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AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

Policies and Procedures for Preparing Public Health Products Should Be Strengthened

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Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the Agency for Toxic Substances and Disease Registry's (ATSDR) policies and procedures for product preparation. ATSDR investigates community exposures related to chemical sites and releases; works with federal, tribal, state, and local agencies to identify potential exposures; assesses associated health effects; and recommends actions to stop, prevent, or minimize these harmful effects. In conducting these activities, the agency publishes many types of public health products, including public health assessments, health consultations, health study reports, and exposure investigations. Recent reports by the Institute of Medicine[1] and ATSDR's Board of Scientific Counselors[2] have identified various concerns such as the appropriateness and quality of the data used in ATSDR's products, the methodology and design of the studies, and clearance policies.

This committee has held two previous hearings that focused on its concern about the quality of ATSDR's products. In response, ATSDR has noted that multiple factors have posed challenges for the agency, including limitations in the ability of available science to answer community questions about the effect of chemical exposures, limitations in ATSDR's ability to collect data related to exposures, and reductions since 2004 in the number of ATSDR staff and resources available to conduct the agency's mission. My testimony is based on our April 2010 report,[3] which is being publicly released today, and addresses the extent to which ATSDR's policies and procedures for product initiation, development, and review and clearance provide reasonable assurance of public health product quality.

[1]See Institute of Medicine, *Review of ATSDR's Great Lakes Report Drafts (Letter Report)* (Washington, D.C.: National Academies Press, 2008).

[2]ATSDR's Board of Scientific Counselors is an advisory committee that provides advice and guidance to the ATSDR Director. At ATSDR's request, the Board of Scientific Counselors convened a work group to evaluate the agency's peer review processes. The board issued a report in March 2009; as of May 11, 2010, the report was not available on ATSDR's Web site.

[3]See GAO, *Agency for Toxic Substances and Disease Registry: Policies and Procedures for Public Health Product Preparation Should be Strengthened*, GAO-10-449 (Washington, D.C.: Apr. 30, 2010).

To address this question, we reviewed ATSDR's policies and procedures and interviewed officials to identify guidance related to the preparation of public health products. We focused our review on those policies and procedures related to public health assessments, health consultations, exposure investigations, and health study reports because these products are considered to be ATSDR's core public health products and concerns have been raised about the quality of products such as these, in which ATSDR identifies potential exposures to hazardous chemicals and assesses associated health effects. We compared the policies and procedures ATSDR uses to guide the preparation of its public health products to the standards described in the *Standards for Internal Control in the Federal Government*,[4,5] and the related *Internal Control Management and Evaluation Tool*.[6]

We also interviewed employees in ATSDR's headquarters, employees in 3 of ATSDR's 10 regional offices, and employees in 3 of 30 cooperative agreement partner offices to gain a better understanding of ATSDR and the policies and procedures related to product preparation. Further, we conducted interviews with officials, experts, and researchers outside ATSDR to gain an understanding of ATSDR's relationship with other agencies, to get their perspectives on ATSDR's work, and to learn about the policies and procedures used by other prominent scientific research organizations. A full description of our scope and methodology is included in our report.

We conducted this performance audit from April 2009 to April 2010, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[4]See GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

[5]See Office of Management and Budget *Circular No. A-123, (Revised): Management's Responsibility for Internal Control* (Dec. 21, 2004).

[6]See GAO, *Internal Control Management and Evaluation Tool*, GAO-01-1008G (Washington, D.C.: August 2001).

In brief, we found that the policies and procedures that ATSDR has established for public health product preparation lack some of the critical controls to provide reasonable assurance of product quality. To provide reasonable assurance that agency objectives are being met, federal internal control standards call for agencies to establish policies and procedures, assess risks associated with achieving agency objectives, ensure effective information sharing throughout the organization, monitor agency activities, and establish key areas of authority and responsibility for management and staff. We found that ATSDR's policies and procedures are deficient in the three phases of preparation of public health products: (1) initiation, which includes a decision by the agency to begin work on a public health product and the assignment of staff to prepare the product; (2) development, which includes management approval to proceed with the development of a product and the actual drafting of the public health product; and (3) review and clearance, which is the process by which a product is internally or externally reviewed and disseminated as a final public health product.

- *ATSDR's policies and procedures for work initiation do not establish and describe an adequate assessment of risk or information flow.* When work is being initiated, we found that ATSDR lacks comprehensive policies and procedures for assessing and categorizing the risk of that new work. For example, ATSDR previously incorporated some of the principles of risk assessment when the agency officially classified some hazardous chemical sites as "high-priority" or "focus sites," and required any products resulting from review of those sites to undergo a higher level of review and clearance. However, it no longer does so. Because ATSDR does not currently have policies and procedures that describe how the agency is to comprehensively assess and categorize the risk of work it initiates to prepare public health products, management cannot ensure that it has consistently managed the risk related to new work. Furthermore, since ATSDR's policies and procedures do not establish how information about newly initiated work should flow between management and staff, ATSDR generally relies on various meetings to inform management and staff about new work. The agency is implementing a new database called Sequoia, which may improve the flow of information. However, officials told us that further evaluation is needed to determine if Sequoia could do everything required by management or if some information will have to be captured in separate databases.

- *ATSDR's policies and procedures for product development do not provide for clear management roles and responsibilities or consistent monitoring of product development.* During product development, many of ATSDR's policies and procedures do not clearly define management

roles and responsibilities and do not consistently require that management monitor the development of key components of these products. For example, the primary document—the *Public Health Assessment Guidance Manual*—that guides the development of public health assessments and health consultations, which are among the agency's core products, identifies exposure assessment[7] and health effects evaluation as the two primary technical components of the public health assessment process. However, there is no requirement that staff's work in either of these areas be reviewed and approved by management during the development of a product to ensure its accuracy and appropriateness. Because of these deficiencies, management may be unclear about its responsibilities, and problems that occur during product development may not be identified or addressed until review and clearance, if at all. For example, ATSDR and Institute of Medicine reports show that because scientific concerns were not identified during development of an ATSDR report regarding chemical releases in the Great Lakes region, the document underwent several years of review, and a final report was not issued until more than 4 years after the first draft was written.

- *ATSDR's review and clearance policies and procedures do not always reflect current practices and do not establish a process for ensuring consistent review of all products.* We found that some review and clearance policies do not reflect current practices. For example, ATSDR's *Clearance Quick-Reference Guide* indicates that all public health assessments, health consultations, and exposure investigations must be reviewed and cleared by the division director or the division associate director for science. Yet according to Division of Health Assessment and Consultation (DHAC) management and staff, the review and clearance of DHAC products usually stops after review by branch chiefs within the division.[8] Furthermore, review and clearance policies and procedures direct management and staff to use discretion to identify products that require higher levels of review, rather than making this determination through a comprehensive risk assessment process. While ATSDR policy sets out criteria for when additional review may occur, such as when a document could have a high degree of visibility, there is no required point

[7]An exposure assessment is the process of finding out how people come into contact with a hazardous substance, how much of the substance they are in contact with, and where the substance is located. An exposure assessment reviews data collected by other federal and state government agencies, and differs from an exposure investigation in which ATSDR staff collect and analyze site-specific environmental or biological samples to determine whether individuals have been exposed to hazardous substances.

[8]DHAC is one of four ATSDR divisions.

during a product's preparation when management and staff collectively determine whether a product meets the criteria, and whether additional review is warranted. Thus, the agency cannot ensure that all products consistently receive the appropriate level of review.

In conclusion, while management controls alone cannot guarantee product quality, they can help ensure the development of timely and credible public health products at ATSDR. But ATSDR lacks some critical controls to provide reasonable assurance of product quality, particularly for public health assessments, health consultations, and exposure investigations. Without assessing the risk of work being undertaken by the agency and using those risk assessments to guide agency processes for public health product preparation, ATSDR cannot provide reasonable assurance that its products have undergone the appropriate level of monitoring and review. If established, a risk assessment process could be used to determine the proper level of scrutiny for the initiation, development, and review and clearance phases, thereby ensuring that this determination is made consistently across the agency. Additionally, the agency's policies lack guidance for management about its role in monitoring product development, and do not require management's monitoring and approval of key components of a product during its development. Without adequate monitoring by management during a product's development, product errors may not be caught or significant publication delays may occur during the review and clearance phase, potentially undermining public confidence in the agency's products.

Our report recommends that ATSDR develop policies and procedures to ensure that an assessment of the risk associated with a product is conducted at the time site-specific work is initiated, and that any assigned risk level be re-evaluated throughout product preparation to ensure that it remains appropriate. Our report also recommends that ATSDR revise existing policies and procedures, or develop new guidance, to provide documented direction for various levels of management on their roles and responsibilities in the monitoring of all products prior to review and clearance, such as requirements for management to monitor and approve key components of these products.

In commenting on a draft of the report from which this testimony is based, ATSDR neither agreed nor disagreed with our recommendations and did not address them directly, but stated that the agency has begun to incorporate our recommendations. Although ATSDR did not comment directly on our recommendation that the agency conduct a risk assessment at the time site-specific work is initiated and reevaluate the

assessment throughout product preparation, in its comments ATSDR stated that senior management was looking into formalizing and unifying coordination, triage, and prioritization of all incoming requests across the agency. ATSDR also acknowledged a need to make its prioritization process more explicit throughout the agency. Related to our recommendation that ATSDR revise or develop policies and procedures to include direction for management in monitoring products prior to review and clearance, ATSDR noted that its process to formalize and unify coordination, triage, and prioritization of all incoming requests was expected to include the specification of management and staff roles and responsibilities from initiation through publication.

Mr. Chairman, this concludes my statement. I would be pleased to respond to any questions you or other Members of the Subcommittee may have.

For questions about this testimony, please contact Cynthia A. Bascetta at (202) 512-7114 or bascettac@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Individuals who made key contributions to this testimony include Karen Doran, Assistant Director; George Bogart; Roseanne Price; Mario D. Ramsey; Christina Ritchie; and Carla Willis.

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