# purpose

The purpose of this document is to provide project teams responsible for Enterprise Systems Life Cycle activities a procedure that supports compliance with the requirements of CS 23-4-4-1 Computer System Life Cycle Overview.

This procedure is intended to provide consistent practices when performing computer validation activities for Enterprise Systems.

# scope

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| The scope of this procedure includes the following Corporate groups that are responsible for the development and support of Enterprise Systems.It is also in the scope of this procedure to be the only applicable procedure when computer validation activities are performed in support of implementation and computer validation activities for Enterprise Systems at all Acme locations. |

# definitions & acronyms

## Definitions

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| Acceptance Criteria | The criteria that a system or component must satisfy in order to be accepted by a user, customer or other authorized entity. |
| Change Control | A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect a validated status of facilities, systems, equipment, or processes. The intent is to determine the need for action that would ensure that the system is maintained in a validated state. |
| Commercial Off-the-Shelf Software | Software defined by a market-driven need, commercially available, and whose fitness for use has been demonstrated by a broad spectrum of commercial users. Also known as COTS. |
| Component | Part of a computer system which can be independently developed, tested, modified and retested\*. |
| Computer systems | Hardware, peripheral devices, personnel, and documentation assembled to perform in conjunction with a set of software programs, which are collectively designed to perform a specific function or group of functions. This includes a broad range of systems including, but not limited to: automated manufacturing equipment, packaging equipment, programmable logic controllers, automated laboratory equipment, process control, manufacturing execution, laboratory information management, enterprise resource planning, clinical trials data management, and document management systems. |
| End User | A person whose occupation requires the use of an information system but does not require any detailed knowledge of computers or computer programming. |
| Enterprise System | An enterprise computer system is one with all of the following characteristics:a. System deployment at multiple Acme Facility\*/Functional Units (FFUs),b. Centralized management and control of system development, andc. Centralized management and control of system configuration. |
| Hardware | Physical components of a computer system. |
| Infrastructure | Logical collection of the hardware and software necessary to deliver a computerized application (e.g., hardware/firmware, operating systems, databases, middleware, networks). |
| Intended Environment | The operating environment for the computer system that supports its intended use. The intended environment may be the production environment or a validation environment that adequately simulates the production environment. |
| Logical Security | The software mechanisms that prevent unauthorized access to data or functions of computerized systems. |
| Physical Security | Physical security refers to the protection of building sites and equipment (and all information and software contained therein) from theft, vandalism, natural disaster, manmade catastrophes, and accidental damage. |
| Qualification | The process of demonstrating whether an entity is capable of fulfilling specified requirements. |
| Regulatory Assessment | A document that evaluates a new system or major system enhancements against all applicable health authority regulations and identifies the specific regulatory requirements that the system must satisfy (e.g., computer system validation, electronic signatures, electronic records, GMP/GLP/GCP).  |
| Risk Analysis | A structured process which evaluates the components of a proposed computer system based on the severity of failure, the likelihood of the failure to occur, and the ability to detect the occurrence of the failure. |
| Subsystem | Separates a component of a software system that can be developed, tested, modified and re-tested independently of one another.  |
| Supplier Assessment | Documents information from various sources to determine whether the supplier product or service can adequately meet all relevant project requirements, including any quality and regulatory expectations. |
| System Owner | The designated individual responsible for specifying, acquiring, implementing, validating, and operating a computer system throughout the system’s life cycle.  |
| Test Protocol | A formal document developed from a test plan that presents detailed instructions and procedures for the setup, operation, and evaluation of the results for each defined test.  |
| Testing | An activity in which a system or component is executed under specified conditions, the results are observed and recorded, and an evaluation is made to provide documented evidence of some aspect of the system or component  |
| Traceability  | The relationship between the specific elements of requirements and related elements of the design and testing of a software component or system. |
| Validation Plan | A written plan stating how validation will be conducted. It describes the scope, strategy, deliverables and responsibilities for validation. |

## Acronyms

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| BPM | Business Processes Management |
| CPD |  |
| SLC | System Life Cycle |
| SRC | Service Request Center |
| WCH | Acme Consumer Healthcare |

# Roles and responsibilities

It is the responsibility of corporate groups described in the scope section of this document to create the deliverables required in these phases of the System Life Cycle with the exception of the Performance Qualification protocols that may be developed and approved by site personnel.

These required deliverables shall be centrally approved by management and the quality unit organization following applicable Acme policies and procedures.

# procedure

## Introduction

This procedure describes a System Life Cycle (SLC) approach to computer validation. A SLC provides for an organized process consisting of distinct phases.

This SLC combines accepted elements of Validation with requirements of the Acme IS Project Management process.

The required phases, the activities to be performed, and the deliverables to be produced are identified in the procedure that follows. All required SLC phases must be considered in project planning. Any required SLC stage, activity, or deliverable not applicable must be documented as such with a justification based on the results of a regulatory and/or risk assessment. Phases may be added as necessary and must be defined in documentation of the Project and Validation Plans.

These phases are listed in the general sequence in which they occur. However, it is possible that some of the activities in different phases may run parallel to each other in the timing of the event. The order in which the activities occur must be defined in the Project Plan.

This SLC is outlined in a Flow Chart. (Attachment #1)

Each stage is discussed in the following subsections.

## Solution Planning Stage

In this stage **Project Planning** activities are performed. Project Planning is a management tool that contributes to an organized project. This documentation includes a Project Plan and a Detailed Project Schedule. Planning documentation is not intended to be maintained as validation documentation.

Refer to Acme Policy IS 3, “Acme IS Project Management” for details on project planning.

**Change Management** controls must be established and maintained throughout the SLC to provide mechanisms that maintain system integrity and traceability. Activities include identifying, assessing, communicating, approving, documenting and implementing changes.

Refer to the Enterprise System Change Management procedure for details of the change management process.

A **Regulatory Assessment** must be performed and documented to determine whether the computer system requires validation.

See the attached Regulatory/Risk Assessment tool for details on performing a Regulatory Assessment (Attachment #2).

If the results of a **Regulatory Assessment** determined that validation is required a **Validation Plan** must be prepared. The Validation Plan must address activities, deliverables, roles and responsibilities and procedures that define the validation requirements for the system.

Consideration should be given to the type of application (COTS, Custom, Configurable) when determining the activities and deliverables.

The Validation plan must also identify those methodologies, corporate standards, Regulations, Policies, Conformance Standards and Standard Operating Procedures that are applicable to a specific project.

Refer to the Enterprise System Validation Planning Procedure for details in preparing a Validation Plan.

A **Risk Analysis** must be performed and documented to anticipate risks that could adversely affect the validated state of a computer system. It can be used to determine the extent of the validation effort.

See the attached Regulatory/Risk Assessment tool for details on performing a Risk Analysis (Attachment #2).

The following documents are deliverables required in this phase of the System Life Cycle:

* Regulatory Assessment
* Risk Analysis
* Validation Plan

## Requirements and Preliminary Design Stage

In this stage a **System Requirements** document must be prepared. The requirements are the basis for selecting and/or designing a system. This document will be used to prepare the Design Specification and Validation Testing documents.

Refer to the Enterprise System Requirements procedure for details in preparing a System Requirements document.

A **Traceability** document must be prepared. The traceability document provides for cross-reference of all Requirements to the Design Specifications to the Validation Tests. Traceability is also useful during change management to assess the impact of a change and identify which testing needs to be repeated.

Each Requirement must be addressed in the Traceability document. The relationship of requirement to design specification to validation tests can be one to one or many to one. Typically a matrix format is used to clearly show these links.

If the system will be purchased a **Supplier Assessment** must be performed and documented. The Supplier Assessment is used to evaluate supplier design, development, and support process and quality systems. The Supplier Assessment is also useful in the selection of a system.

Refer to Enterprise System Supplier Assessment Procedure for details in preparing a Supplier Assessment document.

The following documents are deliverables required in this phase of the System Life Cycle:

* System Requirements
* Traceability
* Supplier Assessment

## Design, Develop, Test Stage

In this stage a **Design Specification** document must be prepared. The Design Specification document shall be the basis for development or configuration of the computer system. The requirements are translated into a logical and physical representation of the computer system to be implemented. Which means that the Design specifications shall describe how the requirements are implemented in the application.

Each design specification must be traceable to a requirement and this shall be documented in the Traceability document.

Refer to the Enterprise System Design Specification procedure for details in preparing a Design Specification document.

A **Design Review** must be performed and documented. The design review evaluates the proposed technical design against standards and requirements. It serves to identify problems that require corrective action and changes to the System Requirement and Design Specification documents.

This stage includes **System Development and Configuration** activities. They are the development and engineering of system hardware and software components against the design specifications.

**Development Testing** shall be performed and documented for custom systems. (For configurable and COTS the Supplier Assessment serves to document the quality process used in development.)

Development Testing documentation include the **Testing Plan** and **Test Results**.

The Testing Plan should include unit testing, integration testing, and system testing. It should contain the instructions for executing the tests and documenting the test results, all deviations, and their resolution.

Refer to the Enterprise System Qualification and Testing Procedure for details in preparing Development Testing documentation.

In this stage, consideration must be given to the operation and maintenance procedures that will be used to maintain the system in a validated state. See the Production System Support Stage.

The following documents are deliverables required in this phase of the System Life Cycle:

* Design Specification
* Design Review
* Testing Plan
* Test Results

## System Validation Stage

Validation provides on-going documented evidence ensuring that the operations and performance of the computer system meets predetermined acceptance criteria.

In this stage a **Validation Protocol** must be prepared and approved. The protocol contains tests to evaluate the system performance against the System Requirements. Types of **Validation Testing** include installation, operational and performance qualification. The protocol should also contain the instructions for performing and documenting the tests, all deviations, and their resolution.

Each functional requirement must be traceable to a test case and this shall be documented in the Traceability document.

Validation testing also encompasses **Infrastructure Qualification**. A **Qualification Plan** is prepared. This plan shall define an Installation Operational Qualification of the system infrastructure. The plan should also contain the instructions for performing and documenting the tests, all exceptions, and their resolution.

Refer to the Enterprise System Qualification and Testing Procedure for details in preparing a Validation Protocol.

Refer to the IS 2 Infrastructure Platform Qualification Policy for details in preparing a Qualification Plan.

After the Validation Protocol has been successfully executed and the results documented a **Validation Summary Report** must be prepared.

The report summarizes all the activities defined in the Validation Plan. It shall include all test results (development, validation, infrastructure), analysis, and conclusions. It must also identify any validation related deviations encountered during execution of the validation process and their corrective actions.

The Validation Summary Report is the basis for System Acceptance. Any issues must be addressed to the satisfaction of the system owner and proposed corrective actions must be approved, documented and tracked, including changes in requirements and design, and necessary re-testing.

Software and hardware documentation, validation related documents and standard operating procedures must be reviewed as part of system acceptance.

System Acceptance must be documented. It can be stated in the Validation Summary Report.

The following documents are deliverables required in this phase of the System Life Cycle:

* Validation Protocol
* Qualification Plan
* Test Results
* Validation Summary Report

## Install and Deploy Stage

In this stage the application is installed into the production environment and deployed according to a pre defined Deployment Strategy.

In cases where the validation strategy specifies the validation testing to be performed in the production environment the installation will take place prior to the Validation Stage.

In other cases where the validation strategy specifies the validation testing to be performed in a validation environment two installations will be performed. The first, in the Validation environment, is followed by Validation Testing, and the second in the production environment in this the Insall and Deploy Stage. Both must be documented in an Installation Qualification as defined in the Validation Protocol.

## Production System Support Stage

In this stage maintenance and operation activities are performed to maintain the computer system in a validated state throughout the System Life Cycle.

Procedures and programs must be established and documented for each of the following support functions according to the appropriate Conformance Standards and applicable SOP’S:

**Computer Operations** Day to day operation, support and maintenance of the hardware components, processing of application and monitoring of these processes. Includes Backup and Recovery.

**System Administration** Day to day operation, support and maintenance of the operating system and application components, and monitoring of these processes. Includes Logical Security, Problem Handling, and Archival and Retrieval.

**Facilities Management** Management of the physical space where computer systems reside, environmental controls for the space, and their respective utility systems. Includes Physical Security.

**Disaster Recovery** Instructions for restoring the active computer systems.

**Performance Monitoring** On-going process of assessing the performance of the computer system.

**Periodic Review** Documented assessment of the documentation, procedures, records, and performance of the computer system to determine whether it is still in a validated state.

**Training** Ensuring personnel involved with the computer system maintain the appropriate skills.

**Change Control** Process of identifying, assessing, communicating, approving, documenting, and implementing changes.

The following documents are deliverables required in this phase of the System Life Cycle:

* Operation and Maintenance documentation
* Change Control documentation
* Training Records
* Periodic Review Report

## Decommissioning Stage

In this stage it has been determined to take the system out of service. A **Decommissioning Plan** must be prepared. It must describe the activities for maintaining data integrity and ready retrieval of records (hardcopy and electronic) throughout their retention period. Consideration must be given to both archiving and migration of data.

After execution of the Decommissioning Plan a **Decommissioning Report** is prepared. The report describes the decommissioning approach and lists documents, raw data, and electronic records archived.

Refer to the Enterprise System Decommissioning Procedure for details in preparing a Decommissioning Plan and Decommissioning Report.

The following documents are deliverables required in this phase of the System Life Cycle:

* Decommissioning Plan
* Decommissioning Report

# references

Computer System Life Cycle Overview Conformance Standard, CS 23-4-4-1, Issued 14-Jan-2003

Acme IS Project Management Policy, Acme IS Policy 3, Effective Date 15-Jun-2002

PMConnection Web Site

Infrastructure Platform Qualification Policy, Acme IS Policy 2, Effective Date 29-Sep-2003

# appendices

| **Revision History** |
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| **Revision Level** | **Revision Description** | **Revision Date** |
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approval sheet

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