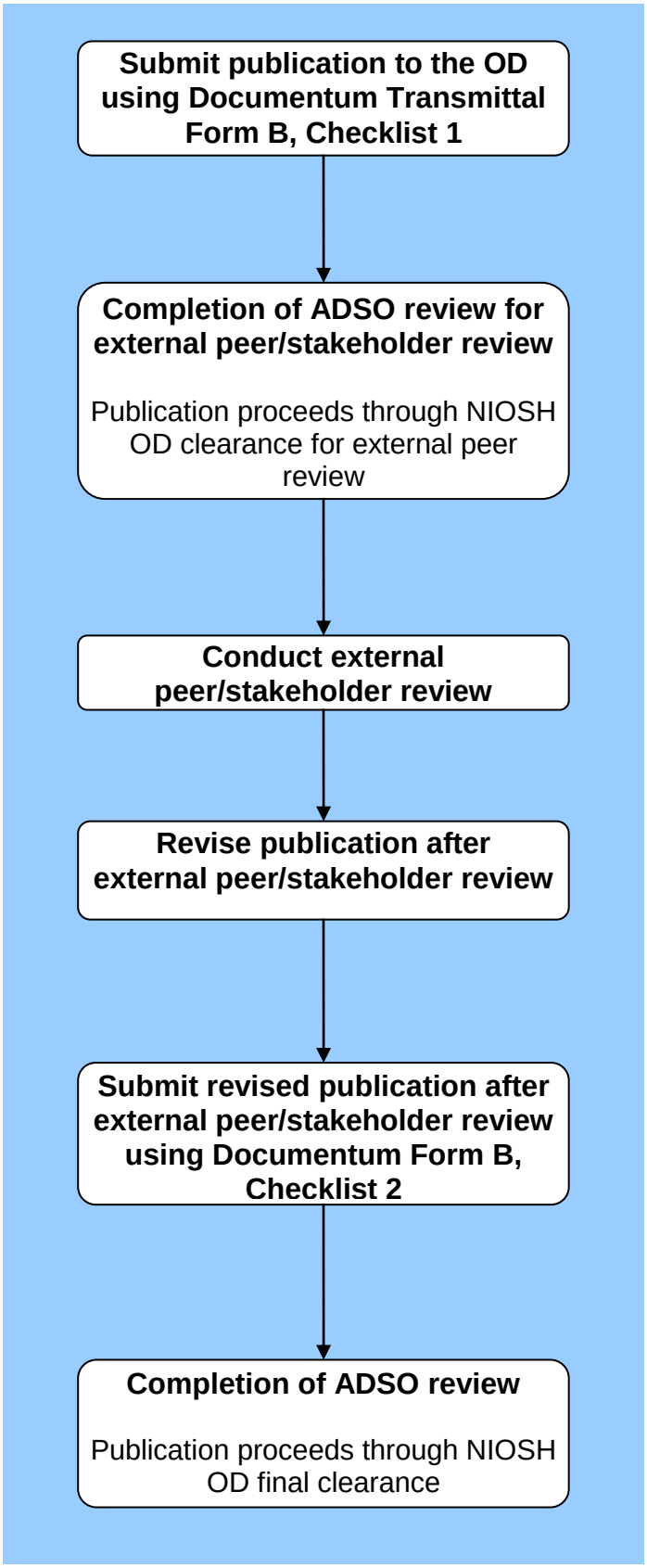
This category does not include:

- *Influential Scientific Information (ISI).* As defined by the Peer Review Bulletin, ISI is scientific information that NIOSH determines will have, or does have, a clear and substantial impact on important public policies or private sector decisions (see Appendix C).
- *Highly Influential Scientific Assessments (HISAs).* As defined by the Peer Review Bulletin, a "Scientific Assessment" is an evaluation of a body of scientific or technical knowledge which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. HISA applies to scientific assessments that NIOSH determines: (i) could have a potential impact of more than $500 million in any year, or (ii) is novel, controversial, or precedent-setting or has significant interagency interest (see Appendix C).
- *Significant Guidance*. NIOSH publications contain significant guidance if they recommend new guidelines or include new or revised Recommended Exposure Limits (see Appendix D and the Good Guidance Practices Bulletin for details).

Refer to Appendix H for a decision flowchart on the applicability of the OMB Bulletins on Peer Review and Good Guidance Practices.

Submission Procedure

1. Submit Document to the OD Prior to External Review Using Documentum Transmittal Form B, Checklist 1, and Include:



- Draft publication.
- Cover memo from the lead author's DLO Director stating:
  - Purpose and type of review (e.g. policy, cross-clearance).
  - Certification that the publication is not ISI, HISA, or significant guidance
  - Description of how the external review will be conducted (e.g. by mail or public meeting).
  - Statement whether any additional background information will be provided to reviewers.
  - Description of how reviewer comments will be handled (e.g. whether NIOSH will publicly disseminate a response to reviewer comments).
  - Potential areas of concern.
- Documentation of internal reviewer comments and how they were addressed.
- Charge to reviewers (see Appendix I).
- Other items listed in Transmittal Form B, Checklist 1.

2. Obtain OD Clearance for External Review

3. Conduct External Review

- Forward the publication and supporting materials to external reviewers following OD clearance for external review.
- For relatively straightforward and uncontroversial publications, review by regular or electronic mail usually is sufficient.

4. Revise Publication after External Review

- Incorporate relevant comments and suggestions from external reviewers into the document.
  - Make a good faith effort to incorporate comments whenever reasonable and feasible.
  - The manner in which the comments are incorporated is at the discretion of NIOSH.
  - All comments are addressed either through incorporation or by documenting reasons why they cannot be accommodated.

5. Submit Revised Publication after External Review Using Documentum Transmittal Form B, Checklist 2, and Include:

- Revised publication.
- Cover memo from the lead author's DLO Director certifying the review and accommodation of comments and highlighting potential areas of concern.
- For internal use, a comprehensive listing of all external comments and how they were addressed in a point-by-point format. Reviewer names and organizational affiliations are associated with specific comments.
- For release to the public upon request (i.e., typically not posted with unlimited access on the NIOSH Internet website):
  - A detailed response to reviewer comments (similar to the internal response), or a synopsis of reviewer comments with highlights of revisions made to the document
  - Peer reviewer names and affiliations which are not associated with specific comments
  - Stakeholder names and affiliations associated with specific comments
- Other items listed in Transmittal Form B, Checklist 2.

6. Completion of ADSO Review

- After review of the materials and resolution of all science-related issues, the ADSO review is complete and the document proceeds through the OD for final clearance for publication.

C. External Review Required of *Influential Scientific Information*

This category of NIOSH publications generally includes:

- ***Influential Scientific Information (ISI).*** As defined by the Peer Review Bulletin, ISI is scientific information that NIOSH determines will have, or does have, a clear and substantial impact on important public policies or private sector decisions (see Appendix C).

This category does not include:

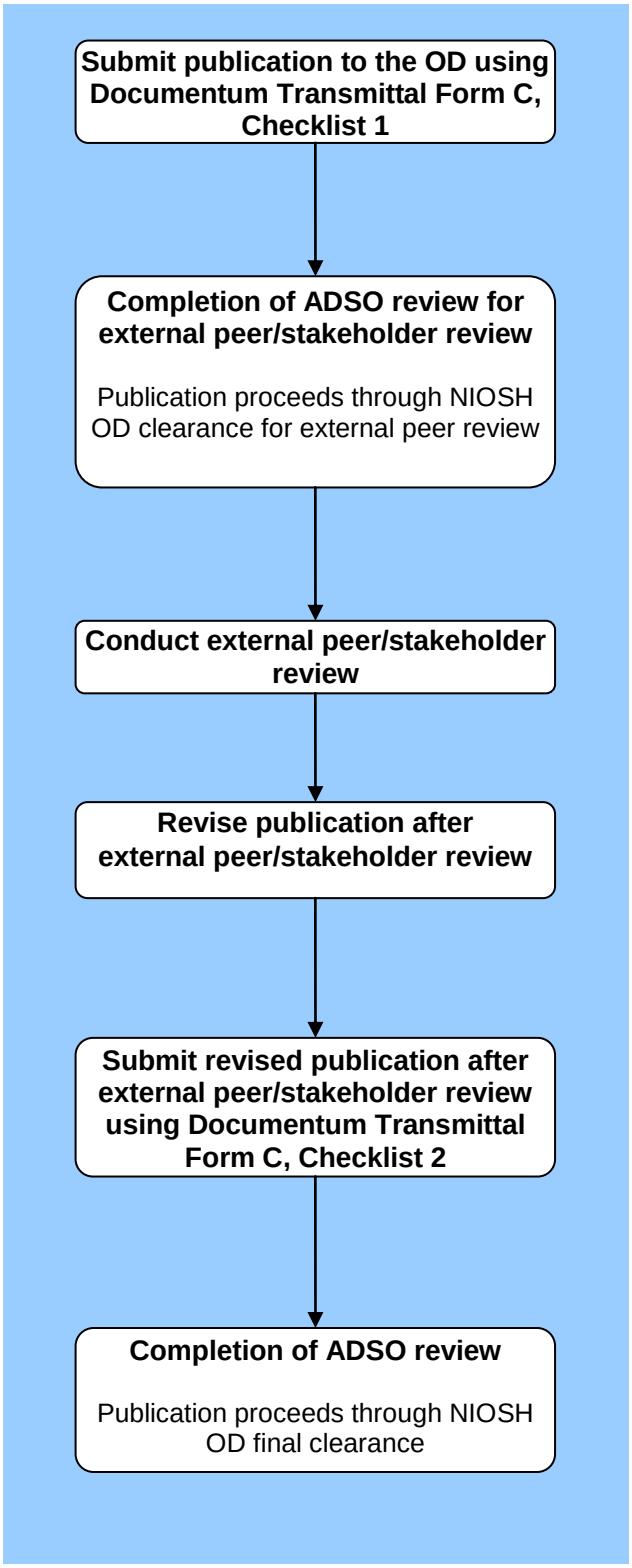
- *Highly Influential Scientific Assessments (HISAs).* As defined by the Peer Review Bulletin, a "Scientific Assessment" is an evaluation of a body of scientific or technical knowledge which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. HISA applies to scientific assessments that NIOSH determines: (i) could have a potential impact of more than $500 million in any year, or (ii) is novel, controversial, or precedent-setting or has significant interagency interest (see Appendix C).
- *Significant Guidance*. NIOSH publications contain significant guidance if they recommend new guidelines or include new or revised Recommended Exposure Limits (see Appendix D and the Good Guidance Practices Bulletin for details).

Refer to Appendix H for a decision flowchart on the applicability of the OMB Bulletins on Peer Review and Good Guidance Practices.

Submission Procedure

1. Submit Publication to the OD Prior to External Review using the Documentum Transmittal Form C, Checklist 1 and include:

- Draft publication
- Cover memo from the lead author's DLO Director stating:
  - Purpose and type of review (e.g. policy, cross-clearance).



- Certification that the publication is ISI, and is not HISA or significant guidance.
- Description of how the external review will be conducted (e.g., by mail or public meeting).
- Statement whether any additional background information will be provided to reviewers.
- Statement that NIOSH will publicly disseminate a response to reviewer comments.
- Potential areas of concern.

- Documentation of internal reviewer comments and how they were addressed.
- Charge to reviewers (see Appendix I).
- Other items listed in Documentum Transmittal Form C, Checklist 1.

2. Obtain OD Clearance for External Review

3. Conduct External Review

- Forward the publication and supporting materials to external reviewers following OD clearance for external review.
- For relatively straightforward and uncontroversial publications, review by regular or electronic mail usually is sufficient.

4. Revise Publication after External Review

- Incorporate relevant comments and suggestions from external reviewers into the publication.

  - Make a good faith effort to incorporate comments whenever reasonable and feasible.
  - The manner in which the comments are incorporated is at the discretion of NIOSH.
  - All comments are addressed either through incorporation or by documenting reasons why they cannot be accommodated.

5. Submit Revised Publication after External Review using Documentum Transmittal Form C, Checklist 2 and Include:

- Revised publication.
- Cover memo from the lead author's DLO Director certifying the review and accommodation of comments and highlighting potential areas of concern.
- For internal use, a comprehensive listing of all external comments and how they were addressed in a point-by-point format. Reviewer names and organizational affiliations are associated with specific comments.
- For release to the public upon request (i.e., typically not posted with unlimited access on the NIOSH Internet website):
  - A detailed response to reviewer comments (similar to the internal response), or a synopsis of reviewer comments with highlights of revisions made to the document.
  - Peer reviewer names and affiliations which are not associated with specific comments.
  - Stakeholder names and affiliations associated with specific comments.
- Other items listed in Documentum Transmittal Form C, Checklist 2.

6. Completion of ADSO Review

- After review of the materials and resolution of all science-related issues, the ADSO review is complete and the document proceeds through the OD for final clearance for publication.

D. External Review With Public Comment *Before* Peer Review: Option 1

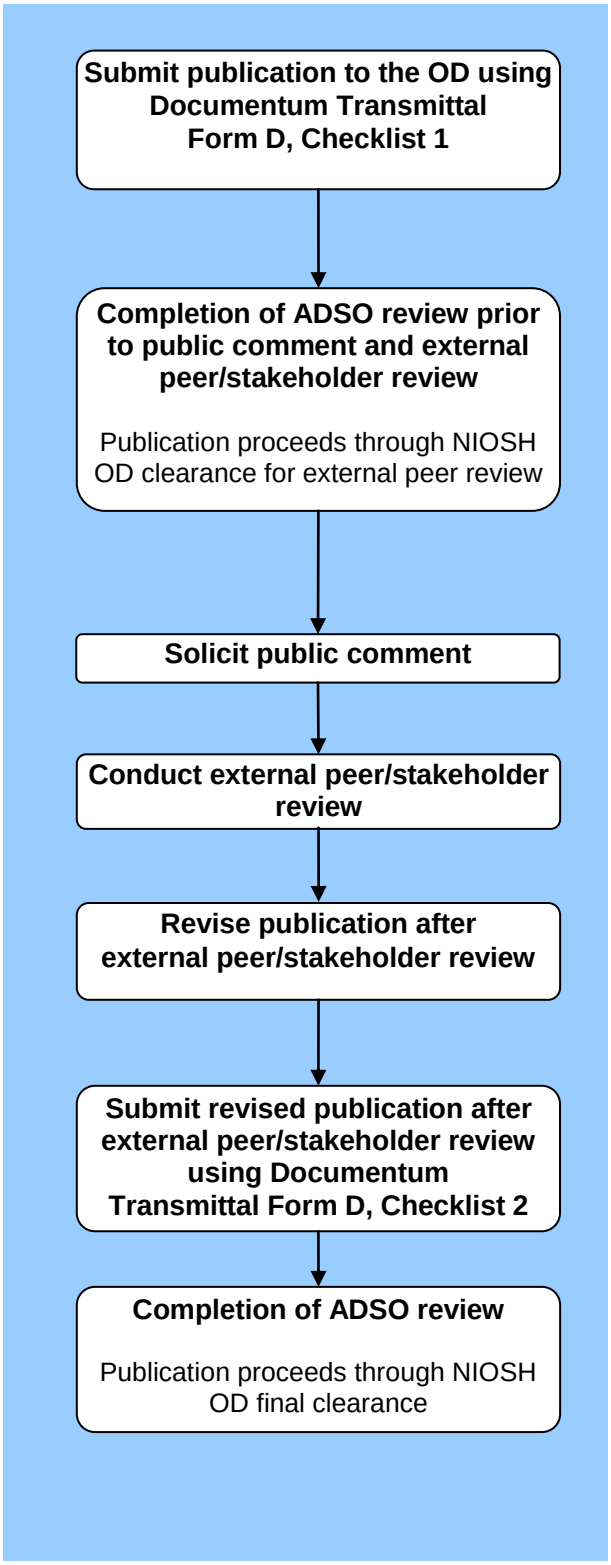
Option to Solicit Public Comment Prior to External Peer and Stakeholder Review

There are two options for timing solicitation of public comment, either before (this subsection D) or after (see subsection E) external peer and stakeholder review. See Appendix E for advantages and disadvantages of each option.

This category of NIOSH Publications includes:

- ***Influential Scientific Information (ISI)***. As defined by the Peer Review Bulletin, ISI is scientific information that NIOSH determines will have, or does have, a clear and substantial impact on important public policies or private sector decisions (see Appendix C).
- ***Highly Influential Scientific Assessments (HISAs)***. As defined by the Peer Review Bulletin, a "Scientific Assessment" is an evaluation of a body of scientific or technical knowledge which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. HISA applies to scientific assessments that NIOSH determines: (i) could have a potential impact of more than $500 million in any year, or (ii) is novel, controversial, or precedent-setting or has significant interagency interest (see Appendix C).
- ***Significant Guidance***. NIOSH publications contain significant guidance if they recommend new guidelines or include new or revised Recommended Exposure Limits (see Appendix D and the Good Guidance Practices Bulletin for details).

Refer to Appendix H for a decision flowchart on the applicability of the OMB Bulletins on Peer Review and Good Guidance Practices.



Submission Procedures

1. Submit Publication to the OD Prior to External Review using Documentum Transmittal Form D, Checklist 1 and Include:

- Draft publication
- Cover memo from the lead author's DLO Director stating:
  - Purpose and type of review (e.g. policy, cross-clearance).
  - Statement whether the publication is ISI or HISA.
  - Statement whether the publication contains significant guidance.
  - The public comment and external review sequence.
  - Description whether a public meeting will be held.
  - Statement whether any additional background information will be provided to reviewers.
  - Statement that NIOSH will publicly disseminate a response to reviewer comments.
  - Potential areas of concern.
- Documentation of internal reviewer comments and how they were addressed
- Charge to reviewers (see Appendix I).
- Advance HHS notification of the intent to request public comments on the draft publication (see Appendices J and K).
- Draft Federal Register notice (FRN) inviting the public to comment on the draft publication (see Appendices M and N).
- Other items listed on Documentum Transmittal Form D, Checklist 1.

2. Obtain OD Clearance for External Review

- The ADSO submits advance notification to HHS at least 5 days before release of the publication for public comment

3. Invite Public comment

- Establish an electronic docket where public comments are received and eventually made available to other members of the public (see Appendix M).
- Publish an FRN inviting the public to comment on the draft publication.
- Provide opportunities for public comment through:
  - Posting the publication on the NIOSH Internet website (always required)
  - Mailing the publication to the public (upon request)
  - Organizing a public review meeting (on a case-by-case basis). A public meeting may be useful for open discussion of complex recommendations, such as establishing a new REL

4. Summarize comments provided by the public

For brevity, organize comments according to common themes, avoiding an extensive point-by-point format.

5. Forward the publication, summary of public comments, and other supporting materials to external peer and stakeholder reviewers

6. Revise Document After External Peer and Stakeholder Review

- Incorporate relevant comments and suggestions from external peer and stakeholder reviewers and from the public.
  - Make a good faith effort to incorporate comments whenever reasonable and feasible.
  - The manner in which the comments are incorporated is at the discretion of NIOSH.
  - All comments are addressed either through incorporation or by documenting reasons why they cannot be accommodated.

7. Submit Revised Publication After External Review Using Documentum Transmittal Form D, Checklist 2 and Include:

- Revised publication.
- Cover memo from the lead author's DLO Director certifying the review and accommodation of comments and highlighting potential areas of concern.
- For internal use, a comprehensive listing of all external comments and how they were addressed in a point-by-point format. Reviewer names and organizational affiliations are associated with specific comments.
- For release to the public:
  - A detailed response to reviewer comments (similar to the internal response), or a synopsis of reviewer comments with highlights of revisions made to the document.
  - Peer reviewer names and affiliations which are not associated with specific comments.
  - Stakeholder names and affiliations associated with specific comments.

- HHS Advance Notification Form stating intent to publish (see Appendix L).
- FRN prepared announcing availability of the final publication.
- Other items listed in Documentum Transmittal Form D, Checklist 2.

8. Completion of ADSO Review

- The ADSO:
  - Reviews the final HHS Advance Notification Form (see Appendix L) prepared by lead author's DLO.
  - Provides HHS with advance notification of the intent to issue a final publication.
  - Reviews the final FRN prepared by lead author's DLO announcing final availability of the publication (see Appendices M and N).
- After review of the materials and resolution of all science-related issues, the ADSO review is complete and the document proceeds through the OD for final clearance for publication.

9. Publish the Document

- Publish the FRN announcing availability of the final publication.
- Post the publication on the NIOSH Internet website.
- Provide a link from the final publication to the peer, stakeholder, and public comments report and the NIOSH response those comments.

E. External Review With Public Comment *After* Peer Review: Option 2

Option to Conduct External Peer and Stakeholder Review Prior to Soliciting Public Comment

There are two options for timing solicitation of public comment, either before (previous subsection D) or after (this subsection E) external peer and stakeholder review. See Appendix E for advantages and disadvantages of each option.

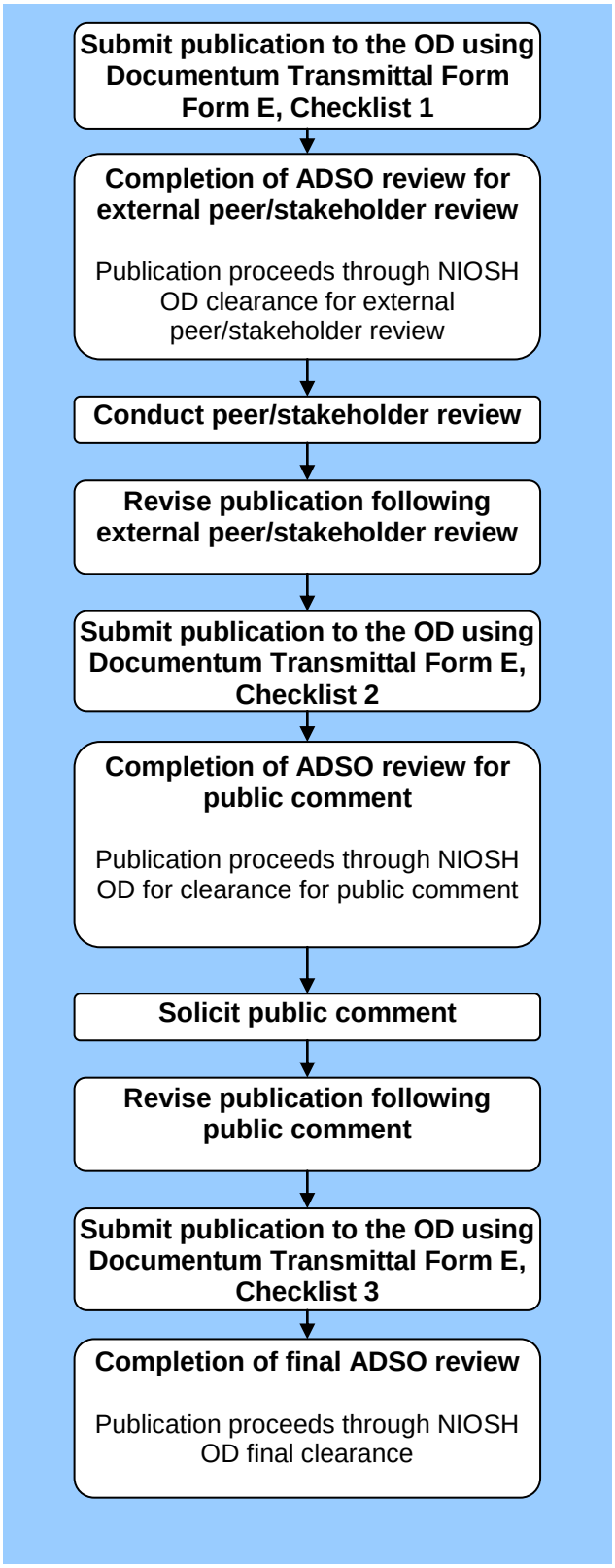
This category of NIOSH Publications includes:

- ***Influential Scientific Information (ISI)***. As defined by the Peer Review Bulletin, ISI is scientific information that NIOSH determines will have, or does have, a clear and substantial impact on important public policies or private sector decisions (see Appendix C).
- ***Highly Influential Scientific Assessments (HISAs)***. As defined by the Peer Review Bulletin, a "Scientific Assessment" is an evaluation of a body of scientific or technical knowledge which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. HISA applies to scientific assessments that NIOSH determines: (i) could have a potential impact of more than $500 million in any year, or (ii) is novel, controversial, or precedent-setting or has significant interagency interest (see Appendix C).
- ***Significant Guidance*.** NIOSH publications contain significant guidance if they recommend new guidelines or include new or revised Recommended Exposure Limits (see Appendix D and the Good Guidance Practices Bulletin for details).

Refer to Appendix H for a decision flowchart on the applicability of the OMB Bulletins on Peer Review and Good Guidance Practices.

Submission Procedures

1. Submit Publication to the OD Prior to External Review Using the Documentum, Transmittal Form E, Checklist 1 and Include:



- Draft publication
- Cover memo from the lead author's DLO Director stating:
  - Purpose and type of review (e.g. policy, cross-clearance).
  - Statement whether the publication is ISI or HISA.
  - Statement whether the publication contains significant guidance.
  - Potential areas of concern.
  - Description of the public comment and review sequence.
  - Statement whether a public meeting will be held.
  - Statement whether any additional background information will be provided to reviewers.
  - Statement that NIOSH will publicly disseminate a response to reviewer comments.
- Documentation of internal reviewer comments and how they were addressed.
- Charge to reviewers (see Appendix I).
- Other items listed in the Documentum Transmittal Form E, Checklist 1.

2. Obtain OD Clearance for External Review

3. Conduct External Peer and Stakeholder Review

- Forward the publication and supporting materials to external reviewers following OD clearance for external review.

4. Revise Publication After External Review

- Incorporate relevant comments and suggestions from external peer and stakeholder reviewers.
  - Make a good faith effort to incorporate comments whenever reasonable and feasible.
  - The manner in which the comments are incorporated is at the discretion of NIOSH.
  - All comments are addressed either through incorporation or by documenting reasons why they cannot be accommodated.

5. Submit Revised Publication After External Review Using Documentum Transmittal Form E, Checklist 2 and Include:

- Revised publication.
- Cover memo from the lead author's DLO Director certifying the review and accommodation of comments and highlighting potential areas of concern.
- For internal use, a comprehensive listing of all external comments and how they were addressed in a point-by-point format. Reviewer names and organizational affiliations are associated with specific comments..
- For release to the public:
  - A detailed response to reviewer comments (similar to the internal response), or a synopsis of reviewer comments with highlights of revisions made to the document.
  - Peer reviewer names and affiliations which are not associated with specific comments.
  - Stakeholder names and affiliations associated with specific comments.
- Advance HHS notification of the intent to request public comments on the revised publication (see Appendices K and L).
- Draft Federal Register Notice (FRN) inviting the public to comment on the draft publication (see Appendices M and N).
- Other items listed in the Documentum Transmittal Form E, Checklist 2.

6. Obtain Clearance to Post for Public Comment

- After review and resolution of issues in the revised document, the ADSO recommends posting for public comment.
- The ADSO submits advance notification to HHS no less than 5 days before release of the document for public review.

7. Invite Public Comment

- Establish an electronic docket where public comments are received and eventually made available to other members of the public (see Appendix M).
- Publish an FRN inviting the public to comment on the draft publication.
- Provide opportunities for public comment through:
  - Posting the publication on the NIOSH Internet website (always required).
  - Mailing the document to the public (upon request).

- Organizing a public review meeting (on a case-by-case basis). A public meeting may be useful for open discussion of complex recommendations, such as establishing a new REL.

8. Revise Document Following Public Comment

- Incorporate relevant comments and suggestions from the public.
  - Make a good faith effort to incorporate comments whenever reasonable and feasible.
  - The manner in which the comments are incorporated is at the discretion of NIOSH.
  - All comments are addressed either through incorporation or by documenting reasons why they cannot be accommodated.

9. Submit Revised Document After Public Comment Using the Documentum Transmittal Form E, Checklist 3 and Include:

- Revised publication.
- Cover memo from the lead author's DLO Director certifying the revised publication and accommodation of public comments and highlighting potential areas of concern.
- Comprehensive listing of all public comments and how they were addressed in a point-by-point format; names and organizational affiliations are associated with specific comments.

10. Completion of ADSO Review

- The ADSO:
  - Reviews the final HHS Advance Notification Form (see Appendix L) prepared by lead author's DLO.
  - Provides HHS with advance notification of the intent to issue a final publication.
  - Reviews the final FRN prepared by lead author's DLO announcing final publication (see Appendices M and N).
- After review of the materials and resolution of all science-related issues, the ADSO review is complete and the document proceeds through the OD for final clearance for publication.

11. Publish the Document

- Publish an FRN announcing availability of the final publication.
- Post the publication on the NIOSH Internet website.
- Provide a link from the final publication to the peer, stakeholder, and public comments reports and the NIOSH response to those comments.

List of Appendices

Appendix A. Director's Memorandum on NIOSH Scientific Information Quality Review

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date: March 18, 2005

From: Director
National Institute for Occupational Safety and Health

Subject: NIOSH Scientific Information Quality Review

To: All Division/Laboratory Directors
National Institute for Occupational Safety and Health

The Information Quality Act (2000), 44 U.S.C. §3516, requires each Federal agency to ensure the quality, objectivity, utility, and integrity of the information it disseminates.

Ensuring the quality of the information products generated by NIOSH (through printed or electronic means) is a responsibility we all share. Procedures to review the quality, objectivity, utility and integrity of the information NIOSH disseminates are the responsibility of the Director and have been delegated to the Office of the NIOSH Associate Director for Science. When reviewing any NIOSH informational product,[1] the Associate Director for Science is responsible for ensuring that all NIOSH information products meet information quality standards as required by the Office of Management and Budget,[2] the Department of Health and Human Services,[3] the Centers for Disease Control and Prevention[4] and those of the NIOSH.[5]

The job of the Associate Director for Science, and the Senior Scientists in the Washington and Atlanta OD who carry out the scientific informational product reviews, is a tough one. It is the

[1] The term "NIOSH Informational Product" does not refer to informational products produced by government-funded scientists if those informational products are not represented as the views of NIOSH. To qualify for this exemption, NIOSH scientists are required to include in their informational product a clear statement that "the findings and conclusions in this report are those of the author(s) and do not necessarily represent the views of NIOSH." See OMB, Final Peer Review Bulletin, Section I.3.

[2] Office of Management and Budget. Final Information Quality Bulletin for Peer Review. December 15, 2004. http://www.whitehouse.gov/omb/inforeg/peer2004/peer_bulletin.pdf Accessed March 11, 2005.

[3] United States Department of Health and Human Services. HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public. http://aspe.hhs.gov/infoquality/Guidelines/ Accessed March 11, 2005.

[4] United States Department of Health and Human Services. Guidelines for Ensuring the Quality of Information Disseminated to the Public. Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry. http://aspe.hhs.gov/infoquality/Guidelines/cdcinfo2.shtml Accessed March 11, 2005.

[5] NIOSH Information Products Review and Clearance Policy and Procedures. Policy and procedures are under development and are expected to be disseminated by September, 2005.

job of the Senior Scientists to review science-related information from the perspective of the world external to NIOSH. And that world has changed. Statements about science now often invite serious scrutiny. Whether part of the larger issue of the erosion of public trust in institutions and professions that in the 20th century were highly regarded, is hard to know for sure. Whatever the origin, society is concerned by any source of bias and demands the disclosure of such biases. Society now demands that its government be completely transparent and that an opportunity for comment be given in any situation where policy is being developed, even in non-rulemaking situations. Furthermore, comments provided to government must be addressed by government and a reason or reasons given for why a comment was not accepted, even in non-rulemaking situations.

Quality is one of the NIOSH's Core Values. We utilize only the best science, the highest level of data quality and the most transparent and independent peer review. I trust that each of you will understand that in order to meet the high standards we have set for ourselves, the job of the information quality reviewers--Senior Scientists in the Office of the Associate Director for Science--need both to be seen and understood as an instrumental part of achieving a larger NIOSH goal and accepted as an essential part of getting the scientific information you have generated out to a larger audience.

If NIOSH is to succeed in its mission to provide national and world leadership to prevent work-related illnesses and injuries, our science must be unimpeachable. Science that does not meet this level of quality cannot be recommended for clearance. The Office of the Associate Director for Science fulfills this important responsibility on your behalf and at my request. I trust that you will provide them with your support.

John Howard, M.D.

Appendix B. Classification of NIOSH Scientific Information Products by Applicability of Peer Review Bulletin and Good Guidance Practices Bulletin[1]

Scientific Information Product	Peer Review Bulletin	GGP Bulletin
• Any products that recommend a new REL	HISA	SG
• Criteria Documents	HISA	SG
• Alerts	ISI	SG
• Current Intelligence Bulletins	ISI	SG
• Manual of Analytical Methods (new methods or significant updates only)	ISI	
• Pocket Guide to Chemical Hazards • Bibliographies, Anthologies, and Research Compendia • Conference Proceedings • Fact Sheets, Brochures, Pamphlets, and Newsletters • Mining Information Circulars • MMWR articles • NORA Reports • Reports of Investigation • Statistical Reports (e.g. surveillance) • Technical Reports • Training Materials • Web pages • Workplace Solutions		

[1] Note that while publications are classified on a case-by-case basis, the table demonstrates how publications usually are classified. The term *publication* refers to print, electronic, or video format.

HISA – Highly influential scientific assessment **ISI** – Influential scientific information	**OMB Peer Review Bulletin** http://www.whitehouse.gov/omb/fedreg/2005/011405_peer.pdf
SG – Significant guidance	**OMB Good Guidance Practices Bulletin** http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf

Appendix C. Summary of Review Policy for Publication of Influential Scientific Information and Highly Influential Scientific Assessments

OMB has defined two special categories of influential information, ISI and HISAs. According to the Peer Review Bulletin, ISI is information that the agency expects to have a clear and substantial impact on important public policies or private sector decisions. A HISA is defined as an evaluation of a body of scientific or technical knowledge which typically synthesizes multiple factual inputs, data, models, and assumptions, and then applies best professional judgment to bridge uncertainties in the available information. A HISA meets either one of the following criteria:

- It has a potential impact of more than $500 million in any one year on either the public or private sector; or
- It is novel, controversial, or precedent-setting, or has significant interagency interest.

In general, NIOSH publications are considered ISI if they identify new hazards or recommend new guidelines. Publications are HISAs if they include new or revised RELs. Appendix B contains a table that shows the suggested classification of NIOSH publications according to Peer Review Bulletin requirements.

Appendix D: Summary of Review Policy for Significant Guidance Publications

The Good Guidance Practices Bulletin establishes technical definitions for guidance publications, significant guidance publications, and economically significant guidance publications and outlines procedures for their development and revision. The term "guidance publication" means an agency statement of general applicability and future effect, other than a regulatory action that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue. The definition of a guidance publication encompasses all guidance materials, regardless of format or title.

The Good Guidance Practices Bulletin also distinguishes between significant and economically significant guidance publications. The term "significant guidance document" means a guidance document disseminated to regulated entities or the general public that may reasonably be anticipated to:

- Lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities.

Economically significant guidance publications are a subset of significant guidance publications; they may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy or a sector of the economy. Economically significant guidance publications do not include guidance publications on federal expenditures and receipts.

Although OMB only requires public notice and an opportunity for public comment with agency feedback for economically significant guidance publications, this distinction is inconsistent with NIOSH values for scientific quality. Given the national and international impact of NIOSH activities, it is expected that the majority of NIOSH significant guidance publications will also be determined to be economically significant. Consequently, all NIOSH guidance publications that meet the OMB definition for a significant guidance publication will comply with all of the requirements for economically significant guidance publications as outlined in the Good Guidance Practices Bulletin (see NIOSH Policy on the Implementation of the OMB Final Bulletin for Agency Good Guidance Practices).

In general, NIOSH publications are considered to contain significant guidance if they recommend new guidelines or include new or revised RELs. Appendix B contains a table that shows the general classification of NIOSH publications by applicability of the Good Guidance Practices Bulletin.

Appendix E. Advantages and Disadvantages of the Relative Timing of External Review and Public Comment

	Advantages	Disadvantages
D. Option to Solicit Public Comment Prior to Conducting External Peer and Stakeholder Review	• Public comments can be shared with peer reviewers for consideration during their review. This is likely to improve the quality of the peer review. • There is no NIOSH OD clearance check-point after public comment is solicited and before external peer and stakeholder review is conducted. This might result in a shorter overall review and clearance process.	• Publications may change significantly in response to external peer review. This may draw criticism from the public. In order to avoid this, the NIOSH OD may recommend the publication receive a second round of public comment (on a case-by-case basis). • Because there is no NIOSH OD clearance check-point after public comment is solicited and before external peer and stakeholder review is conducted, important but unaddressed issues may first be discovered during the final NIOSH OD review and clearance. Addressing these issues may require significant effort and cause delays.
E. Option to Conduct External Peer and Stakeholder Review Prior to Soliciting Public Comment	• Publications revised in response to peer review are closer to their final version and therefore, the public is presented with a higher quality publication. This likely improves the public comment process. • The NIOSH OD clearance check-point after external peer and stakeholder review is conducted and before public comment is solicited provides an opportunity to identify important and unaddressed issues early. Addressing these issues will likely not require a lot of effort.	• The NIOSH OD clearance check-point after external peer and stakeholder review is conducted and before public comment is solicited might increase the overall time required for the review and clearance process. • Peer reviewers do not have access to public comments during their review process. As a result, some public comments may need further scientific clarification in order to be adequately addressed. Then, the NIOSH OD may recommend that the publication receive a second round of peer review (on a case-by-case basis).

Appendix F. ADSO Review Worksheet

I. Publication Thumbnail Sketch and Review Process Summary

A. Thumbnail Sketch Elements

- ☐ Purpose
- ☐ Audience
- ☐ Need for information product

B. Publication Development and Review Process Summary Elements

- ☐ Summary of previous ADSO review issues (if applicable)
- ☐ Publication developmental stage (e.g. draft publication for public review)
- ☐ Requested review outcome (e.g. NIOSH OD clearance for final publication)

II. Overall Assessment and Recommendations

- ☐ This publication has been
  - ☐ Approved
  - ☐ Approved with changes (additional review not required)
  - ☐ Approved with changes (additional review is required)
  - ☐ Not approved at this time
- ☐ Issues requiring further resolution (if applicable)
- ☐ Suggestions for changes (if applicable)
- ☐ Guidance for future document development (if applicable)

III. Review Elements

A. Science Quality

- ☐ Did the lead DLO solicit collaboration from other DLOs to ensure that others with relevant expertise within NIOSH are aware of the publication and concur with its content, conclusions, and recommendations?
- ☐ Are the objectives of the work and the need that prompted its development clearly stated?
- ☐ Does the publication contain preliminary/unpublished data, and if so, are conclusions drawn from this data justified?
- ☐ Are scientific data accurately displayed?
- ☐ Are factual statements adequately supported by scientific citation?
- ☐ Does the final publication reflect adequate consideration of internal and external peer review comments?
- ☐ Were sources of uncertainty or alternate interpretations for the data addressed, and were caveats acknowledged?
- ☐ Were associations among variables distinguished from causal relationships?
- ☐ Were intermediate steps in the flow of arguments presented?
- ☐ Are the conclusions and recommendations appropriately generalized and supported?

B. NIOSH Scientific Policy

- ☐ Is the publication's topic sensitive, which may affect the level of scrutiny it will receive after publication?
- ☐ Does this scientific product contain findings or policy related to:
  - ☐ Departmental, Presidential, OMB or Congressional priorities
  - ☐ Media interests
  - ☐ High profile health and safety topics (e.g. emergency preparedness or terrorism, nanotechnology, pandemic influenza)
- ☐ Is the publication expected to impact regulatory activities?
- ☐ Is there an urgent need for the publication's dissemination?
- ☐ Has the DLO or document author identified, acknowledged and/or characterized any policy-related issues or controversies?
- ☐ Has the ADSO reviewer identified, acknowledged and/or characterized any policy-related issues or controversies?
- ☐ Did prior participants in the review and clearance process (e.g. peer, stakeholder, or public reviewers) identify and/or characterize any controversial issues with policy statements?
- ☐ Did the authors provide clear and concise responses to policy-related comments received during peer, stakeholder, and public review that were of sufficient quality to represent the Institute's viewpoint in a manner that is publishable on the Institute's Internet website?

- ☐ Are science policy statements new, consistent with prior expressions of NIOSH policy, or revisions to existing NIOSH policy? If science policy statements are revisions, are departures from previous NIOSH policy clearly explained?
- ☐ Does the product contain or create any inconsistencies between NIOSH policy and another agency (e.g. Department of Labor)?
- ☐ Does the product contain critical language that
  - ☐ May be critical of other agencies or departments?
  - ☐ May create a perception of bias, limiting the impact of the underlying message?
  - ☐ May be critical of companies, products, institutions, organizations, or societies?
- ☐ Has care been taken to specifically avoid identifying, criticizing and/or endorsing companies, products, institutions, organizations, or societies?
- ☐ Does the publication provide critique or recommendations that have the potential for unintended consequences or adverse effect?
- ☐ Is mandatory language used appropriately (e.g. shall, must, is required)?

C. Administrative Standards

- ☐ Does this product contain influential scientific information or a highly influential scientific assessment as defined by the OMB Peer Review Bulletin? If yes,
  - ☐ Is there a plan to update the Peer Review Agenda Internet website (i.e. identification of stakeholders and peer reviewers, charge to peer reviewers, comments, etc.)?
  - ☐ Does the submission include the Peer Review Agenda Transmittal form?
  - ☐ Are stakeholders and peer reviewers appropriately identified?
  - ☐ Are statements of independence/conflict of interest for peer reviewers available (required for highly influential scientific assessments)?
  - ☐ Are appropriate disclaimers used? For example, if the publication is being submitted for clearance for external review, does the publication bear the following disclaimer: "This information is distributed solely for the purpose of pre dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy," (see NIOSH Policy on the Use of Disclaimers for Scientific information Products)?
  - ☐ Are there any recommendations regarding notification of authors to make document reviewers or collaborators aware that they may be included on the Peer Review Agenda Internet website?
  - ☐ Are there any recommendations regarding the plan for a public meeting (required for highly influential scientific assessments)?
- ☐ Does this product contain significant guidance as defined by the OMB Good Guidance Practices Bulletin? If yes, are there any recommendations regarding:
  - ☐ A plan to provide HHS with 5 day advance notification?
  - ☐ The HHS Advance Notification Form (e.g. is it clear and concise?)?
  - ☐ Writing a Federal Register Notice (if applicable)?
  - ☐ Establishment of a public docket for comments?
  - ☐ Notification of authors to provide document reviewers or collaborators with a courtesy notification that the document will be made available for public comment?
  - ☐ Response to comments document and its posting to the NIOSH Internet website?
  - ☐ Updating the Peer Review Agenda Internet website (if applicable)?
  - ☐ Coordination of the Federal Register Notice with posting of the publication to the NIOSH Internet website, and the anticipated clearance by HHS?
- ☐ Does this product require cross-clearance by other CDC Centers or Offices or other federal agencies (see Clearance of Information Products

Disseminated Outside CDC for Public Use)?

- ☐ Does the research raise dual use concerns (see Oversight and Clearance of Dual Use Research of Concern)? Dual use research of concern is research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health, agriculture, plants, animals, the environment, or materiel. Such research requires scrutiny and review for dual use potential prior to initiation of research as well as during the scientific review and publication process. Scientists must be mindful of dual use issues while research is being conducted as dual use concerns may develop during the execution of a research plan.

D. Communication Issues

See Appendix N for details.

- ☐ Is the publication free of grammatical or typographical errors?
- ☐ Does this product conform to an established publication format (see the NIOSH Identity Guide)?
- ☐ Is the publication written with a consistent style throughout and does it read as a whole?
- ☐ Is the publication clearly organized?
- ☐ Is the intended audience clearly defined?
- ☐ Are references complete and do they include the sources for statistical tables and graphs?
- ☐ Are recommendations clearly written for the intended audience?
- ☐ Is this publication likely to generate Congressional, media, or political interest?
- ☐ Are critical audiences effectively anticipated (e.g. if it is already known that the audience will be skeptical of the publication's conclusions, a more lengthy and detailed rationale may need to be presented to establish credibility with the audience)?
- ☐ Are there specific communication issues that need to be referred to OHC?

Appendix G. Considerations for Writing a NIOSH Publication

Characteristics of NIOSH publications include provision of sufficient background information, balanced presentation of issues, presentation of new information, and respectful treatment of audiences, including audiences that may disagree with NIOSH conclusions. Authors of NIOSH publications are responsible for producing high-quality science and evidence-based guidelines and recommendations that are effectively communicated. Recommendations are most relevant and have the most impact when they are based on analyses that use sound and transparent methodology and high-quality data. Effectiveness of the presentation is improved when the message is relevant, substantiated, clear, and important.

Consider the following elements during the writing phase of document development. These are the same elements on which the ADSO review focuses.

Attend to the Basics

- Eliminate grammatical and typographical errors.
- Conform to an established format (see the NIOSH Identity Guide).
- Write in a consistent style throughout the document.
- Logically organize the content.
- Include complete references and sources for tables and figures.

Add Value

- Be sure the publication's contribution is clear and relevant.
- Base conclusions and recommendations either on original NIOSH-supported research or on existing research that is synthesized in a new and useful manner.
- Avoid duplicating conclusions and recommendations that are available elsewhere.

State Goals

- Provide NIOSH stakeholders with useful scientific information or guidance on existing or emerging issues.
- Link goals for the publication to the need that prompted its development.

Anticipate Critical Audiences

- Anticipate the need for more background or detailed information for some audiences.
- If it is known that an audience will be skeptical, additional rationale may be required to establish credibility.

Use High-Quality Data

- Use data derived from sound methodology.
- Avoid over-generalization of preliminary or unpublished data.
- Display data accurately.

Support Factual and Background Information

- Reinforce factual and background statements with references.

Substantiate Conclusions

- Ensure that conclusions are appropriately generalized and supported.
- Address areas of uncertainty and data limitations.
- Acknowledge alternate interpretations.
- Distinguish associations among variables from putative causal relationships.
- Present intermediate steps in the flow of arguments in a logical format.

Derive Recommendations from Scientific Conclusions

- Base policies and recommendations clearly and directly on conclusions derived from high-quality science.
- Formulate recommendations with the understanding that NIOSH publications represent official positions of the Institute, are broadly disseminated, may be used to

address urgent public health needs, and may influence regulatory activities.

Synthesize Information

- Draw upon other peer-reviewed studies and relevant information when NIOSH research does not address all policy issues.

Use the Hierarchy of Controls

- Arrange recommendations in a sequence that follows the hierarchy of controls (see http://www.cdc.gov/niosh/topics/engcontrols/) as closely as possible.

Cite Previous Policy

- Explicitly state whether policy statements are consistent with prior expressions of NIOSH policy or are departures from it.

Anticipate Sensitivities, Complexities, and Priorities

- The following types of publications may receive higher than usual attention after publication:
  - Topics that are sensitive, technically complex, original, or unique
  - Publications related to high-profile health and safety topics, e.g. emergency preparedness, terrorism, nanotechnology, and pandemic influenza
  - Subject matter that is included in Presidential, OMB, Congressional, or HHS priorities
- Complexity will increase the difficulty of clearly communicating a topic and appropriately disentangling the policy issues.

Acknowledge Controversies

- Identify controversies explicitly and present alternative viewpoints in a balanced manner.

Avoid Overly Critical Language or Unintended Endorsements

- Ensure that companies, products, institutions, or organizations are not inappropriately identified, criticized, or endorsed.
- Language that is explicitly or harshly critical of other agencies, departments, or organizations detracts from NIOSH credibility and impartiality.
- Inappropriate language can create a perception of bias, limiting the impact of the underlying message.

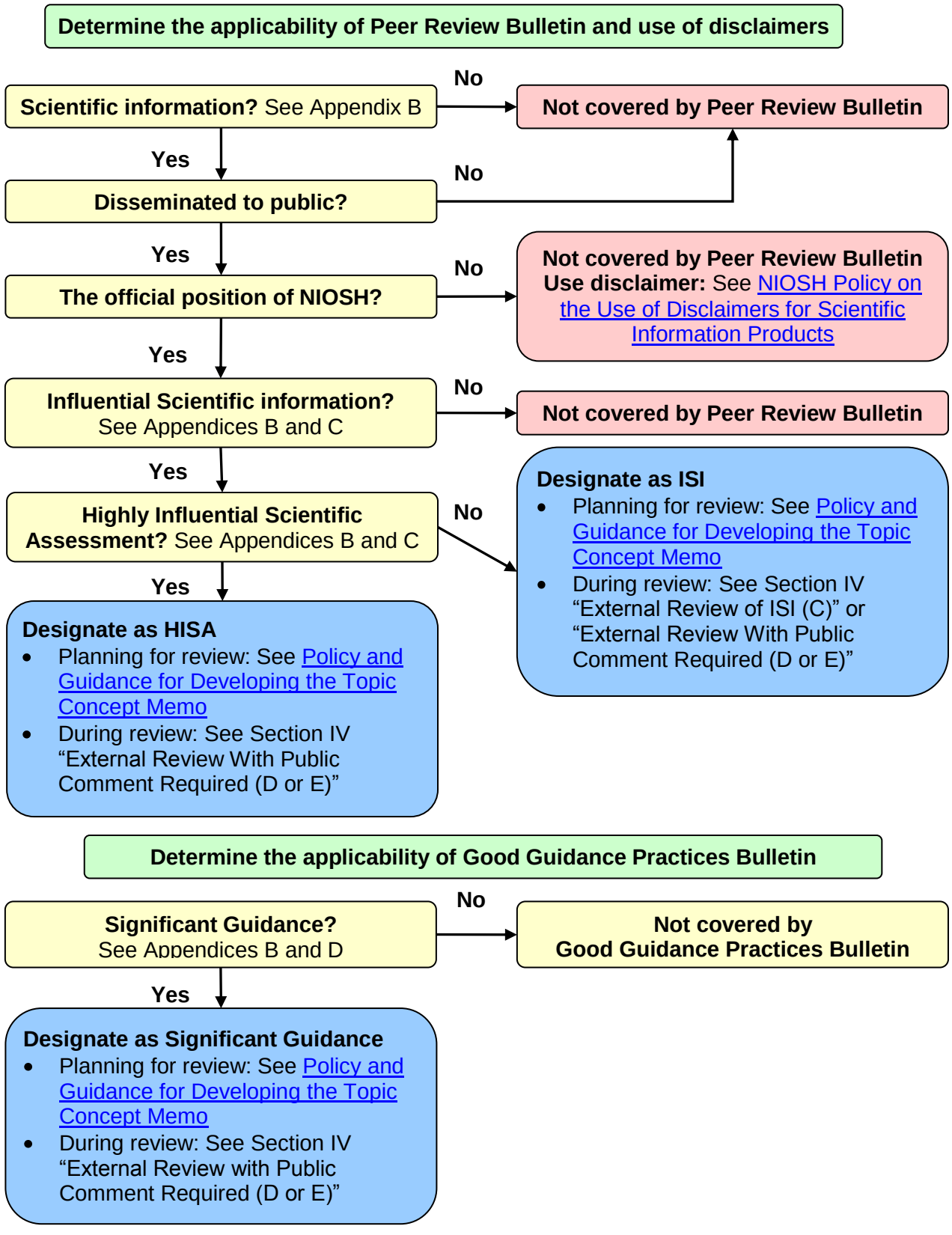
Use Mandatory Language Appropriately

- Clearly distinguish between guidance and statutory or regulatory requirements.
- Avoid mandates such as “shall,” “must,” “required,” or “requirement,” unless the terms are used to describe statutes or regulations.
- Laws of nature, scientific principles, and technical requirements may be described in mandatory terms as long as it is clear that NIOSH guidance does not inappropriately impose legally enforceable rights or obligations.

Relate Recommendations to the Audience

- Compose recommendations in language appropriate for the intended audience. Avoid highly technical terms in recommendations aimed at non-experts.

Appendix H. Decision Logic for Determining the Applicability of Peer Review or Good Guidance Practices Bulletin and Use of Disclaimers

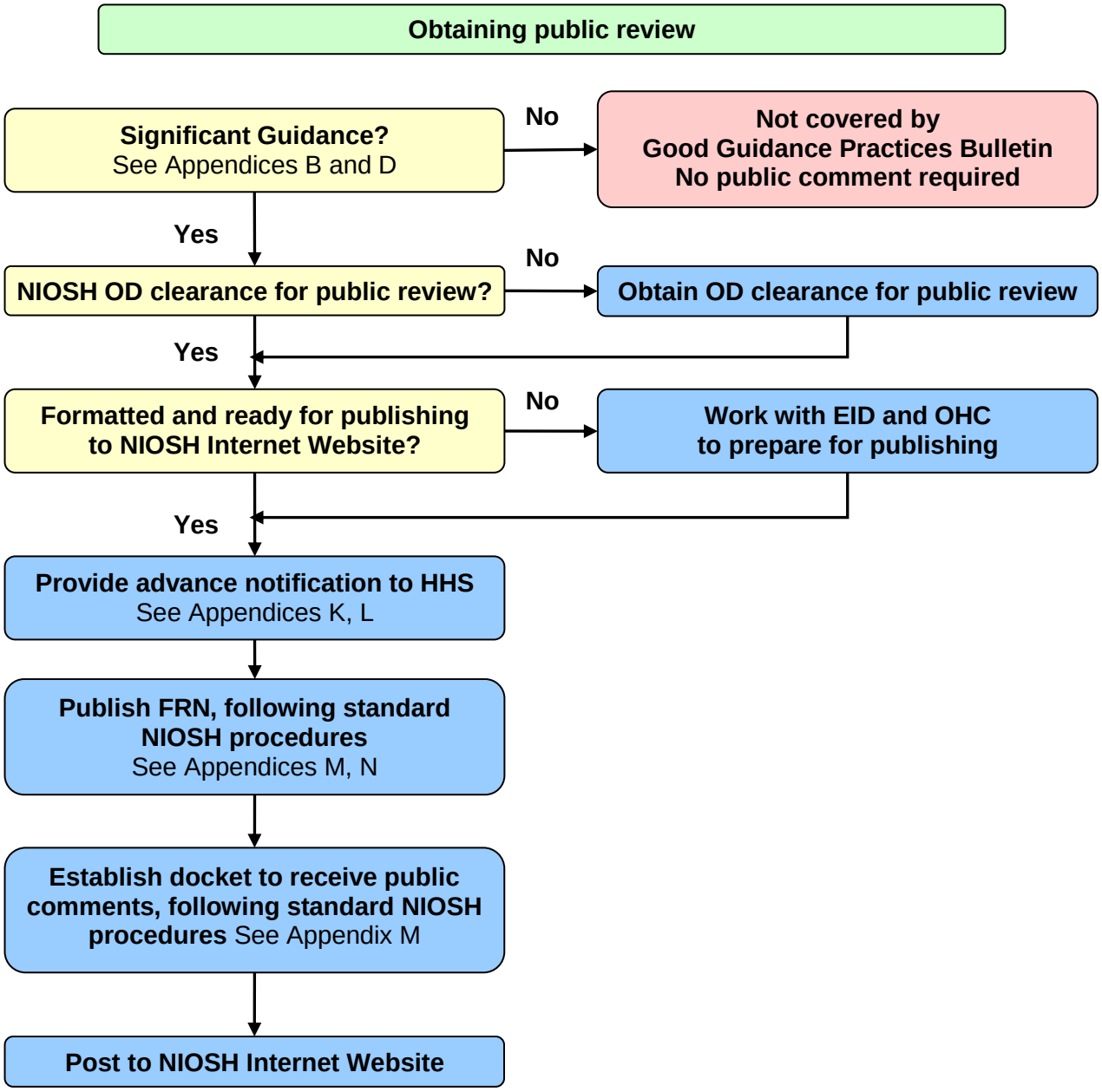


Appendix I: Charge to Reviewers

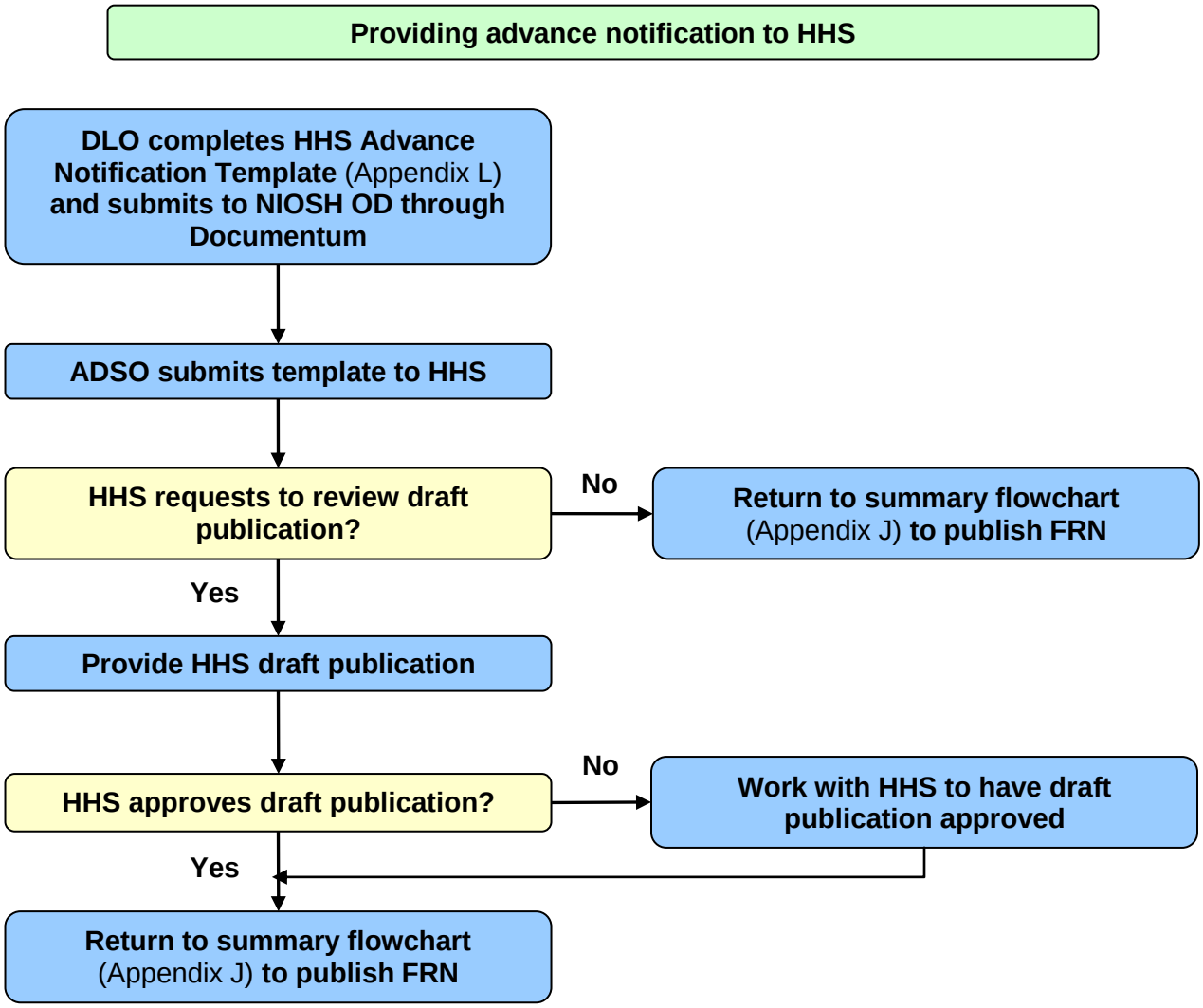
Include a charge to reviewers in Documentum for publications requiring external peer and stakeholder review. Based upon technical or end-user issues, it may be necessary to draft different charges for peer and stakeholder reviewers. The charge communicates the scope and expectations for the review with the following information:

- Purpose of the publication and any other background information that may not be self-evident from the publication itself
- Purpose of the review
- Scope of the review
- Specific questions that the reviewers should address
- How reviewer comments will be used and distributed, including what will be made public following the review
- Whether reviewer names will be kept anonymous and whether their comments will be distributed with attribution or as part of an overall summary of the review
- Other directions or instructions to reviewers that may be necessary for completing the review

Appendix J. Summary Flowchart for Public Review of Draft Significant Guidance Publications



Appendix K. Process Flowchart for Advance Notification of HHS for Draft Significant Guidance Publications



Appendix L. HHS Advance Notification Template and Example for Significant Guidance Publications

NIOSH provides HHS with advance notification:

- No less than 5 days before dissemination of a draft significant guidance NIOSH publication for public review
- No less than 5 days before NIOSH issues a final significant guidance publication

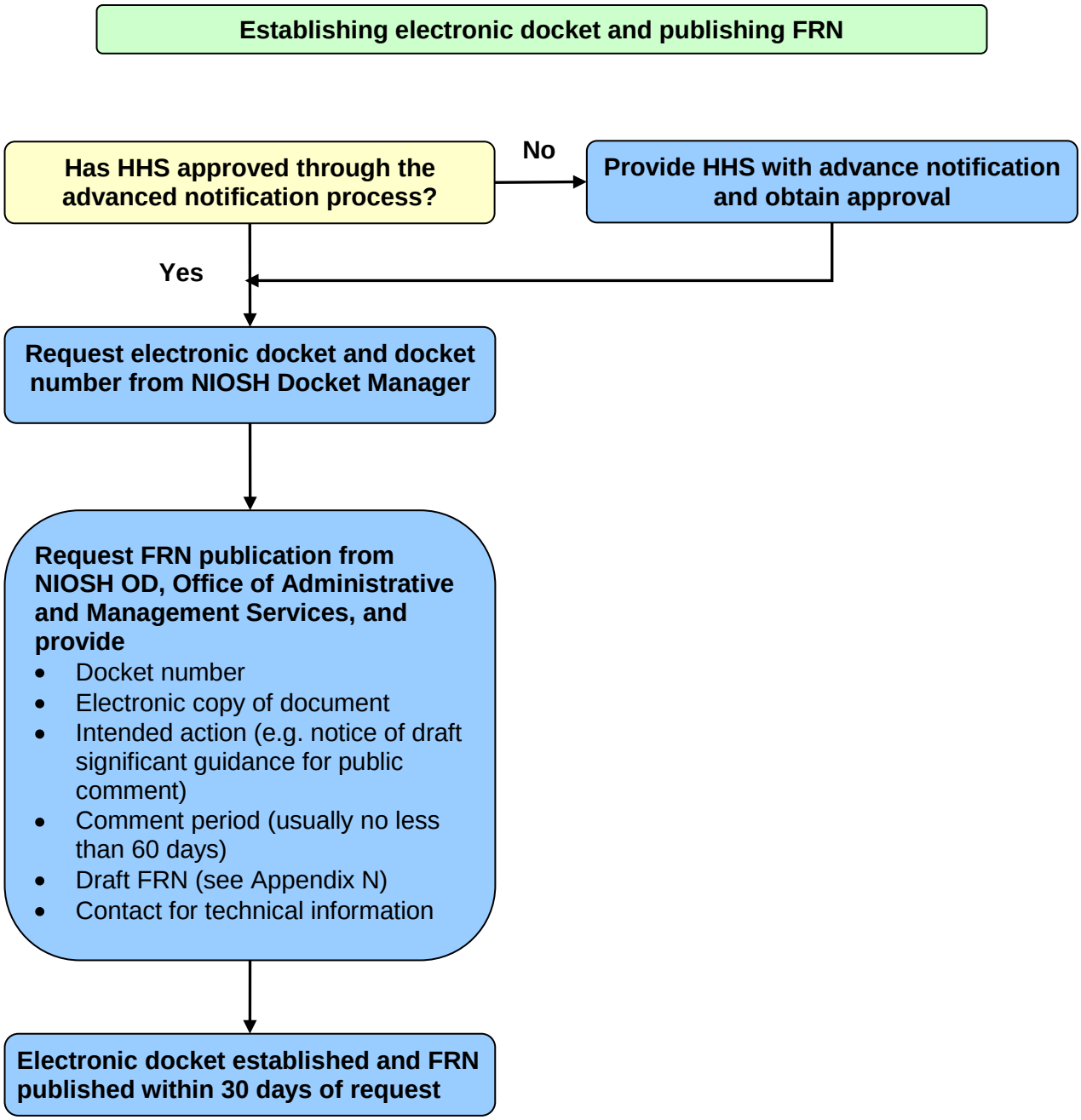
Template

Date	Give the date that item is expected to occur and indicate if the date is tentative	
Title	Provide a title for the item	
Category	Indicate the category of your item	
	Congressional Budget/Funding FOIA Requests Grants	Media Meetings/Conferences Policy (HHS or Intergovernmental) Reports/Publications
Agency point of contact and phone number		
Author (if item is report/publication)		
Brief description of item		

Example

Date	NIOSH estimates that this draft document will be published to enable public comment in response to the Federal Register Notice on 03/01/2009.
Title	Draft Updates to the List of Hazardous Drugs of the NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings
Category	Reports/Publication: NIOSH Alert
Agency point of contact and phone number	John Piacentino 202-245-0634
Author (if item is report/publication)	Tom Connor
Brief description of item	NIOSH has prepared a draft update to the list of hazardous drugs in the NIOSH Hazardous Drug Alert, originally published in 2004.The draft list identifies 25 drugs that fit the NIOSH definition of hazardous drugs and proposes one deletion from the original list. Periodic updates to the list of hazardous drugs are necessary to ensure that health care workers and their employers continue to have current information about the health risks posed by working with hazardous drugs.

Appendix M. Summary Flowchart for Electronic Docket and Federal Register Notice



Appendix N. Federal Register Notice Example for Significant Guidance Publications

BILLING CODE 4163-19-P
Docket Number {Insert Docket Number}

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)

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: {Insert the intended action, see examples below}

- Notice of Draft Publication Available for Public Comment
- Notice of Draft Publication Available for Public Comment and Public Meeting
- Notice of Issuance of Final Guidance Publication

Summary: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability of the following **{Insert action from above}** entitled **{Insert publication "title"}**. The publication and instructions for submitting comments can be found at **{Insert hyperlink}**. Comments may be provided to the NIOSH docket **{and given orally at the following meeting, if applicable}**.

Public Comment Period: {Insert dates of public comment, usually no less than 60 days}

Public Meeting Time and Date: {If applicable}

Place: {If applicable}

Purpose of Meeting: {If applicable} To discuss and obtain comments on the draft publication, **{Insert publication "title"}.** Special emphasis will be placed on discussion of the following: **{Insert any special considerations or emphasis areas}**

Status: {If applicable; read sample text as not all information may apply to your situation} The forum will include scientists and representatives from various government agencies, industry, labor, and other stakeholders, and is open to the public, limited only by the space available. The meeting room accommodates 80 people. Due to limited space and security clearance requirements, notification of intent to attend the meeting must be made to the NIOSH Docket Office no later than **{Insert date}**. Persons wanting to provide oral comments at the meeting are requested to notify the NIOSH Docket Office no later than **{Insert date}** at 513/533-8611 or by email at nioshdocket@cdc.gov. Priority for attendance will be given to those providing oral comments. Other requests to attend the meeting will then be accommodated on a first-come basis. Unreserved walk-in attendees will not be admitted due to security clearance requirements.

Persons wanting to provide oral comments will be permitted up to 20 minutes. If additional time becomes available, presenters will be notified. Oral comments given at the meeting will be recorded and included in the docket. Written comments will also be accepted at the meeting. Written comments may also be submitted to the NIOSH Docket Office, Robert A. Taft Laboratories, 4676 Columbia Parkway, MS C-34, Cincinnati, Ohio 45226, telephone 513/533-8611. All material submitted to the Agency should reference docket number **{Insert docket number}** and must be submitted by **{Insert date}** (public review closing date) to be considered by the Agency. All electronic comments should be formatted as Microsoft Word. Please make reference to docket number **{Insert docket number}**.

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.

Summary: **{Insert publication summary}** This guidance publication does not have the force and effect of the law.

Contact Persons For Technical Information: **{Insert contact person}**

Reference: **{Insert publication reference}** Web address for this publication: **{Insert hyperlink}**

Dated:

_____

James D. Seligman
Chief Information Officer
Centers for Disease Control and Prevention