

Title Change Management Policy	Document # IT-ETO-POL-0004	Revision 04	Effective Date See EDMS
Document Type Policy	Group Enterprise Technology and Operations (ETO)		Page 1 of 11

1.0 Review and Approval

This document has been reviewed and approved by the following individuals. Our collective signatures acknowledge that the document was reviewed, approved, and is ready for implementation.

Document Approval	Signature	Date
Emma Regan Senior Manager Change And Release Process Owner	Signatures Captured within Electronic Document Management System (EDMS)	
Nestor Gomez Director, IT, Enterprise Technology & Operations		
Shelly LaPointe Senior Manager IT Quality Assurance, Regulatory & Compliance Affairs		

2.0 Revision History

Revision	Description and Reason for Changes	Revised By	Approved Date
A	Initial Release	Neil Duser	See EDMS
B	Process update based on the merge of GIS and EAS into ETO	Emma Regan	See EDMS
01	Move to MasterControl 11.7 upgrade, new numbering system.	Luis Alfaro	See EDMS
02	Update Definition in line with ITL best practices Added process improvements based on maturity	Emma Regan	See EDMS
03	Added policy improvements based on maturity – Emergency Change process improvements	Emma Regan	See EDMS
04	Update ITQA Sign off Improved Standard Change definition	Emma Regan	See EDMS

Title Change Management Policy	Document # IT-ETO-POL-0004	Revision 04	Effective Date See EDMS
Document Type Policy	Group Enterprise Technology and Operations (ETO)		Page 2 of 11

3.0 Purpose

The purpose of this policy is to establish a Change Management policy for Enterprise Technology and Operations (ETO). The intent is to ensure that all changes, as identified in the scope, are identified, prepared, documented, reviewed, and authorized in a controlled, comprehensive, and systematic nature, in order to ensure regulatory compliance.

4.0 Scope

4.1 In Scope

This policy applies to all employees, part-time employees, and contractors at ETO, as described in IT-QARC-POL-0002 Quality Manual, that perform changes using the Change Management System at ETO are within the scope of this policy.

Any changes made by ETO to the infrastructure, network, all production computer systems, including hardware, operating systems, applications and facilities that impact GxP Systems or the Qualified State of the Datacenter.

4.2 Out of Scope

Changes to policies, procedures, and work instructions are tracked using the process outlined in IT-QARC-SOP-0009 Document Management.

5.0 References

Document Reference	Document Title
IT-QARC-POL-0002	Quality Manual
IT-QARC-SOP-0009	Document Management
IT-QARC-POL-0003	Signature Policy
IT-QARC-POL-0011	Training Policy
IT-QARC-POL-0004	Quality System Management Review

Title Change Management Policy		Document # IT-ETO-POL-0004	Revision 04	Effective Date See EDMS
Document Type Policy	Group Enterprise Technology and Operations (ETO)			Page 3 of 11

6.0 Definitions

Term	Definition
Approver(s)	Anyone defined within the process responsible for ensuring information is correct and that the change is ready to progress to the next phase.
Back Out (Process)	An activity that restores a service or other configuration item to a previous baseline. Back-out is used as a form of remediation when a change or release is not successful.
CAB	Change Advisory Board, The CAB is a cross functional team of stakeholders in IT and Change requestors who provide input and recommendations for changes. There are 3 voting members, representing the Applications, Infrastructure, and Change Management department.
Change Freeze	Scheduled times in the calendar year, requested by the Business and IT leadership, where changes are limited in order to protect the business by ensuring all systems remain stable during the critical timeframes (i.e. quarter-end timeframe).
Change Management	The process responsible for controlling the lifecycle of all changes, enabling beneficial changes to be made with minimum disruption to IT services
Change Management Team	Administrative Change Team that governs and facilitates the Change Management process.
Change Period	A regular, agreed time when changes or releases may be implemented with minimal impact on services
Change Record	A record containing the details of a change. Each change record documents the lifecycle of a single change. A change record is created for every request for change that is received, even those that are subsequently rejected. Change records should reference the configuration items that are affected by the change.
Change Request	A formal proposal for a change to be made. It includes details of the proposed change, and may be recorded on paper or electronically. The term is often misused to mean a change record, or the change itself.
Configuration Item (CI)	Any component or other service asset that needs to be managed in order to deliver an IT service. Information about each configuration item is recorded in a configuration record within the configuration management system (CMDB) and is maintained throughout its lifecycle by service asset and configuration management. Configuration items are under the control of change management. They typically include IT services, hardware, software, buildings, people and formal documentation such as process documentation and service level agreements.

Title Change Management Policy		Document # IT-ETO-POL-0004	Revision 04	Effective Date See EDMS
Document Type Policy	Group Enterprise Technology and Operations (ETO)			Page 4 of 11

Term	Definition
Configuration Management Database (CMDB)	A database used to store configuration records throughout their lifecycle. The configuration management system maintains one or more configuration management databases, and each database stores attributes of configuration items, and relationships with other configuration items.
Emergency Change	Encompasses changes that need to be evaluated, assessed and authorized after the change has been made in Production, normally reserved for restoring service immediately due to a P1 or P2 Incident, however this may also be used for Alerts to prevent the interruption of service and Unauthorized Changes.
Normal Major (Change)	Type of Change. Major Changes are considered more complex and higher risk. Changes are tracked.
Normal Minor (Change)	Type of Change. Minor Changes are considered to be low risk, low impact, and/or isolated changes. Changes are tracked.
IT Change Requestor	The person, from the business or IT, requesting the change. The requestor is the responsible owner for the RFC through to completion.
RFC	RFC or Request for Change, is a documented, formal request for the implementation of a change.
ServiceNow	ServiceNow is an IT Application that is used for managing change management and RFCs, within the Change Management Module.
Standard Change	Type of Change. Standard Changes are repeatable, standardized processes that are documented and pre-approved formally by the CAB or by Ci Owner (Director or level up). Standard changes are low risk changes that can be performed without additional approval, as required. NOTE: Standard changes must have additional pre-approval to be labelled as such by the compliance team for validated systems (applications/infrastructure)

Title Change Management Policy	Document # IT-ETO-POL-0004	Revision 04	Effective Date See EDMS
Document Type Policy	Group Enterprise Technology and Operations (ETO)		Page 5 of 11

7.0 Roles and Responsibilities

Role	Responsibility
Approver(s)	Approvers are responsible for assuring the total quality of all requests including all documentation requirements. Has the authority to approve or reject changes.
Change Manager / Change Management Team	Process owner for Change Management. Responsible for writing and maintaining procedure(s) that follow this policy in order to ensure process compliance. Review and approve the policy for use.
Functional Managers	Ensure individuals required to follow the policy are trained. Work with QA to determine the effective date. Review and approve the policy for use.
Quality / Validation / GXP IT / IT Quality & Compliance	Responsible for ensuring that this policy follows regulatory guidelines. Responsible for alerting Change Management team to regulations and requirements that require this policy to be updated. Work with Management to determine effective date. Review and approve the policy for use.
Information Security Manager	Responsible for ensuring that this policy follows regulatory guidelines and information security best practices. Review and approve the policy for use.
Stakeholders	Responsible for understanding their role as outlined by this policy. Accountable for all changes that they have a stake in, and to understand the impact of changes which may affect their responsible area. Responsible for alerting Change Management team to regulations and requirements that require this policy to be updated.
Subject Matter Experts (SME)	Subject Matter Experts should take the lead role in the verification of computerized systems. Subject Matter Expert responsibilities include planning and defining impact assessments verification strategies, defining acceptance criteria, selection of appropriate test methods, execution of verification tests, and reviewing results.
System Owner	Responsible for defining and documenting changes in conjunction with the change management procedures.

Title Change Management Policy		Document # IT-ETO-POL-0004	Revision 04	Effective Date See EDMS
Document Type Policy	Group Enterprise Technology and Operations (ETO)			Page 6 of 11

8.0 Policy Requirements:

- 8.1 All Change Management Activities must be performed in accordance with established Change Management Procedures at ETO.
- 8.2 All users of the Enterprise Change Management System, including those outside of the ETO QMS, as documented in IT-QARC-POL-0002 Quality Manual, must be trained to use the Change Management System prior to receiving access, as outlined in the IT-QARC-POL-0011 Training Policy.
- 8.3 Established Change Management Procedures must be followed in order to systematically document all changes that fall within the scope of this policy.
- 8.4 There must be sufficient technical documentation to provide for easy recoverability of the original system state.
- 8.5 A history of Production updates must be retained for an adequate period to allow for recoverability.
- 8.6 The process must ensure that proposed changes are appropriately reviewed to assess impact and risk of implementing the change. Ensure that changes are suitably evaluated, authorized, documented, tested, and approved before implementation, and subsequently closed.
- 8.7 The process should allow the rigor of the approach, including the extent of documentation and verification, to be scaled based on the nature, risk, and complexity of the change.
- 8.8 Documented change management procedures must be developed and followed for executing any change. These procedures, at a minimum, must address the following requirements:
 - 8.8.1 Define the activities at each of the following change lifecycle phases:
 - 8.8.1.1 Change Request Submission
 - 8.8.1.2 Change Request Risk Assessment
 - 8.8.1.3 Change Request Approval
 - 8.8.1.4 Change Testing
 - 8.8.1.5 Change Implementation
 - 8.8.1.6 Change Final Review and Closure
 - 8.8.2 The change life cycle phases are required for every change type, but may be consolidated, combined, or rearranged depending on the type of change. For example, Emergency changes may submit a Change Request following change execution.

Title Change Management Policy		Document # IT-ETO-POL-0004	Revision 04	Effective Date See EDMS
Document Type Policy	Group Enterprise Technology and Operations (ETO)			Page 7 of 11

- 8.8.2.1 Identify roles and responsibilities for each phase of change lifecycle.
- 8.8.2.2 Establish change performance criterion for the post implementation review of changes.
- 8.8.2.3 Establish metrics to monitor and evaluate the effectiveness of the ETO Change Management process.

8.9 Change Categorization

- 8.9.1 Change categorization is the method used to establish types of changes based on the impact, risk and complexity of a change. As examples:
 - 8.9.1.1 Due to their high impact, risk and/or complex nature “Major” changes must follow the Normal change process to ensure that those changes are adequately assessed, planned, tested, approved, communicated and documented.
 - 8.9.1.2 Changes with limited impact, low risk and are relatively simple may be considered a “Minor” change. Changes of this type would not require the same level of assessment, testing or communication. They may also require limited approvals, not at the exclusion of Quality Assurance, while ensuring adequate documentation and communication.
 - 8.9.1.3 Changes that occur at regular intervals and are implemented in an expected manner may be considered “Standard” in nature. Such changes should be managed via standardized procedures. On-Boarding, Repairs and Patch Management procedures are examples of Standard changes.
- 8.9.2 Administrative Activities that will not require a change record, or any form of documentation, as part of the change management process prior to execution must be well defined.

Title Change Management Policy	Document # IT-ETO-POL-0004	Revision 04	Effective Date See EDMS
Document Type Policy	Group Enterprise Technology and Operations (ETO)		Page 8 of 11

8.10 Emergency Changes

- 8.10.1 Implementation of emergency changes should be based on risk and should be subsequently reviewed, documented, verified, and approved in a timely fashion according to the appropriate procedure. What constitutes an Emergency change must be clearly defined.
- 8.10.2 Inefficiency should not be regarded as rationale for a change becoming an Emergency.
- 8.10.3 Standard changes should not be allowed to escalate to Emergency status through the accumulation of internal failures or delays.
- 8.10.4 A proceduralized Emergency change process must exist to ensure that:
 - 8.10.4.1 These changes are in response to a genuine emergency
 - 8.10.4.2 Emergency changes are properly documented as part of a change record
 - 8.10.4.3 The change is evaluated in a timely manner to ensure integrity, accuracy, and compliance to the process
 - 8.10.4.4 The appropriate level of approval has been obtained prior to a change.
- 8.10.5 For executed Emergency Changes, a Change Request may be entered after the change execution.
- 8.10.6 There must be complete Change Record documentation of all emergency changes, including justification (problem and/or business need) and all approvals/rejections.

Title Change Management Policy		Document # IT-ETO-POL-0004	Revision 04	Effective Date See EDMS
Document Type Policy	Group Enterprise Technology and Operations (ETO)			Page 9 of 11

8.11 Change Records - Change Records are required for every type of change. Change records must include the following elements, at a minimum:

- 8.11.1 Documentation to ensure that proposed changes are appropriately reviewed to assess impact to the validated/qualified state of a system and risk of implementing the change.
- 8.11.2 Documentation to ensure that changes are appropriately authorized, planned, documented and approved prior to execution, and as part of the implementation closure
- 8.11.3 Documentation of approval or rejection
- 8.11.4 Determine whether or not a security assessment is needed
- 8.11.5 A clearly defined and documented scope of systems/processes that are being changed
- 8.11.6 Detailed information on other systems which may be impacted by the change implementation
- 8.11.7 Detailed information on the technical changes required
- 8.11.8 Detailed information on the, business, quality, or regulatory need/purpose for a change
- 8.11.9 Back Out procedures, in order to document how a change can and will be reversed, or remediated, if issues occur during or following execution
- 8.11.10 Documentation showing that changes are scheduled based on priority, resources and risk.
- 8.11.11 Documentation of change impact related to compliance with all regulatory requirements (FDA).
- 8.11.12 Detailed information on how the change will be tested, if possible. Documentation of functionality testing, when performed, must verify that the change does not adversely impact the data confidentiality, data integrity, and data availability of the system.
- 8.11.13 A determination of validation /qualification activities must be performed. For approved changes, all necessary qualification, verification and validation tasks should be performed to ensure that planned changes are implemented correctly, all documentation is complete and up to date, and no unacceptable changes have occurred.
- 8.11.14 Vulnerability scans for new and updated applications must occur before changes are promoted to the production environment.
- 8.11.15 Detailed plan on how the change will be monitored, reported, and communicated to all affected parties.

Title Change Management Policy		Document # IT-ETO-POL-0004	Revision 04	Effective Date See EDMS
Document Type Policy	Group Enterprise Technology and Operations (ETO)			Page 10 of 11

8.12 Segregation of Duties

- 8.12.1 Segregation of duties must be maintained while processing change requests. The approver of the change request must not be the same as the requestor of the change or the implementer of the change.
- 8.12.2 Segregation of duties must exist between development and production. Individuals who program changes in development cannot transport changes to production unless proper systematic monitoring is in place. In the case where staff is limited, compensating controls must be put in place to mitigate risk.
- 8.12.3 When making changes, testing changes, approving changes and moving changes into Production, adequate segregation of duties and separation of environments must exist to promote and ensure the integrity of those changes.

8.13 Scheduling & Communication

- 8.13.1 Whenever possible, changes must be scheduled during predefined Preventative Maintenance Window periods. Ideally these Maintenance Windows should be determined at the beginning of each year and should be communicated to all Thermo Fisher Scientific system owners, IT departments, and infrastructure stakeholders so that changes can be planned for accordingly.
- 8.13.2 No Major changes to finance systems, including those housed on the Mainframe, are permitted on the Sunday before a quarter-end, unless it is part of an Emergency Change or an Approved Normal Urgent Change.
- 8.13.3 All business users must be notified in advance of any planned system unavailability due to the implementation of system changes.
- 8.13.4 A list of scheduled changes must be maintained by the Change Control Manager.
- 8.13.5 System owners, whose GxP validated systems may be impacted by a change must be informed of approved changes, prior to implementation.
- 8.13.6 All changes require appropriate levels of approval prior to plan start date and time.

Title Change Management Policy		Document # IT-ETO-POL-0004	Revision 04	Effective Date See EDMS
Document Type Policy	Group Enterprise Technology and Operations (ETO)			Page 11 of 11

8.14 Approvals

- 8.14.1 Approvers are responsible for ensuring the quality of the change made, including changes made to documentation.
- 8.14.2 The Information Security manager must be involved as an approver on changes that may influence the information security of ThermoFisher Scientific.
- 8.14.3 Approvals should encompass direct stakeholders and Subject Matter Experts within Thermo Fisher Scientific.
- 8.14.4 Documented delegates of approvers are acceptable, as per IT-QARC-POL-0003 Signature Policy.
- 8.14.5 Approvers must document the reason for any rejection within the change record.
- 8.14.6 Approvals can be overridden in exceptional circumstances by a Change Manager if email authorisation is attached and reasons why are documented within the change

8.15 Tracking of Changes

- 8.15.1 Tracking and trending information must be reported on during the Quality System Management Reviews that occur as per IT-QARC-POL-0004 Quality System Management Review.
- 8.15.2 A review of changes from the prior change period must occur on a regular basis.
- 8.15.3 Changes performed during the prior change period that have resulted in any Incidents/Problems/CAPA's must be documented, including information concerning their resolution.

Signature Manifest**Document Number:** IT-ETO-POL-0004**Revision:** 04**Title:** Change Management Policy

All dates and times are in Eastern Standard Time.

IT-ETO-SOP-0002/POL-0004 Change Management Updates**Functional Area Approval**

Name/Signature	Title	Date	Meaning/Reason
Emma Regan (EMMA.REGAN)	Sr Manager, IT	04 Feb 2020, 05:57:15 AM	Approved
Nestor Gomez (NESTOR.GOMEZ)		06 Feb 2020, 10:14:12 PM	Approved
Shelly LaPointe (SHELLY.LAPOINTE)	Sr Manager, IT	11 Mar 2020, 01:07:27 PM	Approved

QA Approval

Name/Signature	Title	Date	Meaning/Reason
Shelly LaPointe (SHELLY.LAPOINTE)	Sr Manager, IT	11 Mar 2020, 01:08:09 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Luis Alfaro (LUIS.ALFARO)			
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Shelly LaPointe (SHELLY.LAPOINTE)	Sr Manager, IT	11 Mar 2020, 01:08:36 PM	Approved