**SMG 3210.3**

# FDA Staff Manual Guides, Volume III - General Administration

## Information Resources Management

## Information Technology Management

## FDA Enterprise Performance Life Cycle Policy

Effective Date: 11/15/2022



### 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, scope 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:

### A. Authorization

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

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

b. Ten standard life cycle phases with associated deliverables

c. Exit criteria that define the minimum criteria that shall be met before advancing to the next iterative or life cycle phase

d. Stage gate reviews, under IT governance jurisdiction, that formally review project progress against exit criteria prior to advancing to the next life cycle phase

**B. EPLC Management Objectives**

All IT projects and IT Project Managers shall:

a. Ensure IT projects follow the standard life cycle phases and develop deliverables as identified in the EPLC Framework Overview Document

b. Follow clearly established requirements to meet cost, schedule, scope, and performance baselines

c. Monitor and react to variances from established baselines to reduce the risk of cost overruns and schedule delays

d. Meet or exceed production timelines and leverage the re-use of successful processes and products across multiple projects

e. Communicate project status to necessary stakeholders enabling the establishment of project-level accountability and transparency through reports for ODT leadership

f. Complete the Project Process Agreement

g. Seek Governance approval for any individualized tailoring of Project Process Agreement

IT Governance shall:

a. Follow processes which authorize the implementation and operation of the EPLC methodology for IT project management

b. Establish authority for each EPLC phase during the initial project approval process

c. Provide a minimum set of core activities and deliverables for all IT projects

d. Provide project templates and tools to assist with project activities

e. Consult with Project teams as needed to assist with stage gate review submission per availability of EPLC resources

f. Communicate and facilitate Critical Partner discussion

g. Review and provide disposition on any requests to individually tailor a Project Process Agreement

## C. 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. Projects shall not be implemented and/or deployed into production until Implementation Stage Gate Review is approved by Governance.

The IT Project Manager shall:

a. 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:

a. Facilitate stage gate reviews to determine if the project has met the stage gate review exit criteria

b. 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

## D. 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:

a. Identifying the business need

b. Documenting correct, clear and adequate functional and non-functional requirements

c. Following processes that ensure the system operation within the as-is and/or target enterprise architecture

d. Adequate testing of the IT solution

e. Appropriate operations and maintenance and cyber security documentation

f. All stage gate reviews are not required, except the following IT Governance stage gate reviews must be held and cannot be waived and/or combined:

- Concept Stage Gate Review at the end of the Concept Phase
- Planning Stage Gate Review at the end of the Planning Phase
- Design Stage Gate Review at the end of the Design Phase (if Waterfall methodology project)
- Implementation Stage Gate Review during the Implementation Phase

### E. Reporting and Monitoring

All Project Managers shall:

a. Report to the IT Governance organization, missed milestones, stage gate review results and/or variances in percentage of project cost, schedule, or performance

b. 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

### A. FDA Chief Information Officer (CIO)

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

### B. IT Governance Organization

Components of the IT Governance Organization are:

a. Information Technology Investment Review Boards (ITIRBs)

b. Working groups/Technical Review subject matter experts

c. CIO

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

a. Ensuring that the appropriate rigor for EPLC is fully integrated into FDA processes

b. Ensuring EPLC processes are implemented for IT projects and programs and that the EPLC information is used effectively

c. Ensuring that projects are technically sound, follow established IT investment management practices, and meet the Business Owner's needs

d. Conducting and facilitating Stage Gate Reviews through Critical Partners and the facilitation and resolution of Investment issues

e. Monitor IT projects and report variances in project scope, schedule or cost.

f. Determining whether to require additional work to meet exit criteria or to approve advancement to the next phase

**C. Business Owner**

The Business Owner is responsible for the following:

a. Identify and validate project goals and business need

b. Actively participating throughout the IT project life cycle to ensure the project remains on target for high priority business needs

c. Identifying the Project Success Factors to be satisfied by the project

d. Review and approve project artifacts in coordination with IT Project Manager

e. Providing funding for the IT project

f. Identify IT Investment

g. Establishing and approving changes to cost, scope, schedule, and performance goals

h. Participating in Stage Gate Reviews

i. Validating that the IT project initially meets business requirements and continues to meet business requirements

## D. IT Project Manager

The IT Project Manager is responsible for the following:

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

b. Ensuring that all appropriate business stakeholders and technical experts are involved throughout the life cycle of an IT project

c. Proactively reporting missed project milestones and variances in percentage of project cost, schedule, and performance

d. Maintaining information on project status, control, performance, risk, corrective action, and projected outlook

e. Storing project documents which are considered as records in appropriate FDA approved Records Management System

f. Planning and conducting phase activities and verifying that the set of deliverables for the phase is complete

g. Conducting Project Reviews and Stage Gate Reviews at specified points in the life cycle

## E. 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:

a. Participation at specified Stage Gate Reviews to evaluate the completeness, accuracy, and adequacy of EPLC phase deliverables

b. Providing specific recommendations and report any issues identified during the review to the IT Governance organization, IT Project Manager, and the Business Owner

c. Independently assessing whether the project meets exit criteria for advancement to the next phase

d. Provide recommendations to project team via voting process

e. Be responsive to IT Governance inquiries and needs

## 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), July 18, 2012

HHS-OCIO Policy for Information Systems Security and Privacy, November 18, 2021

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

HHS-OCIO Policy for IT Capital Planning and Investment Control, September, 2016

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 November 15, 2022.

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

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| Revision | 02/16/2018 | N/A | Director, Office of Enterprise Portfolio Management (OEPM) | FDA Chief Information Officer |
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