



Highlights of [GAO-09-820](#), a report to congressional committees

Why GAO Did This Study

The Project BioShield Act of 2004 (BioShield Act) increased the federal government's ability to procure needed countermeasures to address threats from chemical, biological, radiological, and nuclear agents. Under the BioShield Act, the Department of Health and Human Services (HHS) was provided with new contracting authorities (increased simplified acquisition and micropurchase thresholds, and expanded abilities to use procedures other than full and open competition and personal services contracts) and was authorized to use about \$5.6 billion in a Special Reserve Fund to procure countermeasures. Based on the BioShield Act's mandate, GAO reviewed (1) how HHS has used its purchasing and contracting authorities, and (2) the extent to which HHS has internal controls in place to manage and help ensure the appropriate use of its new authorities. To do this work, GAO reviewed contract files and other HHS documents, including internal control guidance, which GAO compared with federal statutes and federal internal control standards.

What GAO Recommends

GAO recommends that HHS include comprehensive risk assessment statements in its written guidance on the internal controls for the BioShield contracting authorities for which the agency was required to establish controls. HHS agreed with the recommendation and said it would provide additional guidance.

[View GAO-09-820 or key components.](#)
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PROJECT BIOSHIELD

HHS Can Improve Agency Internal Controls for Its New Contracting Authorities

What GAO Found

Since 2004, HHS has awarded nine contracts using its Special Reserve Fund (Fund) purchasing authority under the BioShield Act to procure countermeasures that address anthrax, botulism, smallpox, and radiation poisoning. HHS may procure countermeasures that are approved by the Food and Drug Administration and ones that are unapproved, but are within 8 years of approval. Of the nine contracts, one was terminated for convenience and the remaining eight are valued at almost \$2 billion. HHS officials told GAO that additional contracts are likely to be awarded in the near future as the Fund provides funding through fiscal year 2013. In addition, HHS has used one of its new contracting authorities, simplified acquisition procedures, although it has not used this authority since 2005.

HHS has established internal controls on its new purchasing and contracting authorities. In addition to the language in the BioShield Act, which sets up a broad framework of controls over the use of the Special Reserve Fund, the internal controls for this purchasing authority are documented in a variety of internal policy and procedure documents and interagency agreements, which provide guidance on roles and responsibilities for how the controls are to be implemented. In response to BioShield Act requirements, HHS also established internal controls for three of the contracting authorities: the increased simplified acquisition threshold and its use with Special Reserve Funds, the increased micropurchase threshold, and the use of personal services contracts. Federal internal control standards state that, among other things, management needs to comprehensively identify risks, analyze them for possible effect, and determine how risks should be managed. Although some of the risk statements in a memo HHS issued identify some risks and one mentions possible negative consequences that could occur without proper controls in place, the risk statements for using the increased micropurchase threshold and increased simplified acquisition procedures lack analysis of specific risks. In particular, the memo does not discuss a key risk associated with using simplified acquisition procedures—namely, that an agency is prohibited from obtaining cost or pricing data for acquisitions at or below the simplified acquisition threshold. Without this data, the agency may not be able to determine if the price of a contract is fair and reasonable. Moreover, not having adequately documented and appropriately communicated risk assessments potentially results in future employees not knowing or understanding the risks or trade-offs involved in using the authorities. With employee turnover, HHS' reliance on the knowledge of current personnel to appropriately implement key controls will not enable future employees to make sound, informed, and consistent decisions.