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# Purpose:

This SOP defines the steps and process for periodic review of validated systems to ensure that each system remains in a validated state.

# SOP Scope:

This SOP applies to all validated computer systems and software.

# Responsibilities

The Quality Assurance Manager is responsible for

* Assigning a quality assurance representative to conduct the validation review and prepare the Periodic Validation Review report
* Reviewing and approving the Periodic Validation Review report

The Assigned Quality Assurance Representative is responsible for

* Conducting the validation review and preparing the Periodic Validation Review report

The Information Technology Manager is responsible for

* Providing the Quality Assurance Representative with data needed to complete the Periodic Validation Review, e.g., records of system incidents
* Reviewing and approving the Periodic Validation Review report

The System Owner is responsible for

* Providing the Quality Assurance Representative with data needed to complete the Periodic Validation Review, e.g., records of user training
* Reviewing and approving the Periodic Validation Review report

# Procedures:

## Periodic Validation Review Frequency and Timing

The frequency of periodic validation review is determined by the system risk level, as determined by SOP-XXX System Risk Assessment. Systems with a higher risk level are reviewed more frequently than systems with a lower risk level.

| **Criticality Level** | **Periodic Validation Review Frequency** |
| --- | --- |
| High | Every 2 years |
| Medium | Every 3 years |
| Low | Not required |

When a system undergoes a complete re-validation, e.g., due to a new major release, the periodic validation review cycle is reset.

The dates of each system’s most recent periodic validation review and next planned periodic validation review are recorded in the Computer System and Software Inventory attachment within the Validation Master Plan.

## Periodic Validation Review Approach and Report

The periodic validation review activities described below are documented in a Periodic Validation Review Report.

| **Review Component** | **Description** |
| --- | --- |
| Regulatory | **Purpose:** Confirm that the system continues to meet regulatory requirements**Procedure and documentation:*** List each regulation and regulatory guidance document related to the system
* Identify any changes to these documents since the original date of system validation or most recent periodic review (whichever date is more recent)
* Assess changes in regulatory expectations vs. system functionality, documentation, and validation
* Document any gaps, or if no gaps detected, document the conclusion that the system continues to meet regulatory expectations
 |
| Intended Use | **Purpose:** Confirm that the system continues to be used as intended**Procedure and documentation:*** List each SOP that documents how users use the system
* Assess the most recent version of the User Requirements vs. the current user SOPs to identify any uses of the system that are not addressed within the User Requirements.
* Document uses of the system that were not addressed in validation, or if no additional uses detected, the conclusion that the system continues to be used as intended
 |
| Issues | **Purpose:** Confirm that the system continues to function in a manner suitable for intended use**Procedure and documentation:*** List all Incidents and CAPAs associated with the system since the original date of system validation or the most recent periodic review (whichever date is more recent)
* Assess Incidents and CAPAs to identify any technical issues, e.g., performance, security, reliability, that are impacting the ability to use the system for regulated activities
* Document any gaps, or if no gaps detected, document the conclusion that the system continues to function in a manner suitable for intended use.
 |
| Training | **Purpose:** Confirm that the system’s users continue to be able to be able to operate the system for intended use.**Procedure and documentation:*** Refer to the list of system Incidents and CAPAs, recorded for step above
* Assess Incidents and CAPAs to identify any training issues that are impacting the ability to use the system for regulated activities
* Document any gaps, or if no gaps detected, document the conclusion that the system users continue to be able to be able to operate the system for intended use.
 |
| Validation Documentation | **Purpose:** Confirm that all system validation documentation has been retained**Procedure and documentation:*** List all changes to the system since the original date of system validation or the most recent periodic review (whichever date is more recent)
* For the original validation and each change within the periodic review period, confirm that all validation deliverables listed within the Validation Plan(s) and Change Requests
* Document any gaps, or if no gaps detected, document the conclusion that all system validation documentation has been retained
 |
| Change Management  | **Purpose:** Confirm that as changes were made to the system, the associated system documentation, SOPs, and training materials were updated.**Procedure and documentation:*** Refer to the list of system changes, recorded for step above
* Assess each change within the periodic review period to confirm that
	+ changes impacting system documentation, e.g., Requirements, Designs, Trace Matrices, required updates to these documents
	+ changes impacting system functionality, user interfaces, and reports required updates to user SOPs and training materials
* Document any gaps, or if no gaps detected, document the conclusion that as changes were made to the system, the associated system documentation, SOPs, and training materials were updated.
 |
| Validation Procedure | **Purpose:** Confirm that the system’s validation documentation meets current PIM validation standards**Procedure and documentation:*** List all changes to SOP-XXX Computer System Validation since the original date of system validation or the most recent periodic review (whichever date is more recent)
* Assess the system’s validation documentation to identify any SOP-XXX Computer System Validation requirements that have not been met.
* Document any gaps, or if no gaps detected, document the conclusion that the system continues to be validated according to current standards.
 |
| Supporting Procedures | **Purpose:** Confirm that the system continues to be supported by the procedures required for regulatory compliance.**Procedure and documentation:*** List all of the SOPs that support the regulatory compliance of the system, e.g., User Access Management, Audit Trail Review, Back-Ups
* Assess a sampling of the output of each procedure to ensure that it is being followed
* Document any gaps, or if no gaps detected, document the conclusion that the system continues to be supported by the procedures required for regulatory compliance.
 |

Upon completion of the periodic validation review activities above, a summary of gaps and a conclusion regarding the validated state of the system is documented in the Periodic Validation Review Report.

## Gaps Detected During Periodic Validation Review

Gaps identified within the Periodic Validation Review Report are recorded as CAPAs, assessed, and tracked to completion of remediation, per SOP-XXX Corrective and Preventive Action.

CAPA actions to remediate gaps can include any activities needed to return the system to a validated state, e.g.:

* re-validation of the system
* updates to validation deliverables
* updates to the system Risk Assessment
* updates to system SOPs
* changes to system infrastructure
* changes to system functionality
* retraining system users.

## Periodic Validation Review Report Approval and Retention

Periodic Validation Review Reports are approved by the Quality Assurance Manager, Information Technology Manager, and System Owner.

Approved Periodic Validation Review Reports are retained for the duration specified within SOP-XXX Record Retention.