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January 14, 2015

Achieving a Risk-Based Approach to Compliance Management

Featuring: Holland & Knight | Kiewit

Achieving a Risk-Based Approach to Compliance Management

Moderator:
Joe LeBas
Chief Strategy Officer
Convercent

Kwamina Williford
Partner
Holland & Knight

Chris Caron
Compliance Director
Kiewit

Foundation for a Risk-Based Compliance Program

To be deemed an effective compliance program, an organization must engage in periodic risk assessments when designing, implementing, and modifying its compliance and ethics program.

U.S. Sentencing Guidelines 8B2.1, cmt 7

Concept accepted by federal enforcement agencies:

- Department of Justice
- Securities and Exchange Commission
- Department of Health & Human Services, Office of Inspector General

The Basics: How Can it Work?

Step 1: Understanding Your "Risk Profile"

Risk profile: An organization's overall exposure to some specific risk or group of risks.

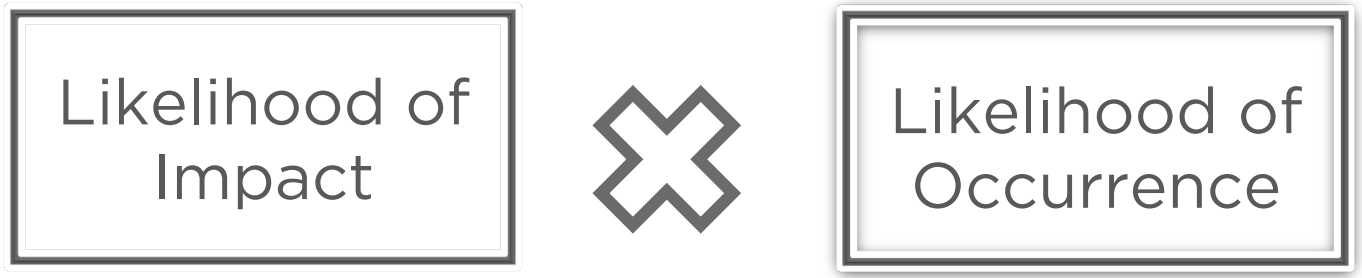
Considerations include:

- Strict Regulatory Scrutiny
- Industry Enforcement Climate
- Recent Complaints / Litigation / Audit Results
- Managerial Buy in on Compliance – "Tone from the Top"
- Organization's Compliance History
- Existence of Internal Controls

Step 2: Analyze Risk

Risk is any issue that impacts an organization's ability to meet its objectives.

When analyzing risk, look at measuring:



Create common language to analyze risks

Step 2: Analyze Risk

What is the Likelihood of Impact? *Sample metrics for analysis*

Scale	Legal liability	Health and Safety	Operations (class/research)	Financial Loss	Reputation
-1- Insignificant	Violation with little or no fine/action probable	No injuries or no medical treatment required	Very minor, no operational loss	< $1 M or <1% of Operating Budget	Minor impact to reputation, mention in local news paper
-2- Minor	Civil fines and/or penalties up to $50,000; little risk of exclusion	First Aid Treatment	Impacts 1 department; possible closure 1-2 days	$1M -$10M or 1% of Operating Budget	Adverse local public attention or complaints
-3- Serious	Serious breach of regulation with investigation or report to authority possible; fines up to $100,000	Medical Treatment / Hospitalization	Impact beyond 1 department; closes operations for 1 week	$10-20M or 2% of Operating Budget	Probably short terms bad press & highlighted concern from community; some constituent fall out
-4- Disastrous	Criminal investigation probably, loss of business unit accreditation possible, major litigation, fines up to $1M	Death or extensive injuries	Impacts entire school or business unit and ability to operate for up to 2 weeks	$20-50 M or 6% of Operating Budget	Substantial adverse national media / public attention; constituent fall out.
-5- Catastrophic	Significant prosecution and litigation; criminal conviction and/or exclusion; fines and penalties in excess of $1M	Multiple deaths or severe permanent disabilities	Entire University is unable to operate for a month or longer	>$50 M or <6% of Operating Budget	Prolonged negative press; serious media outcry; sponsors/ board questions management; substantial constituent fallout

Step 2: Analyze Risk

What is the Likelihood of Occurrence? *Sample metrics for analysis*

Scale	Likely Occurrence
-1- Rare	Aware of something like this happening elsewhere; expected to occur once every 10 years; **very effective policies, mandatory training, activities monitored and audited.**
-2- Unlikely	Event does occur somewhere from time to time; expected once every 4 to 10 years; responsible persons ensure compliance with policies, regular training, internal monitoring and auditing of activities.
-3- Possible	Event has occurred at least once during your career; expected once every 3 years; policies are followed and updated, training provided when needed; some informal monitoring.
-4- Likely	Event has occurred several times or more during your career; expected once a year; policies and procedures in place; compliance not enforced or mandated; some on the job training and no monitoring.
-5- Almost Certain	Event has occurred in the last six month; expected more than once a year; No controls in place.

Step 3: Prioritize Risk

Likely Impact x Likely Occurrence = Risk Level

Highest Likelihood
Highest Impact

Lowest Likelihood
Lowest Impact

Risk Level	Score Range
Extreme	17-25
High	14-16
Substantial	10-13
Medium	5-9
Low	1-4

Step 4: Managing Risk in Approach to Compliance

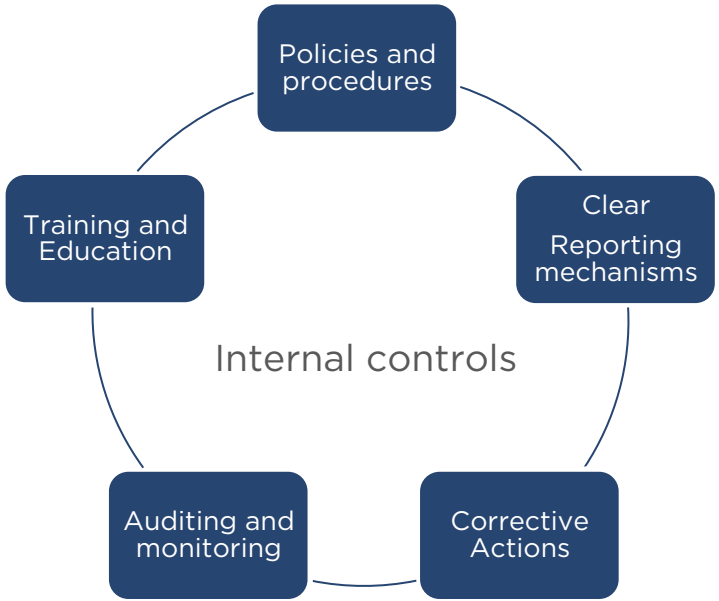
Prioritize highest risk areas that impact compliance obligations first:

- Ensure management has buy in on importance of addressing risks to compliance
- Prioritize resources based on risk levels
- Ensure internal controls exist

Note: Lower risk areas should not be ignored, and should be addressed with the requisite priority.

Step 4: Managing Risk in Approach to Compliance

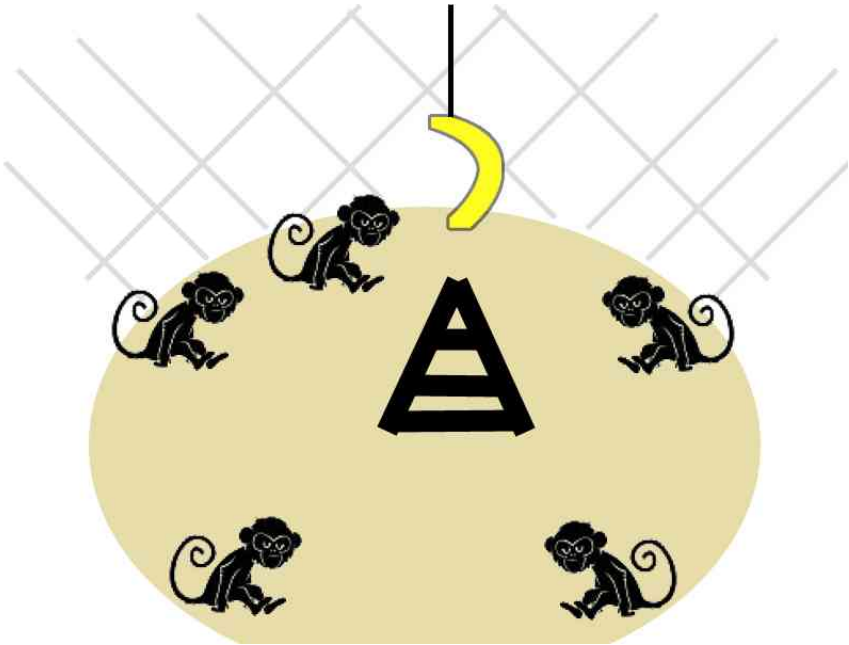
Develop and prioritize internal controls to help manage the risk and promote compliance



Holland & Knight

The Five Monkeys Experiment

In 1967 ....



This will be easy, right?

"But we've always done it that way!"	"What's this going to cost us?"	"How long will it take until everything is compliant?"
Make sure your efforts don't conflict with the company goals	Make sure your budget reflects the entire picture	Make sure you set realistic expectations
Understand what "that way" really means	Understand how budgets drive your company	Understand where Compliance fits in schedule-wise
Explain that some changes result from regulation changes	Explain that cost avoidance is your goal	Explain that Compliance efforts will be ongoing

Risk? What Risk?

Enterprise Risk Assessment
Focus on Compliance topics
Categorize each risk by policy or regulatory topic
Do the ERA on a set schedule

Identify Past Compliance Issues
Internal audits
External audits / fines
Industry issues

Managing the Risk You Know

Each Compliance risk must have an associated procedure

- Policy statements
- Procedures manuals
- Expectations

Determine which Compliance risks impact each business unit

- Let them choose from the list
- Let them rate the likelihood of occurrence
- Let them rate the risk impact

Mitigate each compliance risk appropriately

- Procedures / Training / Monitoring
- Assessments
- Measurement

	Impact		
Likelihood	**Marginal**	**Moderate**	**Critical**
Well Above Average	Elevated (5)	Elevated (10)	Elevated (15)
Somewhat Above Average	Standard (4)	Elevated (8)	Elevated (12)
Average Occurrence	Standard (3)	Elevated (6)	Elevated (9)
Somewhat Below Average	Standard (2)	Standard (4)	Elevated (6)
Below Average	Standard (1)	Standard (2)	Standard (3)

Easy and Hard Learned Lessons

- If management doesn't support the program, it won't happen
- If you rely on training alone, you'll be training forever
- If you're only a cop, you'll be the last to know about issues
- If you make Compliance easy or rewarding, people will get it done
- If you don't update your program regularly, you're creating hard to change habits

Thank you. Questions?

You'll receive a recording of this webinar along with a copy of the presentation slides shortly. Thank you for attending!