

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

ADMINISTRATIVE - COMPETITIVE SOURCING

AUTHORITY FOR PERFORMANCE OF COMMERCIAL ACTIVITIES

Effective Date: 08/01/2014

1. AUTHORITIES DELEGATED.

The following commercial activities authorities must be exercised pursuant to the standards set forth in OMB Circular A-76, Performance of Commercial Activities. (See the Limitations paragraph, below, for those authorities restricted to the Commissioner and Department of Health and Human Services (HHS) officials.)

- A. To appoint competition officials in writing, and hold these competition officials accountable, for the timely and proper conduct of streamlined or standard competitions through the use of annual performance evaluations. (Note: This excludes the authority to appoint the Human Resources Advisor, see the Limitations paragraph, below.)
- B. To identify savings resulting from completed streamlined and standard competitions in accordance with OMB Circular No. A-11, Preparation, Submission, and Execution of the Budget.
- C. To consult with the Contracting Officer (CO) on whether amending the solicitation closing date is in the best interest of the government, in cases where the CO has been notified by the Agency Tender Official (ATO) that the agency tender cannot be submitted by the solicitation closing date.

2. TO WHOM DELEGATED.

- A. The authorities under paragraphs 1A and 1B are delegated to the FDA Competitive Sourcing Manager (CSM). HHS General Administration Manual Chapter 18-10 requires that the HHS OPDIV Head designate a senior management official of their immediate staff as the OPDIV CSM. The FDA CSM is the Deputy Commissioner for Operations & Chief Operating Officer, Office of Operations (OO). (Note: The authority under paragraph 1B is re-delegated only one level below the OPDIV Head, as restricted under the HHS delegation.)
- B. The authority under paragraph 1C is delegated to the Director, Office of Acquisitions and Grants Services (OAGS), Office of Finance, Budget, and Acquisitions (OFBA), Office of Operations (OO). (Note: This authority is re-

delegated only to the Head of the Contracting Activity, as restricted under the HHS delegation.)

3. LIMITATIONS.

The following authorities are reserved for the Commissioner or Departmental officials.

A. The Commissioner is authorized to:

1. Exempt a commercial activity performed by government personnel from performance by the private sector.
2. Justify, in writing, designations of government personnel performing inherently governmental activities.
3. Use Reason Code A to exempt commercial activities performed by government personnel from private sector performance and provide sufficient written justification for Reason Code A exemptions.
4. Approve, in writing, Performance Work Statements (PWS) team determinations on whether the FDA will provide all prospective service providers with Government-Furnished Property (GFP).
5. Approve, in writing, requests from a Contracting Officer (CO) to require a private sector source to include a performance bond.
6. Determine whether the commitment of additional resources will enable the Agency Tender Official (ATO) to correct a material deficiency in an agency tender within the time specified by the CO. This authority includes the authority to advise the Source Selection Authority (SSA) to exclude the agency tender from the standard competition when it is determined that the reasonable commitment of additional resources will not enable the ATO to correct a material deficiency in the agency tender.
7. Evaluate the CO's written documentation and make a written determination to either (a) revise the solicitation or (b) implement the agency tender, in the specific situation where an agency, in performing a standard competition, does not receive private sector offers or public reimbursable tenders, determines that all offers and public reimbursable tenders are non-responsive, or determines that prospective providers are not responsible.

If the OPDIV Head determines that the appropriate course of action is to revise a solicitation, the determination needs to indicate whether doing so will impact the established time limit. If an impact is anticipated, then a copy of the determination shall be provided to the CSO through the Competitive Sourcing

Program Manager, in order for the CSO to consult with OMB. (Note: See paragraph 3.B., below, regarding exceeding the time limit.)

- B. The HHS Assistant Secretary for Administration (ASA), as the HHS Competitive Sourcing Official, is required, without delegation, to consult with the Deputy Director for Management, Office of Management and Budget (OMB), if revising a solicitation would result in exceeding the established time limit for the standard competition. Based on the consultation, it may be appropriate to review the original determination and either make modifications or provide additional documentation.
- C. The authority to appoint the Human Resources Advisor (HRA) is reserved to the Deputy Assistant Secretary for Human Resources, DHHS, and may be re-delegated to the OPDIV Human Resource Director. The HRA shall be appointed in consultation with, and at the request of, the OPDIV Head or designee who has functional responsibility for the FDA Competitive Sourcing Program. If the HRA's participation on the Most Efficient Organization (MEO) team may result in a potential conflict of interest, a second HRA shall be appointed to maintain acquisition integrity.

4. REDELEGATION AND CERTIFICATION.

The authorities re-delegated may not be further re-delegated. A copy of this re-delegation will be furnished to the ASA, DHHS.

5. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on August 1, 2014.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	11/20/2009	N/a	OC/OA/OM/ OBOHCP/OMP	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	08/01/2014	N/a	OO/OHR/ MASS	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs