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Compliance management systems — Guidance for the evaluation of effectiveness

Systèmes de management de la conformité — Lignes directrices pour l'évaluation de l'efficacité

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Foreword

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This document was prepared by Technical Committee ISO/TC 309, *Governance of organizations*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

An effective compliance management system supports an organization. It enables the organization to demonstrate its commitment to complying with:

— relevant laws;

— regulatory requirements;

— industry codes;

— organizational standards;

— standards of good governance;

— generally accepted best practices;

— ethics;

— the expectations of the interested parties.

Compliance becomes sustainable when it is embedded in the culture of the organization and in the behaviour and attitude of personnel under the control of the organization. Embedded compliance positively influences the compliance performance of the organization.

ISO 37301 sets out the requirements and provides guidance for establishing, developing, implementing, evaluating and improving an effective and responsive compliance management system within an organization. This document provides guidance to support the implementation of the requirements in ISO 37301 related to evaluating the performance of a compliance management system (including monitoring, measurement, analysis, evaluation and management reviews) and thus ensuring continual improvement in any type of organization.

The framework can also be used to evaluate the effectiveness of other types of compliance management systems.

Compliance management systems — Guidance for the evaluation of effectiveness

1 Scope

This document establishes principles and an evaluation indicator framework for assessing the effectiveness of a compliance management system. This includes evaluation criteria for specified indicators. This document also provides guidance as well as suggestions on the evaluation model.

The guidance provided in this document aims to support the monitoring, measurement, analysis and evaluation of a compliance management system. It aims to support management review of the compliance management system to foster continual improvement. It does not add to, change or otherwise modify requirements for compliance management systems or any other standards.

This document is applicable to the activities for evaluating the effectiveness of the compliance management system in all organizations, regardless of the type, size and nature, including organizations from the public, private or non-profit sector.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 37301, *Compliance management systems — Requirements with guidance for use*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 37301 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
effectiveness
extent to which planned activities are realized and planned results are achieved

[SOURCE: ISO 37301:2021, 3.13]

3.2
evaluation indicator
measurable reference point of the current status or condition of a compliance management system activity

Note 1 to entry: Evaluation indicators can be quantitative or qualitative.

3.3
evaluation indicator framework
schema comprised of *evaluation indicators* (3.2) that reflects the effectiveness of a compliance management system

4 General principles

The evaluation of the effectiveness of a compliance management system should be based on the following principles:

a) Objectivity: The evaluation indicator framework can be used in different contexts and for different purposes and is established so that the results of an evaluation reflect the actual status of the compliance management system.

b) Completeness and scalability: The evaluation criteria for each indicator considers the planning, development, implementation and continual improvement of processes, the achievement of planned results and the degree of achievement.

c) Traceability: The evaluation results are verified through objective methods and evidence of documented information as well as other supporting information.

5 Evaluation methodology

5.1 General

The effectiveness of the compliance management system refers to its ability to consistently achieve its objectives and intended results. Moreover, an effective compliance management system results in improved performance and enhanced value for the organization and its interested parties.

The evaluation methodology provides for three dimensions: policy and procedures; conduct and culture; and results and impacts. These are evaluated along a scale with five levels of effectiveness (see 5.2). Every evaluation indicator can be evaluated along these dimensions. The evaluation indicator framework provides indicators aligned with the requirements of a compliance management system compliant with ISO 37301.

The evaluation criteria provide indicators for assessing the individual parts of a compliance management system at a detailed granularity (see Clause 6). Applying the evaluation criteria outlined in this document ensures that activities are consistently evaluated and that inadequacies and areas for continual improvement are identified, which in turn helps the organization adapt to changing conditions or requirements.

5.2 Evaluation scales

Table 1 outlines the three dimensions and scales for measuring the effectiveness of a compliance measurement system.

Table 1 — Scales for the evaluation of the effectiveness of a compliance management system

Scales	Description		
	Policy and procedures	Conduct and culture	Results and impacts
Level 1	Few processes exist and most of them are incomplete.	Behaviour within the organization does not reflect any alignment with the standard procedures.	No apparent impacts or recognizable results.
Level 2	Processes are implemented inconsistently, not formally defined and communicated separately.	There is understanding of the standard procedures, but the procedures are not systematically enforced.	Results are inconsistent; alignment with objectives is coincidental rather than intentional.
Level 3	Processes are implemented and documented but not assessed to determine whether they are fulfilling the related requirements.	Behaviour begins to reflect compliance measures yet there is significant room for improving alignment and effectiveness.	Results are only loosely aligned with objectives and not consistent throughout the scope of the compliance management system.
Level 4	Processes are integrated into organizational processes; they are monitored, measured and evaluated.	Behaviour is actively managed to align with the standard procedures with continuous evaluation and proactive adjustments to enhance compliance, reduce risks and reinforce a culture of ethical conduct.	Results are aligned with the defined objectives and fully integrated in the organizational process.
Level 5	Processes are integrated into the organization process and are continually improved; correction measures are implemented to ensure the effectiveness of the compliance management system.	Behaviour is actively managed to align with the standard procedures; compliance measures are fully embedded within the organizational behaviour through continuous monitoring, feedback and adaptation.	Results are integrated in a feedback loop that fosters continual improvement and adaptation to changing conditions.

5.3 Evaluation indicator framework

The framework provides indicators for each component of the compliance management system in line with ISO 37301. The indicators are based on a single requirement or a group of requirements related to a component of ISO 37301. The framework is outlined in Table 2.

Table 2 — Composition of the evaluation indicator framework

Dimensions of the evaluation indicator framework	Indicator description
Planning and establishment of the compliance management system	Analysis of the context of the organization, including requirements of interested parties
	Identification and update of compliance obligations
	Determination of the scope of the compliance management system and assessment of compliance risk
	Leadership and commitment of governing body and top management
	Implementation of compliance governance principles
	Maintenance and promotion of compliance culture
	Assignment of roles, responsibilities and authorities for personnel at different levels
	Compliance policy and setting of objectives
	Planning of actions to address risks and opportunities and the resources required

Table 2 *(continued)*

Dimensions of the evaluation indicator framework	Indicator description
Implementation of the planned compliance management system	Operational actions to address risk and opportunity
	Allocation of resources
	Competences, capacity building and raising awareness
	Employment process, rewards and disciplinary actions
	Training
	Internal and external communication
	Establishment of a mechanism for raising concerns
	Implementation of processes for investigation
	Management of documented information
Evaluating performance and improvement of the compliance management system	Monitoring, measurement, analysis and evaluation of performance
	Internal audit
	Management review
	Actions to address nonconformity and/or noncompliance and correction
	Continual improvement in a planned manner

6 Evaluation criteria

6.1 Planning and establishment of the compliance management system

6.1.1 Analysis of the context of the organization, including requirements of interested parties

6.1.1.1 Policy and procedures and conduct and culture evaluation

The dimensions on policy and procedures and conduct and culture, which are used to analyse the context of the organization, including the requirements of interested parties, should be evaluated according to Table 3.

Table 3 — Evaluation criteria for policy and procedures and conduct and culture related to analysis of the context of the organization, including requirements of interested parties

Scales	Description
Level 1	The procedures for the analysis of the context of the organization, including identification of interested parties relevant to the compliance management system, are not established.
Level 2	There are procedures for the analysis of the context of the organization, including identification of interested parties relevant to the compliance management system, but the procedures are incomplete. The procedures have not been implemented in business activities or are inconsistently implemented.
Level 3	Comprehensive procedures for analysing the context of the organization, including identification of interested parties relevant to the compliance management system, have been established and specify the following: — responsibility for analysing the context of the organization; — scope of the context that needs to be analysed, including internal and external issues that affect the organization's ability to achieve the intended results of the compliance management system; — considerations of the requirements of the interested parties; — input resources to be considered for analysing the context of the organization. Analysis of the context has been conducted in some businesses or only part of the internal and external issues that affect the organization's ability to achieve the intended results of the compliance management system have been analysed, and appropriate documented information has been created and maintained.
Level 4	Comprehensive procedures as specified at Level 3 have been established and adjusted based on past practices. Analysis of the context of the organization, including identification of interested parties relevant to the compliance management system, have been fully implemented for all businesses in accordance with the procedures. Appropriate documented information has been created, maintained and updated to reflect changes in the analysis.
Level 5	Comprehensive procedures as specified at Level 3 have been established and fully embedded within organizational processes. The procedures are consistently monitored and evaluated; they are continually improved and adapted to changing parameters in the internal and external context of the organization. Analysis of the context of the organization is regularly reconducted and updated based on changes in the internal and external issues. Updated documented information is adjusted to serve the needs of functions throughout the organization.

6.1.1.2 Results and impacts evaluation

The results and impacts related to analysis of the context of the organization, including the requirements of interested parties, should be evaluated according to Table 4.

Table 4 — Evaluation criteria for results and impacts related to analysis of the context of the organization, including requirements of interested parties

Scales	Description
Level 1	Internal and external issues, including interested parties and their relevant requirements, that affect the organization's ability to achieve the intended results of the compliance management system have not been determined.
Level 2	Internal and external issues, including interested parties and their relevant requirements, that affect the organization's ability to achieve the intended results of the compliance management system are determined inconsistently.
Level 3	Internal and external issues that affect the organization's ability to achieve the intended results of the compliance management system have been partially determined or only for some business activities. Identification of interested parties and consideration of their requirements concerns are only for some business activities.
Level 4	Internal and external issues, including interested parties and their relevant requirements, that affect the organization's ability to achieve the intended results of the compliance management system have been determined for all relevant business and are proactively managed.
Level 5	Internal and external issues, including interested parties and their relevant requirements, that affect the organization's ability to achieve the intended results of the compliance management system have been determined based on extensive analysis, including consideration of the legal, cultural, technical and business environment. Analysis of context is reviewed and updated based on changes in the internal or external environment. The affected personnel within the organization participate in the determination of the analysis of the internal and external issues and have a good understanding of their impacts. External interested parties are consulted to incorporate the relevant requirements to the compliance management system into the analyses of the context of the organization.

6.1.2 Identification and update of compliance obligations

6.1.2.1 Policy and procedures and conduct and culture evaluation

The dimensions on policy and procedures and conduct and culture related to identifying and updating compliance obligations should be evaluated according to Table 5.

Table 5 — Evaluation criteria for policy and procedures and conduct and culture related to identification and update of compliance obligations

Scales	Description
Level 1	The procedures for identifying and updating compliance obligations are not established.
Level 2	There are procedures for identifying and updating compliance obligations, but the procedures are incomplete. The procedures have not been implemented in business activities or are inconsistently implemented.
Level 3	Comprehensive procedures for identifying and updating compliance obligations have been established, which specify the following: — identification and analysis of the relevant requirements of interested parties; — the scope of compliance obligations; — documented information for identifying and updating compliance obligations. Compliance obligations for certain activities, products and services have been identified and updated, or the procedures have been implemented when noncompliance occurs. Appropriate documented information has been created and maintained.
Level 4	Comprehensive procedures as specified at Level 3 have been established and adjusted based on past practices in identifying and analysing compliance obligations. The mandatory compliance obligations and some voluntary compliance obligations derived from activities, products and services have been identified, maintained and updated according to the established schedule. Appropriate documented information has been created, maintained and updated to reflect changes in compliance obligations and measures to address these changes.
Level 5	Comprehensive procedures as specified at Level 3 have been established and fully embedded within organizational processes. The procedures are consistently monitored and evaluated; they are continually improved and adapted to changing parameters in the internal and external context of the organization. The mandatory compliance obligations and any voluntary compliance obligations derived from activities, products and services have been identified, maintained and updated according to the established schedule in particular on decisions on changes or expansion of business activities. Updated documented information has been created and is maintained to demonstrate to external stakeholders that the organization has kept pace with the latest developments over time.

6.1.2.2 Results and impacts evaluation

The results and impacts related to identifying and updating compliance obligations should be evaluated according to Table 6.

Table 6 — Evaluation criteria for results and impacts related to identification and update of compliance obligations

Scales	Description
Level 1	The compliance obligations have not been determined.
Level 2	The compliance obligations are only occasionally and inconsistently determined.
Level 3	Compliance obligations are only determined for certain activities, products and services or where non-compliance occurs.
Level 4	Mandatory compliance obligations and some voluntary compliance obligations derived from activities, products and services have been determined and proactively managed. Changes to compliance obligations are considered in the compliance risk assessment.
Level 5	The mandatory compliance obligations and voluntary compliance obligations have been determined and recorded. These are related to the organization's activities, products, services and relevant aspects of its operations. Determination of the mandatory and voluntary compliance obligations is based on independent data analysis. Resources have been allocated for the comprehensive and timely determination of relevant compliance obligations and the impact on the business activities of the organization. The determination of compliance obligations is regularly updated to identify changed or new compliance obligations and their impact on the business activities of the organization, which are incorporated into the compliance risk assessment. Change or expansion of business activities consider the impact of compliance obligations.

6.1.3 Determination of the scope of the compliance management system and assessment of compliance risk

6.1.3.1 Policy and procedures and conduct and culture evaluation

The dimensions on policy and procedures and conduct and culture related to determining the scope of the compliance management system and assessment of compliance risk should be evaluated according to Table 7.