



## Guidelines for Ensuring the Quality of Information Disseminated to the Public

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#### 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 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](http://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](http://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](mailto: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](mailto: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.

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