

## Corporate Compliance Forms and Tools Compliance Program Implementation Checklist

Actions	Responsible Party	Best Practice	Completion Date
Appointment of Compliance Officer and Commi	Appointment of Compliance Officer and Committee		
Select and appoint a chief compliance officer (CCO)	CEO/governing board	High-level authority; position of power equivalent to business functions; "independent"/does not report to chief financial officer or general counsel	
<ul> <li>Select and appoint compliance committee(s) (CC):         <ul> <li>Create CC charter to include scope of CC responsibilities, compliance officer, and board of directors</li> </ul> </li> <li>Provide compliance and risk area training, including the three lines of defense model, to the compliance committee members</li> <li>Identify specific compliance subtopics for implementation</li> <li>Create subcommittees or task forces</li> <li>Assign each task force to a specific compliance subtopic</li> </ul>	CEO/governing board/CCO	Ideally lead by CEO/CCO. Should include representative of all key business functions, including finance, human resources, audit, risk management, legal, and data security	
Ensure CC meets on a regular basis after implementation  • Ensure CC minutes are created and retained for each meeting	CCO	Should meet no less than quarterly	

Conduct a compliance risk assessment and prioritize findings:  CC Initial risk assessment should be conducted as soon as feasible as the CC's first order of business  • Identify industry-specific risk areas	Compliance Risk Assessment (once CC is in place)		
<ul> <li>Identify all relevant laws, regulations, and government or regulatory body guidance</li> <li>Identify areas of previous compliance issues within the organization</li> <li>Agree upon risk definitions</li> <li>Determine metrics to be used (e.g., impact, severity, frequency, effectiveness of controls, gross risk v. net risk)</li> <li>Determine methodology to be used (questionnaire, interviews, both)</li> <li>Identify subject matter experts and risk owners in the first line of defense to participate in assessment</li> <li>Conduct assessment phase using methodology selected</li> <li>Collect and tabulate results of assessment to identify top risks/emerging risks/well-controlled risks</li> <li>Create a risk matrix</li> <li>Share risk matrix with members of senior management and board of directors and obtain feedback</li> <li>Develop risk management/mitigation plans for all top risks and assign responsibility for each plan</li> <li>Track progress of implementation of risk mitigation/management plans and document</li> </ul>	<ul> <li>Identify industry-specific risk areas</li> <li>Identify all relevant laws, regulations, and government or regulatory body guidance</li> <li>Identify areas of previous compliance issues within the organization</li> <li>Agree upon risk definitions</li> <li>Determine metrics to be used (e.g., impact, severity, frequency, effectiveness of controls, gross risk v. net risk)</li> <li>Determine methodology to be used (questionnaire, interviews, both)</li> <li>Identify subject matter experts and risk owners in the first line of defense to participate in assessment</li> <li>Conduct assessment phase using methodology selected</li> <li>Collect and tabulate results of assessment to identify top risks/emerging risks/well-controlled risks</li> <li>Create a risk matrix</li> <li>Share risk matrix with members of senior management and board of directors and obtain feedback</li> <li>Develop risk management/mitigation plans for all top risks and assign responsibility for each plan</li> <li>Track progress of implementation of risk mitigation/management plans</li> </ul>	CC	

## Developing Code of Conduct, Policies and Procedures

Create and distribute code of conduct:

- Draft compliance code of conduct
- Obtain approval of code of conduct
- Adoption of code of conduct by CC/board of directors
- Translation of code into all company languages
- Distribute code electronically with communication campaign and explain to all employees the key points of the code and how to access/find it
- Provide training on content of the code to all employees
- Provide employees without computer access with access to printed copy upon request
- Obtain signed acknowledgement of code of conduct from all employees

CC/CCO

CCO and their team often take the lead in initial code drafting and reviews with the CC

Source of the code should be the organizational values adopted by the company, aligned closely with the organization's mission statement

Code is written in affirmative voice (e.g., "we behave this way") as opposed to a prohibitive voice (e.g., "you may not"). It must be easily understood, without legalese.

Attestation to be obtained no less than annually

Draft structural policies and procedures: CCO and their team often take the lead in initial drafting CC/CCO of policies and procedures for review and approval by CC • Mission/goals/directives of compliance program • Policy/procedure for creation and approval of new policies • Conflicts-of-interest disclosure policy and procedure • Compliance education policy • Testing of compliance education retention • Anonymous reporting mechanism • Investigative policy, including mechanism for feedback to reporters/protection of confidentiality where possible • Open-door/speak-up policy • Nonretaliation policy • Anti-bribery/anti-corruption policy • Gift policy (both giving and receiving) • Nondiscrimination/workplace respect policy • Auditing and monitoring of compliance program policy • Auditing work plan/procedure • Auditor independence • Conducting background checks • Disciplinary action guidelines • Enforcement of disciplinary action Regulatory response plan/policy (i.e., responding to dawn raids, search

warrants, visits, subpoenas, and document requests from

regulators)

<ul> <li>Draft substantive policies and procedures:</li> <li>Complete risk assessment (described earlier)</li> <li>Draft specific substantive policies and procedures that address identified risk areas</li> </ul>	Risk owners with guidance from CCO and CC	Risk owners should follow the guidelines included in the "policy on policies" and use the approved policy template to draft appropriate policies to address/mitigate risks they own
Obtain approval of policies and procedures from CC	Risk owners and CCO	Risk owners to follow prescribed policy approval procedure
Obtain approval of policies and procedures from executive committee where needed	Risk owners, CC, and CCO	
Obtain approval of policies and procedures from board of directors where needed	CCO and CC	
Distribute policies and procedures, ensure accessibility in a policy/procedure library, and provide training and tools to all affected employees	CCO	CCO and their team to work with IT and internal communications teams to ensure availability of all policies and procedures to employees as well as with the training and development team to develop and deliver appropriate employee training
Obtain signed certification of receipt and understanding of policies and procedures and initial conflicts of interest disclosures from all affected employees	ссо	CCO and their team to work with IT and HR to ensure attestation/certification/disclosure

Annual review of compliance policies, CCO CCO and their team typically handle this annual review processes, and procedures: and revalidation • Review all compliance-related policies, processes, and procedures for applicability and accuracy and to ensure consistency • Validate policy ownership has not changed • Update policies, processes, and procedures as needed • Create new policies, processes, and procedures for new risk areas identified • Obtain required approvals for revised policies, processes, and procedures • Document proof of review for all nonrevised policies, processes, and procedures • Track review and revision dates for each • Distribute any revised policies, processes, and procedures to all appropriate employees/contractors

 Obtain signed certification of receipt and understanding for all applicable revised policies, processes, and

procedures

Review policies, processes, and procedures owned by functions other than compliance:

- Prepare a policy, process, and procedure request memo (upon creation/implementation of the compliance program and annually thereafter)
- Designate a task force or delegate review of specific policies, processes, and procedures to various task forces to recommend any revisions to each
- Provide recommendations to the departments with a timeline for each one to submit its revisions or a written explanation of why it believes the policy, process, or procedure should not be revised
- Documentation of each revision and each policy, process, and procedure that does not require revision

CCO/CC

Memo should request copies of all operational, financial, or other compliance-related departmentspecific policies, processes, and procedures from all departments

Creation of Reporting Channels/Systems

Determine reporting channels to be offered: CC/CCO Multiple internal reporting channels should be offered, including direct reporting to manager, HR, Compliance, • Ensure channels are available in all or Legal, as well as an option to report confidentially to company languages helpline (either over-the-phone or web-based) • Ensure at least one channel allows for reporting of issues outside of chain of command • Ensure at least one channel allows for confidentiality of reporting • Allow for different methods of reporting (telephonic, online, in writing, verbal, face-to-face) to accommodate varying levels of reporter access and skill • How will reports from all reporting channels be captured and input into one issue management system for tracking/resolution? Develop issue management process/system CC/CCO Users may fear retaliation/identification unless external to track the handling of all incoming reports: third party-hosted option is provided • Choose a third party to host outside If no dedicated investigator staff is available, consider helpline training existing members of other control functions to serve as investigations, such as Audit, HR, Legal, and • Choose issue management Compliance tool/system to be used and configure/customize system for your Be aware of the potential for conflicts of interest between investigators and subjects and require an organization objectivity certification from each investigator • Determine issue types to be tracked Some issues will have the potential to cause loss of life • Determine issue metrics to be and/or severe injury or material financial loss; you will tracked, including issue volume; time need an escalation protocol for immediate notice to to close for investigations; materiality senior management metrics; regional, geographic, or business unit metrics; or subject Materiality criteria may include level of implicated matter metrics person, potential financial loss, issue type, and more • Determine staffing for tracking and Ensure data privacy concerns are properly accounted for before initiating electronic searches of any kind investigation of issues • Consider creation of an investigations Investigation reports should be reviewed prior to case committee (IC) comprising control closure to ensure they are well documented, thorough,

Copyright © 2024 by Society of Corporate Compliance and Ethics (SCCE) & Health Care Compliance Association (HCCA). No claim to original US Government works. All rights reserved. Usage is governed under this website's <u>Terms of Use</u>.

and complete

function representatives to oversee

handling of issue reports and

investigations

- Create list of persons qualified to act as investigators
- Develop investigations training for persons chosen to serve as investigators
- Conduct training for all investigators
- Create objectivity certification for all investigators
- Determine issue reporting metrics to be tracked and format for reporting
- Create standard forms including standard issue report, investigation report, root cause analysis, mitigation plan, and resolution report
- Develop escalation protocol for emergency situations where loss of life or serious injury are reported
- Develop materiality criteria and escalation protocol for material matters that should be immediately brought to the attention of the CC and/or the board of directors
- Develop a mechanism for providing feedback to anonymous reporters regarding progress of issue investigation and ultimate resolution
- Develop process to obtain approval for retrieval of electronic data from information systems including laptops and cell phones in conjunction with IT and Legal
- Develop case closure process to ensure all investigations are well documented and complete.

Ensure employees know and understand the consequences of noncompliance:

- Develop clear disciplinary guidelines for compliance violations and failures
- Communicate disciplinary guidelines to all employees and make them available for review on demand
- Ensure the fact finder in investigation is separate and apart from the disciplinary decision-maker
- Consider creation of multi-function disciplinary committee to ensure consistent application of discipline across the organization and unbiased administration of the disciplinary guidelines
- Develop audit plan to ensure consistency of disciplinary action for similar violations across the organization to avoid discriminatory application of guidelines

CC/HR

Levels of discipline will likely vary depending on severity and materiality

Discipline options should be agreed upon with HR and may include verbal reprimand, written warning, written reprimand, suspension, and termination

Develop communication campaign to CC/CCO with Encourage reporting from both employees and third announce and educate constituents on Internal parties availability of and expectations related to Communications Make sure all issues are captured and tracked in one reporting channels and on investigations issue-tracking system process: Management and the board may believe fewer reports • Ensure communications are available means fewer problems. Educate them that "silence is in all company languages not golden" when it comes to reporting channels, and • Emphasize retaliation prohibition that silence is an indicator of culture problems, hiding of issues, and a fear of retaliation. • Educate all managers on how to handle reports received from employees and open-door practices and whom they should escalate to in order to ensure issue is added to tracking system • Educate all control functions on how to handle incoming reports and how to ensure issues are entered into the chosen issue-tracking system (develop standard operating procedures and work instructions) • Educate CC and board of directors on reporting channels and emphasize that more reporting is better Launch reporting channels CC/CCO Monitor launch carefully to ensure systems are working correctly. Consider testing external phone numbers and web reporting systems from different company locations and countries to ensure functionality. **Investigation of Reported Issues** 

Investigate all reported issues in a timely manner:  Ask investigator to create a written investigations plan  Best practice is having investigator have someone take notes for them during all interviews  Interview reporter  Interview personnel identified in investigations plan  Determine whether data collection from computer systems is warranted/required/allowed and gather if appropriate  Conduct site visits and walk-throughs as specified in the investigations plan  Review policies, processes, procedures, laws, regulations, and guidance identified in investigations plan  Obtain legal opinions where needed	IC/CCO	If matter is material, consider whether investigation should be run under attorney—client privilege and whether there is the potential of a conflict of interest between the reporter and the organization. If so, provide Upjohn warning.	
<ul> <li>Create investigation case file and report:         <ul> <li>Ensure careful documentation of every portion of the investigation</li> </ul> </li> <li>Interview notes should be created for each interview</li> <li>Facts and supporting documents should be carefully summarized</li> </ul>		Documentation should include interview notes, all documents, and applicable policies and regulations that were reviewed as part of the investigation  This is a fact-finding stage only	

Determine findings of the investigation:

 Do the facts collected indicate the allegation has been substantiated, partially substantiated, not substantiated, is not a compliance issue, or that reporter has not provided enough information to investigate? IC

- If issue is substantiated in whole or in part, determine root cause and develop corrective action plan (see below) and provide details of same in final investigation report
- If issue is substantiated in whole or in part, provide facts to disciplinary committee for determination of whether discipline is appropriate and creation of disciplinary action plan
- If discipline is administered, ensure case closure process is completed, including description of disciplinary measures taken in the final report
- If issue is not a compliance issue, refer to appropriate function for review
- If reporter has not supplied sufficient information, make a request for same
- If issue is not substantiated, ensure case closure process is completed

Not all cases will involve misconduct. Some will involve misunderstanding or lack of information or an unclear policy or procedure.

In some cases, employee discipline is not necessary but employee training may be.

Conduct root cause analysis to determine factors that caused the issue      Create time-bound corrective action plan to ensure:	IC/CC		
Build initial compliance training program. Use results of compliance risk assessment to:  • Identify employees for whom initial compliance education will be required  • Identify employees for whom specific subject matter compliance education will be required  • Identify vendors, contractors, and	CCO/CC	Consider a combination of in-person, online, facilitator-lead, and self-study approaches  Consider use of written materials, posters, facilitator guides, articles in company publications or on company intranet, blog posts, PowerPoint presentations, emails, podcasts, videos, and communication campaigns  Candidates to conduct training: compliance officer/compliance staff, HR partners, Legal, outside	

Copyright © 2024 by Society of Corporate Compliance and Ethics (SCCE) & Health Care Compliance Association (HCCA). No claim to original US Government works. All rights reserved. Usage is governed under this website's <u>Terms of Use</u>.

customers for whom compliance education is desired

- Identify other stakeholders or other entities for which compliance education is desired
- Determine content and duration of compliance education courses for each audience
- Determine frequency of training required for each audience
- Determine most appropriate mode of training for each audience
- Determine most appropriate persons to conduct training
- Develop training materials and translate into all company languages
- Determine mechanism for tracking who has and has not completed required education courses
- Will you create a penalty for failure to timely complete courses?
- Determine responsibility for followup and tracking of persons who have failed to complete courses
- Determine mechanism for obtaining participant feedback on the course
- Determine how to measure
   effectiveness of training. Will there be
   a "before and after" knowledge
   check? A quiz they must pass in order
   to complete the course? A knowledge
   retention measure days/weeks after
   course completion?
- Document training and education plan as well as a schedule developed through above activities

consultants

Content can be developed internally by compliance staff, purchased from a vendor and used as is, purchased externally but customized, prepared by consultants, created by internal communications/education or subject matter expert teams, or made through a combination of approaches

Consider a penalty for failure to timely complete courses. Provide managers with list of their employees who have failed to timely complete. Consider having manager contact tardy participants directly to request completion. Consider written reprimand/warning for failure to complete. Consider cutting off systems access as a consequence of failure.

Conduct initial compliance education CCO/CC Data and metrics should be reported to the CC and, where appropriate, to the senior leadership team and/or campaign: board of directors • Track completion data Target course completion rate should be 100%, • Track effectiveness metrics excepting those on approved leaves of absence • Report data and metrics to CC and associated risk owners • Collect course evaluations and synthesize feedback to create action items to improve next education campaign Ongoing education program development and CCO/CC Once initial education program has been completed, enhancement: look to enhance and grow the program using a riskbased approach • Track who has and has not been offered education courses Consider in-person education sessions combined with compliance town halls to ensure nonremote employees • Identify audiences to be targeted for have personal access to compliance officer and staff future compliance education efforts Consider conducting climate and culture surveys as part • Identify alternative education of in-person visits methods for those without systems access or in remote locations • Develop additional content for such audiences and translate into local languages as needed • Implement alternative training/education methods and track completion and effectiveness metrics

<ul> <li>Train managers to discuss compliance during their staff meetings:</li> <li>Provide them with discussion guides and "train the trainer" materials</li> <li>Provide a case study of a compliance failure in your industry</li> <li>Provide a case study of a compliance failure at our company and how it was handled</li> <li>Provide managers with issue metrics from their areas to educate their employees on potential compliance vulnerabilities</li> <li>Provide managers with risk assessment results to educate their teams about compliance risks in their areas</li> </ul>	CCO/CC	Compliance training shouldn't only come from compliance and is often more meaningful when coming directly from an employee's supervisor and team  Managers can feel ill equipped to discuss compliance and like they don't have the expertise needed to do so. Give them the tools and make it easy to include compliance topics in their team meetings.	
<ul> <li>Continuing education/compliance expertise:</li> <li>CO and CC members regularly attend high-level continuing education and compliance conferences/seminars</li> <li>Subscribe to compliance journals/newsletters/blogs</li> <li>Join compliance-related organizations</li> <li>Subscribe to government and other mailing lists</li> </ul>	CCO/CC	Continuing education is vital to ensure compliance leadership has most current information on regulations and enforcement actions that may change the organization's risk profile	
Auditing			
Complete risk assessment (described earlier)	CC/CCO		

<ul> <li>Draft audit plans for each risk area identified:         <ul> <li>Determine the objectives of the audit</li> </ul> </li> <li>Determine the appropriate sample selection method for each audit</li> <li>Determine which policies, processes, and procedures will be audited</li> <li>Determine the audit criteria</li> <li>Determine if legal counsel should be involved in the audit process</li> </ul>	Internal Audit (IA)/CC	IA should ensure the controls and mitigation strategies designed for each identified risk have been appropriately implemented and are working in practice
Develop an audit schedule using a risk-based prioritization	IA	Frequency of each audit, how many audits at once, expected duration of each audit should be set as part of the schedule
Determine the appropriate party to conduct each audit	IA/CC	Internal audit, outside consultant, legal counsel, CC representative, CCO  Take care that no function is auditing itself. The function that owns a risk cannot also audit its mitigation of same.
Certify the independence/objectivity of the auditor	IA/CC	Consider having auditor self-certify to objectivity and absence of any conflict actual or perceived  Be aware of potential to corrupt an audit if auditor is not completely independent
Conduct the audit	IA	Audit should not be scheduled until an appropriate amount of time has passed after implementation of controls/mitigation measures following the risk assessment. Functions need time to implement and maintain controls prior to being audited on same. Suggested cadence is no sooner than six months following control/mitigation implementation.

Determine the appropriate corrective action plan for any problems identified	IA/CC	Ensure plan is time-bound, documented in writing, approved by CC, and ensure specific action plan owner is assigned responsibility for implementation of corrections
Prepare a written audit report	IA	Written report should be completed as soon as is reasonable. Recommended cadence is no more than 10 business days following audit completion.
Determine whether legal counsel should be involved in the audit resolution based on findings	IA/CC	Be aware of potential need for attorney—client privilege protection prior to issuance and need for limited distribution depending on results of audit
Ongoing Compliance Monitoring		
Develop compliance and culture surveys for specific audiences:  Determine what you want to know from whom Choose your audiences based on risk Choose your inquiries based on risk Involve members of local management to ensure local sponsorship and buy-in	cc/cco	Employees, customers, suppliers, dealers/distributors, board of directors
Survey employees, customers, and other constituencies on compliance issues:  • Ensure local language is used  • Consider holding in-person roundtables regarding compliance  • Provide written surveys  • Consider allowing anonymous responses	CC/CCO	Ask whether they are aware of policies, processes, and procedures and whether they know where to go for assistance. Consider asking whether they are aware of potential violations and whether they have witnessed any failures to enforce policies, processes, or procedures.

<ul> <li>Consider having user experience tested and reported back to you</li> <li>Identify potential compliance weaknesses in processes</li> <li>Identify areas that lack sufficient checks and balances</li> <li>Look for separation of duties and approvals</li> <li>Add potential problem areas identified to audit plan/schedule</li> <li>Revise processes as needed</li> <li>Update process flow charts with corrected process</li> <li>Educate affected employees on changes</li> </ul>		
<ul> <li>Request forms used by each department for review to determine whether any create a potential compliance problem</li> <li>Review the forms</li> <li>Provide recommendations for revisions and improvements to forms, as needed</li> <li>Review the revised forms on a regular cadence</li> </ul> Effective Compliance Communications	Examples include billing worksheets, dunning cycle statements, expense tracking forms, gift approval forms, time and effort tracking forms	

<ul> <li>Publicize compliance metrics throughout the organization:</li> <li>Consider annual reporting of issue metrics including volume, issue type, geography, and outcome</li> <li>Consider issuance of regular "Help Me Understand" publications with clear explanations of specific compliance policies, topics, or risks</li> <li>Consider a compliance department or officer blog with regular updates about the things the compliance team is working on</li> <li>Work with your internal communications team to develop compliance-related content for internal company publications and the intranet</li> </ul>	CCO/CC	Ensuring transparency of compliance program operations adds to a culture of organizational justice and builds trust
<ul> <li>Maintain open lines of communication:</li> <li>Advocate for open-door/speak-up policy adoption</li> <li>Give people managers a tool kit and educate them on how to behave in ways that encourage open communication on their teams</li> <li>Educate people managers on the importance of diversity of opinion and the concept of psychological safety and their close connection to a culture of compliance</li> </ul>	CCO/CC	

Ensure that processes are in place to protect
employees from retaliation:

• Adopt retaliation prohibition policy

• Create retaliation audit program to
review employment terminations/job
eliminations against issue reporters

• Create retaliation audit program to
review performance appraisal data
against all issue reports to detect any
signs of retaliatory review

• Consider making all allegations of
retaliation automatically material
under your issue escalation criteria

This document is only available to subscribers. Please  $\log$  in or purchase access.

Purchase Login