D. Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry

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

Contents

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 Department of Health and Human Services (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, 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 fiscal year 2000, the workforce of CDC comprised approximately 8,500 full-time equivalents 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 employees 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, an office in Washington, D.C., and a staff of approximately 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. All subsequent references to CDC also include ATSDR, unless specified.

II. Scope and Applicability of Guidelines for CDC

The Office of Management and Budget’s (OMB) guidelines apply to information disseminated by CDC on or after October 1, 2002. The Guidelines 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, grant, or cooperative agreement is subject to these Guidelines. They apply to information in all media; print, electronic, audiovisual, and oral. Below are examples of the types of information that 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 substantive reports, brochures, documents, newsletters, and audiovisual products

Oral information, including speeches, interviews, expert opinions when they represent CDC official positions

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

Press releases and interviews

Information for public filings, subpoenas, or adjudicative processes

III. Types of Information Disseminated by CDC to the Public

Annually, CDC produces hundreds of publications of various types and provides more than 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 comply with CDC policy and procedures for preparation, review, approval, and distribution. Please see http://www.cdc.gov/od/foia/policies/clearance.htm. The types of information disseminated by CDC to the public include the following, however, the OMB Guidelines are not directly applicable to all of the information in these categories.

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 its *Morbidity and Mortality Weekly Report* (*MMWR*) or non-CDC publications of journals, books, chapters, editorials, reviews, proceedings, or abstracts. These are usually authored or co-authored by CDC staff scientists as part of their official duties or may be authored by 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 substantive information in connection with, and as a by-product 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, 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, and the 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 media for the same information. These media include the following:

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, electronic mail, automated voice and facsimile 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 theQuality 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. CDC has guidelines to address the general principles concerning the responsibilities of 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," which can be found on the Internet at http://www.cdc.gov/od/foia/policies/clearance.htm.

The individual Centers, Institutes, and Offices and Division Associate Directors for Science (ADS) are responsible for ensuring 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.

The Associate Directors for Science in Centers, Institutes, and Offices (CIOs) or Divisions 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 HHS Overview Part I, D.4.d. These standards include the following:

- **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 the peer review of disseminated information.
- **Integrity**: CDC ensures 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

1. 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 or oral presentation of scientific information by individual employees must undergo a formal review and clearance process before dissemination. Publications and reports are reviewed by the first level supervisor, the branch or staff chief, the division or office director, and usually the Centers, Institutes, and Offices Associate Directors for Science. These reviews include 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.

Several intramural research programs are 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. Laboratory data are reviewed to ensure that good laboratory data practice was followed for sampling, methodology, instrumentation, and analysis. In addition, 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, the *MMWR* is subject to routine CDC review and approval procedures in the originating Centers, Institutes, and Offices for the article or report. Because information disseminated in the *MMWR* often has impact on the practice of public health, the CDC ADS provides an additional review of science and policy. Health Alerts related to bioterrorism that are disseminated by CDC are also reviewed 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, depend on data reporting 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 require 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.

2. 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. In order to ensure 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, workshops, etc., 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.

In order to ensure 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 analytical information products, except oral presentations, undergo a formal clearance process before dissemination. Publications and reports, whether in electronic or paper form, are reviewed by a designated official within the author’s division or office, and usually t Centers, Institutes, and Offices Associate Directors for Science. 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). The Centers, Institutes, and Offices Associate Directors for Science 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 for accuracy and appropriate confidentiality protections. Oral presentations are often, though not always, subject to supervisory review.

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 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 under Section 515 of Public Law 106-554 of information disseminated by the agency, individuals must follow the procedures described below:

(1) Complaints or requests 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, Georgia 30333, by electronic mail at: InfoQuality@cdc.gov, or by facsimile transmission to (770) 488-4995.

(3) Complaints must state that a request for correction of information is being submitted under Section 515 of Public Law 106-554.

The complaint must contain:

(1) 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;

(2) The specific reasons for believing the information is in error and supporting documentation, if any;

(3) The specific recommendations for correcting the information;

(4) A description of how the person submitting the complaint is affected by the information error; and

(5) The name, mailing address, telephone number, electronic mail address, and organizational affiliation, if any, of the individual making the complaint.

B. CDC/ATSDR Responsibility

CDC will respond to all requests for correction within 45 working days of receipt. If the request requires more than 45 working 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, Georgia 30333, by electronic mail at InfoQualityAppeals@cdc.gov, or by facsimile to (770) 488-4995.

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

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

The OMB Guidelines provide special considerations that must be taken into account in certain risk assessments information, 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 (SDWA) of 1996 (42 U.S.C. 300g-1(b)(3)(A) and (B)."

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 Safe Drinking Water Act 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 the following:

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

VIII. Special Considerations for Agency Dissemination

CDC is sometimes responsible for the dissemination of authoritative health, medical and safety information on a real time basis in order to protect the health of the public again urgent and emerging threats (e.g, imminent threats to public health or homeland security). In these circumstances information may be disseminated on an expedited basis. Accordingly, nothing in these guidelines relating to reproducibility or peer review shall be construed to limit or delay the timely flow of vital information from CDC to medical providers, patients, health agencies, and the public in accordance with the latitude described in both the OMB and the HHS Guidelines.

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