

**GUIDANCE FOR IMPLEMENTING
"DOCUMENTED INFORMATION" CLAUSE USING
PROCESSES AND CONTROLS OF ISO
30301:2011 Management system for records**

EXPLANATORY PAPER

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1 INTRODUCTION

Since 2012 ISO Directives included an Annex SL 'Proposals for management system standards', with a clause on "*High level structure, identical core text and common terms and core definitions for use in Management Systems Standards*".

The term '**Documented information**' was introduced as part of the common terms for Management System Standards (MSS), and requirements related to documentation are grouped in Appendix 1, clause 7.5.

Clause 7.5 includes significant changes compared with former versions of MSS, and is aligned with best practice in the document and records management field.

Based on best practice and experience in the transition to a digital environment, in 2011 *ISO 30300 Management systems for records – Fundamentals and vocabulary* and *ISO 30301-Management systems for records- Requirements* were published as the first products of a series of standards. This series, apart from constituting a Management System Standard by itself, can help and support organizations to implement documentation requirements of other management systems.

The purpose of this paper is to explain 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

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2-1. ISO 30301:2011. Table of content

The main purpose of having a *High level structure, identical core text and common terms and core definitions*, is to facilitate the integrated use and implementation of different MSS. Each MSS is focused on an 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 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

Creation and management of information are integral to any organization's activities, processes and systems, independent of whether or not it has implemented a formal MSS. Information can be used to communicate messages or instructions, to plan, to document decisions or results and to provide evidence of actions. In all these cases information need to be fixed or documented, and can be 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

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



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. Documented information resulting from the implementation of a MSS could be included in the scope of a Management System for Records.

The processes and controls in ISO 30301 and guidance for implementation in ISO 30302 can be used when implementing other MSS. The term 'records' in the ISO 30300 series should be understood as 'documented information'.

In the 21st century, almost all organizations are involved in digital transition initiatives. Consequently documented information should be aligned with these developments and created in digital formats using technology for its creation and control.

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 HLS (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 of this change is based on the common processes used to create and control all forms of documented information.

From a practical point of view, standardized terminology simplifies documentation processes and takes advantage of available technology for the creation and control of documented information.

Each organization decides what, when and how documented information shall be created and captured and the requirements for its control, 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 over time.

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

4.1 Approach

<p>7.5 Documented information</p> <p>7.5.1 General</p> <p>The organization's XXX management system shall include:</p> <p>a) documented information required by this International Standard /this part of ISO XXXX/this Technical Specification;</p> <p>b) documented information determined by the organization as being necessary for the effectiveness of the XXX management system.</p> <p>NOTE The extent of documented information for a XXX management system can differ from one organization to another due to:</p> <ul style="list-style-type: none">— the size of organization and its type of activities, processes, products and services;— the complexity of processes and their interactions;— the competence of persons. <p>7.5.2 Creating and updating</p> <p>When creating and updating documented information the organization shall ensure appropriate:</p> <ul style="list-style-type: none">— identification and description (e.g. a title, date, author, or reference number);— format (e.g. language, software version, graphics) and media (e.g. paper, electronic);— review and approval for suitability and adequacy. <p>7.5.3 Control of documented information</p> <p>Documented information required by the XXX management system and by this International Standard /this part of ISO XXXX/this Technical Specification shall be controlled to ensure:</p> <p>a) it is available and suitable for use, where and when it is needed;</p> <p>b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).</p> <p>For the control of documented information, the organization shall address the following activities, as applicable:</p> <ul style="list-style-type: none">— distribution, access, retrieval and use;— storage and preservation, including preservation of legibility;— control of changes (e.g. version control);— retention and disposition. <p>Documented information of external origin determined by the organization to be necessary for the planning and operation of the XXX management system shall be identified, as appropriate, and controlled.</p> <p>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.</p>
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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 for identifying the documented information to be created and the requirements for its control.

The analysis needed 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.

The results of this analysis are not only what, when and how documented information shall be created and captured for each business processes, but also the

control instruments to be used when operating. 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 schema of the structured information or metadata (typical from 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.

4.1.2 Information systems

Although documented information for a management system could be retained in paper form, this practice is not aligned with organization's and society's transition to a digital environment. Most organizations are concerned about how to manage the information they produce and receive in increasing amounts, so a range of information systems may be put 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 re-create 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 basis 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, the control instruments, defined in the previous analysis, are used and allow 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 assure review and approval is established when needed. Establishing a process of versioning, with one or more steps of approval, is a method that can be applied to specific documented information.



4.2.2 Control of documented information

Defining the processes to access documented information requires analysing and identifying the applicable access or use permissions. Access rules are defined and documented including 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 storage in adequate conditions and the capability to retrieve and understand the information when needed. This relates to the retention periods to be applied to the documented information and requires specific actions when disposing or retaining electronic documented information.

Changes affecting documented information should be allowed through implementing the access rules and permissions. Permissions could apply to different processes such as versioning, change on access rules, transfer of storage, addition of metadata, etc. All these 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 (to be applied when analyzing business processes and the associated documented information). 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 organization has determined the content, context and control information (metadata) that shall be included in the records (A.1.2)
Creating and updating: format (e.g. language, software version, graphics) and media (e.g. paper, electronic);	The organization has decided in what form and structure the records shall be created and captured (A.1.3). The organization has determined appropriate technologies for creating and capturing records (A.1.4).
Creating and updating: review and approval for suitability and adequacy.	The organization has determined what, when and how records shall be created and captured for each business process (A.1.1).
Control: distribution, access, retrieval and use	The organization has established rules and conditions for use of records over time (A.2.2).
Control: storage and preservation, including preservation of legibility	The organization has determined how to maintain the usability of the records over time (A.2.3)
Control: control of changes (e.g. version control);	The organization has determined what control information (metadata) shall be created through the records processes and how it will be linked to the records and managed over time (A.2.1).
Control: retention and disposition	The organization has implemented authorized disposition of records (A.2.4).