

MEASURING THE EFFECTIVENESS OF A COMPLIANCE PROGRAM

Lessons learned from USA



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The views expressed are personal and do not necessarily reflect Astellas position or approach

MEASURING THE EFFECTIVENESS OF A COMPLIANCE PROGRAM

Why measure?



Demonstrate compliance with laws



Track attainment of internal objectives



Demonstrate efficient allocation of resources (or ask for more?)



Motivate employees



Find improvement opportunities



THE COMPLIANCE MATURITY CURVE

Your organization

Stakeholder Value

Optimised

Reactive

Informal

Standardised

Managed

REACTIVE

- Tone from the top absent
- Ad hoc & informal structure
- Loosely applied resources
- Tactical, reactive execution
- Limited / local risk assessment
- Disjointed or no monitoring exists
- Fragmented reporting
- Incompatible systems / technology

INFORMAL

- Leadership acknowledges need
- Limited global policies
- Inconsistent reporting lines. Some local dedicated resource
- Limited backend monitoring and use of KRI*
- Some system integration at local level
- Limited application of technology

STANDARDISED

- Leadership sets clear expectations
- Global policy architecture
- Standardised reporting lines
- Business acumen and compliance/risk knowledge
- Standard taxonomy of risks
- Monitoring process / tools that are not uniform
- Standardised reports using KRI/KPI*
- Standard systems, interfaces & models

MANAGED

- Management actively involved
- Global policies/ limited transparency
- Proactive insightful analysis
- Aligned and consistent monitoring
- Standardised executive dashboards
- Standard data models, tools & applications

OPTIMISED

- Management demonstrates ownership
- Clear governance and risk transparency
- Clear functional roles
- Proactive value-add strategic partner
- Globally consistent & optimised process
- Continuous and consistent monitoring, including self-monitoring
- Global data analytics driving insightful reports
- Integrated systems and technology facilitate program

MEASURING THE EFFECTIVENESS OF A COMPLIANCE PROGRAM

Why the US example?

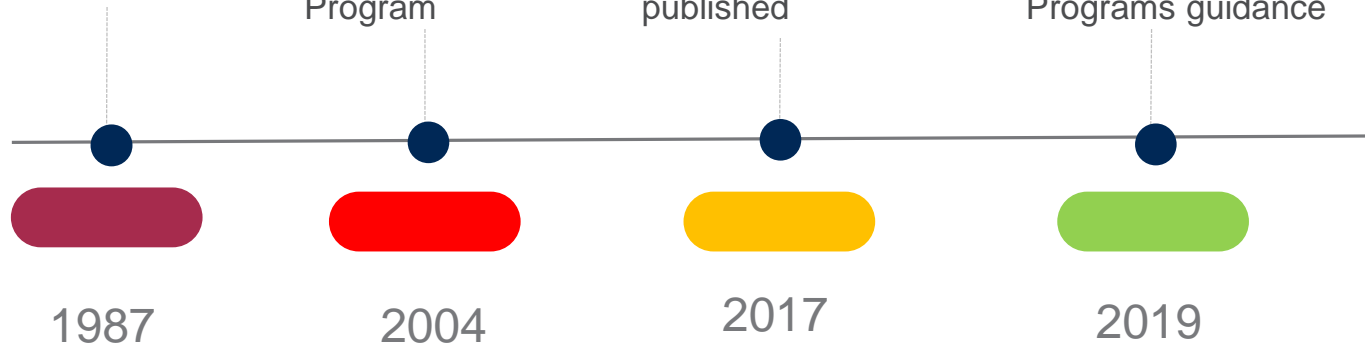


DOJ publishes the Federal Sentencing Guidelines Manual

DOJ defines the Seven Pillars of an Effective Compliance Program

DOJ Evaluation of Corporate Compliance Programs Guidance published

Updated DOJ Evaluation of Corporate Compliance Programs guidance



Seven Elements of an Effective Ethics and Compliance Program

Standards and Procedures

- Adopt a Code of Conduct
- Distribute Code to all employees, officers, and directors
- Require Code certification
- Require new employee acknowledgement of the Code

Response and Prevention

- Implement a written investigation process
- Review investigation results with BOD
- Voluntarily report misconduct to authorities

Enforcement and Discipline

- Impose sanctions consistently when Code violations occur
- Include ethics as an evaluation factor in employee performance reviews
- Factor ethics in salary increases and bonus payments

Auditing and Monitoring

- Provide a 24/7, toll-free Compliance & Ethics Hotline
- Monitor new laws, regulations, and rules, and implement changes as needed
- Analyze hotline reporting to identify emerging issues by geography, business unit, or risk

Oversight

- Appoint a Chief Compliance & Ethics Officer (CCO)
- Provide oversight of compliance and ethics issues
- Report misconduct directly to the Board of Directors (BOD)
- Report at least annually to the BOD

Management Due Diligence

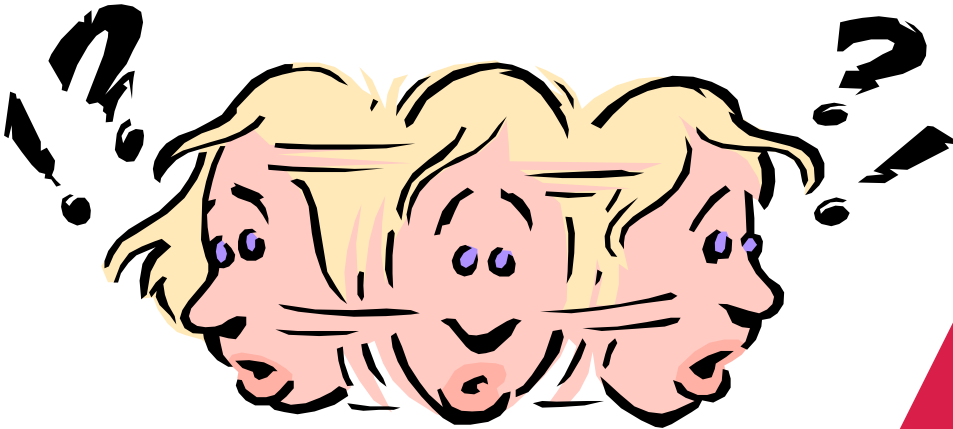
- Perform background checks on all new management employees
- Perform periodic background checks on all existing management employees

Communication and Training

- Regularly communicate to employees regarding compliance and ethics
- Include compliance and ethics components in your employee orientation
- Provide compliance and ethics training



DOJ EVALUATION OF CORPORATE COMPLIANCE PROGRAMS

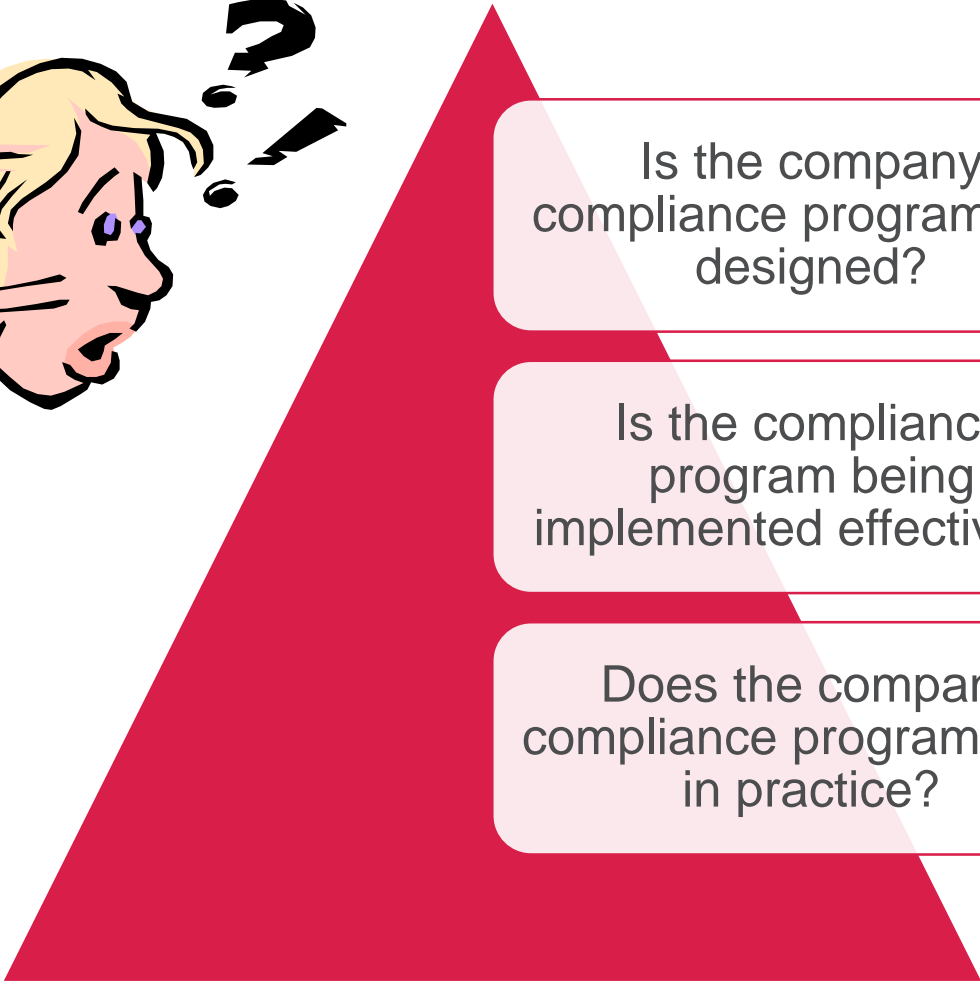


U.S. Department of Justice

U.S. Department of Justice
Criminal Division

Evaluation of Corporate Compliance Programs

Guidance Document
Updated: April 2019



Is the company compliance program well designed?

Is the compliance program being implemented effectively?

Does the company compliance program work in practice?

DOJ EVALUATION OF CORPORATE COMPLIANCE PROGRAMS

12 subject areas falling under each one of the 3 critical questions

Corporate Compliance Programs should focus on these areas to increase their effectiveness and ensure they meet regulatory expectations

Is the company compliance program well designed?

- Risk Assessment
- Policies & Procedures
- Training & Communications
- Confidential Reporting Structure and Investigation Process
- Third Party Management
- Mergers and Acquisitions

Is the compliance program being implemented effectively?

- Commitment by Senior and Middle Management
- Autonomy and Resources
- Incentives and Disciplinary Measures

3

Does the company compliance program work in practice?

- Continuous Improvement, Periodic Testing, and Review
- Investigation of Misconduct
- Analysis and Remediation of Any Underlying Misconduct

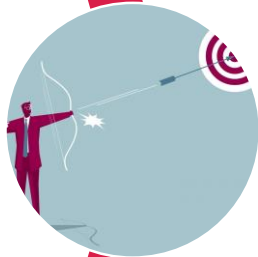
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Effectiveness



A program that “prevents and detects violations of law ...
The hallmark of an effective program to prevent and detect violations of law is that the organization exercised **due diligence** in seeking to prevent and detect criminal conduct.”



“[t]he failure to prevent or detect the instant offense **does not mean** that the program is not generally effective in preventing and deterring misconduct”



“[t]he Department recognizes that **no compliance program can ever prevent all criminal activity** by a corporation's employees.”



Design & Implementation of your Compliance Program



Is your program designed to cover the 12 areas of the Guidelines?



Is your program implemented as designed?



Do you benchmark your program with industry practice?



Do you document your efforts effectively?



Is your program adequately resourced?



Does your program cover the risks that you have identified in your industry?

The Impact of your Compliance Program:

Is each element, as designed and implemented, working the way it should?

Program Hallmarks Template	Process Maturity Scale & Program				
	1. Needs Improvement	2. Operational	3. Best Practice	4. Transformational	Aggregate Rating
Standards of conduct should be comprehensive, well-written, organized and their fundamental goal of preventing misconduct and ensuring compliance.					
(organizational mission, vision and values)					
Conduct; CEO Introduction; audience-appropriate writing level; learning aids used)					
(highest risk policies or procedures)					
(policy management process/governance)					
(non-retaliation policy availability and prominence)					
by comprehensiveness; ease of access; easy to understand; contain clear guidance)					
he compliance program should be delegated to high-level personnel with authority, including access to the Board. In addition, the company's governing edgeable about and practice oversight of the compliance program.					
inancial and reporting structure are documented; adequate resources and authority)					

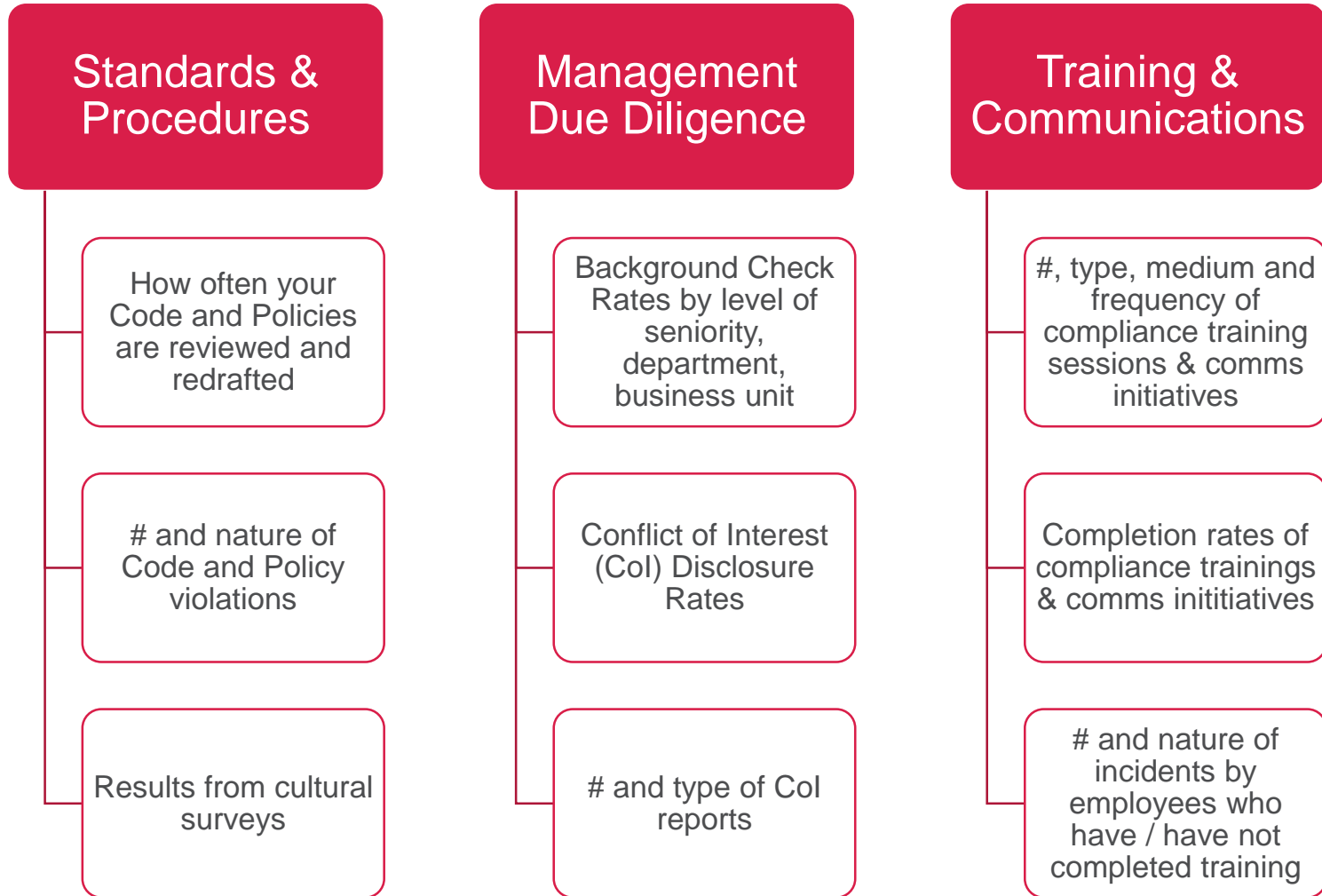


Create your own Compliance Risk Assessment framework – Identify your Key Risk Indicators

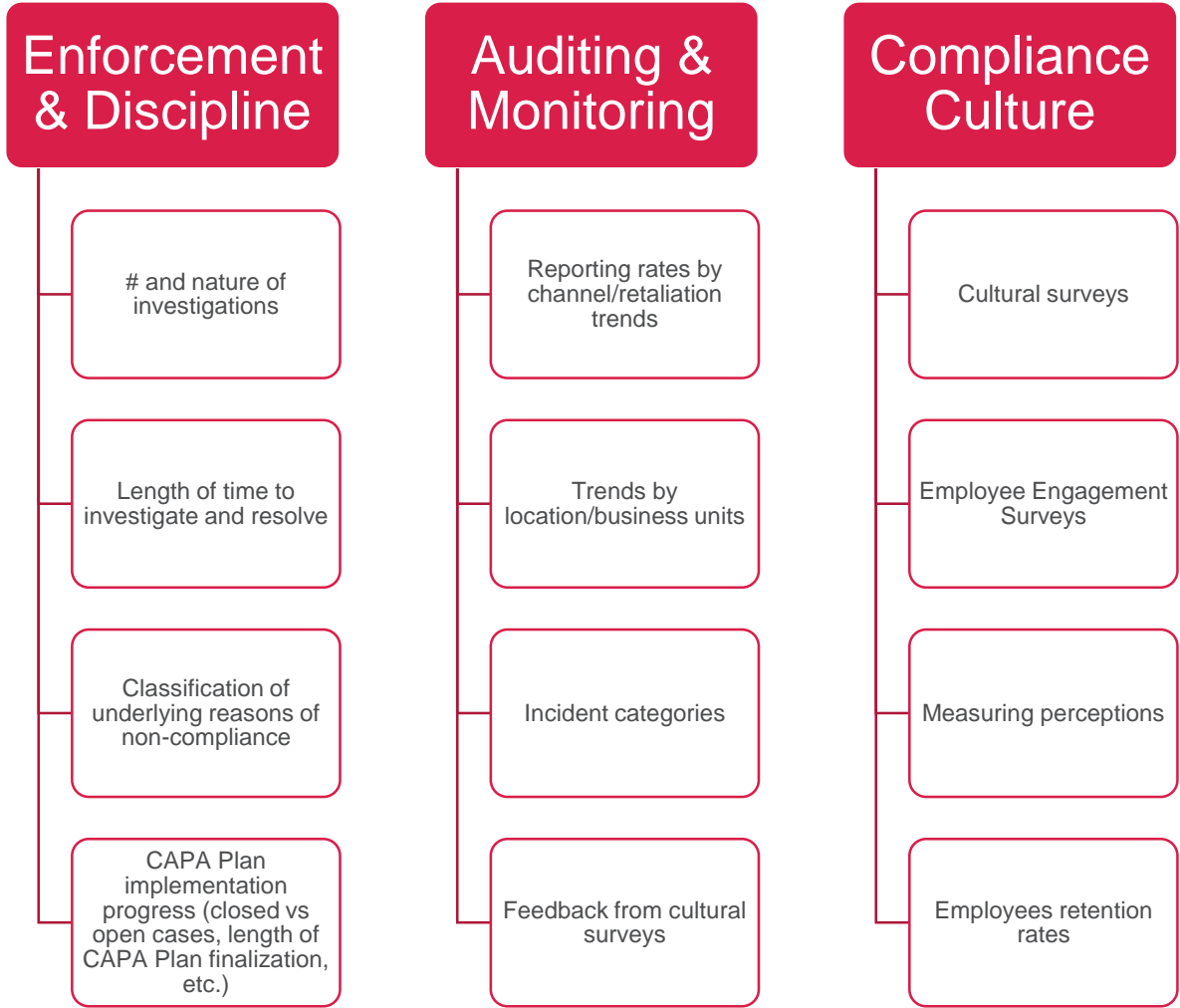
Define your Compliance Program Metrics

Build a metrics-filled Board Report

METRICS TO GATHER



METRICS TO GATHER



The Office of Inspector General Resource Guide

Measuring Compliance Program Effectiveness: A Resource Guide

HCCA-OIG Compliance Effectiveness Roundtable
Roundtable Meeting - January 21, 2017 / Washington, DC

Element 1: Standards, Policies, and Procedures

	What to Measure	How to Measure
	Access:	
1.1	Accessibility	<ul style="list-style-type: none"> Review link to employee accessible website/intranet that includes the Code of Conduct Survey - Can you readily access or reference policies and procedures? (Yes/No/Don't know) Survey - How and where do employees actually access policies and procedures? Test key word search (searchable) Audit and interview staff to show policies
1.2	Actual Access	Audit how many actual "hits" on policies and procedures
1.3	Accessible language for code, standards and policies	Flesch Kincaid measuring standard – no more than 10th grade reading level
1.4	Compliance program awareness and communication	<ul style="list-style-type: none"> Survey employees to determine the extent to which the code of conduct and other compliance communications are available to employees Review to ensure the standards, policies, and awareness material is updated and distributed within organization's guidelines
1.5	Impaired or disabled accessibility	Review accessibility options. Look at methods and speak to individuals.
1.6	Policy communication	Communication strategy of policies
1.7	Availability of policy content	Conduct surveys and observation