

ADVANCED ETHICS AND COMPLIANCE PROGRAM DESIGN



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Advanced Program Objectives

- ❑ Embed, monitor and promote ethics and compliance culture
- ❑ Design, implement and enforce effective financial and compliance controls
- ❑ Maintain an effective ethics and compliance program that evolves in response to changing business conditions and risks



Dual Tracks: Culture and Controls



Global Ethics and Compliance Programs

- Multi-layered: headquarters, regional and local
- Risk profiles vary depending on:
 - Geographic footprint and business
 - Government regulation
 - Domestic
 - International



Challenges of Global Compliance Organizations

- Promoting and monitoring culture through levels of organization and across cultures
- Tension sometimes occur between global organization controls and local requirements
- Monitoring of program requires new strategies and effective use of automation and data analytics



Changing the Mindset from Reactive to Proactive

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|--|--|
| <ul style="list-style-type: none">□ Proactive Priorities□ Focus on culture and risk profile□ Identifying risk factors□ Monitoring incidents, reporting, and control violations□ Monitoring culture□ Interventions□ Remediation and prevention | <ul style="list-style-type: none">□ Reactive Priorities□ Response to potential misconduct□ Investigations□ Root cause analysis□ Remediation: Post-event assessments and modifications |
|--|--|

The Importance of Corporate Culture

Ethics and Profitability

An effective E&C program often results in greater profitability.

“ Culture causes performance, not vice versa.”

-Dizik, Alina, “*The Relationship Between Corporate Culture and Performance*,”
21 February 2016, THE WALL STREET JOURNAL.

Companies with an “ethical culture” outperformed those
that made no such claims in three important financial measures:
(1) market value added; (2) economic value added; and (3) price/earnings ratio.

-Simon Webley and Elise More, “*Does Business Ethics Pay?*”, 2003, INSTITUTE OF BUSINESS ETHICS, London, UK.

“The best corporate citizens list, which includes Hewlett-Packard, Intel, General Mills, I.B.M.
and Kimberly-Clark, had a total return on shareholder value of 2.37 percent over three
years. But the 30 worst had a negative 7.38 percent return.”

- Stephanie Clifford, “*Magazine to Publish a Corporate ‘Black List’*,” 2010, NEW YORK TIMES.

Ethics in the Workplace: Statistics*



*Corporate Culture:
Evidence from the Field,
National Bureau of
Economic Research
John R. Graham,
Campbell R. Harvey,
Jillian Popadak,
Shivaram Rajgopal,
NBER Working Paper
No. 23225, 2017

- **Compliance can promote this message to gain buy-in from corporate stakeholders.**
- Survey of 1,900 CEOs and CFOs + 19 interviews found that:
 - ▣ **92%** of senior executives believe that improving culture will increase firm value.
 - ▣ **85%** believe that a poorly implemented, ineffective culture increases the chance an employee may act unethically or illegally.
 - ▣ **79%** of senior executives place culture among the top 3 or 5 value drivers of the company.
 - ▣ **69%** believe "leadership needs to invest more time in the culture."

Ethics in the Workplace: Statistics



- 2013 Survey¹ found that misconduct rates declined in companies with strong ethical cultures (88 to 20 percent).
 - ▣ Two-thirds of companies (67 percent) include ethical conduct as a performance measure in employee evaluations, up from 60 percent in 2011.
- 2016 Study² shows 97% of values- based entities demonstrate better performance than their competitors in all of the 17 countries represented in the study.
 - ▣ This compares to 80% and 30%, respectively, for more traditional command-and-control or rules-based organizations.

1. The Value of Corporate Culture, National Bureau of Economic Research
Luigi Guiso, Paola Sapienza, Luigi Zingales, NBER Working Paper No. 19557, 2013.

2. Ethics and Compliance Program Effectiveness Report, LRN, 2016.

Ethics in the Workplace: Statistics



- ❑ NBER 2013 Survey found that misconduct rates declined in companies with strong ethical cultures (88 to 20 percent).
- ❑ Code of Ethics training is increasing (74 to 81 percent)
- ❑ Two-thirds of companies (67 percent) include ethical conduct as a performance measure in employee evaluations, up from 60 percent in 2011.
- ❑ Almost three out of four companies (74 percent) communicated internally about disciplinary actions when wrongdoing occurs.

Culture Currency: Reputation



“Lose money and I will forgive you. Lose even a shred of reputation and I will be ruthless. Wealth can always be recreated, but reputation takes a lifetime to build and often only a moment to destroy.”

A List of Culture Questions

- ☐ Does the organization provide clear guidance to the employee concerning expected conduct?
- ☐ Would the employee report misconduct committed by another employee?
- ☐ Does the employee's supervisor set a good example of ethical behavior?
- ☐ Does the Board and senior management set a good example of ethical behavior?
- ☐ Is the employee asked to complete tasks that conflict with company values and expectations?
- ☐ Does employee work in an environment in which everyone treats each other with respect?
- ☐ Is management aware of unethical and/or illegal conduct and report and correct?
- ☐ Is management receptive to employees' opinions about work assignments and ethical conduct?
- ☐ Does management reward and recognize employees for ethical conduct?
- ☐ Does management punish employees fairly for unethical or illegal conduct?

DOJ & Culture of Compliance

- ☐ Has senior management clearly articulated company standards, communicated them in unambiguous terms, adhered to them scrupulously, and disseminated them throughout the organization?
 - ☐ What words and actions have senior management taken to promote or reflect company culture?
 - ☐ What concrete actions have senior leaders taken to demonstrate commitment to compliance (and remediation)? Words alone are not enough!!
 - ☐ Is the culture of compliance reinforced in middle management and among all employees in the company?
- ☐ Begs the question of C-Suite Compliance -- Does the company include C-Suite and performance in risk assessment?
- ☐ Assessment of tone at the top focuses on operationalizing program
 - ☐ What shared commitment and specific actions taken by senior leaders and key stakeholders (business and operational managers, Finance, Procurement, Legal, Human Resources)?
 - ☐ How is information shared among these functions?

CCO + CE(thics)O = Separate Functions?

- Chief compliance officers have served as chief ethics
- Is dual hat outdated?
- What coordination concerns exist?
- Walmart Model
 - ▣ Chief Ethics Officer
 - ▣ Chief Compliance Officer
 - ▣ Chief Legal Officer
- Many companies creating separate chief ethics officer
- Responsible for culture
- Walmart example: Internal investigations
- Ethical conduct is distinct from compliance with code and legal requirements?

Changing Your Dashboard

Compliance Data and Analytics

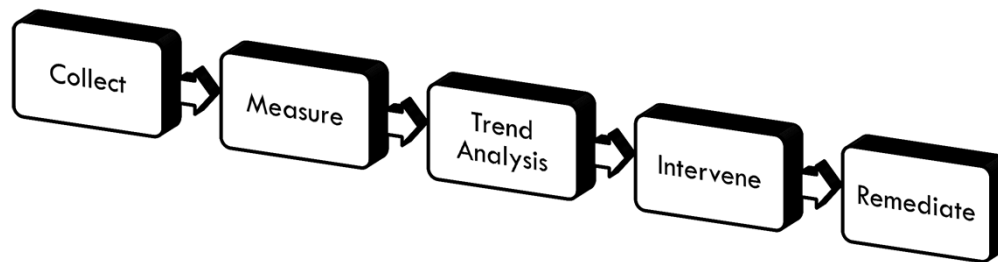
Data has to be used for monitoring, assessments and testing of compliance programs

- Compliance programs generate large amounts of data
- Data analytics is a tool that can be used to identify “anomalies” in compliance and finance-related controls
- Specific data should be collected and monitored beyond “standard” categories that are not insightful (e.g. annual certifications, number of training programs)

Developing a New Dashboard: Watching the Information Flow

- Report quarterly on culture
- Report quarterly on compliance with controls
- Monitor employee concerns and incident management
 - Number and types of reported concerns (slice and dice information)
- Report on internal investigation function
 - Number and types of code of conduct violations
- Train and test middle managers and employees
 - Is the message understood?
- Ongoing compliance monitoring, reviews and remediation status
- Risk profiles and continuous updates
- Policy Management

Information and Action



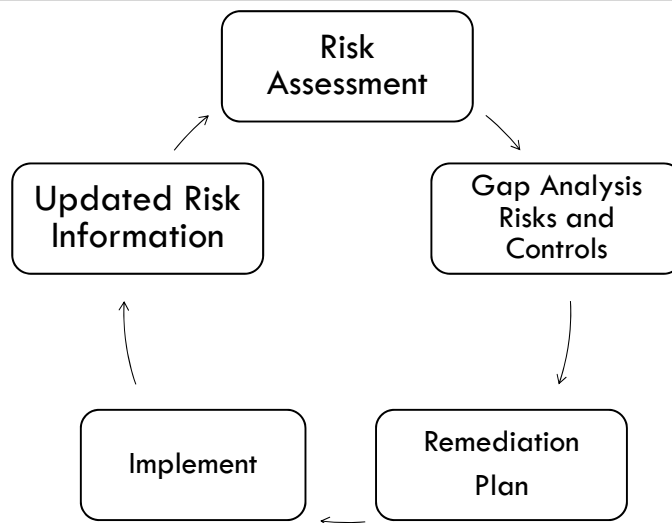
Measure ethical culture



There are many ways to gather information – what is best for your company?
What does your company already do?

- Manager and Employee Surveys
 - ▣ Easy to conduct
 - ▣ Focus on regions, lines of business, high risk countries and activities
 - ▣ Keep questions to minimum and make completion easy
- Focus Groups
 - ▣ Maintain confidentiality – assure employees that no one will be identified
- Proactive confidential interviews: senior managers, middle managers and cross-section of employees
- Establish exit interview program with Human Resources
- Measure and sample senior management communications on ethics
- Internal audits include culture measurement/questions

Risk Assessment and Continuous Process



Continuous Risk Monitoring: Information

- Risk assessment is the **foundation** of your compliance program
- Update risk assessment from regional and local sources
- Conduct targeted surveys: divide as needed to update information annually
- Focus on specific risk factors
 - ▣ FCPA (foreign official interactions)
 - ▣ Antitrust: Interactions with competitors
 - ▣ Healthcare Fraud: Billing, Quality of Care, Reimbursement
 - ▣ Sanctions: Geographic and customer risks
 - ▣ AML: If non-financial institution, 3P payments
- Identify and update risk profile
- Schedule update process



Leveraging Middle Managers

Pushing Tone Throughout Organization

- CEO requires direct reports and all managers to communicate compliance message
 - Each year senior managers commit to specific task to promote compliance and ethics
 - Each year senior managers evaluated based on the compliance and ethics program factor
- Compliance and ethics modules distributed throughout organization to local offices (in foreign language) and promoted by local management
- Leadership development programs emphasize importance of compliance and ethics

Spreading the Word

- Communicate proactive message
- Encourage reporting concerns
- Ensure system responds to concerns
- Creating messages/talking points
- Tailor to function (e.g. sales, operations/manufacturing, logistics)
- Embed with managers
 - Managers are on the front line, give them the tools they need



Creating Responsive and Knowledgeable Managers

- Train managers to encourage and respond to employee concerns
 - Give them kits (talking points, suggested topics/messages)
 - Encourage them to tailor message to their comfort level
- What to do with concern?
- How to treat the employee?
- Importance of no retaliation
- Reward managers for their open door policy
 - Leverage results of surveys to reward managers who strengthen corporate culture
 - “Would you feel comfortable reporting a concern to your manager?”



Embedding Compliance in the Business

Creating Compliance Partnerships with Business Operations

- ❑ Most effective E&C programs are embedded in business.
- ❑ Compliance officers and business managers are joining together to address compliance requirements.
- ❑ Value-add of compliance and need to compete in marketplace consistent with company's values, culture and compliance requirements
- ❑ Compliance commitment is fast becoming part of sales marketing pitches and documents
- ❑ Trusted relationships with customers, vendors and suppliers

Critical Role of Local Compliance Officer

- Local compliance officers play an indispensable role in developing on-the-ground compliance operations.
- LCOs have to engage business counterparts, meet and communicate constantly with business counterparts, and bring compliance solutions to the table:
 - Knowing how to say “No,” but offering alternative solutions
 - Making compliance transparent and communicating expectations
 - Develop checklists, cover sheets and other “go-bys” to make compliance for business easier
 - Consistent line-drawing between prohibited and permissible activities
 - Avoid “best friend” role of business and maintain integrity
- LCOs require strong support from regional counterparts to develop best practices and address local risks and conditions
- Sum of the parts of corporate-regional-local compliance operations cannot succeed without effective performance at every level

Incentivizing Supervisors and Managers to Own Compliance

- ❑ Positive rewards for ethics and compliance responsibilities
- ❑ Evaluation process should include this factor
- ❑ Cutting-edge companies are making bonus and bonus levels dependent on specific evaluation on ethics and compliance performance



Financial and Compliance Controls

Compliance and Internal Controls

- DOJ and SEC risk of accounting controls enforcement has increased
- Companies face conflicting incentives
- Companies are creating their own internal “statutes” for civil and criminal prosecution
- Benefit of a specific internal control may be outweighed by risk of civil or criminal prosecution



Taking a Seat at the Controls Table

- ❑ Global companies maintain robust accounting internal controls
- ❑ Guidepost is “materiality”
- ❑ Compliance interest is frequently non-material transactions
- ❑ Legal and compliance need to address enforcement risks



Breaking Down Silos and Barriers to Cooperation

- ❑ Cross-functions
 - Procurement
 - Materials supply
 - Vendor onboarding
 - Accounts payable
 - Contract management
 - Compliance and Legal
- ❑ Information sharing capability
- ❑ Danger of silos and technology bars



Third-Party Risk Management: Contract-Invoice-Payment Process

- Standardize contracting, invoice and payment systems:
 - ▣ Invoice received
 - ▣ Contract matched with invoice
 - Require contract to have detailed scope of work
 - ▣ Verification of services provided
 - ▣ Appropriate payment amount
 - No unexplained charges
 - ▣ Eliminate segregation of duty conflicts



Standardizing Vendor/Supplier Onboarding Process

- Starts with vendor onboarding process
 - ▣ Different procurement functions at risk for non-standard onboarding process
- Define information needed for types of risk management systems
- Ends with coordination of legal, procurement and financial risks

- Information sharing and access is critical to process
- Vendor onboarding should drive the process and operate with robust information collection

Third-Party Risk Management and Automation

- Business sponsorship
- Risk ranking (assign weights and factors (e.g. country CPI, financial))
- Anti-Corruption
 - ▣ Identifying PEPs
 - Example: JV partner owns 10% of a venture and a government official owns 1% of that 10%; the arrangement may be a screen for bribery
- Sanctions Compliance (OFAC 50 percent rule)
- AML/KYC Requirements
 - ▣ Third party payments
 - ▣ Bank account verification
 - ▣ Use of shell companies – obtain beneficial ownership
- Reputational risks



Contract Management and Representations

- Contracts versus Purchase Orders rules
- Consistent contracting protocols
- Risk mitigation practices and provisions
 - ▣ Develop specific representations and warranties beyond standard
 - ▣ Address all risks – Anti-corruption, AML, sanctions
 - ▣ Description of services
 - ▣ Participation in training
 - ▣ Payment terms and invoice requirements
 - ▣ Robust auditing and termination
 - ▣ Comparable compliance program
 - ▣ Integrate code of conduct or rely on supplier, distributor codes



Internal Compliance Review Function

Ethics and Compliance Internal Reviews

- Separate, independent unit
- Responsibility for conducting compliance "reviews"
- Independent of internal audit function
- Culture and controls expertise
- Focus on non-material compliance controls
 - ▣ Third party risks and payments
 - ▣ GMET
 - ▣ Financial issues under materiality standard



Automation Generates Valuable Data

- Consistent means of improving program
- Emerging area in compliance
- Many automated platforms for:
 - ▣ Initial diligence screening
 - ▣ Continued monitoring
 - ▣ Third party management
 - ▣ Clearance process regarding expenses
 - Including tracking of GMET recipients
 - ▣ Policy Management
 - ▣ Training
 - ▣ Incident tracking and monitoring
 - ▣ Hotline reporting and recordkeeping



Potential Areas of Focus

- | | |
|--|---|
| □ Tone at the top | doctors) incentives, coding and billing (Medicare/Medicaid), quality of service |
| □ Training | □ Charitable/Political Contributions |
| □ Due diligence | □ Hotline and Reporting |
| □ Vendor/supplier onboarding | □ Data Security |
| □ Business Gifts, Meals, Entertainment | □ Mergers & Acquisitions |
| □ Discounts, Rebates, Pricing | □ Joint Ventures |
| □ Sponsorships and Events | □ Investigations |
| □ Tenders and Competitive Bidding | □ Culture of Compliance |
| □ Research and Development | |
| □ Interactions with HCP | |
| □ Healthcare Providers (hospitals, | |

Compliance Review Tools

- ☐ Culture and controls compliance
- ☐ Desk-Top audits
- ☐ Transaction Testing
 - ☐ Internal and External (Agents, Distributors)
- ☐ Issue Spot-Checks
- ☐ Country, division, region compliance documentation and sampling
- ☐ Risk assessment and culture survey compliance
- ☐ Training compliance

Promoting Organizational Justice and
A Speak Up Culture

Organizational Justice



People want to know
what happened –
COMMUNICATE!

- ❑ A justice system that is fair and consistent
- ❑ Role of Chief Ethics Officer?
- ❑ Separate internal investigations unit
- ❑ Committee to review investigations and respond (legal, human resources, internal audit)
- ❑ Track and report – timely resolutions for routine investigations -- 60 to 90 days
- ❑ Internal investigations protocols
- ❑ Publicize discipline in numbers to avoid privacy problems

Incident Management and Data

- ❑ Important trends in incident management and data collection
- ❑ Data on incidents expands beyond “investigations”
- ❑ Demonstrates management commitment to culture
- ❑ Positive encouragement of reporting employee concerns
- ❑ Protection of whistleblowers (increasing retaliation)
- ❑ Timely responses to employee concerns
- ❑ Routine incident response in no more than 2-3 weeks
- ❑ Routine investigations within 60 days

Confidential Reporting and Investigation

- ❑ Mechanism for employees and others to report misconduct on confidential basis (anonymous hotlines or ombudsmen)
- ❑ Efficient, reliable, and properly funded investigation process to document company's response, including any disciplinary or remediation measures taken.
- ❑ Lessons learned should be used to update their internal controls and compliance program and focus future training on such issues, as appropriate.
- ❑ Compliance has full access to reporting and investigative information
- ❑ How does company assess effectiveness of confidential reporting system and investigative function?
 - Investigations properly scoped and conducted
 - Investigation function is independent and objective, and properly documents investigations?
- ❑ Has the company's investigation function been used to identify root causes, system vulnerabilities, and accountability lapses, including among supervisory manager and senior executives?
- ❑ What has been the process for responding to investigative findings?
- ❑ How high in company are investigative findings reported?


Do You Need an Independent Ombudsman?

- ❑ Companies are suffering from higher rates of retaliation
- ❑ Retaliation occurs in immediate three-week period after report
- ❑ Independent Ombudsman can address these issues and promote reporting of concerns



Enlisting Managers to Receive and Respond to Concerns

- Designate Ethics Ambassadors or Ombudspeople in organization
- Receive information
- Interact with employee
- Enter data into incident management system
- Generates valuable database for monitoring concerns and conduct



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Internal Investigation Program Structure

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Supervisory Committee	<ul style="list-style-type: none">• Reviews and monitors internal investigations• Resolves investigations
Internal Investigation Unit	<ul style="list-style-type: none">• Where is IIU located? Audit, Legal, Compliance?• Depending on size of company, (1) centralized versus local; and (2) Hotline investigators/case management
Collectors/Receptors	<ul style="list-style-type: none">• “Ombudspeople”• Located throughout Company

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Internal Committee Oversight and Consistent Discipline

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- Internal committee to oversee internal investigation program
- Review internal investigations
- Routine investigations 60-90 days
- Progress of longer investigations
- Decision to continue, close, resolve and discipline
- Met out prompt, fair and consistent discipline



Incentives and Discipline

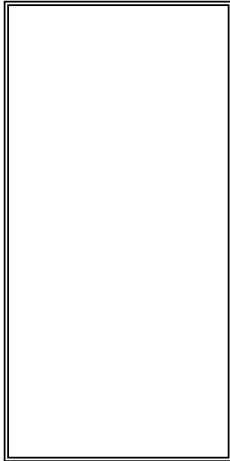
- Clear disciplinary procedures, applied reliably and promptly, and commensurate with the violation.
 - What is company's record on imposing discipline (especially to similarly situated individuals)?
 - Are managers and supervisors held accountable? Important emphasis!!
 - Is discipline consistently meted out?
- Who is involved in disciplinary procedures? Human Resources? Committee of key stakeholders?
- What positive incentives does the company offer to encourage ethics and compliance?
 - Positive incentives: personnel evaluations, bonuses and promotions, rewards for improving and developing a company's compliance program, and rewards for ethics and compliance leadership.
 - Recognition for compliance professionals and internal audit staff. Promotions?
- Working in compliance a way to advance an employee's career.

Targeted Training of Responsible Persons

Targeted Training

- Training and certification for all directors, officers, relevant employees, and, where appropriate, agents and business partners
- Mix of web-based and in-person training (topics: company policies and procedures, instruction on applicable laws, practical advice to address real-life scenarios, and case studies.)
- How does company determine who should be trained and for what subjects?
 - Who are “relevant control people” – e.g. accounts payable, third party due diligence responsibility, internal investigations
 - Risk-based or targeted training now expected, not just mass, company-wide code of conduct training
- Format/Content (e.g. sales or accounting personnel) appropriate
- Language appropriate for audience
- Has the company measured effectiveness of training?

Questions?



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- Anti-corruption due diligence, compliance, enforcement defense and internal investigations
- The Volkov Law Website:
<http://volkovlaw.com>
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