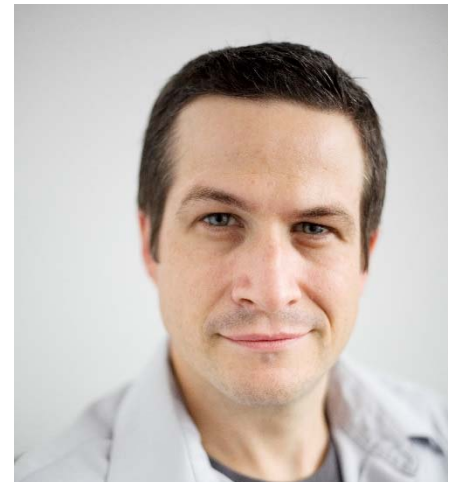


Building Effective Document Control in an ISO 9001:2015 Quality Management System

Tim Lozier, Director of Product Strategy at Verse Solutions



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Agenda

- **Review some of the key drivers in quality today**
- **Outline the market view**
- **Delve into Document Control Elements**
 - Handling all document types
 - Initiating proper rules for approval
 - Connecting Employee Training
 - Making changes to documentation
 - Reporting on effectiveness of the Document Control System
 - Filtering data and document security
- **How Document Control effectiveness impacts you in the ISO 9001:2015 framework**
- **Summary**



First...a Baseline

....We asked the market about their mindset on Quality Management...

**...specifically around who they are,
what drives them, and...**

...where technology fits into their world.



Who Did We Talk To?

What is the size of your organization (in revenue)?

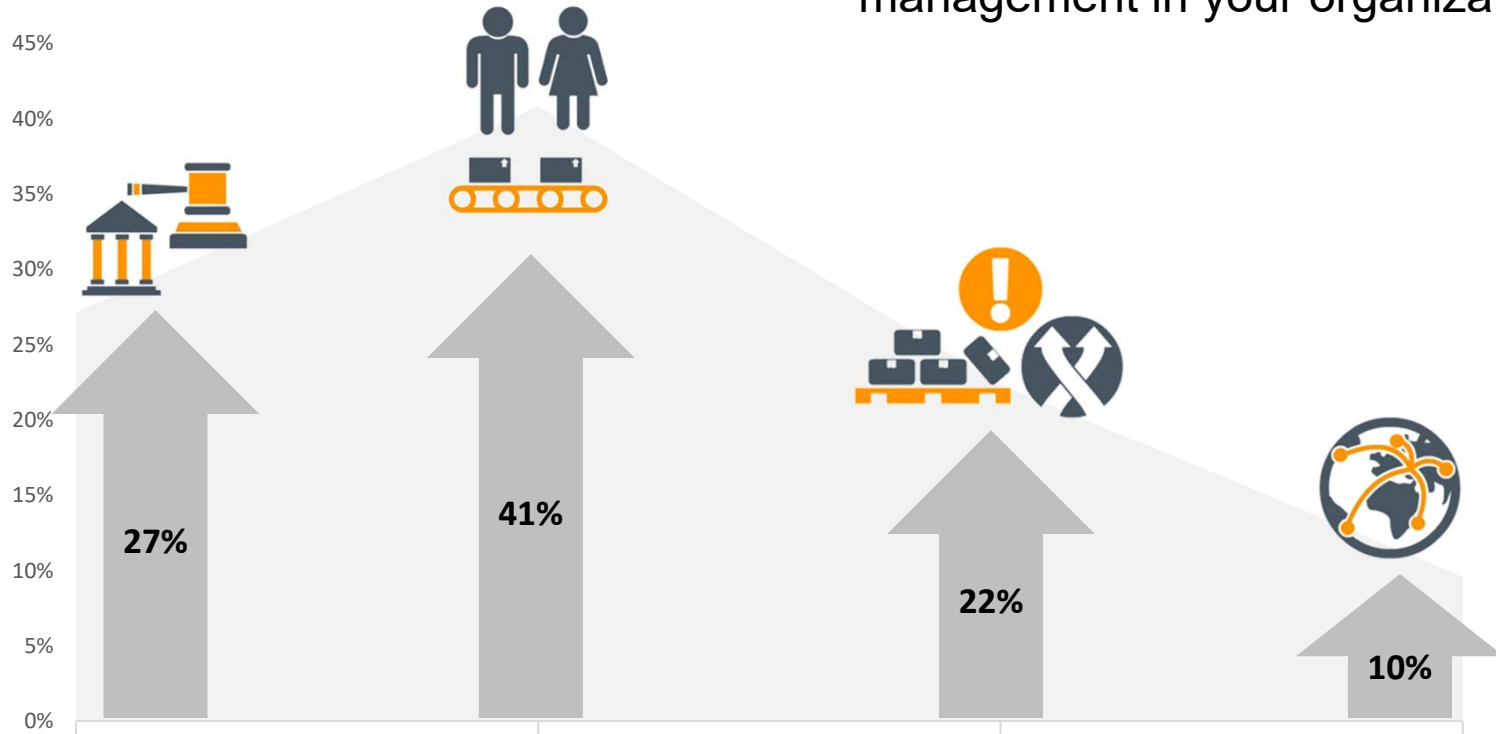


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What's Driving Quality Management?

What is the primary driver for quality management in your organization?



Registration to ISO and similar international standards

Meeting customer and product regulatory requirements

Product and process improvement driven by quality (e.g. reduce risks and variations)

Strategic directives for operational efficiency (e.g. reduce costs and product defects)



What's Driving Quality Management?

What is the primary driver for quality management in your organization?

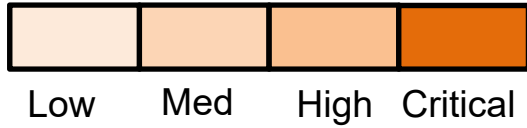


It's about getting your house in order and the culture of quality:

The majority of organizations are focused primarily on ensuring they are staying compliant with their standards and regulations, while satisfying the customer needs. Part of getting your house in order is effective processes, documentation and following those properly



The Quality Management Landscape



How critical are the below processes toward achieving your quality management objectives?

Document Control/
Training

NCM /
Deviations

Supplier
QM

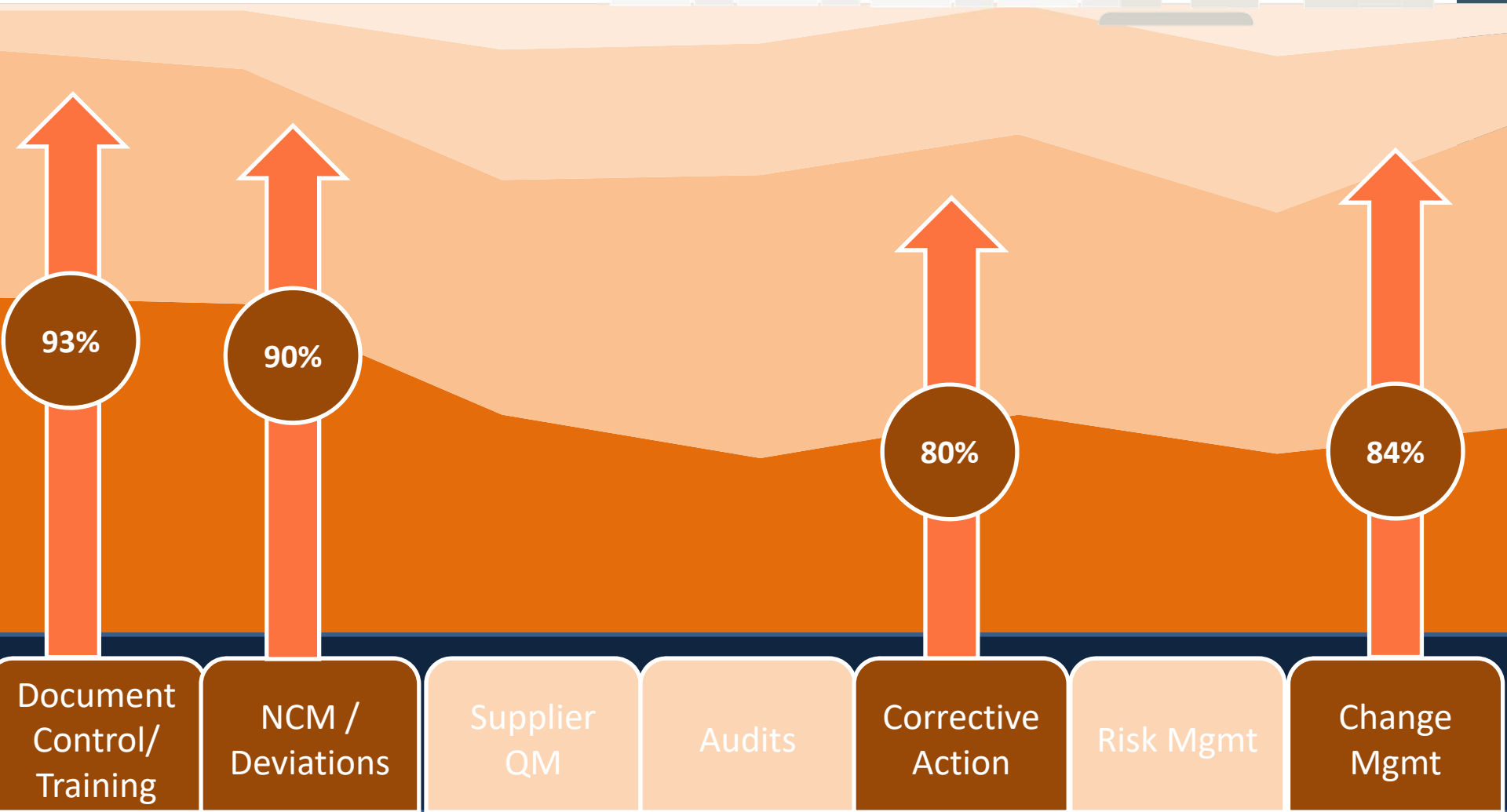
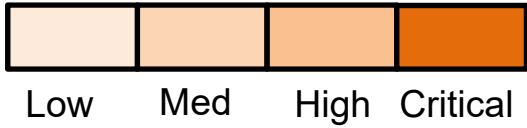
Audits

Corrective
Action

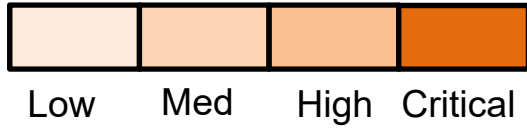
Risk Mgmt

Change
Mgmt

The Quality Management Landscape



The Quality Management Landscape



**This is where I'm spending today:
So...
How is this being managed?**

93%

90%

80%

84%

Document
Control/
Training

NCM /
Deviations

Supplier
QM

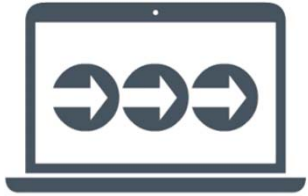
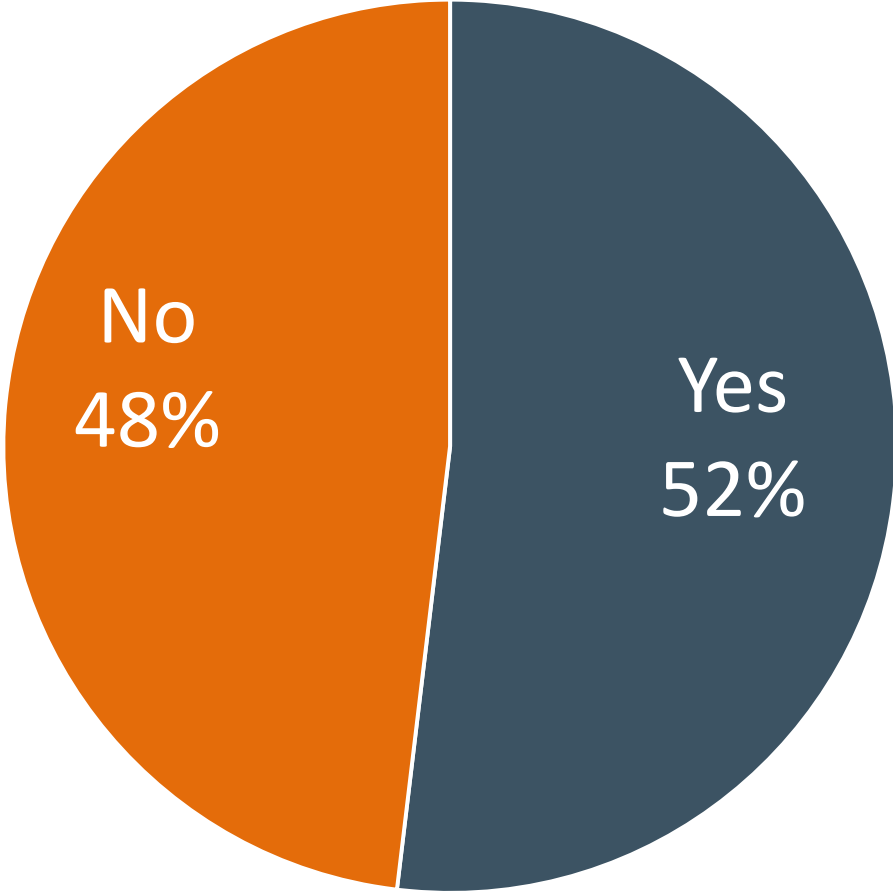
Audits

Corrective
Action

Risk Mgmt

Change
Mgmt

Are You Currently Using Automated Solutions?



(whoa.)



If You're Not Automated, What Are You Using?



Email / spreadsheets

50.8%

Paper-based, manual systems

49.2%

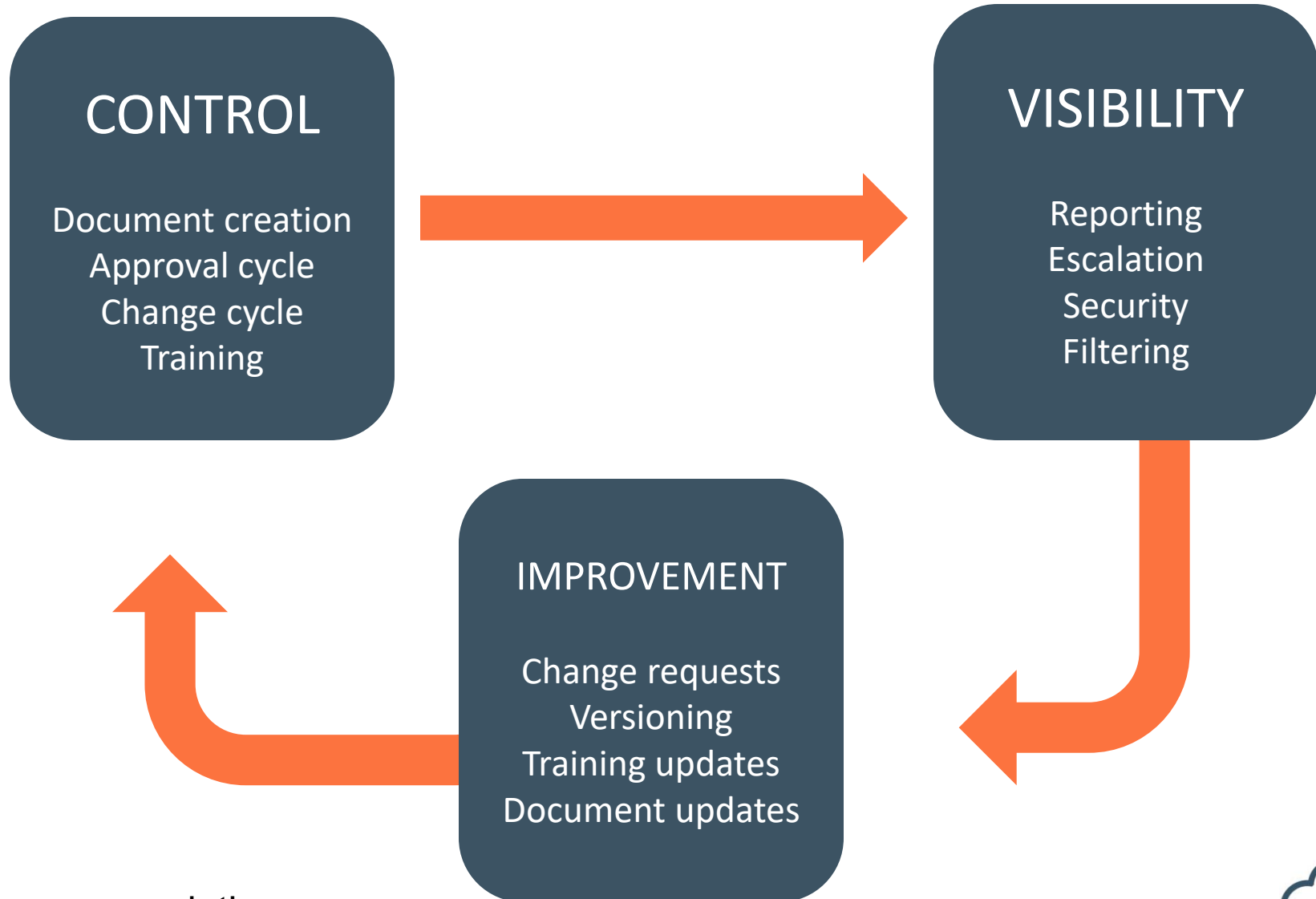


Are we introducing unnecessary **RISK** into the equation?

- Email is not a tracking tool
- Spreadsheets can be risky
- What if a process changes? How do we impact change?
- What about the processes we **DON'T** know about?



What Is Needed in Document Control?



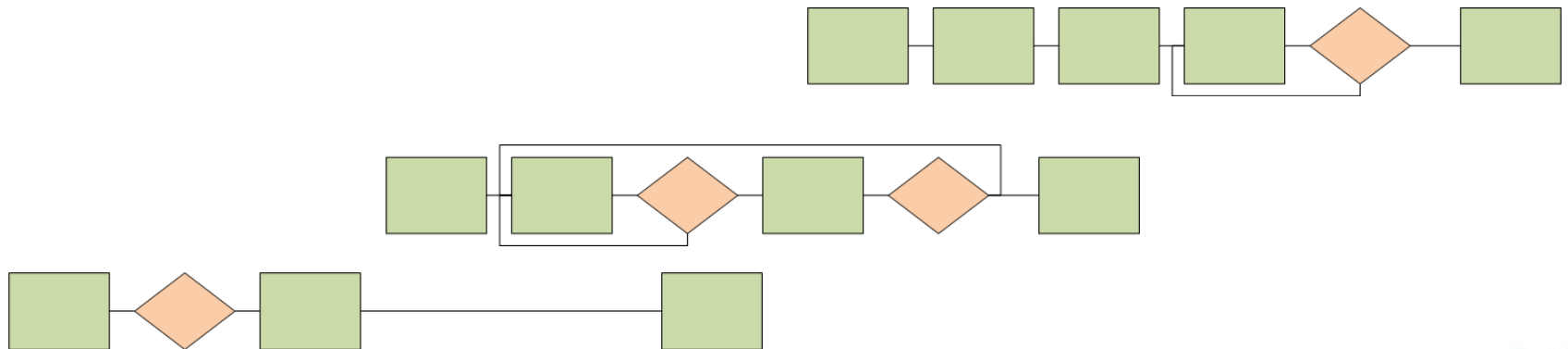
Why Document Control?

- **Central to Quality, Compliance Management Systems**
- **Processes are what drives compliance**
- **Keeping control of our processes provides a strong level of governance; Document Control keeps processes “in check”**



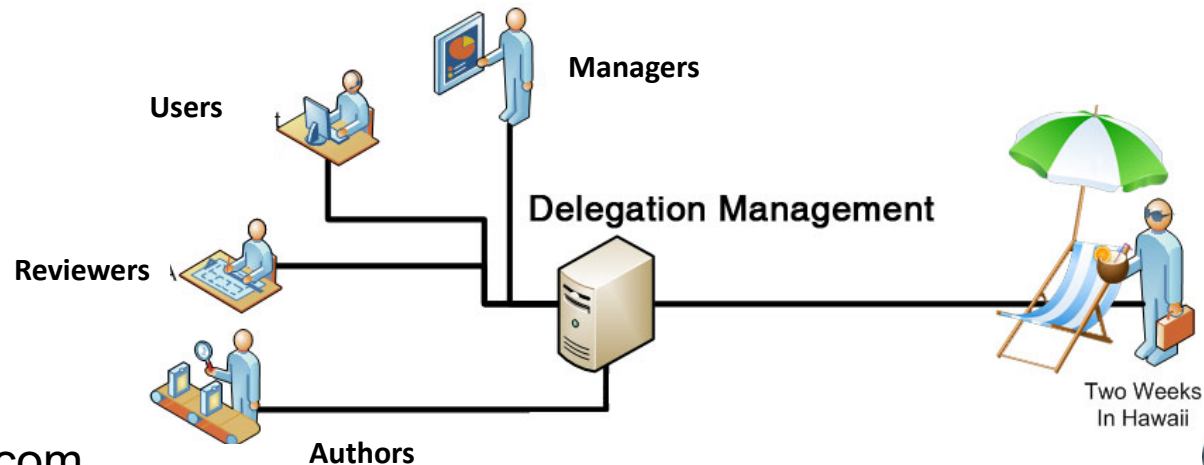
1. Workflows for All Document Types

- **Not all documents are the same!**
- **Procedures | Work Instructions | Specifications | Job Descriptions**
 - All may have different reviewers/approvers
 - May have different “Meta Data” – way to describe the record
- **Workflows need to be flexible for all document types**
 - Each type should have its own dedicated workflow
 - Multiple routing options – intelligence in the workflow
- **Flexible workflow is a cornerstone of process efficiency**



2. Review and Approval Business Rules

- **Reality – we don't operate in a linear fashion**
 - Approvals of documents don't always happen linearly
 - Work gets delayed; people go on vacation; reviews move back and forth in the workflow
 - Document Control Systems should account for reality
- **Document Control should have flexible routing options**
 - Recognition of multiple approval paths (sequential, concurrent, voting, etc.)
 - Delegation Rules – Assign delegates while someone is out
 - Escalation Rules – Escalate documents approaching due dates



3. Integration with Employee Training

- **Documents are only as good as the people trained on them**
 - Processes cannot be adhered to if no one is trained on them
 - How can we ensure the most recent documents are the ones we are trained on?
- **Linking Document Control to Employee Training Systems**
 - Part of the workflow – “Add to Training” on documents
 - Based on meta data, we can automatically designate training plan
 - Awaiting Release – do not release a document to the world until training process is complete
- **Direct link between Document Control and Training closes the loop on the “processes to people” workflow**



Speaking of Integration....

- **MS Office is still the primary document type**
 - We all use Word, Excel, PowerPoint, Visio
 - Documents are best created in these formats
- **Document Control should integrate – Why?**
 - Preserve the “Meta Data” – document identification syncs with data within the Doc Control form
 - Integration maintains a consistency with the Office files and the Doc Control system
- **Office Integration provides a link from the actual document to the form data that controls it!**



4. Seamlessly Make Change Requests

- **Document Control is not a “Set it and Forget it” thing**
 - Processes change, documents change; repeat
 - Document Control should be able to foster document changes
- **Change is a process that must be managed**
 - Cannot make changes “ad-hoc” - changes must be approved
 - Workflow is an important part of change requests
 - Change request must have the same robust workflow, review and approval process
- **Controlled documents stay live until the change is complete!**
 - Approved documents are one thing, but should also become active once training is complete – (Awaiting Release phase)



change management



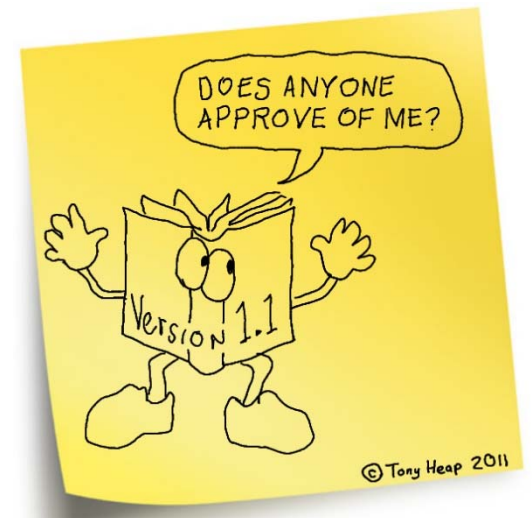
5. Searching and Reporting

- **Back to the concept of “meta data”**
 - Helps to categorize the documentation
 - Helps to find the documents
 - Ties documentation together
- **Searching for records and documents**
 - Needs to be easy; needs to be central
 - Filter and Find – and do it quickly
- **Reporting on effectiveness**
 - Be able to see what’s completed, still ongoing
 - Escalate on which documents are overdue
 - Tie into training – what documentation has been trained on?



6. Filtering and Security

- **It's called Document CONTROL for a reason**
 - Approved records need security and control
 - Read-only, locked-down documentation
- **Access to documents needs to be variable**
 - Who can see which documents?
 - Who can issue changes?
 - Who can approve changes?
- **Proper revisioning is important**
 - Visibility into the most current version
 - Archive old copies – get them out of the way
 - Single Source of the Truth – in one place



© Tony Heap 2011



Why Automation Fits into the ISO Dynamic

Quality is pervasive to the entire organization

Quality needs a central place to “live”

Need centralized, common place to collaborate on quality

Need to build a single source for visibility and control

This new interpretation brings ISO to a new level of focus, and also recognizes the changes in technology and best practices for quality management.

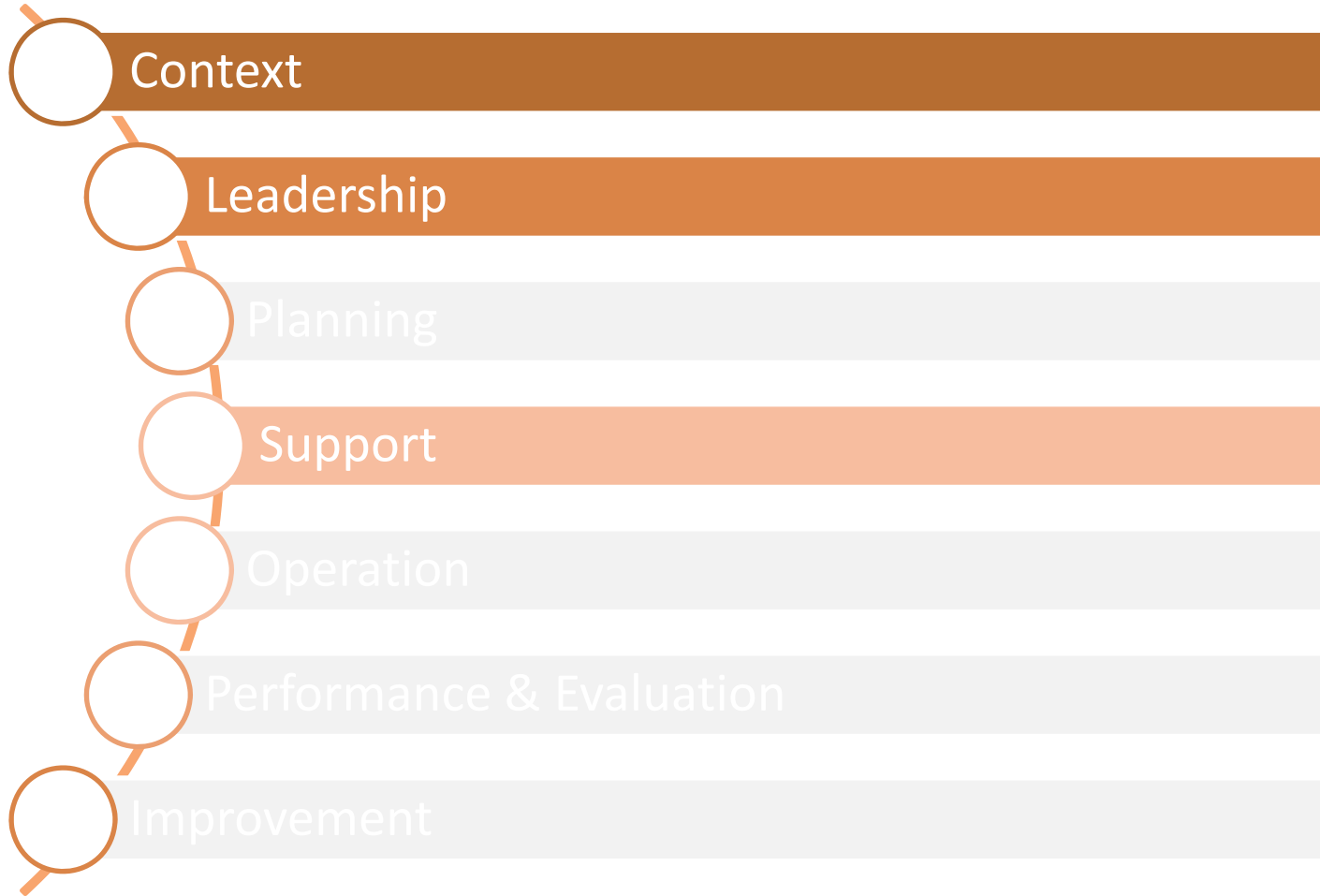
This is where automation impacts quality.



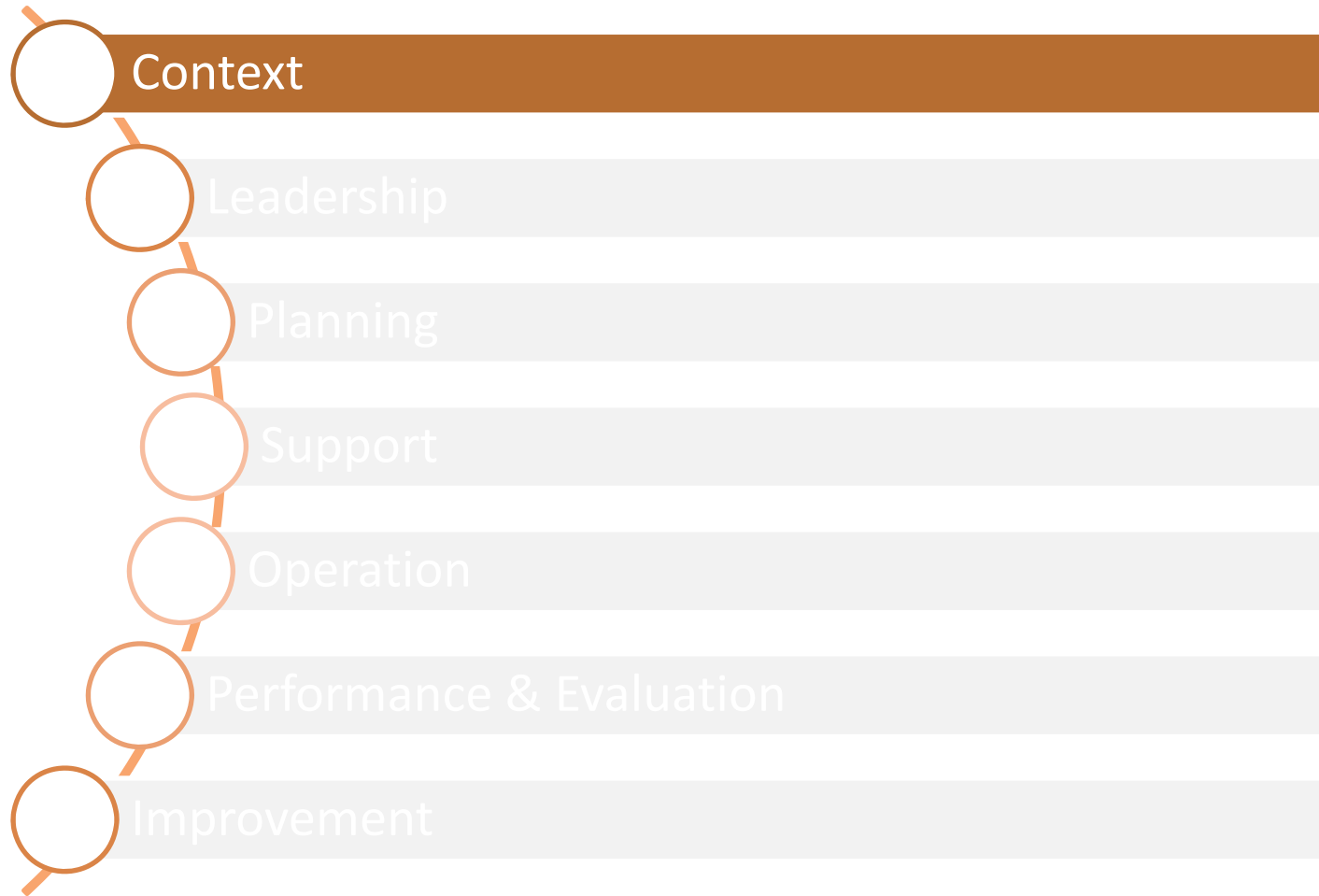
Where Does Doc Control Meet ISO?



Where Does Doc Control Meet ISO?



Where Does Doc Control Meet ISO?



Where Does Doc Control Meet ISO?

Context

Mapping out Your QMS:

How your organization will manage quality

Technology fits in Section 4, in which there is language centered on establishing a “Process-Based Quality Management Systems”



Where Does Doc Control Meet ISO?

Context

Technology Consideration:

Collaborating on Processes

- Build a feedback loop on managing quality
- Everyone sees the process, agrees upon it
- Visibility, control....ENROLLMENT!



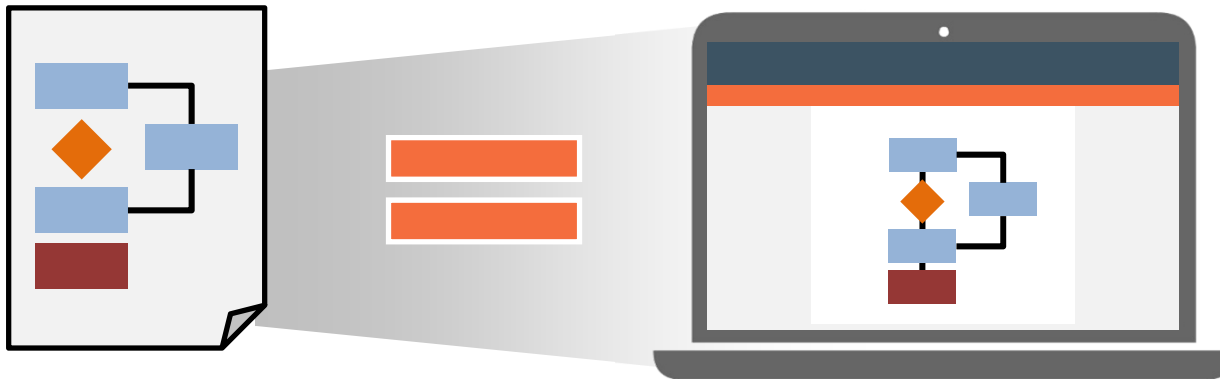
Where Does Doc Control Meet ISO?

Context

Technology Consideration:

Flexibility of a Process-Based Solution

- Map the solution to your processes
- Configurable – workflows, forms, fields, etc.
- Solution needs to match your unique processes
- Solution needs to adapt!



Where Does Doc Control Meet ISO?

Context

For instance:



Draft

Initial
Approval

Review

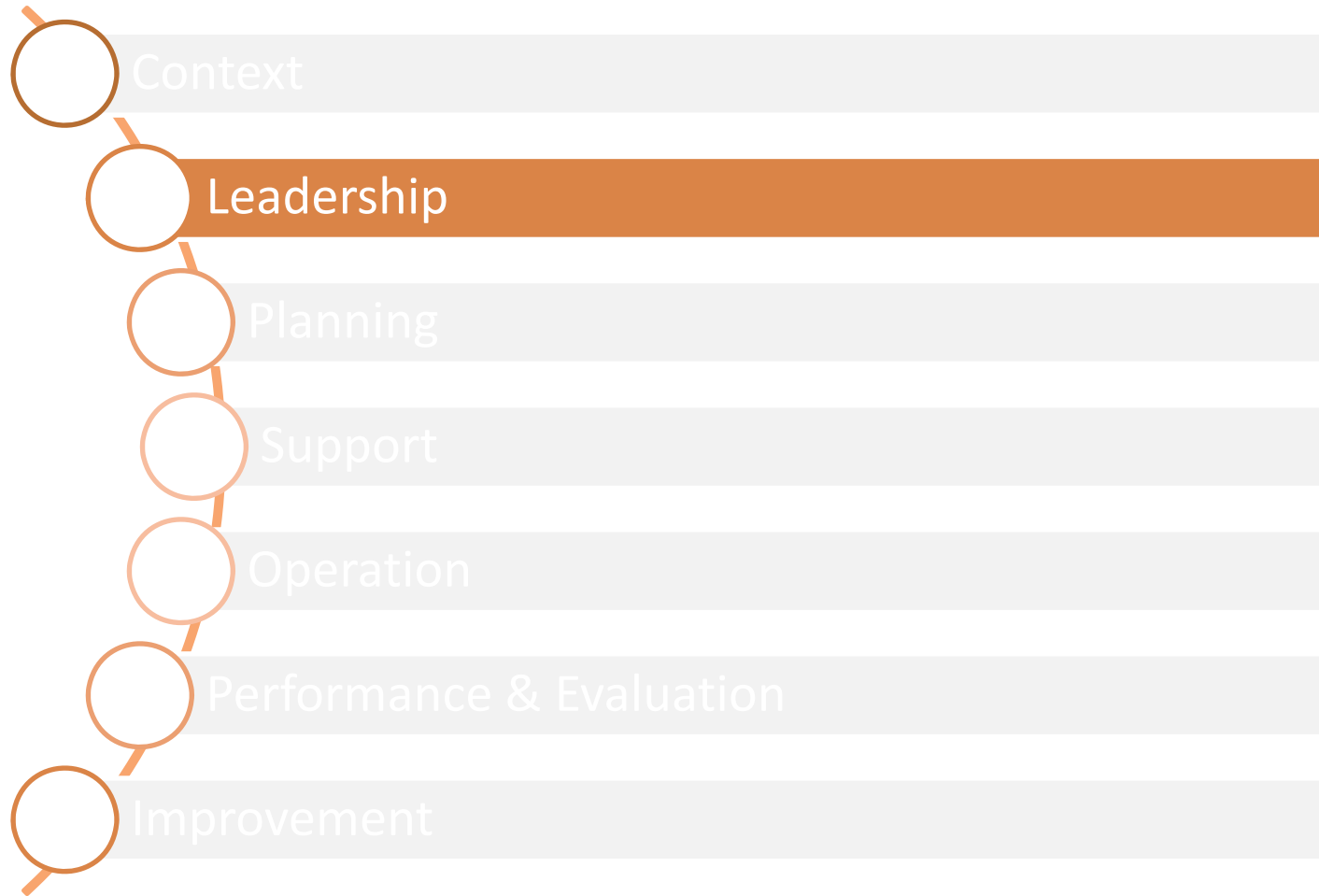
Final
Approval

Awaiting
Release

Approved



Where Does Doc Control Meet ISO?



Where Does Doc Control Meet ISO?

Leadership

Building Leadership

No one representative; establish a focus on quality, customer and companywide commitment

Establish a quality “policy” – NOT NECESSARILY A MANUAL –broader look at leading quality



Where Does Doc Control Meet ISO?

Leadership

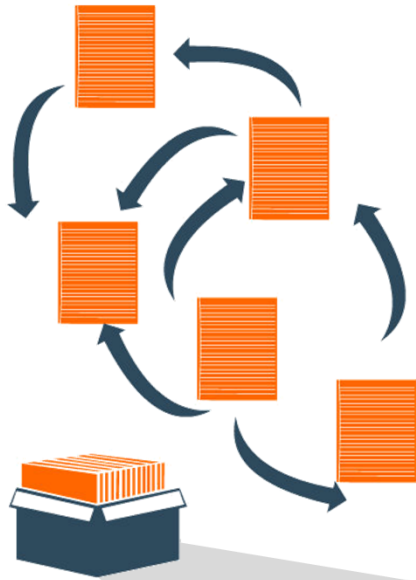
Technology Consideration:

Centralized, Common Solution

- All processes are central to the organization
- Visibility and access of the solution

Document Control:

- Central repository, all policies, roles and access
- Consistency in communication, dissemination of information



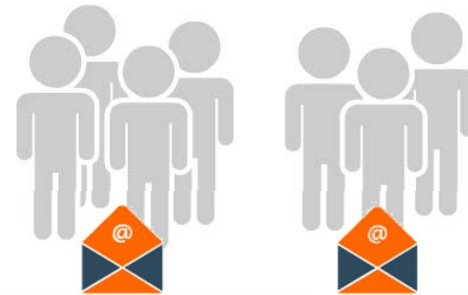
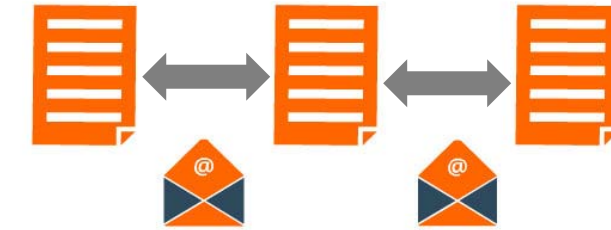
Where Does Doc Control Meet ISO?

Leadership

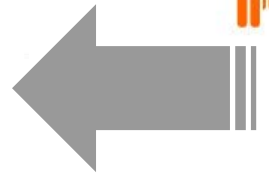
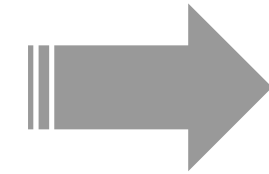
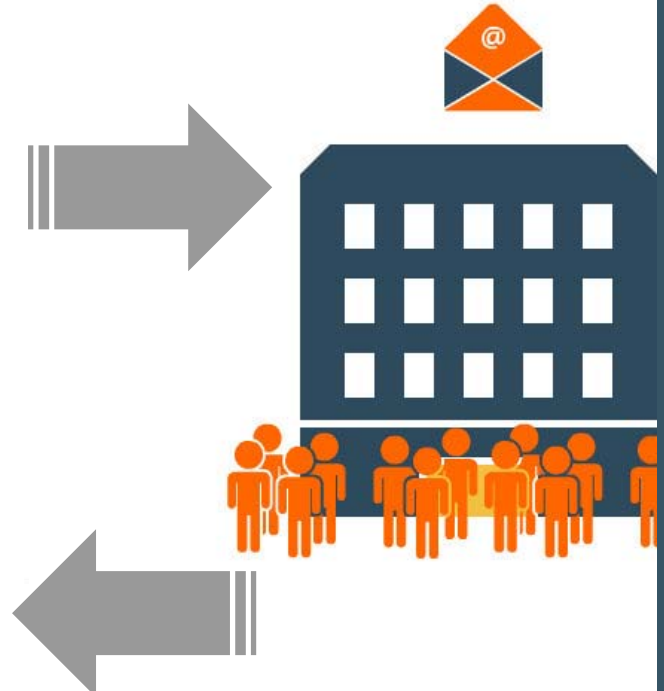
For instance:



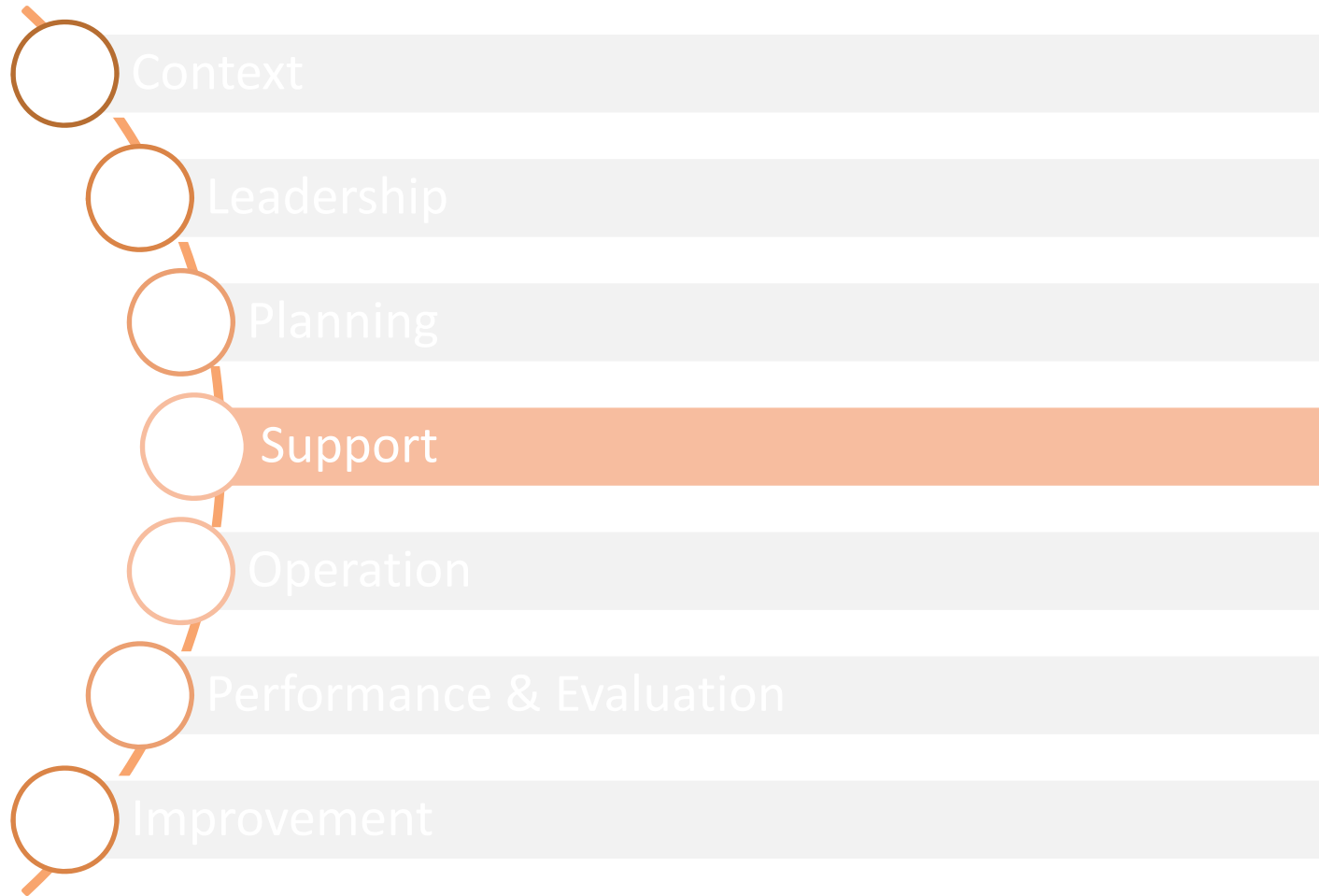
REVIEW, APPROVAL



REVISION CONTROL



Where Does Doc Control Meet ISO?



Where Does Doc Control Meet ISO?

Support

How Do We Deliver Quality?

Focusing not only on the people but also the infrastructure

Ensuring competency and documentation



Where Does Doc Control Meet ISO?

Support

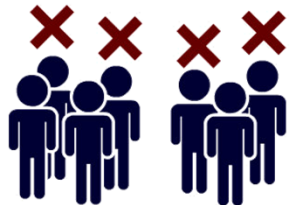
Technology Consideration:

Document Control & Training

- Centralized your documentation - Single Source! Controlled – no errant copies

PLUS.....

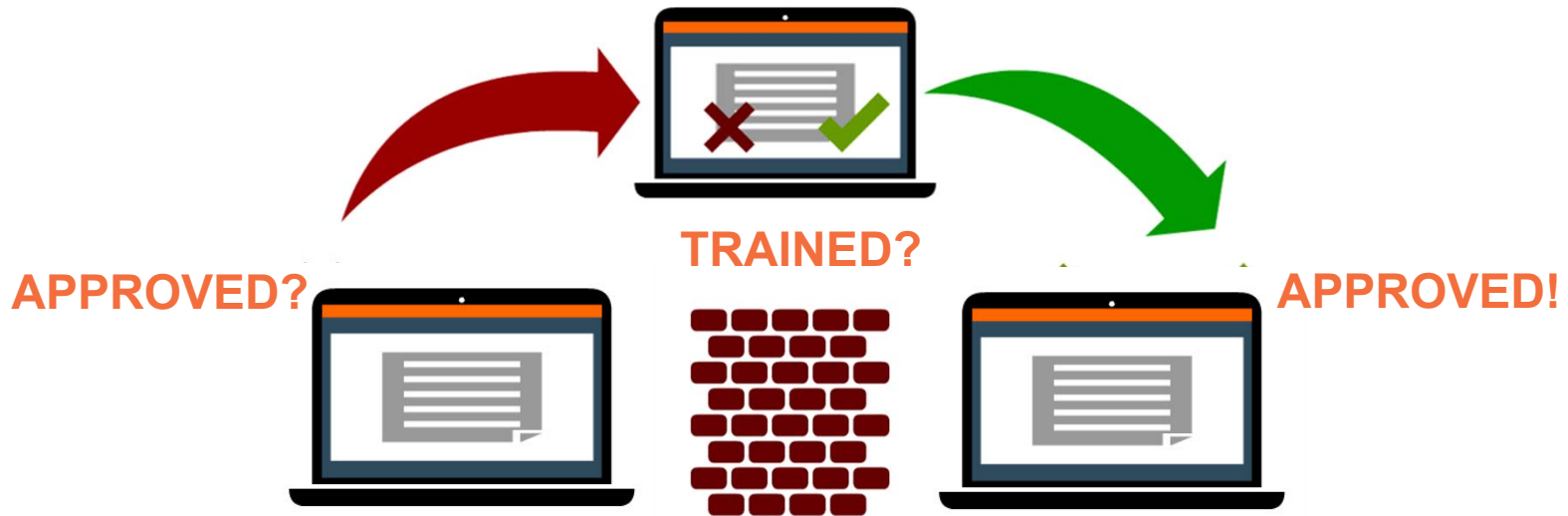
- Integrate documents to your training
- Link approved documents to a training system
- Approved documents are automatically flagged
- Training – take tests, self-certify, update records



Where Does Doc Control Meet ISO?

Support

For instance:



Draft

Initial Approval

Review

Final Approval

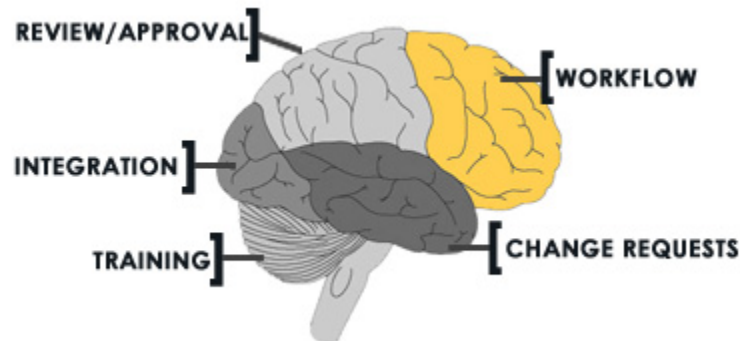
Awaiting Release

Approved



Document Control – “The Brains”

- **If Corrective Action is the heart of the Compliance System, then the Document Control System is the “Brains”**
- **Holds all the information of the processes’ records**
- **Sets the foundation for compliance; how we behave, act, enforce and regulate**
- **A good Document Control System will:**
 - Automate the Review and Approval process, intelligently
 - Provide seamless link to controlled documents
 - Initiate an intelligent and process-driven management of change
 - Provide a way to educate employees on newly released documents



Thank you! Questions?



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