

**FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION**

**INFORMATION RESOURCES MANAGEMENT**

**INFORMATION TECHNOLOGY MANAGEMENT**

**FDA ENTERPRISE PERFORMANCE LIFE CYCLE POLICY**

Effective Date: March 1, 2018

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**1. PURPOSE**

This Policy serves as the authority for performing Enterprise Performance Life Cycle (EPLC) requirements, objectives, responsibilities, and standards for managing Information Technology (IT) projects in the Food and Drug Administration (FDA) as an IT Project Management requirement.

**2. BACKGROUND**

Health and Human Services (HHS) requires the use an enterprise-wide approach to project management that demonstrates measurable results for each IT Investment that justifies actions taken as IT projects are developed. With the enactment of the Federal IT Acquisition Reform Act (FITARA) in December 2014, HHS has incorporated the EPLC into the HHS FITARA Implementation Plan.

A key to successful IT management is the use of a project management methodology that incorporates government and commercial best practices implemented with a consistent and repeatable process, while providing a standard structure for planning, managing and overseeing IT projects over their entire life cycle. The EPLC provides that methodology for FDA.

EPLC establishes a project management and accountability environment where both Development, Modernization and Enhancement (DME) and Operation and Maintenance (O&M) FDA information technology (IT) projects consistently achieve successful outcomes that maximize alignment with

Department-wide and individual FDA goals and objectives. Implementation of the EPLC methodology allows FDA to improve the quality of project planning and execution, reducing overall project risk, and consistently achieve successful outcomes. Those outcomes will maximize alignment with business needs and meet approved cost, schedule and performance milestones.

EPLC enables FDA to approach the management of IT projects from an enterprise perspective, leveraging successful business solutions and the minimization of duplicate services and business capabilities between FDA IT investments and FDA partners. These investments and their interfaces must be adequately established through robust enterprise architecture. Adherence to recognized IT standards, as well as Section 508 Compliance, records management, security, and privacy requirements is essential to this goal.

### **3. POLICY**

FDA officials shall apply this Policy to all Federal employees and contractor personnel. All organizations collecting and/or maintaining IT data, using and/or operating information systems on behalf of the FDA are subject to this Policy.

This Policy applies to all FDA IT Projects throughout their entire lifecycle, regardless of funding source, whether owned and operated by FDA or operated on behalf of FDA.

This Policy shall be applied in conjunction with applicable Enterprise Architecture (EA), Capital Planning and Investment Control (CPIC), Earned Value Management (EVM), Records Management, Section 508 Compliance and Cyber Security Policies.

This Policy does not supersede any other applicable law or higher-level agency directive, or existing labor management agreement in effect as of the effective date of this Policy.

The FDA Chief Information Officer (CIO) has established the following FDA Enterprise Performance Life Cycle Policy:

#### **3.1 Authorization**

FDA shall establish, through the EPLC methodology, a consistent and repeatable process for managing FDA IT projects that encompasses the following:

- A standard approach for the intake, planning, managing, and governing of each IT project over its entire life cycle

- Ten standard life cycle phases with associated deliverables
- Exit criteria that define the minimum criteria that shall be met before advancing to the next iterative or life cycle phase
- Stage gate reviews, under IT governance jurisdiction, that formally review project progress against exit criteria prior to advancing to the next life cycle phase

### **3.2 EPLC Management Objectives**

All IT projects shall:

- Follow the standard life cycle phases and develop deliverables as identified in the EPLC Framework Overview Document
- Follow clearly established requirements to meet cost, schedule and performance baselines
- Monitor and react to variances from established baselines to reduce the risk of cost overruns and schedule delays
- Meet or exceed production timelines and leverage the re-use of successful processes and products across multiple projects
- Communicate project status to necessary stakeholders enabling the establishment of project-level accountability and transparency

IT Governance shall:

- Follow processes which authorize the implementation and operation of the EPLC methodology for IT project management
- Establish authority for each EPLC phase during the initial project approval process
- Provide a minimum set of core activities and deliverables for all IT projects
- Provide project templates and tools to assist with project activities

### **3.3 Stage Gate Review Objectives**

IT projects shall not move to the next EPLC phase without satisfactorily producing the required deliverables and having stage gate review exit criteria assessed.

The Project Manager shall:

- Determine/verify that the project has produced all deliverables and met or mitigated all stage gate review exit criteria requirements

The IT Governance organization shall:

- Facilitate stage gate reviews to determine if the project has met the stage gate review exit criteria
- Based on these reviews, exercise its decisional authority to either approve moving the project to the next phase, to conditionally approve moving to the next phase, or to deny further progress of the project

The IT Governance organization may delegate stage gate review approvals to the appropriate project authority, except for:

- Investment Selection Review at the end of the Concept Phase
- Project Baseline Review at the end of the Planning Phase
- Preliminary Design Review during or at the end of the Design Phase
- Operational Readiness Review during the Implementation Phase

### **3.4 EPLC Tailoring**

The IT Governance organization may approve tailoring of projects as necessary to take into consideration specific circumstances such as project type, size, risk, or scope of influence.

Project Managers may propose a tailoring plan that excludes deliverables or processes, except for the following fundamental elements:

- Identifying the business need
- Documenting correct, clear and adequate functional and non-functional requirements
- Following processes that ensure the system operation within the as-is and/or target enterprise architecture
- Adequate testing of the IT solution

- Appropriate operations and maintenance and cyber security documentation

### **3.5 Reporting and Monitoring**

All Project Managers shall:

- Report to the IT Governance organization, missed milestones, stage gate review results and/or variances in percentage of project cost, schedule or performance
- Develop Corrective Action Plans and/or Baseline Change Requests as appropriate

IT Governance shall implement appropriate measures to monitor and report the implementation and operation of EPLC.

## **4. RESPONSIBILITIES**

### **4.1 FDA Chief Information Officer (CIO)**

The FDA CIO oversees the development, implementation and management of the EPLC policy, procedures and processes.

### **4.2 IT Governance Organization**

Components of the IT Governance Organization are:

- Information Technology Investment Review Boards (ITIRBs)
- CIO Council/Technical Review subject matter experts
- CIO

The IT Governance Organization is responsible for the EPLC policy and the following:

- Ensuring that the appropriate rigor for EPLC is fully integrated into FDA processes
- Ensuring EPLC processes are implemented for IT projects and programs and that the EPLC information is used effectively
- Ensuring that projects are technically sound, follow established IT investment management practices, and meet the Business Owner's needs

- Conducting and facilitating Stage Gate Reviews through Critical Partners and the facilitation and resolution of Investment issues
- Determining whether to require additional work to meet exit criteria or to approve advancement to the next phase

#### **4.3 Business Owner**

The Business Owner is responsible for the following:

- Actively participating throughout the IT project life cycle to ensure the project remains on target for high priority business needs
- Identifying the business needs and performance measures to be satisfied by the project
- Improving the competitiveness of their IT projects in the Select process through improved performance management and alignment with mandates, organization strategic objectives, priorities, audit findings, or material weaknesses
- Validating and endorsing the business process models and requirements documentation for their projects
- Providing funding for the IT project
- Establishing and approving changes to cost, schedule and performance goals
- Participating in Stage Gate Reviews
- Validating that the IT project initially meets business requirements and continues to meet business requirements
- Participating in user acceptance testing to validate system requirements is met

#### **4.4 IT Project Manager**

The IT Project Manager is responsible for the following:

- Ensuring that all project team members comply with the requirements of this policy for day-to-day management of the project

- Ensuring that all appropriate business stakeholders and technical experts are involved throughout the life cycle of an IT project
- Proactively reporting missed project milestones and variances in percentage of project cost, schedule, and performance
- Maintaining information on project status, control, performance, risk, corrective action and projected outlook
- Storing project documents which are considered as records in appropriate FDA approved Records Management System
- Planning and conducting phase activities and verifying that the set of deliverables for the phase is complete
- Conducting Project Reviews and Stage Gate Reviews at specified points in the life cycle

#### **4.5 Critical Partners**

Critical Partners are functional managers representing portfolio and project management specified subject matter disciplines such as Enterprise Architecture, Security, Section 508, Capital Planning and Investment Control, and Records Management. Critical Partners are responsible for the following:

- Participation at specified Stage Gate Reviews to evaluate the completeness, accuracy and adequacy of EPLC phase deliverables
- Providing specific recommendations and report any issues identified during the review to the IT Governance organization, IT Project Manager, and the Business Owner
- Independently assessing whether the project meets exit criteria for advancement to the next phase

#### **5. REFERENCES**

Office of Management and Budget (OMB) Circular A-11, Part 7, Exhibit 300, "Planning, Budgeting, Acquisition and Management of Capital Assets" (July 2010)

Office of Federal Procurement Policy (OFPP) Memorandum, "The Federal Acquisition Certification for Program and Project Managers" (April 25, 2007)

HHS-OCIO Policy for Information Technology (IT) Enterprise Performance Life Cycle (EPLC), October 6, 2008

HHS-OCIO Policy for Information Systems Security and Privacy, July 30, 2014

HHS-OCIO Policy for Enterprise Architecture, August 7, 2008

HHS-OCIO Policy for IT Capital Planning and Investment Control, February 26, 2010

HHS-OCIO Policy for IT Earned Value Management, December 30, 2005

Enterprise Performance Life Cycle Framework Overview Document, Version 2.0, July 18, 2012

## 6. EFFECTIVE DATE

The effective date of this Policy is March 1, 2018.

## 7. Document History – SMG 3210.3, FDA Enterprise Performance Life Cycle Policy

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	03/31/2005	N/a	Strategy and Planning Staff, OCIO, HFA-83	Rod Bond, Director
Revision	02/16/2018	N/a	Director, Office of Enterprise Portfolio Management (OEPM)	FDA Chief Information Officer

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