



Auditing Improvement and Change Management 2.19

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- **2.19 Improvement and Change Management**

- 2.19.1 The facility should maintain an effective change management program.
- 2.19.2 The facility should utilize quantifiable risk analysis tools on activities to mitigate potential quality issues.
- 2.19.3 The facility should retain documentation of changes

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- **That word “should”**
- **Legal definition: Should means an action that is recommended but not mandatory.**
- **It is an operative word that simply means to achieve the desired goals and objectives it is strongly recommended the action be taken.**
- **How are we going to audit this?**



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- **KEEP IT SIMPLE**
- **An audit of change management must review results to identify key improvement opportunities.**
- **Strong change management means planned implementations, proven/tested solutions, scheduled upgrades, training, contingencies, measures and metrics.**
- **The fundamental question to ask yourself is simply:**
 - **Are changes being implemented in a controlled or haphazard manner?**

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- **Auditors need to perform the following tasks during change management program audits:**
- **Let's explore some of these...**



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- **Understand the change management process and principles**
 - A process that ensures people are able to embrace organizational change successfully
 - People comprise an organization and will make or break the success of an initiative.
 - A systematic approach to managing change

Commonly Accepted Principles of Change Management

- **Start at the top**
 - Does the executive team model enthusiasm and support?
- **Address the people issues**
 - Change affects a person's perceived stability; are stakeholders on board?
- **Explain the why**
 - Does each internal area impacted understand exactly how it will impact them?
 - Does everyone believe the end-result is achievable?
 - Customized messaging may be prudent as one message usually does not fit all within an organization
- **Involve everyone impacted**
 - From top to bottom
 - Without buy-in at all layer's critical initiatives may not be successful
- **Communicate, communicate, communicate**
 - Lack of information can create confusion and lack of faith in a work effort
 - Is progress communicated throughout the endeavor?

Commonly accepted Principles of Change Management

- **Create buy-in**
 - Change must be owned by leadership and adopted by all members of an organization
 - Instances may warrant incentive plans, rewards, etc.
- **Be clear about culture**
 - Leadership must be clear about how the organization will look in the future and how all participants will behave
- **Assess organizational behaviors early and often**
 - What's the temperature of the internal environment?
 - How are employees handling change?
 - Are behaviors productive?
 - Do changes need to be made to better support initiative?
 - It is far better to make small changes along the way to rectify any concerns to ensure successful implementation of any desired change

Commonly accepted Principles of Change Management

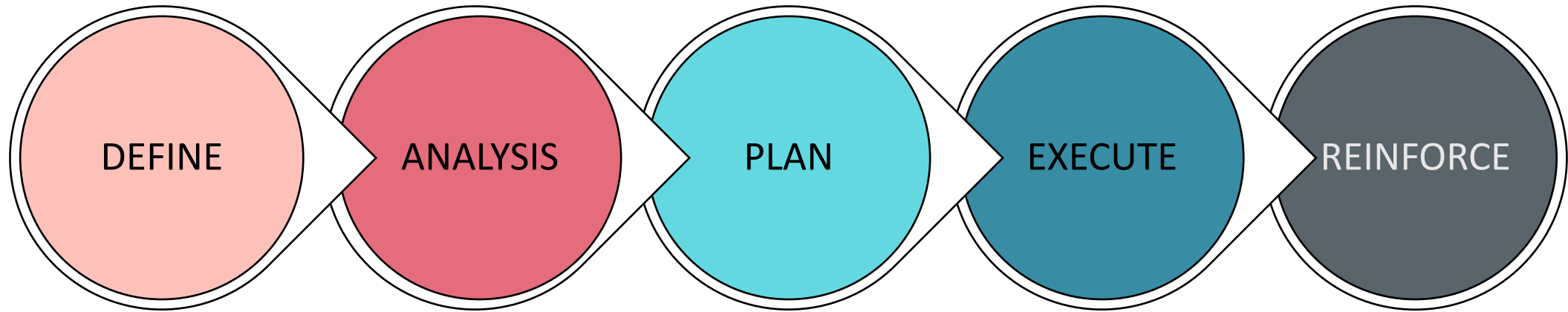
- **Get personal**

- It is critical for leadership to understand the impact change has on an individual.
- Are team members allowed to ask questions to better help them handle and manage the change they are experiencing?

- **Be ready for the unplanned**

- Nothing ever goes exactly as planned
- Incorporating the ability to adjust is a necessary part of change management

The Change Management Process



The Change Management Process

- **Define**
 - Problem
 - Ideal solution(s)
 - Scope
- **Analysis**
 - Stakeholders (who is involved)
 - Align expectations and perceptions
 - Risks
 - Costs
- **Plan**
 - Steps
 - Communication
 - Process modeling

The Change Management Process

- **Execute**

- Measures, metrics and reporting
- Tools

- **Reinforce**

- KPI's (Key Performance Indicators)
 - KPIs are powerful tools if they are used as indicators of the delivery of the goals
 - If the KPIs become the goals, then they turn into toxic material that will inhibit performance and improvement
- Rectify pain points
- Address fears
- “Tweak” plan and processes

KPI's vs Metrics

KPIs	Metrics
All KPIs are metrics	All metrics are not KPIs
KPIs give a holistic view of the performance of different functions	Metrics give you a picture of how different activities rolled out within the function are progressing
KPIs tell you where you stand with respect to the overall goal	Individual metrics do not give any insights on there own

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- **Determine the quality of the information generated by the program and assess whether it is adequate to manage the process.**
 - How well does it follow the principles of change management?
 - How well does it follow the change management process?
- **If the program does not follow the principles and processes then we have an item of concern and opportunities for improvement.**

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- **Assess performance metrics**
 - For their existence
 - Effectiveness
 - Monitoring activities
 - Response to any program deviations.

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- **Evaluate the risk management controls in place**
 - What are they using?
 - Are they quantifiable? objective, data driven.
 - Are they qualitative? subjective, based on institutional knowledge.
 - The goal is that risk management tools be quantifiable.
 - Are they preventive, detective or corrective?
 - They may want to consider a good balance between.
 - Are they effective to evaluate and mitigate risk?

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- **Define tests to confirm the operational effectiveness of change management activities including.**
 - Management and staff interviews.
 - May provide insight as to KPIs being indicators of the delivery of goals or are they the goals themselves
 - Should include all the stakeholders.
 - Is everyone in understanding and on board?
 - Documentation reviews.
 - How are they documenting it?
 - Report reviews.
 - How do they communicate it?
 - Data analysis.
 - How are they monitoring/tracking it?

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- **Address items of concern and recommend opportunities for improvement**
 - Procedure effectiveness in addressing and outlining the process
 - Tools used for change management
 - Documentation and retention
 - Follow up and evaluation
 - Training
 - Regulatory requirements
 - Indicators of poor change management

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- **Some indicators of poor change management**
 - Unauthorized changes.
 - Intolerance of unauthorized changes is fundamental to the long-term success of change management programs
 - Unplanned outages, shutdowns
 - Indicate operational problems, and encourage a reactionary environment (firefighting)
 - Fighting fires is not how you stay on top of change management
 - Low change success rate
 - Good change management involves good testing
 - If changes must be “backed out” it is an indicator of poor testing that failed to identify problems in the early stages.

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- **Some indicators of poor change management**
 - High number of emergency changes
 - Emergencies should be emergencies and happen infrequently
 - Poor planning of changes results in a high number of changes
 - Delayed implementations
 - Typically, a sign of unrealistic plans or poor resourcing decisions
 - Good change management practices encourage good planning and more achievable goals over time.

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- **Procedure considerations**

- Do procedures describe the actions to be taken if a change is proposed to a starting material, product component, process equipment, process environment (or site), method of production or testing or any other change that would affect quality?
- Does the SOP address review and approval of changes?
- If changes are classified “major” or “minor” does the procedure clearly define the differences?
- Does the procedure include criteria for the justification of the change?
- Does the procedure address who will evaluate the proposed changes?

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- **Procedure considerations**

- Does the procedure address the process for cancelling a change and is a rationale included?
- Does the procedure describe the process to close a change (after all regulatory approvals...)?
- Does the procedure address delays and the documentation of delays?
- Does the procedure provide allowance for emergency or temporary changes under described conditions?

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- **Procedure considerations**

- Are there requirements for change controls implemented during normal or routine maintenance activities to be documented in a formal change control program?
- Does the procedure address “like for like” changes for traceability and history?
- Does the procedure include criteria to determine if changes will require qualification/re-qualification, validation/re-validation or regulatory filing?
- Does the procedure address change control follow up; formalization, roles and responsibilities.

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- **So what can we take away from all this?**
- **Understand the principles of change management**
- **Understand the process of change management**
- **Understand the difference between KPI's and Metrics**
- **Identify indicators of poor change management**
- **Communicate the items of concern and opportunities for improvement.**



THANK YOU