

Third Edition
September 19, 2011

Best Practice Guidelines for Preparing Scientific Integrity Policies

Examples of useful existing federal and other
scientific integrity policies



**Union of
Concerned
Scientists**

Citizens and Scientists for Environmental Solutions

About this Document

This document is a compilation of select current federal policies and other information that we hope will be useful as agencies and their departments draft their scientific integrity policies. The policies are organized to correspond to the general headings in the White House's scientific integrity guidelines issued December 17, 2011: Foundations of Scientific Integrity in Government, Public Communications, Use of Federal Advisory Committees, and Professional Development of Government Scientists and Engineers.

In each chapter, we provide a portion of the relevant text from the memo, and then provide clarifying comments and a checklist of topics that would make a scientific integrity policy fully responsive to that text. We then address each topic, beginning with the most useful, related agency policy or policies and followed by materials from non-governmental sources such as the National Academies of Science. The federal policies are reprinted directly from agency websites and include URLs. If a relevant policy could not be found for an important area to address, we reference recommendations from UCS that could be developed into agency-or department-specific language.

This document should be viewed as illustrative, not exhaustive. As we were limited to policies easily located on public websites, other agencies also likely have excellent policies we did not include. It provides a starting point that enables agencies and departments to adapt proven language to meet their own unique missions and mandates while protecting the scientific integrity of the information used in decision making. We would welcome additions to this document of existing best practices.

The Union of Concerned Scientists is happy to field any questions or comments as you continue to work through the requirements of the guidelines. We can brief or meet with your team, provide feedback, or assist in any way that will be useful as you move forward with this challenging but important task. As agencies and departments release scientific integrity policies, we will continue to update this document to include them. Please let us know if you are interested in being notified when this document is updated or if we can help you in any way.

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Section I: Foundations of Scientific Integrity in Government

Section I of the Scientific Integrity Memo states:

“Scientific and technological information is often a significant contributor to the development of sound policies. Thus it is important that policymakers involve science and technology experts where appropriate and that the scientific and technological information and processes relied upon in policymaking be of the highest integrity. Successful application of science in public policy depends on the integrity of the scientific process both to ensure the validity of the information itself and to engender public trust in Government.”

Discussion:

Opening up federal science and decision making to public scrutiny is an important means of exposing and ending political interference in science. Policies that fall in this section promote transparency and reaffirm the importance of the scientific process. The blue, italicized text at the top of the page contains our comments and everything below this point is taken directly from the agency’s website.

Policy Checklist:

- Peer Review
- Visitor Log
- Whistleblower Protection
- Data and Methods Sharing
- Release of Draft Scientific Documents
- Protecting Scientific Documents Used in Regulation
- Training & Increased Visibility for Scientific Integrity

Data & Methods Sharing Policy

Many agencies have data sharing policies. The CDC has the most thorough and comprehensive guidance for the timely dissemination of data. Another very good policy is that of the National Aeronautics and Space Administration (NASA), which provides concise yet clear guidance. Because CDC and NASA are not regulatory agencies, these policies do not explicitly address protecting the integrity of the science used in regulation.

CDC/ATSDR Policy on Releasing and Sharing Data*

I. BACKGROUND

The Centers for Disease Control and Prevention (CDC)[[†](#)] and the Agency for Toxic Substances and Disease Registry (ATSDR) are the nation's principal disease prevention and health promotion agencies.[[1](#)] To fulfill their missions, these agencies must collect, manage, and interpret scientific data.

CDC believes that public health and scientific advancement are best served when data are released to, or shared with, other public health agencies, academic researchers, and appropriate private researchers in an open, timely, and appropriate way. The interests of the public—which include timely releases of data for further analysis—transcends whatever claim scientists may believe they have to ownership of data acquired or generated using federal funds. Such data are, in fact, owned by the federal government and thus belong to the citizens of the United States.

However, although CDC recognizes the value of releasing data quickly and widely, CDC also recognizes the need to maintain high standards for data quality, the need for procedures that ensure that the privacy of individuals who provide personal information is not jeopardized, and the need to protect information relevant to national security, criminal investigations, or misconduct inquiries and investigations. The goal is to have a policy on data release and sharing that balances the desire to disseminate data as broadly as possible with the need to maintain high standards and protect sensitive information.

This data release/sharing policy will also ensure that CDC is in full compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA),[[2](#)] (where applicable) the Freedom of Information Act [FOIA],[[3](#)] and the Office of Management and Budget Circular A110,[[4](#)] and the Information Quality Guidelines.

* Available at: <http://www.cdc.gov/od/foia/policies/sharing.htm>

II. PURPOSE

The purpose of CDC's data release/sharing policy is to ensure that (1) CDC routinely provides data to its partners for appropriate public health purposes and (2) all data are released and/or shared as soon as feasible without compromising privacy concerns, federal and state confidentiality concerns, proprietary interests, national security interests, or law enforcement activities.

III. DATA COVERED BY THIS POLICY

This policy applies to any new data collection occurring 90 days or more following approval of this policy. Existing (previously established) data collections systems should be in compliance with this policy either within 3 years of policy approval (the cycle for surveillance and information system evaluation stipulated by the CDC Surveillance Coordination Group) or at the time of data system revisions, whichever occurs first. All data should be released as soon as feasible without compromising privacy concerns, federal and state confidentiality concerns, proprietary interests, national security interests, or law enforcement activities. Requests for data during a public health emergency will be handled on a case-by-case basis. The following data are covered by this policy:

- Data collected by CDC using federal resources.
- Data collected for CDC by other agencies or organizations (through procurement mechanisms such as grants, contracts, or cooperative agreements).
- Data reported to CDC (e.g., by a state health department).[\[5\]](#)

For the purpose of this policy, we use the following definitions:

CDC personnel: CDC employees, fellows, visiting scientists, and others (e.g., contractors) who are involved in designing, collecting, analyzing, reporting, or interpreting data for or on behalf of CDC.

Data: Scientific records which are as accurate and complete as possible.

Data release: Dissemination of data either for public use or through an ad hoc request that results in the data steward no longer controlling the data.

Data sharing: Granting certain individuals or organizations access to data that contain individually identifiable information with the understanding that identifiable or potentially identifiable data cannot be re-released further unless a special data sharing agreement governs the use and re-release of the data and is agreed upon by CDC and the data providers.

For a complete list of terms used in this policy, see [Appendix B](#).

IV. DATA NOT COVERED BY THIS POLICY

This policy does *not* cover data shared with CDC but owned by other organizations (e.g., data provided to CDC by a managed care organizations, preferred provider organizations, or technology firms for a specific research project). Such data may be covered by other policies or procedures that reflect pertinent laws, regulations, and agreements (such as FOIA).

V. BENEFITS OF RELEASING OR SHARING CDC DATA

- Sharing data with partners involved in collecting, analyzing, or using data will improve (1) the quality of CDC data and (2) the consistency of data across CDC.
- Sharing data will also (1) ensure that CDC scientists, contractors, awardees, and grantees are held accountable for their findings, (2) provide opportunities for study results to be validated, and (3) uncover new areas for research.[\[6\]](#),[\[7\]](#)
- Quality improves when scientists share data with partners and ask for feedback during data collection and analysis.
- Releasing or sharing data can (1) improve public health practitioners' understanding of various research methods, (2) encourage analysts from other disciplines (e.g., economists, social scientists) to examine public health questions, and (3) build trust with outside partners and the public by allowing an open critique of CDC investigations.
- U.S. states and territories have a long-standing history of voluntarily reporting individually identifiable data to CDC on incident conditions or diseases that are of public health importance.[\[8\]](#) Although the electronic exchange and accumulation of data on individual cases promises public health benefits, it also creates a threat to individual privacy. The Council of State and Territorial Epidemiologists asked CDC to develop procedures that balance the need for data protection with the need to share, as broadly as possible, data collected in the interest of public health. Without such a balance, data may need to be withheld from non-CDC researchers solely to protect individual privacy.

VI. GUIDANCE FOR CIOs

In this document, CDC sets forth (1) the guiding principles to be followed when releasing/sharing data and (2) the various ways in which data can be released. Each Center/CDC organization, however, is responsible for developing specific procedures for its staff to follow. Indeed, because issues related to data release can vary from project to project, Centers/CDC organizations may need specific data release procedures for each project. For example, state and local health departments have a continuing ownership and interest in whether and how CDC re-releases data they have supplied. Custodians of such data should consult the CDC-CSTE Intergovernmental Data Release Guidelines Working Group report-

<http://intranet.cdc.gov/od/ocso/ssr/drgwg.pdf> which contains data release guidelines and procedures for CDC programs re-releasing state-provided data. The guidelines and procedures in the Working Group report may be useful for other data systems as well.”

Guiding Principles

All CDC procedures on releasing or sharing data must be guided by the following principles.

Accountability

As a public health agency of the U.S. government, CDC is accountable to the public and to the public health community for the data it produces through research. By extension, CDC scientists are accountable for their work, and their findings are subject to independent validation. CDC scientists must conduct research with integrity; the resulting data must be of the highest possible quality; and funds must be fully accounted for.

Privacy and confidentiality

CDC recommends that, unless there is a valid public health purpose (e.g., a longitudinal study that requires record linkage), programs should not collect nor maintain identifiable data.

- **Trust:** Any release or sharing of public health data will acknowledge that (1) data systems are built on trust between the individuals who provide personal data and the agencies that collect those data and (2) that CDC will respect the privacy rights of individuals and others who provide personal or proprietary data. All release/sharing must be consistent with the confidentiality assurances under which the data were collected or obtained.
- **Privacy Act:** Identifiable data that are maintained in certain systems of records may only be released in accordance with the Privacy Act (<http://www4.law.cornell.edu/uscode/5/552a.html>) which generally permits disclosing such data only with consent. However, the Privacy Act does permit data release without a subject's consent under limited conditions. One example is a release that is compatible with the purpose for which the data were collected.
- **Formal confidentiality protection for research subjects:** Some data collected by CDC may be given formal confidentiality protection under Sections 301(d) or 308(d) of the Public Health Service (PHS) Act. Programs that apply for such protection must make a compelling case that the information sought is so sensitive that research subjects are unlikely to provide valid data without this formal confidentiality protection.[1] When data have formal confidentiality protection, CDC's policy is to share those data only under conditions that are consistent with the conditions under which the data were collected. It is CDC's responsibility to ensure that inadvertent disclosure does not occur (See [Appendix C](#)).

Stewardship

CDC holds data in public trust. Good stewardship of data requires that CDC release or share data in accordance with the objectives and conditions under which the data were collected or obtained and that appropriate policies and procedures for data release be set up.^[9]

Scientific practice

Before any data are released/shared, all phases of data collection, transmission, editing, processing, analysis, storage, and dissemination must be evaluated for quality.^{[10],[11]} Preliminary data from a research project may be shared with outside partners for quality assessment but not for publication. Personnel who share data for quality assessment must follow procedures that are consistent with confidentiality agreements and other constraints.

Efficiency

Releasing data to the public and sharing data with partners is an efficient way of ensuring that data are used to their full potential, that work is not duplicated, and that funds are not spent unnecessarily.

Equity

CDC affirms the principles and practices developed to ensure impartiality and credibility of federal statistical activities.^{8,[12]} CDC strives to have data release policies that are fair to all users, regardless of their organizational affiliation.

VII. HOW TO RELEASE DATA

All released data must be as complete and accurate as possible, and data must be released in accordance with the guiding principles set out in this document in one of two ways:

- Release for public use without restrictions.
- Release to particular parties with restrictions.

Restrictions can be imposed because of legal constraints or because releasing the data would risk (1) disclosing proprietary or confidential information or (2) compromising national security or law enforcement interests.

CDC recommends that data be released in the form that is closest to microdata and that still preserves confidentiality.

Release of data for public use

Data that CDC collects or holds and that can be legally released to the public should be released through a public-use data set within a year after the data are evaluated for quality and shared with any partners in data collection. Procedures for releasing public-use data should be consistent with CDC's Public Health Information Network's functions and specifications.

To ensure that issues of confidentiality, proprietary use, and informed consent are addressed correctly, CIOs may choose to develop specific data release plans for each data set. Each plan should include the following:

- A procedure to ensure that confidential information is not disclosed, for example, a list of steps to reduce this risk.[13],[14]
- A procedure to ensure that data are released in a form that does not endanger national security or compromise law enforcement activities.[15]
- A procedure to ensure that proprietary data (i.e. data owned by private organizations such as Managed Care Organizations, Preferred Provider Organizations, or technology firms) are not released inadvertently.
- Analysis plans and other documentation required by the OMB regulation on data quality.
- Instructions for non-CDC users on the appropriate use of the data.
- The date the data will be released, which should be as soon as possible after they are collected, scrutinized for errors, and validated. This release should occur no more than one year after these activities.
- The formats in which the data will be released (e.g., SAS, ASCII). For each format, give specifications (e.g., variable definitions) and information on standards for transmission.[16]

CIOs may release data without restrictions for public use through the CDC Information Center. Data may also be shared through CDC/ATSDR Scientific Data Repository and its data dissemination portal CDC WONDER (URL: <http://wonder.cdc.gov/welcome.html>)

Finally, CIOs may respond to individual requests.

Data shared with restrictions

To the extent possible, CDC recommends sharing data that cannot be released for public use with public health partners. For such restricted data, special data sharing agreements must be developed. Below are two examples of how data can be shared with partners; these methods are not mutually exclusive:

- **Data release under controlled conditions:** Data that cannot be released through a public-use data set or a special-use agreement may be analyzed by appropriate non-CDC researchers at CDC-controlled data centers (e.g., the Data Center established at NCHS; see <http://www.cdc.gov/nchs/r&d/rdc.htm> for a description). Alternatively, CDC may consider licensing non-CDC researchers to use certain data. Licensing would allow researchers access to identifiable data by extending legal responsibilities to those external researchers.⁹ Before making the data available, however, CIOs must evaluate any

requests for permission to use their confidential or private data to ensure that the data will be used for an appropriate public health purpose.

• **Data release through a special-use agreement:** Data that cannot be released publicly but that need not always be under CDC’s control can be released to appropriate non-CDC researchers through a special-use agreement. Such agreements should be specific about issues related to co-authorship, reviews of findings produced through using the data, reports published about those findings, and the date the data are to be returned. All data sharing agreements should include the following:

- Evidence that the party to whom the data are being released need the data for a legitimate public health purpose.
- A list of restrictions on the use of the data.
- The names of every person who will have access to the data.
- Information on any laws pertaining to the agreement.
- Security procedures that the non-CDC user must follow to protect the data from unauthorized use and the penalties for not following them.
- A list of restrictions on releasing analytic results.
- Procedures for returning the data. For an example of a set of procedures, see the CDC and ATSDR policy on data release to departing employees.[\[17\]](#), [\[18\]](#)
- Provisions that govern emergency requests for identifiable or otherwise confidential data.

An example of a special-use agreement is in the CDC/CSTE Intergovernmental Data Release Guidelines Working Group Report.⁵

VIII. IMPLEMENTATION OF CDC’S DATA-RELEASE/SHARING POLICY

Each CIO will set up procedures to ensure that CDC’s policy on data release/sharing is followed. No later than 1 year after this policy is approved, CIOs should send a report on their procedures to the CDC Associate Director for Science (ADS).

One way a CIO might choose to set up procedures on data release/sharing is to authorize a data-release review board to do so. This board might report to the CIO ADS, and it might include the CIO’s Information Resources Manager and stewards of relevant data sets for which the CIO is responsible. Where appropriate, subject-matter experts from the CIO should advise the board on specific data release issues.

Components of CIO procedures on data release/sharing:

Each CIO must ensure that the following components are in their procedures for data release and data sharing:

An evaluation of data quality:

Evaluation of data quality must include tests for completeness, validity, reliability, and reproducibility.¹¹

An evaluation of the risk of disclosing private or confidential information:

Before releasing/sharing any data, the data steward must assess the risk that personal information will be disclosed and decide whether some data need to be further de-identified.[19] For example, under the Health Insurance Portability and Accountability Act (HIPAA), 18 variables are considered identifiers, the removal of which would render the dataset de-identified. This rule, while not applicable to CDC releasing public health information, serves as a useful guide for creating de-identified data and information.²

Those assessing the risk that confidential information will be disclosed should recommend the statistical methods to be used for disclosure protection (e.g., suppression, random perturbations, recoding, top- or bottom-coding).[20], [21] The recommended methods should balance the risk of disclosure against the possibility that reducing the risk of disclosure will also reduce the usefulness of the data for public health practice and research.

Documentation:

All released data must have documentation that shows the conditions under which the data were collected, what the data represent, the extent of the data's completeness and accuracy, and any potential limitations on their use. Careful documentation increases the likelihood that secondary data users will interpret data correctly.

Data elements to be documented are listed in Appendix D.

CDC will develop standards for the elements needed to document data. These standards could be developed on the basis of a review of best practices for data archiving.[22],[23] Specifically, CDC standards for documentation should be compatible with those of private industry. For examples of standards, see www.pueblo.lbl.gov; www.fgdc.gov/standards; www.nbi.gov/datainfo/metadata/standards; www.isotc211.org; <http://www.icpsr.umich.edu/DDI>; or <http://gcmd.gsfc.nasa.gov/Aboutus/standards>.

Public release disclosure statement:

Information that will preclude misinterpretation of data should accompany all released data.

Obligations of non-CDC data users

Public use data agreements should include instructions that non-CDC data users must agree not to link data with other data sets. In addition, these agreements should include instructions to report to the CDC ADS any inadvertent discovery of the identity of any person and to make no use of that discovery.

Obligations of grantees, contractors, and partners

As of three years following approval of this policy, CDC expects researchers who are supported by CDC funding to make their data available for analysis by other public health researchers. Consequently, CDC requires that mechanisms for, and costs of, data sharing be included in contracts, cooperative agreements, and applications for grants. CDC reviewers must check whether applications for CDC funds include mechanisms for, and costs of, sharing data. The costs of sharing or archiving data may be included in the amount of funds requested in applications for first-time or continuation funds. Applicants for CDC funds who incorporate data release into their study designs can (1) readily and economically set up procedures for protecting the identities of research subjects and (2) produce useful data with appropriate documentation. Awardees who fail to release data in a timely fashion will be subject to procedures normally used to address lack of performance (e.g., reduction in funding, restriction of funds, or grant termination).^[24] Researchers who contend that the data they collect or produce are not appropriate for release must justify that contention in their applications for CDC funds.

IX. MEMORANDA OF UNDERSTANDING (MOUs) ALREADY IN PLACE

CIOs should examine the MOUs they have with other organizations or agencies to ensure that they are consistent with this data release and sharing policy and with any program-specific implementations of this policy. New MOUs should be written to ensure consistency with this policy. Any CIOs with MOUs that are inconsistent with CDC's data release policies should report that fact to the CDC ADS. Include in the report information about whatever steps have been taken to bring the MOUs into compliance with CDC's data release/sharing policy.

X. TRAINING

To ensure that this policy is followed correctly, CIOs must train their personnel in the procedures for data release/sharing. They can do so in several ways: through new Human Resources Management Office (HRMO) courses, during new employee orientation programs, at ethics certification courses, or as part of training on the CIO's local area network (LAN).

XI. CDC's COMMITMENT

CDC is committed to establishing and implementing procedures based on this policy. In addition, CDC will swiftly address any breach in the policy. Breaches consist of willful acts (e.g., deliberate disclosures that constitute scientific misconduct as defined by the Office of

Research Integrity) and inadvertent disclosures (e.g., errors in judgment with no intent to do harm).

NASA Data Rights & Related Issues*

Preamble

In order to implement our data policy tenet that algorithms, including scientific source code, be included in the term data, and be shared fully and openly, the following alternate “Data Rights” clause was created by NASA to include in Cooperative Agreements and Contracts with data providers supported by NASA.

1. Introduction

NASA’s Earth Science program was established to use the advanced technology of NASA to understand and protect our home planet by using our view from space to study the Earth system and improve prediction of Earth system change. To meet this challenge, NASA promotes the full and open sharing of all data with the research and applications communities, private industry, academia, and the general public. The greater the availability of the data, the more quickly and effectively the user communities can utilize the information to address basic Earth science questions and provide the basis for developing innovative practical applications to benefit the general public. A primary objective of this program is to facilitate the enhancement of the National Information Infrastructure to affect the emergence of an Environmental Information Economy capable of providing for the routine exchange of environmental data and information. To meet the objectives of this program, scientific data product algorithms and data products or services produced through the program shall be made available to the user community on a nondiscriminatory basis, without restriction, and at no more than the marginal cost of fulfilling user requests.

Included below is the Data Rights clause created specifically for this type of partner agreement, which will be part of the Cooperative Agreement between NASA and successful Earth Science Data System solicitation respondents.

2. Rights in Data Clause

The following Rights in Data clause created for NASA’s Earth Science Data Cooperative Agreements is used for this Cooperative Agreement and replaces the standard Rights in Data clause (1260.30) of the “NASA Grant and Cooperative Agreement Handbook.”

* Available at: <http://science.nasa.gov/earth-science/earth-science-data/data-information-policy/data-rights-related-issues/>

NASA Rights in Data, December 2006

A. Introduction

NASA intends to protect Recipient's rights to data that embodies trade secrets or comprises commercial or financial information which is privileged or confidential. No data transfer or "cross fertilization" of concepts will be performed by NASA participants, should two or more cooperative agreements be awarded. While NASA will require that the data that embodies trade secrets or comprises commercial or financial information which is privileged or confidential generated by the Recipient be delivered to NASA for dissemination to employees of NASA, of JPL, and of appropriate support contractor personnel, such data marked with a suitable notice or legend will be protected for the 2-year period of exclusivity set forth in paragraph D.3 of this clause. Support contractor personnel will be provided access to the such data generated as a part of these studies only under suitable protective conditions and use by support contractor personnel will be limited to governmental purposes only.

B. Definitions

1. "*Data*" means recorded information, regardless of form, the media on which it may be recorded, or the method of recording. The term includes, but is not limited to, data of a scientific or technical nature, software and documentation thereof, and data comprising commercial and financial information.
2. "*Computer Data Base*" means a collection of Data in a form capable of being processed and operated on by a computer through the use of a computer program performing the function of storing, manipulating, or formatting. A "computer data base" is not software.
3. "*Metadata*" means information about a Data set provided by the data supplier or the generating algorithm and which provides a description of the content, format, and utility of the Data set. Metadata provide criteria, which may be used to select Data for a particular scientific investigation.
4. "*Object Code*" means machine language, i.e., that programming language directly readable by a computer.
5. "*Software*" means computer programs (a set of statements or instructions, in object code, to be used directly or indirectly in a computer in order to bring about a certain result), source code, source code listings, and design details, algorithms, processes, flow charts, formulae and related material that would enable the software or a functionally equivalent software to be reproduced, recreated, or recompiled, regardless of the form or media on which such information is recorded.
6. "*Software Documentation*" means Data that explain the capabilities of the software, or provide operating instructions for using the software, to obtain the desired results from a computer such as: (a) owner's manuals, (b) user's manuals, (c) installation instructions, (d) operating instructions, and other similar items.

C. Data Products

1. Scientific Data: Earth system science products, with accompanying metadata and quality assessments, made available through production or services provided by the project. Some examples of Scientific Data include: geophysical parameters, such as sea surface temperature, sea surface height, atmospheric pressure/temperature levels, precipitation, atmospheric chemical species and aerosols, ice sheet mass balance, and various terrestrial surface measurements.
2. Scientific Computer Data Base: Collection of Scientific Data.
3. Scientific Software: Scientific software is that software used for processing raw instrument Data into Scientific Data.
4. Information System Software: Software produced as part of the project pursuant to the technology objectives of this Cooperative Agreement that comprises any part of, access to, or management of Data in the data system of the project, or tools that access, manipulate, or analyze Scientific Computer Data Base. Some examples of Information System Software include client/server applications, user interfaces, tools for selecting, manipulating and analyzing Scientific Data, and database management software.

D. Data Rights

1. Data exchanged between NASA and Recipient under this Cooperative Agreement will be exchanged without restriction as to its disclosure, use, or duplication except as otherwise provided below in this clause. In particular, rights in Scientific Data, Scientific Computer Data Bases, and Scientific Software, as defined in paragraph C of this clause, are provided under this paragraph D.1.
2. Background Data: (Recipient's and NASA's)
 - a. Recipient: In the event it is necessary for Recipient to furnish NASA with Data which existed prior to, or produced outside of, this Cooperative Agreement, and such Data embodies trade secrets or comprises commercial or financial information which is privileged or confidential, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used by NASA and its contractors (under suitable protective conditions) only for the purpose of carrying out NASA's responsibilities under this Cooperative Agreement. Upon completion of activities under this Cooperative Agreement, such Data will be disposed of as requested by Recipient. A.27-3
 - b. NASA: Earth Observing System Core System (ECS) Software - No license rights to the ECS software are granted or implied by this Cooperative Agreement. ECS software is being provided for Government purposes and may not be used for commercial purposes during or upon completion of this Cooperative Agreement. Upon completion of activities under this Cooperative Agreement, such Data will be disposed of as requested by NASA. Any modification to these rights will be expressly made through a separate written agreement.
3. Data first produced by Recipient:
 - a. In the event Data first produced by Recipient in carrying out Recipient's responsibilities under this Cooperative Agreement is furnished to NASA, and Recipient considers such Data to embody trade secrets or comprise commercial or financial

information which is privileged or confidential, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence for a period of two years after completion of this Cooperative Agreement and be disclosed and used by the Government and its contractors (under suitable protective conditions) only for use as a tool for Government research by or on behalf of the Government during that period. In order that the Government and its contractors may exercise the right to use such Data for the purposes designated above, NASA, upon request to the Recipient, shall have the right to review and request delivery of Data first produced by Recipient. Delivery shall be made within a time period specified by NASA.

b. In particular, rights in Information System Software, as defined in paragraph C of this clause, are provided under this paragraph D.3, except that object code shall be treated under paragraph D.1 of this clause as Data exchanged without restriction as to its disclosure, use or duplication.

c. Within one month of the completion of this Cooperative Agreement, the recipient shall provide written documentation of its intent to commercialize “Data first produced by Recipient” under this Cooperative Agreement. If the Recipient intends to commercialize such Data, Recipient shall mark the Data with a suitable notice and NASA shall, to the extent permitted by law, maintain such Data in confidence for a period of two years after completion of this Cooperative Agreement. During the aforementioned restricted period, NASA will disclose such Data to third parties (under suitable protective conditions) only with the Recipient’s written approval. After the restricted period expires, NASA shall have the rights specified in paragraph D.1 of this clause.

d. If the Recipient determines not to commercialize such Data (or otherwise make the data available to the user community, such as “open source”), or if the Recipient fails to provide written documentation indicating its intent to commercialize the Data, Recipient agrees that NASA shall have the rights specified in paragraph D.1 of this clause and all such Data can be made available without restriction as to its disclosure, use or duplication. Alternatively, at NASA’s option, NASA may require the recipient to assign any copyright in such Data to NASA or its designee.

4. Data first produced by NASA: Data first produced by NASA in carrying out NASA’s responsibilities under this Cooperative Agreement that would embody trade secrets or would comprise commercial or financial information that is privileged or confidential if it had been obtained from the Recipient, will be marked with a suitable notice or legend and maintained in confidence for an agreed period of up to two (2) years after completion of this Cooperative Agreement, with the express understanding that during the aforesaid period such Data may be disclosed and used (under suitable protective conditions) by or on behalf of the Government for Government purposes only, and thereafter for any purpose whatsoever without restriction on disclosure and use. Recipient agrees not to disclose such Data to any third party without NASA’s written approval until the aforementioned restricted period expires.
5. Copyright:
 - a. In the event Data is exchanged with a notice indicating the Data are protected as a published copyrighted work, or are deposited for registration as a published work in the U.S. Copyright Office, the following paid-up licenses shall apply:

(i) If it is indicated on the Data that the Data existed prior to, or was produced outside of, this Cooperative Agreement, the receiving party and others acting on its behalf, may reproduce, distribute, and prepare derivative works for the purpose of carrying out the receiving party's responsibilities under this Cooperative Agreement; and

(ii) If the furnished Data does not contain the indication of paragraph D.5.a.(i) of this clause, it will be assumed that the Data was first produced under this Cooperative Agreement, and the receiving party and others acting on its behalf, shall be granted a paid-up, nonexclusive, irrevocable, world-wide license for all such Data to reproduce, distribute copies to the public, prepare derivative works, and perform publicly and display publicly, by or on behalf of the receiving party. For Data that is computer software, the right to distribute shall be limited to potential users in the United States.

b. When claim is made to copyright, the Recipient shall affix the applicable copyright notice of 17 U.S.C. 401 or 402 and acknowledgment of Government sponsorship to the Data when and if the Data are delivered to the Government.

6. Oral and Visual Information:

If information which the Recipient considers to embody trade secrets or to comprise commercial or financial information which is privileged or confidential is disclosed orally or visually to NASA, such information must be reduced to tangible, recorded form (i.e., converted into Data as defined herein), marked with a suitable notice or legend, and furnished to NASA within 10 days after such oral or visual disclosure, or NASA shall have no duty to limit or restrict, and shall not incur any liability for, any disclosure and use of such information.

7. Disclaimer of Liability:

Notwithstanding the above, NASA shall not be restricted in, or incur any liability for, the disclosure and use of:

a. Data not identified with a suitable notice or legend as set in paragraphs D.2.a., D.3.a., and D.3.c. of this clause; or

b. Information contained in any Data for which disclosure and use is restricted under paragraphs D.2. or D.3. of this clause, if such information:

(i) is publicly available at the time of disclosure or thereafter becomes publicly available without breach of this Cooperative Agreement;

(ii) is known to, in the possession of, or developed by NASA independent of carrying out the NASA's responsibilities under this Cooperative Agreement;

(iii) is received from a third party having the right to disclose such information without restriction; or

(iv) is required to be produced or released by the receiving Party pursuant to a court order or other legal requirement.

E. Marking of Data

All Data or Information System Software object code created under this Cooperative Agreement, by NASA or the Recipient shall be marked with the notice provided below.

- Copyright <enter year of first publication> <enter Participant's name OR United States Government as represented by the Administrator of the National Aeronautics and Space Administration, as applicable>. No copyright is claimed in the United States under Title 17, U.S. Code to any U.S. Government created work. This work has been developed under Cooperative Agreement with NASA and the Government has certain rights. This work is released without restriction as to its disclosure, use or reproduction. Software shall not be disassembled, reverse engineered, or made into human readable form.
- This work is provided "as is" without any warranty of any kind, either express, implied, or statutory, including, but not limited to, any warranty that the software will conform to specifications, any implied warranties of merchantability, fitness for a particular purpose, and freedom from infringement, and any warranty that the documentation will conform to the software, or any warranty that the software will be error free.
- In no event shall NASA be liable for any damages, including, but not limited to direct, indirect, special, or consequential damages, arising out of, resulting from, or in any way connected with this work, whether or not based upon warranty, contract, tort, or otherwise, whether or not injury was sustained by persons or property or otherwise, and whether or not loss was sustained from, or arose out of the results of, or use of, the work provided hereunder.

F. Lower Tier Agreements

Recipient shall include this provision, suitably modified to identify the parties, in all subcontracts or lower tier agreements, regardless of tier, for experimental, developmental, or research work conducted under or in association with this Cooperative Agreement.

Visitor Log Policy

The White House Visitor log policy is groundbreaking in the fact that for the first time the public can see who their leaders in the White House are meeting with. It could be improved upon by including additional clarity regarding who is subject to it and by reducing the time between meetings and their disclosure.

White House Voluntary Disclosure Policy Visitor Access Records*

The President has decided to increase governmental transparency by implementing a voluntary disclosure policy governing White House visitor access records. The White House will release, on a monthly basis, all previously unreleased WAVES and ACR access records that are 90 to 120 days old. For example, records created in January 2010 will be released at the end of April 2010. The short time lag will allow the White House to continue to conduct business, while still providing the American people with an unprecedented amount of information about their government. No previous White House has ever adopted such a policy.

The voluntary disclosure policy will apply to records created after September 15, 2009, and the first release of records (covering the month of September) will occur at the end of the year, on or about December 31, 2009. We expect that each monthly release will include tens of thousands of electronic records. Since the White House considers these records to be subject to the Presidential Records Act, it will continue to preserve them accordingly.

The White House voluntary disclosure policy will be subject to the following exceptions:

1. The White House will not release fields within the access records that implicate personal privacy or law enforcement concerns (e.g., dates of birth, social security numbers, and contact phone numbers); records that implicate the personal safety of EOP staff (their daily arrival and departure); or records whose release would threaten national security interests.
2. The White House will not release access records related to purely personal guests of the first and second families (i.e., visits that do not involve any official or political business).
3. The White House will not release access records related to a small group of particularly sensitive meetings (e.g., visits of potential Supreme Court nominees). The White House will disclose each month the number of records withheld on this basis, and it will release such records once they are no longer sensitive.
4. Visitor information for the Vice President and his staff at the White House Complex will be disclosed pursuant to the policy outlined above. It is not possible, however, to release visitor information for the Vice President's Residence in an identical format to the White

* Available at: <http://www.whitehouse.gov/VoluntaryDisclosure/>

House Complex at this time because the Residence is not equipped with the WAVES and ACR systems that are in place at the White House Complex. The Office of the Vice President will, instead, release the guest lists for official events at the Residence and will also review the Vice President's and Dr. Biden's daily schedules and release the names and dates of visitors to the Residence who appear on those schedules. The Vice President's staff is working with the Secret Service to upgrade the visitor records system at the Residence. When the electronic update is complete, visitor information for the White House Complex and the Residence will be released in a common format.

WAVES and ACR records created between January 20 and September 15, 2009 will not be subject to the voluntary disclosure policy. Instead, the White House will respond voluntarily to individual requests submitted to the Counsel's Office that seek records during that time period, but only if the requests are reasonable, narrow, and specific (e.g., requests that list specific possible visitors). Responses to reasonable requests will be subject to the four exceptions described above.

Whistleblower Policy

NASA provided a personal assurance that whistleblowers would not be prosecuted. Though not technically a “policy” this is strong language that supports the actions of well-intended whistleblowers. Strong statements such as this one that encourage staff to speak out about possible abuses of science and assure protections against retaliation are critical to the creation and maintenance of a culture of scientific integrity.

NASA Handling Disagreement with Superiors’ Decisions and Whistleblowing (Letter to employees from NASA Inspector General)*

The mandate of the Office of Inspector General (OIG) is to root out fraud, waste, and abuse, as well as promote the economy and efficiency of the Agency. Because it reports to both the NASA Administrator and to Congress, the OIG is uniquely positioned to give objective and independent commentary on NASA operations. The OIG also can and does look at matters that it thinks most important to protect taxpayer investments in NASA. Those matters may include examining whether management fairly addresses concerns raised by employees on myriad topics. In the wake of the Shuttle Columbia accident, the OIG has a profound interest in ensuring that NASA is vigilant in establishing and sustaining an environment that encourages the free flow of information. Such vigilance pertains especially to safety and ensuring that those who raise issues are protected from reprisal.

Disagreements With Decisions of Superiors

The Columbia Accident Investigation Board cited as one cause of the Space Shuttle Columbia accident “organizational barriers that prevented effective communication of critical safety information and stifled professional differences of opinion” NASA has been working on improving its communication through organizational and process change and through effective leadership.

Organizations are designed to ensure information relevant to making a decision is communicated to the appropriate level of management. Decisions must be made and carried out or nothing gets accomplished. In order that there be orderly implementation of decision-making in an organization, subordinates generally must accept decisions of superiors.

Instances will arise when an employee believes a superior or other decision-maker is headed down a wrong path and that a higher level of review is necessary because of the importance of the decision. How such a matter is handled is tremendously sensitive, because an employee’s suggestion to raise a matter to a higher level could be seen as repudiating a superior’s decision.

* Available at: <http://oig.nasa.gov/whistleblower.pdf>

This should not be a deterrent to those who have important views to express. How leaders react to and handle contrary views is critical to the integrity of Agency decision-making.

I communicate to my staff that should an employee and a supervisor disagree on an important issue, and the employee believes the issue merits a higher level review, the employee should suggest to the supervisor that they discuss the issue with the person next highest in the chain of supervision (or with whomever it is that needs to know the information). This to me is a very appropriate suggestion to make to a superior, and I have communicated to my staff that if a supervisor is unwilling to accommodate the request, the employee should feel free to move up the chain of supervision without the supervisor's consent.

As a practical matter, because of the ease of e-mail, employees are free to communicate with whomever they believe is the appropriate level. However, a cost in terms of efficiency of organizational operations could result if leaders and managers are barraged with communications more appropriately handled at lower levels or if normal processes break down. In my experience, given the ease of electronic communications, looping ever-higher levels of management into the resolution of issues is not as burdensome to the efficient operations of an organization as the failure to bring transparency to important decisions.

In my view, an important decision that does not have substantial transparency to it warrants greater attention and scrutiny. Ensuring that risks the Agency accepts are transparent and that the extent of risks has been fully considered is critical. To the extent normal Agency processes do not fulfill these ends, individual employees should be particularly sensitive to ensuring appropriate parties are informed.

At NASA, employees can take issues they have on safety or engineering reliability to one or more of the following: the Independent Technical Authority being established at NASA, the local or Agency Office of Safety and Mission Assurance, the NASA Safety Reporting System, local or Agency Ombudspersons, or the OIG. The NASA Engineering and Safety Center may also be able to assist in certain instances. Without addressing the effectiveness of any of these alternatives, the fact is that multiple alternatives are open to an employee.

Employees are required to report certain matters such as fraud, waste, abuse and corruption to the appropriate authorities. If an employee believes that a supervisor (or any other person) is engaged in such types of activities, the employee has a duty to bring the matter to the attention of others. The OIG is the best avenue for reporting. The OIG will vigorously protect employees from reprisal for making a complaint or disclosing information to the OIG.

Whistleblowing

Reprisal for whistleblowing is inimical to the free flow of information and must be protected against. Protections for whistleblowing are contained in a complex body of statutes, regulations, and court decisions with varying technical requirements. (See attached guidelines.) For example, the Whistleblower Protection Act applies to disclosures that a Government employee makes about violations of laws, gross mismanagement, gross waste of funds, abuse of authority, or a substantial and specific danger to public safety. But that law applies only to "protected

disclosures” made by civil service employees and does not include communications to one’s supervisor concerning normal day-to-day duties. The protection of Federal employee whistleblowers falls within the province of the Office of Special Counsel (OSC), an independent agency. For further whistleblower information, Federal employees should access OSC’s website at www.osc.gov. To report whistleblower issues, call the OSC Whistleblower Disclosure Hotline at 800-572-2249. Certain disclosures by prime contractor employees are also protected (see item 4 in attachment).

The OIG does not adjudicate or enforce whistleblower rights, but does instead determine whether Agency operations are economical, efficient, effective, and in compliance with laws and regulations. In that regard, the OIG will pursue whistleblower matters that it determines warrant consideration. The OIG can be an advocate to the NASA Administrator and can report to the Congress on Agency activity. Many times whistleblower matters we consider are difficult to untangle because they involve personality conflicts and/or professional disagreements on complex technical issues. Whistleblowers, including confidential and anonymous sources, may bring to light fraud, waste, and abuse, as well as violations of law, safety issues, or suggestions to improve the Agency. In some cases, whistleblower disclosures can be validated and criminal or civil remedies pursued and recommendations made to enhance Agency operations. However, sometimes after conducting an investigation or audit, our Office is unable to validate a whistleblower’s statements. Notwithstanding the challenges associated with these matters, the OIG believes it plays an important check and balance to Agency action.

The Inspector General Act protects disclosures made in good faith to the OIG if they relate to violations of law, mismanagement, abuse of authority, or a substantial and specific danger to the public health and safety. The OIG will vigorously protect employees from reprisal for making a complaint or disclosing information to the OIG.

Whistleblower Guidelines

The following guidelines assist the OIG and the whistleblower.

1. The Inspector General Act of 1978, as amended, 5 USC Appendix, § 7.

The IG Act of 1978 protects civil service employees who disclose instances of violations of law, rules, or regulations, or mismanagement, gross waste of funds, abuse of authority or a substantial and specific danger to the public health and safety. The disclosure must be made to the OIG. Knowingly false reports to the IG, or reports made without regard to their truth or falsity, are not protected.

2. Whistleblower Protection Act of 1989, 5 USC § 1211 et seq.

The Whistleblower Protection Act of 1989 is another provision that protects civil service employees for disclosures relating to violations of law, rules, or regulations; gross mismanagement; gross waste of funds; abuse of authority, or a substantial and specific danger to the public health and safety. Applicants for Federal employment and former Federal employees are protected under this statute. The Office of Special Counsel (OSC) administers the law. The OIG may investigate such matters and refer them to the OSC, or may work these cases jointly with the OSC. The OSC has authority to litigate before the Merit Systems Protection Board to seek a stay of the alleged retaliatory personnel action while its investigation is pending. When the OSC fails to act, the aggrieved employee or applicant may petition for protection directly to the Merit Systems Protection Board.

3. False Claims Act, 31 USC § 3730(h).

The False Claims Act protects private sector employees who assist in False Claims Act litigation in the Federal courts. Reprisals for assisting in OIG investigations of false claims are also protected. The employee must bring suit in Federal District court to seek a remedy. In addition to other employment remedies, the employee may also seek two times back pay owed as well as attorneys' fees.

4. Federal Acquisition Streamlining Act (FASA), § 6005, amending 10 USC § 2409.

FASA protects private sector employees of NASA prime contractors if the disclosure is made to the Department of Justice, Congress, or to the OIG and if the disclosure concerns a substantial violation of law pertaining to a contract, including its competition or negotiation. The statute does not, however, protect employees of NASA subcontractors. The disclosure must also relate to a substantial violation of law pertaining to a NASA prime contract or its formation. Employees who believe they are aggrieved may file a signed, written complaint with the OIG. Unless the complaint is frivolous, under the law the OIG must investigate and submit a report to the employee, the employer, and the NASA Administrator. The employer and employee can comment on the report, and the Administrator can request further fact finding. If the Administrator finds reprisal for protected disclosures has occurred, the Administrator can abate the reprisal by ordering reinstatement, back pay, and attorneys' fees. NASA can enforce the Administrator's order in Federal district court. A party aggrieved by the Administrator's order can seek review in Federal circuit court.

5. Sarbanes-Oxley Act of 2002, P.L. 107-204, § 806 (codified at 18 USC § 1514A).

The Sarbanes-Oxley Act provides protection to employees of publicly traded corporations for disclosures and testimony and investigative assistance related to fraud against shareholders, mail fraud, wire fraud, and violations of the U.S. Securities and Exchange Commission rules. The U.S. Department of Labor enforces the law, although the OIG can refer cases to them. The significance of this Sarbanes-Oxley Act is that disclosure to the immediate supervisor is protected. In contrast, other statutes and case law, such as those that interpret the Whistleblower Protection Act, have held that disclosures to immediate supervisors, particularly when they are the alleged wrongdoers, are not whistleblowing disclosures.

6. Sarbanes-Oxley Criminal Provision, 18 USC § 1107. Retaliation Against Informants.

It is a criminal offense to threaten any employee's livelihood in retaliation for providing truthful information to law enforcement in an investigation of a Federal criminal offense. The provision protects private and public sector employees from retaliation. The protected disclosures must actually be truthful, not just have reason to believe they may be truthful. The retaliation must be knowing and intentional. If convicted of this felony, the sentence can include a fine and 10 years of imprisonment.

7. Research Misconduct Regulation Implementing Office of Science and Technology Policy policy. (NASA regulation 14 CFR 1275.104(e), 69 Federal Register 42102 et seq., effective July 14, 2004).

To the extent permissible by law, the identities of whistleblowers who wish to remain anonymous will be kept confidential by the OIG.

Peer Review Policy

The Office of Management and Budget (OMB) has outlined basic information about peer review in the document titled, "Final Information Quality Bulletin for Peer Review." Many scientific agencies have a peer review process; however some provide more detail regarding the extent and content of the review. The USGS has a peer review policies that are very specific and detail the specific process of review. NOAA has a policy that specifically addresses conflicts of interest in the peer review process.

USGS Peer Review Policy*

502.3 - Fundamental Science Practices: Peer Review

1. Purpose and Scope. Peer review, as a cornerstone of scientific practice, validates and ensures the quality of published USGS science. This policy establishes the requirements for peer review of USGS information products and applies to all USGS scientific and technical information, whether it is published by the USGS or an outside entity.

2. Authority. Office of Management and Budget (OMB) and Department of the Interior (DOI) guidelines address means to safeguard both excellence and objectivity of science through peer review.

A. OMB, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (February 22, 2002)

B. OMB, Final Information Quality Bulletin for Peer Review (December 16, 2004)

C. DOI, Information Quality Guidelines Pursuant to Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (October 2, 2002)

3. References.

A. SM 502.1 - Fundamental Science Practices: Foundation Policy

B. SM 502.2 - Fundamental Science Practices: Planning and Conducting Data Collection and Research

C. SM 502.4 - Fundamental Science Practices: Review, Approval, and Release of Information Products

D. SM 205.18 - Authority to Approve Information Products

E. SM 1100.6 - Use of Copyrighted Material in USGS Information Products

F. 432-1.S1 - USGS General Records Disposition Schedule

G. USGS, Guidelines for Ensuring the Quality of Information Disseminated to the Public

* Available at: <http://www.usgs.gov/usgs-manual/500/502-3.html>

4. Definitions.

A. *Information Product.* An information product is the compilation of scientific communication or knowledge such as facts, data, or interpretations in any medium (for example, print, digital, or audiovisual) or form (including textual, numerical, graphical, and cartographic) to be disseminated to a defined audience or customer, scientific or nonscientific, internal or external (see [SM 1100.1](#) and [SM 1100.3](#)).

B. *Peer Review.* Also referred to as refereeing, technical peer review, or scientific peer review, peer review is scrutiny of work or ideas by one or more others (peers) who are sufficiently well qualified, who are without conflict of interest, and who are not associated with the work being performed. A peer is defined as one who is of equal standing with another; in science, the implication is that education and/or experience qualify one to comment on the work of others in a particular field of expertise. These persons may be internal or external to the organizational entity in which the review is conducted.

5. Policy. Peer review is required for all information products, whether published and disseminated by the USGS or by an outside entity, and regardless of media (print, digital, audiovisual, or Web), if the work was funded, whole or in part, by the USGS or if USGS affiliation is identified with the authorship. In keeping with practices in the broader scientific community, directives from Government authorities, and USGS Fundamental Science Practices, the following is policy:

A. Peer reviews must include at least two qualified scientists who have no stake in the outcome of the review, who are not associated with the work being performed, and who are without conflict of interest.

B. Only peer-reviewed information products may be forwarded to an Approving Official for Bureau Approval for official release (see [SM 502.4](#) and [SM 205.18](#)). Information products sent to an Approving Official must include a reconciliation document indicating how review comments were addressed.

C. Articles for publication in a scientific journal must have first gone through the USGS peer review process, as outlined in this policy, and receive Bureau Approval for release prior to being submitted to the journal.

D. Involvement of non-USGS authors does not allow USGS authors to bypass the USGS review and approval process. Conversely, USGS scientists who are authors in publications by outside entities, or where a non-USGS author is the lead, must comply with USGS review and approval processes first or the USGS scientist may not be listed as an author.

E. Office of Management and Budget (OMB) requirements for peer review must be met ([Final Information Quality Bulletin for Peer Review](#)).

6. Responsibilities. Adherence to and accountability for this policy are the responsibility of employees at various organizational levels. The USGS recognizes the primary responsibility of

scientists and their supervisors in developing information products that adhere to this policy. Specific responsibilities are as follows:

A. *Associate Directors*. Associate Directors set policy for USGS peer review practices. They collaborate with Regional Directors regarding the content and application of consistent USGS peer review practices.

B. *Regional Directors*. Regional Directors execute the policies and practices governing peer review and are accountable for compliance by those in their lines of authority. They collaborate with Associate Directors regarding the content and application of consistent USGS peer review practices.

C. *Science Center Managers*. Science Center (Cost Center) Managers or their equivalent ensure that an accepted and consistent peer review process is in place within their unit. They appoint qualified peer reviewers for the work conducted by scientists they supervise. They ensure that only properly peer reviewed products are forwarded to delegated Approving Officials for approval and release (see [SM 502.4](#) and [SM 205.18](#)). Managers ensure that archival records related to peer review are maintained in their center.

D. *Approving Officials*. Approving Officials, as delegated (see [SM 205.18](#)), ensure that USGS standards for scientific quality are met by confirming that peer review requirements are met in accordance with this policy and its guidelines and by conducting a policy review (see [SM 502.4](#)) of information products before approving them for release. They also ensure that authors have adequately addressed review comments (that is, a reconciliation document is part of the approval package).

E. *Authors*. Authors support the peer review process by suggesting or nominating qualified peer reviewers to science center managers for their own work and the work of other USGS scientists and by participating in peer review of the work of others (see "Guidelines" below).

F. *Geospatial Information Office*. The Geospatial Information Office maintains the policy documents and procedures that pertain to USGS Fundamental Science Practices.

7. Guidelines for Peer Review. The following information provides additional guidance to ensure that peer review requirements are met:

A. *Reviewer Selection*. Qualified reviewers must be true peers, must not be associated with the work being performed, and should be selected for their relevant scientific and technical expertise, including those who may apply different methods of study to related scientific questions. Peer reviewers should be sought outside a scientist's own discipline where appropriate. Reviewers should be able to ensure that the science is effectively presented with the intended audience in mind and be cognizant of controversial or high-visibility issues that may be relevant to public policy. Guidance on peer review criteria for "influential scientific information and highly influential scientific assessments," as defined by the Office of Management and Budget, is found in [OMB, Final Information Quality Bulletin for Peer Review](#).

B. *Number of Reviewers.* Two peer reviews by qualified scientists are mandatory for all information products. One reviewer must be from outside the originating office; the other may be from the originating office of the information product. Additional peer review may be necessary, depending on the scientific complexity of the product and the [intended audience](#).

C. *Reviewer Ethics and Conduct.* USGS pursues vigorous and open peer review of its science and its information products. Issues related to scientific excellence, objectivity, integrity, and conflict of interest are dealt with in accord with established DOI and USGS codes of scientific conduct.

D. *Nondisclosure prior to publication.* In agreeing to be a peer reviewer for a USGS information product, reviewers must agree to be bound by the strictest scientific ethics in ensuring confidentiality of the science that is being reviewed and to not disclose or divulge any results or conclusions, or to make any public statements regarding the science before it is published and released.

E. *Documentation and Records.* Review and approval records for published USGS information products and for information products and articles published by outside sources include information such as author, title, purpose, publishing media, and signatures for peer review, editorial review, delegated Bureau Approval, and other appropriate USGS and outside source review and approval concurrences. Included as well is the consent or permission of the copyright owner for using copyrighted materials in USGS information products and articles (see [SM 1100.6](#)). These records are part of the official record and are archived in accordance with USGS Records Disposition Schedule requirements (see [SM 432-1.S1](#), Chapter 1300) at the originating office.

NOAA Policy on Conflicts of Interest for Peer Review*

Introduction

In December 2004, the White House Office of Management and Budget (OMB) issued a Final Information Quality Bulletin for Peer Review (Bulletin) establishing minimum peer review standards, a transparent process for public disclosure of peer review planning, and opportunities for public participation. The OMB Bulletin, implemented under the Information Quality Act (Public Law 106-554), is intended to enhance the quality and credibility of the federal government's scientific information, and applies to influential scientific information disseminated on or after June 16, 2005.

* Available at: http://www.cio.noaa.gov/Policy_Programs/NOAA_PRB_COI_Policy_110606.html

The Bulletin directs federal agencies to adopt or adapt the National Academy of Sciences' (NAS) policy for committee selection with respect to evaluating conflicts of interest when [\[Note 1\]](#) selecting peer reviewers who are not federal government employees. [\[Note 2\]](#) The National Oceanic and Atmospheric Administration (NOAA) has adapted the NAS conflict of interest policy as set forth below.

Conflict of Interest Policy

It is essential that individuals serving as peer reviewers of influential scientific information or highly influential scientific assessments that NOAA intends to disseminate not be compromised by any significant conflict of interest. For this purpose, **the term "conflict of interest" means any financial or other interest which conflicts with the service of the individual on the review panel because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization.** Except for those situations in which NOAA determines that a conflict of interest is unavoidable and promptly and publicly discloses the conflict of interest, no individual can be appointed to review documents subject to the OMB Bulletin if that individual has a conflict of interest that is relevant to the functions to be performed.

General Principles

Involves an Interest

The term "conflict of interest" means something more than individual bias. There must be an *interest*, ordinarily financial, that could be directly affected by the work of the peer reviewers.

Conflict of interest requirements are objective and preventive. They are not an assessment of one's actual behavior or character, one's ability to act objectively despite the conflicting interest, or one's relative insensitivity to particular dollar amounts of specific assets because of one's personal wealth. Conflict of interest requirements are objective standards designed to eliminate certain specific, potentially compromising situations from arising, and thereby protect the individual, other peer reviewers, NOAA, and the public interest. The individual, the other peer reviewers, and NOAA should not be placed in a situation where the findings and conclusions of a review could be reasonably questioned, and perhaps discounted or dismissed, simply because of the existence of conflicting interests.

Applies Only to Current Interests

The term "conflict of interest" applies only to *current interests*. It does not apply to past interests that have expired, no longer exist, and cannot reasonably affect current behavior. Nor does it apply to possible interests that may arise in the future but do not currently exist, because such future interests are inherently speculative and uncertain. For example, a pending formal or informal application for a particular job is a current interest, but the mere possibility that one might apply for such a job in the future is not a current interest.

Potentially Affects the Interests of Others

The term "conflict of interest" applies not only to the personal financial interests of the individual but also to the *interests of others* with whom the individual has substantial common financial interests if these interests are relevant to the functions to be performed. Thus, in assessing an individual's potential conflicts of interest, consideration must be given not only to the interests of the individual but also to the interests of the individual's spouse and minor children, the individual's employer, the individual's business partners, and others with whom the individual has substantial common financial interests. Consideration must also be given to the interests of those for whom one is acting in a fiduciary or similar capacity (e.g., being an officer or director of a corporation, whether profit or nonprofit, or serving as a trustee).

Covers a Broad Range of Financial Interests

The term "conflict of interest" as used herein ordinarily refers to *financial* conflicts of interest. In assessing potential conflicts of interest in connection with an individual's service as a peer reviewer, particular attention will be given to the following kinds of *financial interests* if they are relevant to the functions to be performed:

- Employment relationships (including private and public sector employment and self-employment).
- Consulting relationships (including commercial and professional consulting and service arrangements, scientific and technical advisory board memberships, and serving as an expert witness in litigation).
- Stocks, bonds, and other financial instruments and investments including partnerships.
- Real estate investments; patents, copyrights, and other intellectual property interests.
- Commercial business ownership and investment interests.
- Service provided in exchange for honorariums and travel expense reimbursements.
- Research funding and other forms of research support.
- Financial ties to entities regulated by NOAA, other stakeholders and NOAA itself.

Limits Access to Confidential Information

During the course of peer review activity for NOAA, the opportunity to have access to confidential information, if abused or misused, may confer an unfair competitive advantage. If an individual during the course of participating in a peer review for NOAA obtains and uses, or intends to use, confidential information not reasonably available to the public for the individual's own direct and substantial economic benefit, such conduct constitutes a conflict of interest. The same rule applies if the individual discloses, or intends to disclose, such information (albeit lawfully) to other individuals or to organizations in such a manner that a direct and substantial

economic benefit may be conferred on such individuals or organizations. These restrictions do not apply to information once it has entered the public domain.

In some situations - for example, access to confidential or proprietary information, - special limitations on access to and use of such information will be imposed. Substantial legal penalties may apply for noncompliance. In addition, an individual employed by or associated with a particular organization or enterprise should not be given access to proprietary information of a competitor or potential competitor unless appropriate safeguards have been established that reasonably protect the interests of all parties. Otherwise, such access may create an unfair competitive advantage, as well as possible liability for improper disclosure and use. For further guidance regarding access to confidential information, contact the NOAA Office of the General Counsel.

Limits Reviews of One's Own Work

It is not uncommon for individuals serving as peer reviewers to find that their own published and professional work, in common with others in the field, is part of the technical basis and literature for the information being reviewed. This ordinarily would not constitute a conflict of interest. However, an individual should not serve as a peer reviewer when a critical review and evaluation of the individual's own work, or that of his or her immediate employer, is a central purpose of the review, because that would constitute a conflict of interest, although such an individual may provide relevant information to the peer reviewers.

Public Statements and Positions

An individual may have become committed to a fixed position on a particular issue through public statements (e.g., testimony, speeches, interviews), through publications (e.g., articles, books), through close identification or association with the positions or perspectives of a particular group, or through other personal or professional activities. This would ordinarily constitute a potential source of bias but not a conflict of interest. However, in situations where there is some significant, directly related interest or duty of the individual - e.g., where the individual is currently president of a professional society that espouses the same fixed position on the issue - the situation may constitute a conflict of interest.

Implementation of this Conflict of Interest Policy

Requires Background Information and Confidential Conflict of Interest Disclosures

To address questions of conflict of interest, individuals selected to perform peer review of scientific information subject to the OMB Bulletin are required to submit certain background information and information regarding conflicts of interest to NOAA (or the entity commissioned by NOAA to manage the peer review process) for review. NOAA has developed a "Background Information and Confidential Conflict of Interest Disclosure" form for this purpose.

The disclosure of relevant information is a *continuing obligation* for the duration of the peer review process for which the "Background Information and Confidential Conflict of Interest Disclosure" form was prepared. If during an individual's period of service as a peer reviewer it becomes apparent to the individual that there has been a change in the information disclosed, or that there is new information that needs to be disclosed, such information must be reported promptly to NOAA or the entity commissioned by NOAA to manage the peer review process.

Except as otherwise provided herein, specific conflict of interest information obtained by NOAA, or the entity commissioned by NOAA to manage the peer review process, from the "Background Information and Confidential Conflict of Interest Disclosure" form, from amended disclosures, and from the public and other sources will be held in confidence by NOAA. Access to such information within NOAA will be limited to those offices whose proper business requires access to that information. Such information will not be released by NOAA, or the entity commissioned by NOAA to manage the peer review process, except with the approval of the individual to whom the information pertains, unless release is required by law.

Requires Public Notice

For peer reviews of information subject to the OMB Bulletin, NOAA will disclose the names of the reviewers and their affiliation in a report of findings and conclusions prepared by the peer reviewers. The report will be posted on the Department of Commerce Information Quality web site (http://www.osec.doc.gov/cio/oipr/info_qual.html). For peer review of highly influential scientific assessments, the report will also include the credentials and relevant experiences of each peer reviewer. Reviewers shall be notified in advance regarding the extent of disclosure and attribution planned by the agency.

Uses Background Information to Make Determinations on Conflicts of Interest

Information obtained from the "Background Information and Confidential Conflict of Interest Disclosure" forms and from other sources, including the public, will be used by NOAA in addressing and resolving questions of conflict of interest. Except for those situations in which the agency determines that a conflict of interest is unavoidable and promptly and publicly discloses the conflict of interest, no individual can be appointed to serve (or continue to serve) as a peer reviewer for NOAA of information subject to the OMB Bulletin if the individual has a conflict of interest that is relevant to the peer review to be performed.

A particular individual's conflict of interest may be determined to be unavoidable if, for example, the individual's qualifications, knowledge, and experience are particularly valuable to the peer review in question and the agency is unable to identify another individual with comparable qualifications, knowledge, and experience who does not also have a conflict of interest. Determinations that a conflict of interest exists and that a conflict of interest is unavoidable are made jointly by the NOAA office managing the peer review (or commissioning the entity to manage the peer review) and the NOAA General Counsel's office.

Department of the Interior Scientific Integrity Policy*

There are several aspects of the Department of Interior (DOI) SI Policy that are unique and useful in implementing section I of the December 17 memo from OSTP. First, the policy clearly articulates that it applies to all employees: career, political appointees, contractors, and volunteers. Second, it reaffirms peer review as the gold standard for agency science. Third, the policy emphasizes that scientists should be hired for scientific positions. Finally, it describes procedures for reporting and resolving allegation of scientific misconduct. For more information about the DOI policy, an annotated version of this policy can be found on our website.±

Applies to Career, Political Appointees, Contractors, and Volunteers

A. All DOI employees, including political appointees, (hereafter employees) when they engage in, supervise, manage, or influence scientific and scholarly activities, or communicate information about the Department's scientific and scholarly activities, or utilize scientific and scholarly information in making agency policy, management or regulatory decisions.

B. All contractors, cooperators, partners, permittees, leasees, and grantees who assist with developing or applying the results of scientific and scholarly activities.

C. All volunteers who assist with developing or applying the results of scientific and scholarly activities.

Reaffirms peer review as the gold standard

(1) I will do my best to support the scientific and scholarly activities of others and will not engage in dishonesty, fraud, misrepresentation, coercive manipulation, censorship, or other misconduct that alters the content, veracity, or meaning or that may affect the planning, conduct, reporting, or application of scientific and scholarly activities.

(2) I will offer respectful, constructive, and objective review of my employees' scientific and scholarly activities and will encourage their obtaining appropriate peer reviews of their work. I will respect the intellectual property rights of others and will substantiate comments that I make about their work with the same care with which I carry out and report the results of my own activities.

* Available at: http://elips.doi.gov/app_dm/act_getfiles.cfm?relnum=3889

± Available at: http://www.ucsusa.org/assets/documents/scientific_integrity/Annotated-DOI-Comments.pdf

Reaffirms that scientists should be hired for scientific positions

D. Ensure that the selection and retention of employees in scientific and scholarly positions or in positions that rely on the results of scientific and scholarly activities are based on the candidate's integrity, knowledge, credentials, and experience relevant to the responsibility of the position.

Reaffirms that scientists should be hired for scientific positions

3.8 Procedures for Reporting and Resolving Allegations Regarding Loss of Scientific and Scholarly Integrity. The Department is dedicated to preserving the integrity of the scientific and scholarly activities it conducts, and are conducted on its behalf. It will not tolerate loss of integrity in the performance of scientific and scholarly activities or in the application of science and scholarship in decision making. This section outlines procedures for reporting and resolving allegations in a timely and fair manner (see Appendices A-1 and A-2).

A. Reporting an Allegation. Allegations of scientific and scholarly misconduct with respect to DOI employees, volunteers, contractors, cooperators, partners, permittees, leasees, and grantees must be submitted in writing. The Department will consider allegations submitted within 60 days of discovery of alleged misconduct. Allegations may be submitted by individuals or entities, internal or external to the Department. Misconduct includes intentional fabrication, falsification, or plagiarism and is not the result of honest error or difference of opinion, such as with a scientific and scholarly process or a management decision. Cases of fraud, waste, and abuse should be directly referred to the Office of Inspector General.

UCS & GAP Suggested Whistleblower Language

While federal employees are protected under the Whistleblower Protection Act, agencies are encouraged to adopt stronger language that more specifically outlines scientists' protections. In partnership with the Government Accountability Project (GAP), UCS has developed strong whistleblower language that would enhance protections for federal scientists.

It shall violate agency policy for any individual with authority to recommend or take a personnel action to censor or discriminate in any way because an employee or applicant discloses, is about to disclose, or is associated with the disclosure of research or other information that the employee or applicant reasonably believes is evidence of illegality, gross waste, gross mismanagement, abuse of authority or a substantial and specific danger to public health or safety, unless the information's public release is specifically prohibited by statute or specifically designated pursuant under Executive Order to be kept classified in the interest of national defense or the conduct of foreign affairs.

There shall be no exceptions to this right, including but not limited to motives for the disclosure; the disclosure being part of job duties; the disclosure having been made previously; whether the disclosure was oral or in writing, whether the disclosure is categorized as Controlled Unclassified Information or Critical Infrastructure Information; or the amount of time that has passed since events in the disclosure. If disclosure is specifically prohibited by Executive Order or the information is classified, the same rights against censorship and discrimination apply to disclosing the information to the agency head or delegee, the Office of Inspector General, or the U.S. Office of Special Counsel.

US Code: Disclosure of Violations

The federal procedure for disclosure of violations is outlined in the United States Code, Section 1213. Through this process, federal scientists can bring to light concerns about the integrity of science.

5 USC Sec. 1213. Provisions relating to disclosures of violations of law, gross mismanagement, and certain other matters*

(a) This section applies with respect to -

(1) any disclosure of information by an employee, former employee, or applicant for employment which the employee, former employee, or applicant reasonably believes evidences -

(A) a violation of any law, rule, or regulation; or

(B) gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety;

if such disclosure is not specifically prohibited by law and if such information is not specifically required by Executive order to be kept secret in the interest of national defense or the conduct of foreign affairs; and

(2) any disclosure by an employee, former employee, or applicant for employment to the Special Counsel or to the Inspector General of an agency or another employee designated by the head of the agency to receive such disclosures of information which the employee, former employee, or applicant reasonably believes evidences -

(A) a violation of any law, rule, or regulation; or

(B) gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.

(b) Whenever the Special Counsel receives information of a type described in subsection (a) of this section, the Special Counsel shall review such information and, within 15 days after receiving the information, determine whether there is a substantial likelihood that the information discloses a violation of any law, rule, or regulation, or gross mismanagement, gross waste of funds, abuse of authority, or substantial and specific danger to public health and safety

* Available at: <http://uscode.house.gov/uscode-cgi/fastweb.exe?getdoc+uscview+t05t08+133+1++%28%29%20%20AND%20%28%285%29%20ADJ%20USC%29%3ACITE%20AND%20%28USC%20w%2F10%20%281213%29%29%3ACITE>

(c)(1) Subject to paragraph (2), if the Special Counsel makes a positive determination under subsection (b) of this section, the Special Counsel shall promptly transmit the information with respect to which the determination was made to the appropriate agency head and require that the agency head -

(A) conduct an investigation with respect to the information and any related matters transmitted by the Special Counsel to the agency head; and

(B) submit a written report setting forth the findings of the agency head within 60 days after the date on which the information is transmitted to the agency head or within any longer period of time agreed to in writing by the Special Counsel.

(2) The Special Counsel may require an agency head to conduct an investigation and submit a written report under paragraph (1) only if the information was transmitted to the Special Counsel by -

(A) an employee, former employee, or applicant for employment in the agency which the information concerns; or

(B) an employee who obtained the information in connection with the performance of the employee's duties and responsibilities.

(d) Any report required under subsection (c) shall be reviewed and signed by the head of the agency and shall include -

(1) a summary of the information with respect to which the investigation was initiated;

(2) a description of the conduct of the investigation;

(3) a summary of any evidence obtained from the investigation;

(4) a listing of any violation or apparent violation of any law, rule, or regulation; and

(5) a description of any action taken or planned as a result of the investigation, such as -

(A) changes in agency rules, regulations, or practices;

(B) the restoration of any aggrieved employee;

(C) disciplinary action against any employee; and

(D) referral to the Attorney General of any evidence of a criminal violation.

(e)(1) Any such report shall be submitted to the Special Counsel, and the Special Counsel shall transmit a copy to the complainant, except as provided under subsection (f) of this section. The complainant may submit comments to the Special Counsel on the agency report within 15 days of having received a copy of the report.

(2) Upon receipt of any report of the head of an agency required under subsection (c) of this section, the Special Counsel shall review the report and determine whether -

(A) the findings of the head of the agency appear reasonable; and

(B) the report of the agency under subsection (c)(1) of this section contains the information required under subsection (d) of this section.

(3) The Special Counsel shall transmit any agency report received pursuant to subsection (c) of this section, any comments provided by the complainant pursuant to subsection (e)(1), and any appropriate comments or recommendations by the Special Counsel to the President and the congressional committees with jurisdiction over the agency which the disclosure involves.

(4) Whenever the Special Counsel does not receive the report of the agency within the time prescribed in subsection (c)(2) of this section, the Special Counsel shall transmit a copy of the information which was transmitted to the agency head to the President and the congressional committees with jurisdiction over the agency which the disclosure involves together with a statement noting the failure of the head of the agency to file the required report.

(f) In any case in which evidence of a criminal violation obtained by an agency in an investigation under subsection (c) of this section is referred to the Attorney General -

(1) the report shall not be transmitted to the complainant; and

(2) the agency shall notify the Office of Personnel Management and the Office of Management and Budget of the referral.

(g)(1) If the Special Counsel receives information of a type described in subsection (a) from an individual other than an individual described in subparagraph (A) or (B) of subsection

(c)(2), the Special Counsel may transmit the information to the head of the agency which the information concerns. The head of such agency shall, within a reasonable time after the information is transmitted, inform the Special Counsel in writing of what action has been or is being taken and when such action shall be completed. The Special Counsel shall inform the individual of the report of the agency head.

(2) If the Special Counsel receives information of a type described in subsection (a) from an individual described in subparagraph (A) or (B) of subsection (c)(2), but does not make a positive determination under subsection (b), the Special Counsel may transmit the information to the head of the agency which the information concerns, except that the information may not be transmitted to the head of the agency without the consent of the individual. The head of such agency shall, within a reasonable time after the information is transmitted, inform the Special Counsel in writing of what action has been or is being taken and when such action will be completed. The Special Counsel shall inform the individual of the report of the agency head.

(3) If the Special Counsel does not transmit the information to the head of the agency under paragraph (2), the Special Counsel shall inform the individual of -

(A) the reasons why the disclosure may not be further acted on under this chapter; and

(B) other offices available for receiving disclosures, should the individual wish to pursue the matter further.

(h) The identity of any individual who makes a disclosure described in subsection (a) may not be disclosed by the Special Counsel without such individual's consent unless the Special Counsel determines that the disclosure of the individual's identity is necessary because of an imminent danger to public health or safety or imminent violation of any criminal law.

(i) Except as specifically authorized under this section, the provisions of this section shall not be considered to authorize disclosure of any information by any agency or any person which is –

(1) specifically prohibited from disclosure by any other provision of law; or

(2) specifically required by Executive order to be kept secret in the interest of national defense or the conduct of foreign affairs.

(j) With respect to any disclosure of information described in subsection (a) which involves foreign intelligence or counterintelligence information, if the disclosure is specifically prohibited by law or by Executive order, the Special Counsel shall transmit such information to the National Security Advisor, the Permanent Select Committee on Intelligence of the House of Representatives, and the Select Committee on Intelligence of the Senate.

Protecting Scientific Documents Used in Regulation*

Agencies should incorporate safeguards for protecting the integrity of scientific documents as they change hands in the course of regulatory reviews. One of the best ways to do this is to add increased transparency to the process.

A.1. Agencies should look for ways to disclose more information about how a regulation was developed. The rule-making docket should contain:

- A stated scientific rationale for any decision informed by science.
- All scientific studies in an agency's possession related to a proposed regulation, regardless of whether the study was directly cited or whether it directly informed the ultimate proposal.
- Completed and peer-reviewed drafts of agency documents prepared by scientific or technical staff before they are subjected to White House or interagency review.
- A minority report voicing any significant dissenting scientific evidence or opinions and an explanation of how the agency resolved such differences of opinion.
- All official interagency communications regarding rules under review, including those from the White House.
- Identification by name of each official and employee who participated in the decision.

(Similar transparency requirements have already been incorporated into the FDA Amendments Act of 2007, and should be adapted for other federal agencies.)

* Available at: http://www.ucsusa.org/assets/documents/scientific_integrity/UCS-Comments-to-OSTP-on-SI-Memo.pdf

Training and Increased Visibility for Scientific Integrity*

It is important to include references to the training employees will receive and concerning where the policies will be posted and how employees will be reminded of these provisions. Receiving them once when newly employed and posting them on a bulletin board is not enough.

A.2. Agencies should proactively educate federal scientists and researchers regarding their rights and protections. This includes:

- Mandatory briefings for new hires
- Requirements for posting educational information in workplaces
- Regular in-service trainings

* Available at: http://www.ucsusa.org/assets/documents/scientific_integrity/Federal-Science-and-the-Public-Good-Exec-Sum-12-08-Update.pdf

Section II: Public Communications

Section II of the Scientific Integrity Memo states:

“Agencies should develop public communications policies that promote and maximize, to the extent practicable, openness and transparency with the media and the American People while ensuring full compliance with limits on disclosure of classified information.”

Discussion:

This section articulates the need for a comprehensive media policy at each Agency. Under this policy, scientists will be able to speak to the public and media about scientific and technological matters. Scientists are expected to clearly delineate when they are speaking as a private citizen or as a representative of the Agency. The blue, italicized text at the top of the page contains our comments, while everything below this point is taken directly from the agency’s website.

Policy Checklist:

- Media Policy

Media Policy

Among science and regulating agencies, the Department of Health and Human Service's Centers for Disease Control and Prevention (CDC) has the most comprehensive and detailed policy for communicating with the media. Their policy is easy for employees to understand, very accessible, and provides a specific outline of their guidelines. This policy implies but does not explicitly state that scientists and researchers, as any federal employees, have a right to express personal opinions with appropriate disclaimers, although it is quite clear in stating that the policy only applies to official agency communications. In addition, it could be more explicit about giving scientists the right to review, approve, and comment publically on the final version of any proposed publication that significantly relies on their research, identifies them as an author or contributor, or purports to represent their scientific opinion.

CDC Guidelines for Ensuring the Quality of Information Disseminated to the Public*

I. Agency Mission

The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) are two of the operating components of the HHS. CDC has remained at the forefront of public health efforts to prevent and control infectious and chronic diseases, injuries, workplace hazards, disabilities, and environmental and occupational health threats for more than 50 years. CDC is the lead federal agency for protecting the health and safety of people — at home and abroad, providing credible information to enhance health decisions, and promoting health through strong partnerships.

CDC seeks to accomplish its mission by working with partners throughout the nation and world to monitor health, detect and investigate health problems, conduct research to enhance prevention, develop and advocate sound public health policies, implement prevention strategies and programs, promote healthy behaviors, foster safe and healthful environments, and provide leadership and training.

CDC has developed and sustained many vital partnerships with public and private entities that improve service to the American people. In FY 2000, the workforce of CDC comprised approximately 8,500 FTE in 170 disciplines with a public health focus. Although CDC's national

* Available at: <http://aspe.hhs.gov/infoquality/Guidelines/cdcinfo2.shtml>

headquarters is in Atlanta, Georgia, more than 2,000 CDC employees work at other locations nationwide including virtually all States. Approximately 160 are assigned overseas in 45 countries. In addition, CDC is comprised of 12 Centers, Institutes, and Offices (CIOs). These organizational components, listed below, respond individually in their areas of expertise and pool their resources and expertise on cross-cutting issues and specific health threats.

- National Center on Birth Defects and Developmental Disabilities
- National Center for Chronic Disease Prevention and Health Promotion
- National Center for Environmental Health
- National Center for Health Statistics
- National Center for HIV, STD, and TB Prevention
- National Center for Infectious Diseases
- National Center for Injury Prevention and Control
- National Immunization Program
- National Institute for Occupational Safety and Health
- Epidemiology Program Office
- Public Health Practice Program Office
- Office of the Director

ATSDR was established in 1980 by the Comprehensive Environmental Response, Compensation, and Liability Act, also known as Superfund. ATSDR works to prevent exposures to hazardous wastes and to environmental releases of hazardous substances. Working with States and other Federal agencies, ATSDR seeks to prevent exposure and adverse health effects associated with exposure to hazardous substances from waste sites. The agency conducts public health assessments, health studies, surveillance activities and health education training in communities around waste sites or exposed to environmental releases. ATSDR also develops toxicological profiles of hazardous chemicals found at these sites. The agency has 10 regional offices and an office in Washington, DC, and a staff of about 400 persons.

Although CDC and ATSDR are separate agencies, both strive to protect and improve the health of the American public. The Director of CDC also serves as the Administrator of ATSDR.

Unless otherwise specified, all subsequent references to CDC also include ATSDR and all practices and procedures described in this document apply to both agencies.

II. Scope and Applicability of Guidelines for CDC

CDC will ensure that disseminated information meets the standards of quality set forth in the OMB, HHS and CDC guidelines. It is CDC's policy to ensure and maximize the quality, objectivity, utility, and integrity of information that it disseminates to the public. We strive to provide information that is accurate, reliable, clear, complete, unbiased, and useful. We are committed to integrating the principle of information quality into every phase of information development, including creation, collection, maintenance, and dissemination. CDC guidelines do not apply to the National Center for Health Statistics (NCHS). While NCHS is a component of CDC, NCHS is the nation's principal health statistics agency and as such has separate guidelines.

The pre-dissemination review described in the guidelines only applies to information disseminated on or after October 1, 2002. The administrative mechanism for correction applies to information that the agency disseminates on or after October 1, 2002, regardless of when the agency first disseminated the information.

The guidelines apply to information in all media — print, electronic, audiovisual, and oral. They apply to substantive information, such as studies and reports, rather than to information pertaining to basic agency operations. Information that is disseminated at the request of CDC or with specific CDC approval through a contract, a grant, or a cooperative agreement is subject to these guidelines.

Examples are provided below of the types of information that the CDC considers within and outside the scope of the guidelines.

A. Covered Information

- Scientific research papers, books, journal articles, reports, and similar materials, unless they have disclaimers to distinguish the research from CDC views and positions;
- Other official reports, brochures, documents, newsletters, and audiovisual products;
- Oral information, including speeches, interviews, expert opinions only if representing CDC's views, official positions, or policies;
- Statistical information - statistical analyses, aggregated information by programs.

B. Information Not Covered

- Documents not authored by CDC (either directly or by contract) and not representing official views, including research and science supported by CDC funding;
- Opinions where the presentation makes it clear that what is being offered is personal opinion rather than fact or CDC's views;
- Archival information disseminated by CDC (for example, Internet distribution of published articles);
- Information dissemination limited to government employees or agency contractors or grantees;
- Information intended solely for intra- or inter-agency use or sharing of government information, such as evaluation of a specific public health program to assess the success in achieving its objectives, technical assistance reports, training materials, manuals;
- Information intended to be limited to public filings, subpoenas, or adjudicative processes;
- Press releases that support the announcement or give public notice of information that CDC has disseminated elsewhere.

III. Types of Information Disseminated by CDC to the Public

Annually, CDC produces hundreds of publications of various types and provides over 100,000 pages of Web content for access by the public. All publications that carry the CDC logo are considered official publications or releases, and must follow CDC policy and procedures for preparation, review, approval, and distribution (www.cdc.gov/od/foia/policies/clearance.htm).

Examples of the types of information disseminated by CDC to the public are listed below. Some types fit into more than one category and are mentioned in each.

A. Scientific research studies.

CDC encourages professional dissemination of scientific research by employees and those funded by CDC to conduct research. These research studies may be published by CDC, such as the *Morbidity and Mortality Weekly Report* (MMWR) or non-CDC publications including journals, books, chapters, editorials, reviews, proceedings or abstracts. These are usually authored by or co-authored by CDC staff scientists as part of their official duties or may be authored by CDC partners, CDC advisory committees, or working groups convened by CDC.

B. Statistical products

CDC releases data sets and disseminates statistical reports produced by its data collection programs. These include vital statistics, population-based health surveys, and surveys of health care providers.

C. Programmatic and administrative information.

CDC disseminates community health assessments and information in connection with and as a byproduct of the administration of programs, such as Program-in-Brief documents, At-A-Glance documents, and program brochures.

D. Authoritative health, medical and human services information aimed at consumers and health and human services professionals.

CDC publishes the *MMWR* which includes *Recommendations and Reports*. CDC generates Health Alerts, Public Health Advisories, and guidelines for dealing with specific public health threats. CDC also provides the website *Travelers' Health*, which publishes guidelines for international travelers including the "Yellow Book" and official expert opinions. CDC produces and broadcasts science educational materials and training modules, including Public Health Grand Rounds Satellite broadcasts, Web-assisted Audio Conferences for State and Local Health Policymakers, and the Health Training Network Satellite Broadcast.

E. Public health surveillance, and epidemiology information.

CDC publishes the *MMWR Summary of Notifiable Diseases* and *CDC Surveillance Summaries*, and other surveillance summaries on a variety of infectious diseases such as HIV/AIDS and tuberculosis, as well as other non-infectious conditions such as Birth

Defects Surveillance, National Oral Health Surveillance, Pediatric Nutrition Surveillance, Pregnancy Nutrition Surveillance, Hazardous Substance Release/Health Effects Database, Flu Bulletin, Influenza Season Reports and Occupational Morbidity and Mortality Surveillance, Adult Blood Lead Epidemiology and Surveillance, Coal Workers X-ray Surveillance Program, National Surveillance System of Pneumoconiosis Mortality, National Traumatic Occupational Fatalities Surveillance System. In addition CDC publishes outbreak investigations or other items reported in the MMWR that are not authoritative or urgent. ATSDR disseminates information products including Public Health Assessments, Public Health Consultations, Fact Sheets, health study reports, Toxicological Profiles, Case Studies in Environmental Medicine, and Hazardous Substances and Public Health (newsletter).

IV. Types of Dissemination Methods

CDC disseminates information through a wide range of methods, often using more than one medium for the same information.

- A. **Print**,
including publications in peer-reviewed literature, published reports, periodicals, brochures, books, and correspondence;
- B. **Electronic**,
such as the CDC Website, CD-ROM, Listserv, e-mail, automated voice and fax systems, hotlines and clearinghouses;
- C. **Audiovisual**,
broadcast scripts, audio or videotapes, and videocasting. CDC's Public Health Training Network makes satellite broadcasts and Webcasts available nationally.
- D. **Oral**,
formal speeches, oral presentations, and interviews, or commentaries for publication or broadcast.

V. Agency Quality Assurance Policies, Standards and Processes for Ensuring the Quality of Information Dissemination to the Public.

- A. **Overview**
CDC's policies and procedures are designed to ensure and maximize the quality of its information products with regard to their utility, objectivity, and integrity. The agency's quality assurance process begins at the inception of the information development process. CDC has guidelines to address the general principles concerning the responsibilities of the CDC staff in the collection and recording of data, publication practices, authorship determination, peer review, confidentiality of information, collaborations, and human subjects research. Authorship issues and review and clearance procedures are set forth in the "Authorship of CDC Publications and the Clearance Procedures for Scientific and Technical Documents" (www.cdc.gov/od/foia/policies/clearance.htm).

CDC reviews the quality (including the objectivity, utility, and integrity) of information before it is disseminated and treats information quality as integral to every step of the development of information, including its creation, collection, maintenance and dissemination. Further, CDC is committed to demonstrating in its Paperwork Reduction Act clearance packages that each draft information collection will result in information that will be collected, maintained, and used in a way that is consistent with OMB, HHS and CDC information quality guidelines. The individual CIO Associate Directors for Science (ADS) or designee are responsible for assuring the quality of information disseminated by CDC and that the quality assurance methods and procedures described in Overview of Quality Assurance Policies and Practices in HHS are met. To meet the standards for external merit review of research and scientific studies and intramural research programs, CDC policy is to peer review extramural research and intramural research studies and programs.

The CIO ADS or designee are responsible for clearance of documents originating in that CIO before dissemination and for ensuring that the necessary clearances are obtained and that written material distributed is appropriate and consistent with HHS policy. While each CIO can determine preparation, review and approval procedures, all must meet standards provided by the ADS, CDC and those provided in the HHS Part I Overview D.4.d.

- **Utility** CDC addresses utility, a measure of the usefulness of information products to its intended users, by staying informed of user needs through information product research and user needs assessment, user feedback, consultation with advisory committees, and conference participation.
- **Objectivity** CDC provides assurance that information is accurate, reliable, and unbiased. Objectivity is achieved through existing review and clearance procedures and, in many cases, the peer review of disseminated information.
- **Integrity** CDC assures the integrity of its data and information products through the enforcement of rigorous controls that protect against unauthorized access, revision, or corruption. Some of the controls used at CDC include access control, user authentication, encryption, access monitoring, provision of unalterable electronic content, and audit trails.

B. CDC Information Review and Approval Policies and Procedures by Type of Information

a. Health and Public Health Information

1. Scientific research studies

CDC encourages professional dissemination of scientific research and other information by its employees. Publications or presentations by CDC employees are expected to meet high standards of quality, make a substantial contribution to the field, and contain sufficient information for the informed audience to assess its validity. Publication of scientific information by individual employees must undergo a formal review and clearance process by the CIO ADS or designee before dissemination. This review includes the evaluation of data collection measures for completeness, accuracy and timeliness, data management and analysis,

clarity and accuracy of presentation, and validity of interpretation of findings.

Oral presentations undergo appropriate supervisory review. Laboratory data are reviewed to assure that good laboratory data practice was followed for sampling, methodology, instrumentation and analysis.

Intramural research programs will be subject to review and monitoring by external, objective peer review through an advisory committee or board of scientific counselors. Scientific research studies submitted to journals are subject to peer review of methods and findings by the journal prior to publication. ATSDR has a mandated policy for external peer review of all intramural and extramural research study protocols and findings prior to public dissemination.

2. **Authoritative health, medical and human services information aimed at consumers and health and human services professionals**

CDC disseminates authoritative health and medical information routinely as part of its mission. As an example, articles or reports for publication in the MMWR are subject to routine CDC review and approval procedures in the originating CIO. Because information disseminated in the MMWR often has impact on the practice of public health, the CDC ADS must also review and approve it. Health Alerts related to bioterrorism that are disseminated by CDC are also reviewed and approved at the CDC ADS level prior to release.

3. **Public health surveillance and epidemiology information**

CDC often obtains surveillance information from third parties, such as States, grantees, or community-based organizations. Reliance on third parties places limits on CDC's quality assurance, although the accuracy, completeness and timeliness of the information are subject to sample audits, site visits, and an evaluation for completeness and consistency with trends and external controls. The *MMWR Summary of Notifiable Diseases*, for example, depends on data reported from States. CDC conducts audits and checks for consistency for trends before reporting these data. ATSDR produces Toxicological Profiles for hazardous substances found at National Priorities List sites as well as other documents that undergo public comment periods before being finalized and distributed. The Toxicological Profiles and other ATSDR documents are first produced as drafts and are then subject to public comments following announcement in the Federal Register and using other means. Only after considering the comments, the profiles and documents are finalized and then distributed to the public.

ATSDR has a government to government policy on Tribal Nations that specifies how the agency works with and respects Tribal rights, sovereignty, and culture. Data or information collected from American Indian/Alaska Native communities requires approval from the Tribal

government and direct involvement in the research or study from concept to completion. The Tribe reserves the right to review and critique the design and findings. Issues of release and ownership of data, information or other products must be agreed to by the Tribal government. Close collaboration and involvement of the Tribe is essential to ensure quality, utility, objectivity and integrity of information prior to being disseminated.

b. Statistical products

CDC routinely employs a number of widely accepted methods and procedures for ensuring quality, including independent assessments of statistical methodologies, peer reviews, and observance of professional standards. To insure the utility of CDC statistical and analytic information products, CDC conducts independent research and consults experts in areas such as data collection, data analysis and a variety of substantive topics and areas. Additionally, CDC maintains ongoing contact with users, and participates in conferences, and workshops in order to objectively assess and identify the current and future data needs of CDC's constituents. Further, CDC employs a wide variety of dissemination mechanisms to make its statistical and analytic information products widely available and broadly accessible.

To assure that statistical and analytic information products are accurate, reliable, and unbiased, CDC obtains these data through generally accepted statistical theory and practice. Dissemination of data also follows generally recognized guidelines in terms of defining acceptable standards regarding minimum response rates, maximum standard errors, cell size suppression, quality of coding and other processing operations. CDC also maintains staff expertise in areas such as concept development, survey planning and design, data collection, data processing and editing, data analysis, evaluation procedures, and methods of data dissemination.

All CDC statistical and analytic information products undergo a formal clearance process before dissemination. Publications and reports, whether in electronic or paper form, are reviewed by a CIO ADS or designee. These reviews cover the clarity of descriptive text, the appropriateness of the methodology, the soundness of the analysis, the adherence to confidentiality and disclosure avoidance restrictions, the readability of tabular and graphic presentations of data. Finally, all products undergo editorial review, (e.g., formatting, proofreading, spell checks, proper punctuation). Oral presentations undergo appropriate supervisory review. The CIO ADS or designee may also review for programmatic and policy implications on behalf of and in consultation with other division or senior staff. In addition, all public-use tapes are reviewed by the CIO ADS or designee for accuracy and appropriate confidentiality protections.

CDC statistical and analytic information products are derived using generally acceptable statistical practices and methodologies which are clearly documented and available to the public. These procedures enable responsible statisticians and

analysts outside of CDC to replicate CDC's statistical methods and obtain results consistent with those obtained by CDC.

VI. Agency Administrative Complaint Procedures

CDC has developed administrative mechanisms to allow affected persons to seek and obtain correction of disseminated information that does not comply with OMB, HHS and CDC guidelines.

CDC will establish a Website to advise information consumers of the agency's information quality guidelines, the process to submit a complaint, information needed by the complainant, and a description of the complaint adjudication process. CDC will centralize the initial receipt, logging, and tracking of all complaints received under this provision in the Management Analysis and Services Office (MASO), Office of Program Services. Complaints will be forwarded to the office that has subject matter responsibility for the information product in question.

A. Responsibility of the Complainant

To seek a correction of information disseminated by the agency, individuals must follow the procedures described below:

1. complaints or requests for review and correction of information must be in written (hard copy or electronic) form;
2. requests shall be sent to CDC by mail at CDC/ATSDR, Attn: MASO, MS-E11, 1600 Clifton Road, N.E.; Atlanta, GA 30333 or by e-mail at: InfoQuality@cdc.gov; and
3. requests shall state that an information quality request for correction is being submitted.

The complaint must contain:

4. a detailed description of the specific information that needs to be corrected including where the information is located, i.e. the publication title, date, and publication number, if any, or the Website and Web page address (url), or the speech title, presenter, date and place of delivery;
5. the specific reasons for believing the information does not comply with OMB, HHS or CDC guidelines and is in error and supporting documentation, if any;
6. the specific recommendations for correcting the information;
7. a description of how the person submitting the complaint is affected by the information error; and
8. the name, mailing address, telephone number, e-mail address, and organizational affiliation, if any, of the individual making the complaint.

Complainants should be aware that they bear the 'burden of proof' with respect to the necessity for correction as well as with respect to the type of correction they seek.

B. CDC/ATSDR Responsibility

CDC will respond to all requests for correction within 60 calendar days of receipt. If the request requires more than 60 calendar days to resolve, the requestor will be informed that more time is required, notified of the reason why, and provided an estimated decision date. Based on a review of the information provided, the agency will determine whether a correction is warranted and, if so, what action to take. CDC will respond to the requestor by letter or e-mail, explaining the findings of the review and the actions that the agency will take, if any. The response will consider the nature and timeliness of the information involved and such factors as the significance of the correction on the use of the information and the magnitude of the correction. The response will describe how the complainant may request reconsideration of the CDC decision.

C. Appeals

If the individual submitting the complaint does not agree with CDC's decision (including the corrective action, if any), the complainant may send a written hard copy or electronic request for reconsideration within 30 days of receipt of the agency's decision. The appeal must state the reasons why the agency response is insufficient or inadequate.

Complainants must attach a copy of their original request and the agency's response to it. Clearly mark the appeal with the words, "Information Quality Appeal," and send the appeal by mail to CDC/ATSDR, Attn: MASO, MS-E11; 1600 Clifton Road, N.E., Atlanta, GA 30333 or by e-mail to InfoQuality@cdc.gov.

The agency will respond to all requests for appeals within 60 calendar days of receipt. If the request requires more than 60 calendar days to resolve, the agency will inform the complainant that more time is required and indicate the reason why and an estimated decision date.

The agency official who resolved the original complaint will not have responsibility for the appeal. MASO will direct all appeals to an appropriate CDC official in the Office of the Director based on the nature of the information product and complaint.

VII. Influential Scientific, Financial and Statistical Information

CDC considers the information disseminated in the *MMWR Recommendations and Reports*, the Hazardous Substance Release/Health Effects Database, Toxicological Profiles, ATSDR Public Health Assessments, and Federal Register publications related to science as influential scientific information.

Risk Assessment

Some of the influential information that we disseminate is based on an analysis of the risks to the public of certain actions or exposures to hazardous substances. For purposes of this guidance, we are defining risk as the likelihood that injury or damage is or can be caused by a substance, technology, or activity. We use risk analysis (the integration of risk assessment with risk management and risk communication) as a tool to enhance the scientific basis for all of our regulatory decisions.

The OMB Guidelines provide special considerations that must be taken into account in certain risk assessments, those that provide the basis for the dissemination of influential information. The guidelines state that "With regard to analysis of risks to human health, safety, and the environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (SDWA) (42 U.S.C. 300g-1(b)(3)(A) and (B))."

The SDWA risk assessment principles are as follows:

1. To the degree that the agency action is based on science, the agency shall use
 - a. the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices
 - b. data collected by accepted methods (if reliability of the method and the nature of the decision justify use of the data)
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.
3. In a document made available to the public in support of a regulation, the agency shall specify, to the extent practicable
 - a. Each population addressed by any estimate of applicable risk effects
 - b. The expected risk or central estimate of risk for the specific populations affected
 - c. Each appropriate upper-bound or lower-bound estimate of risk
 - d. Each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty and
 - e. Peer-reviewed studies known to the agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile the inconsistencies in the scientific data

Many of our actions are based on scientific experts' judgments using available data, are essentially qualitative and do not lend themselves to the types of quantitative risk assessments contemplated by the SDWA principles. As a result, we have adapted the general principles for risk assessments from the SDWA to fit these situations.

1. The agency will use
 - a. the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer-reviewed science and supporting studies when available

- b. data collected by accepted methods (if reliability of the method and the nature of the decision justify use of the data)
2. In the dissemination of public information about risks, the agency will ensure that the presentation of information about risk effects is comprehensive, informative, and understandable.

In situations where a quantitative risk assessment is conducted, we generally follow basic risk assessment principles in the NAS paradigm of 1983. Our needs for quantitative risk assessments range over a wide variety of hazards including physical hazards encountered during exposure to toxic substances and antimicrobial resistance to antibiotic therapy. Thus, we also ascribe to the statement from NAS when it revisited the risk assessment process in 1994 (*Science and Judgment in Risk Assessment*, NAS 1994): "Risk assessment is not a single process, but a systematic approach to organizing and analyzing scientific knowledge and information." In each of the areas we regulate, we apply risk assessment practices to the specific task that are widely accepted among relevant domestic and international public health agencies.

For quantitative risk assessments in support of the dissemination of influential information, CDC intends to apply the following principles:

1. The agency will use
 - a. the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer-reviewed science and supporting studies when available.
 - b. data collected by accepted methods (if reliability of the method and the nature of the decision justifies use of the data).
2. In the dissemination of public information about health risks, the agency shall ensure that the presentation of information is comprehensive, informative, and understandable, within the context of its intended purpose.
3. In a document made available to the public, the agency shall specify, to the extent practicable-
 - a. Each population addressed by any estimate of applicable effects;
 - b. The expected or central estimate of risk for the specific populations affected;
 - c. Each appropriate upper-bound and/or lower-bound risk estimates;
 - d. Data gaps and other significant uncertainties identified in the process of the risk assessment and the studies that would assist in reducing the uncertainties; and
 - e. Additional studies not used in the risk assessment that support or fail to support the findings of the assessment and the rationale of why they were not used.

VIII. Special Considerations for Agency Dissemination

Special consideration also applies to information products that are urgent in nature and because of the potential risk to human health and safety, certain information products may be disseminated in an expedited manner without having fully complied with all normal quality guidelines; however, basic quality principles and processes will still apply and be followed.

UCS Model Media Policy*

While the CDC media policy is very good, there are places where it could be more specific. Agency employees should be informed that they can speak publicly about any scientific topic as long as they make it clear that they are expressing personal views and not official agency positions. Public affairs officers should be instructed to act as communication facilitators, not gatekeepers. Scientists should be given the right of last review on pieces that include or represent their work. Our model media policy addresses these issues.

Section 1: Purpose

.01 This Order establishes the __ (agency) __ media policy governing media communications including advisories, press releases, statements, interviews, news conferences, and other related media contacts. Public affairs offices have been established to facilitate the active dissemination of agency research results and to coordinate media and public relations activities. A principal goal of public affairs is to help __ (agency) __ most efficiently achieve its agency mission through policy making based on sound and objective science.

Section 2: Rights

.01 Scientists and other staff ("employees") have the fundamental right to express their personal views, provided they specify that they are not speaking on behalf of, or as a representative of, the agency but rather in their private capacity. So long as this disclaimer is made, the employee is permitted to mention his or her institutional affiliation and position if this has helped inform his or her views on the matter. The employee is also allowed to make reasonable use of agency time and resources for the purposes of expressing their personal views (i.e., accommodations comparable with what would be allowed on other personal matters).

.02 Employees have the right to review, approve, and comment publicly on the final version of any proposed publication that significantly relies on their research, identifies them as an author or contributor, or purports to represent their scientific opinion.

.03 Final authority over the content of and parties to any particular media communication resides with the reporter and the scientist with whom he or she communicates.

Section 3: Responsibilities

.01 Public affairs is responsible for:

1. promoting media attention on important scientific and institutional developments;
2. coordinating and facilitating contact between journalists and the requested agency staff;

* Available at: http://www.ucsusa.org/assets/documents/scientific_integrity/Model-Media-Policy-1.pdf

3. providing both reporters and scientists with timely, accurate, and professional media assistance; and
4. providing draft press releases or other public statements to agency scientists whose work is included, to assure the accuracy of scientific information being communicated.

.02 Employees are responsible for working with public affairs to make significant research developments accessible and comprehensible to the public.

.03 Employees are responsible for the accuracy and integrity of their communications and should not represent the agency on issues of politics or policy without prior approval from the public affairs officer (PAO).

Section 4: Media and Public Interactions

.01 To help public affairs best fulfill its responsibilities, employees should:

1. keep the PAO informed of any media interest or potential for interest in their work;
2. notify the PAO of impending media contacts and provide the PAO with a recap of the non-confidential aspects of the media conversation afterward;
3. review drafts of press releases written by the PAO both for their format and non-scientific content, as well as for the accuracy of scientific information being communicated; and
4. work with the PAO to review presentations or news conferences for their format and content to assure the accuracy of scientific information being communicated.

.02 Public affairs officers should:

1. respond to all initial media inquiries within 20 minutes, or as soon as possible;
2. do all they can to help reporters get the appropriate information needed for an article;
3. know the reporter's deadline to ensure timely response;
4. provide contact information where they will be available, even after hours, on weekends, and on holidays;
5. draft regional and national press releases whenever warranted;
6. ensure a timely turnaround on press releases (within one week or less);
7. develop (or coordinate the development of) talking points in collaboration with the relevant experts for the release of scientific papers and other agency products;
8. assure agency compliance with the No Fear Act (a federal law that holds agencies accountable for violations of employee protection laws) by informing employees of their rights under federal anti-discrimination and whistleblower protection laws; and
9. assure that as part of any relevant agency communications to its employees, the agency includes the congressional addendum required by the Anti-Gag Statute, reaffirming the supremacy of the Whistleblower Protection Act (protecting non-classified public communications) and other congressional acts over conflicting agency policies.

Section 5: Media Coverage

.01 In the spirit of openness, media representatives must be granted free access to open meetings of advisory committees and other meetings convened by this agency, as well as permission to reasonably use tape recorders, cameras, and electronic equipment for broadcast purposes.

.02 The PAO coordinating a meeting may be present, or consulted, to undertake all responsibilities of a news media nature, including but not restricted to necessary physical arrangements.

.03 It shall be the responsibility of the PAO to cooperate fully with and accede to all reasonable requests from news media representatives. In instances where conflicts or misunderstandings may arise from the expressed views, wishes, or demands on the part of news media representatives, such matters should be referred at once to the director of the Office of Public, Constituent and Intergovernmental Affairs (OPCIA) for resolution.

.04 The OPCIA director shall exercise full authority and assume responsibility for all decisions involving the news media and related activity.

Section 6: Internal Reporting

.01 The agency will offer an internal disclosure system to allow for the confidential reporting and meaningful resolution of inappropriate alterations, conduct, or conflicts of interest that arise with regard to media communications. The system shall also allow for the employee's written assessment of whether the matter was resolved to his or her satisfaction.

Section 7: Anti-gag Addendum

To comply with the Anti-Gag Statute (SEC. 820 of the Transportation, Treasury, Housing and Urban Development, the Judiciary, and Independent Agencies Appropriations Act of 2006, PL 109-115, passed November 30, 2005), the __ (agency head title) __ shall issue a general memorandum to all agency and contractor employees informing them that all nondisclosure forms, policies, or agreements are modified by the addendum below, which is incorporated by reference into all relevant agency communications and supersedes any conflicting agency policies or rules.

"These restrictions are consistent with and do not supersede, conflict with, or otherwise alter the employee obligations, rights, or liabilities created by Executive Order No. 12958; section 7211 of title 5, United States Code (governing disclosures to Congress); section 1034 of title 10, United States Code, as amended by the Military Whistleblower Protection Act (governing disclosure to Congress by members of the military); section 2302(b)(8) of title 5, United States Code, as amended by the Whistleblower Protection Act (governing disclosures of illegality, waste, fraud, abuse or public health or safety threats); the Intelligence Identities Protection Act of 1982 (50 U.S.C. 421 et seq.) (governing disclosures that could expose confidential Government agents); and the statutes which protect against disclosure that may compromise the national security, including sections 641, 793, 794, 798, and 952 of title 18, United States Code, and section 4(b) of the Subversive Activities Act of 1950 (50 U.S.C. 783(b)). The definitions,

requirements, obligations, rights, sanctions, and liabilities created by said Executive order and listed statutes are incorporated into this agreement and are controlling.

"Provided, that notwithstanding the preceding paragraph, a nondisclosure policy form or agreement that is to be executed by a person connected with the conduct of an intelligence or intelligence-related activity, other than an employee or officer of the United States Government, may contain provisions appropriate to the particular activity for which such document is to be used. Such form or agreement shall, at a minimum, require that the person will not disclose any classified information received in the course of such activity unless specifically authorized to do so by the United States Government. Such nondisclosure forms shall also make it clear that they do not bar disclosures to Congress or to an authorized official of an executive agency or the Department of Justice that are essential to reporting a substantial violation of law."

Section III: Use of Federal Advisory Committees

Section III of the Scientific Integrity Memo states:

“Agencies should develop policies, in coordination with the General Services Administration and consistent with the Administration’s guidance on lobbyists serving on Federal advisory committees (FACs), for convening FACs tasked with giving scientific advice...”

Discussion:

Policies that fall in this section are those that aim to limit conflicts of interests on advisory committees and create a more transparent advisory selection process. The Scientific Integrity Memo is particularly detailed in this section and provides good guidance for what to include in agency policies. Points 1-5 are all important but point 5 is repeated here for additional emphasis because of its importance. Several federal policies have been included in this section: FDA’s policy for selecting advisory members, NIH’s general employee conflict of interest policy, and NAS’s conflict of interest policy for advisory members. In our opinion, the World Health Organization’s International Agency for Cancer Research (IARC), has the gold standard for conflict of interest policies, and we have included it after the existing federal policies. In addition the Scientific Integrity Memo includes the following which should be repeated in each agency policy:

5. Except when explicitly stated in a prior agreement between an agency and a FAC, all reports, recommendations, and products produced by FACs should be treated as solely the findings of such committees rather than of the U.S. Government and thus are not subject to intra- or inter-agency revision.

The blue, italicized text at the top of the page contains our comments, and everything below this point is taken directly from the agency’s website.

Policy Checklist:

- Advisory Committee Selection
- Conflict of Interest
- Integrity of Advisory Committee Products

Advisory Committees and Conflicts of Interest Policy

On paper, the DHHS's Food and Drug Administration (FDA) has a rigorous standard for establishing conflicts of interest among advisory committee members. The National Institutes of Health and the National Academies of Sciences also have very clear conflict of interest policies. IARC's policies have been included because they incorporate a retrospective time frame of when conflicts may have occurred. The key here is to maintain high scientific quality of those who serve while balancing bias, reducing conflicts of interest and adding transparency to each of these procedures. A strong standard for establishing conflicts of interest can be severely compromised by the granting of waivers exempting scientists from the standard.

Guidance for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees*

FDA's policy for evaluating whether a waiver should be issued is more stringent than the Waiver Criteria 2000 Guidance (that this guidance replaces) in four major ways. First, FDA intends to apply a stricter policy with respect to granting waivers for those whose personal financial interests and those of their immediate family exceed certain levels. Under this guidance, if an individual or her spouse or minor child has disqualifying financial interests whose combined value exceeds \$50,000, she generally would not participate in the meeting, regardless of the need for her expertise.

Second, FDA does not intend to issue a waiver in certain circumstances where the agency has determined that the conflict of interest is significant. These circumstances are enumerated and described in Section H (Step 7) of this guidance.

Third, FDA will apply a more stringent test to all waivers than is contemplated by some of the laws that the agency administers. FDA is choosing to limit the waivers the agency grants and harmonize our implementation of the various statutory provisions by applying a stricter test than would be required in some cases. Although 18 U.S.C. 208(b)(3) authorizes the agency to grant a waiver to an SGE where a balancing test is met -- "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved"-- FDA will also apply to all waivers for SGEs the generally stricter standard established by section 712

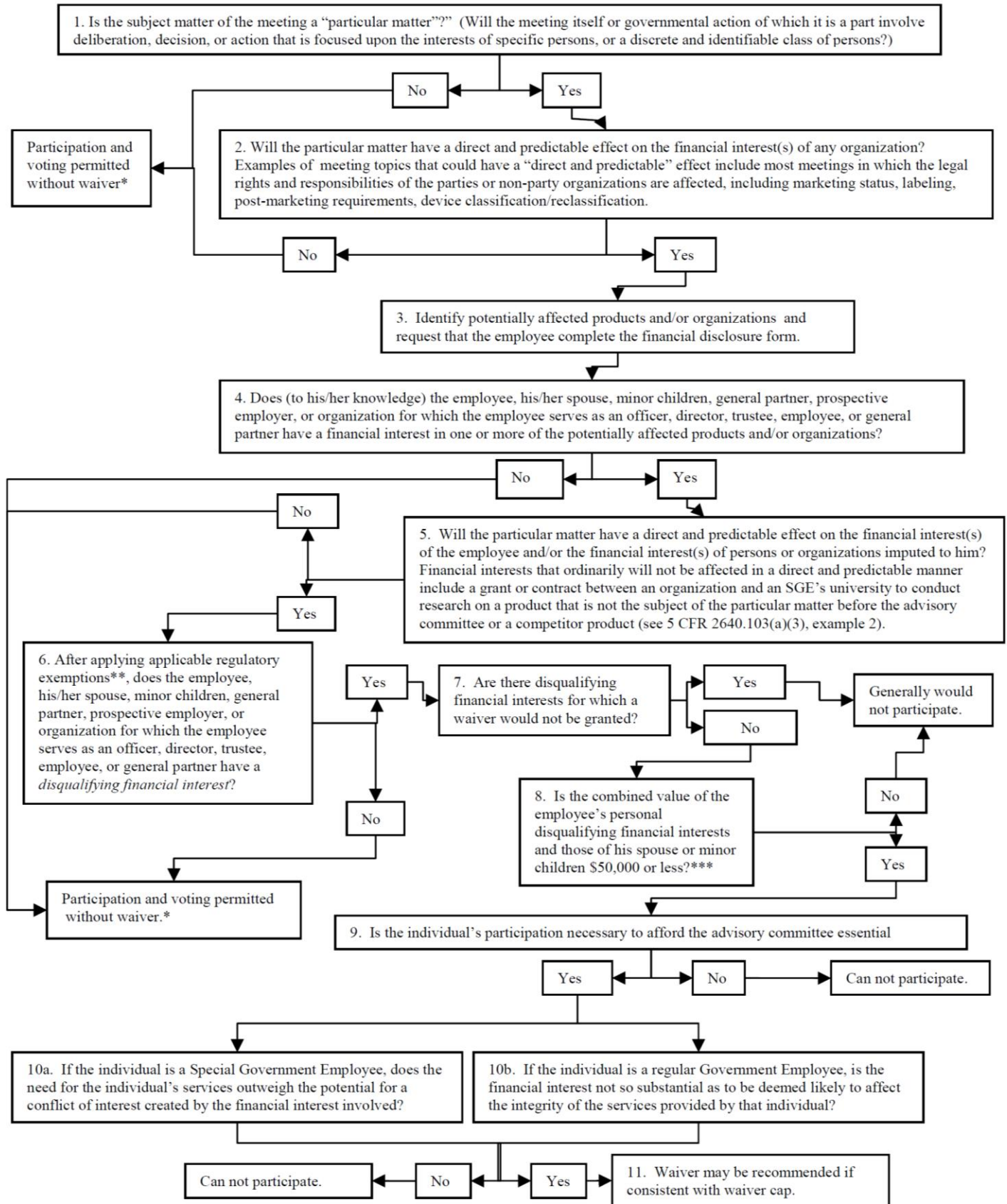
* Available at: <http://www.fda.gov/oc/advisory/waiver/coiguidedft.html>

(c)(2)(B) of the Act, requiring a showing that the waiver “is necessary to afford the committee essential expertise.” Similarly, for regular Government employees, where the test under 18 U.S.C. 208(b)(1) is whether the “financial interest is not so substantial as to be deemed likely to affect the integrity of the services provided by that individual,” FDA will also require a showing of essential expertise. In order to meet the “essential expertise” standard, the agency will conduct a needs analysis -- recommending in most cases that staff document their search for an equally qualified expert with few or no conflicts of interest. An expanded search for unconflicted, qualified experts is consistent with FDAAA’s focus on recruitment of advisory committee members with no conflicts of interest and may assist in minimizing the numbers of waivers needed.

Fourth, as discussed in Section II, FDA will limit the number of waivers the agency grants each year, in accordance with section 712(c)(2)(C) of the Act. By applying the \$50,000 limit for personal financial interests and the strict “essential expertise” test, FDA intends that the agency will meet the waiver limits incorporated in FDAAA. However, the agency intends to further limit numbers of waivers if necessary to assure that the FDAAA waiver caps are met, even if an employee’s personal financial interests are at or below \$50,000, and the “essential expertise” test is met.

FDA's Criteria for Determining Conflicts of Interest

Available: <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf>



NIH Conflict of Interest Policy (summary)*

The public must be assured that research decisions made at NIH are based on scientific evidence and not by inappropriate influences.

Senior management and people who play an important role in research decisions must meet a higher standard of disclosure and divestiture than people who are not decision-makers.

To advance the science and stay on the cutting edge of research, NIH employees must be allowed interaction with professional associations, participation in public health activities, and genuine teaching opportunities.

Here is a summary of the revised regulations:

1. Divestiture of prohibited financial interests
2. Senior employees¹ (and their spouses and minor children) may not retain:
3. an aggregate interest in a substantially affected organization (SAO)² in excess of \$15,000;
4. an aggregate interest in SAO sector funds in excess of \$50,000.

Exceptions may apply for certain types of financial interests such as pensions, diversified mutual funds (including non-healthcare sector funds), technology transfer, and exceptional circumstances.

Other NIH employees continue to be subject to government-wide laws that require divestiture in cases where it is reasonably necessary to resolve a conflict of interest with the employee's official duties but will not be subject to a blanket prohibition.

Disclosure of financial interests

Employees who file either a Public (SF 278) or Confidential (OGE 450) Financial Disclosure Report and those non-filers who serve as clinical investigators identified on an NIH clinical study are required to report the value of any interest in a SAO.

Employees who do not meet these criteria are generally not required to disclose interests in SAOs.

Outside Activities

Unless an exception applies, NIH employees may not:

- engage in employment with a SAO, supported research institution, or healthcare provider or insurer;

* Available at: http://www.nih.gov/about/ethics/summary_amendments_08252005.htm

- engage in a self-employed business activity with these types of organizations; or
- teach, speak, write, or edit for compensation for these types of organizations.

Employment with related trade, professional, or similar associations; on data and safety monitoring boards; in relation to a Grand Rounds program; as a lecturer in an established course; or on grant or scientific review committees is generally permissible with prior approval. Previously established exceptions to the broad prohibitions remain: teaching a course that requires multiple lectures; clinical practice; writing or editing for a peer-reviewed journal; and presenting a CME or CME-like lecture.

Outside employment that involves manual or unskilled labor, hobbies, artistic endeavors, or interests unrelated to the health and scientific research of the NIH, such as retail sales, coaching a youth team, scouting activities, clerical work, and building trades are generally permissible without prior approval unless the outside entity is a prohibited source.

Awards

With prior approval, employees (including senior level) can accept gifts associated with bona fide awards for meritorious achievement.

However, if the source of the award can be affected by the employee's duties or those of any subordinates, gifts valued in excess of \$200 may not be accepted.

Training

Employees are advised that government and HHS-wide conflict of interest laws and regulations continue to apply in addition to the NIH-specific provisions, and that each employee will be required to receive ethics training in 2005.

*1. Senior employees include the NIH Director and Deputy Director, senior staff within the Office of the Director that report directly to the NIH Director; the Directors, Deputy Directors, Scientific Directors, and Clinical Directors of each Institute and Center within NIH; Extramural Program Officials who report directly to an Institute or Center Director; and equivalent employees.

*2. Substantially affected organization means: a) a biotechnology or pharmaceutical company; a medical device manufacturer; or a corporation, partnership, or other enterprise or entity significantly involved, directly or through subsidiaries, in the research, development, or manufacture of biotechnological, biostatistical, pharmaceutical, or medical devices, equipment, preparations, treatments, or products; b) any organization a majority of whose members are of this type; and c) any other organization determined by the designated agency ethics official or designee to be substantially affected by NIH's programs, policies, or operations.

NAS Conflict of Interest Policy*

It is essential that the work of committees of the institution used in the development of reports not be compromised by any significant conflict of interest. For this purpose, **the term "conflict of interest" means any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization.** Except for those situations in which the institution determines that a conflict of interest is unavoidable and promptly and publicly discloses the conflict of interest, no individual can be appointed to serve (or continue to serve) on a committee of the institution used in the development of reports if the individual has a conflict of interest that is relevant to the functions to be performed.

General Principles

The term "conflict of interest" means something more than individual bias. There must be an *interest*, ordinarily financial, that could be directly affected by the work of the committee.

Conflict of interest requirements are *objective* and *prophylactic*. They are not an assessment of one's actual behavior or character, one's ability to act objectively despite the conflicting interest, or one's relative insensitivity to particular dollar amounts of specific assets because of one's personal wealth. Conflict of interest requirements are objective standards designed to eliminate certain specific, potentially compromising situations from arising, and thereby to protect the individual, the other members of the committee, the institution, and the public interest. The individual, the committee, and the institution should not be placed in a situation where others could reasonably question, and perhaps discount or dismiss, the work of the committee simply because of the existence of such conflicting interests.

The term "conflict of interest" applies only to *current interests*. It does not apply to past interests that have expired, no longer exist, and cannot reasonably affect current behavior. Nor does it apply to possible interests that may arise in the future but do not currently exist, because such future interests are inherently speculative and uncertain. For example, a pending formal or informal application for a particular job is a current interest, but the mere possibility that one might apply for such a job in the future is not a current interest.

The term "conflict of interest" applies not only to the personal financial interests of the individual but also to the *interests of others* with whom the individual has substantial common financial interests if these interests are relevant to the functions to be performed. Thus, in assessing an individual's potential conflicts of interest, consideration must be given not only to the interests of the individual but also to the interests of the individual's spouse and minor children, the individual's employer, the individual's business partners, and others with whom the individual has substantial common financial interests. Consideration must also be given to the interests of those for whom one is acting in a fiduciary or similar capacity (e.g., being an officer or director of a corporation, whether profit or nonprofit, or serving as a trustee).

* Available at: http://www.nationalacademies.org/coi/bi-coi_form-0.pdf

Financial Interests

The term "conflict of interest" as used herein ordinarily refers to *financial* conflicts of interest. In assessing potential conflicts of interest in connection with an individual's service on a committee of the institution used in the development of reports for sponsors, particular attention will be given to the following kinds of *financial interests* if they are relevant to the functions to be performed: employment relationships (including private and public sector employment and self-employment); consulting relationships (including commercial and professional consulting and service arrangements, scientific and technical advisory board memberships, and serving as an expert witness in litigation); stocks, bonds, and other financial instruments and investments including partnerships; real estate investments; patents, copyrights, and other intellectual property interests; commercial business ownership and investment interests; services provided in exchange for honorariums and travel expense reimbursements; research funding and other forms of research support.

Access to Confidential Information

The opportunity to have access to confidential information during the course of committee activities at the institution, if abused or misused, may confer an unfair competitive advantage. If an individual during the course of participating in a program activity of the institution obtains and uses, or intends to use, confidential information not reasonably available to the public for the individual's own direct and substantial economic benefit, such conduct constitutes a conflict of interest. The same rule applies if the individual discloses, or intends to disclose, such information (albeit not unlawfully) to other individuals or to organizations in such a manner that a direct and substantial economic benefit may be conferred on such individuals or organizations. These restrictions do not apply to information once it has entered the public domain.

In some situations -- for example, access to classified information, medical records, etc. -- special limitations on access to and use of such information will be imposed. Substantial legal penalties may apply for noncompliance. In addition, an individual employed by or associated with a particular organization or enterprise should not be given access to proprietary information of a competitor or potential competitor unless appropriate safeguards have been established that reasonably protect the interests of all parties. Otherwise, such access may create an unfair competitive advantage, as well as possible liability for improper disclosure and use. For further guidance regarding access to confidential information, contact the Office of the General Counsel.

Reviewing One's Own Work

It is not uncommon for individuals serving on committees of the institution being used in the development of reports for sponsors to find that their own published and professional work, in common with others in the field, is part of the technical basis and literature for the committee. This ordinarily would not constitute a conflict of interest. However, an individual should not serve as a member of a committee with respect to an activity in which a critical review and evaluation of the individual's own work, or that of his or her immediate employer, is the central purpose of the activity, because that would constitute a conflict of interest, although such an individual may provide relevant information to the program activity.

Public Statements and Positions

An individual may have become committed to a fixed position on a particular issue through public statements (e.g., testimony, speeches, interviews, etc.), through publications (e.g., articles, books, etc.), through close identification or association with the positions or perspectives of a particular group, or through other personal or professional activities. This would ordinarily constitute a potential source of bias but not a conflict of interest. However, in situations where there is some significant, directly related interest or duty of the individual -- e.g., where the individual is currently president of a professional society that espouses the same fixed position on the issue -- the situation may constitute a conflict of interest.

Employees of Sponsors

There are special rules for employees of sponsors. *An individual who is employed by the agency or other entity which is sponsoring the study or other activity in which a particular committee is engaged ordinarily cannot be a member of that committee (although the individual can be an agency liaison representative) because the institution provides independent reports and other services to sponsors, and it would generally constitute a conflict of interest for sponsor employees to serve on such committees.* However, in special circumstances and to the extent not prohibited by federal or state laws or regulations, such an individual may serve as a member of such a committee where the following requirements are met: (1) the service of the individual on the committee must be based upon the unique scientific or technical expertise which the individual brings to the committee; (2) the individual must not be involved in any way within the agency in any deliberative or decision-making process or any policy-making or similar process relating to the study or other activity or the expected or intended results of the study or other activity; and (3) it must be specifically determined during the committee appointment process that service by the individual will not compromise, or appear to compromise, the independence or objectivity of the particular study or other activity in which the committee is engaged. In the work of the institution, scientists, engineers, health specialists, and others working at national laboratories often meet the above requirements, while senior government officials and government officials in policymaking roles do not.

Categorizing Program Activities for Conflict of Interest Purposes

At any given time, committees of the *National Academies* are engaged in hundreds of studies and other activities involving thousands of volunteers working on topics that range across the entire spectrum of science, technology and public policy. The diversity and complexity of this undertaking make it difficult to state complete, all-encompassing rules that will anticipate and address every possible situation involving a potential conflict of interest. However, APPENDIX A to this Policy on **Committee Composition** and Balance and Conflicts of Interest for Committees Used in the Development of Reports, incorporated herein and made a part hereof, contains guidelines applying conflict of interest principles to some commonly occurring categories of program activities. These guidelines are provided as an aid to defining and identifying possible conflicts of interest for committees engaged in such program activities.

IARC Conflicts of Interest*

The assistance of distinguished authorities knowledgeable in a variety of medical and scientific professions is essential to the solution of international health issues. **It is expected that persons qualified to serve as an expert for the World Health Organization (WHO) may have private interests related to the subject of their expertise. At the same time, it is imperative that situations be avoided in which such interests may unduly affect, or may be perceived to affect, an expert's impartiality or the outcome of work in which he/she was involved.**

To assure the highest integrity, and hence public confidence, in the activities of the Organization, WHO regulations and policies require that all experts serving in an advisory role disclose any circumstances which could give rise to a **potential conflict of interest** (i.e., any interest which may affect, or may reasonably be perceived to affect, the expert's objectivity and independence). Accordingly, in this Declaration of Interest form, you are requested to disclose any financial, professional or other interest relevant to the subject of the work or meeting in which you will be involved and any interest that could be significantly affected by the outcome of the meeting or work. You are also asked to declare relevant interests of others who may, or may be perceived to, unduly influence your judgment, such as immediate family members, employers, close professional associates or any others with whom you have a substantial common personal, financial or professional interest.

Kindly complete this form and submit it to WHO Secretariat, well in advance of the meeting or work. You are also asked to inform the Secretariat of any change in this information that occurs before or during the course of the meeting or work. If WHO considers that a potential conflict of interest exists, one of several outcomes can occur, depending on the circumstances involved: (i) you may be invited to continue to participate in the meeting or work, provided that your interest would be publicly disclosed; (ii) you may be asked not to take part in the portion of the meeting, discussion or work related to your interest, or not participate in related decisions; or (iii) you may be asked not to take part in the meeting or work altogether. Non-completion of the DOI form would preclude further consideration of an expert's participation.

Experts are requested to agree that any relevant conflicts may be **publicly disclosed** to other meeting participants and in the resulting report or other work product. The Secretariat will assume that you consent to such a disclosure, unless you check "no" in the space provided on the last page of this form. The information disclosed by you **may later be made available** to persons outside of WHO if the objectivity of the work or meeting in which you are involved is questioned and the Director-General considers disclosure to be in the best interests of the Organization, although only after discussion with you.

Name:
Institution:
Email:

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans
Volume 101: Some Chemicals in Industrial and Consumer Products, Food Contaminants, and Water
Chlorination By-Products
Lyon, France: 15-22 Feb 2011

Please see the attached list of agents to be reviewed

Please answer each of the questions below. If the answer to any of the questions is "yes", briefly describe the circumstances on the last page of the form.

The term "you" refers to yourself, your employer and your immediate family members (i.e., spouse (or partner with whom you have a similar close personal relationship) and your minor children). "Commercial entity" includes -- aside from any commercial business -- an industry association, research institution or other enterprise whose funding is significantly derived from commercial sources having an interest related to the subject of the meeting or work. "Organization" includes a governmental, international or non-profit organization. "Meeting" includes a series or cycle of meetings.

EMPLOYMENT AND CONSULTING

Within the past 3 years, have you received remuneration from a commercial entity or other organization with an interest related to the subject of the meeting or work? Please also report any application or negotiation for future work.

- | | |
|--|----------------|
| 1a Employment | Yes [] No [] |
| 1b Consulting, including service as a technical or other advisor | Yes [] No [] |

* Available at: <http://monographs.iarc.fr/ENG/Meetings/vol101-doi.pdf>

RESEARCH SUPPORT

Within the past 3 years, have you or your department or research unit received support or funding from a commercial entity or other organization with an interest related to the subject of the meeting or work? Please also report any application or award for future research support.

- 2a Research support, including grants, collaborations, sponsorships, and other funding Yes [] No []
- 2b Non-monetary support valued at more than US\$1000 overall (include equipment, facilities, research assistants, paid travel to meetings, etc.) Yes [] No []

INVESTMENT INTERESTS

Do you have current investments (valued at more than US\$10 000 overall) in a commercial entity with an interest related to the subject of the meeting or work? Please also include indirect investments such as a trust or holding company. You may exclude mutual funds, pension funds or similar investments that are broadly diversified.

- 3a Stocks, bonds, stock options, other securities (e.g., short sales) Yes [] No []
- 3b Commercial business interests (e.g., proprietorships, partnerships, joint ventures) Yes [] No []

INTELLECTUAL PROPERTY

Do you have any current intellectual property rights that might be enhanced or diminished by the outcome of the meeting or work?

- 4a Patents, trademarks, or copyrights (also include pending applications) Yes [] No []
- 4b Proprietary know-how in a substance, technology or process Yes [] No []

PUBLIC STATEMENTS AND POSITIONS (during the past 3 years)

- 5a As part of a regulatory, legislative or judicial process, have you provided an expert opinion or testimony, related to the subject of the meeting or work, for a commercial entity or other organization? Yes [] No []
- 5b Have you held an office or other position, paid or unpaid, where you may be expected to represent interests or defend a position related to the subject of the meeting or work? Yes [] No []

ADDITIONAL INFORMATION

- 6a If not already disclosed above, have you worked for the competitor of a product which is the subject of the meeting or work, or will your participation in the meeting or work enable you to obtain access to a competitor's confidential proprietary information, or create for you a financial or commercial competitive advantage? Yes [] No []
- 6b To your knowledge, would the outcome of the meeting or work benefit or adversely affect interests of others with whom you have substantial common personal, financial or professional interests (such as your adult children or siblings, close professional colleagues, administrative unit or department)? Yes [] No []
- 6c Is there any other aspect of your background or present circumstances not addressed above that might be perceived as affecting your objectivity or independence? [e.g., travel support or participation in a speakers bureau sponsored by an interested party during the past 3 years] Yes [] No []

TOBACCO OR TOBACCO PRODUCTS (answer without regard to relevancy to the subject of the meeting or work)

- 7 Within the past 3 years, have you had employment or received research support or other funding from the tobacco industry or had any other professional relationship with an entity, directly involved in the production, manufacture, distribution or sale of tobacco or tobacco products or representing the interests of any such entity? Yes [] No []

EXPLANATION OF "YES" RESPONSES: If the answer to any of the above questions is "yes", check above and briefly describe the circumstances on this page. If you do not provide the amount or value of the interest where requested, it will be assumed to be significant.

Nos. 1–4, 7: Type of interest, question number, and category (e.g., Intellectual Property 4.a copyrights) <u>and</u> basic descriptive details	Name of company, organization, or institution	Belongs to you, a family member, employer, research unit, or other	Amount of income or value of interest (if not disclosed, is assumed to be significant)	Current interest (or year ceased)

Nos. 5–6: Describe the subject, specific circumstances, parties involved, time frame, and other relevant details

CONSENT TO DISCLOSURE. The Secretariat will assume that you consent to the disclosure of any relevant conflicts to other meeting participants and in the resulting report or work product, unless you check "no" in the space provided here. If you check "no", the Secretariat will not disclose the information without your prior approval, although this may result in your not being able to participate in the meeting or conference. No []

DECLARATION. I hereby declare on my honour that the disclosed information is true and complete to the best of my knowledge.

Should there be any change to the above information due to the fact that I acquire additional interests, I will notify the responsible staff of WHO and complete a new declaration of interests detailing the changes. This includes any change which occurs before or during the meeting or work itself and through the period up to the publication of the final results.

Date _____

Signature _____

Date _____

Signature _____

(to be signed again at the meeting)

UCS Additional FAC Concerns*

While the policies included here and the Federal Advisory Committee Act cover a great deal, there are places where they could be more specific. It is critical that definitions of conflict of interest include threshold amounts at which they apply, clarity around who they apply to, and specific information about the time frames in which they apply.

- More clarity is needed about which committees address scientific or technical issues and which are policy or stakeholder committees. Separating these functions will make it easier to ensure the proper COI disclosure occurs.
- For scientific or technical committees, we advocate stronger guidelines on financial COI. The goal should be conflict-free scientific committees, with “invited specialists” to ensure the committee has access to needed experts with conflicts. If that goal is unattainable in certain cases, restrictions on the number of COI waivers and heightened transparency when a waiver is issued are needed.
- Under FACA, committee members can be appointed as “representatives” (who provide stakeholder input and have, by definition, a conflict of interest), “special government employees” (SGE) or “consultants.” SGEs are subject to the criminal financial conflict-of-interest statute (18 U.S.C. §208) and are barred from participating in any decision that could impact their financial interest (unless given a waiver).

In 2008 GAO testified that certain federal agencies inappropriately appoint all FACA committee members as “representatives” thereby bypassing the COI screening. This loophole should be closed, and agencies should adopt stricter guidelines for appointing members to FACA panels – particularly in the case of scientific or technical panels.

- Agencies that use contractors to form advisory committees shall manage these committees under the provisions of FACA.
- Any subgroups or task forces formed by a federal advisory panel shall operate under the provisions of FACA.

* Available at: http://www.ucsusa.org/assets/documents/scientific_integrity/Federal-Science-and-the-Public-Good-Exec-Sum-12-08-Update.pdf

Section IV: Professional Development of Government Scientists & Engineers

Section IV of the Scientific Integrity Memo states:

“Agencies should establish policies that promote and facilitate, as permitted by law, the professional development of Government scientists and engineers. Such policies should, consistent with Federal ethics rules, job responsibilities, and existing agency policies regarding political appointees...”

Discussion:

This section requires that federal scientists be allowed to participate in scientific organizations, serve on professional society boards, and engage in outside scientific and scholarly activities. The blue, italicized text at the top of the page contains our comments, while everything below this point is taken directly from the agency’s website.

Several aspects of Peer Review Policies fall into this section. These policies were discussed at length in Section I and can be found on page 26.

Policy Checklist:

- Publishing Guidance
- Dissenting Opinion Procedures
- Peer Review
- Encourage Participation in Scientific Community

Publishing Policy

The Department of Interior's Fish & Wildlife Service (FWS) has the most extensive policy guidelines for employees publishing research and presenting information at scientific meetings. We believe it is the gold standard among federal publishing policies. The CDC media policy (page 38) also contains more general publishing guidelines for employees.

FWS Policy Review Guidance for Scientific Publications (Sec 117 FW 1)*

1.1 What is the purpose of this chapter? This chapter:

A. Describes the requirements for employees publishing scientific information in any outlet, including Service reports, reports for other agencies, [Journal of Fish and Wildlife Management](#), [North American Fauna](#), and non-Service peer-review journals; and

B. Makes it clear that we do not review these scientific publications for policy purposes.

1.2 What is the policy? Our policy is that for scientific publications within the scope of this chapter, Service employees must:

A. Include a disclaimer on the publication (see [section 1.4](#)), and

B. Provide a copy of the draft publication to their supervisor to ensure the supervisor is aware of it. Supervisory policy review or approval is not implied or required.

1.3 What is the scope of this chapter? This chapter:

A. Applies to publishing scientific information anywhere if:

(1) An employee either writes it during official duty hours or writes it based primarily on knowledge he or she acquires during duty hours, or

(2) The content of the article is based on scientific activities that the Service funded in whole or in part, includes the author's Service position title, or refers to the author's Service duty station in the author affiliations.

B. Does not apply to:

(1) Publishing personal expressions of information that do not include the author's Service position title or refer to the author's Service duty station in the author affiliations. These include:

* Available at: <http://www.fws.gov/policy/117fw1.html>

(a) Articles and reports an employee writes on his or her own time that are not related to projects and activities the employee performs for the Service, and

(b) Letters, editorials, essays, or other documents an employee writes on his or her own time for reasons not related to Service work.

(2) Scientific information we publish as official Service positions or policy, such as findings in Federal Register notices, rulemakings, official reports from Program offices, Service Manual chapters, etc. These types of documents undergo extensive Service review for policy implications that we define elsewhere (e.g., [011 FW 2](#), [Part 202](#), etc.).

1.4 Why do we require a disclaimer and what does it say?

A. We require that authors add a disclaimer because we do not specifically review the articles or reports for policy implications, and they may or may not represent the official views of the Service.

B. The disclaimer must say:

“The findings and conclusions in this article are those of the author(s) and do not necessarily represent the views of the U.S. Fish and Wildlife Service.”

C. The disclaimer:

(1) Does not diminish the quality of the science that is being reported or the credentials of the authors. We can still use these articles and reports in legal processes and for developing official Service policy; and

(2) Will be automatically attached to all articles published in the [Journal of Fish and Wildlife Management and North American Fauna](#). When authors submit articles to these publications, they must confirm that they have read and understand this chapter, and that they have provided a copy of the article to their supervisor.

1.5 What happens if an employee doesn't include the disclaimer or provide a copy of an article to his or her supervisor? This chapter reflects the importance that we place on scientific publication and shows a high level of trust and faith in employee conduct. We consider failure to incorporate the disclaimer or provide articles to supervisors as a possible violation of our Scientific Code of Professional Conduct (see [212 FW 7.6](#)).

Dissenting Opinions Policy

It is expected that as a part of the normal process of scientific discovery differences in professional opinions may arise. The Nuclear Regulatory Commission has a very comprehensive and effective policy for such situations. The FDA also has a commendable dissenting opinion policy that was established in the FDA Amendments Act of 2007.

NRC Procedures for the Expression, Monitoring, and Disposition of Differing Professional Opinions*

In the free and open discussion of agency issues, professional differences of opinion are common. Employees normally try, and are encouraged, to resolve their concerns through discussions with their co-workers and supervisors. In addition, individual employees are permitted to document their concerns and attach them to proposed staff positions or other documents to be forwarded with the position as it moves through the management approval chain. These informal day-to-day discussions and/or concerns attached to documents moving through the management approval chain are not part of the DPO process. (1)

Therefore, a difference of opinion, developed in the free and open discussion of technical, legal, or policy issues, only becomes a differing professional opinion (DPO) when the employee submits a formal concern in accordance with the guidance in Section (B) below and the procedures presented in this handbook. Exhibit 1, “Guidelines for Processing Differing Professional Opinions,” and Exhibit 2, “Flowchart of the Differing Professional Opinions and Appeals Process,” are provided to assist the submitter with the DPO process. (2)

Guidelines for Processing Differing Professional Opinions

The potential submitter of a differing professional opinion (DPO) and his or her management should engage in discussions as soon as the potential DPO issues have developed. There are no time limits for the completion of these informal discussions, no tracking requirements, and no requirement to keep written records; however it is a precondition to filing a DPO that a reasonable effort is made to engage in these discussions. At the conclusion of these discussions, if the employee still believes that the agency and the public would be better served if another opinion prevailed, he or she may submit a formal DPO by following the procedures stated below. (See Handbook 10.159, Section (B).)

* Available at: <http://pbadupws.nrc.gov/docs/ML0417/ML041770431.pdf>

The DPO Submission. The submitter must file a written DPO statement with the Differing Professional Opinions Project Manager (DPOPM) in accordance with the requirements of Management Directive (MD) 10.159 (see NRC Form 680). The written statement must provide evidence that the precondition presented in Handbook 10.159 has been met. The submitter must also provide the names of three potential panel members in order for the package to be considered complete or a statement that he or she will not provide names of potential ad hoc panel members. (See Handbook 10.159, Section (B).) (1)

Withdrawing a DPO. A DPO may be withdrawn at any time before the issuance of a decision. To initiate a withdrawal, the submitter should file a written request with the DPOPM, who will notify the appropriate office director (OD) or regional administrator (RA). Withdrawal does not preclude the OD or the RA from pursuing the issue raised, but the continued pursuit of the issue will no longer be subject to DPO process rules and/or time frame requirements. (See Handbook 10.159, Section (G).)

Screening of the DPO by the DPOPM. The DPOPM will review the written submittal for compliance with the criteria stated above under “The DPO Submission.” Filings submitted as DPOs that do not meet these criteria will be returned to the submitter without action. Typically, within 8 calendar days of receipt the DPOPM will issue a memorandum to the filer (with a copy to the appropriate OD or RA) indicating that the DPO has either been rejected or accepted for action. The decision to reject a DPO by the DPOPM is final. The justification for the action taken will be stated in the memorandum. The DPOPM may call upon agency subject matter experts, as appropriate, for assistance in the screening process to ensure that the issues are clearly delineated. (*For tracking purposes, the DPO “process clock” starts on the day this memorandum is issued.*) (See Handbook 10.159, Section (D)(3).) (2)

Appointment of the DPO Ad Hoc Panel by the OD or the RA. Generally within 8 calendar days after receipt of the DPO from the DPOPM, the cognizant OD or RA will select the members of the ad hoc panel, keeping in mind any chain of command concerns relevant to the issue or to the submitter, and will appoint them to the panel by issuing a standard tasking memorandum to each member (with a copy to the DPOPM). DPO panels should not involve individuals who have directly participated in the formulation of the agency position. (See Handbook 10.159, Section (D)(4).) (3)

Clarification of DPO Issues by the Ad Hoc Panel. Generally within 8 calendar days of the issuance of the panel memorandum, the panel chair will schedule and conduct a meeting with the submitter to discuss the scope of the issue(s). Issues that exceed those originally presented will not be considered by the panel. After this meeting, the panel will develop a schedule of milestones for the completion of the review of the DPO. Copies of this schedule will be sent to the filer, the OD or the RA for the DPO, and the DPOPM. Any changes in the schedule should be reported to the DPOPM, who will forward copies of the changes to the filer and to the OD or the RA for the DPO. (See Handbook 10.159, Section (D)(4).) (4)

Ad Hoc Panel Report Issued to the OD or the RA. Ad hoc panels are expected to complete their review and make their recommendation to the OD or the RA within 30 calendar days of the meeting with the filer. (See Handbook 10.159, Section (D)(4).) (5)

Report Is Returned to the Panel With Comments. At his or her option, the OD or the RA may return the report to the panel with specific comments (e.g., revise for clarification or provide further information). Revised panel reports will be provided to the OD or the RA generally within 7 calendar days. This time frame may not be appropriate for more complex cases and may be extended with the approval of the EDO, or Commission, as appropriate, through the DPOPM. (See Handbook 10.159, Section (D)(4).) (6)

Management Decision Is Issued. The OD or the RA will issue his or her decision to the DPO filer generally within 10 calendar days of the acceptance of the final panel report. Decision memorandums should include appropriate recognition of the submitter's efforts, if deemed appropriate by the OD or the RA. Copies of the decision memorandum will be sent to the filer, the filer's management, the OD or the RA for the DPO, the DPOPM, and any individuals or organizations tasked with followup actions or implementations. If the submitter has requested confidentiality, all documents will be redacted. All routine DPO cases should be completed within 60 days of acceptance of the issue as a DPO, and all complex cases within 120 days. This time frame may only be extended with the approval of the EDO, or the Commission for employees reporting to the Chairman or the Commission, through the DPOPM. (See Handbook 10.159, Section (D)(5).) (7)

Decision Implementation and Reporting. Implementation of a management decision (including follow-up actions) will be tracked by the DPOPM. (See Handbook 10.159, Sections (D)(5) and (6).) (8)

DPO Appeal Process

DPO Appeal. An appeal may be filed no later than 21 calendar days after issuance of the management decision. The appeal should be addressed to the EDO or the Commission, as appropriate, and submitted to the DPOPM in accordance with the requirements of MD 10.159 (see NRC Form 690). The DPOPM will send a copy of the appeal to the OD or the RA for the DPO. (See Handbook 10.159, Section (E)(1).) (1)

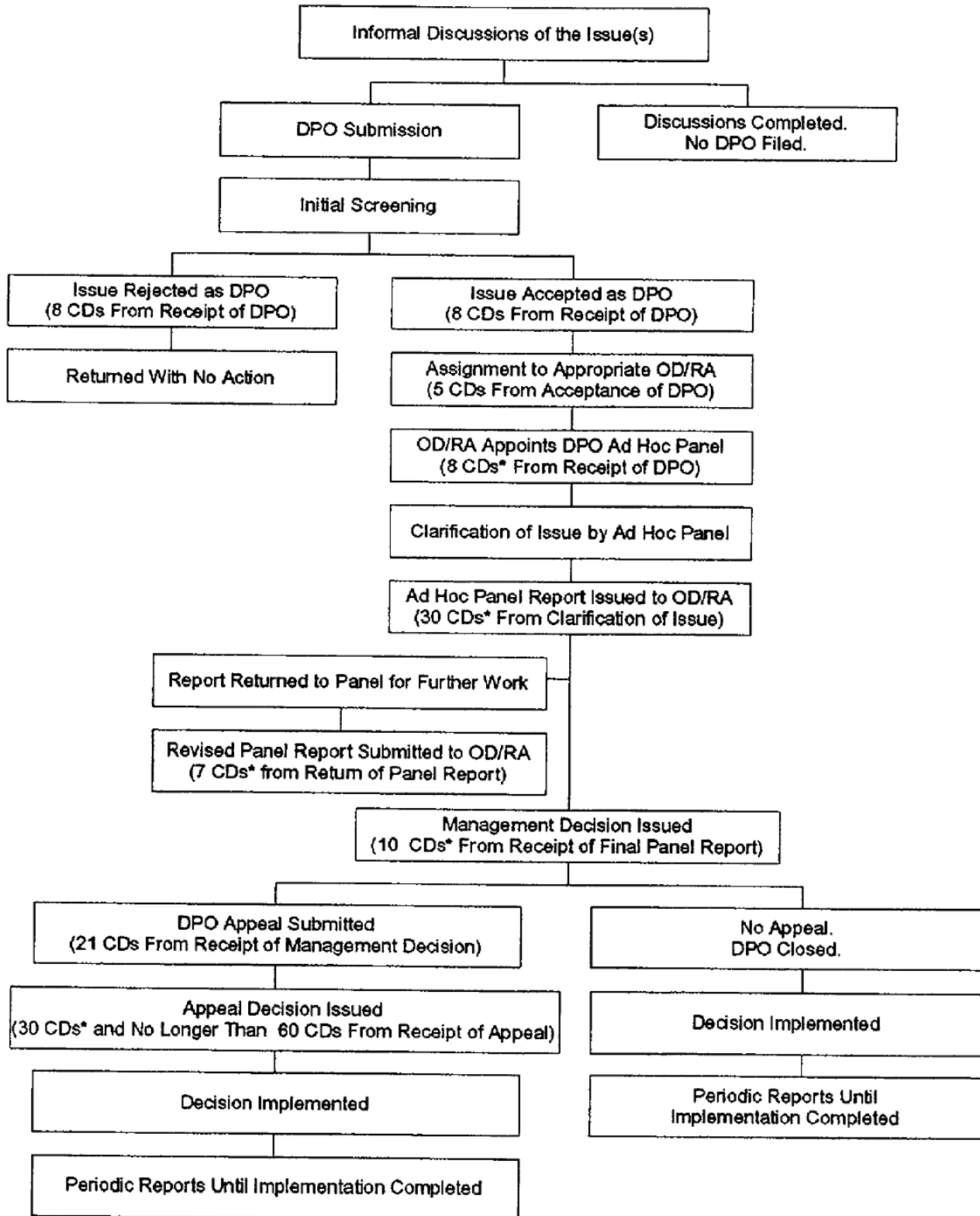
Withdrawing an Appeal. A DPO appeal may be withdrawn at any time before the issuance of the decision. To initiate a withdrawal, the submitter should file a written request with the DPOPM and send a copy of the request to the EDO or the Commission, as appropriate. (See Handbook 10.159, Section (G).)

Appeal Summary Decision. An appeal decision will be issued by the EDO or the Commission, as appropriate, generally within 30 days but no later than 60 calendar days after receipt of the appeal. Copies of the decision will be provided to the OD or the

RA for the DPO, the DPOPM, and individuals or organizations tasked with followup or implementation actions. Upon issuance of the decision to the filer, the DPO process will be concluded and the matter will be considered closed. (See Handbook 10.159, Section (E)(2).) (2)

Decision Implementation and Reporting. Implementation of an appeal decision will be tracked by the DPOPM. (See Handbook 10.159, Sections (D)(5) and (6).) (3)

Flowchart for Processing Differing Professional Opinions



CD means calendar days.
 * Generally in this time frame.

FDA Amendment Act of 2007: Section 916*

SEC. 916. ACTION PACKAGE FOR APPROVAL.

Section 505(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(1)) is amended by--

[[Page 121 STAT. 959]]

(1) redesignating paragraphs (1), (2), (3), (4), and (5) as subparagraphs (A), (B), (C), (D), and (E), respectively;

(2) striking ``(1) Safety and'' and inserting ``(1)(1) Safety and''; and

(3) adding at the end the following:

``(2) Action <<NOTE: Publication. Website. Deadlines.>> Package for Approval.--

``(A) Action package.--The Secretary shall publish the action package for approval of an application under subsection (b) or section 351 of the Public Health Service Act on the Internet Web site of the Food and Drug Administration--

``(i) not later than 30 days after the date of approval of such application for a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act; and

``(ii) not later than 30 days after the third request for such action package for approval received under section 552 of title 5, United States Code, for any other drug.

``(B) Immediate publication of summary review.--Notwithstanding subparagraph (A), the Secretary shall publish, on the Internet Web site of the Food and Drug Administration, the materials described in subparagraph (C) (iv) not later than 48 hours after the date of approval of the drug, except where such materials require redaction by the Secretary.

``(C) Contents.--An action package for approval of an application under subparagraph (A) shall be dated and shall include the following:

``(i) Documents generated by the Food and Drug Administration related to review of the application.

``(ii) Documents pertaining to the format and content of the application generated during drug development.

``(iii) Labeling submitted by the applicant.

``(iv) **A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and within the review team and how they were resolved, recommendations for action, and an explanation of any nonconcurrence with review conclusions.**

* Available at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110

``(v) The Division Director and Office Director's decision document which includes--
``(I) a brief statement of concurrence with the summary review;
``(II) **a separate review or addendum to the review if disagreeing with the summary review; and**
``(III) a separate review or addendum to the review to add further analysis.
``(vi) Identification by name of each officer or employee of the Food and Drug Administration who--
``(I) participated in the decision to approve the application; and
``(II) consents to have his or her name included in the package.
``(D) Review.--**A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final.**

[[Page 121 STAT. 960]]

``(E) Confidential information.--This paragraph does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter listed in section 552(b) of title 5, United States Code.''.
''

Department of Interior SI Policy*

The Department of Interior Policy commendably fulfills the one key aspect of Section IV. The policy clearly encourages scientists participate in the scientific community. This is excellent wording that should be implemented at each Agency.

Encourages full participation for scientists in the scientific community

The Department encourages the enhancement of scientific and scholarly integrity through engagement with the communities of practice represented by professional societies. The Department encourages employees to participate in outside professional organizations in order to enhance their professional development, especially when that participation advances the Department's mission, programs, and operations. Department scientists, scholars, and other professionals should engage in scientific, scholarly, and other activities with these professional networks in accordance with the following guidelines.

* Available at: http://elips.doi.gov/app_dm/act_getfiles.cfm?relnum=3889

Referenced Policies

CDC Data and Methods Sharing Policy

- <http://www.cdc.gov/od/foia/policies/sharing.htm>

NASA Data and Methods Sharing Policy

- <http://science.nasa.gov/earth-science/earth-science-data/data-information-policy/data-rights-related-issues/>

White House Visitor Log Policy

- <http://www.whitehouse.gov/VoluntaryDisclosure/>

NASA Whistleblower Policy

- <http://oig.nasa.gov/whistleblower.pdf>

USGS Peer Review Policy

- <http://www.usgs.gov/usgs-manual/500/502-3.html>

NOAA Conflict of Interest on Peer Review Policy

- http://www.cio.noaa.gov/Policy_Programs/NOAA_PRB_COI_Policy_110606.html

Department of Interior SI Policy

- http://elips.doi.gov/app_dm/act_getfiles.cfm?relnum=3889

5 US Code Sec. 1213

- <http://uscode.house.gov/uscode-cgi/fastweb.exe?getdoc+uscview+t05t08+133+1++%28%29%20%20AND>

CDC Media Policy

- <http://aspe.hhs.gov/infoquality/Guidelines/cdcinfo2.shtml>

FDA Advisory Committee Selection Policy

- <http://www.fda.gov/oc/advisory/waiver/coiguidedft.html>

NIH General Conflict of Interest Policy

- http://www.nih.gov/about/ethics/summary_amendments_08252005.htm

NAS Advisory Committee Conflict of Interest Policy

- http://www.nationalacademies.org/coi/bi-coi_form-0.pdf

IARC Advisory Committee Conflict of Interest Policy

- <http://monographs.iarc.fr/ENG/Meetings/vol101-doi.pdf>

FWS Publishing Policy

- <http://www.fws.gov/policy/117fw1.html>

NRC Dissenting Opinions

- <http://pbadupws.nrc.gov/docs/ML0417/ML041770431.pdf>

FDA Dissenting Opinions

- http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110

Other Relevant Links

UCS Comments on Regulatory Review Policy

- http://www.ucsusa.org/assets/documents/scientific_integrity/UCS-Comments-to-OSTP-on-SI-Memo.pdf

UCS Annotated DOI Scientific Integrity Policy

- http://www.ucsusa.org/integrity_resources

UCS Federal Science and the Public Good: Securing the Integrity of Science in Policy Making

- http://www.ucsusa.org/assets/documents/scientific_integrity/Federal-Science-and-the-Public-Good-Exec-Sum-12-08-Update.pdf

UCS Media Policy

- http://www.ucsusa.org/assets/documents/scientific_integrity/Model-Media-Policy-1.pdf

The Union of Concerned Scientists is the leading science-based nonprofit organization working for a healthy environment and a safer world.



National Headquarters

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