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GUIDELINES FOR CHANGE MANAGEMENT AND RISK ASSESSMENT OF VALIDATED COMPUTERISED SYSTEMS IN A GLP ENVIRONMENT

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Legal position of AGIT papers

According the ordinance on GLP, art. 4:

> „The Federal Office of Public Health (FOPH), the Federal Office for the Environment (FOEN) and the Swiss Agency for Therapeutic Products (Swissmedic) may issue joint guidelines on the interpretation of GLP Principles."

Legal position of AGIT papers

„The group's objective is to propose practical approaches which test facilities may use to fulfil regulatory expectations.

In any case, test facility management may choose different approaches that are in compliance with the GLP principles“

AGIT - Basics

Validation of Computerised Systems, Version 2.0

- Perform a Validation as a GLP study
  - Role of QA

- Responsibilities and definitions
  - System owner

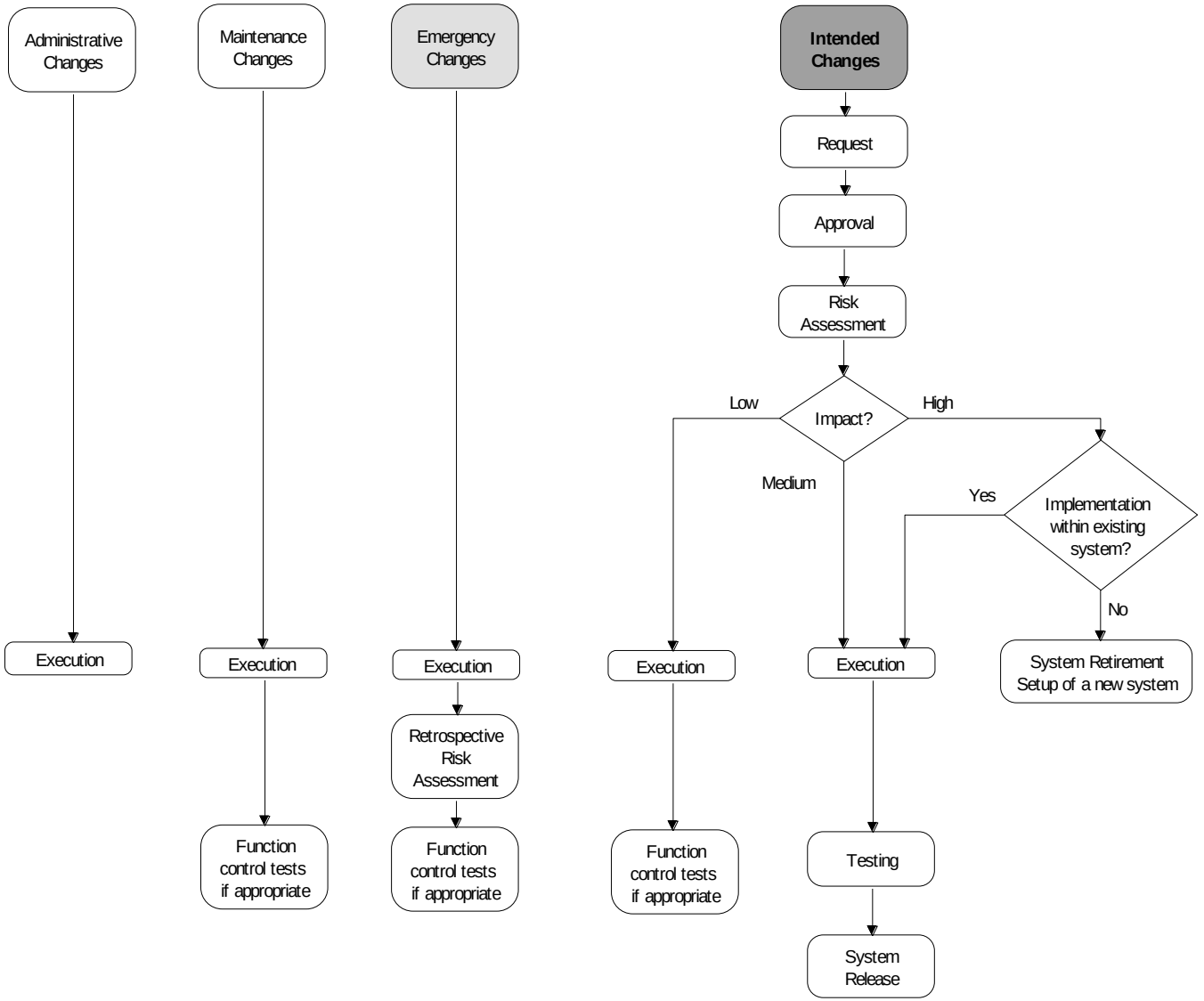
- AGIT guidelines are complementary modules

Need for CMRA

- User requirements ⇨ ⇨ validation ⇨ release ⇨ operation ⇨ system retirement

- Change management process ensures the validation status throughout the entire system life cycle
- Change management requires a controlled process to monitor and document all changes on released systems.
- Changes should be evaluated with regards to their impact (risk assessment) on the validation status and appropriate measures should be taken to keep the system in a validated state.

Concept


Administrative Changes
Maintenance Changes
Emergency Changes
Intended Changes
Request
Approval
Risk Assessment
Impact?
Low
Medium
High
Implementation within existing system?
Yes
No
Execution
Execution
Execution
Execution
Execution
System Retirement
Setup of a new system
Retrospective Risk Assessment
Function control tests if appropriate
Function control tests if appropriate
Function control tests if appropriate
Testing
System Release

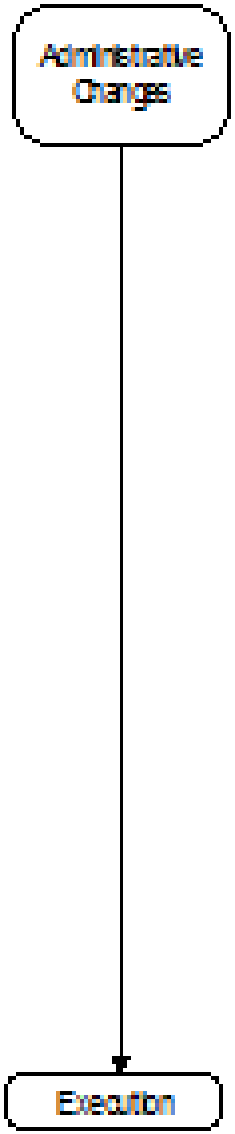
Administrative changes

- Change of roles and responsibilities, e.g. system owner, registered users, should be documented

- Functionality of the computerised system unaffected ⇨ no further measures.

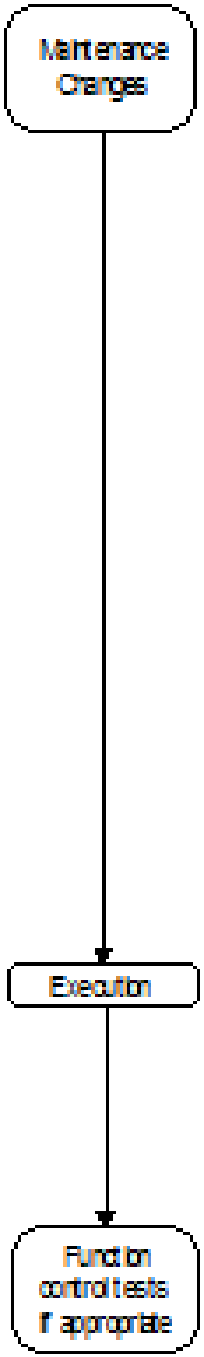
- Education and training
- Personnel documentation

} if necessary



Maintenance changes

- Replacement of attrition parts during regular maintenance
- functionality usually not affected
- documentation of these changes by maintenance report, documentation in log book or log file
- If appropriate, function control tests should be performed
- Define hardware components that are “attrition parts” in an SOP.



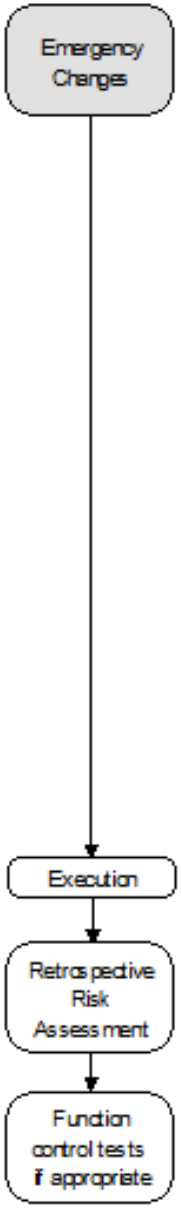
Maintenance changes

- Software upgrades in the context of maintenance can be critical
- the impact of all changes in software should be evaluated

☞ Handle as “intended change”

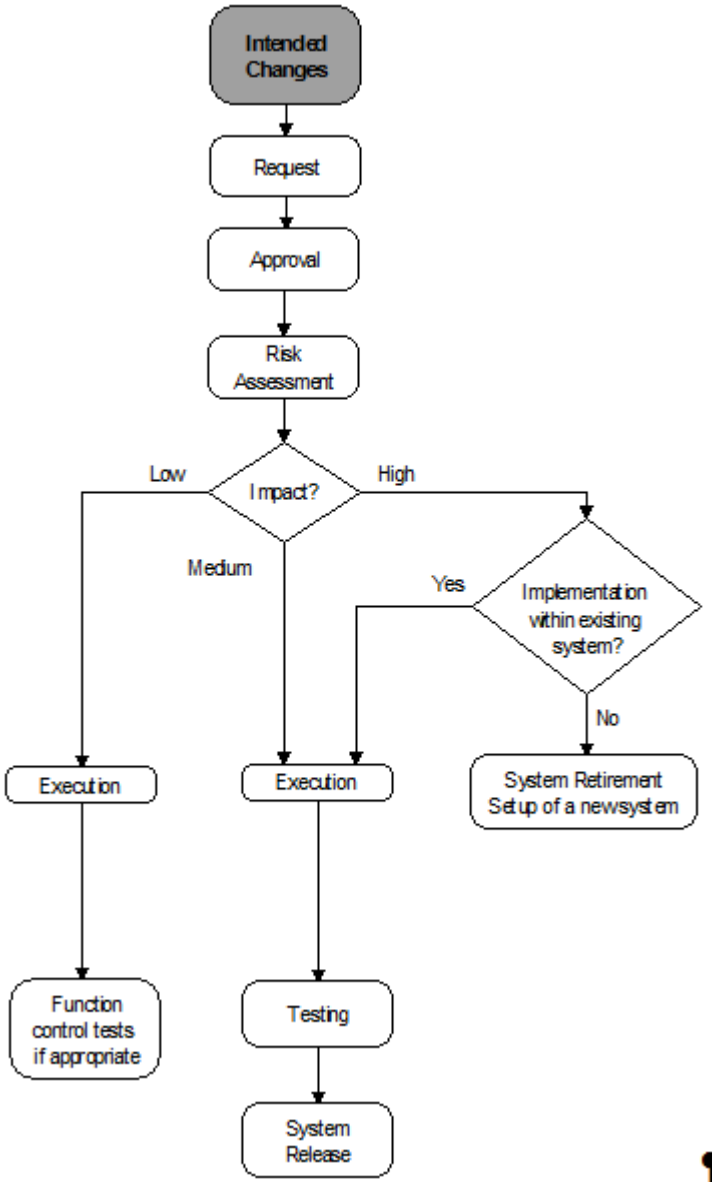
Emergency changes

- After a system failure (e.g. hardware crash), an immediate change may be required
- System owner and others involved (e.g. IT) decide on immediate changes to prevent a loss of data integrity
- Change control procedures retrospectively
- Depending on retrospective risk assessment or if function control tests fail, follow the “intended changes” procedure
- In this case, the status is no longer validated, until new release



Intended changes

- Request
- Request approval/rejection
- Risk assessment
- Actions
- Implementation
- Close of change



Request

- Documented request to the system owner (may be requested by different parties)
- Include justification, urgency of the change and affected elements of the system
- Preliminary evaluation of the overall effort for the implementation of change for the business decision
- TFM or system owner approves/rejects the request (documented).
- The request could also be approved/rejected after the risk assessment

Risk assessment

- Update user requirements if new functionalities will be used
- Identify affected user requirements/functional specifications.
- Decide on testing of each affected user requirement/functional specification
- The extent of testing should be described in the corresponding test plan/test script.
- Justify if you decide that no testing is needed for an affected user requirement/functional specification

Testing needed?

UR	Affected?	Test?	Justification
6 digits for Study number	Yes	No	New: 32 instead of 8 digits.
Manual Integration	No	--	--
Auto integration	Yes	Yes	--

Intended change: low impact

- If a change has a **low impact** on the computerised system the validation status remains unchanged
- The change and the correct functioning of the computerised system should be documented.
- If appropriate, function control tests should be performed

Medium/high impact

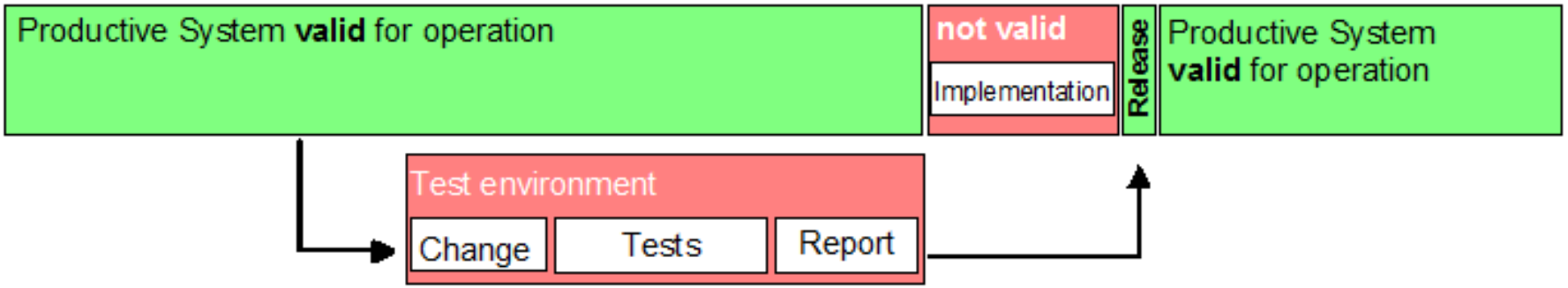
- If a change has a **medium/high impact** on the computerised system, the validation status will change to “not validated” as of change execution and the computerised system should therefore not be used for GLP purposes.
- After identification of all affected user requirements, a test plan (approved by system owner) should be established in order to prove that these user requirements are tested and QA should be involved according to SOP.

Medium/high impact

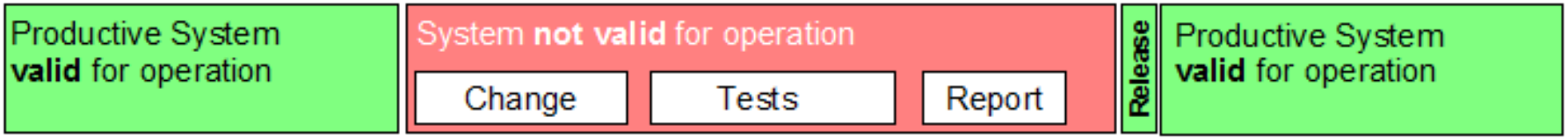
- The defined tests should be executed and reported. Alternatively a function control test, already defined in an SOP, can be used if appropriate.
- If evidence is given that all tested user requirements are met, the computerised system is suitable for its intended use.
- The computerised system can be released by the test facility management/system owner for productive use for GLP studies.

Implementation

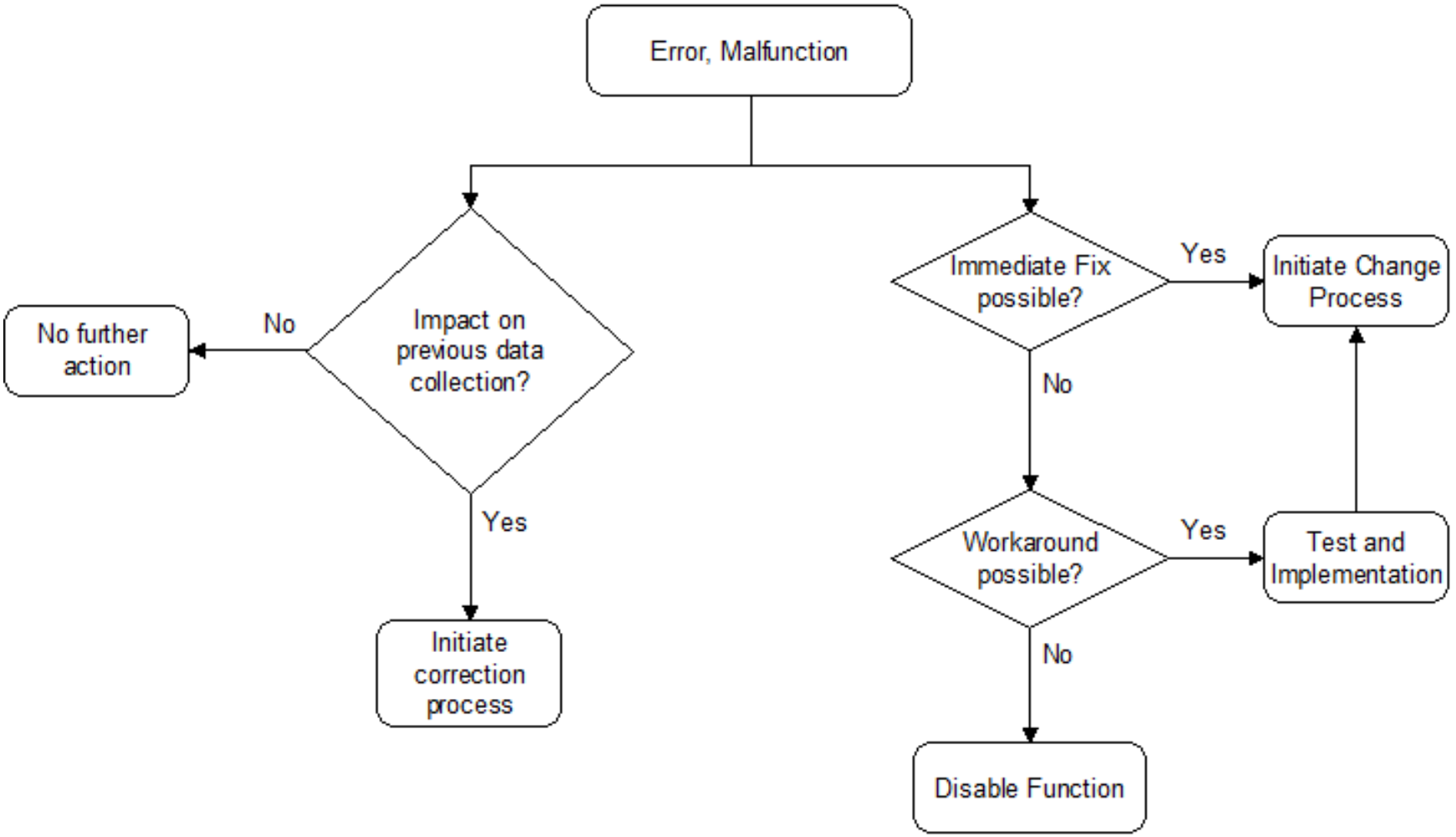
With test environment:



Without test environment:



Error handling



Responsibilities

- The **management** of the test facility
  - overall responsibility for compliance with the GLP principles
  - procedures to ensure that computerised systems are suitable for their intended purpose, and are validated, operated and maintained in accordance with the principles of GLP
  - Responsibilities for computerised systems must be defined and described in policies and procedures. This responsibility may be delegated to a designated system owner.

- The **system owner**
  - ensures that a computerised system is operated and maintained according to the principles of GLP
  - maintained in a validated state

Responsibilities

- The **personnel** involved in executing tests are responsible for performing activities in accordance with the GLP Principles and recognised technical standards.
- The **Quality Assurance (QA)** should be integrated in the change management process. The QA involvement should be described in an SOP. The following topics should be addressed:
  - Information process on planned activities
  - Review of documents (e.g. test plan, test report)
  - Inspection of activities.