Department of Health and Human Services

Centers for Medicare & Medicaid Services
Center for Consumer Information
and Insurance Oversight

Guide to Enterprise Life Cycle Processes, Artifacts, and Reviews

Final

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Foreword

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Executive Summary

The Centers for Medicare & Medicaid Services (CMS), Center for Consumer Information and Insurance Oversight (CCIIO) is responsible for implementation of the healthcare insurance exchanges under the mandates of the Patient Protection and Affordable Care Act of 2010 (hereafter simply the "Affordable Care Act"). CMS presents this *Guide to Enterprise Life Cycle Processes, Artifacts, and Reviews* to help each State better understand the CMS Enterprise Life Cycle for information technology (IT) systems development and assure the timely and compliance implementation of their respective health insurance exchanges.

This brief introduction to CMS' ELC clarifies the Agency's expectations for reasonable demonstration of mature program management and technical processes in planning, design, and development aspects for the State-based Exchanges (SBE), State-based Partnership Exchanges (SPE), and the Federally Facilitated Exchange (FFE) models. The ELC calls for specific information during early phase life-cycle reviews. The details in the guide should help States recognize and plan for the substantial similarities—and differences—between their IT system development life cycle processes and the ELC processes, artifacts, and reviews.

CMS MITA Requirements

This guide also defines a range of CMS process and technical requirements essential for approval of State Medicaid IT projects according to the *Enhanced Funding Requirements: Seven Conditions and Standards.* CMS is a principal stakeholder in the development of State Medicaid IT systems, and has established a core set of requirements in the Medicaid Information Technology Architecture (MITA) binding on the States for process, standards, and architecture (and codified by CFR Part 433). CMS recommends that States incorporate these requirements into their baseline set of project requirements. The design review process will include evaluation of State compliance with these requirements. Table 2 shows a mapping between each condition or standard and where evidence of compliance should appear in the ELC artifact set.

Understanding the Enterprise Life Cycle for IT

CMS has organized the Enterprise Life Cycle to help State development programs follow a structured and disciplined approach to planning, designing, and implementing their systems. CMS is committed to maintaining a systematic, repeatable ELC process for all system development within the Agency's environment. The Agency's emphasis on collaboration and cooperation in the crucial endeavor of Exchange development underscores the importance of knowing precisely what each State must build; the development artifacts is, of course, important but of secondary value.

The ELC consists of a sequence of phases with specific sets of objectives. To obtain timely approval of State Exchange development projects, States must show that they have largely completed the objectives of each phase through a formal review process before proceeding to the next phase.

The guide presents the key ELC processes applicable to State development project managers and engineering teams throughout the entire IT life cycle. The *Project Management Processes*

support the basic activities of planning, project assessment and control, and risk management. The *Technical Processes* of stakeholder requirements definition, requirements analysis, and architectural design guide the engineering team's activities through the first two phases of the ELC. The State must be able to show a MITA assessment and roadmap to MITA compliance for any aspects of their project that are Medicaid related. During the course of each review, CMS and the States will evaluate the degree of progress and whether the project is prepared to transition to the next life cycle phase.

By following standard consistent approach that is compatible with the ELC, States can demonstrate their systematic and repeatable process that helps them build *exactly what they need.*

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1. Introduction

The Centers for Medicare & Medicaid Services (CMS), Center for Customer Information and Insurance Oversight (CCIIO) has developed this white paper to assist States in working with the CMS Enterprise Life Cycle (ELC) for information technology (IT) system development.

1.1 Purpose and Scope

This white paper provides States with a practical and high level understanding of the CMS ELC, and the related program management and technical processes essential to plan, design, and develop individual State Exchange and Medicaid IT systems, including the State-based Exchanges (SBE), State-based Partnership Exchanges (SPE), and Federally Facilitated Exchange (FFE) models. Although the scope of these projects (hereafter simply the "State development projects") will vary widely from state to state, the supporting management and technical processes should be similar. This white paper focuses on the life-cycle processes and events that occur in the early phases of the CMS ELC (i.e., Initiation and Planning, and Requirements, Analysis, and Design).

This white paper provides basic information on a range of binding CMS process and technical requirements, such as the *Enhanced Funding Requirements: Seven Conditions and Standards*, for State Medicaid IT projects[1]. This document also describes specific information that States will be required to provide during early phase life-cycle reviews.

1.2 Background

The Enterprise Life Cycle establishes a structured, disciplined approach for planning, designing, and implementing IT systems. Each phase of the ELC has a specific set of objectives. In addition to building State Exchange systems consistent with the project management and technical processes of the ELC, States that have received CCIIO Establishment Grants are also required to follow the Establishment Review Process, which builds on the ELC. State development projects must show that they have completed the objectives of each ELC phase through a formal review process before proceeding to the next phase.[2] Figure 1 depicts the phases, consults, and reviews of the full ELC.

[1] For a detailed and authoritative treatment of these requirements see the original document that appears in the Reference Section.

[2] Under certain circumstances, projects may obtain conditional approval to proceed if they are substantially compliant.

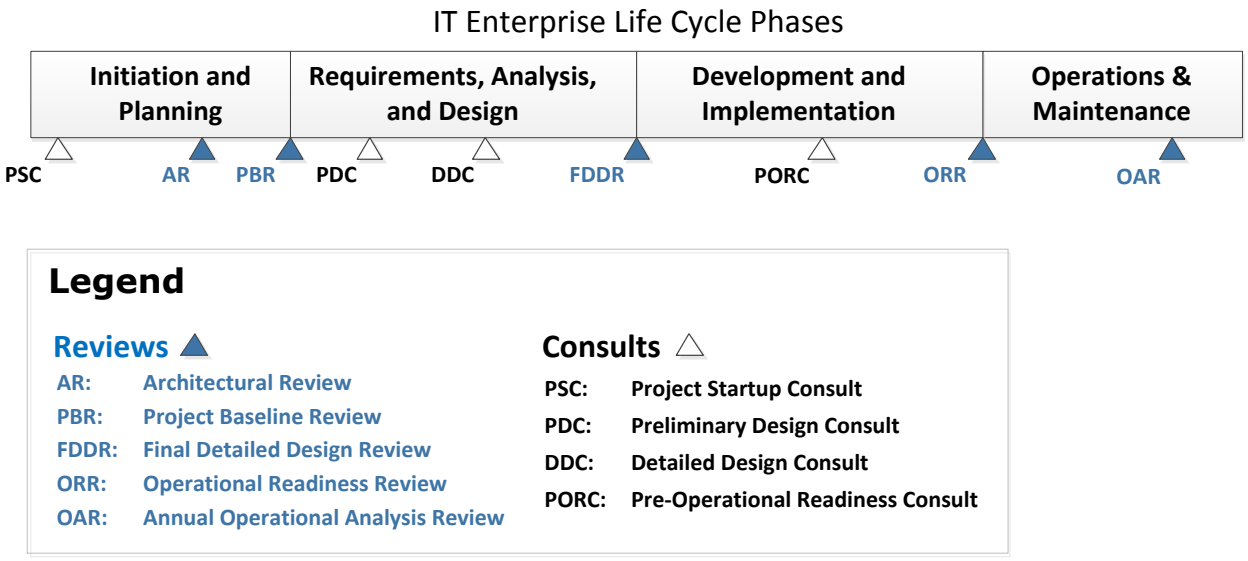


Figure 1. IT ELC Phases, Consults, and Reviews

State development projects demonstrate progress to CMS during ELC reviews through their artifacts and discussions with various subject matter experts (SME). By using industry best practices[3] in developing their systems, State development projects can follow a systematic approach to system design. Section 2 describes the core processes State projects should follow. Each process consists of the following five elements:

- **Purpose** –the objective of the process
- **Description –** how the process relates to the project as a whole
- **Inputs –** the information and/or artifacts required to support this process
- **Activities –** the distinct set of activities that constitute the process
- **Outputs –** the information and/or artifacts generated by the process

The standard set of processes in the ELC guide the development team through a systematic, repeatable sequence that helps the team understand *exactly* what it must build. The development of artifacts is important, but of secondary value.

[3] The processes described here are based on ISO/IEC 15288:2008, the international standard for systems and software engineering life cycle processes. This standard is also the basis for the International Council of Systems Engineering (INCOSE) Systems Engineering Handbook.

2. Enterprise Life Cycle Processes

This section describes key ELC processes that guide the State development project managers and engineering team throughout the entire life cycle. The Project Management Processes support the basic activities of planning, project assessment and control, and risk management. The Technical Processes guide the engineering team's activities through the first two phases of the ELC.

2.1 Project Management Processes

The purpose of Project Management processes is to systematically establish and evolve project plans, support their consistent execution, and assess progress and control of the project throughout its life cycle. Project Management processes are iterative in nature because they must support project management's response to unforeseen events and changing conditions affecting the project. As shown in Figure 2, the Project Planning process spans the entire life of the project, from Initiation and Planning through Operations & Maintenance. Figure 2 depicts the application of Project Planning, Project Assessment and Control, and Risk Management relative to the four phases of the ELC and critical stage reviews.

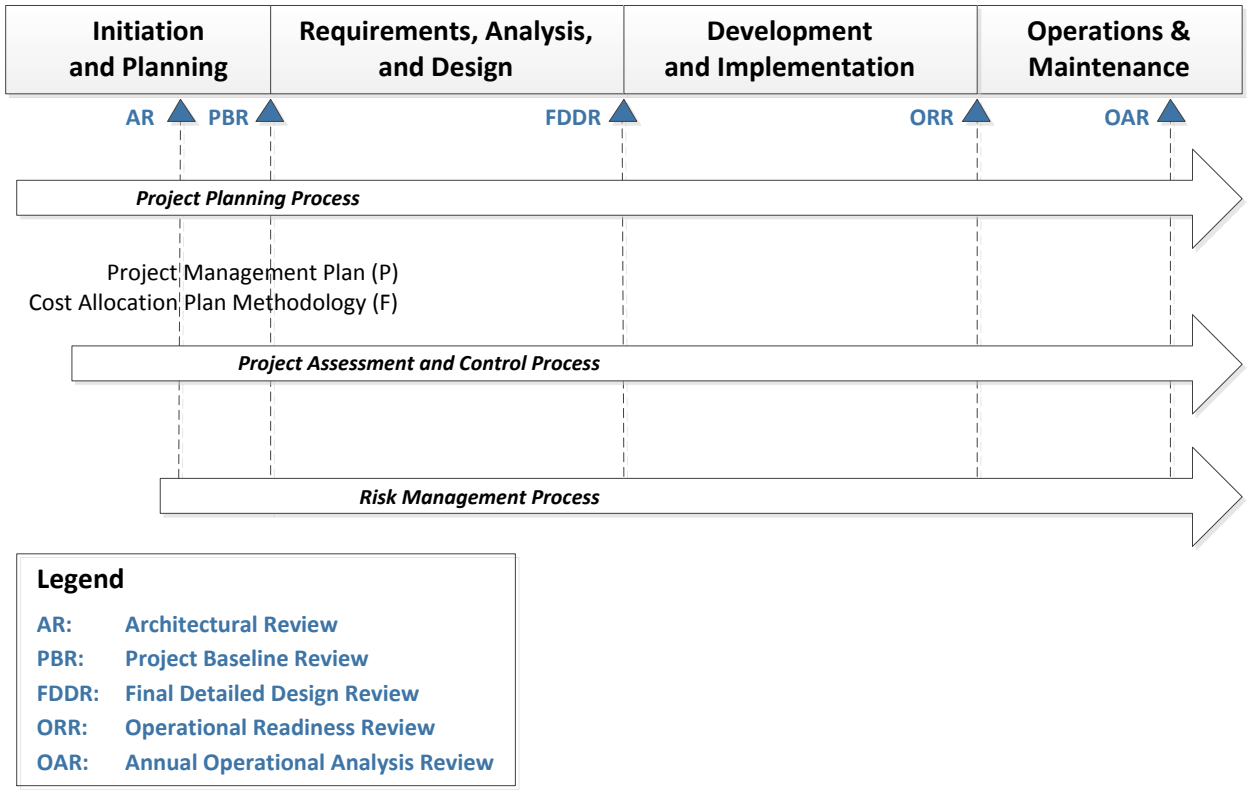


Figure 2. Project Management Processes Relative to ELC Phases

The following subsections present the purpose, description, inputs, activities, and outputs of each of the Project Management Processes.

2.1.1 Project Planning Process

Purpose: The purpose of the Project Planning Process is to create and document a set of practical and efficient plans to guide the execution of the project as a whole. This process is responsible for defining tasks, task outputs, schedules, and required human and infrastructure resources. A critical part of this process is defining and establishing the boundaries for the project scope.

Description: Project planning establishes the direction and infrastructure resources necessary to assess and control the progress of a project. The process of plan development identifies the details of the required work and the correct set of personnel, skills, and facilities. Once a complete set of tasks has been identified, a schedule and set of resource requirements can be determined. After initiating the project, project management must continuously assess and control the execution of the plan.

Inputs: Inputs to the Planning Process include the following sources:

1. **Foundation documents –** define project scope and/or establish authority.
2. **Supply Proposal –** serves as the project proposal and provides technical results from the initial concept exploration stage.
3. **IT Life Cycle Model –** guides scheduling and planning.
4. **Project Portfolio –** provides authorization to initiate the project and define project goals.
5. **Project Direction –** provides organizational direction to the project, which may include sustainment of projects, and assessment and termination criteria.
6. **Strategy Documents –** define overall approaches for major technical activities such as testing, Verification & Validation (V&V), configuration management, acquisition, and supply, etc.
7. **Skilled Personnel –** defines what personnel within the organization will be needed, and when.
8. **Program Directives –** provide internal project directives based on assessment and control activities.
9. **Corrective Actions –** define actions resulting from project-related consults or reviews.

Activities: The Project Planning Process includes the following activities:

1. **Define the Project**
   - Analyze the project proposal and related agreements to define the project scope and boundaries, and identify project objectives and constraints
   - Establish necessary procedures and practices to carry out the planned effort
2. **Plan the Project Resources**
   - Establish the roles and responsibilities for project authority
   - Define major, top-level work packages for each task and activity, and tie each work package to identified resources and procurement strategies
   - Develop a project schedule based on objectives and work estimates
   - Define the infrastructure and services required

- Define the costs and estimate the project budget
- Plan the acquisition of materials, commercial products, and services

3. **Plan Project Technical Management**
   - Prepare a plan to coordinate the technical activities that will occur throughout the life cycle
   - Prepare a plan to assess and manage various forms of risk that will be encountered throughout the life cycle
   - Prepare a plan to manage the technical configuration of the system elements, and identify a systematic approach for identifying and handling change requests

Outputs: The principal output of the Project Planning Process will be the Project Management Plan (PMP). The PMP is a comprehensive plan that covers the following topics:

1. **Acquisition Needs –** a description of the systems, subsystems, and system elements essential to accomplishing the project goals
2. **Project Procedures and Standards –** project-unique procedures and standards to guide the technical effort
3. **Project Infrastructure Needs –** a description of the infrastructure needs to accomplish the project; these needs are derived from and require coordination with the sponsoring organization
4. **Project Human Resource Needs –** a description of the required skillsets and personnel to accomplish the project; these needs are derived from and require coordination with the organization
5. **Project Schedule –**a top-level milestone schedule and multiple levels (also called tiers) of more detailed schedules and task descriptions with completion criteria
6. **Project Budget –** typically includes labor, infrastructure, acquisition, and enabling system costs along with reserves for risk management
7. **Project Constraints –** identification of potential or actual limitations or restrictions that may affect the project or system solution

2.1.2 Project Assessment and Control Process

Purpose: The purpose of the Project Assessment and Control Process is to determine the status of the project and provide direction to ensure that the project performs according to plans and schedules, and within projected budget. This process evaluates, periodically and at major milestones and reviews, the progress and achievements against requirements, plans, and overall business objectives. When significant variances are detected, this process communicates information for management action. This process redirects the project activities and tasks, as appropriate, to correct identified deviations and variations from other project management or Technical Processes.

Description: The Project Assessment and Control Process collects data to evaluate the adequacy of the project's progress, the availability of necessary resources, and compliance with project standards and performance measures. The programmatic and technical reviews of this process

occur at specified phases of the life cycle. These reviews measure the progress of the project, and may identify new risks or areas that require additional investigation.

Inputs: Inputs to the Project Assessment and Control Process include:

1. Planning documents that are baselined during the Project Planning Process (i.e., the Project Management Plan, the project schedule, and budget)
2. Project procedures and processes
3. Project reports and review outcomes

Activities: The Project Assessment and Control Process includes the following activities:

1. **Assess the Project**
   - Determine actual and projected cost against budget, and actual and projected time for completion against the established schedule
   - Evaluate project progress against established criteria and milestones
   - Participate in required life-cycle reviews, audits, and inspections to determine readiness to proceed to next milestone
2. **Control the Project**
   - Initiate corrective actions when assessments indicate deviation from approved plans
   - Initiate preventive actions when assessments indicate a trend toward deviation
   - Initiate problem resolution when assessments indicate unsatisfactory performance

Outputs: Outputs of the Project Assessment and Control Process include the following:

1. **Project Status Report –** information on the health and maturity of the project work effort generated periodically
2. **Project Directives –** internal project directives based on action required due to deviations from the project plan
3. **Change Requests –** requests to update any established, formal baselines

2.1.3 Risk Management Process

Purpose: The purpose of the Risk Management Process is to identify, analyze, manage, and monitor the risks continuously throughout the entire life cycle of a project or system.

Description: Risk management is the disciplined approach to dealing with uncertainty that is present throughout the entire systems life cycle. The objective is to achieve a proper balance between risk and opportunity. This process guides project management in understanding, avoiding, and mitigating, where necessary, the potential cost, schedule, and technical risks to a project or system. The process supports a proactive and rational approach to anticipate and respond to negative outcomes.

Inputs: Inputs to the Risk Management Process include:

1. **Candidate Risks and Opportunities –** identified by any stakeholder and originate from any life-cycle process. In many cases, risk situations are identified during the Project Assessment and Control Process through the process of ELC consults and reviews.

Activities: The Risk Management Process includes the following activities:

1. **Plan Risk Management –** define and document the risk strategy for the project
2. **Manage the Risk Profile –** define and document risk thresholds and acceptable and unacceptable risk conditions

Outputs: Outputs to the Risk Management Process include:

1. **Risk Management Strategy –**describes an approach for dealing with identified risks, which typically involve one of four options: avoidance, mitigation, transference, or acceptance. Once an approach is selected, detailed actions to implement this approach are developed.
2. **Risk Register –** sometimes referred to as a risk matrix, the Risk Register contains the findings of the Risk Management Process
3. **Risk Report –** documents and communicates the project risks along with rationale, assumptions, treatment plans, and status. For selected risks, the project team produces an action plan direct the proper response to the risks

2.2 Technical Processes

In the early phases of the ELC, the technical development team should focus on developing a comprehensive understanding of what system capabilities are needed by the various stakeholders. Typically, this is a very complex process when multiple stakeholders are involved. Because requirements form the foundation for all subsequent work, accuracy of requirements capture is critical. This process starts during the system planning stage and should be largely complete by the end of the requirements definition stage. Stakeholder requirements serve as inputs to the requirements analysis process in which requirements are analyzed, validated, and evaluated for consistency and practicality. Once a baseline of requirements is available, the technical development team can begin the process of architectural design. Figure 2 illustrates the three technical processes, and some of the related artifacts.

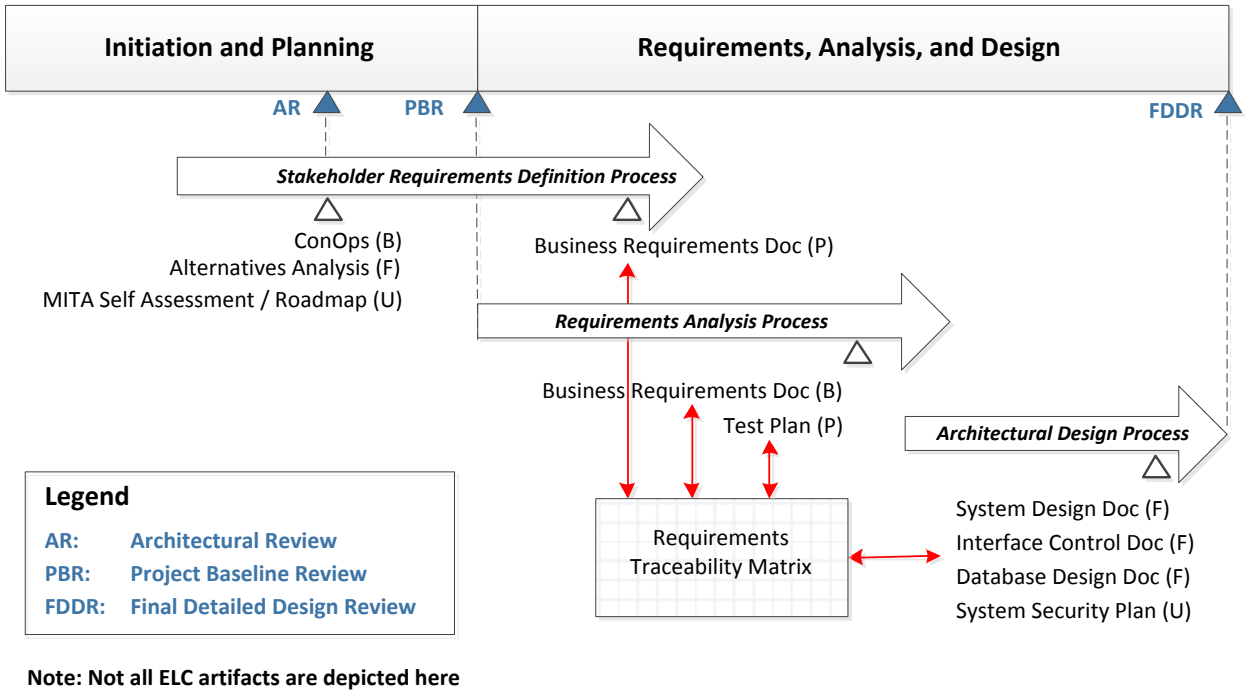


Figure 3. Key Technical Processes and Artifacts that Support Design

The technical development team must be able to map all technical artifacts mapped back to stakeholder requirements as the team progresses through the life cycle. Accordingly, all design features and capabilities should be mapped back to requirements; in later phases, test cases are mapped to each design feature and its source requirement. This discipline is essential to verify a complete system design. Complex projects may involve several hundred to thousands of requirements that will be developed, analyzed, and managed. Once documented, the development team should manage each requirement through change control and establish its traceability to subsequent design features and test cases. Best practices call for a requirements management tool to assist the State development team in this process. A requirements management tool will greatly aid both the development team and the CMS technical review team.

2.2.1 Stakeholder Requirements Definition Process

Purpose: The purpose of the Stakeholder Requirements Definition Process is to define the requirements for a system that can provide the capabilities needed by the system stakeholders. This process involves identifying stakeholders, or classes of stakeholders, involved with the system throughout its life cycle, and their needs, expectations, and desires. This process helps establish the foundation that supports subsequent requirements analysis and technical design processes.

Description: Stakeholder requirements govern the system's development and are an essential factor in further defining or clarifying the scope of the development project. A stakeholder is any entity (individual or organization) that has a legitimate interest in the system. Typically, stakeholders include organization decision makers, regulatory bodies, system integrators, support

organizations, and individual users. All stakeholder requirements should have bi-directional traceability (from the requirement to the source document or the stakeholder need).

Inputs: Inputs to the Stakeholder Requirements Definition Process include the following items:

1. **Source Documents –** extract, clarify, and prioritize all of the written descriptions contained in the source documents relevant to the particular stage of procurement activity
2. **Stakeholders' Needs –** description of users' and other stakeholder needs or services that the system will provide
3. **Project Constraints –** includes cost, schedule, resource, and solution constraints

Activities: The Stakeholder Requirements Definition Process consists of the following three activities:

1. **Elicit Stakeholder Requirements**
   - Identify the stakeholders that will have an interest in the system throughout its entire life cycle, and elicit requirements
2. **Define Stakeholder Requirements**
   - Define constraints imposed by agreements or interfaces with legacy systems
   - Create scenarios to define the conceptual system design documents, the range of anticipated uses of the system, the intended operational environment, and interfacing systems, platforms, or products
   - Establish critical and desired system performance
3. **Analyze and Maintain Stakeholder Requirements**
   - Analyze requirements for clarity, completeness, and consistency
   - Negotiate modifications to resolve impractical requirements
   - Validate, record, and maintain stakeholder requirements throughout the system life cycle
   - Establish and maintain a requirements traceability matrix (RTM) to document how the formal requirements are intended to meet the stakeholder objectives and achieve stakeholder agreement

Outputs: Outputs of the Stakeholder Requirements Definition Process establish the initial set of set of stakeholder requirements for project scope and associated agreements. For the Healthcare Insurance Exchange Program, a principal artifact will be the Concept of Operations (ConOps). The ConOps describes the way the system works from the stakeholders' perspective. The ConOps encompasses the user description and summarizes the needs, goals, and characteristics of the system's entire user community, including operations, maintenance, and support personnel.

2.2.2 Requirements Analysis Process

Purpose: The purpose of the Requirements Analysis Process is to transform the stakeholder view of desired services into a technical view of the target system. This process builds a

representation of a future system that will meet stakeholder requirements, and develops a set of measurable system requirements that specify the characteristics of the future system.

Description: System requirements are the foundation of system definition and the basis for the architectural design, integration, and verification processes. Each requirement carries a cost; therefore, early in the project life cycle it is essential to establish a complete set of minimum requirements. Any change in requirements that may occur later in the development cycle can produce a significant cost impact on the project. The output of this process must be compared for traceability to and consistency with the stakeholder requirements. The Requirements Analysis Process adds the verification criteria to the defined stakeholder requirements.

Inputs: Inputs to the Requirements Analysis Process include any decisions or data resulting from previous stages of development and consist of the following:

1. The System ConOps
2. Stakeholder Requirements
3. Stakeholder Requirements Traceability

Activities:

1. **Define the System Requirements**
    - Define the functional boundary of the system in terms of the behavior and properties to be provided
    - Define each function that the system is required to perform
    - Define implementation constraints introduced by stakeholder requirements or represent unavoidable limitations in the solution
    - Specify system requirements and functions, as justified by risk identification or criticality of the system, that relate to such critical qualities as health, safety, security, reliability, availability, and supportability
2. **Analyze and Maintain the System Requirements**
    - Analyze the integrity of the system requirements to ensure overall integrity of each requirement or set of requirements
    - Review the analyzed requirements with applicable stakeholders to ensure that the specified system requirements adequately address their needs and expectations
    - Demonstrate traceability between the system requirements and the stakeholder requirements
    - Maintain the set of system requirements together with the associated rationale, assumptions, and decisions throughout the system life cycle

Outputs: Outputs of the Requirements Analysis Process are technical descriptions of future system characteristics that meet Stakeholder Requirements. ***Note*:** These descriptions are not the specific solution for development. These outputs include the following:

1. Performance Requirements
2. Functional Requirements

3. Non-Functional Requirements
4. Architectural Constraints

2.2.3 Architectural Design Process

Purpose: The purpose of the Architectural Design Process is to define a specific optimal solution that satisfies system requirements. This design process identifies and explores one or more implementation strategies at a level of detail consistent with the system's technical and commercial requirements and risks. The design requirements resulting from this process are the basis for verifying the future system and will be used for devising an integration and verification strategy.

Description: The Architectural Design Process requires the participation of systems engineers in conjunction with appropriate subject matter experts to conduct technical analyses and make decisions to identify a set of system elements.

Inputs: The primary inputs to the Architectural Design Process are the baselined project documents developed during the Requirements Analysis and Stakeholder Requirements Definition Processes. The inputs include the following:

1. The System ConOps
2. Business and System Requirement Documents
3. System Functional Interfaces and Interface Control Documents (ICD)
4. Requirements Traceability Matrix

Activities: The Architectural Design Process includes the following activities:

1. **Define the Architecture**
   - Define a consistent logical architecture; capture the logical sequencing and interaction of system functions or logical elements
   - Partition system requirements and allocate them to system elements with associated performance requirements
   - Evaluate available COTS solutions
   - Identify interfaces and interactions between system elements (including human elements of the system) and with external systems
   - Define Validation &Verification criteria for the system elements
2. **Analyze and Evaluate the Architecture**
   - Evaluate the use of COTS products for compatibility with the design
   - Evaluate alternative design solutions
   - Support definition of the system integration strategy and plan
3. **Document and Maintain the Architecture**
   - Document and maintain the architectural design and relevant decisions that produced agreement on the baseline design
   - Establish and maintain traceability between requirements and system elements

Outputs: The result of the Architectural Design Process is an architectural design that is placed under configuration management. This baseline typically includes the following types of information:

1. **System Architecture –** a description of the system architecture, typically presented in a set of architectural views, along with justification for the decisions
2. **Interface Requirements –** interface requirements supporting a plan for system integration and verification strategy
3. **System Element Requirements –** allocated and derived requirements are assigned to system elements and documented in a RTM
4. **System Element Descriptions –** detailed system element descriptions
5. **System Element Requirements Traceability –** all system element requirements should have bi-directional traceability, including to their source, such as the originating system requirements

3. CMS MITA Requirements

CMS is a principal stakeholder in the development of State Medicaid IT systems, and has established a core set of binding requirements for States regarding processes, standards, and architecture. 42 CFR Part 433 establishes specific requirements for Medicaid funding, which CMS defines in the *Enhanced Funding Requirements: Seven Conditions and Standards*[4]. States should incorporate these requirements into their baseline set of project requirements.

During the design review process, CMS will evaluate each State for compliance with these requirements. Table 1 provides a very high level description of the seven standards or conditions, and describes where States should address each requirement in their ELC artifact set. This table does not provide an exhaustive and detailed view of the standards and conditions, but is solely intended to show a mapping between the topics and the program artifacts.

Table 1. Evidence for Compliance with the Seven Conditions and Standards

Standard or Condition	Aspect	Source of Evidence
Modularity Standard	• Use of open interfaces and exposed application programming interface • Use of a modular approach to system design • Separation of business rules from core programming • Use of a business rules engine • Provide business rules in both human and machine-readable formats • Indicate how change control practices will be used to manage rules	*System Design Document*. Information on change control should be found in the PMP under the Change Management Plan.
	Use of a formal systems development methodology and Systems Development Life Cycle (SDLC)	Should be presented as part of the ELC Design Review discussion
	Document the services layer and individual service profiles	The service layer should be documented in the *System Design Document*. If the service is exposed as a web-service, it must be documented in more detail in an Interface Control Document.
	Document and submit business rules to a designated Department of Health and Human Services (HHS) repository	Information should be in the *Business Rules Document* and posted on CALT once the Business Rules Repository is established

[4] A reference to this document appears the References Section and this should be used as the complete and authoritative definition for these requirements

Standard or Condition	Aspect	Source of Evidence
MITA Condition	Perform MITA Self Assessments and develop MITA Roadmaps (Medicaid only)	MITA Self-Assessment document, and MITA Roadmap document
	Develop ConOps and business process models.	*Concept of Operations* document
Industry Standards and Conditions (HIPAA –1996, Rehabilitation Act Section 508c, federal civil rights laws, standards adopted by the Secretary under Section 1104 of the Affordable Care Act, and Section 1561 of the Affordable Care Act)	Identify all relevant industry standards and produce development and testing plans to ensure compliance	This information should be found in the *System Design Document* and, in certain cases, the ICDs. Compliance with Section 508c should be found in the *Section 508 Product Assessment Package.*
	Implement practices and procedures for system development phase to ensure compliance	This information should be presented as part of the ELC Design Review.
Leverage Condition	Identify components and solutions developed cooperatively between States	*System Design Document*
	Identify components and solutions that are good candidates for reuse. Develop plans for reuse and make artifacts available to other States.	*System Design Document*
	Identify consideration of SOA-based, cloud-hosted solutions, and conversely, any custom, bottom-up developments	This information should be captured in the *System Design Document* and in the *PMP* (Development Approach Plan).
	Identify areas for customization of reused solutions	This information should be captured in the *System Design Document* and discussed during the ELC Design Review.
	Identify existing redundant services and plans to eliminate them	Although this information is not part of the artifact set, it should be discussed during the ELC Design Review.
Business Results Condition	Provide support for measuring the degree of automation, quality of customer service, and periodic performance testing	*System Design Document*
	Support for 21st century customer service	This information should be provided in the *Concept of Operations Document* and be provided as part of the ELC Design Review.
	Adhere to performance standards and testing	Capture this information in Service Level Agreements (SLA)/MOUs, the *Requirements Document*, *Test Plan*, *Test Reports*, and *POA&Ms*.
Reporting Condition	Solutions should produce transaction data, reports, and performance information that would contribute to program evaluation and improvement in business operations	This information should be captured in the *Business Requirements Document*, the *Database Design Document*, the *Data Management Plan*, and the *System Design Document*.

Standard or Condition	Aspect	Source of Evidence
Interoperability Condition	Demonstrate that the solution will support interface standards regarding: • Technology (web services) • Protocols • Security and privacy controls • Data-level semantics (XML vocabulary) Interoperability must be ensured between the Exchange, and other health information exchanges, public health agencies, human service programs, and community organizations providing outreach and enrollment assistance services.	

4. Consults, Reviews, and Expectations

The ELC provides a series of consults and reviews at specific times throughout the life cycle. The consult provides a forum where States can share with CMS the status of their development projects. Consults are informal events to discuss problems and issues, and develop joint approaches to remediation. A consult involves no formal programmatic consequences. The ELC supports additional consults if necessary.

Reviews, on the other hand, serve as formal gates for specific projects or programs. Each project review has three possible outcomes: Go, No Go, or Go with Conditions. States must show an acceptable level of progress and maturity in their development projects before they may proceed to the next ELC phase. The objectives for the five (5) project reviews are as follows:

- **Architectural Review –** this review focuses on establishing whether the State has a clear and well-defined System ConOps, and a comprehensive PMP. Project scope and boundary must be clearly defined at this review. Each State must be able to demonstrate a MITA assessment and roadmap to MITA compliance for any Medicaid-related aspects of their project.
- **Project Baseline Review (PBR) –**a successful PBR demonstrates that the project planning process is largely complete, and that a fully developed ConOps and PMP have been established and baselined.
- **Final Detailed Design Review (FDDR) –** a successful FDDR demonstrates that a complete set of system designs have been produced, that the design is founded on a complete set of requirements, and the project is ready to proceed with system development activities. All systems, subsystems, interfaces, and operational threads are fully specified, documented, and baselined. CMS expects that an independent party has validated the system requirements and the system and detailed designs before it conducts this review.
- **Operational Readiness Review (ORR) –** a successful ORR determines whether the system is ready to go into production. The State must demonstrate it has concluded all system testing, and completed any remedial actions, all operator and user training for the support staff, and all privacy, security, and accreditation activities.
- **Annual Operational Analysis Review (OAR) –**during the Operations & Maintenance Phase, the OAR examines the operating status of the system through a variety of key performance indicators and determines whether the system is performing in an efficient and effective manner.

During the course of each gate review, CMS will evaluate each State development project to determine progress achieved and whether the project is prepared to enter the next ELC phase. Table 2 presents the success criteria for programmatic reviews. Table 2 only references primary artifacts; the complete set of artifacts required during each review is available on CALT in the *Establishment Review and Medicaid IT Review – IT Gate Review Artifact Mappings* document.

Table 2. Success Criteria for Initial ELC Review

Architectural Review	
Success Criteria	**Questions for the States**
• ConOps developed • Project Planning started • Cost & Budget Plan is complete • MITA analysis started	• Has a System ConOps been developed that clearly identifies scope and boundary for the proposed solution? • Has the ConOps been baselined? • Has a preliminary Project Management Plan been developed? • Has the program conducted a MITA Self-Assessment and developed a Roadmap as required for Medicaid-specific project elements?
Project Baseline Review	
The Architectural Review has been passed and any outstanding conditions from that review have been satisfactorily addressed. ConOps and PMP are finalized.	• Has the System ConOps been validated and finalized? • Is the Project Management Plan largely complete, and has it been finalized? • Has a preliminary Privacy Impact Assessment been developed?
Final Detailed Design Review	
The Project Baseline Review has been passed and any outstanding conditions from that review have been satisfactorily addressed. Prior to participating in the FDDR, it is expected that the State Exchange requirements, design, and test artifacts have undergone a thorough Independent Verification & Validation (IV&V) process by an independent third party.	*Requirements:* • Is the Stakeholder Requirements Definition process largely complete? • Have the Stakeholder requirements been documented and baselined? • Is the Requirements Analysis Process largely complete? • Is the business architecture largely complete and all business processes identified, modeled, and documented? • Have the System requirements been documented and mapped back to Stakeholder requirements? • Has the Business Requirements Document been finalized? • Have are all business rules been identified and placed under change control? • Have the System Security Plan and the Information Security Risk Assessment (ISRA) documents been baselined? • Have all SLAs/MOUs have identified and largely developed?
Requirements are complete. The architecture and detailed design have been mapped back to the requirements. A well-defined test strategy is in place, and all requirements have been mapped to test cases.	*Design:* • Has the system architecture been documented and mapped to system requirements? • Has the detailed system design been documented and mapped to requirements? • Has the System Design Document been finalized? • Have all the Interface Control Documents been developed and finalized? • Have the Database Design Document and the Data Management Plan been developed and finalized? • Has an Implementation Plan been baselined?
	Test: • Has a program test strategy been defined and a Test Plan Document been baselined? • Have all of the requirements been traced to test cases identified in the Test Plan Document?

Acronyms

AR	Architecture Review
CALT	Collaborative Application Lifecycle Tool
CCIIO	Center for Consumer Information and Insurance Oversight
CMS	Centers for Medicare & Medicaid Services
ConOps	Concept of Operations
COTS	Commercial Off-the-Shelf
DDC	Detailed Design Consult
ELC	Enterprise Life Cycle
FDDR	Final Detailed Design Review
FFE	Federal Facilitated Exchange
HHS	Department of Health and Human Services
ICD	Interface Control Document
INCOSE	International Council of Systems Engineering
ISRA	the Information Security Risk Assessment
IT	Information Technology
IV&V	Independent Verification and Validation
MITA	Medicaid Information Technology Architecture
MOU	Memorandum of Understanding
OAR	Operational Analysis Review
ORR	Operational Readiness Review
PBR	Project Baseline Review
PDC	Preliminary Design Consult
PMP	Project Management Plan
POA&M	Plan of Action & Milestones
PORC	Pre-Operational Readiness Consult
PSC	Project Startup Consult
RTM	Requirements Traceability Matrix
SBE	State-Based Exchange
SDLC	System Development Life Cycle
SLA	Service Level Agreement

SME	Subject Matter Expert
SOA	Service-Oriented Architecture
SPE	State-Partnership Exchange
V&V	Verification and Validation
XML	eXtensible Markup Language

List of References

1. *Enhanced Funding Requirements: Seven Conditions and Standards. Medicaid IT Supplement* (MITS-11-01-v1.0), Version 1.0, Centers for Medicare & Medicaid Services, (CMS) April 2011.
2. *Establishment Review and Medicaid IT Review – IT Gate Review Artifact Mappings*, CMS, (available on CALT).
3. *IT Enterprise Life Cycle (ELC)* v2.0 Model, CMS, Date.
4. *Systems Engineering Handbook: A Guide for System Life Cycle Processes and Activities*, Version 3.2, International Council of Systems Engineering, January 2010.
5. *Systems and software engineering — System life cycle processes*, International Standards Organization, ISO/IEC 15288, 2nd Ed., 2008.

Medicaid Information Technology Enterprise Life Cycle Model

The purpose of using an oversight process in the form of the IT ELC model is to:

- Assess progress in IT projects along the lifecycle,
- Monitor and oversee IT projects to ensure compliance with Federal regulations, policy, and procedures,
- Provide the forum for direct feedback and technical assistance to States in a collaborative environment,
- More easily identify follow up items, next steps, and technical assistance needs for States through the use of artifact submission and formal reviews to ensure States meet key overarching elements while supporting a coordinated review strategy for both the Federal team and the State team to best support successful IT project implementations,
- Facilitate reusability, collaboration and acceleration of work products to support successful and timely IT implementations.

IT projects typically utilize a development framework to guide the project work (e.g. Enterprise Life Cycle) for a structured and disciplined approach to planning, designing, and implementing systems by executing a sequential series of technical and management processes. The ELC model is organized as a sequence of phases with a specific set of activities and objectives. Figure 1 provides the high level overview of the Medicaid IT ELC model.

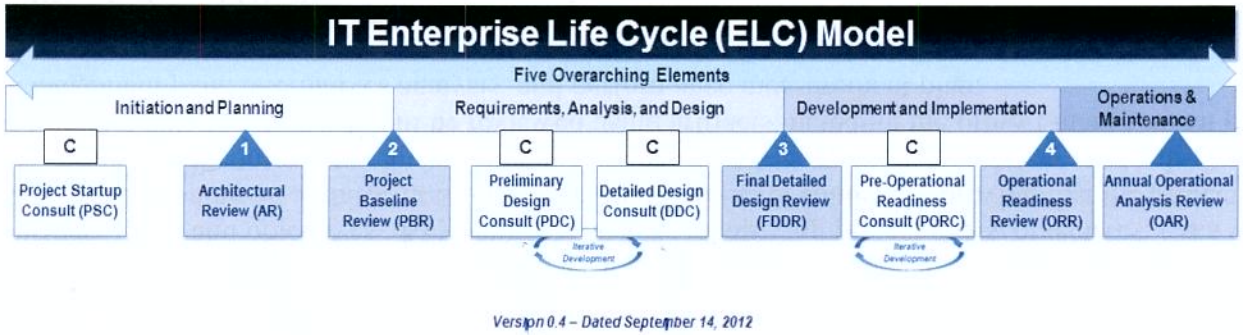


Figure 1: Medicaid IT ELC Model

Architecture Review (AR)

During an architectural review, the business needs are assessed to ensure they are sound and conform to the target architecture including the Exchange Reference Architecture, Medicaid Information Technology Architecture (MITA), and the seven standards and

conditions. Additional considerations include determining whether the proposed project potentially duplicates, interferes, contradicts or leverages another investment that may exist, is proposed, is under development, or is planned for in the near future. Through the review of artifacts including a Concept of Operations, business process models, and acquisition strategy, key next steps towards progress in the planning and subsequent phases can be determined.

Project Baseline Review (PBR)

During the initiation and planning phase which is assessed at the PBR, the business owner(s) of an Exchange and Medicaid / CHIP eligibility and enrollment system identifies what the project is intended to accomplish and presents the plans for achieving the business goals and objectives. Key activities such as identifying project goals, objectives, risks with clear and measurable success factors, developing an architectural framework and high-level content, approving that the project business needs will be met and that the solution will conform to required architecture and all CMS statutory, regulatory, and sub-regulatory guidance, and analyzing how the project will be managed, will be reviewed using artifacts including the project management plan, project schedule, risk management plan, alternatives analysis, and performance measurement plan.

Final Detailed Design Review (FDDR)

At this gate, verification to ensure that the detailed design satisfies the requirements of the project and conforms to required architecture and the seven conditions and standards are validated. During the requirements, analysis, and design phase, a common set of business rules are refined and business requirements are validated and decomposed into functional and non-functional requirements. Requirements are used to define the design in detail, including inputs, processes, outputs, and interfaces, and leads to further detailed project management planning. During this review, artifacts including a systems design document, business requirements and rules, and interface control documents will be reviewed to determine validation to project requirements.

Operational Readiness Review (ORR)

A primary purpose of the ORR is to determine if the solution is ready for deployment into a production environment and that it is ready to support business operations. Final determination will ensure the final IT solution or automated system/application has been developed, tested, validated, and verified, and is ready for release into a production environment for sustained operations and maintenance support. Examining test results, the contingency / recovery plan, and performing an actual system test along with review of other artifacts will determine the readiness of the solution to production.

IT ELC Review Entry Criteria

Regardless of the development methodology followed by the project, the IT ELC Reviews will be scheduled at key points within the life cycle of the project depending on the level of maturity and the activities accomplished by the project. Table 1 provides a guide to determining when to schedule a gate review based on the entry criteria that must be met before that review.

Table 1: IT ELC Review Entry Criteria

Review	Entry Criteria and Timing
AR	• An AR can be scheduled during the planning phase, before the PBR and after the PSC • For Medicaid enhanced funding projects, this could also be after the State has initiated planning through either an approved Planning Advance Planning Document (PAPD) or an Implementation Advance Planning Document (IAPD). In preparation for preparing for the review, the State will submit the relevant artifacts which support the five overarching elements and CMS has conducted a preliminary review and assessment of the content. The high-level scope and architecture of the targeted system and environment has been documented and can be articulated to support the review • The State has provided evidence of the plan for reuse in their design and development • The State has provided evidence of the plan to meet the seven standards and conditions for Medicaid enhanced Federal funding • The State has submitted all the relevant artifacts two weeks in advance of the review, which support the five overarching elements and CMS has conducted a preliminary assessment of the content
PBR	• A PBR is scheduled near the end of the planning phase, before the PDC and after the AR • For Medicaid enhanced funding projects, this could be after the State is near completion of their approved PAPD scope of work or has completed planning activities within the approved IAPD scope of work that supports design, development, and implementation. In preparation for the review, the

Review	Entry Criteria and Timing
	State has submitted all the relevant artifacts which support the five overarching elements and CMS has conducted a preliminary review and assessment of the content • The timeline, major milestones, risks, and mitigation strategies have been articulated • Key stakeholders have been identified and plans are in place to communicate to the stakeholders as well as involve them throughout the duration of the project • High-level system operations and business processes have been developed • The State has provided evidence that they are planning for reuse in their design and development • The State has provided evidence of the plan to meet the seven standards and conditions for Medicaid enhanced Federal funding • The State has submitted all the relevant artifacts two weeks in advance of the review, which support the five overarching elements and CMS has conducted a preliminary assessment of the content
FDDR	• A FDDR is scheduled when a State is nearing completion of the requirements, analysis and design phase, before the PORC and after the DDR • A systems integrator is on-board and has completed majority of the design and is starting work to actually develop the system(s) • Business requirements are complete in iteration; Medicaid business rules in both human & machine readable formats are documented and submitted to CALT • A rules engine platform and data model has been defined • Test Plan and Use / Test Cases are developed • Design is determined, development is underway, and interfaces have been clearly identified and defined • Reuse results are more defined both in terms of what the State is reusing from another State(s) or the Federal government and what the State has identified that can be reused by other IT projects • Clear evidence for adherence of development to achieve the seven standards and conditions • An independent Validation and Verification (IV&V) contractor has reviewed the design artifacts and results of the IV&V report have been submitted to CMS • A strong understanding of the system, security, and privacy design is demonstrated with clear linkages to requirements which are base-lined • A Contingency Plan / Recovery Plan is in the preliminary stage of maturity • Risks are being continuously identified with plans to mitigate the risks • The State has identified reused components in their design and development • Security and privacy plans and considerations must be base-lined • The State has submitted all the relevant artifacts two weeks in advance of the review, which support the 5 overarching elements and CMS has conducted a preliminary assessment of the content
ORR	• A ORR is scheduled when the State's IT project is nearing the completion of the development and implementation phase of the lifecycle and the State has submitted all the relevant artifacts which

Review	Entry Criteria and Timing
	support the 5 Overarching Elements and CMS has conducted a preliminary review and assessment of the content • All or a majority of the unit and system testing is concluded with no major defects, and any remedial actions finished • All operator and user training for the support staff is completed or near completion • The State has provided evidence of reused components in their design and development • The efficiencies of meeting the seven standards and conditions for Medicaid enhanced Federal funding are visible in the system operations including performance measures • All privacy, security, and accreditation activities are completed, MOUs / SLAs and Data Use Agreements are in place • The State has submitted all the relevant artifacts two weeks in advance of the review, which support the 5 overarching elements and CMS has conducted a preliminary assessment of the content

Medicaid IT ELC Consults

Formal IT ELC reviews can be supported by informal consultations or consults between CMS, States and other relevant partners. Consults are opportunities for strategic direction setting and information sharing for the purposes of eventually leading up to successful reviews. The IT ELC identifies four consults including: Project Start-Up Consult (PSC), Preliminary Design Consult (PDC), Detailed Design Consult (DDC), and Pre-Operational Readiness Consult (PORC). More consults may be conducted depending on CMS assessments and State needs. The format and content of consults will be determined by the upcoming review and the level of maturity of the project at the time of the consult. More than one consult of a particular type may be conducted depending on the needs of the IT project.

Project Start-up Consult (PSC)

This is a meeting typically held at the beginning of a project where State and Federal stakeholders meet to share preliminary information and discuss expectations, key milestones, and timelines for the project.

Preliminary Design Consult (PDC)

This consult should be scheduled after the Architectural Review (AR) and the Project Baseline Review (PDR), but before the Detailed Design Consult and the Final Detailed Design. The purpose of this consult is to discuss the business requirements development and business architecture, and to verify that the preliminary functional and non-functional requirements are in conformance with the target architecture, specifically the Medicaid Information Technology Architecture (MITA). Additionally, issues regarding security analysis and planning should be discussed to ensure that the scope and nature of this effort is understood, and that the State has appropriate technical resources to support the project requirements. Initial work on test planning should be discussed to understand the strategy and resources that include infrastructure, and staffing.

Detailed Design Consult (DDC)

This consult should be scheduled before the Final Detailed Design Review. The purpose of this consult is to serve as a follow-up to the PDC and should focus on any issues that were uncovered as the State proceeds through the Requirements, Analysis and Design Phase. This consult can begin the verification that the detailed design satisfies the requirements for the release and is in conformance

with the business architecture, standards, and the target architecture specifically MITA. This could be the last consult prior to the Final Detailed Design Review (FDDR) so the goal would be to resolve all significant open design issues.

Preliminary Operational Readiness Consult (PORC)

This consult should be scheduled before the Operational Readiness Review. The purpose of this consult is to help States prepare for the upcoming Operational Readiness Review (ORR) which occurs at the end of the Development and Implementation Phase. During this consult, the list of items required to pass the ORR should be critically examined to ensure that the ORR can be successfully passed.

IT ELC Consults Entry Criteria

Regardless of the States IT development methodology, the IT ELC consults will be scheduled at key points within the life cycle of the project depending on the level of maturity and the activities accomplished by the project. Table 2 provides a guide to determining when to schedule an IT consult based on the entry criteria that must be met before the consult takes place.

Table 2: IT ELC Consults Entry Criteria

Consults	Entry Criteria and Timing
PSC	• This consult is scheduled at the beginning of a project • The State project team must be in place, funding must be secured, and any relevant permissions must be granted to execute the work associated with the project • A packet of material is provided to the State to reuse

Consults	Entry Criteria and Timing
PDC	• This consult is scheduled after the Architectural Review (AR) and the Project Baseline Review (PDR), but before the DDC and the FDDR • Depending on the needs of the State and CMS' assessment, several PDCs may be scheduled. This may include consults after key iterations that include riskier or more complex functionality in an agile development environment • Project scope must be solidified and based on the scope, detailed business process models and at least high-level functional requirements should have been started • Preliminary requirements capture has started and a requirements management plan is being used to ensure traceability • The State has provided evidence of identifying and managing risks including risk mitigation plans • The State has provided evidence of reuse in business process model and requirements development • The State has provided evidence of the plan to meet the seven standards and conditions for Medicaid enhanced Federal funding • Security and privacy plans and considerations must be identified
DDC	• This consult is scheduled after the PDC and before the FDDR • Depending on the needs of the State and CMS' assessment, several PDCs may be scheduled. This may include consults after key iterations that include riskier or more complex functionality in an agile development environment • Major modules for the overall system must be identified and detailed functional and non-functional requirements capture must be well underway • System security understanding must be matured and documented to the extent that an overall approach and execution plan is clear • All major interfaces must be identified and documentation for design must have begun • All Request for Proposals (RFPs) related to finalizing a systems integrator should be underway • The State can demonstrate evidence through IT artifacts of how the IT project will be meeting the seven standards and conditions for Medicaid enhanced Federal funding • The State has provided evidence of reuse in system and security design development • Security and privacy plans and considerations must be base-lined

Consults	Entry Criteria and Timing
PORC	• This consult is scheduled after the FDDR and before the ORR • Depending on the needs of the State and CMS' assessment, several PDCs may be scheduled. This may include consults after key iterations that include riskier or more complex functionality in an agile development environment • Code reviews and tests must be well underway • A clear and detailed implementation plan must be in place • The State has provided evidence of reuse in development and implementation planning • There is evidence in testing results and in the soon to be operational system that meets the seven standards and conditions for Medicaid enhanced Federal funding • Security and privacy plans and considerations must be finalized

Table 3 - ELC Medicaid IT Reviews Progress Measurement

Notes: Description of items under "Link to Key Element, Federal Regulation for Medicaid, CHIP" are listed at Medicaid.gov, Information Technology page. Description of items under "Related Establishment Review Exchange IT Activity" can be found in SERVIS tool.

#	Overarching Element	#	Progress Measure (Evidence)	Supporting Artifact	Link to Key Element, Federal Regulation for Medicaid, CHIP	Related Establishment Review Exchange Activity (SBE,SPE)
1. Architecture Review (AR) and Project Baseline Review (PBR)						
1	What approach is the State taking to creating / implementing a shared eligibility service that will ensure a seamless and efficient eligibility and enrollment experience for consumers / applicants?	1.1.1	Has the eligibility determination and redetermination process been identified? What type of Exchange model will the State be implementing and how will it interoperate with Medicaid and CHIP? a) State based Exchange (SBE): Where will the shared eligibility service reside and what is the planned solution? Does the project include plans to interact with the Federal Data Services Hub (Hub)? What other automated State verifications are planned? b) State Partnership Exchange (SPE) and Federally Facilitated Exchange (FFE): Where will the shared eligibility service reside and what is the planned solution? Are there plans to interact with the Federal Data Services HUB? What other automated State verifications are planned? How will the State integrate with the Hub to interoperate with the FFE? Has the State submitted an Advance Plan Document (APD) and developed a cost allocation methodology that supports the project in terms of scope and solution? Is the State invoking the OMB A-87 exception and provided required reporting elements?	• Concept of Operations and supplements: Business Process Models	1, 2	3.7

#	Overarching Element	#	Progress Measure (Evidence)	Supporting Artifact	Link to Key Element, Federal Regulation for Medicaid, CHIP	Related Establishment Review Exchange Activity (SBE,SPE)
		1.1.2	Is there a demonstrated understanding of scope, high-level business operations, stakeholders, and interactions? Does the architecture fulfill the overarching business needs? Is there a good understanding of the end-to-end workflow? • FFE / SPE: Is there a clear process flow from the State system to the Hub and through the Hub to the FFE that includes the required integration points? • SBE: Is there a clear process flow to the Hub? • Is enrollment in the Medicaid / CHIP program included in the high-level operations plan?	• Project Management Plan • Concept of Operations and supplement: Architectural Diagrams	1, 2, 3, 4, 5	9.5 9.7
		1.1.3	Have high-level scenarios been developed to define the conceptual system including the range of anticipated uses of the system, the intended operational environment; and interfacing systems, platforms, or products? SPE: Is there high level understanding of the scope of functionality to be delivered by the State versus the FFE?	• Concept of Operations	1, 2, 4	9.5
		1.1.4	Is the State IT project's plan to use CMS' codified policy, financing structure, and investments in systems to support the Exchange, Medicaid and CHIP programs efficient and streamlined?	• Concept of Operations • Cost Allocation Plan Methodology	1, 2, 3, 4, 5	9.5
		1.1.5	How is the State planning and designing to achieve real-time eligibility determinations for its citizens and are they planning to automate all required verifications in support of real-time decisions?	• Concept of Operations • Business Process Models		

#	Overarching Element	#	Progress Measure (Evidence)	Supporting Artifact	Link to Key Element, Federal Regulation for Medicaid, CHIP	Related Establishment Review Exchange Activity (SBE,SPE)
		1.1.6	How is the State planning on integrating the shared eligibility service with the State's MMIS system?	• Concept of Operations • Business Process Models		
		1.1.7	Have the implications of change to the State's project scope to include the Medicaid expansion been considered in the design to ensure accommodation for scale?	• Technical Documents • Question to the State	1, 4	N.A.
2	How does the State's project management plan support delivering required business results in a phased approach to meet key deliverable dates?	1.2.1	Is the project scope, cost, and schedule consistent with original estimates in the APD or are updates required? How does the State project management plan including schedule, align with programmatic milestones to ensure that business capabilities will be delivered in time to meet statutory and regulatory deadlines in support of all Exchange, Medicaid, and CHIP applicants and beneficiaries?	• Project Management Plan and supplements: Project Schedule, Financial Management Plan, Financial Status Report • Cost Allocation Plan	1, 2, 3, 4	9.4, 9.5
		1.2.2	Have all stakeholders who have an interest in the system been identified? FFE / SPE: Is the State in active discussions Federal stakeholders to understand the expectations to connect to the Hub and to the FFE through the Hub? SBE: Is the State in active discussions with Federal stakeholders to understand the connectivity requirements to the Hub? When will the State be ready to stub test to the Hub? For States integrating their shared eligibility solution with other human services programs, is the State working with Federal and State partners to support these programs in the design and development?	• Project Management Plan and supplement: Communications Plan • Refer to On-boarding Plan and State Requirements to Establish Interfaces to the Hub	2	9.5

#	Overarching Element	#	Progress Measure (Evidence)	Supporting Artifact	Link to Key Element, Federal Regulation for Medicaid, CHIP	Related Establishment Review Exchange Activity (SBE,SPE)
		1.2.3	Has the State committed to a formal system development methodology to ensure ease of change and maintenance of systems? Does the methodology included well defined phases for inception through to close out? Does it include planning with schedules, target dates, and budgets? Does the methodology exhibit controls over the project's life with written documentation, formal reviews, signoff and acceptance by the system owner? Is it a well-documented and repeatable process with clear input and output (artifacts) to be MITA compliant? (Sub-regulatory Guidance for 7 S&Cs, Version 1.0, Modularity Standard)	•		
		1.2.4	Has the project been defined, including: • Analysis of the project proposal and related agreements to define the project scope and boundaries, identify project objectives and constraints • Establishment of procedures and practices necessary to carry out planned effort • Process to determine actual and projected cost against budget, actual and projected time against the established schedule • Process to evaluate project progress against established criteria and milestones • Use of a systematic approach to designing, engineering, and deploying solutions? • Consideration of life cycle reviews, audits, and inspections to determine readiness to proceed to next milestone	• Project Management Plan and supplements	1, 2, 4	9.4

#	Overarching Element	#	Progress Measure (Evidence)	Supporting Artifact	Link to Key Element, Federal Regulation for Medicaid, CHIP	Related Establishment Review Exchange Activity (SBE,SPE)
		1.2.5	Have project resources been planned, including: • Establishment of the roles and responsibilities for project authority • Acquisition plan • Defining major top-level work packages (work-breakdown structure or WBS) for each task and activity, each work package should be tied to identified resources and procurement strategies • Developing a project schedule based on objectives and work estimates • Defining the infrastructure and services required • Defining costs and estimated project budget • Planning the acquisition of materials, commercial products and services	• Project Management Plan and supplements	1, 2, 4	9.4
		1.2.6	Have project technical management processes been defined, including: • Preparing a plan to co-ordinate the technical activities that will occur throughout the life cycle • Preparing a plan to assess and manage various forms of risk that will be encountered across the life cycle • Preparing a plan to manage the technical configuration of the system elements, and identify a systematic approach for identifying and handling change requests	• Project Management Plan and supplements	2	9.4

#	Overarching Element	#	Progress Measure (Evidence)	Supporting Artifact	Link to Key Element, Federal Regulation for Medicaid, CHIP	Related Establishment Review Exchange Activity (SBE,SPE)
		1.2.7	Are processes in place to control and validate the project, including: • Initiating corrective actions when assessments indicate deviation from approved plans • Initiating preventive actions when assessments indicate a trend toward deviation • Initiating problem resolution when assessments indicate unsatisfactory performance • Is there a strategy to conduct and analyze Independent Verification and Validation (IV&V) reporting?	• Project Management Plan and supplements	2	9.4
3	What project risks has the State identified and what contingencies are available / in place? How are the contingency plans triggered?	1.3.1	Has a risk assessment with mitigation strategy for the project been defined and documented? Has a process been put in place to manage the Risk Profile including defining and documenting risk thresholds and acceptable and unacceptable risk conditions?	• Project Management Plan and supplement: Risk Management Plan	3	9.4
		1.3.2	Are project risks being documented and communicated along with rationale, assumptions, treatment plans, and current status? For selected risks, are there action plans being produced to direct the project team to properly respond to the risks?	• Project Management Plan and supplement: Risk Management Plan	2, 3	9.4

#	Overarching Element	#	Progress Measure (Evidence)	Supporting Artifact	Link to Key Element, Federal Regulation for Medicaid, CHIP	Related Establishment Review Exchange Activity (SBE,SPE)
		1.3.3	Has the State developed sound processes for continually identifying and managing risks, budgets, and schedule challenges? For FFE / SPE model solutions that may change to an SBE model, is there a risk plan which includes the longer term strategy for moving from an FFE / SPE model to SBE model, and if so, have the associated risks and mitigation strategies been identified that would the impact Medicaid and CHIP systems?	• Project Management Plan and supplement: Risk Management Plan	2, 3	9.4
4	How does the State's project meet / not meet the 7 Standards and Conditions and CMS IT Guidance?	1.4.1	Does the analysis demonstrate alignment with MITA and an understanding of current and desired target level MITA maturity? Is there an assessment of the Business, Information, and Technical architecture? Is a maturity model roadmap been documented?	• Can be applicable to all artifacts	4	9.1
		1.4.2	Does the system use a modular, flexible, approach separating business rules from core programming? Does the overall architecture decompose into well-defined component parts?	• Concept of Operations	4	9.7
		1.4.3	"Modular" means reducing the complexity of a larger problem by breaking it down into small well defined pieces. Modularity accomplishes re-usability, maintainability, and reliability. Has the State developed a lighter weight and loosely coupled approach to the design of their health care system, including E&E functions? (42 CFR Part 433 Medicaid Program; page 21956)	• Concept of Operations and supplement: Business process models	4	9.7
		1.4.4	Does the system use proven system development methodologies?	• Project Management Plan	4	9.7

#	Overarching Element	#	Progress Measure (Evidence)	Supporting Artifact	Link to Key Element, Federal Regulation for Medicaid, CHIP	Related Establishment Review Exchange Activity (SBE,SPE)
		1.4.5	Confidentiality and privacy are critical to protecting beneficiaries and providers. Does the solution meet the standard to ensure alignment with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy, security and transaction standards? (42 CFR Part 433 Medicaid program, page 21957, Sub-regulatory Guidance for 7 S&Cs, Version 1.0, Industry Standard), section 1104 and 1561 of the Affordable Care Act	• Concept of Operations and supplement Architectural Diagrams • NIST Level 2 Security	4	9.1
		1.4.6	Does the State incorporate the accessibility standards established under section 508 of the Rehabilitation Act OR standards that provide greater accessibility for individuals with disabilities? (Sub-regulatory Guidance for 7 S&Cs Version 1.0, Industry Standard) Is there compliance with Federal Civil Rights Laws? Is there compliance to Section 1104 and Section 1561 of the Affordable Care Act?	• Project Management Plan	4	9.4
		1.4.7	Will the systems generate data in support of program evaluation efforts and ongoing improvements in program delivery and outcomes? (Sub-regulatory Guidance for 7 S&Cs Version 1.0, Leverage Condition)	• Project Management Plan	4	9.4
		1.4.8	Interoperability Condition - Does the initiation, concept, and planning phase ensure a seamless coordination and integration with the Exchange, and allow for interoperability with health information exchanges, public health agencies, human services programs, and community organizations providing outreach and enrollment assistance services? (42 CFR Part 433, page 21965)	• Project Management Plan • Concept of Operations	4	9.4

#	Overarching Element	#	Progress Measure (Evidence)	Supporting Artifact	Link to Key Element, Federal Regulation for Medicaid, CHIP	Related Establishment Review Exchange Activity (SBE,SPE)
		1.4.9	Does the system currently support accurate and timely processing and analytics for reporting on claims (including claims of eligibility), adjudications, and provides effective communications with providers, beneficiaries, HHS stakeholders and the public?	• Project Management Plan and supplements: Performance Management Plan and Performance Measures	4	9.4
		1.4.10	Have open architecture standards (non-proprietary) for ease of information exchanges been identified? Do the interfaces to the Hub follow industry standards and adhere to the set of CMS provided Hub interface specifications?	• Concept of Operations and supplements Architectural Diagrams and Technical Architectural Diagrams	4, 5	9.7
		1.4.11	The State has begun investigating privacy considerations	• Privacy Impact Assessment		10.1
5	What deliverables and components from the State's project can be / should be made available for re-use by other states?	1.5.1	Have alternatives been considered, e.g., leverage existing technology, buy COTS / GOTS, utilize a transfer system, partner with another State, share configuration artifacts? Have cost and architectural trade-offs been considered? Are there components of the FFE or from another State's Eligibility and Enrollment (E&E) IT project that are being leveraged for reuse?	• Alternatives Analysis	4, 5	9.7
		1.5.2	Does the solution promote sharing, leverage, and reuse of Medicaid technologies and systems within and among States? Identify examples (Sub-regulatory Guidance for 7 S&Cs Version 1.0, Leverage Condition).	• Concept of Operations	5	9.7
		1.5.3	Has reusability and interoperability been incorporated as part of overall architecture considerations?	• Concept of Operations and supplements: Architectural Diagrams and Technical Architectural Diagrams	1, 4, 5	9.7

#	Overarching Element	#	Progress Measure (Evidence)	Supporting Artifact	Link to Key Element, Federal Regulation for Medicaid, CHIP	Related Establishment Review Exchange Activity (SBE,SPE)
		1.5.4	Is the State working with other States and with Federal agencies to develop and deploy shared services to minimize expenses and reduce risks? (I.T. Guidance 2.0, Section 1.2)	• Project Management Plan • Concept of Operations	1, 4	9.4, 9.7

2. Final Detail Design Review (FDDR)						
1	What approach is the State taking to creating / implementing a shared eligibility service that will ensure a seamless and efficient eligibility and enrollment experience for consumers / applicants?	2.1.1	Has the design addressed accepting and processing applications that have been transferred from agencies administering other Insurance Affordability Programs Eligibility for Medicaid and CHIP based on MAGI (assessments or determinations)	• Business Requirements, Use Cases, and User Stories • Business Rules in both human and machine readable formats	1, 4	3.7
		2.1.2	Has each function of the system been defined in terms of behavior and properties?	• Business Requirements, Use Cases, and User Stories • Business Rules	1	9.5
		2.1.3	Has the State completed a full systems requirements process (in addition to the overall business requirements analysis) and is there traceability?	• Business Requirements, Use Cases, and User Stories • Business Rules	1	9.5
		2.1.4	Have all the critical and desired requirements been established including, performance, functional, non-functional, architectural constraints, etc.? Has a Requirements Traceability Matrix (RTM) been created to document how the formal requirements are intended to meet the stakeholder objectives and achieve stakeholder agreement?	• Project Management Plan and supplement: Performance Measurement Plan	1	9.5
		2.1.5	Has the State identified any ground up development activity and explained why this ground up activity has been selected? How will customization be minimized? (Sub-regulatory Guidance for 7 S&Cs Version 1.0, Leverage Condition)	•	1	
		2.1.6	Has the State identified existing duplicative system services within the State and is seeking to eliminate these services if the work is cost effective? (Sub-regulatory Guidance for 7 S&Cs Version 1.0, Leverage Condition)	•	1	
		2.1.7	How flexible is a State in their IT infrastructure to allow adding a new Medicaid group or scaling to accommodate expansion, possibly at a later point in time?	•	1	

		2.1.8	How does the design achieve real-time eligibility determinations for its citizens and are all existing verifications automated in support of real-time decisions? Does the design support a customer centric solution and not a caseworker centric solution?	• Interface Control Documents to all verification sources including the HUB • Verification Planning	1	
		2.1.9	Does the design and requirements include the integration of the shared eligibility service with the State's MMIS system?	• Interface Control Documents • Design Document	1	
		2.1.10	Medicaid Policy Review in accordance with 42 CFR Parts 431, 433, 435, 457, "Medicaid Program: Eligibility Changes Under the Affordable Care Act of 2010", 3/16/2012	• Requirements Document • Business Rules • Test Cases / User Stories	1	
		2.1.11	How is the State checking for and handling pended applications within the business process?	• Use Scenario	1	
		2.1.12	Does the State have solutions to ensure meeting the Critical Success Factors? If not automated as part of Plan A, how will the State achieve these factors as part of Plan B?	• Plan B, Contingency	1	
		2.1.13	For States interoperating with the FFE, how will the solution transfer cases and can the system aggregate and disaggregate a cases on an individual basis or household basis to support eligibility determinations?	• Requirements, System Design, Interface Control Documents, Use Cases	1	
2	How does the State's project management plan support delivering required business results in a phased approach to meet key deliverable dates?	2.2.1	Have updates to the planning documents been made and are the updates being governed by a disciplined Change Management process? Have updates to project budget, project schedule, and risk register been analyzed to ensure milestones are being met, mitigation strategies are in place and executed when needed, and project is progressing according to plan?	• Project Management Plan and supplement: Change Management Plan, Financial Status Report, Project Schedule, and Risk Register	2	9.4

		2.2.2	Have all relevant industry standards and produce development and testing plans to ensure compliance been identified? Are the types of tests, the acceptance criteria for those tests, and the manner of testing defined in sufficient detail? Is a plan in place for measuring degree of automation, quality of customer service, and periodic performance testing?	• Project Management Plan supplement: Test Plan	2	9.4
		2.2.3	Has the State provided additional analysis of shared services and budget impact in cases where the OMB A-87 Exception was exercised?	• Budget, Additional Reporting Requirement	Requirements in Accordance with Tri-Agency Letters (dated 8/2011, 1/2012)	
3	What project risks has the State identified and what contingencies are available / in place? How are the contingency plans triggered?	2.3.1	Have implementation constraints or unavoidable solution limitations been defined? FFE / SPE: Is there a long-term implementation strategy in place to move from a FFE / SPE model to a SBE model and resulting implications to the Medicaid systems and interfaces?	• Implementation Plan	3	9.6
		2.3.2	Are the Business Continuity / Disaster Recovery strategy and courses of action for system loss sufficiently documented?	• Contingency / Recovery Plan	3	9.6
		2.3.3	Are first responders and all subsequent hand-offs and transitions described in different detailed scenarios? Do all systems have a clearly identified business owner?	• Contingency / Recovery Plan	3	9.6
		2.3.4	What are the findings from the IV&V analysis? Also, how successful is the State in achieving its own project performance measures?	•		
4	How does the State's project meet / not meet the 7 Standards and Conditions and CMS IT Guidance?	2.4.1	Do design and development meet the 7 Conditions and Standards including: • A MITA self-assessment and MITA Roadmap has been completed (as applicable) • Solutions which produce transaction data, reports and performance information that would contribute to program evaluation and improvement in business operations	• Business Requirements, Use Cases, and User Stories	4	9.6

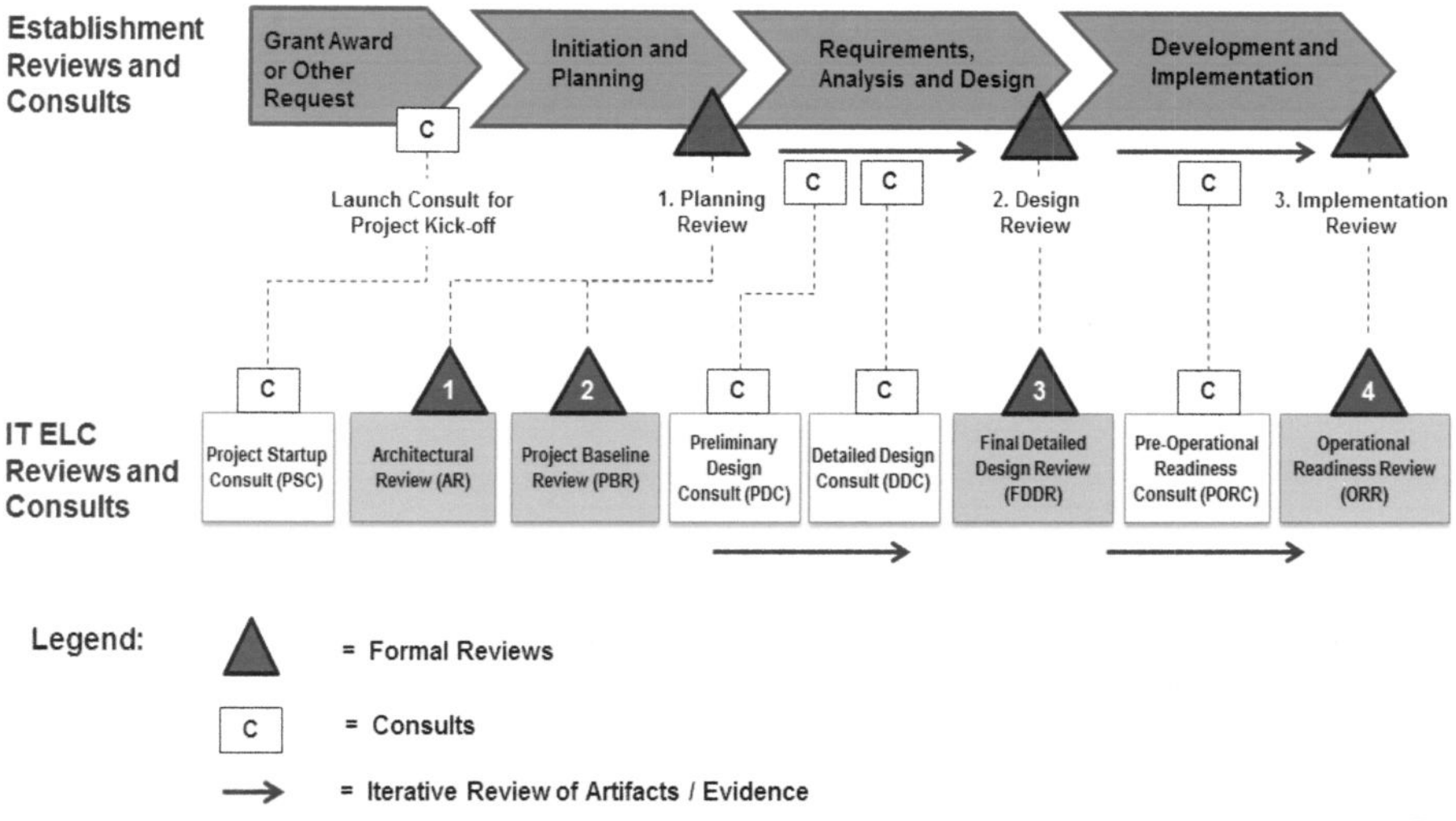
		2.4.2	Has a consistent and logical architecture been defined that captures the logical sequencing of system functions? Have services layer and services profiles been documented?	• Systems Design Document	4	9.7
		2.4.3	Is there demonstrated evidence that the solution will support interface standards regarding: • technology (web-services) • protocols • security & privacy controls • data-level semantics (XML vocabulary)	• Systems Design Document	4	9.7
		2.4.4	Does the solution meet all Security and Privacy requirements, standards, and accommodate persons with disabilities in accordance to Federal laws and Hub and FFE architectural requirements?	• NIST Level 2 Security	4	10.1
		2.4.5	Are there adequate safeguards in place to protect the confidentiality of all Federal information received through the Hub, including but not limited to Federal tax information? Is there written policy and plans to establish and implement safeguards that ensure the critical outcomes in Privacy and Security standards consistent with 45 CFR 155.260(a)-(g)	• Systems Security Plan (SSP) • Information Security Risk Assessment (ISRA) • Privacy Impact Assessment (PIA) • Data uses/ Data Exchange/ Interconnection Security Agreements	4	10.1
		2.4.6	Is there development of Safeguard Procedures Report for submission to IRS related to the protection of Federal tax information	• IRS Safeguards Report	4	10.3
		2.4.7	Has system security considerations and design been detailed and base-lined?	• Systems Security Plan • Information Security Risk Assessment	4	
		2.4.8	Has the system privacy requirements for design been detailed and base-lined?	• Privacy Impact Assessment	4	
		2.4.9	Has the State accessed the Services Catalog? Has the State established a secure connection to the Hub?	•	4	

			Add other Data Elements from Milestone 8?	•	4	
5	What deliverables and components from the state's project can be / should be made available for re-use by other states?	2.5.1	Have reusable and shared components been identified? Does the solution promote sharing, leverage, and reuse of Medicaid technologies and systems within and among States? Identify examples (Sub-regulatory Guidance for 7 S&Cs Version 1.0, Leverage Condition)	• Systems Design Document	4, 5	9.7
		2.5.2	Has the State identified any components and solutions that have a high applicability for other reuse by other States? If so, has the State participated in advising and reviewing these artifacts and in the development and testing path for these solutions to promote reuse? (Sub-regulatory Guidance for 7 S&Cs Version 1.0, Leverage Condition)	• Systems Design Document	4,5	9.7
		2.5.3	Has the State identified any components and solutions that are being developed with the participation of or contribution by other States? (Sub-regulatory Guidance for 7 S&Cs Version 1.0, Leverage Condition)	• Systems Design Document	4.5	9.7
		2.5.4	Have modular services layer and individual service profiles been identified to the extent that another components can easily be identified and reused?	• Systems Design Document	1, 4, 5	9.7
		2.5.5	Is there use of a business rules engine, separating business rules from core application logic? Have business rules in both human and machine readable formats been uploaded to CALT?	• Systems Design Document	4, 5	9.7
		2.5.6	How does the Medicaid, and CHIP infrastructure and information systems project meet the statutory and regulatory requirements to support Medicaid enhanced Federal Financial Participation funding to ensure compliance with the Seven Conditions and Standards (Modularity, MITA, Industry Standards, Reuse, Business Results, Reporting, Interoperability)	• Project Management Plan • Concept of Operations and supplements: Architectural Diagrams and Technical Architectural Diagrams • Systems Design Document	5	9.7

		2.5.7	FFE / SPE: How is the State's progress towards successful testing with the Hub for interoperability? - FFE / SPE: Has the State been determined ready to test with the Hub? If yes, has testing started? Which phase of testing is the State progressing towards? Has the State been determined ready to test interactions with the FFE? - SBE: Has the State been determined ready to test with the Hub? If yes, has testing started? Which phase of testing is the State progressing towards?	• Test Plan • Refer to On-boarding Plan and State Requirements to Establish Interfaces to the Hub	5	
3. Operational Readiness Review (ORR)						
1.	What approach is the State taking to creating / implementing a shared eligibility service that will ensure a seamless and efficient eligibility and enrollment experience for consumers / applicants?	3.1.1		•		
		3.1.2		•		
2	How does the State's project management plan support delivering required business results in a phased approach to meet key deliverable dates?	3.2.1		•		
		3.2.2		•		

3	What project risks has the State identified and what contingencies are available / in place? How are the contingency plans triggered?	3.3.1		•		
		3.3.2		• Risk Register	3, 4	
4	How does the State's project meet / not meet the 7 Standards and Conditions and CMS IT Guidance?	3.4.1	Does the system actually generate the data in support of program evaluation efforts and ongoing improvements in program delivery and outcomes, as planned for in AR/PBR?	•	Sub-regulatory Guidance for 7 S&Cs Version 1.0, Leverage Condition, J. Boughn 1/2012	
		3.4.2	Does the solution's testing results meet all Security and Privacy requirements, standards, and accommodate persons with disabilities in accordance to Federal laws and Hub / FFE architectural requirements?	• NIST Level 2 Security	Sub-regulatory Guidance for 7 S&Cs Version 1.0	
5	What deliverables and components from the State's project are identified and available for re-use by other States?	3.5.1		•		
		3.5.2		•		

IT ELC/Establishment Review Crosswalk



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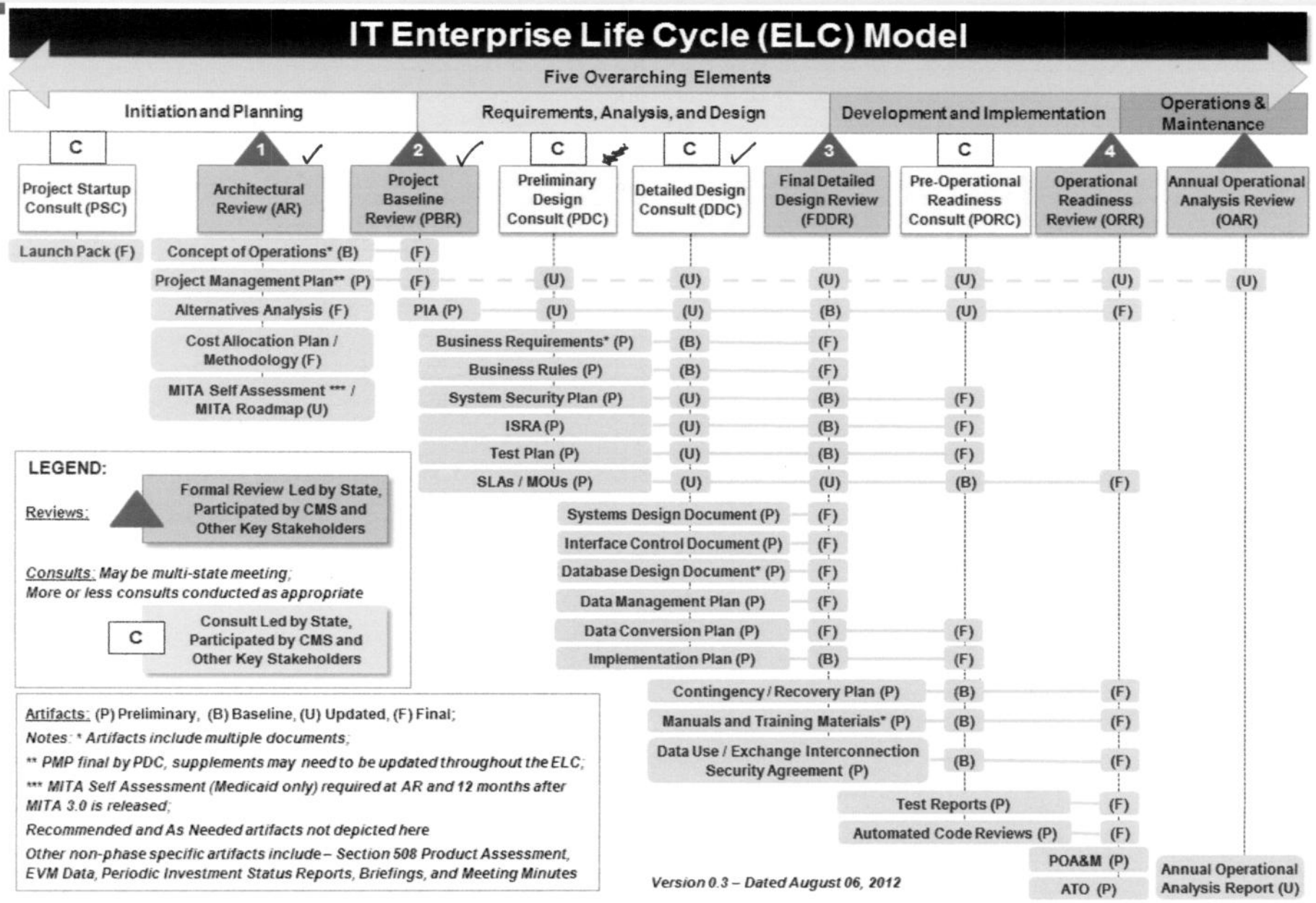
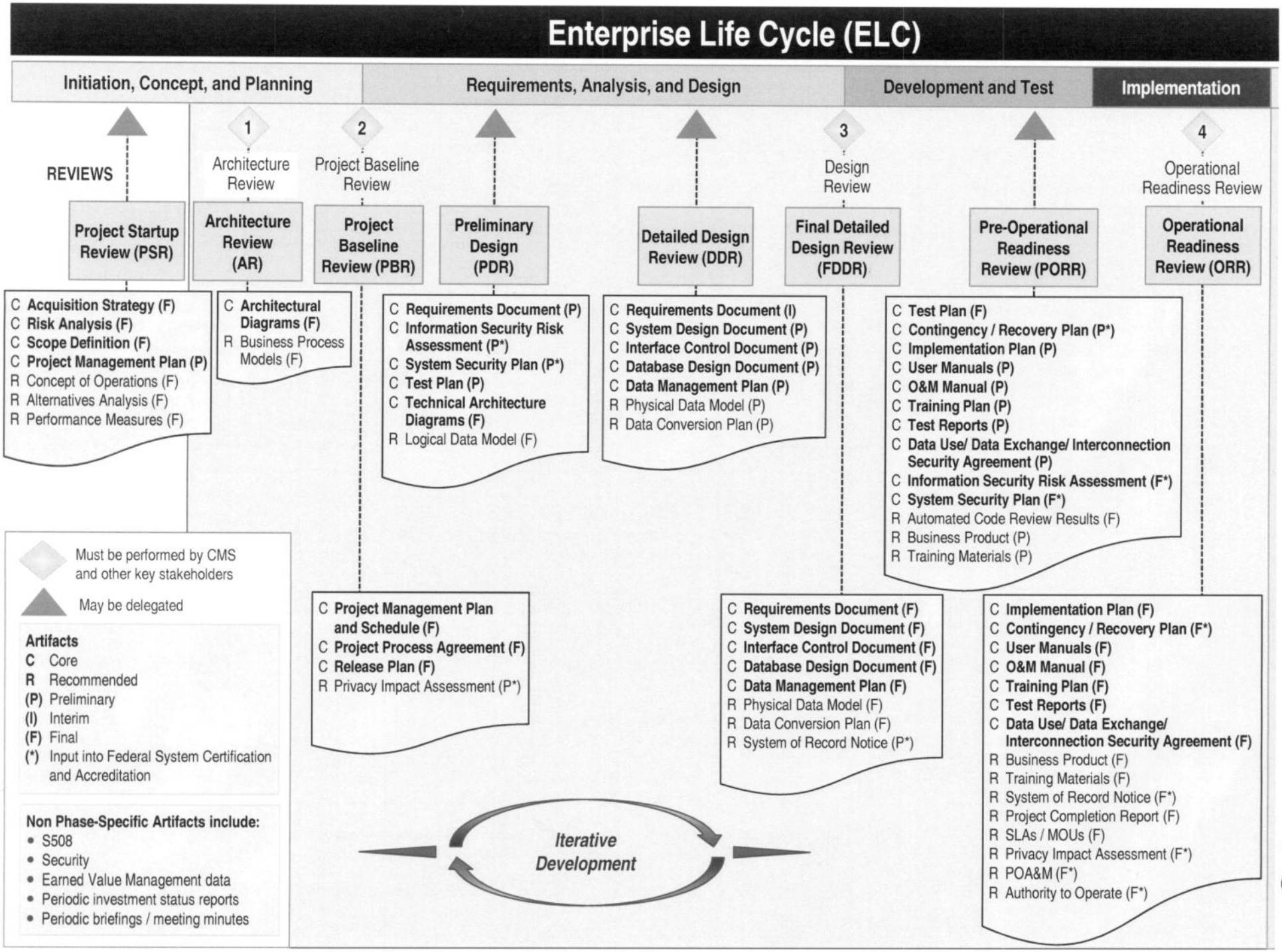
IT ELC Model


IT Enterprise Life Cycle (ELC) Model
Five Overarching Elements
Initiation and Planning
Requirements, Analysis, and Design
Development and Implementation
Operations & Maintenance
C
Project Startup Consult (PSC)
1
Architectural Review (AR)
2
Project Baseline Review (PBR)
C
Preliminary Design Consult (PDC)
C
Detailed Design Consult (DDC)
3
Final Detailed Design Review (FDDR)
C
Pre-Operational Readiness Consult (PORC)
4
Operational Readiness Review (ORR)
Annual Operational Analysis Review (OAR)
Launch Pack (F)
Concept of Operations* (B) (F)
Project Management Plan** (P) (F) (U) (U) (U) (U) (U) (U)
Alternatives Analysis (F) PIA (P) (U) (U) (B) (U) (F)
Cost Allocation Plan / Methodology (F)
MITA Self Assessment *** / MITA Roadmap (U)
Business Requirements* (P) (B) (F)
Business Rules (P) (B) (F)
System Security Plan (P) (U) (B) (F)
ISRA (P) (U) (B) (F)
Test Plan (P) (U) (B) (F)
SLAs / MOUs (P) (U) (U) (B) (F)
Systems Design Document (P) (F)
Interface Control Document (P) (F)
Database Design Document* (P) (F)
Data Management Plan (P) (F)
Data Conversion Plan (P) (F) (F)
Implementation Plan (P) (B) (F)
Contingency / Recovery Plan (P) (B) (F)
Manuals and Training Materials* (P) (B) (F)
Data Use / Exchange Interconnection Security Agreement (P) (B) (F)
Test Reports (P) (F)
Automated Code Reviews (P) (F)
POA&M (P)
ATO (P)
Annual Operational Analysis Report (U)
LEGEND:
Reviews:
Formal Review Led by State, Participated by CMS and Other Key Stakeholders
Consults: May be multi-state meeting;
More or less consults conducted as appropriate
C
Consult Led by State, Participated by CMS and Other Key Stakeholders
Artifacts: (P) Preliminary, (B) Baseline, (U) Updated, (F) Final;
Notes: * Artifacts include multiple documents;
** PMP final by PDC, supplements may need to be updated throughout the ELC;
*** MITA Self Assessment (Medicaid only) required at AR and 12 months after MITA 3.0 is released;
Recommended and As Needed artifacts not depicted here
Other non-phase specific artifacts include – Section 508 Product Assessment, EVM Data, Periodic Investment Status Reports, Briefings, and Meeting Minutes
Version 0.3 – Dated August 06, 2012


Enterprise Life Cycle (ELC)
Initiation, Concept, and Planning
Requirements, Analysis, and Design
Development and Test
Implementation
REVIEWS
1
Architecture Review
2
Project Baseline Review
3
Design Review
4
Operational Readiness Review
Project Startup Review (PSR)
Architecture Review (AR)
Project Baseline Review (PBR)
Preliminary Design (PDR)
Detailed Design Review (DDR)
Final Detailed Design Review (FDDR)
Pre-Operational Readiness Review (PORR)
Operational Readiness Review (ORR)
C Acquisition Strategy (F)
C Risk Analysis (F)
C Scope Definition (F)
C Project Management Plan (P)
R Concept of Operations (F)
R Alternatives Analysis (F)
R Performance Measures (F)
C Architectural Diagrams (F)
R Business Process Models (F)
C Requirements Document (P)
C Information Security Risk Assessment (P*)
C System Security Plan (P*)
C Test Plan (P)
C Technical Architecture Diagrams (F)
R Logical Data Model (F)
C Requirements Document (I)
C System Design Document (P)
C Interface Control Document (P)
C Database Design Document (P)
C Data Management Plan (P)
R Physical Data Model (P)
R Data Conversion Plan (P)
C Test Plan (F)
C Contingency / Recovery Plan (P*)
C Implementation Plan (P)
C User Manuals (P)
C O&M Manual (P)
C Training Plan (P)
C Test Reports (P)
C Data Use/ Data Exchange/ Interconnection Security Agreement (P)
C Information Security Risk Assessment (F*)
C System Security Plan (F*)
R Automated Code Review Results (F)
R Business Product (P)
R Training Materials (P)
C Project Management Plan and Schedule (F)
C Project Process Agreement (F)
C Release Plan (F)
R Privacy Impact Assessment (P*)
C Requirements Document (F)
C System Design Document (F)
C Interface Control Document (F)
C Database Design Document (F)
C Data Management Plan (F)
R Physical Data Model (F)
R Data Conversion Plan (F)
R System of Record Notice (P*)
C Implementation Plan (F)
C Contingency / Recovery Plan (F*)
C User Manuals (F)
C O&M Manual (F)
C Training Plan (F)
C Test Reports (F)
C Data Use/ Data Exchange/ Interconnection Security Agreement (F)
R Business Product (F)
R Training Materials (F)
R System of Record Notice (F*)
R Project Completion Report (F)
R SLAs / MOUs (F)
R Privacy Impact Assessment (F*)
R POA&M (F*)
R Authority to Operate (F*)
Must be performed by CMS and other key stakeholders
May be delegated
Artifacts
C Core
R Recommended
(P) Preliminary
(I) Interim
(F) Final
(*) Input into Federal System Certification and Accreditation
Non Phase-Specific Artifacts include:
• S508
• Security
• Earned Value Management data
• Periodic investment status reports
• Periodic briefings / meeting minutes
Iterative Development