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1 PURPOSE

This document describes the procedure for managing changes to solutions and infrastructure in Information Technology (IT) in accordance with SOP-0022 Service and Solution Lifecycle Management.

2 AUDIENCE

This procedure is intended for IT personnel (colleagues, contractors and vendors) who perform changes to solutions and infrastructure in IT supported and controlled environments.

3 SCOPE

3.1 In scope

All changes to solutions and infrastructure in IT supported and controlled environments. Examples include:
- Bug fixes, problem resolution and vendor supplied patches
- Modifications, upgrades and enhancements
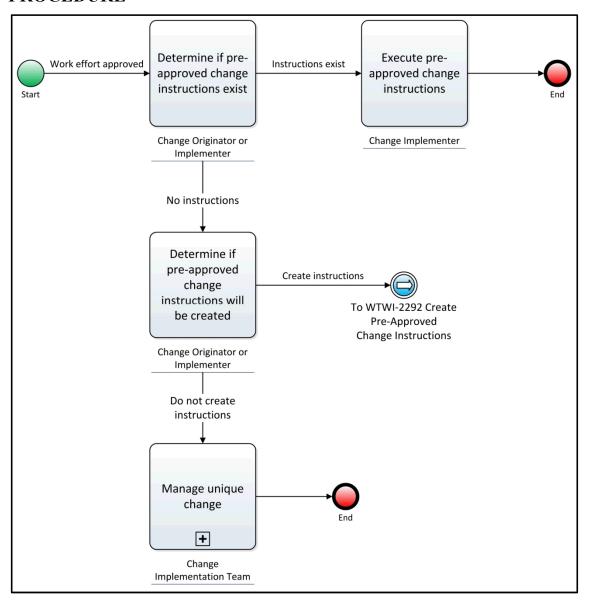- Installations, releases and deployments

3.2 Out of scope

- Initial approval of change work effort (approved change work efforts are the input to this procedure, and governed at the line level)
- Solutions and infrastructure that are NOT supported by IT .
- Solutions and infrastructure that are NOT in a controlled environment. Examples may include proof of concept, proof of technology, new installation for evaluation, sandbox environments, and development environments.
- New solution delivery (governed by Solution Delivery Lifecycle SOPs; generates a change for deployment to a IT supported and controlled environment)
- Qualification of new or major upgrade to infrastructure items (governed by *SOP-0977 IT Infrastructure Qualification*; generates a change for installation to a IT supported and controlled environment)

3.3 Deviations

Unplanned or planned deviations from this SOP will be reported and managed according to *SOP-0890 IT Compliance Event Management*.

4 PROCEDURE

4.1 Determine if pre-approved change instructions exist

	Process Step Inputs:	
	• Work effort	
Step #	**Actions**	**Roles Involved**
4.1.1	Consult your organization's index/inventory of pre-approved changes and determine if there are applicable pre-approved change instructions. If pre-approved change instructions exist for this type of change, go to *4.2 Execute pre-approved change instructions.* If no pre-approved change instructions exist for this type of change, go to *4.3 Determine if pre-approved change instructions will be created.*	Change Originator or Implementer
	Process Step Outputs:	
	• Pre-approved change instructions associated with work effort identified; or • Work effort determined to have no associated pre-approved change instructions	

4.2 Execute pre-approved change instructions

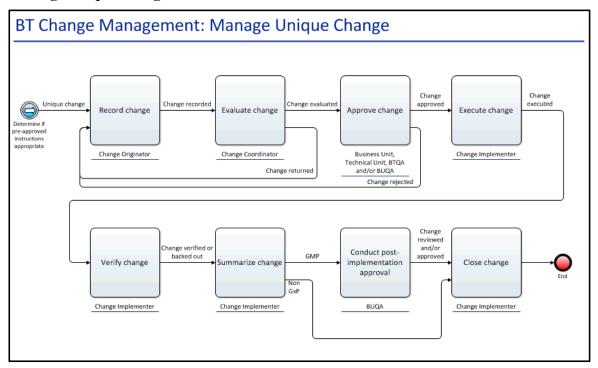|	**Process Step Inputs:**	
	• Work effort • Pre-approved change instructions	
Step #	**Actions**	**Roles Involved**
4.2.1	Execute pre-approved change instructions. *End of process.*	Change Originator or Implementer
	Process Step Outputs:	
	• Closed change	

4.3 Determine if pre-approved change instructions will be created

Process Step Inputs:
- Work effort

Step #	Actions	Roles Involved
4.3.1	Consult your line's requirements for the types of changes that qualify for pre-approved status. If pre-approved change instructions will be created, go to *WTWI-2511* Pre-Approved Template Request Work Instruction If pre-approved change instructions will not be created, go to *4.4 Manage unique change*.	Change Originator or Implementer

Process Step Outputs:
- Work effort deemed appropriate for pre-approved change instructions; or
- Work effort deemed not appropriate for pre-approved change instructions

4.4 Manage unique change

Process Step Inputs: • Work effort		
Step #	**Actions**	**Roles Involved**
4.4.1	<u>Record change</u> Create change record following required components as described in Appendix A. If change will deploy to a production environment, plan verification following SOP-0906 IT Solution Delivery Lifecycle and/or SOP-0977 IT Infrastructure Qualification. If change will include data transfer, the transfer process must be tested prior to use, and the transferred data must be verified for completeness and accuracy. If change includes any new or emerging technologies, consult the *IT Compliance Position Paper Index* in IT On Demand and incorporate any applicable requirements.	Change Originator
4.4.2	<u>Evaluate change</u> Evaluate change record for accuracy and completeness of required components, adherence to governing SOP/WIs, and inclusion of required approvers. If change record is acceptable, forward to approvers and go to step *4.4.3 Approve change.* If change record is unacceptable, record detailed reasons and return to step *4.4.1. Record change.*	Change Coordinator

Process Step Inputs:		
• Work effort		
Step #	**Actions**	**Roles Involved**
4.4.3	<u>Approve change</u> Review the change record to: confirm all required components are included evaluate impact and risk assessments confirm verification is in accordance with impact and risk confirm back out plan is defined confirm required approvers are included If change will deploy to a production environment, verification evidence must be provided as outlined in *SOP-0906 IT Solution Delivery Lifecycle* or *SOP-0977 IT Infrastructure Qualification* as appropriate. If change record is approved, record approval and go to step *4.4.4 Execute change*. If change record is rejected, record detailed reasons for rejection and return to step *4.4.1. Record change*.	Technical Unit, Business Unit, BTQA and/or BUQA as indicated in Appendix C
4.4.4	<u>Execute change</u> Follow plan(s) in approved change record.	Change Implementer
4.4.5	<u>Verify change</u> Follow verification plan in approved change record, including recording/summarizing verification results. If deployment fails, execute back out plan.	Change Implementer

Process Step Inputs:		
• Work effort		

Step #	Actions	Roles Involved
4.4.6	<u>Summarize change</u> Document the outcome of the change, including any issues that occurred or variations from the plan, following the components in Appendix B. Ensure post-implementation tasks as identified in the Change Record or during execution are completed. If change is to a GMP solution, go to step *4.4.7 Conduct post-implementation approval*. Otherwise go to step *4.4.8 Close change*.	Change Implementer
4.4.7	<u>Conduct post-implementation approval</u> BUQA must approve GMP changes post-implementation; contact your BUQA representative for more information.	BUQA
4.4.8	<u>Close change</u> Execute local or tool change closure activities and store change records in approved repository or tool. *End of process*	Change Implementer

Process Step Outputs:		
• Closed change		

5 ROLES AND RESPONSIBILITIES

To ensure that segregation of duties is maintained the following role information must be adhered to for each change:

- The individual filling the Change Implementer role cannot also be the sole Change Approver for a change record.
- The individual filling the Change Coordinator role cannot also fill the Change Implementer role.

Role	Responsibility
Information Technology Quality Assurance (ITQA)	• Review and approve or reject change record when change impacts Validation and SOX solutions • Ensures the IT Change Management methodology is followed, and that the change control is compliant and consistent with SOPs and CRS requirements for solutions subject to SOX and Validation regulations only
Business Unit	• Review and approve or reject change records when change has business impact
Business Unit Quality Assurance (BUQA)	• Review and approve or reject, application changes with GMP impact for controlled environments (Production, QA/Staging, Training). • Conduct post-implementation approval on production application changes with GMP impact.
Change Coordinator	• Evaluate and advance change record to approvers or return change record to Change Originator.
Change Implementer	• Deploy change according to plans in change record • Verify change according to verification plan • Execute back out according to plan if change unsuccessful • Summarize change
Change Originator	• Create change record with required components
Technical Unit	• Review and approve or reject change records when change has technical impact

6 DEFINITIONS

Refer to the Information Technology (IT) Glossary for definitions of terms used in this procedure.

Term/Acronym	Definition
Business impact	A change has business impact if it will impact the system's availability, performance, regulatory status, business process and/or user training.

Term/Acronym	Definition
IT Supported	Any business technology configuration items that are directly managed/delivered by IT , or indirectly managed/delivered through a partner/supplier under IT's contractual control. Such items must be managed/delivered according to IT procedural controls, except for items managed/delivered through a partner/supplier under IT's contractual control where the contract states that the partner/supplier's procedural controls are to be followed instead.
Change	Bug fixes, problem resolution, vendor supplied patches, modifications, upgrades, enhancements, installations, releases and deployments to/of solutions and infrastructure in a IT supported and controlled environment.
Change record	An evidentiary record created as a result of following this procedure. Must contain the components listed in Appendix A, and be retained according to the retention classification in the Records Retention section.
Change summary	An evidentiary record created as a result of following this procedure. Must contain the components listed in Appendix B, and be retained according to the retention classification in the Records Retention section. May be combined with the change record.
Controlled environment	A computer system instance that is supported by IT where no unauthorized changes are applied. Changes to items in controlled environments are managed through this procedure.
GMP application	An application which has been assigned to the Good Manufacturing Practice (GMP) risk domain identified by IT Solution Profiling.
Pre-approved change	Changes governed by internal or vendor supplied instructions that have been approved for repeated execution without approvals on individual changes. Lines may define the types of change appropriate for pre-approval status based on risk, impact, group and/or other considerations.
Pre-approved change instructions	Instructions outlining the activities required to execute, verify, record and close pre-approved changes. See WTWI-2511 Pre-Approved Template Request Work Instruction for more details.

Term/Acronym	Definition
Production environment	A computer system instance with an application or its supporting infrastructure that hosts actual/real data (as opposed to test/training data) or is available on a publicly accessible network or server.
SDLC	Solution Delivery Lifecycle
Unique change	A change that is not solely or appropriately executed with pre-approved work instructions and must follow all unique change activities in this procedure.
Work effort	A request for a change that has been approved for execution; approval is determined according to IT line instructions and is out of scope for this procedure. The work effort is the input/trigger to this procedure.

7 RECORD RETENTION AND MANAGEMENT

The following company records may be created as a result of executing this procedure. Please refer to the following table for the retention classification of these records, per Corporate Policy (CP) 405, Enterprise Records and Information Management Policy.

Record Name	Retention Classification
Change record	INF 01 05
Change summary	INF 01 05
Updated system documentation/elements (requirements/configuration/design/installation specifications, traceability, verification plan, etc.)	INF 01 05
Pre-approved change instructions	INF 01 05

8 SUPPORTING REFERENCES

Record Number	Reference Title
IT On Demand	IT Compliance Position Paper Index
CP 405	Enterprise Records and Information Management Policy
SOP-0023	Service and Solution Operation Domain Policy
SOP-0890	IT Compliance Event Management
SOP-0897	IT Configuration Management

Record Number	Reference Title
SOP-0906	IT Solution Delivery Lifecycle
SOP-0012	IT Solution Profiling
SOP-0977	IT Infrastructure Qualification
WTWI-2511	Pre-Approved Template Request Work Instruction

9 REVISION HISTORY

10 APPENDICES

Appendix	Appendix Name
A	Change record components
B	Change summary components
C	Approvers

Appendix A: Change record

The components listed in the table below must be included in or referenced from a change record; the change record may be a document or recorded within an approved tool.

Multiple changes may be documented within one change record.

A single change record may be used to document changes to multiple controlled environments, provided that the impact to each environment and its associated dependencies is assessed and documented, and the change record clearly outlines the order of deployment and criteria for approval to continue to the subsequent environment. Alternatively, multiple change records may be used to document the changes to each controlled environment. If using separate change records for each environment, link or cross-reference the related records.

Change records for the production environment may not be approved and implemented until the preceding environment's change records are successfully executed.

Component	Characteristics for consideration
Identifier	Each change record must contain a unique identifier.
Change requester and originator information	List names, business line/unit, contact information
Business and technical change overview	Explain the change and why it is required from business and/or technical standpoint
Technical change details	Describe how the technical change will be implemented, including hardware setup, platform software setup, and application setup as applicable
Configuration Items (CIs)	List all CIs which are affected by the change (servers, middleware, applications, etc.). See SOP-0897 IT Configuration Management.
Environment(s)	List controlled environment(s) as appropriate to CI(s) listed above (production, user acceptance testing, validation, etc.)

Component	Characteristics for consideration

Change type (and application sub-type if appropriate)	List type:
	
	• Application Change: A change to software that supports the functionality of a system. Also record sub-type:
	   o *New Application Deployment*: First time deployment of an application.
	   o *Enhancement*: New requirements or functionality added to an existing application.
	   o *Migration*: Transferring data between storage types, formats or computer systems.
	   o *Retirement*: Removal of existing application from the environment.
	   o *Bug Fix:* A change in an application in order to make it function as intended. No new functionality is being introduced.
	
	• Application Data Change: A change to data used or controlled by an application.
	• Infrastructure Hardware Change: A change to computer or communication hardware that supports the enterprise's information management functions.
	• Infrastructure Software Change: A change to computer or communication software that supports the enterprise's information management functions.

Impact assessment	Describe: • Technical impact (to the current system, other systems, data, etc.) • Business impact (to users, system documentation, user procedures, training requirements and/or training materials) • Regulatory impact of the change, including identifying all groups who will be affected by the change Determine impact type: • Technical impact only; or • Technical and business impact
Risk assessment	Describe the technical, business and regulatory risk associated with implementing the change. Include mitigation, monitoring and realization activities appropriate to the level of risk.

Component	Characteristics for consideration

Change priority	List priority:
	• Standard: A change that can be implemented within the designated schedule timeframe.
	• High: A change that requires implementation more quickly than standard priority timeframes.
	• Retrospective: A change that began implementation prior to documentation in response to an immediate and unexpected situation. Retrospective change records must be created within two business days of the start of the implementation effort. In addition to the normal change documentation, include:
	    ➢ Justification for retrospective priority
	    ➢ Copy of authorization request to technology owner and business process owners or delegates
	    ➢ Copy of authorization including date and time, or document verbal confirmation

System documentation	Describe which system documentation will be updated or created and approved. Examples include requirements/design/configuration specifications, traceability, verification plan, etc. as indicated in: • *SOP-0906 IT Solution Delivery Lifecycle* • *SOP-0977 IT Infrastructure Qualification* If the required elements are not documented properly for the system, create a deviation following *SOP-0890 IT Compliance Event Management*.
Implementation contacts	List names, titles and contact information for implementer(s), technology owners, vendors, escalation team, users, support personnel, etc.
Implementation schedule/steps	List or reference the high level plan. Ensure the following elements are addressed: • Schedule of activities, including key dates and time of Go-live • Updating of CI records, etc. for all appropriate environments • Creating, updating and/or approving deliverables as necessary

Component	Characteristics for consideration
Communication plan	List schedule of communications to owners, users, support personnel, etc. who will be impacted by the change. Include: • Systems impacted • Change Schedule - Outage Times • Brief Change Description • Contact person(s) for the Change If the change impacts the business, communicate to the business any activities that may be required such as updating of system documentation, user procedures, training and training materials.
Verification plan & evidence	Document verification plan. See SOP-0906 IT Solution Delivery Lifecycle or SOP-0977 IT Infrastructure Qualification to determine appropriate verification activities and evidence.
Back out plan	List steps required to reverse or remediate the change if unsuccessful.
Approvers	List required approvers. See Appendix C.

Appendix B: Change summary

The components listed in the table below must be included in a Change Summary; the Change Summary may be a document or recorded within an approved tool, and may be combined with the Change Record.

Component	Characteristics for consideration
Change record identifier	Identify change record being summarized by identifier, document name and/or record number
Variations	Document any variations from the plan(s) in the change record
Deliverables	If the Change Summary is not combined with the Change Record (either as one document or linked within an approved tool), list and link or reference all deliverables associated with the change
Outcome	Document whether the change was successfully executed (deployed and verified as per the change record), backed out or remediated

Appendix C: Approvers

Use the following tables to determine required approvers for:
- unique change pre-implementation
- pre-approved change instructions (initial approval of the instructions themselves, not individual execution of pre-approved changes)

Infrastructure Changes Approvers

Change Type	Technical Unit	Business Unit	BTQA	BUQA
Infrastructure: Hardware	Yes	Yes if business impact	No	No
Infrastructure: Software			No	No
Infrastructure Patching*			No	No

*Approvers of low risk, standard Patching RFCs for infrastructure with PSO values will have the ability to formally approve Patching RFCs or remove their CIs from Patching RFCs up until 24 hours prior to implementation window at which time the RFC will auto-approve for all CI approvers who have not responded to the approval request.

Baseline Solution Changes - Approvers*

Change Type	Technical Unit	Business Unit
New Application	Yes	Yes if business impact
Application Enhancement		
Application Migration		
Application Bug Fix		
Application Retirement		

Application Data			

Approval of the change control record for Baseline solutions verifies that all elements required by SOP-0906 IT Solution Delivery Lifecycle have been created in accordance with that procedure.

SOX Solution Changes - Approvers*

Change Type	Technical Unit	Business Unit	BTQA
New Application	Yes	Yes if business impact	Yes
Application Enhancement			Yes
Application Migration			Yes
Application Bug Fix			No
Application Retirement			Yes
Application Data			Yes

Validation Solution Changes - Approvers*

Change Type	Technical Unit	Business Unit	BTQA	BUQA
New Application	Yes	Yes if business impact	Yes	BUQA approval is required for Production and Pre-production controlled GMP environments (QA/Staging, Training environments) if GMP application and any of the following are true: Change affects functionalities that may impact patient safety and/or product quality (e.g., product release, process control, batch records, QA/QC records, distribution, etc.); or change impacts GMP functions
Application Enhancement			Yes	
Application Migration			Yes	
Application Bug Fix			No	
Application Retirement			Yes	
Application Data			Yes	

				and/or GMP data.

*See SOP-0906 for definition of Baseline, SOX, and Validation Solutions System documentation/element approvers

When updating existing or creating new system elements, such as requirements, design, configuration or installation specifications, traceability, verification plans and scripts, and/or validation summaries, approvals are required as indicated in *SOP- 0906 IT Solution Delivery Lifecycle,* and/or *SOP-0977 IT Infrastructure Qualification.*