|  |
| --- |
| This SOP Template (template) is being provided by Praxis Management International, LLC (Praxis) for the "fair use" by you, the User, as that term is defined under the U.S. Copyright Laws. All other use, reproduction or re-transmission in any form or by any means, electronic or mechanical, including photocopying and recording, or by any information storage or retrieval system, without prior written permission from Praxis is prohibited. ©2008-2015 Praxis Management International, LLC. All rights reserved.  Praxis makes no representations or warranties concerning the suitability or use of, or reliance on, the Template. Any actual or implied representation or warranty that the Template does not infringe the intellectual property rights of any third party is specifically hereby void. Any special, indirect or consequential damages or any damages whatsoever resulting from the use or misuse of the Template, the loss of use, data, or profits, whether in an action of contract, negligence, or other tortious action arising out of or in connection with the Template shall be born exclusively by the User. |

**Contents**

[Purpose: 3](#_Toc429120322)

[SOP Scope: 3](#_Toc429120323)

[Scope of Changes: 3](#_Toc429120324)

[Definitions: 3](#_Toc429120325)

[Responsibilities 3](#_Toc429120326)

[Procedures: 4](#_Toc429120327)

[Change Requests 4](#_Toc429120328)

[Impact Assessment 5](#_Toc429120329)

[Authorization 6](#_Toc429120330)

[Cancellation 7](#_Toc429120331)

[Closure 8](#_Toc429120332)

[Record Retention 8](#_Toc429120333)

[Emergency Changes 8](#_Toc429120334)

[ATTACHMENT A: Change Request 12](#_Toc429120335)

[ATTACHMENT B: Change Request Impact Assessment 13](#_Toc429120336)

[ATTACHMENT C: Change Request Authorization 14](#_Toc429120337)

[ATTACHMENT D: Emergency Change Request 15](#_Toc429120338)

[ATTACHMENT E: Emergency Change Request Authorization 16](#_Toc429120339)

# Purpose:

This SOP defines the procedures and controls for managing change to the Information Technology systems used in regulated activities.

# SOP Scope:

This SOP applies to all computer-based systems.

# Scope of Changes:

Many situations within the life cycle of a computerized system can generate a request for changes. Examples include:

* New systems
* Vendor supplied updates and patches
* Hardware, software, operating system, and database upgrades
* Hardware changes
* Configuration changes
* Functionality and performance enhancements
* Defect, incident, and error corrections
* New or modified intended use
* System decommissioning

# Definitions:

Change Control: A formal procedure by which qualified, management representatives assess change impact and authorize changes to validated systems.

Change Request: A documented request for a change to a validated system.

Emergency Change: A modification or repair that must be implemented immediately bypassing the normal Change Control and documentation process.

Major System Function: Sets of requirements that together define a capability or feature of the system.

# Responsibilities

The IT Manager is responsible for

* Implementing the practices for system change control as specified within this SOP.
* Contributing technical expertise the system change impact assessments.
* Authorizing (or rejecting) requests for system changes.

The Business Managers are responsible for

* Contributing business area expertise to system change impact assessments.
* Authorizing (or rejecting) requests for system changes.

The Quality Manager is responsible for

* Contributing expertise on compliance with regulations and regulatory guidelines to system change impact assessments.
* Authorizing (or rejecting) requests for system changes.

# Procedures:

## Change Requests

1. Each request for system change is formally documented by a member of the Information Technology organization using the Change Request form, Attachment A.

| **Change Request Form Instructions** | |
| --- | --- |
| **Information** | **Instruction** |
| **Change Request ID** | Assign a Change Request ID using format YYYYMMDD-nnn.   * YYYY = current year * MM = current month * DD = current day * nnn = sequential number, starting at 001 each day |
| **System Name** | Record the name of the system associated with the requested change. |
| **Change Request Date** | Record the current date. |
| **Requested by** | Record the name of the person requesting the change. |
| **Change Type** | * Check each box that applies to the requested change * If the “Other” box is checked, describe the change. |
| **Change Description** | * Describe the requested change. * If multiple changes are requested, provide a list containing a description of each change. |
| **Change Rationale** | * Provide the reason for the requested change. * If multiple changes are requested, provide a list containing the reason for each change. |
| **Cross Reference** | * If the change addresses a System Incident, provide the Incident ID. * If the change addresses a Deviation, provide the Deviation ID. * If the change addresses a CAPA event, provide the CAPA ID. * If the change is related to, or dependent upon, another Change Request, provide the Change Request ID. * If the change request is due to a previous emergency change, provide the Emergency Change Request ID. |

1. The person who documents the change request delivers the completed Change Request to the IT staff member who is responsible for support of the associated system.

## Impact Assessment

1. The IT staff member responsible for system support, the Business Manager responsible for system use, and the Quality Manager responsible for system compliance collaborate in completing the impact assessment.
2. The IT staff member records the impact assessment in the Change Request Impact Assessment form, Attachment B.

| **Change Request Impact Assessment Form Instructions** | |
| --- | --- |
| **Information** | **Instruction** |
| **Change Request ID** | Record the Change Request ID from the Change Request form. |
| **System Name** | Record the System Name from the Change Request form. |
| **Impact Assessment Date** | Record the date of the impact assessment. |
| **Major System Functions** | * For new systems, new functionality, defect resolution, and decommissioning changes, list and briefly describe the major system functions impacted by the change. * For hardware, operating system, database, and peripheral equipment changes, list the major system functions supported by the change. |
| **Criticality Level** | * For existing major system functions, record each function’s criticality level from the associated System Risk Assessment. * For new major system functions, determine the criticality of the function using the process in *SOP System Risk Assessment*. Record the criticality. |
| **Impact Assessment** | Refer to *SOP System Risk-Based Validation,* Appendix A, for guidance on assessing change impact on the basis of the criticality and complexity levels.  For each deliverable and activity listed on the System Change Request Impact Assessment form:   * Check “Yes” if the change will necessitate creation, update or execution of the deliverable or activity. * Check “No” if the change will not necessitate creation, update or execution of the deliverable or activity. |
| **Explanation** | For each deliverable and activity listed on the System Change Request Impact Assessment form provide a brief explanation of the impact assessment.  Examples:   * URS requires update because change includes new features. * SOP *xyz* requires updating because the business process will change when the new system goes live. * Training materials do not require update because patch will not affect user interactions. * Change will require creation of a Project Plan. |

## Authorization

1. The IT Manager, the Quality Manager, and the Business Manager(s) review the Change Request and the associated Change Request Impact Assessment to decide whether or not the change should be made.
   1. Include the Business Manager(s) responsible for the functions identified in the Impact & Criticality Identification section of the Change Request Impact Assessment form
2. Each person records his/her decision on the Change Request Authorization form, Attachment C.

| **Change Request Authorization Section Instructions** | |
| --- | --- |
| **Information** | **Instruction** |
| **Change Request ID** | Record the Change Request ID from the Change Request form. |
| **System Name** | Record the System Name from the Change Request form. |
| **Decision** | * Check “Approve” to authorize the change. * Check “Reject” to decline to authorize the change. |
| **Name** | Print or type name on the form. |
| **Signature** | Sign the form. |
| **Date** | Record the current date. |

1. After approval is received by all authorizers, work on the change may begin.

## Cancellation

1. The IT Manager, the Quality Manager, or the Business Manager can decide to cancel the change at any point in time prior to implementation of the change.
2. Prior to cancellation, the person who plans to cancel the change notifies the other approvers of his/her decision.
3. The person who cancels the change records the decision on the same Change Request Authorization form that originally authorized the change.

| **Change Request Cancellation Section Instructions** | |
| --- | --- |
| **Information** | **Instruction** |
| **Role** | Print or type the appropriate role:   * Quality Manager * IT Director * Business Manager |
| **Name** | Print or type name on the form. |
| **Signature** | Sign the form. |
| **Date** | Record the current date. |
| **Reason for Cancellation** | Provide the rationale for cancelling the change request. |

1. Upon cancellation of the Change Request:
   1. All new work on the change is halted.
   2. Any work in progress (e.g. source code revisions, document updates) is reverted to the last version prior to change authorization.

## Closure

1. Change requests are closed after the Quality Manager verifies that
   1. The change has been implemented
   2. All deliverables and activities identified on the Change Request Impact Assessment form have been completed.
2. The Quality Manager records the change request’s closure on the same Change Request Authorization form that originally authorized the change.

| **Change Request Closure Section Instructions** | |
| --- | --- |
| **Information** | **Instruction** |
| **Name** | Print or type name on the form. |
| **Signature** | Sign the form. |
| **Date** | Record the current date. |

## Record Retention

1. Records are retained for all routine and emergency change requests. Records include:
   1. Change Requests, Emergency Change Requests
   2. Change Request Impact Assessments
   3. Change Request Authorizations, Emergency Change Request Authorizations
   4. All documents generated as a result of the change
2. Change Request records are retained for the same period of time as the associated electronic records generated by each system.

## Emergency Changes

1. The emergency change process is used to document unplanned modifications or repairs. This process may be used only when one or more of the following conditions is met:
   1. Required to maintain patient safety
   2. Required to maintain personnel safety
   3. Required to maintain product quality
2. The emergency change is formally documented by a member of the Information Technology organization using the Emergency Change Request form, Attachment D.

| **Emergency Change Request Form Instructions** | |
| --- | --- |
| **Information** | **Instruction** |
| **Change Request ID** | Assign a Change Request ID using format E-YYYYMMDD-nnn.   * E = prefix for all emergency change requests * YYYY = current year * MM = current month * DD = current day * nnn = sequential number, starting at 001 each day |
| **System Name** | Record the name of the system associated with the emergency request change. |
| **Change Request Date** | Record the current date. |
| **Requested by** | Record the name of the person requesting the emergency change. |
| **Emergency Type** | Change the box that applies to the type of emergency. |
| **Emergency Description & Rationale** | Describe the situation causing the unplanned modification or repair and the reason that it is classified as an emergency. |
| **Change Type** | * Check each box that applies to the requested change. * If the “Other” box is checked, describe the change type. |
| **Change Description** | * Describe the requested change. * If multiple changes are requested, provide a list containing a description of each change. |

1. The Quality Manager decides whether or not the change should be made as an emergency change.
2. The Quality Manager’s decision is recorded on the Emergency Change Request Authorization form, Attachment E. Authorization can be either written or verbal.
   * When available in person, the Quality Manager completes the form.
   * When the Quality Manager’s decision is verbal, the Information Technology staff member completes the form.

| **Emergency Change Request Authorization Section Instructions** | |
| --- | --- |
| **Information** | **Instruction** |
| **Change Request ID** | Record the Change Request ID from the Emergency Change Request form. |
| **System Name** | Record the System Name from the Emergency Change Request form. |
| **Decision** | * Check “Approve” to authorize the change. * Check “Reject” to decline to authorize the change. |
| **Name** | Print or type the Quality Manager’s name on the form. |
| **Signature** | Quality Manager signs the form. (when available in person) |
| **Alternate Method** | When the Quality Manager provides a verbal decision, the Information Technology staff member records:   * Date and time of decision * IT staff member receiving decision * Method of communication (e.g., telephone)   Example:  Quality Manager J.Jones approved emergency change E-20080522-001 via phone conversation with S.Smith on May 22, 2008 at 8:30 PM. |
| **Date** | Record the current date. |

1. After approval is received by the Quality Manager, work on the change may begin.
2. A routine Change Request, Attachment A, must be initiated within 2 business days of authorization of the Emergency Change Request.
3. Emergency Change requests are closed by the Quality Manager after verification that the change has been implemented.
4. The Quality Manager records the emergency change request’s closure on the same Emergency Change Request Authorization form that originally authorized the change.

| **Emergency Change Request Closure Section Instructions** | |
| --- | --- |
| **Information** | **Instruction** |
| **Name** | Print or type name on the form. |
| **Signature** | Sign the form. |
| **Date** | Record the current date. |
| **Cross Reference to Routine Change Request** | Record the Change Request ID of the routine change request initiated subsequent to the emergency change. |

**References:**

*Eudralex Volume 4, Annex 11: Computerised Systems*, European Commission, October 25, 2005

*Eudralex Volume 4, Annex 15: Qualification and Validation*, European Commission, July 2001

*General Principles of Software Validation; Final Guidance for Industry and FDA Staff*, FDA, January 11, 2002

*Glossary of Computerized System and Software Development Terminology*, FDA, April 30, 2003

*Q7A, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients,* ICH, November 10, 2000

*Q9, Quality Risk Management*, ICH, November 09, 2005

*Good Practices for Computerised Systems in Regulated “GxP” Environments*, PIC/S, September, 2007

*Guidance for Industry: Computerized Systems Used in Clinical Investigations*, FDA, May, 2007

*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Guidance for Industry and FDA Staff*, FDA, May 11, 2005

*PE 005-3, GMP Guide for Blood Establishments,* PIC/S, September 25, 2007

*PE 009-7, Guide to Good Manufacturing Practice for Medicinal Products, Part II and Annexes*, PIC/S, September 1, 2007

*21 CFR Part 11, Electronic Records; Electronic Signatures*, FDA, March 20, 1997

*21 CFR Part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals*, FDA, April 1, 2007

*21 CFR Part 820, Quality System Regulation*, FDA, April 1, 2007

# ATTACHMENT A: Change Request

|  |  |  |
| --- | --- | --- |
| **Change Request ID** |  | |
| **System Name** |  | |
| **Change Request Date** |  | |
| **Requested By** |  | |
| Change Request Description | | |
| **Change Type** | *Check all that apply:* | |
| New system  New functionality  Defect resolution  Decommission | Hardware  Operating System  Database  Peripheral Equipment |
| Other (describe) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **Change Description** | *Describe requested change(s):* | |
| **Change Rationale** | *Provide reason for requested change(s):* | |
| **Cross Reference** |  | |

# ATTACHMENT B: Change Request Impact Assessment

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Change Request ID** |  | | | |
| **System Name** |  | | | |
| **Impact Assessment Date** |  | | | |
| Impact & Criticality Identification | | | | |
| **Major System Functions** | | | | **Criticality Level** |
|  | | | |  |
|  | | | |  |
|  | | | |  |
|  | | | |  |
|  | | | |  |
|  | | | |  |
|  | | | |  |
| Impact Assessment  *Requirements to Maintain a Validated State* | | | | |
| **Deliverable/Activity** | | **Impact** | **Explanation** | |
| Project Plan | |  Yes  No |  | |
| User Requirement s Specification | |  Yes  No |  | |
| Functional Req. Specification | |  Yes  No |  | |
| Risk Assessment | |  Yes  No |  | |
| Vendor Assessment | |  Yes  No |  | |
| Validation Plan | |  Yes  No |  | |
| System Design Document | |  Yes  No |  | |
| Test Plan | |  Yes  No |  | |
| Unit Test Results | |  Yes  No |  | |
| Code Review Reports | |  Yes  No |  | |
| Validation Tests | |  Yes  No |  | |
| Trace Matrix – URS to FRS | |  Yes  No |  | |
| Trace Matrix – FRS to Design | |  Yes  No |  | |
| Trace Matrix – FRS to Val. Tests | |  Yes  No |  | |
| 21 CFR Part 11 Assessment | |  Yes  No |  | |
| Validation Summary | |  Yes  No |  | |
| Deployment Plan | |  Yes  No |  | |
| Data Conversion Plan | |  Yes  No |  | |
| Installation Qualification | |  Yes  No |  | |
| Operational Qualification | |  Yes  No |  | |
| Performance Qualification | |  Yes  No |  | |
| System SOPs and Guidelines | |  Yes  No |  | |
| User Manuals | |  Yes  No |  | |
| Training Materials | |  Yes  No |  | |
| Train Personnel | |  Yes  No |  | |

# ATTACHMENT C: Change Request Authorization

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Change Request ID** | |  | | | |
| **System Name** | |  | | | |
| Authorization of Change | | | | | |
| **Role** | **Decision** | | **Name** | **Signature** | **Date** |
| Quality Manager |  Approve  Reject | |  |  |  |
| IT Director |  Approve  Reject | |  |  |  |
| Business Manager |  Approve  Reject | |  |  |  |
|  Approve  Reject | |  |  |  |
|  Approve  Reject | |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Cancellation of Change | | | |
| **Role** | **Name** | **Signature** | **Date** |
|  |  |  |  |
| **Reason for Cancellation** | | | |
|  | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| Change Request Closure | | | |
| **Role** | **Name** | **Signature** | **Date** |
| Quality Manager |  |  |  |

# ATTACHMENT D: Emergency Change Request

|  |  |  |
| --- | --- | --- |
| **Change Request ID** |  | |
| **System Name** |  | |
| **Change Request Date** |  | |
| **Requested By** |  | |
| Emergency Change Request Description | | |
| **Emergency Type** | Patient Safety  Personnel Safety  Product Quality | |
| **Emergency Description & Rationale** |  | |
| **Change Type** | *Check all that apply:* | |
|  Defect resolution   Hardware   Database | Operating System  Peripheral Equipment |
| Other (describe) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **Change Description** | *Describe requested change(s):* | |

# ATTACHMENT E: Emergency Change Request Authorization

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Change Request ID** | |  | | | |
| **System Name** | |  | | | |
| Authorization of Emergency Change | | | | | |
| **Role** | **Name** | | | **Decision** | |
| Quality Manager |  | | |  Approve  Reject | |
|  | | | | | |
| **OR** | **Signature** | |  | **Date** |  |
| **Alternate Method** | |  | **Date** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Emergency Change Request Closure | | | | |
| **Role** | **Name** | **Signature** | | **Date** |
| Quality Manager |  |  | |  |
|  | | | | |
| Cross Reference to Routine Change Request | | |  | |