Auditing Compliance Effectiveness
THROUGH A LEAN LENS

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Shriners Hospitals for Children
International Headquarters
Specialized Pediatric Care

Our patients are at the heart of everything we do. They inspire us to continue our mission of improving the lives of children and families.

Orthopaedics  Burn Care  Spinal Cord Injury  Craniofacial and Cleft Lip/Palate  Telehealth Care Network

1.4 Million  $38 Million  145,608
Children Treated  Invested in Research  Children Cared For
Since 1922  In 2019  In 2019

Caring for Children in More Places
With 22 locations, telehealth sites, outreach programs and community clinics

[Map showing locations across the United States and other countries with heart icons marking specific locations]
INTRODUCTION
OBJECTIVES

01. Establish two methodologies for developing an audit program for a compliance effectiveness review

02. Discuss the requirements for an effective compliance program and provide best practices for mitigating key risks in areas of vulnerability

03. Provide practical advice and tangible resources for incorporating lean methodologies into your compliance program practices

04. Gain a basic understanding of how lean methodologies can guide decision making during audit processes
This presentation may challenge your way of thinking. It contradicts some of the traditional norms associated with internal auditing. It may seem contrary to the way things have always been done.

The goal of incorporating Lean thinking into your strategy is to improve quality and enhance operations. Improvement sometimes requires a shift in thinking.

A Lean Business Operation:

*Transfers the maximum number of tasks and responsibilities to the stakeholders who actually add value to the product, and it incorporates a system for quickly detecting waste or strain (risks) in operations.*
Points to Ponder

1. **VALUE IS THE GOAL**
   An effectiveness review can feel like a check box exercise. It is useless unless it adds value to the organization.

2. **VALUE IS DEFINED BY THE PRIMARY STAKEHOLDER**
   Auditors must partner with the process owners keeping the organization’s strategic goal and owner short term goals in the forefront of planning and fieldwork. Be flexible with protocols.

3. **Results Must Prompt Action**
   It is not enough to provide a “report card” to your client. Your work should be used as a catalyst for forward action.
Lean methods provide a path to enhance efficiency and improve customer satisfaction. They can make products or services more efficient. Therefore, Lean methods have become a common industry practice.

The process consists of identifying waste and actions that cause strain in operations. Strain can also be referred to as risks or things that inhibit progress.

What is a Lean Method

Why is it Important

Improve Quality

Results in actions or recommendations that make services conform to stakeholder expectations.

Reduce Waste

Identifies any actions that do not add value to the process.

Improve Efficiency and Effectiveness

Reduces time and pinpoints the most effective actions to accomplish tasks. Paves a way to quality.
Expand Your Definition of Risk

Think about risks as anything that **slows** or **hinders** effective and efficient processes – not just the egregious actions that are commonly considered risks.

Consider these items

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**8 Wastes**

The 8 Wastes are eight types of process obstacles that get in the way of providing value to the customer.

- **Defects**: Efforts caused by rework, scrap, and incorrect information.
- **Overproduction**: Production that is more than needed or before it is needed.
- **Waiting**: Wasted time waiting for the next step in a process.
- **Non-Utilized Talent**: Underutilizing people's talents, skills, & knowledge.
- **Transportation**: Unnecessary movements of products & materials.
- **Inventory**: Excess products and materials not being processed.
- **Motion**: Unnecessary movements by people (e.g., walking).
- **Extra-Processing**: More work or higher quality than is required by the customer.

[https://goleansixsigma.com/8-wastes/](https://goleansixsigma.com/8-wastes/)
Remember, the principal audit/review process does not change.

The principal auditor role does not change... internal auditors are the eyes and ears of the Board tasked with assurance and consulting guidance on the adequacy of internal controls

- Clearly define your customer scope and objective
- Gain an understanding of the risks
- Identify the key processes and transactions
- Evaluate the adequacy of internal controls within the scope of the review

A lean audit will not change your role or its overall objectives. It will provide a more definitive path for adding value within the key processes and transactions that occur.
BACKGROUND
Two Organization Types

A

- Consists of multiple regional facilities
  - Report to one overarching governance structure
  - Similar governance structures within facilities
- Fully developed and comprehensive Compliance Program
  - Compliance program several years old
  - Facilities have shared best practices in terms of compliance education & oversight operations
  - Established compliance workflow/plans for each compliance element and functional area
- Internal Audit and separate Compliance function
- Consistent support from Leadership

B

- Consists of multiple national/international facilities
  - One overarching governance structure
  - Varying governance structures within faculties
- Compliance Program in infancy stages
  - Compliance program less than 5 years
  - Facilities have little to no established shared practices for compliance education & oversight
  - Minimal common workflow among facilities
- Compliance function and no Internal Audit
- Limited Leadership understanding of the Compliance Program
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Preliminary Planning
Use available tools to gain an understanding of the organization’s culture, communication flow, program components, and most importantly the – Tone at the Top
Identify Organizational Goals...

What is the cultural state?

A

- Strategic Plan
  - Evidence of Facility Operations in Support of / Aligned to Plan
- Strong Employee Engagement
- Strong Communication and Collaboration Among Facilities
- Stringent Guidelines
  - Perceived Accountability

Workforce are aware of expectations and unity of system operations are defined and documented.

B

- Strategic Plan
  - Complex Plan with Unclear Operational Alignment
- Employee Engagement Strained by Multiple Changes
- Building Collaboration Among Workforce
  - Silos Prominent
  - Little Collaboration Among Facilities
- Accountability Amongst Change
  - Unclear Owners

All actions within an organization should be designed with the strategic plan in mind. However, it will take a number of short-term goals to realize this long-term goal. Focus your efforts here. Use the goals of the immediate stakeholders to shape your plans.

Review will focus on recommendations that will not only remedy short-term goals but will maintain forward movement towards long-term strategies. No quick limited fixes.

Culture of change. Workforce unsure of current or future expectations. Little to no defined and documented unified operations.
Determining Scope

Have a preliminary meeting with key stakeholders before you determine your scope and before planning your risk assessment.

- True effectiveness audit – focuses more on reviewing methods in place to ensure education & training, continuity, implementation, and understanding.
- Evaluates tools in place for opportunities for improvement.

- Assessment focus - effectiveness is centered on the design of program to be implemented.
  - Overall effectiveness is lacking; therefore, partnering is required to guide development.
  - Identify, assess, brainstorm, advise.
Risk Assessment

Audit steps will be directly linked to risk assessment and value stream. Use the standards for an effective compliance program as your guide.

https://www.justice.gov/criminal-fraud/page/file/937501/download

## Risk Assessment

### Initial Evaluation of Risk

<table>
<thead>
<tr>
<th>PROJECT RISK</th>
<th>LIKELIHOOD</th>
<th>IMPACT</th>
<th>INITIAL RISK SCORE</th>
<th>MANAGEMENT AGREEMENT</th>
<th>MITIGATING FACTORS THAT AFFECT RISK PERCEPTION</th>
<th>LIKELIHOOD</th>
<th>ADJUSTED RISK SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential inherent risks related to the process. This portion is developed following the preliminary research and mapping the value stream. It is before your entrance conference.</td>
<td>0=UNLIKELY 1=POSSIBLE 2=PROBABLE 3=HIGHLY LIKELY</td>
<td>0=N/A 1=LOW 2=MEDIUM 3=HIGH</td>
<td>Add likelihood and impact scores</td>
<td>Do managers of this process or area agree with the risk score?(Y/N)</td>
<td>If management does not agree with the risk score, evaluate the mitigating factors of this risk. Then rate the likelihood that the risk could happen and the impact if it did happen, considering the mitigating factors.</td>
<td>0=UNLIKELY 1=POSSIBLE 2=PROBABLE 3=HIGHLY LIKELY</td>
<td>Initial risk score will apply if management agrees. Adjusted score may otherwise apply.</td>
</tr>
</tbody>
</table>

### Standards, Policies, and Procedures

| 1 | Accessibility - employee policy website cannot be accessed by all workforce members | 2 | 3 | 5 | no | All sites are auto tested daily for the website compatibility and alerts are monitored and addressed within 24 hours if system malfunctions occur | 0 | 3 |
### Value Stream – Kaizen

Map value stream before attempting to draft program

| Kaizen – a philosophy which strives for continuous improvement (Goals – transparent and sustainable processes) |
| Control - sustain the current improved performance of the process |
| Process Improvement | & | Process Control |
| No deviation in the performance of the established process – consider standard operating procedures and best practices | Deviations in performance or improvements indicate that alterations to the performance of the operation (SOPs) may be needed |

**Why consider this now?** Begin with end in mind. How will effectiveness be measured?
OIG
Measures effectiveness in terms of existence and proper implementation of program elements

CMS
Measures effectiveness by billing results (accuracy, completeness, timeliness)
Think backwards from expected results. Remember, you will have subflows to map for each element.
Value Stream Lean Tools

...to assist your evaluation

- **Cando**
  5 waste limiting steps: Sort, Set in Order, Shine, Standardize, and Sustain.
  - STANDARDIZE
  - SUSTAIN

- **Visual Factory**
  Communicate information in a way that everyone can understand. Are processes hard to navigate?
  - Clear instructions
  - Clear directives with owners
  - Visual aids to increase understanding
Each step in your audit program should be linked to a specific risk.

Use your value stream to identify key process owners at critical steps in the value stream. They should be invited.

Complete your program. Document the meeting minutes, final scope and objective. Distribute to group in accordance with your process.
Testing
There is no real value to audit if recommendations are not utilized.

Keep the stakeholders involved in every stage of the audit. The best practice standard in one facility may not be readily achievable in another.
Facility with well established compliance program

<table>
<thead>
<tr>
<th>Program Element and Audit Step</th>
<th>Best Practice &amp; System Expectation</th>
<th>Location 1</th>
<th>Location 2</th>
</tr>
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<tr>
<td>Monitoring and Auditing</td>
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<td>The use of audits and/or other risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems</td>
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<td>Billing/coding reviews of hospital claims are performed or initiated by internal parties:</td>
<td>Best Practice &amp; System Expectation</td>
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<td></td>
</tr>
<tr>
<td>a) Internal Staff</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>b) Consultants</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Internal Audit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Determine whether billing/coding reviews of hospital claims are performed or initiated by internal parties and document the frequency at which this occurs</td>
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<tr>
<td>2. Obtain evidence of audit occurrence. Assess controls surrounding audit process.</td>
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<tr>
<td>3. Evaluate corrective measures methodology</td>
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<tr>
<td>4. Assess process for training to include continuity measures and monitoring process.</td>
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<tr>
<td>5. Map value stream and consider recommendations for improvement</td>
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### Facility with newly established program & transitioning system

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**Billing/coding reviews of hospital claims are performed or initiated by internal parties:**

- **a) Internal Staff**
- **b) Consultants**
- **c) Internal Audit**

1. Identify system expectations for auditing and monitoring. If no expectation is established, consider controls surrounding process & incorporate need within recommendation.

2. Identify parties responsible for revenue cycle operations, billing, and reviews. Determine if a method has been established for auditing. What is the current performance expectation?


4. Assess process for training to include continuity measures and monitoring process.

5. Map value stream and consider recommendation for audit and monitoring best practice for system (facility recommendation will be developed following testing conclusion and linked to system best practice expectation).
Management Action Plans
Corrective Measures or management action plans should be considered alongside your stakeholders throughout the course of the audit.

Sufficient to Meet Control Needs, Practical, Valuable to Process Owner
You are the expert in controls, but the owner knows the resources, goals, and overall probability of implementing changes within the operation. Work together.
Determine if a comprehensive risk assessment exists that obtains risks from every level within operations and continuously evaluates risk impact as the risks are reported. This is best achieved through an automated communication system.
Risk Assessment

In organization B, it may be best to recommend the goal of a comprehensive risk assessment. Outline the control path needed to address compliance risks associated with communicating information to the appropriate compliance officials.

Focus on identifying functional areas of risk.

Best Practice Audit Tips

- Obtain the risk assessment performed to identify and prioritize compliance risks and document how the risk assessment was prepared.
- Identify who performed the risk assessment.
- Document the comprehensiveness of the risk assessment.
- Obtain any communication and additional review of the risk assessment.
- Determine how areas unique to the facility are incorporated into the risk assessment.
- Determine if risks exist outside of the documented functional areas (i.e., how are additional functional areas of risk identified).

Facility A

Facility B
Oversight: Designation of a Compliance Officer and Facility-Specific Compliance Leadership

**FACILITY A**
- Confirm that reporting structure is functioning as established at corporate and facility levels.
- Ensure documented responsibility outlines exist for cultural awareness etc.

**FACILITY A**
- Verify that an established budget exists and compliance resources are allocated based upon a risk based plan.

**FACILITY B**
- Identify current governance structure at system and facility levels and assess need and placement for compliance officials.

**FACILITY B**
- Based on value stream identify areas where controls should exist in documented responsibility outline.

**BEST PRACTICE AUDIT TIPS**

### Expectations for Accountability & Support of Program?

- [Best Practice Audit Tips](#)
**Written Standards:** The development and distribution of written standards of conduct, policies, procedures and protocols that promote the facility’s commitment to compliance

<table>
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<th>FACILITY B</th>
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<tbody>
<tr>
<td>Confirm that required governance documents exist for key risks and culture guidance in language that is easily understood. Test to confirm compliant content &amp; implementation within operations.</td>
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<tr>
<td>Verify that communication channels exist to disseminate data, confirm understanding during data transitions, and promote awareness</td>
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<tr>
<td>Assess status of documented governance documents based upon risk assessment, value stream, and regulatory standards. Is a guidance doc needed for content development?</td>
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<tr>
<td>Confirm a plan exists for communication. Evaluate adequacy if in existence or assess control needs if no plan exists. How can current resources be best utilized and positioned for growth in a system plan?</td>
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**BEST PRACTICE AUDIT TIPS**
Education: The development and implementation of regular, effective education and training programs for all affected workforce

**FACILITY A**

- Confirm that education plan is designed based upon a comprehensive risk assessment and is adaptable.
- Assess the adequacy and availability of continuous resources.

**FACILITY A**

- Verify that monitoring exists to promote ownership for understanding, and confirm high risk areas are addressed and corrective measures are enforced.

**FACILITY B**

- Identify resources and methods for dissemination of compliance education at each facility.
- Assess accountability measures.

**FACILITY B**

- Use findings and value stream to determine best education structure to address control needs utilizing available resources.
- Does it already exist within system? Is workforce defined?

**BEST PRACTICE AUDIT TIPS**
Communication: The creation and maintenance of an effective line of communication between the compliance officer and all employees, including a process, such as a hotline or other reporting system, to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect whistle blowers from retaliation.

**BEST PRACTICE AUDIT TIPS**

Does a comprehensive communication system exist for compliance communication at all levels? If so, is it automated, does it identify owners and functional areas, and can it be used for risk assessments?
Response and Discipline: Consequences should be levied consistently regardless of the employee's status within the facility.

**FACILITY A**

Consider the following:
- Is protocol for investigations documented to include ownership, escalation, and assessment?
- Are high risks followed closely?
- Are audits performed to confirm process compliance and corrective measures implementation & follow-up?
- Evaluate methodology to confirm fairness and ongoing education

**FACILITY B**

Consider the following:
- Has the system established any governance for the process?
- Have processes within facilities been identified and evaluated?
- What mechanisms are used? Is there a mechanism for reporting that can address needed controls and communication flow at all locations? Is it achievable with current resources?

BEST PRACTICE AUDIT TIPS
Response and Prevention: The facility responds to improper allegations and establishes controls to prevent further non-compliance.

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<td>Identify process established to ensure facilities have implemented controls to respond to the reported offenses. Does it have controls to promote ownership, timely communication, fairness and continuity.</td>
<td>Verify that incentives as well as corrective measures are in place to promote compliance. How is implementation of these measures monitored? Is implementation aligned with goals?</td>
<td>Identify and assess methods in place at various facilities and determine control needs in a design that will facilitate continuity in response and prevention measures across the system.</td>
</tr>
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**BEST PRACTICE AUDIT TIPS**
Results Analysis & Recommendations
LEAN AUDIT THINKING REMINDERS

Expand your definition of risks and include any item that may result in waste.

Assessing risks and mapping the value stream or process does not end in pre-planning.

Recommendations must fit the culture, the process, support the stakeholder goals, and pave a path to quality / RIGHT-SIZED.

Always consider controls to promote continuity of knowledge and standardization of process.

Keep your stakeholder’s / process owners goals in the forefront of your thinking. Begin with the end.
Using the elements in your discussions and report are the best way to gain stakeholder buy in. Owners must understand the how and the why. The why should include their personal goals, not just the standard.

<table>
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<tr>
<th>CONDITION</th>
<th>Define the happening, issue, or concern</th>
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<tbody>
<tr>
<td>EFFECT</td>
<td>Explain the impact on the operation. Define the waste</td>
</tr>
<tr>
<td>CAUSE</td>
<td>Provide root cause analysis. Explain the how and why it is a waste</td>
</tr>
<tr>
<td>CRITERIA</td>
<td>What is the standard, requirement, or best practice. Explain why is it important for goal achievement</td>
</tr>
<tr>
<td>RECOMMENDATION</td>
<td>Provide controls needed for path to process improvement or corrective measure realization</td>
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