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CLEARANCE OF INFORMATION PRODUCTS DISSEMINATED OUTSIDE CDC FOR PUBLIC USE

Sections:

I. PURPOSE

The Centers for Disease Control and Prevention (CDC)[2] is committed to ensuring that all information products authored by CDC staff members or published by CDC and released for public use are of the highest quality and are scientifically sound, technically accurate, and useful to the intended audience. CDC is also committed to the timely release of information, a paramount responsibility of the nation's public health agency.

II. ABBREVIATIONS, ACRONYMS AND DEFINITIONS

A. For the purpose of this policy, the following acronyms apply:

1. **ADS** – Center-level Associate Director for Science (CDC) and Associate Administrator for Science (ATSDR)
2. **ATSDR** – Agency for Toxic Substances and Disease Registry
3. **CDC** – Centers for Disease Control and Prevention
4. **HHS** – Department of Health and Human Services
5. **NCHM** – National Center for Health Marketing, CDC
6. **NIOSH** – National Institute for Occupational Safety and Health, CDC
7. **NIP** – National Immunization Program, CDC
8. **OCSO** – Office of the Chief Science Officer
9. **OD** – Office of the Director, CDC or Office of the Director within a center, depending upon usage
10. **OMB** – Office of Management and Budget

B. For the purpose of this policy, the following definitions apply:

1. **Author** – either the first CDC-affiliated person named on the authorship line or the person who has primary responsibility for the document. When reporting on work conducted while affiliated with CDC, former CDC personnel are considered CDC authors for clearance purposes. For current CDC personnel, investigations or thesis work done before joining CDC are not considered to be work conducted while affiliated with CDC unless substantial time is devoted to completing this work after joining CDC.

2. **Center** – refers to all CDC centers, institute, NIP, ATSDR, and OD staff offices.
3. **Clearance** – the process of obtaining approvals by the appropriate CDC staff members before an information product is released to the public.
4. **Coauthor** – refers to all other CDC-affiliated authors. When reporting on work conducted while affiliated with CDC, former CDC personnel are considered CDC co-authors for clearance purposes.
5. **Cross-clearance** – the process of obtaining approvals from more than one center.
6. **Cross-clearance coordinators** – those responsible for advising authors on requirements for cross-clearance.
7. **Quality** – to mean utility to the intended audience, objectivity in substance and presentation, and integrity (i.e., protection of information from unauthorized access, revision, or falsification), as defined in the HHS Guidelines for Ensuring the Quality of Information Disseminated to the Public.

III. BACKGROUND

Clearance is the process of obtaining approvals by the appropriate CDC staff members before an information product is released to the public. Clearance should be appropriate for the type of information product under review and should balance the concerns of quality and timeliness. This policy has been developed to promote consistent clearance procedures throughout CDC that ensure that the highest quality reviews are performed in a reasonable amount of time.

This policy describes requirements for clearance, which refers to the approval process within one chain of supervision—for instance, in one branch, division, or center. It also describes requirements for cross-clearance of information products—for instance, by more than one center. Lastly, the policy outlines responsibilities and procedural considerations that centers should take into account when developing their specific clearance procedures.

This policy complements the Guidelines for Ensuring the Quality of Information Disseminated to the Public, Part I—HHS Overview, and Part II.D—Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry.

This policy also complements the CDC Authorship Policy, which describes the criteria that must be met for CDC staff to be listed as authors of information products. In addition, this policy complements the CDC guidelines on outside activities, which stipulate that employees must receive advance approval for work—including writing, editing, or publishing—conducted outside of CDC, if the work "requires the use of professional qualifications readily identified with CDC employment" (see Section VII.C. below).
The role of the coordinating centers in the clearance process has not yet been determined, but at such time that a role is developed, changes or additions to the policy may be made.

This policy should be followed in conjunction with the guidance put forth in the OMB Information Quality Bulletin for Peer Review.

IV. PRE-CLEARANCE PREPARATION AND REVIEW

A. To ensure timeliness, the clearance process should not begin until a thorough pre-clearance preparation and review phase is completed. Before beginning the clearance process, authors and their supervisors should prepare an information product that meets the highest quality standards. Therefore, prior to clearance, authors and their supervisors should:

- Ensure that information is based on sound, ethical science.
- Ensure high quality and appropriateness of written and visual communication.
- Ensure compatibility of information with CDC recommendations. If findings have implications for changing recommendations or policies, authors or their supervisors should alert appropriate supervisors and staff in other centers. A cleared document may contain information that could support the development of new policies.
- Engage the expertise of other units within the originating center, other centers, or CDC staff offices (e.g., Office of the General Counsel), as appropriate, for work that overlaps areas of responsibility.
- Obtain an independent statistical or additional subject matter review when appropriate.
- Coordinate with the Office of Enterprise Communication and the Division of Health Communications, National Center for Health Marketing, about potentially newsworthy work and for any materials to be released to the press.

B. When the information product is ready to begin the clearance process, the first-listed CDC author (or a designee) should obtain documented concurrence from all coauthors and approval from the immediate supervisor to initiate the clearance process as detailed by the center. Depending on the center, for some information products, supervisory approval may constitute clearance.

Clearance is not a forum for extensive peer review or for policy debate. Such discussions belong in the pre-clearance phase. It is not the responsibility of the clearance official reviewing the information product to provide editing comments (e.g., comments on grammar and sentence structure). Review by a writer/editor may occur during the pre-clearance preparation and review phase, or during or after the clearance phase at the discretion of the center.

V. POLICY

A. Clearance

The OD of each center, including CDC OD staff offices, where appropriate, must develop and document clearance procedures for their respective units that are consistent with the steps outlined in this policy. These include, but are not limited to, developing pre-clearance procedures, identifying appropriate staff to manage the clearance process, developing procedures to handle information products related to public health emergencies, establishing timelines, and establishing procedures for resolving disputes. In addition, each center[3] must develop and maintain on the CDC Intranet a matrix that displays the information products produced by the center; that notes whether clearance is required for that information product and which officials, if any, must clear that type of product; that specifies the level of review required; and that displays timelines for

clearance officials. [A sample matrix is found at http://intradev.cdc.gov/ncipc/OCR/clearancematrix2004.doc.][1] The number and qualification of persons responsible for clearance of any type of information product should be commensurate with the following aspects of the particular product:

- visibility or breadth of dissemination;
- topic's level of sensitivity;
- originality of findings;
- scientific or technical complexity;
- potential to impact CDC recommendations, policies, or programs; or
- urgency of need for dissemination.

As appropriate for the type of information product, the center clearance matrix should also designate that informational copies be disseminated to staff whose approval is not required but who need to be aware of the product (e.g., Office of Enterprise Communication).

Examples of information products that could be included in the matrix include journal articles, *MMWR* publications, guidelines, editorials, letters to the editor, books and book chapters, reports and brochures concerning scientific research or programmatic or administrative information, fact sheets, presentation abstracts, presentations (e.g., scripts, slides, posters), material placed on the CDC Internet site, online discussion group postings that are widely disseminated (i.e., PROMED), media materials (e.g., press kits, press releases), training and education materials, data sets, and data documentation. At the discretion of the individual center, printed items that are subsequently posted on the Web need not be resubmitted for clearance as long as they are posted verbatim or are shortened without modifying the information.

B. Cross-Clearance

Clearance is not complete until approvals are received from other centers that share responsibility for specific program areas covered in an information product. These approvals are called "cross-clearance" and permit thorough review of information quality and identification of possible implications for CDC recommendations. However, if authors are from more than one center, but there is no cross-center area of interest, cross-clearance is not necessary. The center with primary clearance responsibility is the center with the first-listed center author or the center where the work was initiated (i.e., in cases when the first-listed CDC author has moved to another organization). To facilitate cross-clearance, the center with primary clearance responsibility should complete its clearance process *before* requesting cross-clearance. Unless clearance comments are minimal, they should be addressed before cross-clearance. To ensure that center cross-clearances can be accurately tracked and that no duplicate review occurs, the first-listed CDC authors should work with their cross-clearance coordinator; authors and supervisors should not independently submit formal cross-clearances.

VI. RESPONSIBILITIES

[1] URLs within this policy that lead to websites on the CDC intranet are not hyperlinked. Websites on the CDC intranet are not accessible to the public.

For the purpose of this policy, the following responsibilities apply:

A. CDC OD, Office of the Chief Science Officer, responsibilities for clearance of information products disseminated outside CDC for public use

Authors and center/office clearance officials should consult the CDC OCSO Web site http://intranet.cdc.gov/od/ads/ for the current list of information products and topics that must receive clearance at the CDC/OD level. For emerging, sensitive, or controversial topics, topics that may generate considerable media interest, or those topics not specified on the OCSO Web site about which there may be questions, authors and center/office clearance officials should contact the OCSO for guidance. This office is also responsible for mediating clearance issues that cannot be resolved at the center/office level, assisting as necessary with clearance education and training conducted within centers, and providing support and training about the clearance process to OD offices that do not have an ADS.

B. Center/office responsibilities for clearance of information products disseminated outside CDC for public use

1. For most information products, final approval on behalf of CDC rests with the center director with primary clearance responsibility (or for offices within the CDC Office of the Director, with the CDC Director); who may delegate this authority to an associate director (e.g., for science, communication, or policy).

   Each center or office has the following clearance responsibilities:

   - Determine the clearance requirement for each information product disseminated to the public and document the requirements and timelines in a matrix that is kept current on the CDC Intranet.
   - Document its procedures for clearance and cross-clearance.
   - Train center OD staff on the intent of the clearance process and the center-specific clearance procedures.
   - Have a process to expedite clearance during public health emergencies or for information products requiring immediate release.
   - Designate at least one cross-clearance coordinator and at least one backup to send, receive, and distribute requests for cross-clearance from other centers. A list of these individuals, along with their contact information, should be kept current on the CDC Intranet.
   - Provide documentation, training, and mentoring to ensure that staff understand the intent of clearance requirements, the center's specific clearance procedures, and the importance of submitting information products that are clearance-ready.
   - Develop a process for resolution of disputes arising during clearance. Disputes that cannot be resolved by the center should be taken to the CDC OCSO for final arbitration.
   - Monitor and evaluate its clearance process to ensure timeliness and improve the process.

2. Center Associate Director of Science. (Offices not having an ADS should appoint another individual to handle this responsibility.)

Clearance. Management of the center's clearance process is usually delegated to the ADS. The responsibility may be shared with associate directors for communication or policy.

Cross-Clearance. Most information products that require cross-clearance are of a scientific or technical nature (e.g., journal articles, professional presentations). Therefore, the following cross-clearance duties are coordinated by each center's ADS:

- Seeking cross-clearance. The ADS of the center with primary clearance responsibility receives recommendations from first authors and their supervisors, other clearing officials, or from the cross-clearance coordinator regarding the need to seek cross-clearance, makes the final determination, and requests cross-clearance. If the center with primary clearance responsibility does not require that its own ADS clear a particular information product that requires cross-clearance, that product still should be forwarded to its ADS office to coordinate cross-clearance. The ADS is responsible for ensuring that all information products originating from their center are blinded, i.e., authors' names are removed or obscured before they are sent to another center for cross-clearance. This responsibility may be delegated to the cross-clearance coordinator.
- Granting cross-clearance. When requests for cross-clearance are received, the ADS reviews the information product and/or designates other reviewers, as appropriate.
- Even when cross-clearance is not required, sharing informational copies of selected information products with other centers or with the CDC OCSO Office may be appropriate.

3. Cross-clearance coordinators' responsibilities. Cross-clearance coordinators are responsible for advising authors on requirements for center cross-clearance. They manage the process of requesting cross-clearance from other centers, and assist the ADS in ensuring that author's names are removed or obscured before the information product is sent to another center for review, and route the returned information products according to center procedures. They also manage the receipt, internal distribution, and return of information products received for cross-clearance from other centers. A center's cross-clearance coordinator may be under the supervision of the center ADS or of another office that can work responsively with the center ADS.

C. CDC employees and managers who perform clearance of information products disseminated outside CDC for public use

Staff members with clearance and cross-clearance responsibilities:

- Should have sufficient up-to-date scientific, technical, and organizational knowledge and depth of experience in a program area to qualify them to certify that information relevant to that program area is of high quality. NOTE: If a clearing official feels that he or she does not have sufficient expertise to review a particular information product, the clearance official may obtain an independent statistical or additional subject matter review.[4]

- Should designate one or more staff members to act in that capacity when they are on leave or otherwise unavailable.
- Should recuse himself/herself from clearance responsibilities for any information product for which he or she is an author. For these situations, an alternative clearing official of equal or higher organizational level should clear the information product.
- Should ensure that the information products they review are of high quality and are scientifically sound and useful to the intended audience.

    - For a draft that is not clearance-ready, the clearance process should stop. The clearance official should return the information product to the previous clearance official and discuss steps necessary to make the draft clearance-ready.
    - For a draft that is clearance-ready, the clearance official may require an author to revise and resubmit to obtain approval, may approve the draft pending revisions but not require resubmission, or may suggest optional changes. Centers should establish procedures for routing the return of comments either through previous clearing officials or to the first author.
    - For all drafts, clearly document comments and concerns.

For each information product, the last clearance official in the originating center should do the following:

- Ensure that any differences among preceding clearance officials are documented and resolved.
- Evaluate the list of approvals to ensure that the clearance is adequate. If appropriate, additional approvals may be requested from within the center, from other centers, or at the CDC/OD level.

D. First-listed CDC author's responsibilities for clearance of information products disseminated outside CDC for public use

The first-listed CDC author of an information product (or a designee) should initiate the clearance process (as detailed by the center with primary clearance responsibility) by obtaining concurrence from all coauthors and approval from the immediate supervisor to begin clearance and by consulting the center's clearance matrix to list all required approval signatures on clearance request form CDC 0.576[5]. (Documents published by CDC, but with no CDC coauthor, require a designee to initiate and track clearance.) NOTE: It is the responsibility of the first-listed author and that author's immediate supervisor to ensure that the steps identified in Section IV are followed.

The first-listed CDC author (in consultation with supervisors) evaluates the need for cross-clearance. The first-listed CDC author will work with the center cross-clearance coordinator and provide recommendations regarding cross-clearance to the center ADS who will make the final determination to request cross-clearance.

Authors should make sure that CDC public use data sets are described correctly and make sure that the data are used appropriately. Therefore, when a CDC author uses a public use data set maintained by another center, but there is no coauthor from that center, an information copy should be forwarded to the ADS

of the center whose data are used. This information copy should be sent at the same time that clearance commences in the author's center.

In the spirit of collaboration, first authors should document and share with coauthors substantive comments received from clearance and obtain their concurrence with the final draft.

E-mail or electronic signatures from the authors are sufficient to indicate concurrence before clearance and concurrence with the final revision; however, hard copy of such concurrence should be included in the project's official record.

E. CDC coauthors' responsibilities for clearance of information products disseminated outside CDC for public use

Clearance initiated by the first-listed CDC author satisfies this policy's requirements and should be considered the official clearance. However, this policy does not prohibit coauthors from sharing informational copies or soliciting additional comments within their own divisions or centers. However, only the center with primary clearance responsibility should initiate cross-clearance.

VII. PROCEDURAL CONSIDERATIONS

The following elements must be considered when developing and documenting detailed clearance procedures.

A. Clearance Timelines

In all cases, public health information should be disseminated in a timely fashion, which requires a rapid response from clearance officials. Rapid clearance is feasible if the pre-clearance process outlined above is carried out effectively.

For each type of information product, each center should set deadlines for routine review and approval by each level of clearance official. Deadlines should reflect the length and complexity of each product and the responsibilities of each clearing official (i.e., a branch chief may take longer for quality control than a clearing official at the center OD level). The clearance matrix should list these deadlines. **Centers should give serious consideration to shortening the overall timeline as much as possible, especially for the shortest, simplest information products, and for products being prepared in response to time-sensitive issues, e.g., a public health emergency, news event, etc. The total timeline for most information products generally should not exceed one month. If the information product is returned to the author for revisions during clearance, the process may exceed one month.**

Centers should institute other procedures to ensure that routine clearance occurs as efficiently and rapidly as possible. Such procedures should include the following:

- Designating alternative staff for clearance when any clearing official is not available;
- Establishing procedures for missed deadlines;
- Evaluating and improving the clearance process; and

- Routing return of comments through either previous clearing officials or the first author.

B. Cross-Clearance Timelines

Rapid cross-clearance should also be feasible because information products should have been improved through a center's clearance process, which must precede cross-clearance. **As a general guideline, centers should cross-clear and return an information product with comments within 2 weeks of receipt for cross-clearance.**

C. Outside Activities

CDC guidelines on outside activities stipulate that employees must receive advance approval for work (including writing, editing, or publishing) conducted outside of CDC if it "requires the use of professional qualifications readily identified with CDC employment." This work includes service on boards or committees that may write or publish information products. The form HHS-520, "Request for Approval of Outside Activity," should be completed and routed through normal supervisory channels to obtain advance approval for writing, editing, or publishing by employees outside of their official CDC duties. Approval may not be granted if the work is determined to be compensated and related to the employee's official duties. If the employee undertakes the activity as part of official duties, clearance should be obtained according to the center clearance matrix.

If approval is received, and the employee intends to use his or her CDC affiliation in connection with the information product, then the employee may either include or permit the inclusion of a title or position as one of several biographical details (when such information is given to identify the person in connection with writing text), provided the title is given no more prominence than other significant biographical details; or the employee may use or permit the use of a title or position, accompanied by the following disclaimer that is required on the information product:

> "This (article, book, etc.) was (written, edited) by (employee's name) in (his, her) private capacity. No official support or endorsement by the Centers for Disease Control and Prevention, Department of Health and Human Services is intended, nor should be inferred."

Failure to receive prior approval for information products that result from outside activities but that require the use of professional qualifications readily identified with CDC employment, or failure to properly use the employee's CDC affiliation in connection with the information products may result in disciplinary action.

D. Filing

Each center is responsible for ensuring that a record copy of all material developed, regardless of whether it is approved or published, is maintained for historical and research purposes. An organizational component within each center (i.e., an office of record) should be identified and given the responsibility for receipt, filing, and disposition of the record copy. A copy of the document and supporting material (i.e., clearance forms, substantive drafts, comments, correspondence, and electronic mail messages) can be maintained in the office of the clearing author in which the document was created. It is recommended that an office, rather than an individual, maintain supporting materials to prevent removal upon departure from employment of the individual. Draft and final information products produced by CDC staff members that are funded by the CDC and created in the course of federal business are considered federal records; as such, they belong to the federal government and cannot be removed from the possession of the government.

E. Retention

Published and unpublished reports and manuscripts developed by staff from completed projects, along with substantive supporting materials that contribute to the understanding of the final report, should be permanently retained in accordance with the CDC Records Control Schedule, B-321 Item 2-33 and a recently approved schedule covering the disposition of substantive supporting material (N1-442-02-2, Item 1c). One official record copy of each document must be held in the office of record a minimum of three years, after which record copies may be transferred to a Federal Records Center. When the material is 20 years old, it must be transferred to the National Archives for permanent historical retention. Other material (e.g., drafts that are purely editorial in nature) and transitory correspondence (e.g., correspondence of limited value, such as that used to change a meeting date or transmit another draft of the document) can be disposed of upon the completion of the final document. More substantive but routine supporting material may be disposed of after 5 years.

VIII. REFERENCES

A. Guidelines for Ensuring the Quality of Information Disseminated to the Public, Part I—HHS Overview. HHS, November 2003.

B. Part II.D—Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry. HHS, November 2003.

C. CDC/ATSDR Office of the Chief Science Officer. Last updated May 2005.

D. CDC-GA-2005-08, Authorship Policy. CDC, January 2002.

E. Standards of Ethical Conduct for Employees of the Executive Branch, Overview, 5 C.F.R. 2635 (January 2005)

F. CDC Ethics Program Activity. Last updated May 2005.

G. CDC Records Control Schedule. CDC, May 1998.

H. Information Quality for Peer Review. Office of Management and Budget M-05-03, 16 December 2004.

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[1] This policy supersedes General Administration CDC-18, Clearance Procedures for Scientific and Technical Documents, issued 5/4/1998.

[2] References to CDC also apply to the Agency for Toxic Substances and Disease Registry (ATSDR).

[3] Note, per definition II.B.2, the term center is used generically throughout to refer to CDC organizational components having clearance management responsibilities (center, institute and/or staff offices).

[4] Information products of a sensitive nature or with broad policy implications may require independent review. Independent review may be internal or external to CDC, in accordance with OMB guidelines.

[5] An Intranet-based system will eventually replace use of the paper form.