Response to Wrongdoing

Agenda

• Federal Sentencing Guidelines
• 7 Elements of Effective Compliance Program
• Department of Justice Guidance
• Sources of Wrongdoing
• What is a Root Cause Analysis?
• What is a Remediation Plan?
• Benefits of RCA/Remediation Plan
• Elements of RCA
• Elements of Remediation Plan
• Case Study
• Recap
Federal Sentencing Guidelines

- Effective 1991
- Authored by United States Sentencing Commission
- Amended several times since inception
- Correlation with how federal judges sentence defendants in criminal cases
- Emphasis on organizational sentencing policy relating to compliance and ethics programs
- Corporation responsible for taking actions to mitigate risk and prevent criminal conduct

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Federal Sentencing Guidelines

- Evolution of elements
- Fundamental vs. Mature
- What does “response” to wrongdoing imply?
- Reactive vs. Proactive

7 Elements of Effective Compliance Program

1) Written policies and procedures
2) Compliance officer and oversight
3) Training and education
4) Internal monitoring and auditing
5) Reporting and investigating
6) Enforcement and discipline
7) Response and prevention
Federal Sentencing Guidelines

Three Key Components of a Compliance Program:

1. Prevention
   - Written policies and procedures
   - Compliance officer and oversight
   - Training and education

2. Detection
   - Internal monitoring and auditing
   - Reporting and investigating

3. Corrective Action
   - Enforcement and discipline
   - Response and remediation
Department of Justice Guidelines

“Principles of Federal Prosecution of Business Organizations” in the Justice Manual includes guidance related to compliance programs

- Guidance first issued in February 2017
- Updated April 2019
- Latest Update June 2020
- Updates reflect DOJ experience and feedback from compliance communities

Department of Justice Guidelines (cont.)

Guidance includes items that prosecutors should consider in conducting an investigation of a corporation in determining penalties, fines, etc.

Factors include:
- Adequacy and effectiveness of compliance program at the time of the offense and at the time of charging decision
- Corporation’s remedial efforts in response to the compliance event
- Program “effectiveness” in evaluating strength of the program
Department of Justice Guidelines (cont.)

Three Key Questions:

1. Is the corporation’s compliance program well designed?

2. Is the program adequately resourced and empowered to function effectively?

3. Does the corporation’s compliance program work” in practice?

Department of Justice Guidelines (cont.)

Does the Corporation’s Compliance Program Work in Practice?

DOJ Guidance (June 2020) addresses RCA and Remediation Plan

• RCA should adequately address what contributed to the misconduct
• Remedial efforts should be thorough and comprehensive
• Remediation plan should be sufficiently designed to prevent similar events in the future
Department of Justice Guidelines (cont.)

Root Cause Analysis and Remediation of Any Underlying Misconduct

• Demonstrate RCA performed in response to misconduct
• Identify systemic issues
• Engage and solicit support/participation from leaders/SMEs
• Should be timely in response to issue
• Demonstrate remediation steps considered if necessary to address results

Department of Justice Guidelines (cont.)

Root Cause Analysis and Remediation of Any Underlying Misconduct (cont.)

• Were appropriate changes or revisions made to the compliance program to mitigate the risk of future occurrences?
• What specific remediation has addressed the issues identified in the root cause and missed opportunity analysis?
• What disciplinary actions did the company take in response to the misconduct and were they timely?
• Were managers held accountable for misconduct that occurred under their supervision?
Sources of Wrongdoing

Source of Wrongdoing
• Whistleblower
• Hotline
• Employee
• Management
• Compliance Department/Legal

Sources of Wrongdoing (cont.)

Determining if Root Cause Analysis (RCA) and/or Remediation Plan is needed:

• Document event/issue in tracking system
• Work with management to gather details and copy of report
• Solicit advise from Legal to determine extent and impact of non-compliance event
• If still unclear “why” event occurred, consider RCA
• Discuss with management/leadership/SMEs to begin process
• Evaluate need for Remediation Plan (after RCA is complete)
What is a Root Cause Analysis?

Definition:
• A researched approach to identify underlying reason for an event
• Determines why compliance failure allowed to happen
• Performed as soon as possible after incident occurs
• Level of effort, resources, techniques are based on significance of even and risk/likelihood of reoccurrence

What is a Remediation Plan?

Definition:
• Tasks/actions that address correcting or mitigating risk of reoccurrence of issues or findings related to a non-compliance event
• Extent of plan based on significance of event and risk of reoccurrence
• Mandated either externally or internally
• Key factor in demonstrating company’s commitment to ensure appropriate steps/actions taken to correct wrongdoing
Benefits of RCA/Remediation Plan

Continuous Monitoring / Continuous Improvement

RCA
• Determines why an event occurred
• Based on objective analysis
• Informs options for potential solutions
• Demonstrates commitment to understanding why an event occurred
• Improves controls and worker accountability
• Establishes foundation for remediation

Benefits of RCA/Remediation Plan (cont.)

Continuous Monitoring / Continuous Improvement

Remediation Plan
• Assigns and confirms accountability for corrective actions
• Demonstrates:
  ▪ Acceptance of responsibility/accountability
  ▪ A commitment to taking steps to correct issue
  ▪ A commitment to prevent future wrongdoing
RCA - Key elements

• Gather preliminary information
• Develop project charter, appoint facilitator, assemble team
• Gather facts to understand what happened
• Review “situations” and “circumstances” to understand what happened
• Review contributing factors to identify underlying process and system issues of the event
• Document changes and recommendations to eliminate root cause(s)
• Team determines how implementation of recommendations will be evaluated

RCA – Keys to success

• Succinct and well-defined scope
• Stakeholder engagement and resources committed
• Transparency around purpose of analysis and work plan
• Quick turnaround
• Analysis scaled to match significance of event and risk of reoccurrence
• Effective transition to Remediation Plan
RCA – Potential Contributing Factors

- **Accountability**: Ownership is unclear
- **Documentation**: Required information is incomplete, inaccurate, or missing
- **Fraud**: Intentional misrepresentation of facts
- **Human Error**: Activities are omitted, not executed properly
- **Inefficiency**: Processes not properly assessed for efficiency/best practice
- **Operational Alignment**: Processes/workers don’t have common objective
- **Monitoring/Oversight**: Activities to accomplish objectives not monitored

RCA – Contributing Factors (cont.)

- **Worker Knowledge-base**: Sufficient training/awareness
- **Physical Safeguards**: Lack appropriate assets, adequate physical security
- **Policies/Procedures**: Missing, outdated, incorrect instructions/directions
- **Segregation of Duties**: Lack of checks and balances
- **Strategic Error**: Unanticipated event or improper assessment of risk
- **System Access/Technology**: Lack of controls/monitoring of system access
RCA Results

RCA Team:
- Establishes consensus on outcome of analysis and final report
- Reviews results with stakeholders (leadership/SMEs)
- Transitions ownership to business/legal/compliance areas for additional steps (Remediation Plan), if necessary

Elements of Remediation Plan

Phase 1
- Review RCA (if conducted)
- Identify stakeholders (including leadership) accountable for plan
- Develop draft plan prior to meeting with stakeholders (optional)
- Meet with stakeholders/SMEs to review results/observations in RCA
- Solicit feedback/comments for use with developing plan
Remediation Plan

Phase 2

• Partner with stakeholders to oversee developing, documenting, and tracking plan to include:
  ▪ Clear, specific, actionable tasks
  ▪ Assigned task owners
  ▪ Reasonable and practical milestones
  ▪ Prioritized tasks
  ▪ Expected results
  ▪ Periodic touchpoints with stakeholders to review status of plan
  ▪ Closeout documentation/submit plan (if applicable)

CASE Study: Transparent Corporation

Background

• Manufactures vials used for distributing vaccine for highly contagious disease
• Worldwide distribution of vials number <60 million
• Distribution Centers located in New York, North Carolina, Florida, Texas, California, and Oregon
• Distribution Centers managed by team of region directors who report to VP of Logistics
CASE Study: Transparent Corporation (cont.)

Compliance Event

• Vials exported out of Oregon, Florida, and New York were not registered and documented in accordance with international trade regulations and tariffs were not paid
• Transparent Corporation investigated by DOJ for failure to pay tariffs
• Senior VP of Supply Chain has requested that Corporate Compliance oversee Root Cause Analysis

CASE Study: Root Cause Analysis (cont.)

Action items:

• Request copy of report conducted by implicated Distribution Centers
• Communicate with leadership to advise RCA will be conducted
• Solicit participants on RCA team from distribution centers (both implicated and not implicated)
• Send communication to implicated areas advising of RCA
• Schedule RCA team kickoff meeting
CASE Study: Root Cause Analysis (cont.)

RCA Team:
• Secures management support
• Names team lead
• Clearly defines scope of RCA
• Creates charter
• Maps out deliverables and steps needed to accomplish
• Establishes milestones, targeted completion date
• Conducts report out to stakeholders

CASE Study: Remediation Plan

Action Items:
• Request copy of RCA
• Communicate with Distribution Center leadership of intent to partner with regional directions to develop remediation plan
• Review issue and scope of RCA
• Distribute RCA to regional directors in advance of meeting to discuss
• In response to RCA, partner with regional directors to develop an actionable plan with specific tasks to mitigate risk of future non-compliance
CASE Study: Remediation Plan (cont.)

Action Items:
• Ensure that plan documents and appropriately addresses actions/tasks needed where non-compliance was detected and ensure consistent with all other centers
• Communicate/train implicated workers
• Meet with leadership to review plan and discuss milestones
• Establish periodic touchpoints with regional directors to confirm all tasks outlined in plan are completed

Recap – Response to Wrongdoing

US Sentencing Guidelines
• Root Cause Analysis / Remediation Plan sited as key elements in supporting response to wrongdoing

Depart of Justice Guidance – June 2020 Guidance
• RCA should adequately address what contributed to the misconduct
• Remedial efforts should be thorough and comprehensive
• Remediation Plan should be sufficiently designed to prevent similar events in the future
Recap – Response to Wrongdoing (cont.)

Root Cause Analysis
• Focuses on determining why
• Objective and fact driven

Remediation Plan
• Details steps/actions needed to address identified deficiencies as a result of an event
• Assigns accountability and ownership

Recap – Response to Wrongdoing (cont.)

Root Cause Analysis / Remediation Plan
• Continuous improvement / continuous monitoring
• Considered key elements of 3rd pillar of effective compliance program:
  ▪ Prevention
  ▪ Detection
  ▪ Corrective Action
• Both focus on correcting issue and mitigating future risk, not blame or investigation
Questions