SMG 3240.2

FDA Staff Manual Guides, Volume III - General Administration

Information Resources Management

Information Technology Acquisitions

Software Asset Management Policy

Effective Date: July 9, 2026

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1. Purpose

The purpose of the Food and Drug Administration's (FDA) Software Asset Management (SAM) Policy is to reduce IT spending and support costs, improve IT governance, delivery, operations and security while ensuring compliance with software licensing, the Federal Information Technology Acquisition Reform Act (FITARA) (found in the National Defense Authorization Act of 2015), and the Making Electronic Government Accountable by Yielding Tangible Efficiencies (MEGABYTE) Act of 2016.

The goal of the SAM Policy is to enable a consistent and systematic approach to management of software assets and associated data while improving budget, asset, acquisition and technology management.

2. Background

Recent laws and directives have changed the nature of how the government manages its software acquisitions, inventories, lifecycles and governance, and require that management to be done centrally. The complexity of software license contracting, entitlements and compliance has grown, greatly increasing enterprise risk if not managed centrally. The intent of Congressional action is to ensure the Executive Branch leverages its buying power for cost savings and improving risk posture in licensing agreements.

In Information Technology Service Management (ITSM) literature (formerly IT Infrastructure Library or ITIL), asset management "is the process responsible for tracking and reporting the value and ownership of financial assets throughout their lifecycle… (and) part of an overall service asset and configuration management process."[1] This SAM policy supports the FDA's strategic goals in managing assets, aligning with ITSM, for compliance, quality and efficiency.

All FDA software assets belong to the Agency per current laws and regulations and are managed by the CIO appointed Software Manager and supporting team. The software inventory is inclusive of all software within the Agency acquired by any means, including open, free, purchased, deployed, subscription and cloud licenses. Under OMB Directives and the MEGABYTE Act the Agency has specific requirements to:

- Centralize software license management with clear roles and responsibilities, ensuring compliance with license agreements
- Provide software license management training (once provided by the Enterprise Software Category Team (ESCT) comprised of GSA, DOD and NASA)
- Develop a governance structure for managing software licenses
- Maintain agency inventory capturing at least 80% of spending on software licenses using auto discovery tools
- Develop a vendor management strategy
- Report under integrated data calls (IDCs) the "spend under management" on cost savings and contract reduction from improved license management

Enterprise Software Category Team (ESCT)

The ESCT is the governance board for Government-wide software initiatives, leadership in guidance on the software category management including on implementation of FITARA, OMB Directives and memos, and the MEGABYTE Act. Under OMB Directives and the MEGABYTE Act the ESCT has specific requirements that include:

- Identify and post existing government-wide agreements to the acquisition gateway

[1] itSMFInternational, The IT Service Management Forum, 2007; Foundations of IT Service Management Based on ITIL V3; Van Haren Publishing; p. 324

- Create and/or identify best in class criteria or agreements

- Reduce redundancy in vehicles and develop at least two new government-wide software agreements

- Create new review process for agencies acquiring software that duplicates software covered by any of the government-wide enterprise software agreements

- Develop government-wide and agency-specific trainings

3. Policy

The following requirements must be followed for managing software assets at the FDA.

A. **Procurement requests** - Software purchases must follow FDA procurement policy and procedures including due diligence of market research by the requester. Market research includes reviewing the current FDA Product Catalog which is the authoritative catalog for relevant business capability or functionality. Market research is a continuous activity and is required for exercising options as well to determine whether the exercise is in the best interest of the Agency or if another solution or vehicle is more appropriate. All software purchases in FDA require approval through the Software Manager and associated processes.

B. **Product Request** - The intake process of the Product Request review approval involves the evaluation of the software/hardware functionality, usability, compatibility, security, and other factors to ensure that it meets the FDA Production Network standards. Current IT intake processes require review for redundancies with current business capability. The goals of these processes include reducing redundancies of purchases in similar products, achieving economies of scale in purchase vehicles, ensuring legal requirements in entitlements, usage and lifecycle, and reducing support costs associated with technology footprint. These factors will affect whether a requested product is added to the Product Catalog. The Product Catalog is a single consolidated list of products that have completed a full review by a selected group of SMEs from various offices within OC/OIM. It also provides helpful information to requesters, such as the current approved version, product descriptions, and customer conditions for use. Inclusion in the Product Catalog is <u>not</u> approval for acquisition, which is a separate process. The product request process should be followed if an item is not listed within the Product Catalog nor managed by the Software License Management Team.

C. **Internally developed software** - Details of all internally developed software and its associated usage terms and conditions must be documented in the Definitive Media Library (DML) using required templates and formats for the documentation. All software code is held and managed within the FDA Microsoft Endpoint Configuration Manager (MECM) tool, ServiceNow Discovery, and the DML where appropriate. This applies to the software, not the files created with the software.

D. **Third-party software** - Typically, software purchased from third parties is licensed, not owned. FDA will use such software in compliance with the contractual terms and conditions or User License Agreements. This includes business systems provided by third parties that are accessed via the Internet or by other means. All processes for acquisition and intake apply.

E. **Deployment and installation** - Only FDA owned or licensed software may be installed on FDA equipment, and only by authorized personnel in accordance with IT policy and procedures. As part of centralized governance, the single authoritative source for authorized software is the DML. Inclusion and retirement from the DML are accomplished by following current change management processes.

F. **Software Licenses Inventory** - The software inventory shall be managed centrally per current law. This is managed by the Software License Management team processes and procedures. FDA Software License Inventory is managed within the SAM Pro module in ServiceNow. SAM Pro is the single authoritative source for tracking and managing software licenses across the platform. Information regarding all software, related purchases and associated license terms and conditions will be managed centrally in the DML which is a part of FDA Information Technology Service Management (ITSM) model. All FDA Software media shall be held and managed within the DML.

G. **Monitoring** - FDA performs scans that detect software use and monitor compliance with license terms and conditions. Unauthorized usage is subject to removal and other existing policies.

H. **Software audits or reviews** - Many software terms and conditions include the right of the vendor to audit or review usage to validate compliance with terms of the agreements or evaluate usage. All requests for engagements shall be directed to the Software License Management (SLM) team, found in the Outlook GAL under "OIMT_Software License Management" (OIMT_SWLicMgmt@fda.hhs.gov) for management and coordination. CORs, managers, supervisors, staff, technical or administrative personnel shall not engage directly with software providers

on authoritative license counts and usage, instead referring inquiries to the SLM team.

I. **Training** – All personnel handling software licenses (including legal, acquisition, technical, and end users) must be trained in relevant management topics. The ESCT is tasked with developing the training. In the interim, inquiries shall be directed to the SLM team.

4. Responsibilities

A. **FDA Chief Information Officer (CIO)**. The FDA CIO has the overall responsibility for FDA IT resources

B. **Software Manager**. The Software Asset Manager (synonymous with Software Manager and Software Category Manager) has responsibility for the SAM program, ensuring compliance with this policy and is supported by a team.

C. **Software License Management Team**. This team supports the Software Manager in executing the processes and procedures to administer the SAM program.

D. **FDA Office of Acquisitions and Grant Services (OAGS)**. OAGS is responsible for dedicated IT Acquisition personnel and for streamlining acquisitions in accordance with FITARA and the MEGABYTE Act.

E. **FDA Configuration Manager (CM)**. CM is responsible for maintaining relevant software licenses in the DML following current procedures.

F. **Enterprise Software Category Team (ESCT)**. The ESCT is composed of DOD, GSA and NASA, is the governance board for Government-wide software initiatives, leadership in guidance on the software category including on implementation of FITARA, OMB Directives and memos, and the MEGABYTE Act.

G. **Vendor Management Office (VMO), DHHS**. The VMO is responsible for collaboration of OPDIVs in development of an HHS plan for software management for HHS CIO Council review and implementation. In the event such a plan or policy conflicts with the FDA plan, the HHS plan takes precedence where practical.

5. Procedures

The procedures related to this policy are carried out by the Software License Management team under the Software Manager.

6. References

Making Electronic Government Accountable By Yielding Tangible Efficiencies (MEGABYTE) Act, June 2016

OMB Directive 16-12: Category Management Policy: Improving the Acquisition and Management of Common Information Technology: Software Licensing, June 2016

Federal Information Management Acquisition Reform Act (FITARA), NDAA 2015

Federal Information Security Management Act (FISMA) of 2014, Public Law 107-347

FDA Configuration Management, Change Management, and Release Management Policy, 2020

FDA Enterprise Architecture (EA) Policy, August 2004

HHS Enterprise Performance Lifecycle (EPLC), 2008

HHS Memorandum of End-of-Life Operating Systems and Applications Policy, 2016

HHS-OCIO Policy for Information Systems Security and Privacy Protection, 2021

HHS Policy for Information Technology Asset Management (ITAM) 2020

7. Effective Date

The effective date of this guide is July 9, 2026.

8. Document History - SMG 3240.2, Software Asset Management Policy

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