American Association of Tissue Banks®

AATB Educational Resource Tool: Change Control

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OUTLINE

I. Introduction

Changes occur within an organization for a multitude of reasons. Changes can be expected or unexpected, permanent or temporary. They may originate from within an establishment or from external sources (e.g., clients, regulatory bodies, vendors). They may impact one department or process or have an inter-departmental or multi-process impact. Changes may be necessary, or they may be voluntarily implemented to adapt to new challenges or realities within the organization or regulatory landscape. Sometimes, changes occur a little over time, and sometimes change results in a paradigm shift, upending how an organization (or the tissue banking industry) acts or thinks. Regardless of their character, change presents challenges and opportunities for organizations; as such, changes need to be managed carefully to ensure the end result is effective.

An organization's response to change requires systematic control. Regulatory bodies have specific expectations to ensure that changes are effectively documented, evaluated, and managed. Establishments should document and implement policies and/or procedures to ensure control and meet those expectations. The most common policies related to change are:

- Change management policy: establishing a process on initiating organization-wide changes (e.g., new/modified process, new equipment, etc.) as well as evaluating changes that impact the state of control of the QMS.
- Document management policy: establishing a process on managing (creating, updating, or retiring) procedures, forms, and other controlled documents.
- IT management policy: establishing a process on making changes (adding, modifying, or eliminating) to applications and other IT systems.

Change control is the discrete component of a comprehensive change management process that focuses on the evaluation of changes that potentially impact one or more organizational systems (e.g., process, policy, controlled documents, applications), making decisions and plans for how to implement, and following through on those plans. The need for change control is often driven by changes to requirements – regulations, standards, application functionality, contracts, etc. – that impose an alternative future state to which an organization's operations must evolve. This evolution tends to be highly methodical and require intensive control because it must thoroughly encompass all potentially impacted systems, provide a clear and defensible approach to achieving the future state, demonstrate conformance to new requirements, and ensure that quality systems are activated throughout to provide records of the transition and establishment of the new operational state. The transition also may be bound by an external timeline, such as the effective date of a new standard, and as such needs to be a well-coordinated project.

An organization should identify/assign personnel that own the change management process. Departmental management/supervision must review and assess potential changes to processes and are expected to initiate the appropriate process in response (e.g., document control, IT changes, change management). Processes and procedures are most effective when they are standardized, clear, and concise so that trained personnel can perform the applicable activities the same way. This method creates a "state of control" and minimizes the risk of unintended or undesired events from occurring (e.g., customer complaints, CAPAs, regulatory audit findings).

Any change that impacts (or potentially impacts):

- validated process(es), equipment, or software system
- regulatory compliance or regulatory licensing

- clients/customers
- vendors, or the supplies/services they provide
- personnel training
- any major components of the QMS

impacts the established "state of control." Therefore, any change that potentially impacts that state of control MUST be evaluated in an established and consistent manner. This is why personnel are expected to follow established processes and procedures, are expected to notify their supervisor if they find an activity is not being performed per SOP, and are prohibited from making any changes (i.e., "improvements," tweaks, or personal preference) without first formally requesting a change.

This tool was developed to provide some best practices and a general process for change control that may be employed case-by-case or as part of a program. It was prompted by the transition brought about by publication of AATB's Standards for Tissue Banking, 15th edition, which is an extensive restructuring of previous versions and may require extensive change control during implementation by accredited tissue banks, in particular.

II. Definitions

- **Change Control:** The discrete component of a comprehensive change management process that focuses on the evaluation of changes that potentially impact one or more organizational systems. It involves assessment and determination of the appropriateness of a proposed alteration to processes, products, or systems, and thorough planning, monitoring, and controlling of changes to ensure they are implemented in a structured and coordinated manner. It includes processes for requesting, evaluating, approving, and implementing changes, as well as documenting and communicating those changes to relevant stakeholders. The primary goal of change control is to minimize the risks associated with changes, such as disruptions to operations, quality issues, or budgetary expenses, while ensuring that changes are effectively incorporated and managed.

- **Change Control File:** A file consisting of relevant documentation pertaining to an identified change and evidence of completion of related activities. This file is crucial for maintaining transparency, accountability, and traceability throughout the change control process.

- **Change Control Group:** A group of representatives from appropriate functional areas that meet to advance the change control process, as well as assess and approve proposed changes. It should be made up of relevant leadership, stakeholders, and subject matter experts.

- **Change Control Plan:** A plan that includes a series of tasks, assigned owners, responsibilities, and target dates to ensure a project goal is met.
    - **General Action Plan:** A high-level plan that summarizes the change and outlines determined requirements, identified impact, and a list of key actions.
    - **Comprehensive Action Plan:** A detailed plan that builds on the general action plan to further define actions to be implemented, along with associated responsibilities, timelines, approval, and training.
    - **Communication Plan**: An approach that outlines how to communicate information to a target audience. It may include such details as:

        - Purpose: What the communication is trying to accomplish and what information will be shared
        - Audience: Who the communication is intended for, and why they are relevant
        - When and where: When the information will be delivered and how the communication will be shared, tracked, and analyzed.
        - Timeline: When tasks need to be completed by
        - Responsibilities: Who is responsible individual(s), points of contact, etc.
    - **Document Management Plan:** An approach that involves coordination of document management needs (development, revision, etc.) to prepare for and implement a response to change.
    - **Learning and Development Plan:** An approach that involves developing and implementing actions to facilitate the learning and skill development of personnel within an organization. May involve but not limited to: training programs, workshops, and other initiatives to enhance staff knowledge, abilities, and competencies.
    - **Measurement and Monitoring Plan:** An approach that outlines the methodology or means for tracking and assessing specific metrics or indicators related to a project, process, or system.
    - **Rollback Plan:** A documented approach that allows you to go back to an earlier version of a feature or process if something goes wrong. This applies to automatic, manual, software, and quality systems.

- **Change Management Lead:** An individual who is responsible for administering the change control process. This may include routing documentation for approvals, verifying proper completion of deliverables, and compiling the change control file.

- **Critical Systems:** Major operational, quality, and/or regulatory-related systems within an organization.

- **Current State:** The existing state of an organization's Quality System, processes, and product/process design, along with the adhered to standards and regulations. May also be known as “as is.”

- **Deliverables:** Outputs, results, or products that are generated or produced as part of a project, process, or agreement. They represent the specific items or outcomes that are expected to be delivered to stakeholders within a certain timeframe and according to defined requirements or specifications.

- **Future State:** The objective or goal of an organization as it relates to a change in the current state (i.e. implementation of new standards, update to a process, or a change in equipment). May also be known as “to be.”

- **Gap Analysis:** An analysis/assessment comparing current procedures (current state) to new requirements or other future state stemming from a new policy, updates to regulations and/or standards, or planned changes to a process. Any disparities identified from the analysis are considered gaps in the quality management system. A gap analysis can also be conducted to document compliance with existing regulations and/or standards.

- **Group Lead:** The member of the change control group who is designated and accountable for the timely execution of the action plan activities. This role could be considered a Project Manager.

- **Impact Categorization:** Determination that a change falls into one of three categories:
    - **Major Change:** A change that significantly or directly impacts critical systems, including products, processes, or the quality system.
    - **Minor Change:** A change that may impact some portions of the quality system, such as documentation, but no changes to product or process.
    - **Inconsequential Change:** A change that, once evaluated, has no impact on critical or quality systems within the organization.

- **Impact Evaluation:** A type of risk tool that identifies and assesses organizational and quality system elements that may be affected by a change. Action items shall be determined and documented to bring these elements back to a state of control and mitigate any potential risk to the safety or efficacy of a product. May also be known as an impact assessment or risk assessment.

- **Implementation:** Process of taking action on the documented plans, strategies, and/or ideas in order to realize, and subsequently close, a change control activity.

- **Leadership (leadership review):** Level(s) of management defined by an organization, who would be responsible for ensuring adequate resource allocation for action item(s) identified in a change control event, as well as review and approval of a change control plan. This may include approval of spending, purchasing, staffing, overtime, etc.

- **Qualification:**
    - **Installation Qualification (IQ):** Process to confirm that equipment and systems used in regulated industries are installed correctly. This may include verifying that the equipment is placed in the correct location, properly connected, and set up according to manufacturer specifications and regulatory requirements.
    - **Operational Qualification (OQ):** A step used to check if equipment and systems in regulated industries work as they should, ensuring that intended use, standards, and other rules are met.
      Performance Qualification (PQ): A step in the validation process used by regulatory agencies to confirm that equipment or systems consistently perform according to predetermined specifications and requirements.

- **Quality Management System (QMS):** A structured and documented approach within an organization that encompasses processes, procedures, and responsibilities aimed at achieving quality policies and objectives. Its primary goal is to ensure that products or services consistently meet customer requirements and comply with regulatory standards. It also fosters a culture of continuous improvement, where processes are regularly reviewed and refined to enhance overall quality and efficiency.

- **Quality Review:** A thorough assessment or evaluation of products, processes, or services to ensure they meet predefined specifications, standards, and requirements. Quality reviews are often conducted by dedicated Quality personnel who compare the actual outcomes or deliverables against established criteria or benchmarks.

- **RACI:** Acronym for Responsible, Accountable, Consulted, Informed in the RACI Matrix. A task is associated with at least one role. This 'association' of the role with a task can be divided into the four association types:
    - **Responsible:** These roles are responsible for completing the task or deliverable.
    - **Accountable:** This role has the final authority for (or is accountable for) the task's completion.
    - **Consulted:** This role functions as an advisor to a task and should be assigned carefully to avoid overuse.
    - **Informed:** This role is kept up to date on task completion. Consult various roles to determine who needs status updates.

- **Regulatory Requirements:** Specific mandates, rules, standards, laws, and directives set forth by governmental agencies or regulatory bodies that organizations must comply with in their operations, products, and services.

- **Resource Implementation:** Allocation of resources to achieve specific goals or objectives. Involves the use of people, tools, and technology, including external general resources, according to plans to achieve goals effectively.

- **Responsible Designee(s):** Individuals with delegated authority to perform designated functions, for which they are trained and qualified, on behalf of the primarily responsible individual.

- **Risk:** The possibility of uncertain or unexpected events that may lead to impact on objectives. Risk represents potential outcomes that could deviate from what was initially planned or anticipated and can arise from various sources, including internal factors such as organizational processes, resources, or personnel, as well as external factors like market conditions, regulatory changes, or natural disasters.

- **Risk Management:** The process of identifying, assessing, prioritizing, and mitigating risks to minimize their impact and increase the likelihood of achieving desired outcomes. Risk management is an integral part of decision-making and planning processes to enhance resilience and ensure sustainable success.

- **SMART Goals:** Acronym for the five criteria on how goals are developed:
    - **Specific:** Include details of what is to be accomplished
    - **Measurable:** Ensure progress can be measured and accomplishment accurately determined
    - **Attainable:** The goal should not be too easy or too hard
    - **Relevant:** The goal should be meaningful and align with strategic intent
    - **Time-bound:** The goal can be met in the amount of time allotted

- **Source of change:** The identified origin of a change, for which change control activities must be taken. This may be internal or external, planned or unplanned.

- **Stakeholder(s):** An individual or group that has an interest in any decision or activity of an organization and may be directly impacted by or responsible for the change. Stakeholders may be internal (e.g., board of directors, management, personnel) or external (e.g., clients, regulatory bodies, investors, suppliers).

- **Standard Operating Procedures Manual (SOPM):** A group of standard operating procedures (SOPs) detailing the specific policies and the procedures used by personnel to carry out assigned functions within the tissue bank.

- **Subject Matter Experts:** Individuals with specific knowledge and expertise in an area that may be gained through diverse education, training, and technical experience.

- **Validation/Plan:** Confirmation through the provision of documented objective evidence that predefined specifications have been fulfilled and can be consistently reproduced. The organization shall document validation plans that include methods, acceptance criteria, and as appropriate, statistical techniques with rationale for sample size. (ISO 13485:2016 Section 7.3.7) See qualification.

III. Change Control Program
Overview of Best Practices

- A training program should be established to define roles and responsibilities in the change control program so that participants understand the expectations related to their role(s) and/or responsibilities.
- A change control program may be coordinated within an organization by an individual or within a functional unit (Change Management Lead). Consider using a RACI Matrix to define roles and responsibilities.
- Ensure your change control program is scalable. Activation of the full change control program will not be required for every possible change event, although most events will warrant evaluation to determine the extent to which the program should be applied. The program therefore should be scalable to a change's magnitude and adaptable to the type of change.
- Ensure your change control program has sufficient scope and authority. It may need to expand beyond initially assumed lines and incorporate unanticipated operational areas. It should be connected to organizational leadership for decision making and support. It also might be accompanied by or incorporated into a change management program that addresses adjacent activities such as development of internal or external communications.
- A proactive approach to evaluating a change that starts early allows for a thoughtful look at the "bigger picture" of the change and minimizes the chance of unintended consequences.
- Ensure your Change Control program has identified representatives (primary and secondary) from each Critical System that will participate in Impact Evaluations. Defined and consistent representation will yield consistent evaluations across time and change control events.
- Account for stakeholders beyond those obviously impacted by change, at least for their awareness. This also may prompt the identification of previously unrealized impacts of the change.
- Engage your Quality personnel early so that applicable quality system elements may be activated and have time to play out as designed.
- Set SMART goals as part of the change action plan.
- When creating SOPs, establish process controls to ensure efficiency in operations, compliance with regulations, and maintaining quality standards. Process controls also will feed into the development of a monitoring and measurement plan.

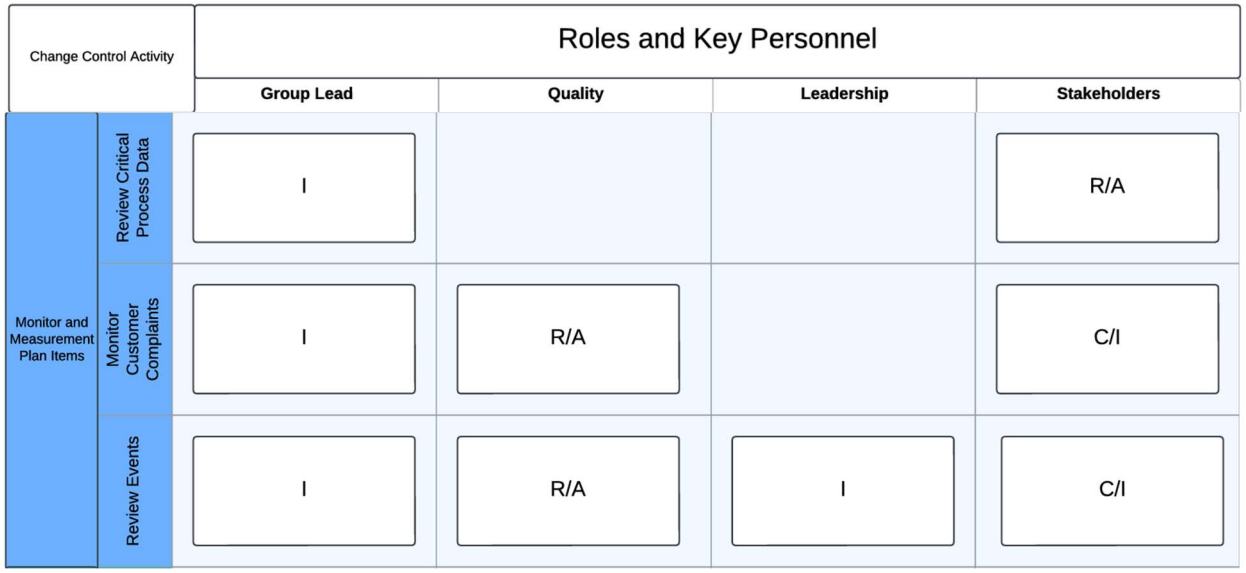
- Unintended consequences may occur, so establishing a rollback plan is key. A rollback mechanism serves as a safeguard to data and system integrity by providing a safety net. By incorporating a reliable rollback mechanism into systems, organizations can minimize risks, improve system reliability, minimize downtime, and protect critical data and operations from adverse events or failures.

Responsibilities

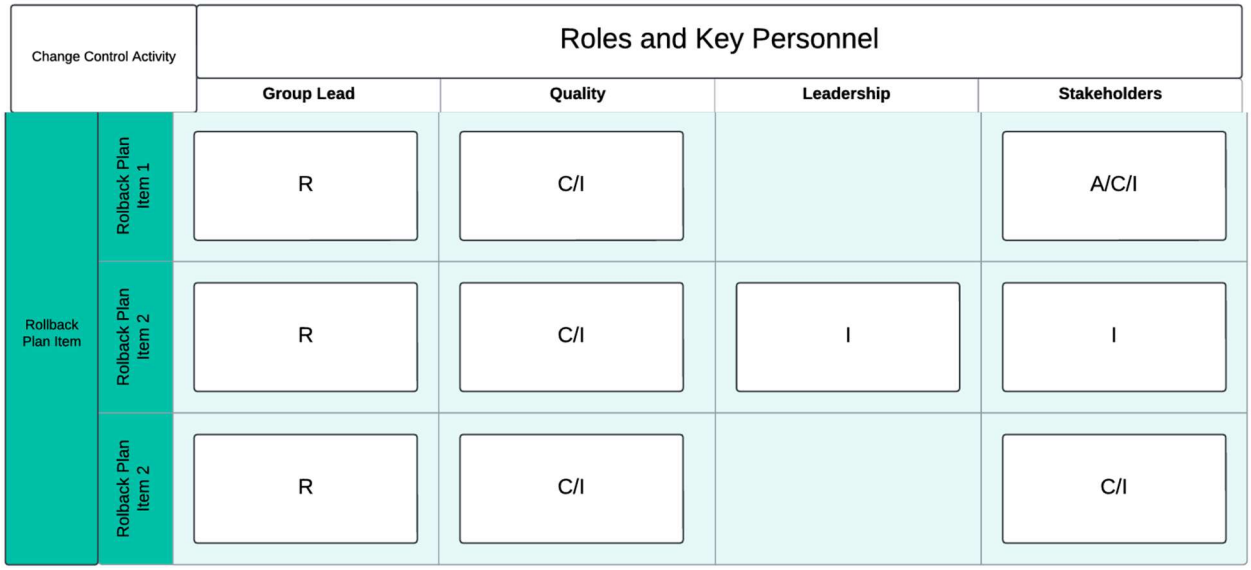
The following RACI matrix is an example of how roles within a change control program might be structured.

Change Control Activity		Roles and Key Personnel			
		Group Lead	**Quality**	**Leadership**	**Stakeholders**
Action Plan Items	Action Plan Item 1	R/A			
	Action Plan Item 2	R/A	C/I	I	
	Action Plan Item 3	R/A	I		I

Change Control Activity		Roles and Key Personnel			
		Group Lead	**Quality**	**Leadership**	**Stakeholders**
Learning and Development Plan Items	Training for Validation	R	A/C		
	SME Designation	R	I	I	A/C
	Training On Approved Procedures		R/A		C/I



Change Control Activity		Roles and Key Personnel			
		Group Lead	Quality	Leadership	Stakeholders
Monitor and Measurement Plan Items	Review Critical Process Data	I			R/A
	Monitor Customer Complaints	I	R/A		C/I
	Review Events	I	R/A	I	C/I



Change Control Activity		Roles and Key Personnel			
		Group Lead	Quality	Leadership	Stakeholders
Rollback Plan Item	Rollback Plan Item 1	R	C/I		A/C/I
	Rollback Plan Item 2	R	C/I	I	I
	Rolback Plan Item 2	R	C/I		C/I

IV. Change Control Process

The following process provides comprehensive, but not all-inclusive, guidance for you to evaluate, adopt, and/or augment your change control program. The full process is not likely to be required for changes of all types and sizes (see best practice regarding scalability). It is described in three phases, although the overall process is continuous and may be recursive if discoveries prompt a return to an earlier step.

Assessment Phase

1. Upon receiving notification of the change, forward the notification to the responsible Change Management Lead.
2. Create a change control file and collect initial information.
    a. Include reference to changes and determination on their applicability.
        i. Provide justification if not applicable.

    b. Document the source of change, including whether it is required or voluntary and the specific timeline/due date. Sources of change include, but are not limited to:
        i. New project, product, process, or equipment
        ii. Modification to an existing product, process, or equipment
        iii. Regulatory requirements
        iv. Result of corrective and preventative action (CAPA)
        v. A planned deviation
        vi. Vendor notification
        vii. Audit observation
    c. Define the change by collecting relevant information, including redlines.
3. Initiate an impact evaluation that identifies impact to elements of the quality system.
    a. Considerations should include impact on the following:
        - Regulatory compliance and communication
        - Facilities
        - Equipment
        - Vendors and purchased products
        - Client compliance and communication
        - IT hardware and software
        - Daily operations (e.g., production, distribution, recovery, testing)
        - Validations (e.g., equipment, process, software)
        - Products
        - Procedures and controlled documents
        - Training requirements (training plans, competency/skill assessments)
    b. Ensure the impact evaluation covers all critical systems of your operation and quality system.
4. Based on the impact evaluation results, categorize the overall potential impact of the change as a major change, minor change, or inconsequential change.
    a. Obtain Change Management Lead approval of impact categorization and the need for further change management.
    b. Follow your organization's risk management process, if present and if applicable.

Development Phase

1. Gather all critical system representation, as well as that of stakeholders and leadership (if necessary), to verify the accuracy of the impact evaluation.
    a. Prioritize the actions of the identified stakeholders based on the significance of the change impact.
    b. Identify stakeholders and leadership (if necessary) who shall approve the change control plans and their respective actions (See Step 11).
2. Assemble a change control group
    a. Identify the members responsible for advancing the process, comprising of subject matter experts, leads, responsible designees, quality, and operations.
    b. Identify a Group Lead to head the change control group, owning the responsibility of reporting back to the stakeholders and leadership at determined intervals. The Group Lead may be a representative of the area that the change most greatly impacts.
    c. Define each change control group member's responsibilities and ownership for deliverables.
3. Outline a General Action Plan

    a. Within the change control group, define key actions with emphasis on the previously identified change requirements, risks, and gaps noted during the impact evaluation.
    b. The Change Management Lead or Quality should review the outlined action plan at this stage, before moving on.
    c. Set SMART goals for each action in the general action plan, including, but not limited to roles and responsibilities.
        - Map each of the outlined actions in the action plan to roles.
        - Ensure each role has a means to communicate progress or concerns within the framework of the plan.
4. Create a comprehensive action plan that aligns with the identified risks, deliverables, and timeline and resolves the gaps identified during the impact evaluation.
    a. Set SMART goals for each action in the comprehensive action plan with target dates (make the goals easily updatable).
    b. Ensure that the stakeholders and leadership are included for approval throughout the process. Initiate a validation plan for changes, if required.
    c. Identify any training requirements that will need to be implemented as part of the goals.
    d. Evaluate whether relevant regulatory requirements are still met for intended changes.
    e. Review the impact evaluation analysis against action plan goals, to determine if all impacted elements have been addressed.
5. Create a communication plan that strategically outlines how the change control group shall inform and guide stakeholders and keep them involved throughout the change control process.
    a. Identify your target audience and evaluate whom you are communicating with, what they care about, and how to communicate so they receive and process the relevant level of information.
    b. Evaluate the most appropriate and effective channels to deliver training and any other applicable communications on the change.
    c. Consider when and where you will announce the change, and how you are reaching and training your target audience.
    d. Inform any identified external stakeholders (clients, regulators, vendors, etc.) of the actions that will impact them.
        i. Provide timely and/or routine notification of the change and its target implementation date to customers so that they can assess the impact on their own operations and quality system.
        ii. Establish a time frame and requirements for communicating with regulatory bodies, if applicable.
    e. Ensure adequate levels of communication are established with and between critical systems, stakeholders and leadership.
    f. Schedule regular status updates/progress reports with all action owners to ensure responsibilities and deliverables are meeting timelines.
    g. Examine the role of key stakeholders (e.g., leadership, management) in promoting understanding of the change.
6. Create a document management plan to ensure that all necessary controlled documents are created, or revised, and fully processed through the organization's document control system.
    a. Identify all current controlled documents (e.g., SOPs, forms) that are impacted and/or what new documents shall be generated.

    b. Document the change in the controlled document(s) using adequate detail and within the standard format for personnel to effectively understand and comply.
    c. Circulate the new or revised documents for review and approval.
7. Create a learning and development plan to define, prepare, and deliver training.
    a. Develop a structured plan that outlines training and development initiatives
    b. Determine subject matter experts with specialized knowledge, expertise, and experience in needed areas.
    c. Determine if creation or revision of training materials are required.
    d. Determine training modalities (e.g., print, electronic media, video, in-person, combination, etc.)
8. Create a monitoring and measurement plan that can confirm implementation effectiveness.
    a. Use the impact evaluation when designing the measuring and monitoring plan to ensure that compliance requirements are met and risks have been mitigated.
    b. Define objectives and goals.
        i. Identify Key Performance Indicators (KPIs).
        ii. Establish baseline benchmarks, best practices, and/or metrics.
        iii. Ensure corrective and preventative actions are clearly documented (if applicable).
    c. Establish a monitoring process.
        i. Determine how your organization will collect, analyze, and review KPIs. Consider options such as dashboards, reports, and presentations.
        ii. Establish the frequency of review.
        iii. Report and communicate results.
    d. Continuously monitor process performance against established controls.
        i. Perform audits to ensure compliance with process controls, SOPs, and regulatory requirements.
    e. Identify additional improvement opportunities.
9. Establish a rollback plan, if deemed necessary.
10. Submit the change control plans to the Change Management Lead for final review and pre-acceptance of the plan so that it can be submitted for approval.
11. Obtain approval of the change control plans from the stakeholders identified in Step 1b *BEFORE* initiating any action from the change control plans.
    NOTE: This is essential as it avoids any concern or misalignment in expectations or actions regarding the change control plans listed above.

Implementation Phase

Once all approvals have been obtained, take action and produce outputs for all deliverables identified in the Change Control plans.

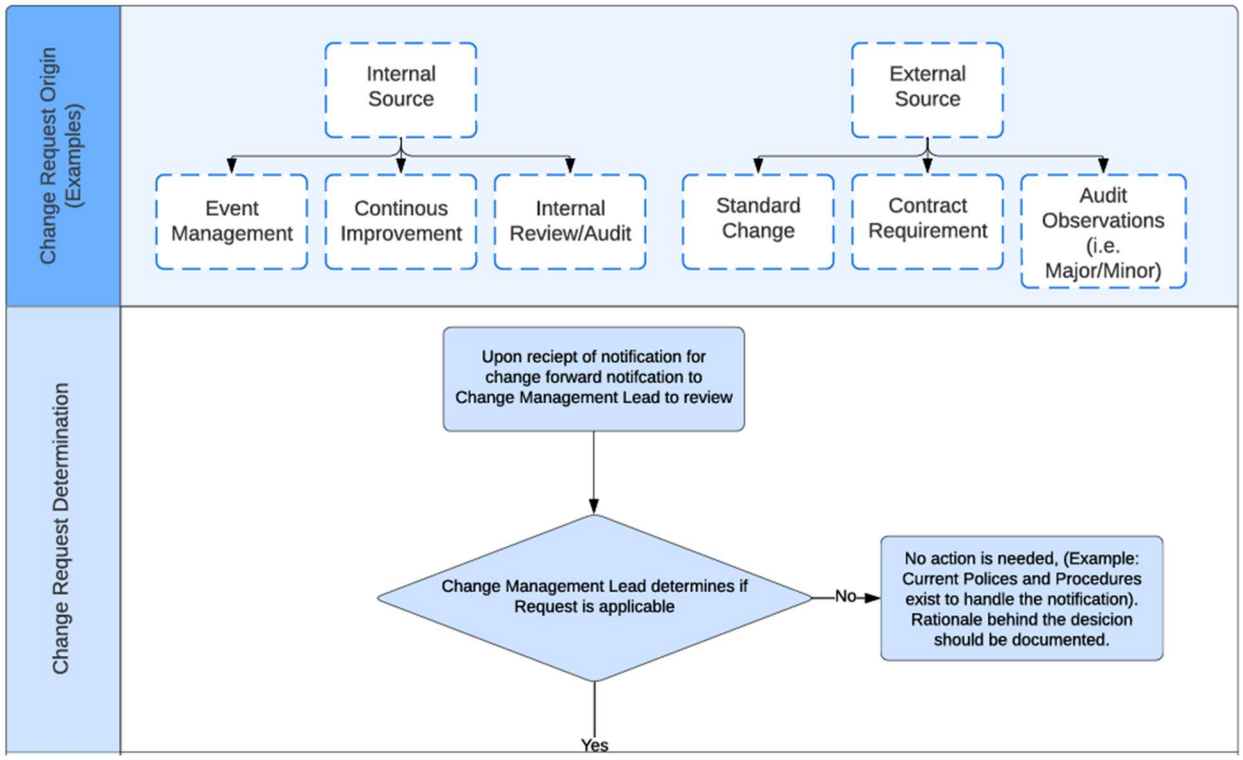
NOTE: It falls within the purview of the AATB to disseminate information regarding the implementation of new Standards, outlining expected actions and outcomes, for future planning purposes.

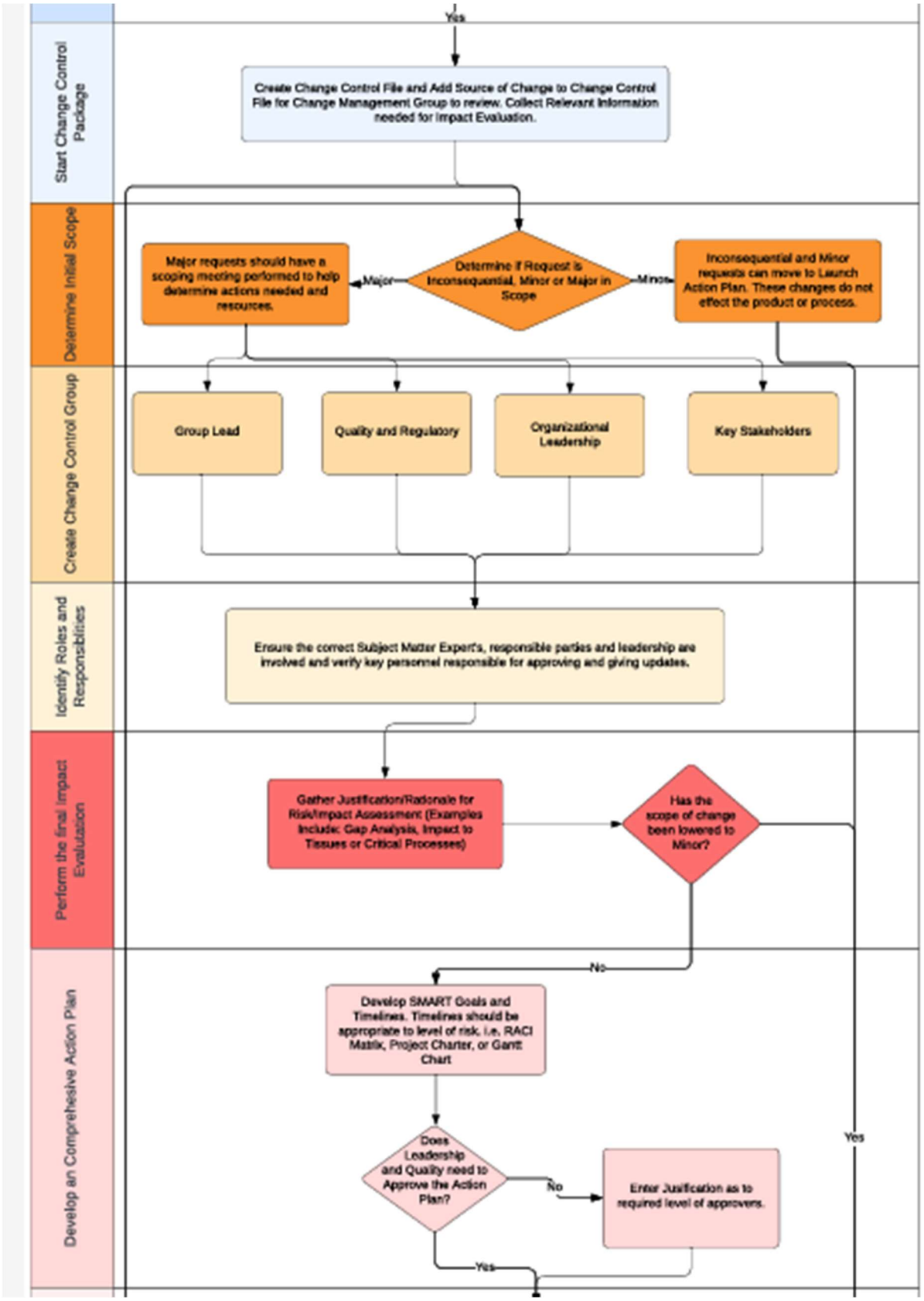
1. The Group Lead is accountable for coordinating the rollout of the change and ensuring all action items owners meet their assigned action target due dates.
2. Ensure controlled documents and training (at a minimum) are in place before implementing the change.

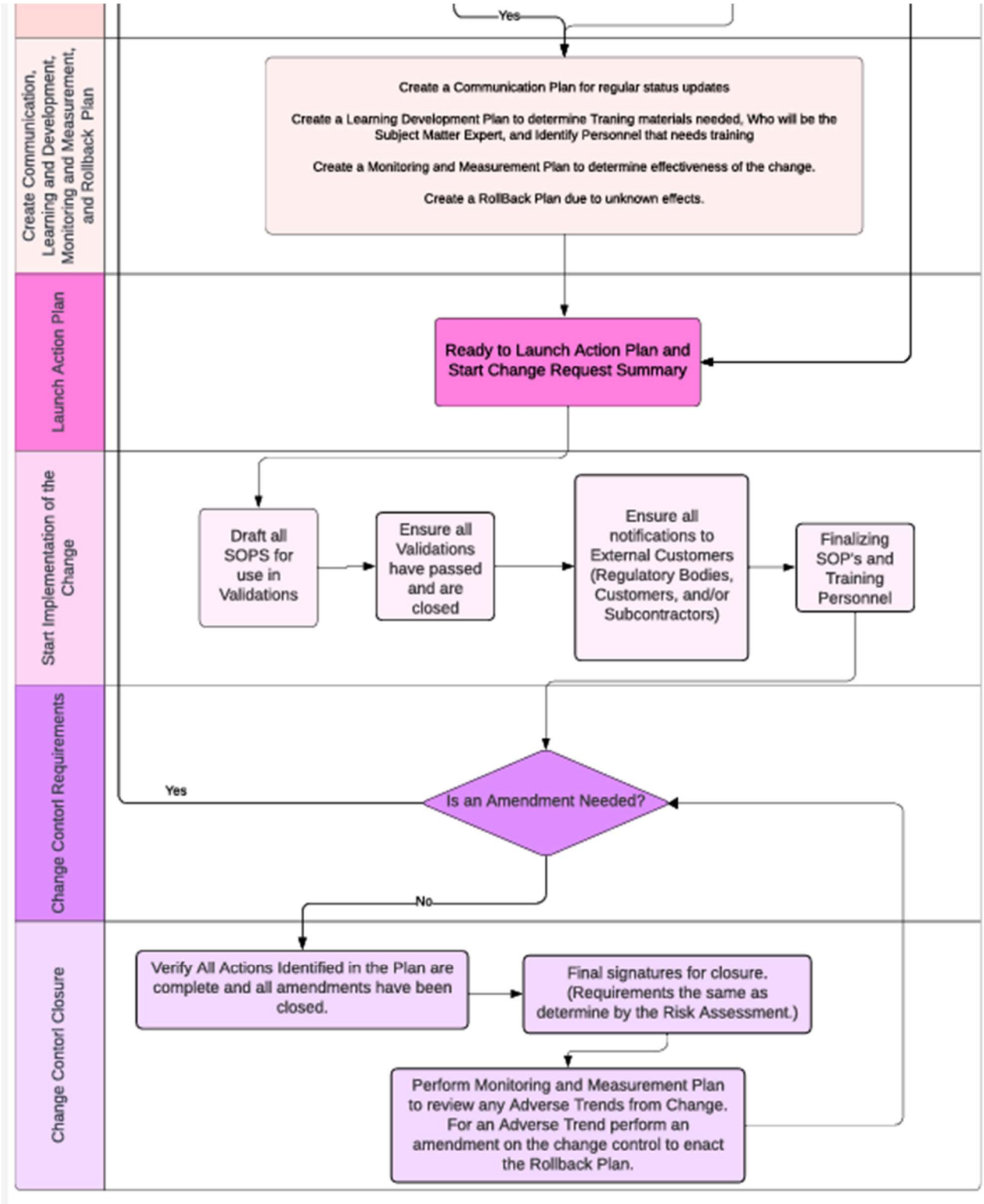
    a. Additional considerations for process, software, and/or equipment changes include the execution and approval of IQ/OQ/PQ validations prior to implementation.
3. Identify if there were any deviations or modifications from the original action plan(s).
    a. If yes, justify those modifications or deviations.
    b. Because the action plan was approved by the stakeholders, modifications or deviations from the original plan shall be reviewed for impact on the overall change and dispositioned by Quality (at a minimum).
4. Execute rollback plan (if warranted).
    a. Identify the reason for and scope of the rollback.
    b. Initiate the rollback process by accessing backup data and any other necessary reversions.
    c. Validate the rollback process to ensure that the systems are returned to functional state.
    d. Communicate rollback outcome to stakeholders, as appropriate.
5. Close out the change
    a. The Change Management Lead shall review the change control file and ensure that all actions identified in the change control plan(s) have been adequately completed.
    b. Evidence of actions performed and/or completed shall be documented and retained or referenced in the change control file.
        i. Objective documentation may be included in CAPA references or audit/revision logs.

Flowchart

The following flowchart is intended to provide a complementary visualization of the process.




Start Change Control Package
Yes
Create Change Control File and Add Source of Change to Change Control File for Change Management Group to review. Collect Relevant Information needed for Impact Evaluation.
Determine Initial Scope
Major requests should have a scoping meeting performed to help determine actions needed and resources.
Major
Determine if Request is Inconsequential, Minor or Major in Scope
Minor
Inconsequential and Minor requests can move to Launch Action Plan. These changes do not effect the product or process.
Create Change Control Group
Group Lead
Quality and Regulatory
Organizational Leadership
Key Stakeholders
Identify Roles and Responsibilities
Ensure the correct Subject Matter Expert's, responsible parties and leadership are involved and verify key personnel responsible for approving and giving updates.
Perform the final Impact Evaluation
Gather Justification/Rationale for Risk/Impact Assessment (Examples Include: Gap Analysis, Impact to Tissues or Critical Processes)
Has the scope of change been lowered to Minor?
Yes
No
Develop an Comprehesive Action Plan
Develop SMART Goals and Timelines. Timelines should be appropriate to level of risk, i.e, RACI Matrix, Project Charter, or Gantt Chart
Does Leadership and Quality need to Approve the Action Plan?
No
Enter Justification as to required level of approvers.
Yes


Yes
Create Communication, Learning and Development, Monitoring and Measurement, and Rollback Plan
Create a Communication Plan for regular status updates
Create a Learning Development Plan to determine Traning materials needed, Who will be the Subject Matter Expert, and Identify Personnel that needs training
Create a Monitoring and Measurement Plan to determine effectiveness of the change.
Create a RollBack Plan due to unknown effects.
Launch Action Plan
Ready to Launch Action Plan and Start Change Request Summary
Start Implementation of the Change
Draft all SOPS for use in Validations
Ensure all Validations have passed and are closed
Ensure all notifications to External Customers (Regulatory Bodies, Customers, and/or Subcontractors)
Finalizing SOP's and Training Personnel
Change Contorl Requirements
Is an Amendment Needed?
Yes
No
Change Contorl Closure
Verify All Actions Identified in the Plan are complete and all amendments have been closed.
Final signatures for closure. (Requirements the same as determine by the Risk Assessment.)
Perform Monitoring and Measurement Plan to review any Adverse Trends from Change. For an Adverse Trend perform an amendment on the change control to enact the Rollback Plan.