April 2010

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

Policies and Procedures for Public Health Product Preparation Should Be Strengthened

GAO Accountability • Integrity • Reliability

Highlights

Highlights of GAO-10-449, a report to congressional requesters

Why GAO Did This Study

The Agency for Toxic Substances and Disease Registry (ATSDR) has faced concerns related to the quality of some of the public health products it publishes. ATSDR investigates community exposures related to certain hazardous chemical sites and releases; assesses associated health effects; and recommends actions to stop, prevent, or minimize harmful effects. ATSDR publishes many types of products, including public health assessments, health consultations, exposure investigations, and health study reports. GAO was asked to examine the extent to which ATSDR's policies and procedures for product preparation, including work initiation, product development, and review and clearance, provide reasonable assurance of product quality. GAO reviewed ATSDR policies and procedures and interviewed agency officials and employees.

What GAO Recommends

GAO recommends that ATSDR develop policies and procedures that direct management to assess the risk level of work when it is initiated and reevaluate the risk level throughout product preparation to ensure it remains appropriate, and that ATSDR revise its policies and procedures to include guidance about management's roles and responsibilities in monitoring product development. ATSDR stated that it has begun to incorporate GAO's recommendations.

View GAO-10-449 or key components.
For more information, contact Cynthia A. Bascetta at (202) 512-7114 or bascettac@gao.gov.

What GAO Found

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. While ATSDR has established some policies and procedures to guide the preparation of its public health products, the policies and procedures do not establish how information is to flow between management and staff during initiation. Absent such policies and procedures, ATSDR generally relies on various meetings to inform management and staff about new work. The agency is also implementing a new database, which may improve information flow. Furthermore, ATSDR does not comprehensively evaluate and categorize the risk of work being initiated. While the agency used to officially classify some hazardous chemical sites as "high-priority" or "focus sites," and require any products resulting from those sites to undergo a higher level of review and clearance, it no longer does so. Because ATSDR does not comprehensively assess and categorize the risk of work being initiated at the agency, management cannot ensure that they have consistently managed the risk related to new work.

Additionally, many of ATSDR's policies and procedures that guide product development do not clearly define management roles and responsibilities and do not consistently require that management monitor the development of key components of these products. These deficiencies may lead management to be unclear about their responsibilities, and may result in problems that occur during product development not being 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.

Moreover, because some review and clearance policies do not reflect current practices, ATSDR staff cannot rely on these policies to accurately or consistently determine review and clearance procedures. 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 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.