More Than Just Compliance: A Review of Campus Laboratory Safety Programs

John Curran

Session Objectives

- Recognize elements of a compliance framework and apply those elements in an audit program.
- Reference key risks related to campus laboratory safety programs.
- Develop an audit approach to assess governance, oversight, and processes of a campus laboratory safety program.
Session Agenda

- Internal Audit at the University of Kansas
- Internal audit approach to campus compliance programs
- The Compliance Framework in concept
- The Compliance Framework in application
  - Laboratory risks and events
  - Laboratory safety at KU
  - Audit approach & results
  - Lessons learned
- Questions
Our Challenges

- Focus on horizontal over vertical audits
- Consider effectiveness and efficiency when developing audit criteria
- Get to root cause
- Avoid becoming a defacto compliance function
- Navigate campus-centric, institutional compliance and risk management programs
- Find a common approach in auditing the multitude of university compliance programs
Horizontal vs. Vertical Auditing

<table>
<thead>
<tr>
<th>Type</th>
<th>Horizontal</th>
<th>Vertical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examples</td>
<td>• Control assessment of central payroll process</td>
<td>• Testing selected controls for a specific campus unit</td>
</tr>
<tr>
<td></td>
<td>• Identifying drivers of cost transfers</td>
<td>• Department transition review</td>
</tr>
<tr>
<td></td>
<td>• Assessing HIPAA compliance program</td>
<td></td>
</tr>
<tr>
<td>Considerations</td>
<td>• Centralized processes facilitate</td>
<td>• Allows for a deeper dive into a specific unit or concern</td>
</tr>
<tr>
<td></td>
<td>• Resource intensive</td>
<td>• Audit impact/value may be limited</td>
</tr>
<tr>
<td></td>
<td>• Added value/impact likely greater</td>
<td></td>
</tr>
</tbody>
</table>

Developing Solid Audit Criteria

• Policies
• Laws and regulations
• Interpretative guidance
• Industry publications
• Case studies and research reports
• External audit reports
• Benchmarking
• Past/comparative performance
• Auditor judgement

Good sources when testing effectiveness and efficiency
Getting to Root Cause

- **Criteria** – What should be; expected condition
- **Condition** – What exists
- **Effect** – The risk or exposure the organization and/or others encounter because the condition is not consistent with the criteria (the impact of the difference)
- **Cause** – The reason for the difference between the expected and actual condition

Timesheets were not always processed in accordance with payroll policies. We found three timesheets for non-exempt employees were not approved by their supervisor as required by policy 404C Disbursements. Signatures on the timesheets did not agree with the employee’s immediate supervisor’s name. We were told that some supervisors delegate their time approval responsibilities. However, the Payroll department does not maintain a list of delegated approvers and does not always know who is authorized to approve timesheets. Without an authorized review and approval it is difficult to determine if the reported hours are accurate.
Hazards of Auditing Compliance

- Avoid becoming a defacto compliance function
- Navigate campus-centric, institutional compliance and risk management programs
- Find a common approach in auditing the multitude of university compliance programs

Three Lines of Defense Model

Adapted from ECIIA/PERMA Guidance on the 8th EU Company Law Directive, article 41
2201 – Planning Considerations

In planning the engagement, internal auditors must consider:

- The objectives of the activity being reviewed and the means by which the activity controls its performance;
- The significant risks to the activity, its objectives, resources, and operations and the means by which the potential impact of risk is kept to an acceptable level;
- The adequacy and effectiveness of the activity’s governance, risk management, and control processes compared to a relevant framework or model; and
- The opportunities for making significant improvements to the activity’s governance, risk management, and control processes.

The Compliance Framework

Application of the Compliance Framework in developing audit criteria for compliance-related programs
How We Have Used It

Audits of campus compliance programs for...

- Export controls (Medical Center)
- HIPAA Privacy (Lawrence Campus)
- Animal Protection (Medical Center)
- Laboratory Safety (Lawrence Campus)

Governance

A combination of individuals filling executive and management roles, program oversight functions organized into structures, and policies that define management principles and decision making.

- Assign Roles & Authority
- Identify Regulations
- Establish Policy
- Provide Training
- Engage Stakeholders
Risk Management

The process of identifying risk, assessing risk, and taking steps to reduce risk to an acceptable level.

- Identify Activities
- Assess Risk
- Monitor and Manage Compliance

Internal Controls

The policies and procedures that help ensure management directives are carried out. They help ensure that necessary actions are taken to address risks to achievement of the entity’s objectives.

- Establish Internal Controls
Performance Management

The process of collecting, analyzing and/or reporting information regarding the performance of an individual, group, organization, system or component.

• Measure Performance
• Improve Continuously

Auditing Performance

• All programs we audit, compliance or otherwise, deliver a service
• Input resources are acquired and applied through processes to produce selected outputs that are intended to achieve certain desired outcomes
The Service Delivery Model

Crosscutting Performance Goals
- Customer and Stakeholder Satisfaction
- Compliance
- Safeguarding Assets
- Information Availability, Reliability & Validity
- Continuous Improvement
- Underlying Values

Efficiency

<table>
<thead>
<tr>
<th>Results</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outputs</td>
<td></td>
</tr>
<tr>
<td>Production / Delivery</td>
<td></td>
</tr>
<tr>
<td>Inputs (Money)</td>
<td></td>
</tr>
<tr>
<td>Inputs (Material &amp; People)</td>
<td></td>
</tr>
<tr>
<td>Acquisition</td>
<td></td>
</tr>
</tbody>
</table>


Applied to the EH&S Function

Crosscutting Performance Goals
- PI and Senior Leadership Satisfaction
- Regulatory Compliance
- Safeguarding of Chemical Inventories
- Accuracy and Completeness of Inspection & Chemical Inventory Records
- Application of Performance Metrics

Efficiency

<table>
<thead>
<tr>
<th>Results</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outputs</td>
<td></td>
</tr>
<tr>
<td>Production / Delivery</td>
<td></td>
</tr>
<tr>
<td>Inputs (Material &amp; People)</td>
<td></td>
</tr>
<tr>
<td>Acquisition</td>
<td></td>
</tr>
<tr>
<td>Inputs (Money)</td>
<td></td>
</tr>
</tbody>
</table>

- Goal Achievement
- Satisfaction
- Quality
- Timeliness
- Productivity
- Unit Cost
- Quantity
- Quality
- Productivity
- Amount
- Near-miss Count
- Workers Comp Claims
- # of Findings per Inspection
- Inspections conducted per FTE
- Filled FTE Count
- Training Hours
- Staff Certifications
- Turnover Rate
- Open FTE Count
- Unit Budget
Laboratory Risks

Typical risks associated with research and teaching laboratories:
- Audit Risk
- Safety
- Safeguarding of Assets/Inventory
- Efficiency

Lab Accidents in the News

- UCLA research assistant dies from burns suffered in a 2009 lab fire (civil and criminal penalties assessed)
- Yale student dies after hair caught in a lathe (2011)
- Texas Tech lab explosion causes serious injury to a grad student (2010)
- Lab fire in KU's Malott Hall causes $800,000 in damage (2011)
Audit Background

• Needed assurance that lab safety was effectively managed
• Aging facilities added to inherent risk
• EHS Department charged with lab safety program; organizationally resides within campus operations & facilities
• Kansas not an “OSHA state”
• Focus was lab spaces with hazardous chemicals present (excluded radiological, biomedical)
• Three-person audit team assigned (senior auditor, staff auditor, and intern)
• Fieldwork represented 8 weeks of work
• Senior auditor resigned two-thirds into fieldwork

Audit Approach

• Researched peer institutions and recommended practices
• Selected two academic departments to gain an understanding of unit-level compliance practices and to make an assessment of the program overall
• Reviewed previous EHS evaluation reports, inspection protocols, and data management
• Accompanied EHS staff and observed the execution of laboratory inspections
Resources We Relied On

- US Chemical Safety & Hazard Investigation Board (CSB) case study of the Texas Tech laboratory explosion (http://www.csb.gov/assets/1/19/csb_study_ttu_.pdf)
- The National Research Council’s “Prudent Practices in the Laboratory” 8th edition (referred to as the “Prudent Practices”)
- The CRC “Handbook of Laboratory Safety” 5th edition

Accident Causation

James Reason’s Swiss Cheese Model of Accident Causation applied to a university setting (CSB case study)
Assign Roles & Authority

Involvement of key stakeholders exists to influence safety culture and practices.

- Are the right stakeholders involved?
- How often do they meet?
- Are they adequately engaged (i.e. input sought) to encourage their participation and buy-in?

Results: New committee structure with senior leadership involvement

Identify Regulations & Establish Policy

Laboratory safety related policies and procedures reflect current regulatory standards.

- Are laboratory safety protocols documented and regularly reviewed in light of regulatory changes and safety events?
- Are policies and procedures accessible to those who need it?
- Does policy identify respective roles and authority, requirements for those subject to the policy, and consequences for non-compliance?

Results: Laboratory safety manual updated
Identify Business Activities

*Inventory of physical laboratory space is complete and accurate.*

- How does laboratory space inventory compare against other space management records?
- Can you validate the inventory through physical inspection?
- Are laboratory spaces marked in accordance with the inventory?

Results: Making use of campus space management system; validating inventory with routine inspections.

Assess Risk

*Laboratory spaces are classified by risk, given the activities performed, chemicals present, and other factors.*

- Is the classification process documented with clear criteria for risk-based classification? (e.g. biosafety level if appropriate)
- Are all laboratory spaces assessed and assigned a risk classification level?
- Are spaces with a higher risk classification level required to have additional mitigation plans?

Results: Percentage of spaces without a classification decreased by half
Identify Activities

*Inventory of chemicals and other hazardous materials exists and is complete and accurate.*

- Where are chemical inventories maintained and are they readily accessible?
- Are the inventories complete and accurate with regular validation?

Results: Timing new chemical inventory system with new facilities coming online.

Establish Internal Controls

*Acquisition, storage, and disposal of chemicals are well controlled.*

- Key Control: EHS approval of selected chemicals
- Key Control: Centralized purchasing of chemicals
Monitor Compliance

Laboratory inspections are scheduled using a risk-based approach?

• Are assigned risk-levels considered when scheduling laboratory visits/inspections?
• How often are high-risk labs visited? How often are all labs visited?
• Is there a mechanism to report unsafe laboratory conditions and practices (e.g. hotline)?

Results: Migrated to institutional hotline

Monitor Compliance

Laboratory inspections are effective to identify and correct unsafe conditions.

• Are inspection items and findings weighted or prioritized based on severity?
• Are inspections thorough enough to capture all major violations and to assess compliance?
• Are pertinent lab personnel present during inspections?
• Do multiple EHS personnel conduct inspections to help ensure quality and completeness of evaluations?
• Does the inspector demonstrate proper assertiveness and knowledge when working with lab personnel?
Measure Performance

Measurable outcomes and performance indicators are established for the laboratory safety program.

- Are meaningful metrics in place to assess safety efforts (outcomes vs. outputs)?
- Are results communicated to key stakeholders and senior leadership?
- Are the results used to make improvements to the program?

Results: Developing as part of larger institutional compliance data collection efforts

Lessons Learned

- If resources allowed, would have surveyed for EHS satisfaction and assessed training efforts
- Consistent with recent recommendations by the American of Public & Land Grant Universities in its “Guide to Implementing a Safety Culture”
- Important to challenge auditors to consider their observations and professional judgement
- The Compliance Framework is useful in developing findings and getting to root cause
- Consider non-laboratory spaces where high-risk chemicals/materi als are stored
Questions

John Curran
University of Kansas
jacurran@ku.edu
(785) 864-3975

Cate Neeley
University of Kansas
cateneeley@ku.edu
(785) 864-8082