

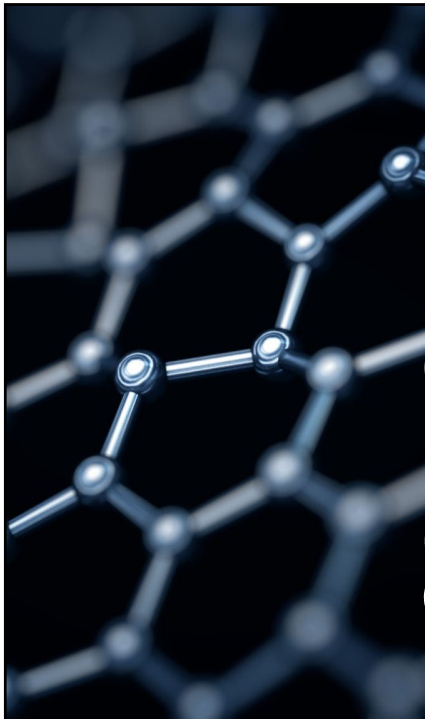
Investigations, Root Cause, and Corrective Actions: Tools, tips & tricks



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In the beginning....

...Research Compliance created

...structure and process

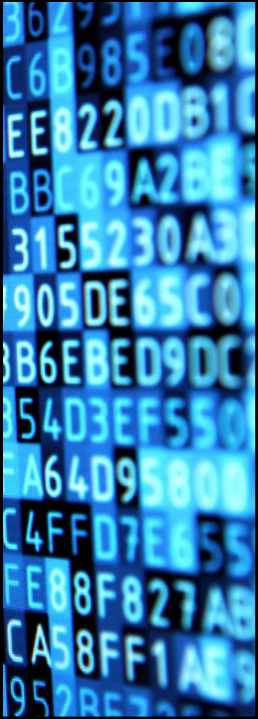
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Give it structure

- Create policy, guidelines, or SOPs—whatever works for your institution
 - Define the process
 - Reporting structures
 - Communication structures
 - What to do with incidental findings
 - Confidentiality
- Training

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How do you keep track of it all?

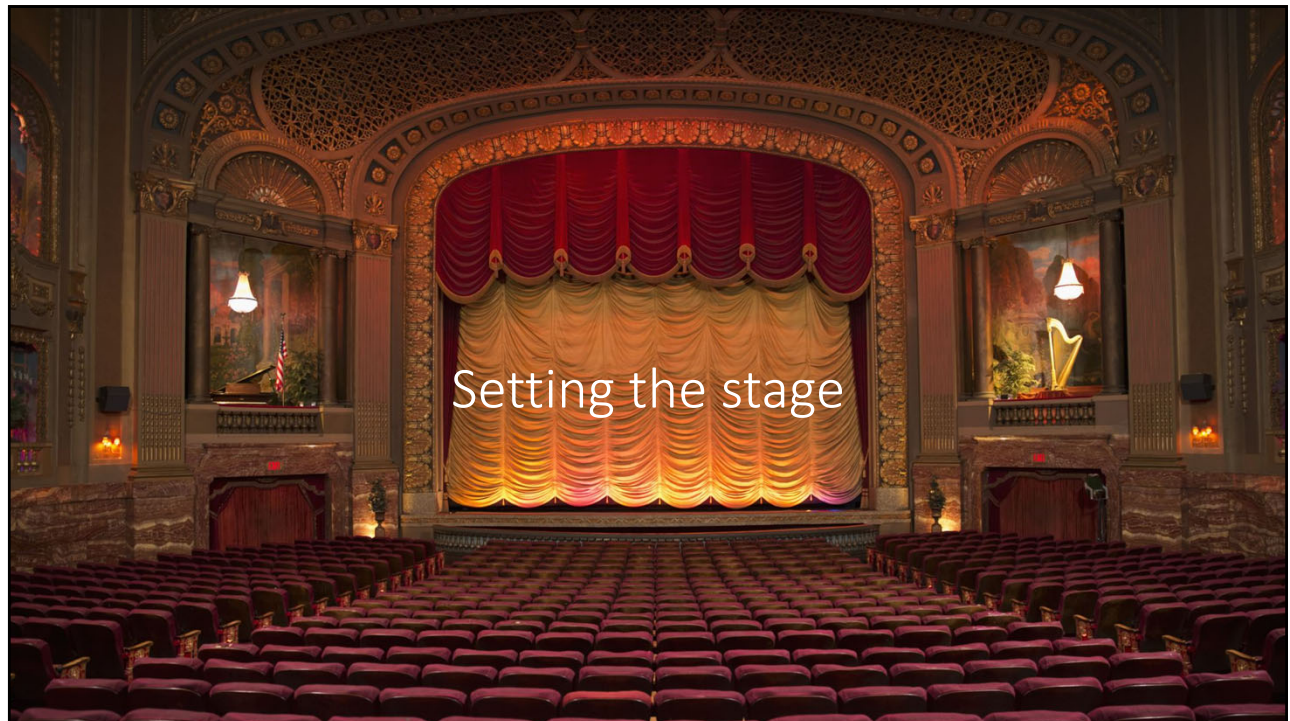
- Case or tracking number
- Evidence numbers
- Naming conventions
- Electronic file structures
- Storage of evidence

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Tools

- Intake forms
- Checklists
- Investigation plans
- Timeline
- Reporting format
- Communication plans
- Chain of Custody
- Evidence Log

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A day in the life...

Its 4pm on Friday and you are psyched to start the weekend. You've got plans with your old roommates to grab a drink and play pool at your favorite beach front bar.

Its been a great week in your Compliance office. You finally got that policy approved and posted, you received the go-ahead on a major multi-point regulation communication campaign, and you are putting the finishing touches on a report due to your boss Monday morning.

Yes, its been a good week in the Compliance office.

But then...the phone rings.




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That sinking feeling

One of the most senior faculty at the institution is being accused by a postdoc of harassment and abuse, conducting unapproved experiments using samples from lab members, and misappropriating grant funds by spending them on personal travel and entertainment for her and her lab manager, who is also her spouse. The accusation is that the abuse and misappropriation may have been going on for years. This faculty is known to be volatile and aggressive and has been known to throw things when she is angry.

You hang up the phone. Your blood pressure is more than a few points higher. Your heart is in your throat.

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Poll Question

What do you do next?

- 1) Cry under your desk
- 2) Ignore it – it'll keep 'til Monday!
- 3) Do the "I knew it, I knew it, I knew it" dance
- 4) Start looking for a new job
- 5) Or...

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You take a deep breath and then...let those MAD research compliance skills kick in!

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Before you start...just remember

01

Make the reporter feel safe to report, i.e. non-retaliation policies, etc.

02

Be a good listener—let them be heard

03

Ask questions

04

Suspend judgement

05

Don't jump to conclusions

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- Get as much information as possible
 - Do you feel safe
 - Timeframes
 - Location of evidence
 - Other witnesses
 - Where did it occur
 - Has the issue been previously reported, if so to whom
- Are grant funds involved
- What if it is anonymous

Taking the Complaint

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Immediate Actions

- Safety of individuals
- Security of the institution or institutional resources
- Data holds
- Restricting access
- Institutional notifications, who needs to know
 - Sr. Leadership
 - Police & Security
 - Departmental leadership/supervisors



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Time Sensitivity

- Are there reporting obligations
- Is there a safety issue—person or institution
- Loss of institutional resources
- Financial loss

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Who needs to be involved

Expertise	Do you need a specific expertise (OGC, IT, etc.)
Access	Do you need access to data, reports, documentation, etc.
Holds	Do you need legal holds (email, share drives)
External Services	Do you need external services (outside counsel, forensic work)

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Who needs to be interviewed

- Do you need to consider the order of the interviews
- Location of interviews
- Who will do the interview(s)
- Documentation of interviews
- What questions need to be asked
- Can they have a support person
- Do they need legal counsel



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Interviews

- Be prepared
- Let them know you are going to take notes
- Start with easy questions that you already may know the answer to
- Ask open-ended questions
- Keep the interview focused on your topic
- Ask follow-up or clarifying questions

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Collection of Evidence

- What need to be collected
- Where is it located
- What type of evidence is it (electronic, physical)
- How will you collect the evidence
- Who will collect the evidence
- Do you need support to collect the evidence (IT, Security, etc.)
- Where will it be stored

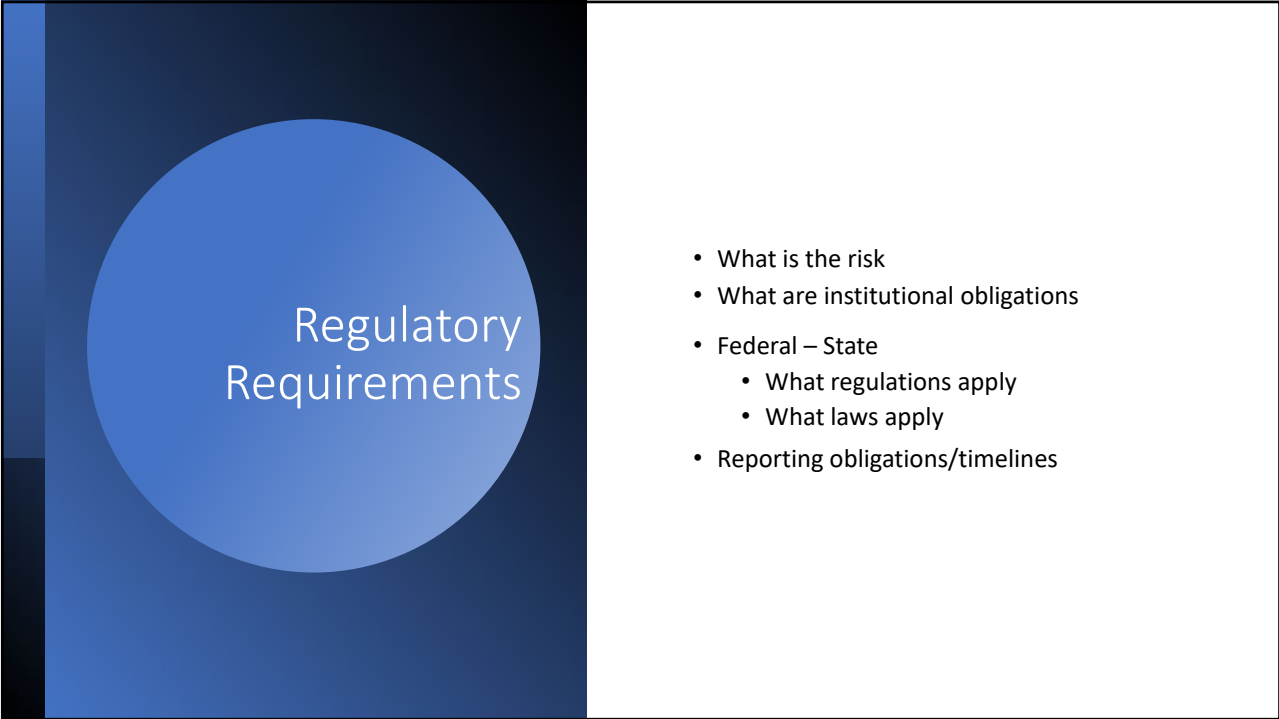
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Collecting Evidence

- Take pictures
- Label everything
- Record and document as you go
- Only collect what pertains to your case
- Keep a Chain of Custody
- Document storage

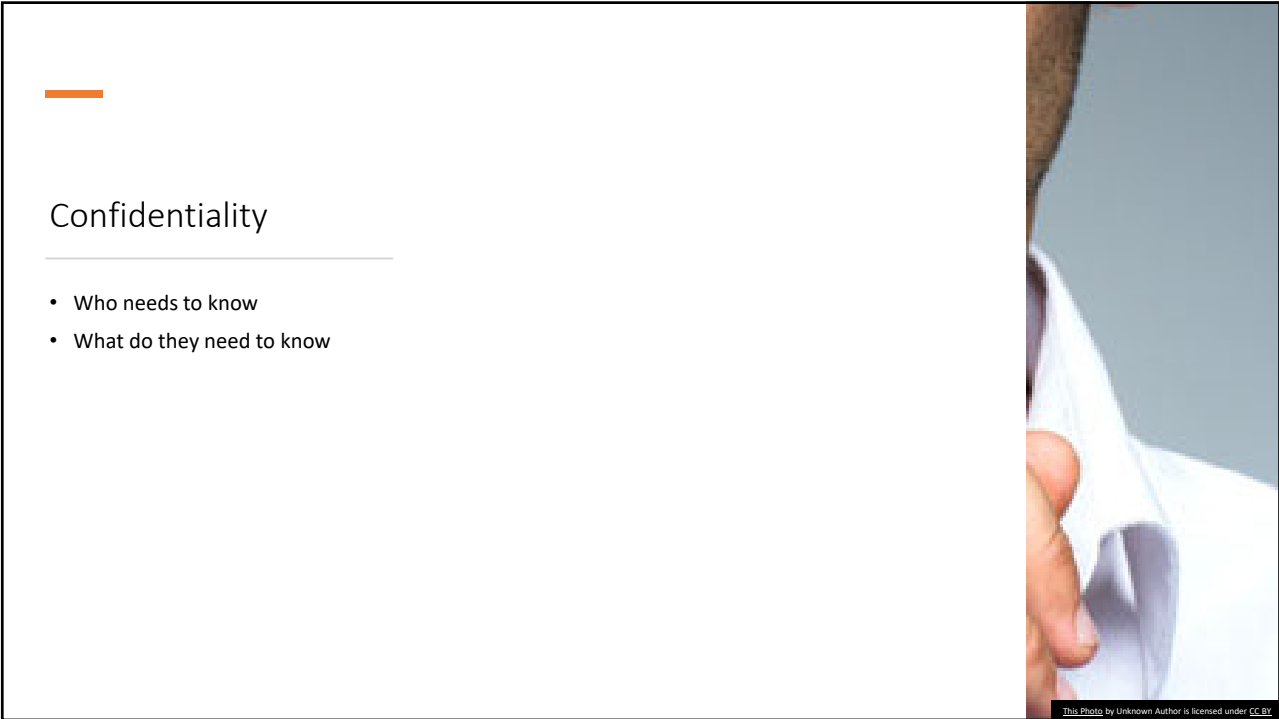
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A slide with a dark blue background on the left and a white background on the right. A large blue circle is centered on the dark blue background, containing the text "Regulatory Requirements".

Regulatory Requirements

- What is the risk
- What are institutional obligations
- Federal – State
 - What regulations apply
 - What laws apply
- Reporting obligations/timelines

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A slide with a white background on the left and a photograph on the right. The photograph shows a person's hand holding a white shirt cuff. The text "Confidentiality" is underlined.

Confidentiality

- Who needs to know
- What do they need to know

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Wrapping up the Investigation

- Interim actions
- Documentation of findings
- Presentations and reports to leadership
- Corrective actions
 - Internal (individual, department)
 - External (regulators)
- Reports to regulators

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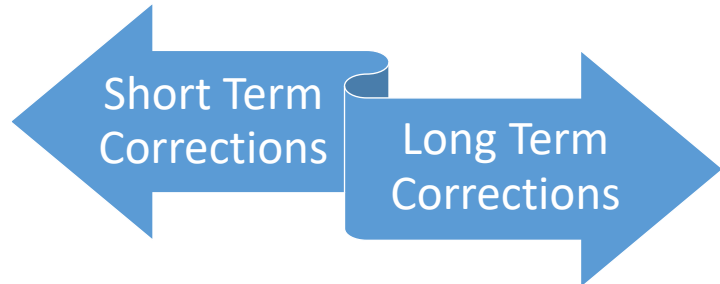
Incidental Findings

- Is it a compliance issue
- Is it related to the current investigation
- Does it require additional investigation
- Who do you need to tell

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Corrective Actions



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Short term (immediate) corrective actions

01

Fix what is non-compliant

02

Report to required agencies

03

Disciplinary actions

04

External correction requirements

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Long term corrective actions

Underlying issues

Prevention and proactivity

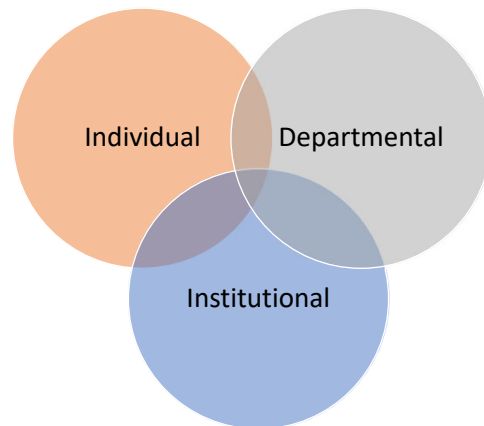
Increase accountability

Lean on seven elements

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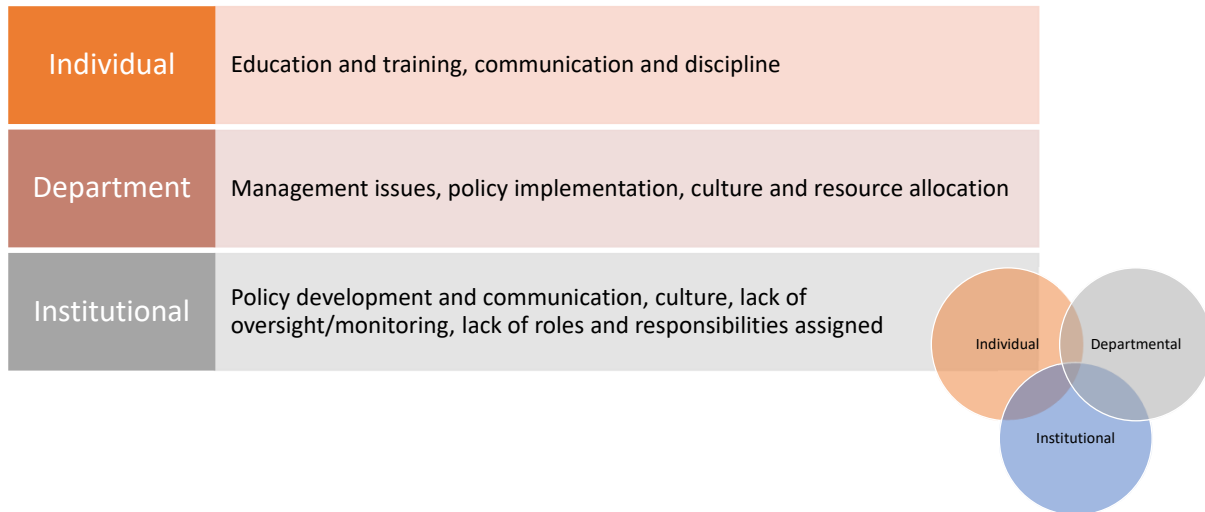


Corrective Actions



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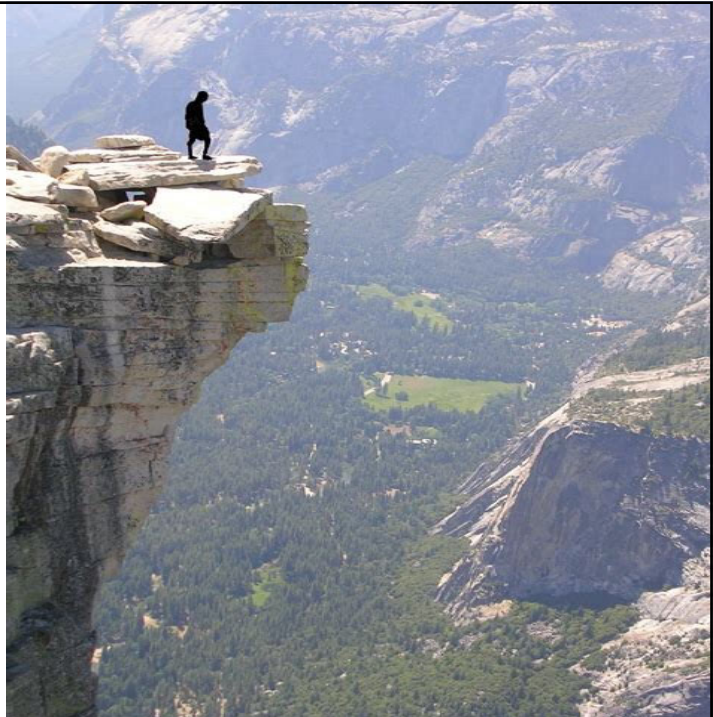
Who receives corrective action?



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Corrective Action Pitfalls

- Not securing buy-in from leadership and management
- Not enlisting partners
- Research Compliance being overly invested
- Not fixing non-compliance first
- Not making measurable corrective actions
- Not making corrective actions specific enough
- Not correcting to policy or regulatory expectations
- Not monitoring and adjusting corrective actions as needed
- Trying to boil the ocean
- Not addressing underlying causes



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Corrective Action Template

CAP #	Action Plan	Corrective or Preventative	Correction term	Responsible Parties	External Resources Required	Stakeholders	Due Date	Outcome Measurement	Additional Info Attached?
Create a number system so each corrective action step can be tracked and reported on	<p>What are you actually expecting them to do?</p> <ul style="list-style-type: none"> Should be specific Should be achievable Should connect to correcting issue 	Is this action to fix non-compliance or is it trying to fix underlying issues?	Short term or long term – will this corrective action be ongoing or will it have a definitive end date?	<p>What managers/ leaders and/or staff member is assigned responsibility for completing the action.</p> <ul style="list-style-type: none"> Assign roles and responsibilities 	<p>What does the manager or individuals need to accomplish goal that they do not have access to yet?</p> <ul style="list-style-type: none"> Funding FTEs Policy Templates Coaching Systems Support personnel 	Which external departments have a role in oversight and support for helping to achieve goal or measurement of completeness?	Set a reasonable due date. May be months or years in the future.	<p>Must have a specific deliverable to measure whether corrective action step is sufficiently completed or sufficiently in progress.</p> <ul style="list-style-type: none"> Documentation Evidence Deliverables 	Anything else to explain corrective action step or plan for executing.

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Monitoring Corrective Actions

Corrective Action Step #3

Goal: Establish standing meetings, no less than quarterly, with PI, Grant Manager, and Research Finance to review expenditures and expenditure documentation.

Expected Outcome: Formation and calendaring of standing meetings and development of standing agenda.

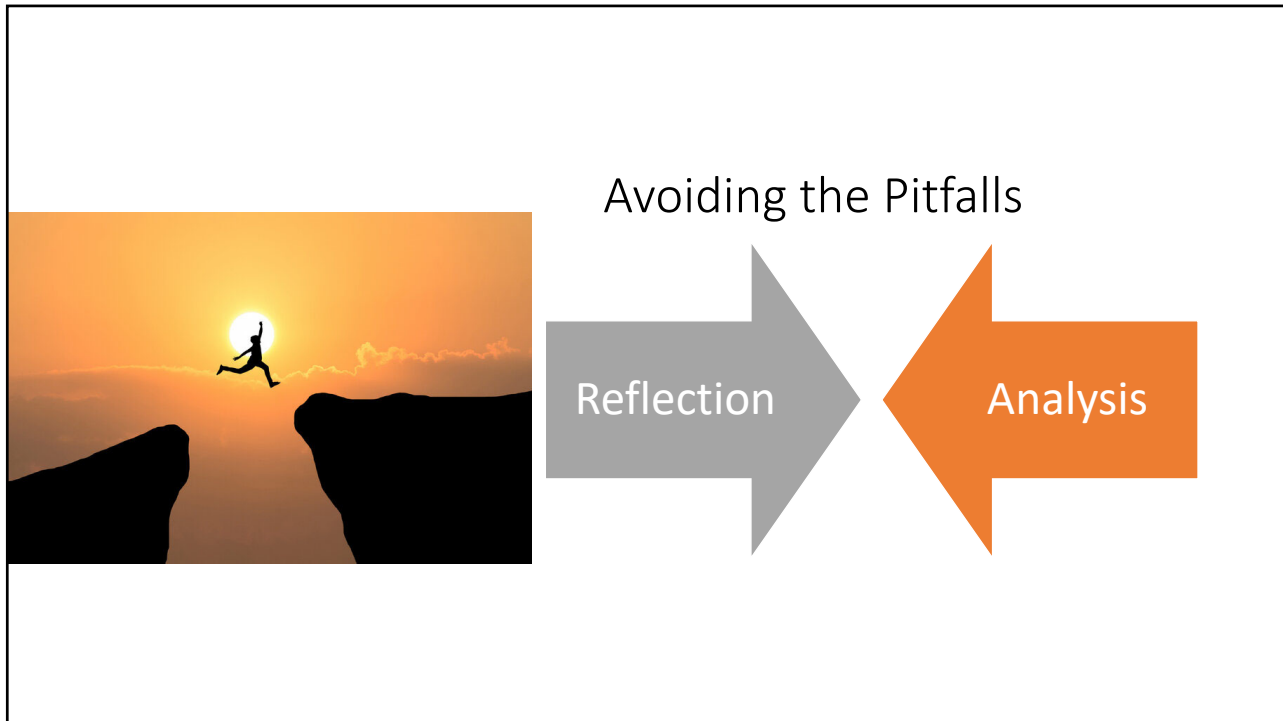
Due Date: July 2024

Status: Not yet started.

Results: [Use outcome measures to frame results as you describe]

Other/Ancillary: Use to make observations and comments about other identified issues, agreed upon changes to corrective action step, and/or leadership feedback.

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Short Term Corrective Actions – Assess for Non-compliance

Bring stakeholders together to ensure that any immediate non-compliance issues have been identified

Review policies and regulations to know what immediate curative actions must be taken e.g.:

- Payback
- Reporting
- Ceasing Actions

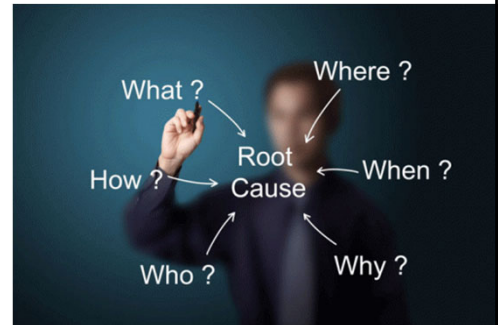


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Long Term Corrective Actions – Root Cause Analysis

Root cause analysis (RCA) is **the process of discovering the root causes of problems in order to identify appropriate solutions.**

- Solve underlying issues
 - Long-term goal is to correct the control environment failures that allowed incident to occur
- Proactive and Preventative compliance
- Deep self-reflection
- Use investigation techniques
 - Look at big and small issues
 - Talk to people – many different perspectives
 - Don't take things for granted

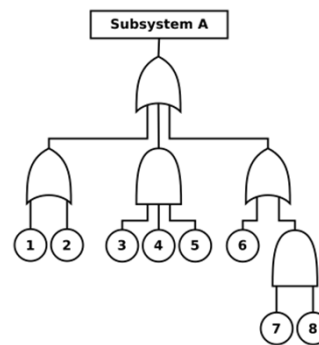
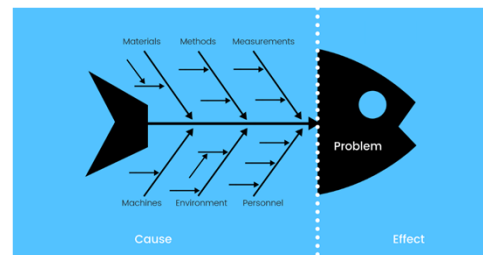


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Conducting Root Cause Analyses

Models for Root Cause Analysis

- Ishikawa Fishbone Diagram
- Fault Tree Analysis
- Affinity Diagrams
- Failure Mode and Effects Analysis
- **5 Whys**
- And many more



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5 Whys

Incident

Why did that happen?

Why did that happen?

Why did that happen?

Why did that happen?

Why did that happen?

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5 Whys – In Practice

INCIDENT: PI is abusive

PI was frustrated and under pressure

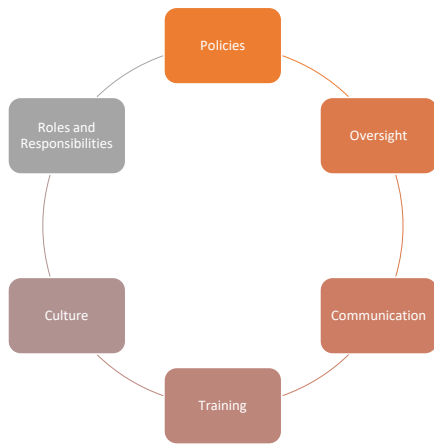
Expectation high and not being met

Did not communicate expectations or set priorities

PI was not trained to think as a manager

PI needs training and support to be a better personnel manager

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Root Cause results

- Typically identify 3-5 root causes per incident/issue
- Usually relate to one or more of the Seven Elements of Compliance
 - Training/education deficits
 - Policies – missing, miscommunicated, misunderstood
 - Communications and reporting not occurring
 - Lack of oversight/accountability/monitoring
 - Risk tolerance and culture
- Sometimes resource issues will be identified – need leadership support
- Sometimes root causes will actually belong to someone else

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Discussion:

What are some root causes that might result from this case?

...accused by a postdoc of harassment and abuse, conducting unapproved experiments using samples from lab members and misappropriating grant funds by spending them on personal travel and entertainment for her and her lab manager, who is also her spouse. The accusation is that the abuse and misappropriation may have been going on for years. This faculty is known to be volatile and aggressive and has been known to throw things when she is angry.

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Tie Corrective Actions to Root Causes

- If lack of training identified...
 - What is effective training for this issue
 - Who needs to be trained and how often
 - Create new trainings or new method of training
 - Are there opportunities for follow-up awareness
- If lack of policy is identified...
 - Identify policy gap and owner
 - Benchmark, draft, approve, and disseminate policy
 - Test for effectiveness of policy
- If lack of oversight/monitoring is identified...
 - Assess current processes for opportunities
 - Assign responsibility
 - Create opportunities for connectivity and reporting



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Discussion:

What are some corrections that might result from this case?

...accused by a postdoc of harassment and abuse, conducting unapproved experiments using samples from lab members and misappropriating grant funds by spending them on personal travel and entertainment for her and her lab manager, who is also her spouse. The accusation is that the abuse and misappropriation may have been going on for years. This faculty is known to be volatile and aggressive and has been known to throw things when she is angry.

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Reporting and keeping leadership informed

- Periodic updates on progress
 - Discuss successes and obstacles
 - Alert to additional issues uncovered
 - Touch on each corrective action item
 - Should connect to incident and root causes
 - Formally close – corrective actions need to end at some point
-
- Pick a unified format e.g. SBAR
 - Situation, Background, Assessment, Recommendation
-
- Do a corrective action plan post mortem 12 months later



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