
**Information and documentation —
Management systems for records —
Requirements**

*Information et documentation — Systèmes de gestion des documents
d'activité — Exigences*

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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Context of the organization	4
4.1 Understanding the organization and its context.....	4
4.1.1 General.....	4
4.1.2 Records requirements.....	5
4.2 Understanding the needs and expectations of interested parties.....	5
4.3 Determining the scope of the MSR.....	6
4.4 Management system for records.....	6
5 Leadership	6
5.1 Leadership and commitment.....	6
5.2 Policy.....	6
5.3 Organization roles, responsibilities and authorities.....	7
6 Planning	7
6.1 Actions to address risks and opportunities.....	7
6.2 Records objectives and planning to achieve them.....	8
7 Support	8
7.1 Resources.....	8
7.2 Competence.....	9
7.3 Awareness.....	9
7.4 Communication.....	9
7.5 Documented information.....	9
7.5.1 General.....	9
7.5.2 Creating and updating.....	10
7.5.3 Control of documented information.....	10
8 Operation	10
8.1 Operational planning and control.....	10
8.2 Determining records to be created.....	11
8.3 Designing and implementing records processes, controls and systems.....	11
9 Performance evaluation	11
9.1 Monitoring, measurement, analysis and evaluation.....	11
9.2 Internal audit.....	11
9.3 Management review.....	12
10 Improvement	12
10.1 Nonconformity and corrective actions.....	12
10.2 Continual improvement.....	13
Annex A (normative) Operational requirements for records processes, control and systems	14
Bibliography	16

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 46, *Information and documentation*, Subcommittee SC 11, *Archives/records management*.

This second edition cancels and replaces the first edition (ISO 30301:2011), which has been technically revised to fully follow the common text of the high level structure (HLS) for all ISO management systems standards (MSS), and to align operational requirements with the guidelines in ISO 15489.

The main changes compared to the previous edition are as follows:

- a new subclause, [4.1.2](#) Records requirements, has been added;
- [subclauses 8.2](#) and [8.3](#) have been redrafted;
- the requirements in [Annex A](#) have been renamed and reordered. Requirements numbered A.1.1.1 and A.1.1.2 are now included in [8.2](#), A.2.5.7 has been deleted from [Annex A](#).

ISO 30301 is part of a family of International Standards on management systems for records.

A list of all products in the ISO 30300 series can be found on the ISO website.

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

0.1 General

Organizational success largely depends upon implementing and maintaining a management system that is designed to continually improve performance while addressing the needs of all interested parties. Management systems offer methodologies to make decisions and manage resources in order to achieve the organization's goals.

Creation and management of records are integral to any organization's activities, processes and systems. They enable business efficiency, accountability, risk management and business continuity. They also enable organizations to capitalize on the value of their information resources as strategic assets, and to contribute to the preservation of collective memory, in response to the challenges of the global and digital environment.

0.2 Management system

Management system standards (MSS) provide tools for top management to implement a systematic and verifiable approach to organizational control in an environment that encourages good business practices.

The standards on management systems for records are designed to assist organizations of all types and sizes, or groups of organizations with shared business activities, to implement, operate and improve an effective management system for records (MSR). The MSR directs and controls an organization for the purposes of establishing a policy and objectives with regard to records and achieving those objectives. This is done through the use of:

- defined roles and responsibilities;
- systematic processes;
- measurement and evaluation;
- review and improvement.

Implementation of a records policy and objectives soundly based on the organization's requirements will ensure that authoritative and reliable information about, and evidence of, business activities is created, managed and made accessible to those who need it for as long as required. Successful implementation of good records policy and objectives results in records and records systems adequate for all of an organization's purposes.

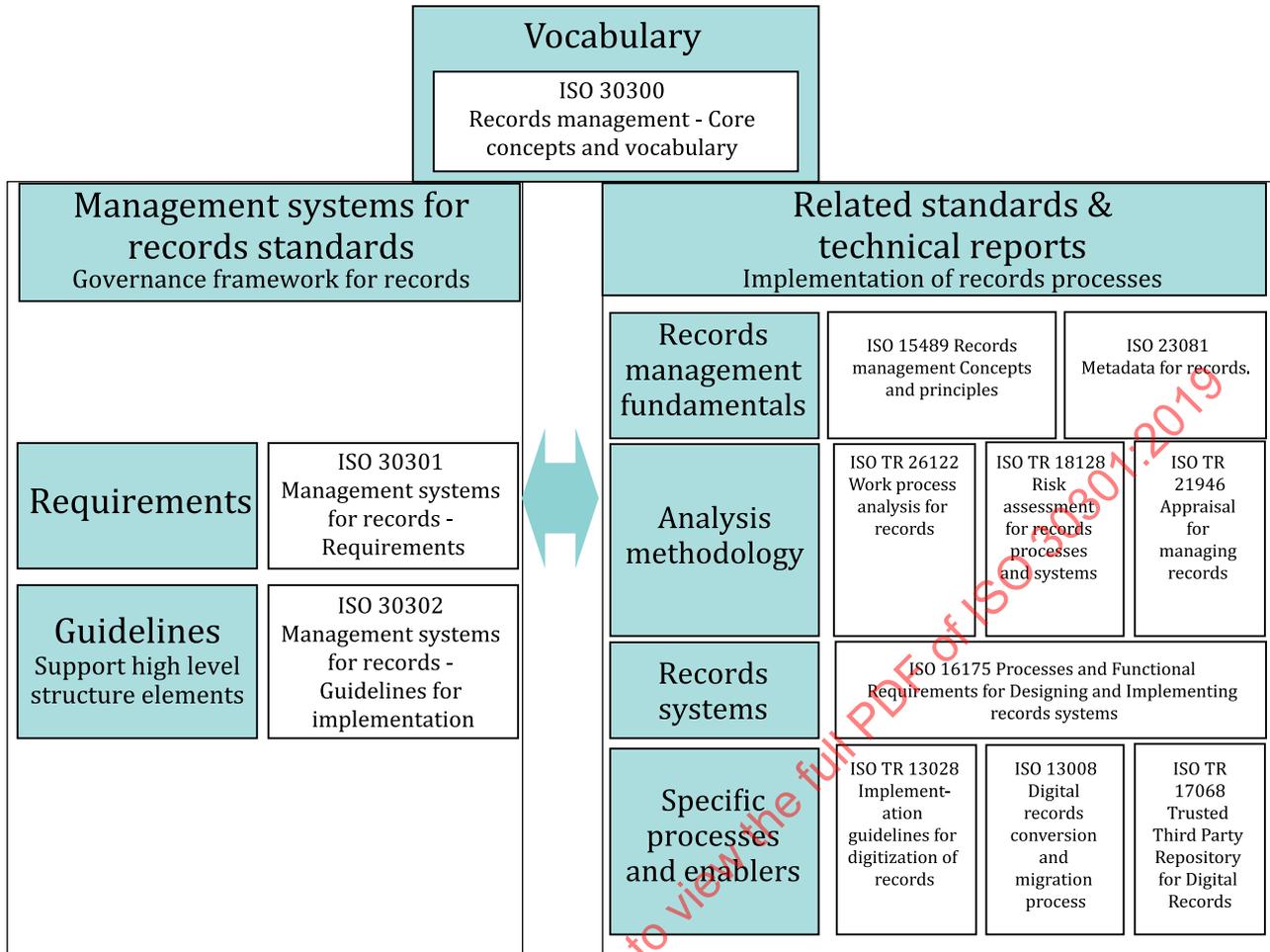
Implementing an MSR in an organization also guarantees the transparency and traceability of decisions made by responsible management and the recognition of public interest.

0.3 Relationship with other records standards

The standards on MSR are developed within the MSS framework to be compatible and to share elements and methodology with other MSS. ISO 15489-1, together with other International Standards and Technical Reports, are the principal tools for designing, implementing, monitoring and improving records processes and controls, which operate under the governance of the MSR where organizations decide to implement MSS methodology.

NOTE ISO 15489 is the foundation standard which codifies best practice for records management operations.

The structure of standards on MSR and the most relevant products for implementing records processes and controls, either published or under preparation, is shown in [Figure 1](#).



NOTE Titles of some products and technical reports are susceptible to change when they are revised. Titles in this figure represent the subject or domain, not the complete official titles of published standards and technical reports. An updated figure with new products is available at <https://committee.iso.org/home/tc46sc11>.

Figure 1 — Standards on MSR and related International Standards and Technical Reports

0.4 MSR family of standards

This family of standards is intended to be used in support of:

- a) top management who make decisions regarding the establishment and implementation of management systems within their organization;
- b) people responsible for the implementation of MSR, such as professionals in the areas of risk management, auditing, management of records, information technology and information security.

The process approach incorporated to a management system for records emphasizes the importance of:

- identifying the organization's records requirements, including interested parties' needs and expectations, and establishing policy and objectives for records;
- implementing and operating controls for managing an organization's risks in relation to its records, in the context of its overall business risks;
- monitoring and reviewing the performance and effectiveness of the MSR;
- continual improvement based on objective measurement.

Figure 2 represents the structure of this document in process approach.

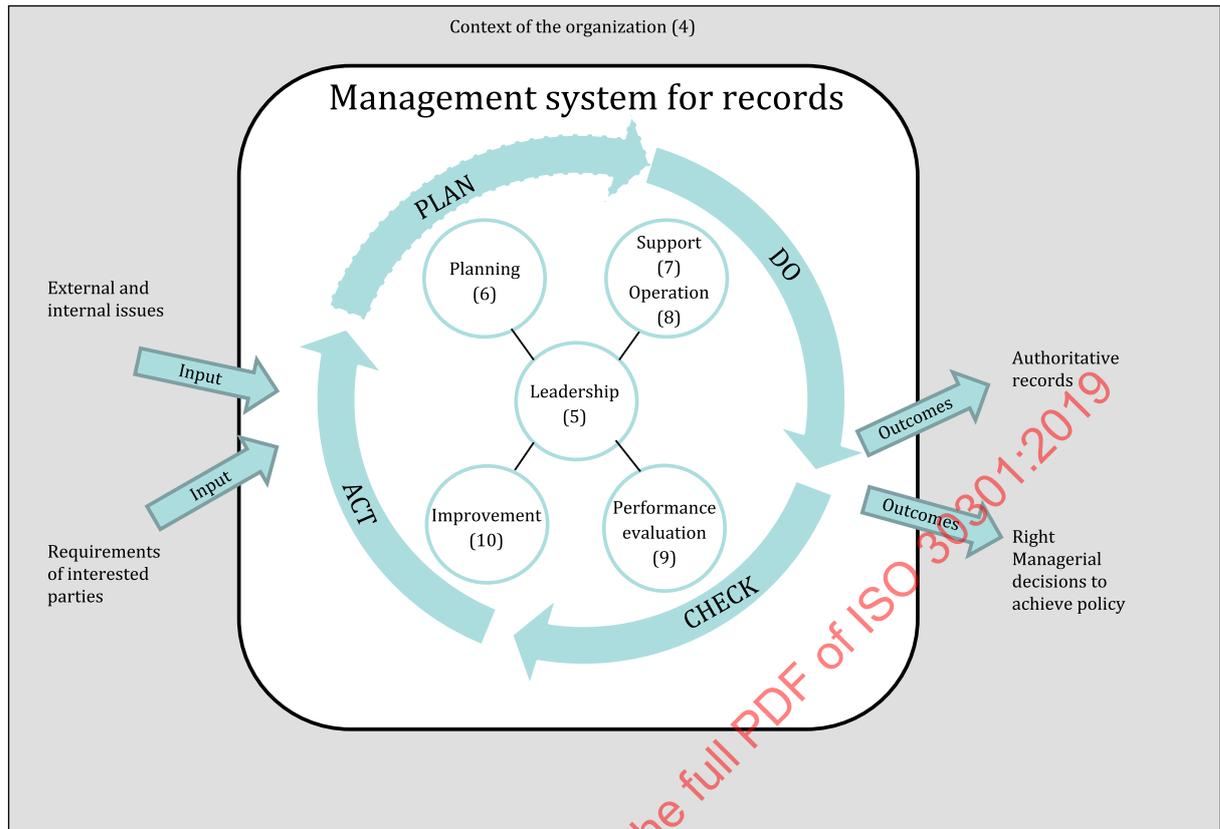


Figure 2 — Structure of MSR in process approach

0.5 Relationship and compatibility with other management system standards

This document conforms to ISO's requirements for management system standards. These requirements include a high-level structure, identical core text, common terms with core definitions, designed to benefit users implementing multiple ISO management system standards.

The term "documented information" is one of the core terms for MSS. Requirements related to documented information are given in 7.5. in all MSS. This document, apart from constituting a MSS itself, can support organizations to implement the documented information requirements of other management systems. For more information, see <https://committee.iso.org/home/tc46sc11>.

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Information and documentation — Management systems for records — Requirements

1 Scope

This document specifies requirements to be met by a management system for records (MSR) in order to support an organization in the achievement of its mandate, mission, strategy and goals. It addresses the development and implementation of a records policy and objectives and gives information on measuring and monitoring performance.

An MSR can be established by an organization or across organizations that share business activities. Throughout this document, the term “organization” is not limited to one organization but also includes other organizational structures.

This document is applicable to any organization that wishes to:

- establish, implement, maintain and improve an MSR to support its business;
- ensure itself of conformity with its stated records policy;
- demonstrate conformity with this document by
 - a) undertaking a self-assessment and self-declaration, or
 - b) seeking confirmation of its self-declaration by a party external to the organization, or
 - c) seeking certification of its MSR by an external party.

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 30300, *Information and documentation — Management systems for records — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 30300 and the following apply.

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

organization

person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.8)

Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

3.2
interested party
stakeholder

person or *organization* (3.1) that can affect, be affected by, or perceive itself to be affected by a decision or activity

3.3
requirement
need or expectation that is stated, generally implied or obligatory

Note 1 to entry: "Generally implied" means that it is custom or common practice for the organization and interested parties that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, for example in documented information

3.4
management system
set of interrelated or interacting elements of an *organization* (3.1) to establish *policies* (3.7) and *objectives* (3.8) and *processes* (3.12) to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The system elements include the organization's structure, roles and responsibilities, planning and operation.

Note 3 to entry: The scope of a management system may include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

3.5
top management
person or group of people who directs and controls an *organization* (3.1) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.

Note 2 to entry: If the scope of the *management system* (3.4) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

3.6
effectiveness
extent to which planned activities are realized and planned results achieved

3.7
policy
intentions and direction of an *organization* (3.1), as formally expressed by its *top management* (3.5)

3.8
objective
result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels [such as strategic, organization-wide, project, product and *process* (3.12)].

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as an MSR objective, or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of MSR, MSR objectives are set by the organization, consistent with the MSR policy, to achieve specific results.

3.9**risk**

effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected — positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential “events” (as defined in ISO Guide 73:2009, 3.5.1.3) and “consequences” (as defined in ISO Guide 73:2009, 3.6.1.3), or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated “likelihood” (as defined in ISO Guide 73:2009, 3.6.1.1) of occurrence.

3.10**competence**

ability to apply knowledge and skills to achieve intended results

3.11**documented information**

information required to be controlled and maintained by an *organization* (3.1) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media, and from any source.

Note 2 to entry: Documented information can refer to:

- the *management system* (3.4), including related *processes* (3.12);
- information created in order for the organization to operate (documentation);
- evidence of results achieved (records).

3.12**process**

set of interrelated or interacting activities which transforms inputs into outputs

3.13**performance**

measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to the management of activities, *processes* (3.12), products (including services), systems or *organizations* (3.1).

3.14**outsource**, verb

make an arrangement where an external *organization* (3.1) performs part of an organization’s function or *process* (3.12)

Note 1 to entry: An external organization is outside the scope of the *management system* (3.4), although the outsourced function or process is within the scope.

3.15**monitoring**

determining the status of a system, a *process* (3.12) or an activity

Note 1 to entry: To determine the status, there may be a need to check, supervise or critically observe.

3.16**measurement**

process (3.12) to determine a value

**3.17
audit**

systematic, independent and documented *process* (3.12) for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: An internal audit is conducted by the organization itself, or by an external party on its behalf.

Note 3 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011.

**3.18
conformity**

fulfilment of a *requirement* (3.3)

**3.19
nonconformity**

non-fulfilment of a *requirement* (3.3)

**3.20
corrective action**

action to eliminate the cause of a *nonconformity* (3.19) and to prevent recurrence

**3.21
continual improvement**

recurring activity to enhance *performance* (3.13)

4 Context of the organization

4.1 Understanding the organization and its context

4.1.1 General

The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended outcome(s) of its MSR.

External issues in the organization's context may include, but is not limited to:

- the social and cultural, legal, regulatory, financial, technological, economic, natural and competitive environment, whether international, national, regional or local;
- key drivers and trends which can have an impact on the objectives of the organization;
- relationships with, and perceptions, values and expectations of, external interested parties (see 4.2).

Internal issues in the organization's context may include, but is not limited to:

- a) governance, organizational structure, roles and accountabilities;
- b) policies, objectives and the strategies that are in place to achieve them;
- c) capabilities, understood in terms of resources and knowledge (e.g. capital, time, people, processes, systems and technologies);
- d) information systems, information flows and decision-making processes (both formal and informal);
- e) technological context, including technologies that are maintained solely by the organization, as well as technologies used for collaboration with other parties;

- f) relationships with, and perceptions and values of, internal interested parties and the organization's culture;
- g) standards, guidelines and models adopted by the organization;
- h) the form and extent of contractual relationships.

4.1.2 Records requirements

The organization shall identify and document the business need for records in order to understand what records should be created, captured and managed.

The organization shall identify, assess and document records requirements affecting its business operations with which it shall comply and for which it requires evidence of compliance. These requirements can be business, legal, regulatory or other requirements.

Business requirements include all the requirements for the performance of the operations or business of the organization. Requirements arise from current business performance, future planning and development, risk management and business continuity planning.

Legal requirements include requirements related to the creation, capture and management of records. Sources of legal requirements are:

- statute and case law, including law and regulations governing the sector-specific and general business environment;
- laws and regulations relating specifically to evidence, records and archives, access, privacy, data and information protection, and electronic commerce;
- the constitutional rules of organizations, charters or agreements to which the organization is a party;
- treaties and other instruments the organization is legally bound to uphold.

Other requirements include non-legal voluntary commitments made by the organization:

- a) voluntary codes of best practice;
- b) voluntary codes of conduct and ethics.

4.2 Understanding the needs and expectations of interested parties

The organization shall determine:

- the interested parties that are relevant to the MSR;
- the requirements of these interested parties.

In relation to records, interested parties expect organizations to be accountable for their actions and retain and make records available when needed. Requirements of the interested parties, may include, but is not limited to:

- a) identifiable expectations about what is acceptable behaviour for the specific sector or organization, including good governance, the proper control of fraudulent or malicious behaviour and transparency in decision making;
- b) protection of involved agents or other interested parties' rights and entitlements;
- c) expectations that information in records will be available for research purposes by particular communities or disciplines;
- d) documentation of significant events that define the historical and cultural experiences.

4.3 Determining the scope of the MSR

The organization shall determine the boundaries and applicability of the MSR to establish its scope.

When determining this scope, the organization shall consider

- the external and internal issues referred to in [4.1.1](#), and
- the requirements referred to in [4.1.2](#) and [4.2](#).

An MSR can be applied:

- a) for one or more specific business processes within an organization;
- b) across a whole organization covering all business processes;
- c) for a number of organizations with shared business processes, such as across a specific sector, trading partners or a collaborative partnership.

When a MSR is established for one or more specific functions across a group of organizations, the scope shall include relationships between, and roles of, each entity.

The scope shall be available as documented information.

4.4 Management system for records

The organization shall establish, implement, maintain and continually improve an MSR, including the processes needed and their interactions, in accordance with the requirements of this document.

5 Leadership

5.1 Leadership and commitment

Top management shall demonstrate leadership and commitment with respect to the MSR by

- ensuring that the records policy and records objectives are established and are compatible with the strategic direction of the organization;
- ensuring the integration of the MSR requirements into the organization's business processes;
- ensuring that the resources needed for the MSR are available;
- communicating the importance of effective records management and of conforming to the MSR requirements;
- ensuring that the MSR achieves its intended outcome(s);
- directing and supporting persons to contribute to the effectiveness of the MSR;
- promoting continual improvement;
- supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

NOTE Reference to "business" in this document can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence.

5.2 Policy

Top management shall establish a records policy that:

- a) is appropriate to the purpose of the organization;

- b) provides a framework for setting records objectives;
- c) includes a commitment to satisfy applicable requirements;
- d) include a commitment to continual improvement of the MSR.

The records policy shall:

- be available as documented information;
- be communicated within the organization;
- be available to interested parties, as appropriate.

The records policy shall include the high-level strategies with regard to the creation, capture and management of authentic, reliable and useable records capable of supporting the organization's functions and activities and protecting the integrity of those records for as long as they are required.

5.3 Organization roles, responsibilities and authorities

Top management shall ensure the responsibilities and authorities for relevant roles are assigned and communicated within the organization.

The assignment of responsibilities shall be appropriately allocated to all personnel at relevant functions and levels within the organization, in particular top management, programme managers, records professionals, information technology professionals, system administrators and all others who create and control records as part of their work.

Top management shall assign the responsibility and authority for:

- a) ensuring that the MSR conforms with the requirements of this document;
- b) reporting on the performance of the MSR to top management.

The organization's top management shall appoint a specific records operational representative who shall have a defined role, responsibility and authority, which includes

- implementing the MSR at the operational level,
- reporting to the top management on the effectiveness of the MSR for review, including recommendations for improvement, and
- establishing liaison with external parties on matters relating to the MSR.

6 Planning

6.1 Actions to address risks and opportunities

When planning for the MSR, the organization shall consider the issues referred to in [4.1](#) and the requirements referred to in [4.2](#) and determine the risks and opportunities that need to be addressed to:

- ensure the MSR can achieve its intended outcome(s);
- prevent or reduce undesired effects;
- achieve continual improvement.

The organization shall plan:

- a) actions to address these risks and opportunities and,

b) how to:

- integrate and implement the actions into its MSR processes;
- evaluate the effectiveness of these the actions.

6.2 Records objectives and planning to achieve them

The organization shall establish records objectives at relevant functions and levels. Successful achievement of the records objectives results in the creation, capture and management of records which are reliable, authentic, have integrity and are useable. The records objectives of an MSR are achieved by the establishment of a records system or systems to capture and control records which are reliable, secure, compliant, comprehensive and systematic.

The records objectives shall:

- a) be consistent with the records policy;
- b) be measurable (if practicable);
- c) take into account applicable requirements;
- d) be monitored;
- e) be communicated;
- f) updated as appropriate.

The organization shall retain documented information on the records objectives.

When planning how to achieve its records objectives, the organization shall determine:

- what will be done;
- what resources will be required;
- who will be responsible;
- when it will be completed;
- how the results will be evaluated.

7 Support

7.1 Resources

The organization shall determine and provide the resources needed for establishment, implementation, maintenance and continual improvement of the MSR.

Resources management includes

- assigning responsibility to personnel competent to perform the roles assigned in the MSR,
- periodic review of the competencies and training of those personnel, and
- maintenance and sustainability of resources and technical infrastructure.

7.2 Competence

The organization shall:

- determine the necessary competence of person(s) doing work under its control that affects the performance of its records processes and systems;
- ensure that these persons are competent on the basis of appropriate education, training, and experience;
- where applicable, take actions to acquire the necessary competence and evaluate the effectiveness of the actions taken;
- retain appropriate documented information as evidence of competence.

NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

7.3 Awareness

Persons doing work under the organization control shall be aware of:

- the records policy;
- their contribution to the effectiveness of the MSR, including the benefits of improved records processes and systems performance;
- the implications of not conforming with the MSR requirements.

7.4 Communication

The organization shall determine the internal and external communication relevant to the MSR including:

- on what it will communicate;
- when to communicate;
- with whom to communicate;
- how to communicate.

7.5 Documented information

7.5.1 General

The organization's MSR shall include:

- documented information as required by this document;
- documented information determined by the organization as being necessary for the effectiveness of MSR.

NOTE The extent of documented information for an MSR can differ from one organization to another due to

- a) the size of organization and its type of activities, processes, products and services,
- b) the complexity of processes and their interactions, and
- c) the competence of persons.

7.5.2 Creating and updating

When creating and updating documented information the organization shall ensure appropriate:

- a) identification and description (e.g. a title, date, author, or reference number);
- b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
- c) review and approval for suitability and adequacy.

7.5.3 Control of documented information

Documented information required by the MSR and by this document shall be controlled to ensure:

- a) it is available and suitable for use, where and when it is needed;
- b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

For the control of documented information, the organization shall address the following activities, as applicable:

- distribution, access, retrieval and use;
- storage and preservation, including preservation of legibility;
- control of changes (e.g. version control);
- retention and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the MSR shall be identified as appropriate, and controlled.

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information, etc.

Documented information of the MSR is part of the records of an organization, which shall be managed in a records system. The MSR documented information creation and control requirements shall be consistent with the general records creation, capture and management requirements ([Clause 8](#) and [Annex A](#)).

8 Operation

8.1 Operational planning and control

The organization shall plan, implement and control the records processes needed to meet the requirements and to implement the actions determined in [6.1](#), by:

- establishing criteria for the records processes;
- implementing control of the records processes in accordance with the criteria;
- keeping documented information to the extent necessary to have confidence that the records processes have been carried out as planned.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that outsourced records processes included in the scope on MSR are controlled.

8.2 Determining records to be created

The organization shall determine what, when and how records shall be created and captured for each business process.

This shall be achieved through:

- the analysis of the business process in order to determine the requirements for records creation, capture and management in relation to continuing operations, and to satisfy accountability and other interested parties' interests (see ISO/TR 26122 and ISO/TR 21946);
- the assessment of the risks that might be incurred through failure to control authentic, reliable and useable records for this business process and to protect the integrity of those records (see ISO/TR 18128).

The results of this analysis shall be documented and authorized by the top management.

8.3 Designing and implementing records processes, controls and systems

The organization shall design and implement records processes, controls and systems taking into account the records requirements in [4.1.2](#) and [Annex A](#).

The records processes and controls in [Annex A](#) should be implemented, taking into account the resources of the organization and the identified risks that can be managed through the creation, capture and management of records.

The organization shall implement the records processes in records systems, manage the operation of the records systems, and establish regular monitoring of the performance of the records systems.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

The organization shall determine:

- a) what needs to be monitored and measured;
- b) the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results;
- c) when the monitoring and measuring shall be performed;
- d) when the results from monitoring and measurement shall be analysed and evaluated.

The organization shall retain appropriate documented information as evidence of the results.

The organization shall evaluate the performance of records processes and systems and the effectiveness of the MSR.

9.2 Internal audit

9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the MSR:

- a) conforms to
 - the organization's own requirements for its MSR;
 - the requirements of this document;

b) is effectively implemented and maintained.

9.2.2 The organization shall:

- a) plan, establish, implement and maintain an audit programme(s), including the frequency, methods, responsibilities, planning requirements and reporting. The audit program shall take into consideration the importance of the processes concerned and the results of previous audits;
- b) define the audit criteria and scope for each audit;
- c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d) ensure that the results of the audits are reported to relevant management;
- e) retain documented information as evidence of the implementation of the audit programme and the audit results.

9.3 Management review

Top management shall review the organization's MSR, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.

The management review shall include consideration of:

- a) the status of actions from previous management reviews;
- b) changes in external and internal issues that are relevant to the MSR;
- c) information on the performance of records processes and systems, including trends in:
 - nonconformities and corrective actions;
 - monitoring and measurement results;
 - audit results;
- d) opportunities for continual improvement.

The outputs of the management review shall include decisions related to continual improvement opportunities and need for changes to the MSR.

The organization shall retain documented information as evidence of the results of management reviews.

10 Improvement

10.1 Nonconformity and corrective actions

When a nonconformity occurs, the organization shall:

- a) react to the nonconformity and, as applicable:
 - take action to control and correct it; and
 - deal with the consequences;
- b) evaluate the need for action to eliminate the cause(s) of the nonconformity in order that it does not recur or occur elsewhere, by:
 - reviewing the nonconformity;
 - determining the causes of the nonconformity;