MOSS ADAMS

Environmental Scanning and Risk Assessment

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Objectives

- Define the key steps in a risk management process – how do we improve it

- Understand how environmental scanning could improve your organization's ability to envision and plan for future risks and opportunities

- Consider how to reduce your risk profile, using the tenets of environmental scanning
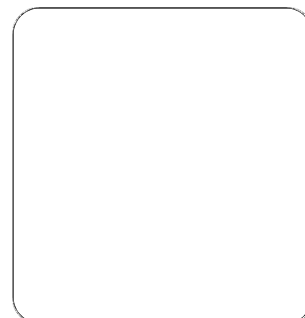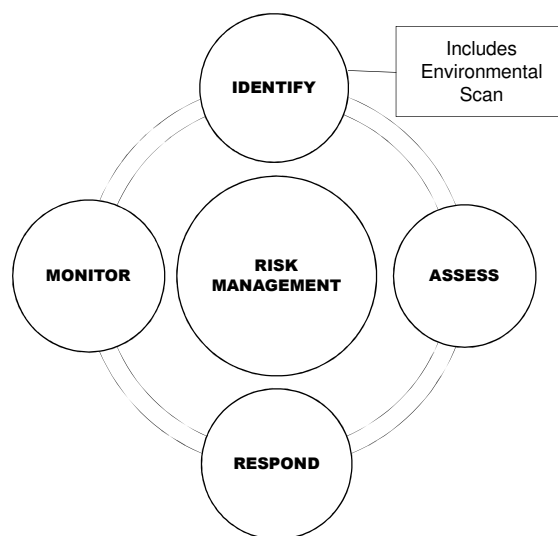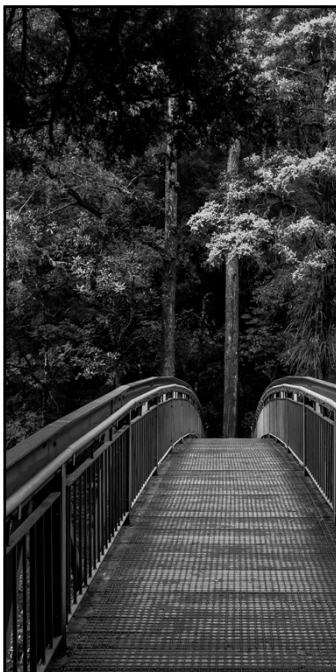
What is risk assessment?

Risk: Anything that will hinder or prevent your organization from achieving its goals or purpose.

Risk Assessment: Evaluating, measuring, and prioritizing likely relevant events or risks that may materially hinder or prevent your organization from achieving its goals or purpose.

Managing risk is a continuous process

Why should you care?

- Office of Inspector General (OIG)

- US Sentencing Guidelines (2004)

- Office for Human Research Protections (OHRP)/Food and Drug Administration (FDA)/ Office of Research Integrity (ORI)

- Centers for Medicare and Medicaid Services

- Health Insurance Portability and Accountability Act (HIPAA)

- Stark/Anti-Kickback

- Organization/Board Responsibilities

In Guidance

- American Health Lawyers Association and OIG compliance guidance for Boards

  o Does the compliance program address the significant risks of the organization?

  o How were those risks determined, and how are new compliance risks identified and incorporated into the program?

  o How is the Board kept apprised of significant regulatory and industry developments affecting the organization's risk?

  o How is the compliance program structured to address such risks?

Why conduct a risk assessment?

- Proactive versus reactive

- Supports enterprise risk management

- Cultural integration

- Raises awareness of program value

- Mitigation of penalties

- Continuous program improvement

- Basis for annual work plan

- Identifies needed resources

- OIG requires for organizations under a CIA
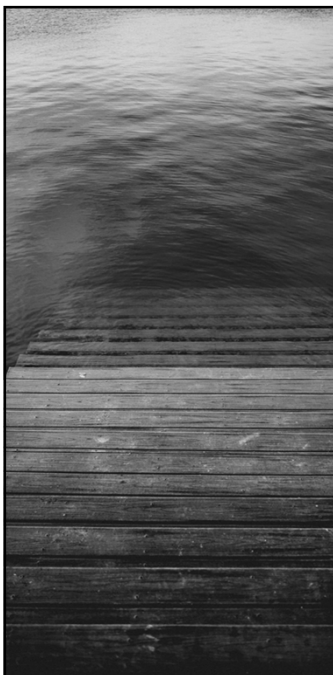
Risks
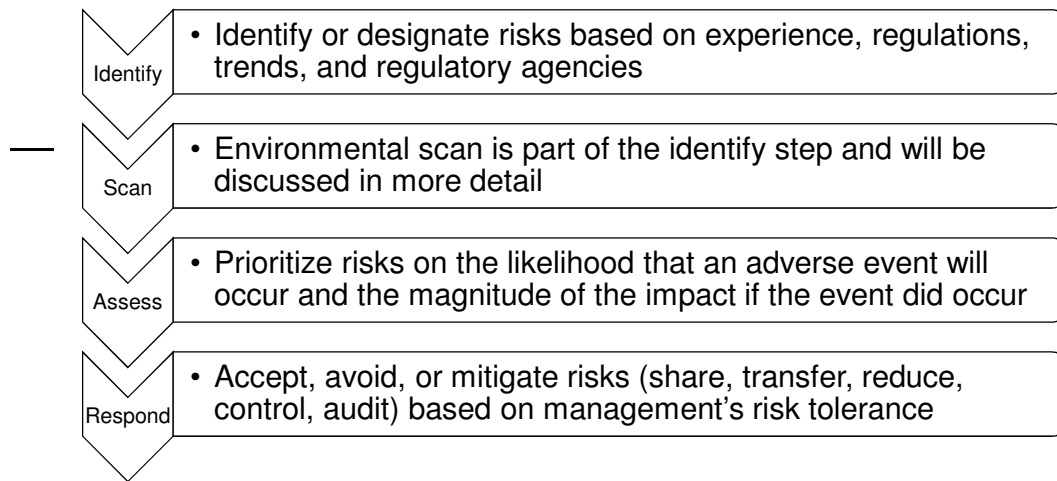## Compliance versus Internal Audit IDENTIFY

Compliance

Threat from violations of laws, regulations, code of conduct or standards of practice
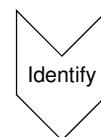
Internal Audit

Same but also consider financial statement risks and other operational risks

Risk management key components

Identify
- Identify or designate risks based on experience, regulations, trends, and regulatory agencies

Scan
- Environmental scan is part of the identify step and will be discussed in more detail

Assess
- Prioritize risks on the likelihood that an adverse event will occur and the magnitude of the impact if the event did occur

Respond
- Accept, avoid, or mitigate risks (share, transfer, reduce, control, audit) based on management's risk tolerance

What is a risk?

Identify

- Exposures now and in the next 3-5 years

- Key process or functions which lack mitigation or could have impact on operations

- Complex studies, processes, or functions with multiple stakeholders, hand-offs, control, and authority

- Key strategic initiatives, mergers, etc

How to identify compliance risks

Identify

- Start with your organization's strategies and key initiatives

- Consider regulations – what has changed

- Updated or deleted policies, and procedures

- Innovation

- Evaluate the OIG work plan, audits, and enforcement activity

- Consult requirements of other federal and state agencies OCR, OHRP, FDA, OSHA, OSHPD

# How to identify compliance risks *(cont.)*

Identify

- Review auditing and monitoring results, prior risk assessments, and reports

- Evaluate how data mining, predictive analytics, and cross-jurisdictional intelligence might impact you

- Survey employees, key stakeholders, vendors

- Conduct individual interviews

- Convene focus groups and brainstorming sessions

- Convene content groups

Other Sources of Risks

Identify
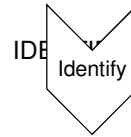
- The OIG Work Plan is just a starting point – search for your specialty in other federal reports and keep current in your reading

  http://oig.hhs.gov/newsroom/whats-new/

- Keep in touch with your specialty societies that follow regulatory changes

- Search your Contractor website and newsletters for updates and changes in your contractor policy
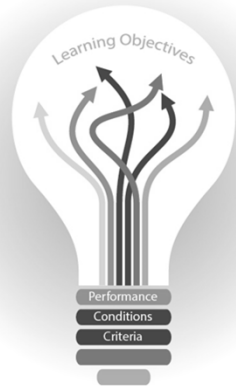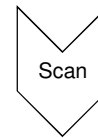
Environmental scanning-What?

Scan
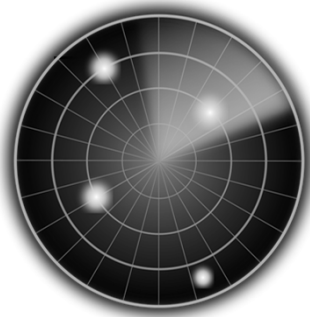
- Systematic process of collecting and analyzing information about an organization's internal and external environments for planning, forecasting, or choosing a preferred future

- Being integrated into leading edge risk management programs

Environmental scanning: Objectives

- Detecting important economic, social, cultural, environmental, technological, and political trends, situations, and events

- Identifying potential opportunities and threats implied by trends, situations, and events

- Gaining an accurate understanding of the strengths and limitations of your organization

- Identifying and assessing risks as part of your risk management program

Environmental scanning: Stakeholders

- Internal
  - Involve cross-functional stakeholders and subject matter experts across the organization

- External
  - Vendors, community physicians, legal and risk management advisers, external financial auditors

Environmental scanning: Techniques

- Review the literature broadly
- Consult your colleagues
- Benchmark with peers
- Survey employees, key stakeholders, vendors
- Conduct individual interviews
- Convene focus groups and brainstorming sessions
- Use delphi-type conferences and polling techniques

Scan

Sample evolving risks

- Ability to control genetics of humans, animals, and plants
- Bionic people
- Connectivity across the continuum of care
- Convergence of 3D digital design, medical imaging, and 3D printing
- Convergence of nanotechnology, biotechnology, information technology, and cognitive science
- Open health care information versus privacy
- Patient choice, patient power
- Rise in telemedicine
- Wearable devices

Scan

Assess and prioritize identified compliance risks

Assess

- Evaluate risks on the likelihood that an adverse event will occur

- Rank risks - High, Medium, Low

ILLUSTRATIVE LIKELIHOOD SCALE		
Rating	**Descriptor**	**Definition**
3	Frequent	▪ > 50% chance of occurrence
2	Possible	▪ > 10% up to 50% chance of occurrence
1	Unlikely	▪ < 10% chance of occurrence

Assess and prioritize identified compliance risks

Assess

- Quantify the magnitude of the impact on your organization if the event did occur

| ILLUSTRATIVE IMPACT SCALE		
Rating	**Descriptor**	**Definition**
3	Major	▪ Financial loss of > $1 million ▪ Significant prosecution, fines or litigation ▪ Corporate integity agreement, federal exclusion ▪ Game-changing loss of market share, loss of major donor support ▪ Multiple senior leaders leave
2	Moderate	▪ Financial loss > $500 thousand to $1 million ▪ Prosecution, fines or litigation ▪ Report to regulator with immediate correction to be implemented ▪ Loss of market share and donor support ▪ Major staff morale problems and increased turnover
1	Minor	▪ Financial loss of < $500 Thousand ▪ Fines or refunds required ▪ Reportable incident to regulator with no follow up required ▪ Little impact on market share or donor support ▪ General staff morale problems and turnover

Incorporating the Risk Assessment

- Risks identified and prioritized
  - ○ High risk is costly to the practice with a high likelihood of occurrence (Impact and vulnerability)
- Controls
  - ○ Policies and procedures
  - ○ Education and training
  - ○ Audits
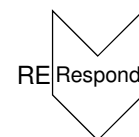 - ○ Quality assessment
  - ○ Management approvals
  - ○ Other
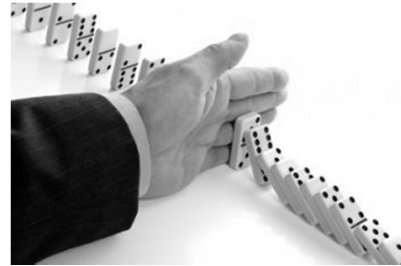
Risk matrix examples

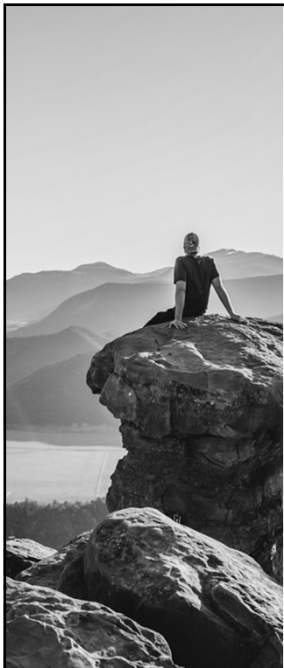## Risk Assessment Heat Map

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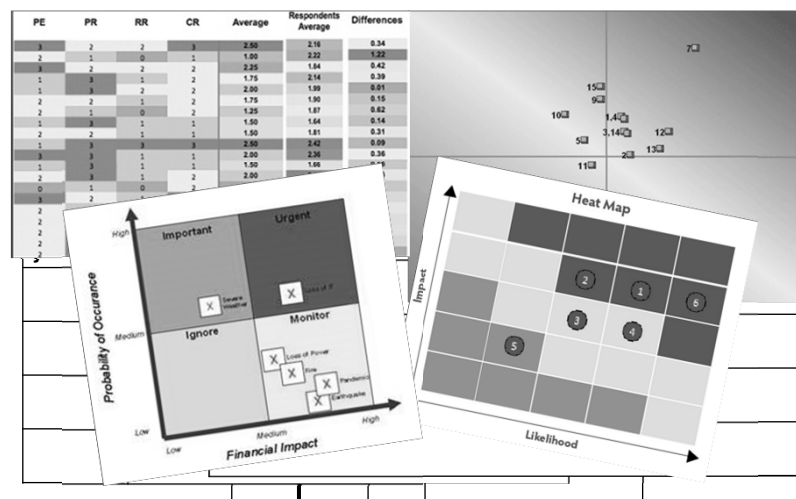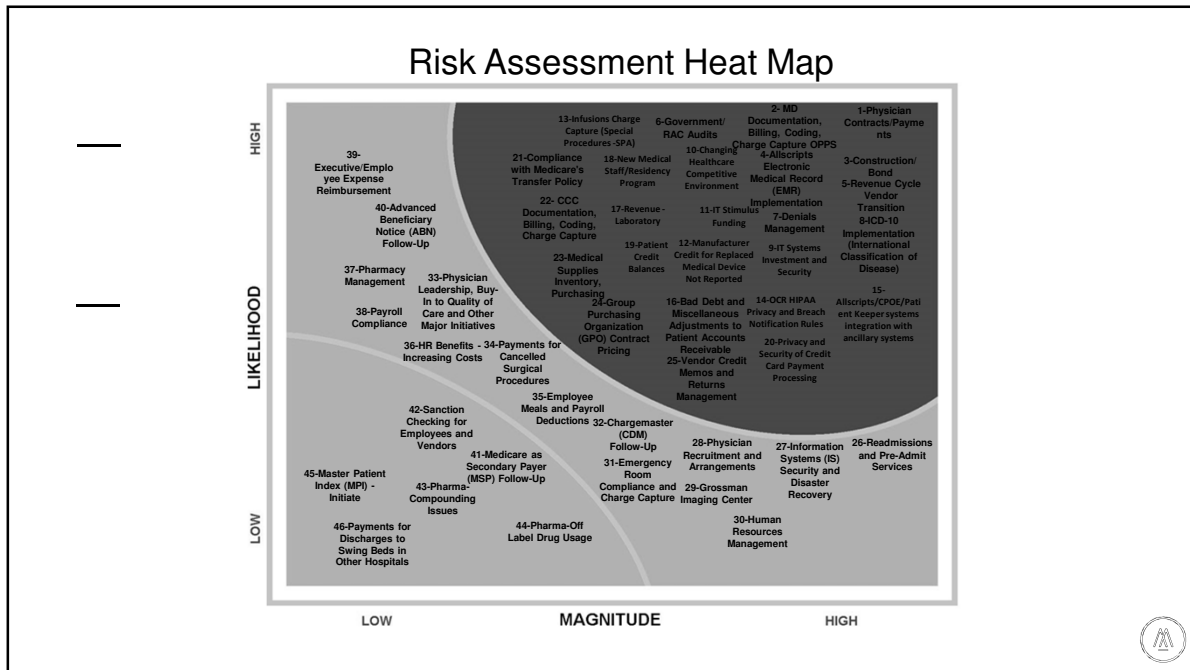
Risk Response Work Plan

RE Respond

- Once risks have been identified and prioritized it is important to take action and address risks
  - o Transfer
  - o Avoid
  - o Reduce
  - o Accept
  - o Monitor
  - o Audit
- Identifying and prioritizing risks can create risk if nothing is done with the information

Reducing risk profile

Respond

- A risk profile is an evaluation of the threats to which an organization is exposed and the organization's willingness to take risks

- Reduce your organization's risk profile by increasing the creativity and efficacy of your organization's risk identification process

- Improve your risk identification process with an effective environmental scanning process

- Take what you learn from environmental scanning and develop scenarios of possible futures

Reducing risk profile

Respond

- Involve a cross section of experts in evaluating threats and opportunities that could impact your organization

- Assess the current initiatives and controls already in place to address risks

- Determine the additional actions and investments needed to adequately address risks
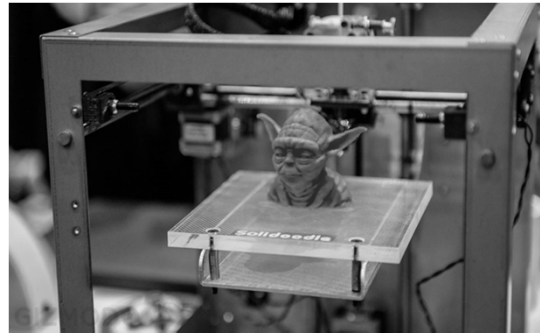
Risk

Part 3 – Reducing risk profile

Case #1 – Convergence of 3D digital design, medical imaging, and 3D printing

- What compliance risks are introduced?

- What mitigation strategies should compliance be using?

- Can you suggest any best practices?

Part 3 – Reducing risk profile

Case #2 – Rise in Telemedicine

- What compliance risks are introduced?

- What mitigation strategies should compliance be using?

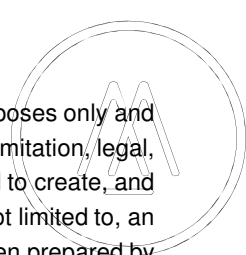- Can you suggest any best practices?

Wrap up

- We quickly ran through the key steps in a robust risk management process

- We defined and explained how environmental scanning can improve how you identify and address risks

- And together we shared our knowledge and experiences regarding a few emerging or evolving risk area

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QUESTIONS?

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