Duke University
Institutional Ethics and Compliance Program

Information for Compliance Liaisons & Managers

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Compliance Management by Liaisons

- Compliance Plans and Processes
  - OIG Guidelines for Effective Compliance Programs
  - The Compliance Plan Cycle
- Compliance Risk Management
- Key Monitoring Elements
- Reporting on Monitoring Activities
- “Right-sizing” Compliance Monitoring
Liaison Responsibilities

- Stay informed: you are the subject matter expert and have the responsibility for oversight!
- Keep others informed: let your management, your customers and the IECP know what you’re doing!
- Maintain your inventory – laws do change!
- Build and maintain your plans based on the OIG guidelines
- Monitor effectively
- Report significant findings
- Follow the Notification Policy
The Compliance Plan Cycle
Just another CQI* process!

- Define
- Measure
- Analyze
- Improve
- Control

*CQI: Continuous Quality Improvement
The Compliance Plan Cycle

- Scope Definition and Inventory
- Risk Analysis and Ranking/Prioritization
- Plan Definition
  - Controls, including Policies & Procedures
  - Education and Communication
  - Monitoring
- Conduct Monitoring and Assess Outcomes
- Make Corrections to the Plan
- Start Over
Compliance Risk Management

- Combines Controls & Monitoring Activities
  - Preventative examples
    - Verification of required training before granting system access
    - Disallow non-compliant line items before processing
    - Training on regulations, policies & procedures
  - Detective examples
    - Review of activity reports
    - Site visits (documentation of specific criteria or behaviors)
    - Scheduled self-reporting (such as Effort Reporting or COI)
  - Responsive examples
    - Investigations resulting from complaint or incident report
    - Reviews related to external regulatory or compliance authorities
What is Monitoring?

Definitions of 'monitor' (ˈmən-ər) (transitive verb)
Dictionary.com · The American Heritage® Dictionary

- To *check the quality or content* of (an electronic audio or visual signal) by means of a receiver.
- To *check* by means of an electronic receiver for *significant content*, such as military, political, or illegal activity.
- To *keep track of systematically* with a view to collecting information.
- To *test or sample*, especially on a regular or ongoing basis.
- To *keep close watch over; supervise*.
- To *direct*. 
Monitoring Key Elements
It takes all 4 to deliver actionable information!

#1: What items and processes were selected for monitoring and what methodology was used?

#2: What were the findings? What are the trends related to the findings?

#3: What was the action plan developed based on the findings?

#4: Were there any findings which were reported outside of Duke?
Monitoring Key Element #1

- What items and processes were selected for monitoring and what methodology was used?
  - How do the selections tie to your risk assessment?
  - What is the process you use to do the monitoring?
  - Do you select items to monitor on a random basis, a cyclical schedule, or a risk basis?
  - Does an error or finding tie directly to a violation or is it just a risk indicator?
Monitoring Key Element #2

- What were the findings? What are the trends related to the findings?
  - What kinds of errors were found?
  - What is the context or scope of the error rate?
    - What is the ‘n’ (the whole picture) that you’re looking at?
    - What is the impact of an error rate at the level you found?
  - Are the error rates getting better or worse over time?
  - Have there been ‘interventions’ such as training or process/control improvements that may be affecting the error rates?
Monitoring Key Element #3

- What action plan was developed based on the findings?
  - If you control the process you’re monitoring, what changes or interventions have been made to make improvements?
  - If you don’t control the process, how have the monitoring results been communicated to the operational manager who does?
  - What action plan have you received from them on how they will make improvements going forward?
  - Are there barriers to making the necessary improvements?
Monitoring Key Element #4

- Were there any findings which were reported outside of Duke?
  - What was reported and to whom?
  - Was this a mandatory report or an institutional decision?
  - Who was involved in the decision and who has been informed?
  - Were there, or will there be, any penalties involved with the findings?
Monitoring Key Elements

Summary:

- Your monitoring should be based on the items that you believe drive the greatest risk.
- Monitoring should produce actionable information – not just data.
- Your monitoring report should make key items clear to any reader.
- If you have the ear of the Audit Committee and the ICSC FOR 30 SECONDS, what do you want them to know?
Risk Based Monitoring

- Duke’s financial constraints drive resource management requirements
- Focus has been on ensuring that monitoring was, at the least, adequate for the assigned risk level
- Shift must now be made to ensure that monitoring levels are resource **appropriate** for risk levels --
  - In general, 100% monitoring of an area would be considered excessive UNLESS it is a regulatory requirement
  - Sample size and selection should be based on assessment of controls in place and prior monitoring results
Risk Based Monitoring

- Monitoring resources must be focused on areas of highest risk.

- Things to consider:
  - What are the areas or processes most likely to fail?
  - Can better controls be put in place to minimize the need for monitoring?
  - What are the most efficient ways to monitor the area?
  - If you need more resources for education, can your monitoring plan be adjusted to free up those resources?
Compliance for Everyone

- Tone at the Top
- Action in the Middle
- Responsibility Throughout

*Compliance Liaisons are the teachers, the mentors, the examples and the resources for compliance to the Duke community*
Supporting a Culture of Compliance

Additional information for operational units & managers
Supporting a Culture of Compliance: Manager Responsibilities

- **Recognize:**
  - Educate yourself on which activities in your area have compliance requirements and what they are
  - Make sure your staff know what to do and that you expect compliance
  - Monitor performance
Supporting a Culture of Compliance: Manager Responsibilities

- Respond:
  - Take action when problems are found
  - Manage performance for compliance along with other operational standards
  - Make time for retraining when needed
  - Ask for help -- the individual compliance areas and the IECP are ready to assist!
Supporting a Culture of Compliance: Manager Responsibilities

- **Report:**
  - Call the appropriate compliance area when you *think* there’s a problem!
  - All ‘non-standard’ requests from outside agencies should be immediately coordinated with compliance or legal.
  - Not reporting a violation is A VIOLATION under most regulations!