URAC Asembia Pharmacy Accreditation Workshop

April 27, 2025

12:00 p.m. – 4:30 p.m.

Resort World Las Vegas

Workshop Agenda

Time	Activity
Noon – 12:45 pm	Lunch
12:45 – 1:00 pm	Welcome & Warm-Up
1:00 – 3:00 pm	Foundational Focus Area Education
3:00 – 4:00 pm	Specialty Pharmacy Revision
4:00 – 4:30pm	Networking

Faculty	Role
Heather Bonome	*Director, Pharmacy*
Heidy Davis	*Pharmacy Reviewer & Educator*
Jenn Richards	*Senior Director, Product Development*
Mallory White	*Pharmacy Reviewer*

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URAC's Pharmacy Quality Management® Programs

Pharmacy

- Infusion Pharmacy Accreditation
- Medicare Home Infusion Therapy Supplier Accreditation
- Mail Service Pharmacy Accreditation*
- Pharmacy Benefit Management Accreditation
- Pharmacy Services Accreditation (chose up to four modules)
  - Community Dispensing
  - Drug Therapy Management
  - Point of Care Testing
  - Vaccine Administration
- Rare Disease Pharmacy Center of Excellence Certification
- Specialty Pharmacy Accreditation*
- Specialty Pharmacy Services

Supplemental Designations

- Opioid Stewardship
- Measurement-Based Care
- Integrated Behavioral Health
- Transitions of Care

** Denotes program is available for small pharmacies*

Focus Areas Under Revision

Foundational Focus Areas – *Not for Review*

- Risk Management (RM)
- Operations and Infrastructure (OPIN)
- Performance Monitoring and Improvement (PMI)
- Consumer Protection and Empowerment (CPE)
- Reporting Performance Measures (RPT)

Program Focus Areas – *Under Review*

- Pharmacy Operations (P-OPS)
- Medication Distribution (P-MD)
- Patient Services and Communications (P-PSC)
- Patient Management (PM)

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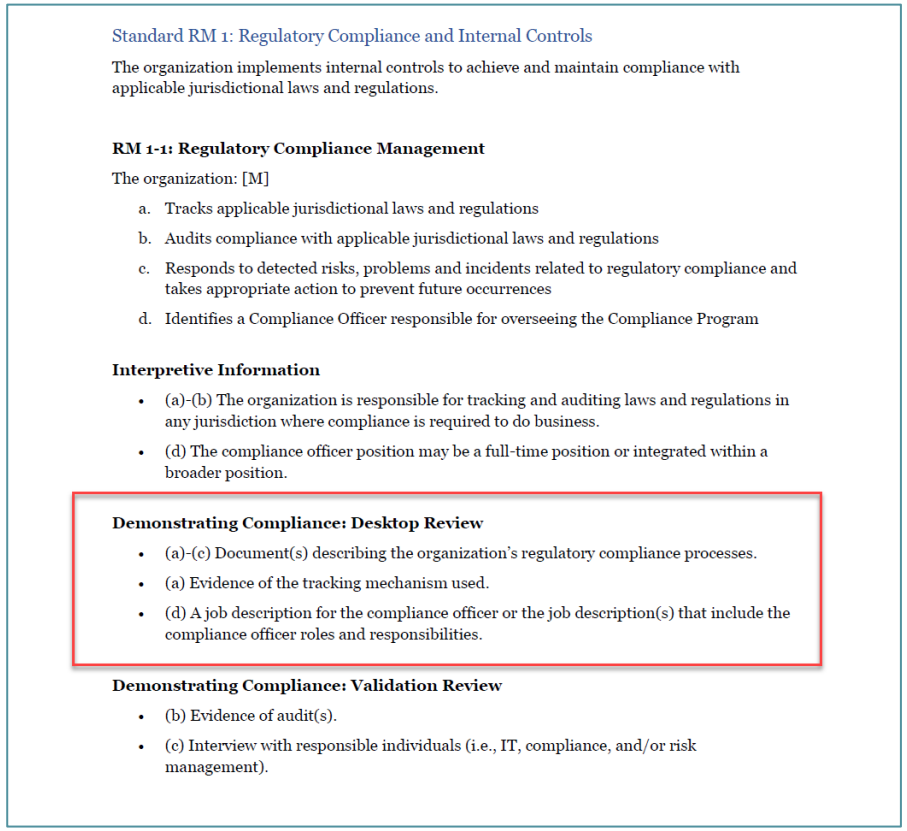
Quick Primer on Desktop Review Documents

Documents & Citations

Follow "*Demonstrating Compliance*" section of Program Guide

Submit one or two documents (max of three)

Add clear and specific citations



Standard RM 1: Regulatory Compliance and Internal Controls

The organization implements internal controls to achieve and maintain compliance with applicable jurisdictional laws and regulations.

RM 1-1: Regulatory Compliance Management

The organization: [M]

a. Tracks applicable jurisdictional laws and regulations
b. Audits compliance with applicable jurisdictional laws and regulations
c. Responds to detected risks, problems and incidents related to regulatory compliance and takes appropriate action to prevent future occurrences
d. Identifies a Compliance Officer responsible for overseeing the Compliance Program

Interpretive Information

- (a)-(b) The organization is responsible for tracking and auditing laws and regulations in any jurisdiction where compliance is required to do business.
- (d) The compliance officer position may be a full-time position or integrated within a broader position.

Demonstrating Compliance: Desktop Review

- (a)-(c) Document(s) describing the organization's regulatory compliance processes.
- (a) Evidence of the tracking mechanism used.
- (d) A job description for the compliance officer or the job description(s) that include the compliance officer roles and responsibilities.

Demonstrating Compliance: Validation Review

- (b) Evidence of audit(s).
- (c) Interview with responsible individuals (i.e., IT, compliance, and/or risk management).

Watch the Documents & Citations webinar on URAC's Client Information Hub https://clients.urac.org/

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Common Documents for Submission

Document(s)	Evidence	Sample	Job Description	Attestation
Formal documentation (P/P, SOPs, Workflow Documents)	Can be anything that demonstrates they are following the standard as specified in the language	An Example	Only when specified	NA
What documents are they holding their employees accountable for following?	Meeting minutes are required when stated		We do not require JDs for all staff	Risk Management

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Common Desktop Review Tips

Process

- Who, What, When, Where, and How

Timely Manner, Periodic, Prompt

- Defined by the organization

Metrics, Goals

- Measurable

Demonstrating Compliance on DTR

- Some standards are only reviewable on DTR

Select Foundational Focus Area Standards

Select URAC Foundational Focus Areas

Risk Management (RM)

- RM 1 Regulatory Compliance Management and Internal Controls
- RM 3 Business Continuity

Operations and Infrastructure (OPIN)

- OPIN 2-1 Clinical Staff Credentialing

Performance Monitoring and Improvement (PMI)

- PMI 1 Quality Management Scope
- PMI 2 Quality Data Collection and Evaluation

Consumer Protection and Empowerment (CPE)

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RM 1: Regulatory Compliance and Internal Controls

Standard Language

The organization implements internal controls to achieve and maintain compliance with applicable jurisdictional laws and regulations.

Intent

Promote Compliance

Create Internal Controls

Develop Oversight

Fix Identified Issues

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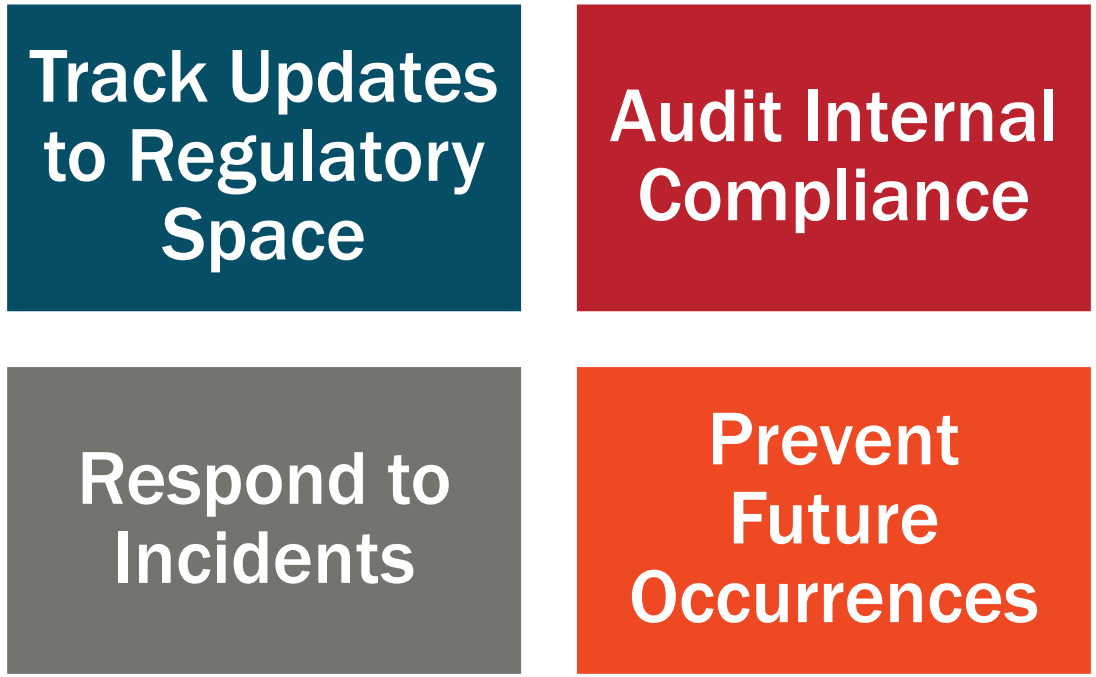
RM 1-1: Regulatory Compliance Management



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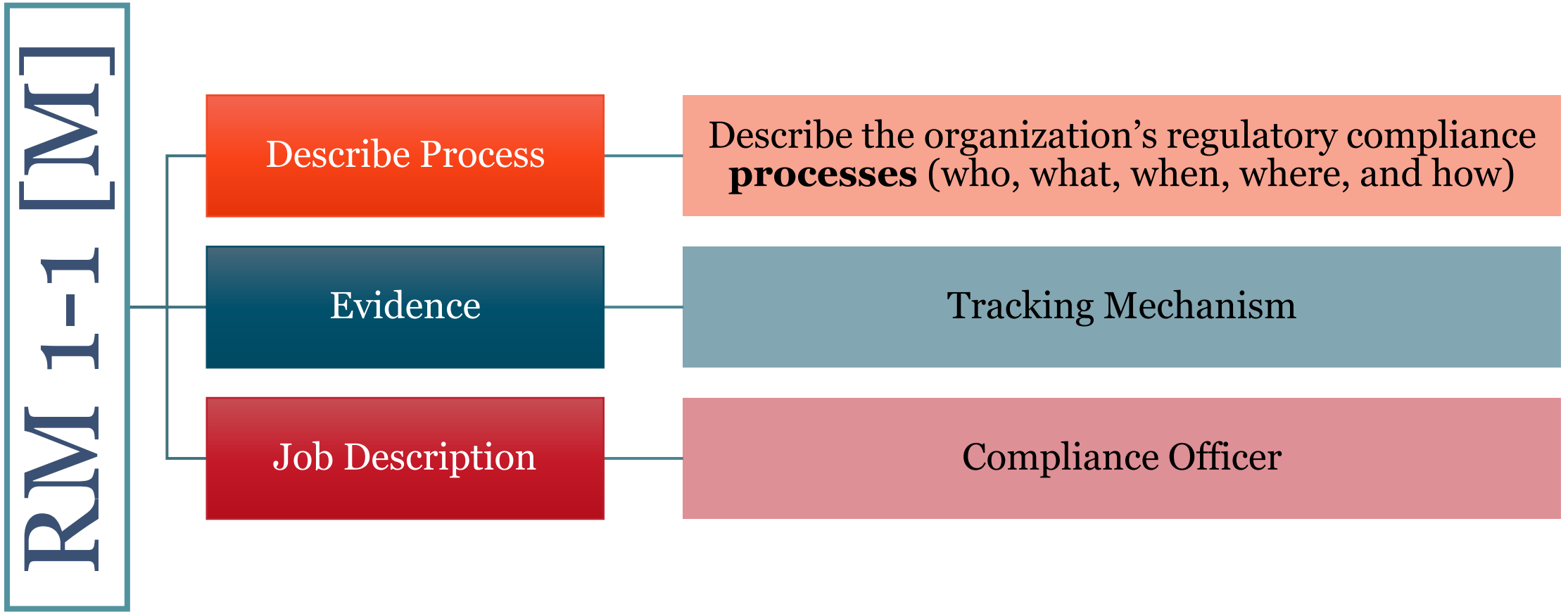
c. Responds to detected risks, problems and incidents related to regulatory compliance and takes appropriate action to prevent future occurrences

d. Identifies a Compliance Officer responsible for overseeing the Compliance Program

RM 1-1: Demonstrating Compliance

- Document(s) describing the organization's regulatory compliance **processes**.
- Evidence of the tracking mechanism used.
- A job description for the compliance officer or the job description(s) that include the compliance officer roles and responsibilities.

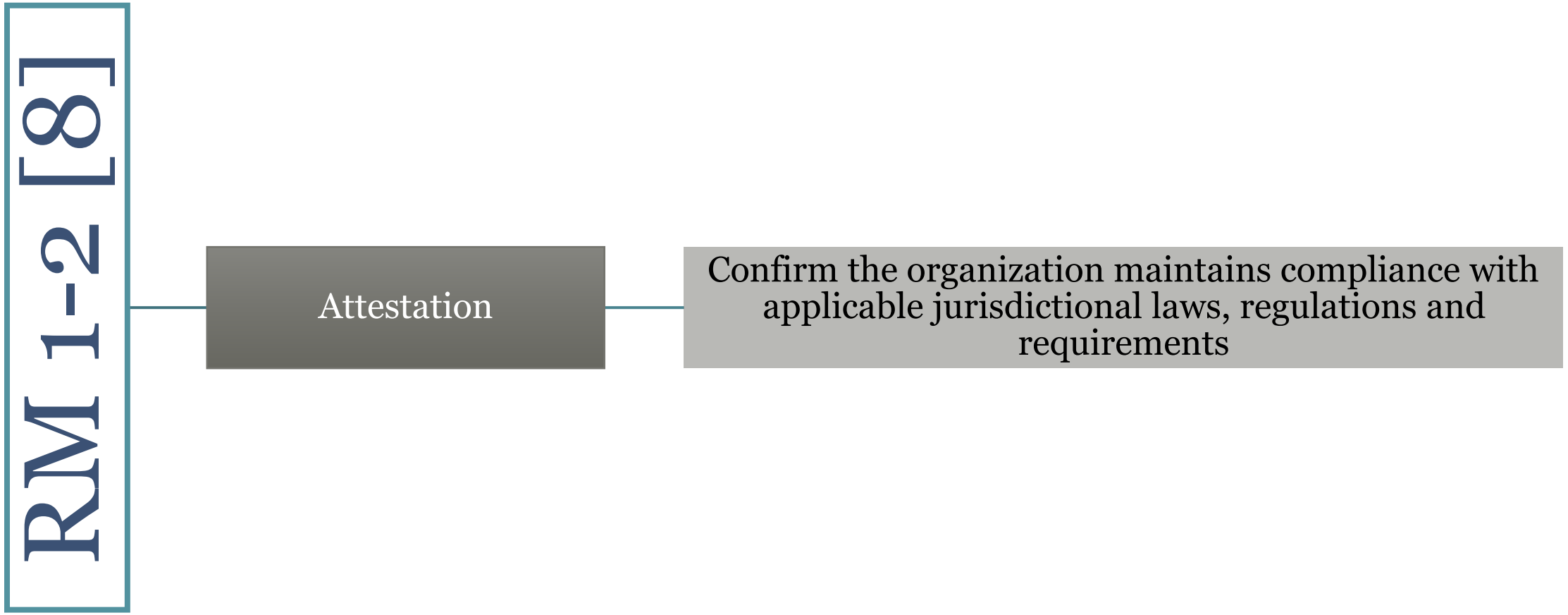
RM 1-1: What to Submit on Desktop



RM 1-2: Demonstrating Compliance

- An attestation confirming the organization maintains compliance with applicable jurisdictional laws, regulations and requirements.

RM 1-2: What to Submit on Desktop



RM 3: Business Continuity

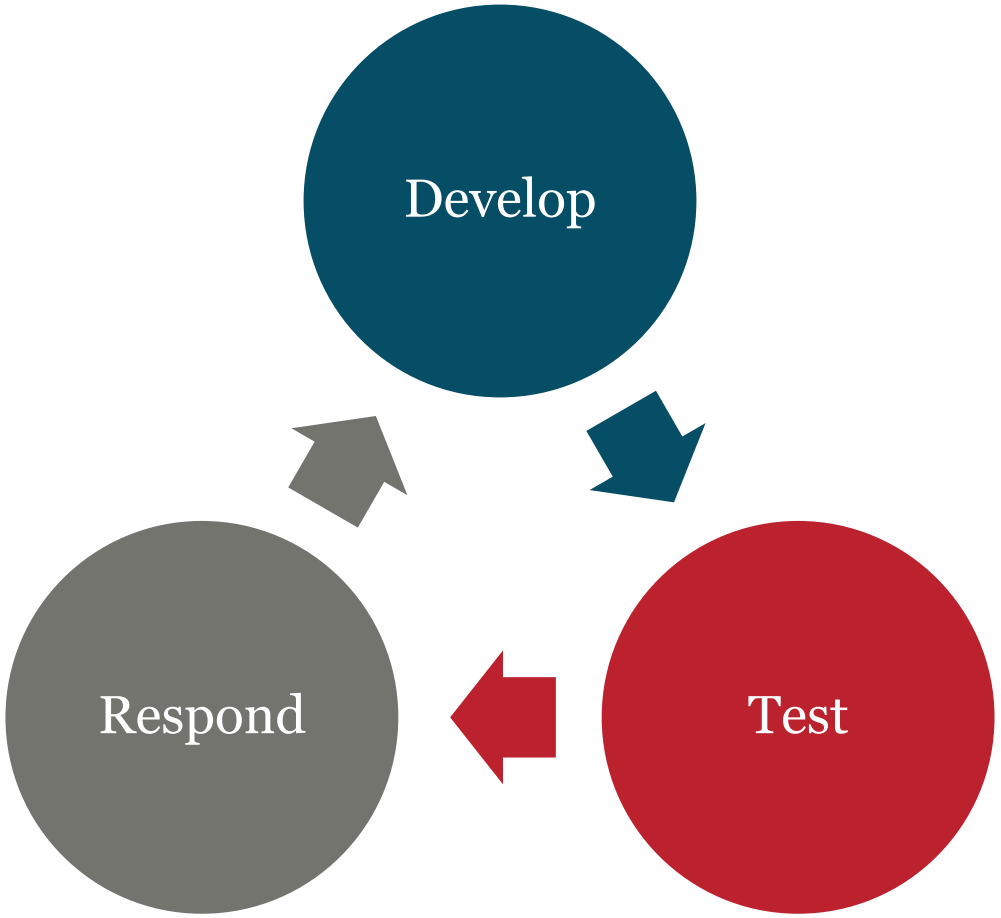
Standard Language

The organization maintains a business continuity plan designed to promote continuity of care during unplanned events.

Intent

Have a plan to maintain business continuity during disruptions

RM 3-1: Business Continuity Plan



The organization:

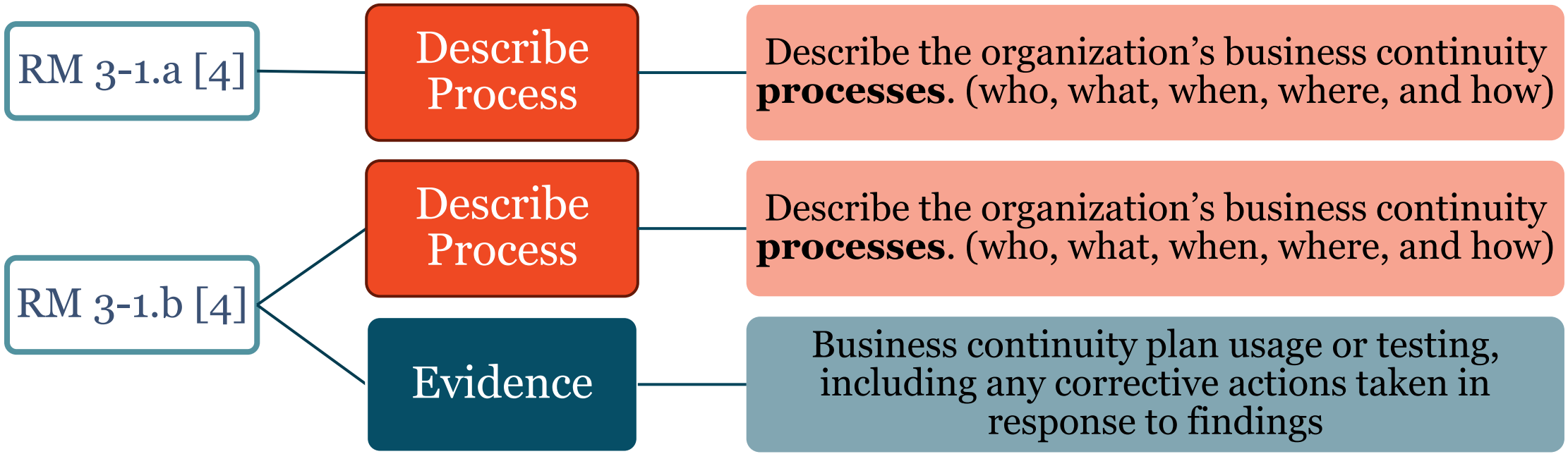
a. Maintains a business continuity plan, which: [4]
   i. Is developed by an inter-departmental team and approved by leadership
   ii. Outlines the systems and processes that must be maintained
   iii. Describes how business continuity is maintained given various scenarios

b. Requires the business continuity plan to be used or tested at least every 2 years and incorporate corrective actions and updates in response to any findings [4]

RM 3-1: Demonstrating Compliance

- Document(s) describing the organization business continuity **processes**.
- Sample documentation of business continuity plan usage or testing, including any corrective actions taken in response to findings.

RM 3-1: What to Submit on Desktop

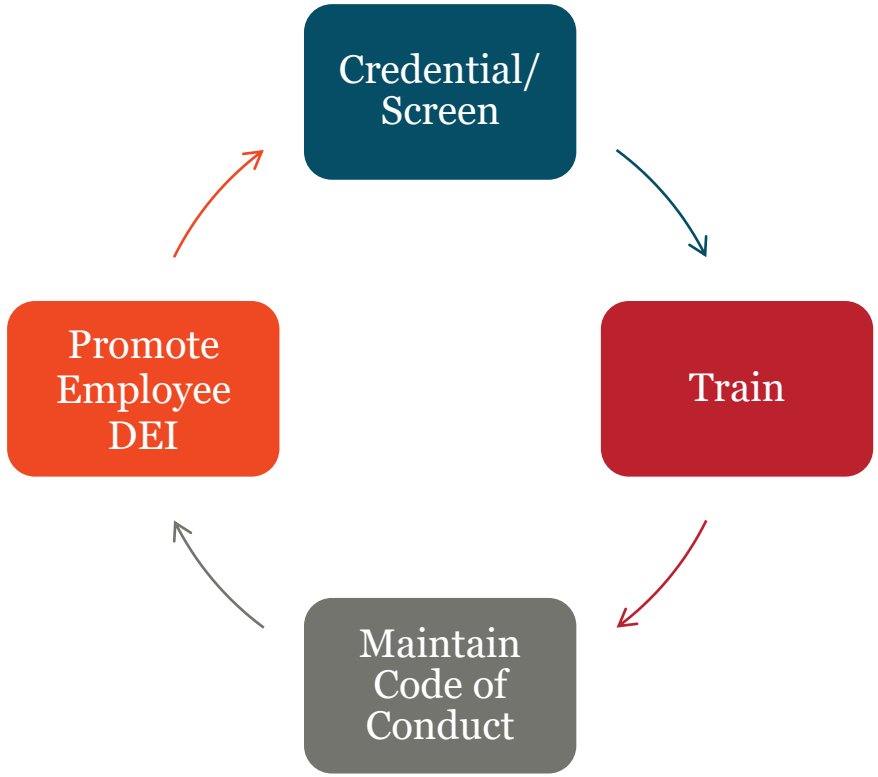


OPIN 2: Staff Management

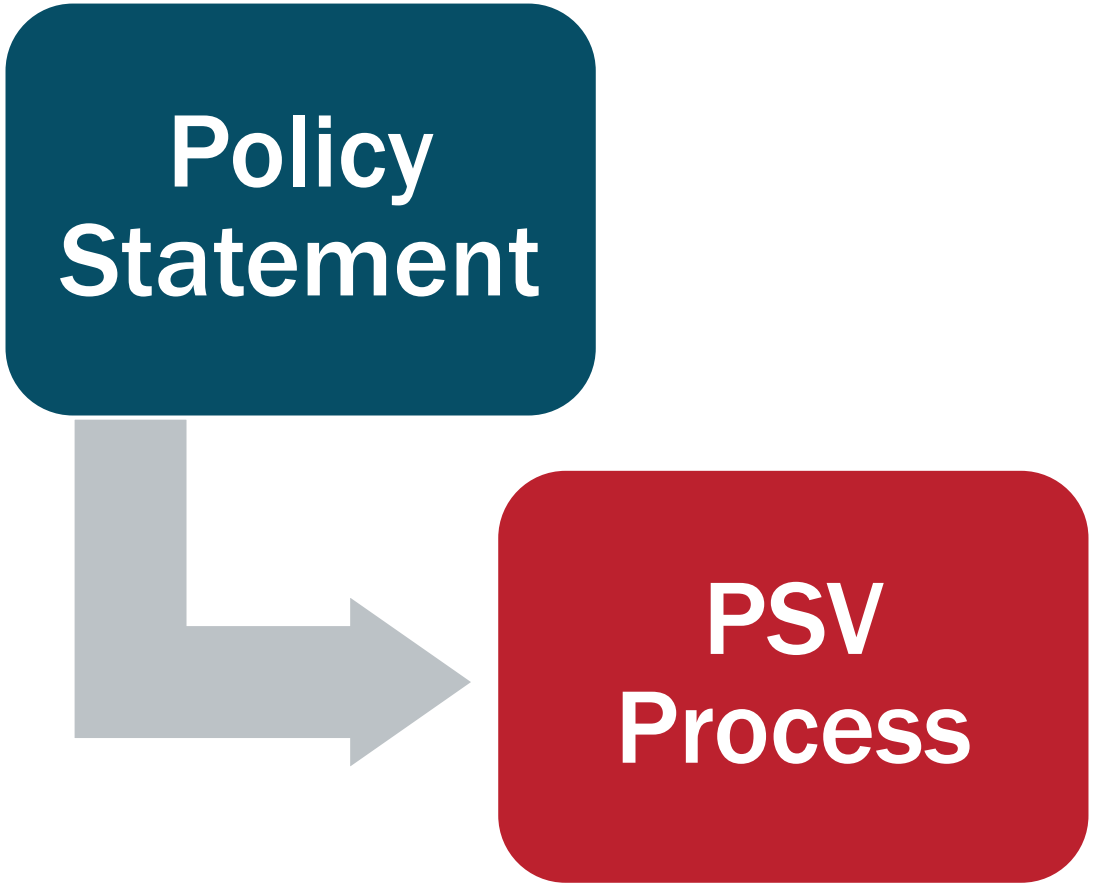
Standard Language

Staff are appropriately licensed and screened prior to hire. Licensure and/or certifications are verified no less than every three years. Staff members are trained initially and on an ongoing basis.

Intent



OPIN 2-1: Clinical Staff Credentialing



The organization:

a. Primary source verifies licensure and/or certification of staff whose job description requires licensure and/or certification: [8]
   i. Prior to hire
   ii. No less than every three (3) years or prior to expiration, whichever is sooner

b. Requires staff to notify the organization in a timely manner of an adverse change in licensure and/or certification status and implements corrective action in response to adverse change(s) [8]

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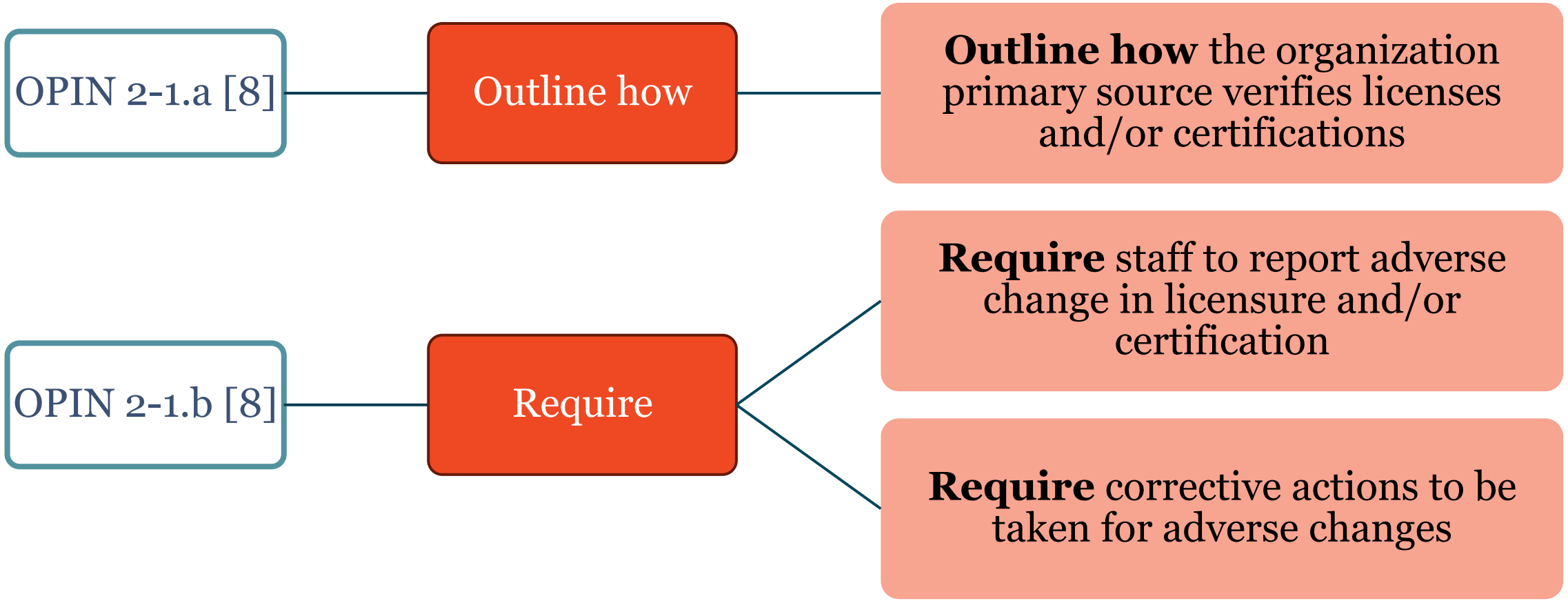
OPIN 2-1: Demonstrating Compliance

- Document(s) **outlining how** the organization primary source verifies licenses and/or certifications.
- Document(s) outlining the organization's **requirement** for staff reporting adverse change in licensure and/or certification and corrective actions taken in response to adverse changes.

OPIN 2-1: What to Submit on Desktop



Quick Note on Employment Screening

- Intent and standard requirements remain the same
- Pharmacy specific drug screening requirement separated out

SPP v5.0

- OPIN 2-2: Employment Screening

SPP v6.0

- OPIN 2-2: Employment Screening
- OPIN-PH 4: Pharmacy Employment Screening

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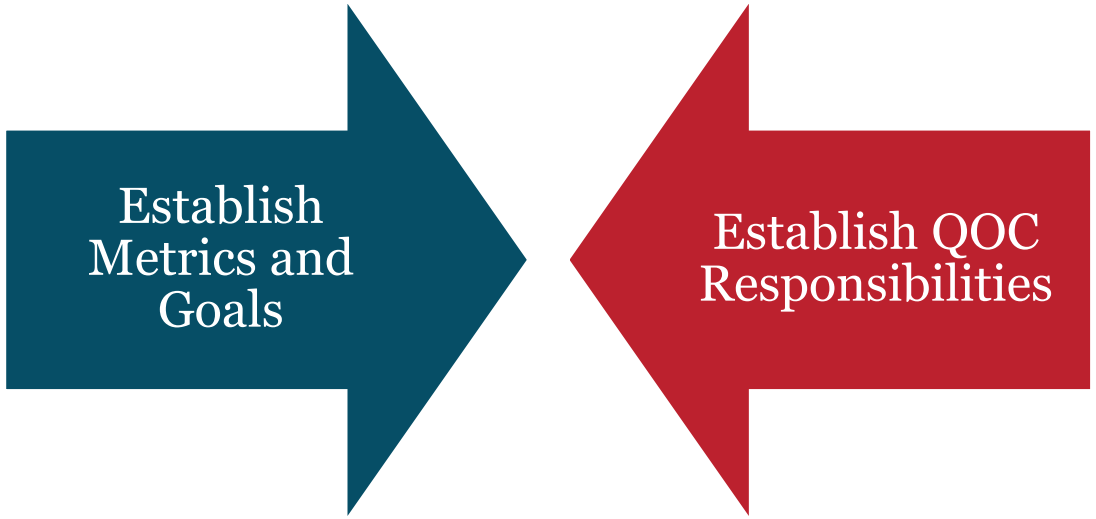
PMI 1: Quality Management Scope

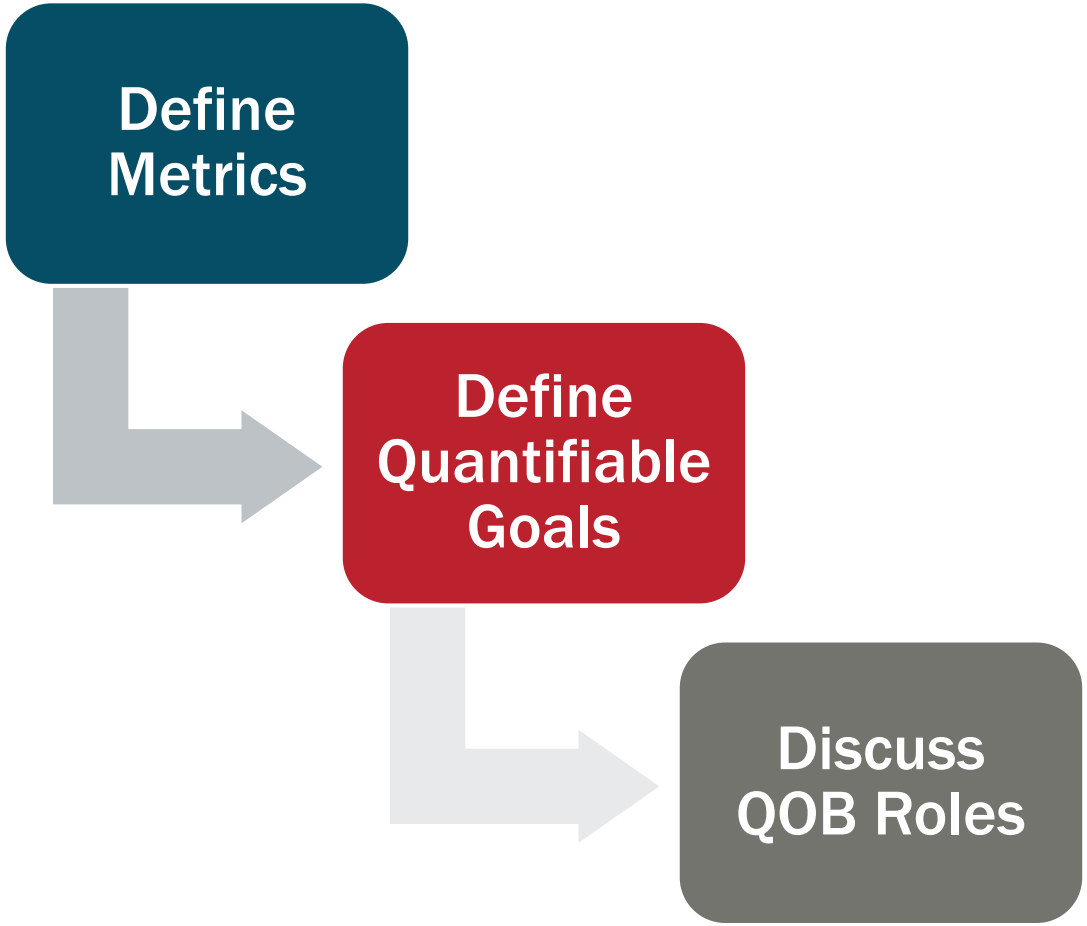
Standard Language

The organization maintains a quality management program, overseen by a quality oversight body, that promotes measurement and implementation of quality improvement activities based on the performance results.

Intent



PMI 1-1: Quality Structure



The organization's quality management program: **[M]**

a. Identifies metrics and the quantifiable goals relevant to the program

b. Maintains a quality oversight body responsible for monitoring metrics and progress in meeting quantifiable goals and overseeing improvement activities

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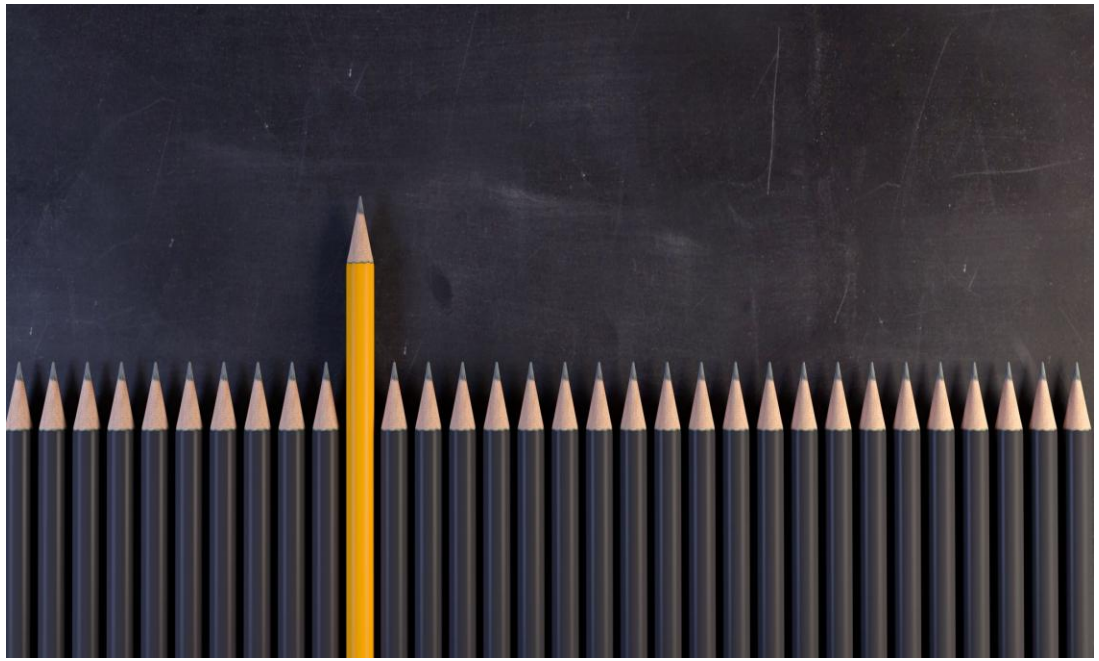
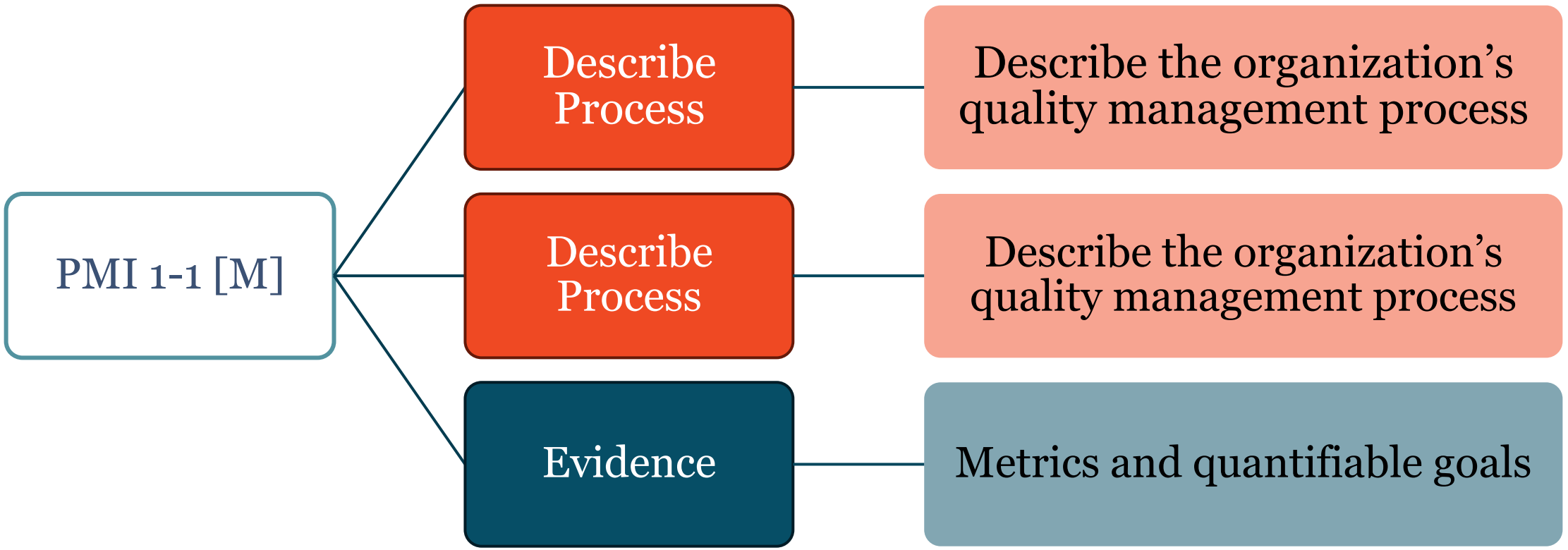
PMI 1-1: Demonstrating Compliance

- Quality management program document(s) describing the organization's quality management **processes**.
- Sample documentation of metrics and quantifiable goals



PMI 1-1: What to Submit on Desktop

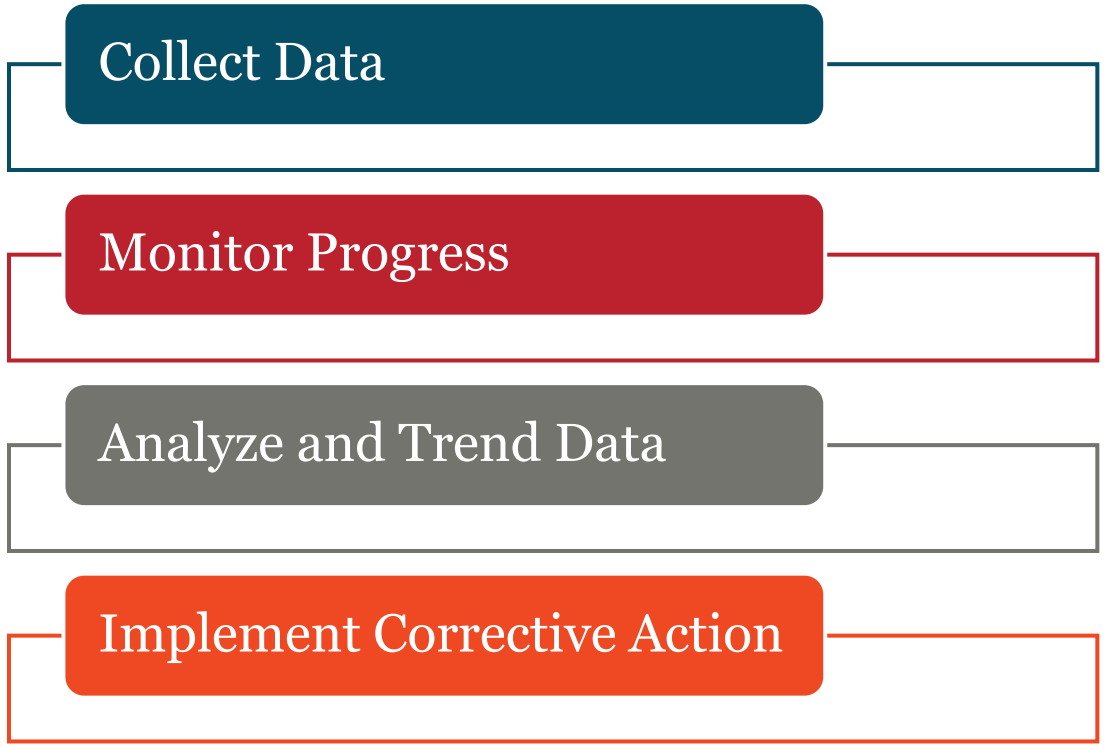


PMI 2: Quality Data Collection and Evaluation

Standard Language

The organization maintains a quality management program that promotes accurate collection, analysis and evaluation of data.

Intent



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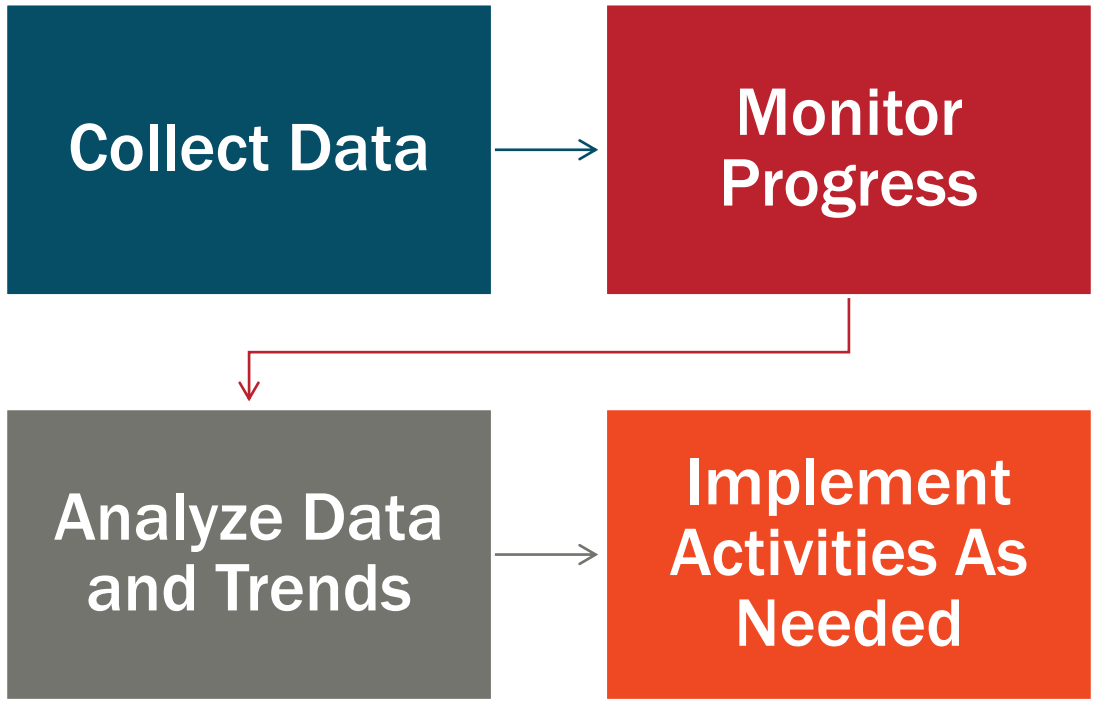
PMI 2-1: Data Collection and Evaluation



The organization's quality management program:

a. Collects accurate data for each metric [8]

b. Monitors progress in meeting the quantifiable goal for each metric [8]

c. Analyzes data and identifies performance trends for each metric at least annually [8]

d. Implements activities to improve performance when metrics are not met [8]

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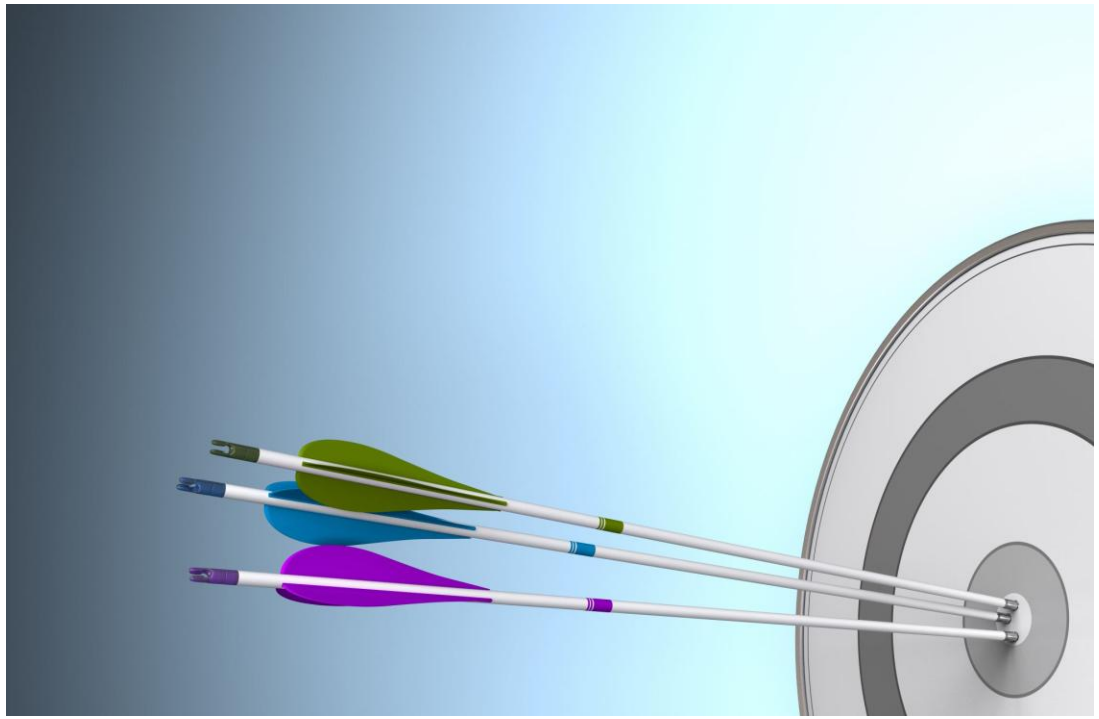
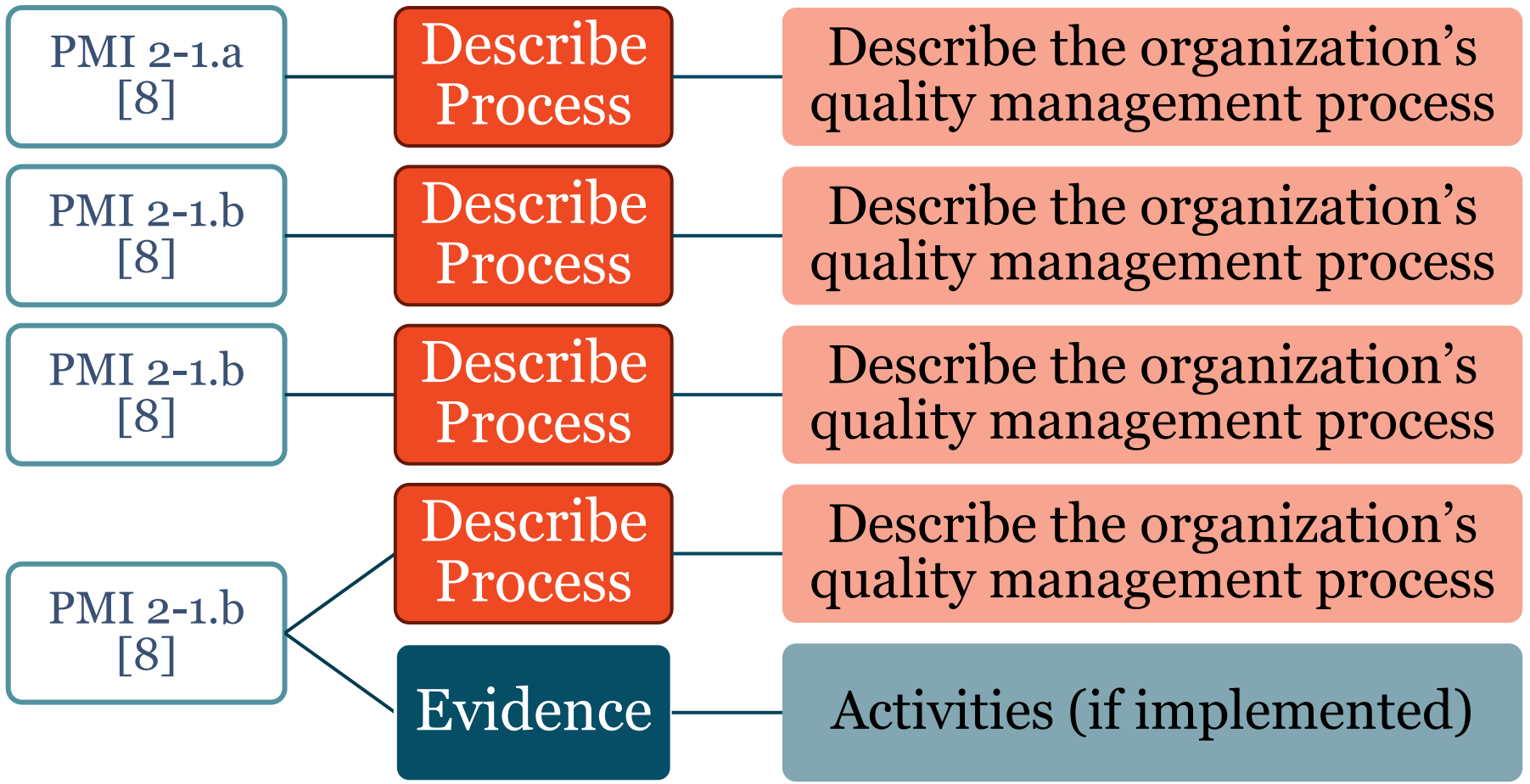
PMI 2-1: Demonstrating Compliance

- Quality management program document(s) describing the organization's quality management **processes**.
- Sample documentation of activities implemented, if applicable



PMI 2-1: What to Submit on Desktop



Questions & Other FFA Topics

Specialty Pharmacy Revision Discussion

Thank you for coming!

Now let's network!