GUIDANCE FOR IMPLEMENTING 'DOCUMENTED INFORMATION' CLAUSE USING PROCESSES AND CONTROLS OF ISO 30301:2019
Management systems for records

EXPLANATORY PAPER

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1 INTRODUCTION

ISO Directives include Annex SL – 'Harmonized approach for management system standards' (MSS). Appendix 2 to Annex SL – 'Harmonized structure for MSS with guidance for use' is the mandatory high level structure (HLS) for developing all MSS, comprising clause numbers, clause titles, text, common terms and core definitions, as well as guidance for use for writers and editors of MSS.

The term **'Documented information'** is one of the common terms for all MSS, and the requirements for documentation are in Annex SL Appendix 1, clause 7.5. These requirements are aligned with best practice in the document and records management field and enable traceability in the design and operation of a management system.

Three other best practice standards supporting organizations to implement documentation requirements of any management systems are:

- *ISO 30300 Information and documentation – Records management – Core concepts and vocabulary*
- *ISO 30301 Information and documentation –Management systems for records – Requirements*
- *ISO 30302 Information and documentation –Management systems for records –Guidelines for implementation.*

ISO 30301 constitute a Management System Standard itself.

This paper explains how the processes and controls in ISO 30301 can help to implement the requirements of the 'documented information' clause (7.5).

2 INTEGRATED IMPLEMENTATION OF MSS

The main purpose of a *high level structure, identical core text, common terms and core definitions* is to facilitate the integrated use and implementation of different MSS. Each MSS is focused on a specific aspect of the management of an organization, but they share common requirements to implement continual improvement. Specific requirements in each MSS are mainly stated in clause 8. Operation.

In ISO 30301, operational requirements are focussed on the records processes and controls stated in clause 8 and normative Annex A. Implementing these processes and controls assures compliance with Annex SL, Appendix 1, clause 7.5. 'Documented Information'.[1]

3 WHAT IS DOCUMENTED INFORMATION?

3.1 General

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[1] This does not mean implementation of ISO 30301 is mandatory to be compliant with these requirements.

Creation and management of information are integral to any organization's processes and systems, whether or not it has implemented a formal MSS. Information is used to communicate messages or instructions, plan, and provide evidence of actions, decisions or results. In all these cases information needs to be 'fixed' or documented, managed and controlled – creating business value for the organization.

'Documented information' is the term used by MSSs to cover all the information required to be controlled and maintained by the organization when implementing a management system. Depending on the organization, documented information for a specific MSS could cover all the information of business value created or received by the organization, or just a part of it. A documented management system is the basis for continuous improvement, but does not mean documentation is the aim of the management system.

ISO 30301 uses the term 'records' in a broad sense to cover all the information of business value produced by an organization in the conduct of business, including that required for a management system. Documented information resulting from the implementation of a MSS is included in the scope of a Management System for Records. The term 'records' in the ISO 30300 series should be understood as 'documented information', in any format.

The processes and controls in ISO 30301 and guidance for implementation in ISO 30302 can be used when implementing other MSS.

3.2 Documented information vs documents and records

Historically, different MSS used the terms "document", "documentation" and "records". One of the main changes of the high-level structure in relation to documentation of a management system is the use of the term 'documented information' instead of the former distinction between 'documents' and 'records'. The rationale for this change is based on the common processes used to create and control all forms of documented information.

Each organization decides what, when and how documented information shall be created and controlled for each business processes or function. Some documented information can become obsolete or superseded - requiring controls for this process. Other information needs to be maintained for many years – requiring preservation action to ensure it is usable into the future.

4 DOCUMENTED INFORMATION PROCESSES AND CONTROLS: How ISO 30301 can help?

4.1 Approach

> **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).

4.1.1 The systematic approach to documented information

Before implementing the specific requirements in clause 7.5 'Documented Information' for any MSS, the systematic approach in ISO 30301 can be used to identify what, when and how documented information shall be created and the requirements for its control.

The analysis for this identification is done in the preliminary phases of designing the MSS and should be aligned with the analysis required for the implementation of any MSS.

For example, an output from this analysis should be a classification scheme which enables the classification of documentation according to the business function or process in which it is created. The business function of "implementing an MSS" can group all documented information relating to the establishment of the management system, such as scope, policy,

manuals, objectives, plans, as well as the specific documentation needed to control operations such as procedures, instructions, specifications, etc. Another output could be the definition of the metadata schema (typical in automated environments) to be captured together with its related documented information.

Using ISO 30301 controls facilitates consistency in the methods of document capture, the criteria for establishing retention periods, and the structure, form and technologies for the creation of the documented information. (See 4.2.3 of this paper.)

4.1.2 Information systems

Most organizations are trying to manage the information they produce and receive in increasing amounts, so a range of information systems might be in place. Documented information should not be managed in an isolated way, and should use designated corporate systems and applications. ISO 30301 includes requirements for operation of these systems which can be:

a) business applications or systems which retain and manage evidence of transactions,
b) databases which recreate documentation as needed, and
c) specialized software used to automate the capture and management of documented information.

Managing the operation of these systems means ensuring they continue to operate in a reliable, secure and compliant manner and cover the complete range of documented information the organization needs.

4.2 Specific requirements

4.2.1 Creating and updating

The identification and description of documented information is done by applying descriptive and contextual information, called metadata. When creating documented information, this is one of the controls that enables the automated identification and description of the documented information.

The format and media of documented information are determined in relation to each business process.

Defining and documenting the method of capture of the documented information for each business process and function is to ensure review and approval is completed when needed. A versioning and approval process can be applied to specific documented information.

4.2.2 Control of documented information

Defining the processes to access documented information requires analysing, defining and documenting the appropriate access or use permissions, including consideration of any mandatory or regulatory requirements. Rules are implemented by defining people and their permissions to view or use documented information and implementing those rules into systems.

Maintaining the usability of the documented information includes backup, storage in adequate conditions, implementation of retention periods, and the capability to retrieve and understand the information when needed.

Changes affecting documented information should be allowed by implementing access rules and permissions. Permissions could apply to different processes such as versioning, change on access rules, transfer of storage, addition of metadata, etc. Changes can be controlled by capturing information about these changes. Technology supports this by capturing the defined control information, which can include also information about different events, e.g. people accessing information, dates of version changes, date/time of use, etc.

Efficient and effective control of documented information includes disposition of the information when the defined retention period concludes. Doing this in a systematic way includes implementing a procedure to define retention periods which ensures that all legal, business and other requirements are taken into account and the appropriate persons approve the decisions taken. Results of the analysis are documented in disposition schedules linked to a specific business process or group of processes. Any documented information, including obsolete or superseded versions, should have a retention period. Disposition can include transfer to other organizations when needed, removing or changing storage locations, and destruction. Destruction action is supervised and documented, and where needed, control information is kept about the information destroyed.

4.2.3 Relationship table

HLS 7.5 Documented information	ISO 30301- Annex A Processes and controls
Creating and updating: identification and description (e.g. a title, date, author, or reference number)	The form and structure of the information required as records for each work process shall be identified and documented (A.1.2) The contextual information about records shall be added at the point of capture (A.1.4.) A unique identifier at the time of capture shall be implemented for work processes which require evidence of capture (A.1.5.) The records shall be grouped (classified) according to the work processes to which they relate (A.1.7.) Metadata schemas for records shall be identified and documented. (A.2.1. - A.2.3.) A scheme or classification to link business activities and records shall be established and documented. (A.2.4.)
Creating and updating: format (e.g. language, software version, graphics) and media (e.g. paper, electronic)	The form and structure of the information required as records for each work process shall be identified and documented. (A.1.2.) The means of maintaining/storing the records shall meet the relevant standards for the medium and technology used, in order to ensure they remain accessible and useable for as long as required. (A.1.8.) Regular conversion of records formats, including conversion from analogue to digital formats (digitization) shall be authorized and documented. (A.1.12.)
Creating and updating: review and approval for suitability and adequacy	When a record supersedes an existing one (updating), such as some of documented information, the new version shall indicate the obsolete one and the changes made (A.1.6.)
Control: distribution, access, retrieval and use	Digital records shall remain accessible and useable over time. (A.1.9.) Actions on records to be recorded in metadata shall be defined and implemented . (A.1.10.) Controlled migration of records to another organization or system shall be authorized and documented (A.1.11.)

HLS 7.5 Documented information	ISO 30301- Annex A Processes and controls
	Access and permissions rules shall be established, documented and maintained. (A.2.5.-A.2.7.)
	The records system shall ensure the integrity/security of the records to prevent unauthorized use, modification, removal, distribution, concealment and/or destruction. (A.3.1.)
Control: storage and preservation, including preservation of legibility	Digital records shall remain accessible and useable over time. (A.1.9.)
Control: control of changes (e.g. version control);	When a record supersedes an existing one (updating), such as some of documented information, the new version shall indicate the obsolete one and the changes made (A.1.6.)
Control: retention and disposition	Criteria to determine retention periods for records according to requirements of each working process shall be established and documented (A.1.14.)
	Decisions about retention and disposition of records based on business, legal and other identified requirements shall be documented in a disposition schedule. (A.2.8.)
	Retention and disposition schedules and actions shall be authorized and documented. (A.2.9.)
	Decisions about the transfer, removal or destruction of records shall be authorized and documented. (A.1.15.)
	Records authorized for destruction shall be destroyed under appropriate supervision. The destruction shall be documented (A.1.16.)
	Control information (registration, identification and history metadata) about records which have been destroyed shall be retained where the nature and complexity of the business and formal accountabilities require it (A.1.17.)