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Organisational Development

IMS Procedure

MANAGEMENT OF CONTROLLED DOCUMENTED INFORMATION

IMS-JRC-M4.1-PRO-0011

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TABLE OF CONTENTS

1 INTRODUCTION

1.1 Purpose and scope

The Commission's Internal Control Standard, ICS 8 [1], requires that the JRC's processes and procedures used for the implementation and control of its activities are effective and efficient, adequately documented and compliant with applicable provisions. A second standard, ICS 11 [1], gives particular focus to the life-cycle of documents and records downstream of their creation. Similarly, ISO 9001:2015 [2] calls for documented information (i.e. documents and records) as required by the standard and deemed necessary by the organisation for the effectiveness of its management system.

This procedure describes how documented information is managed through its life-cycle for what concerns the IMS.

2 EXECUTION

2.1 Documented information management

2.1.1 General requirements

The documented information in the IMS comprises documents and records required by[1]:

- General:
  - ICS [1];
- Quality discipline:
  - ISO 9001:2015 [2];
  - ISO/IEC 17025:2005 [3];
  - ISO/IEC 17043:2010 [4];
  - ISO Guide 34:2009 [5];
  - OECD GLP (1997) [6];
- Environmental discipline:
  - ISO 14001:2015 [7];
  - EMAS III - Regulation (EC) No 1221/2009 [8];
- Health & Safety discipline:
  - BS OHSAS 18001:2007 [9];

taking into account:

- the size and geographical spread of the JRC, and its type of processes and outputs;
- the complexity of the JRC's processes and their interactions;
- the competence of its staff;
- the need to ensure adequate business continuity.

2.1.2 Overview of the origin and control of documented information

The origin of documented information required by the IMS and its corresponding control are presented in Table 1.

[1] Also includes earlier versions of standards if they are still applied.

Table 1: The general control of documented information for the IMS.

Origin	Documented information	Control
Internal	IMS documents as defined in Annexes A and B and bearing a unique IMS ID.	Life-cycle as defined in Figure 1 – see §2.2 - §2.9.[1]
	Ad-hoc JRC documents which impact on the planning and operation of the IMS such as a note from JRC's senior management.	Suitable arrangements in place to manage documents and make them appropriately available to process interested parties (prior to any integration into IMS documents) – see §2.10.
External	Ad-hoc non-JRC documents which impact on the planning and operation of the IMS such as a note from the Commission or a DG which is a domain leader (e.g. DG BUDG).	
	Regulatory and statutory documents which impact on the planning and operation of the IMS.	Suitable arrangements in place to make documents available to interested parties – see §2.10.
	"Standards" documents such as ISO 9001:2015.	
Internal	Records.	Suitable arrangements in place – see §2.11.

1 The requirements and recommendations set out in §2 2 - §2.9 for real (physical) IMS documents, are applicable in substance to virtual documents, although the means of fulfilling the requirements may be adapted taking into account any host information system.

2.2 Identifying an IMS document (addition to the IMS documents list)

An IMS document may be applicable at a JRC or local level [2] and its need must be substantiated by:

a) for an envisaged JRC level document:
- the intended author or his/her IMS responsible verifying that a document meeting the JRC needs does not already exist at a JRC level;

b) for an envisaged local document:
- the intended author or his/her IMS responsible verifying that a document meeting the local needs does not already exist locally or JRC level; and
- the intended author informing the IMS Responsible (Directorate Quality Manager) of the directorate in which the document is intended to be applied and the IMS responsible (Directorate Quality Manager or Unit Quality Officer) supporting the Process Owner about the need to create the local document.[3]

If the need to create a new IMS document remains substantiated taking into account any timely feedback from the informed IMS responsibles, the author (it may be any staff member) is responsible to obtain a unique identifier that is automatically assigned by IMSIS (IMS Information System).[4]

[2] A local document is a document which is only applicable at one site (e.g. environment related) or in one directorate (e.g. facility related).

[3] A Process Owner may give some relaxation of the need for his/her IMS Responsible to be systematically informed.

[4] Until the IMSIS Document Control application is operational, the identifier must be obtained from the IMS Manager or a Directorate Quality Manager.

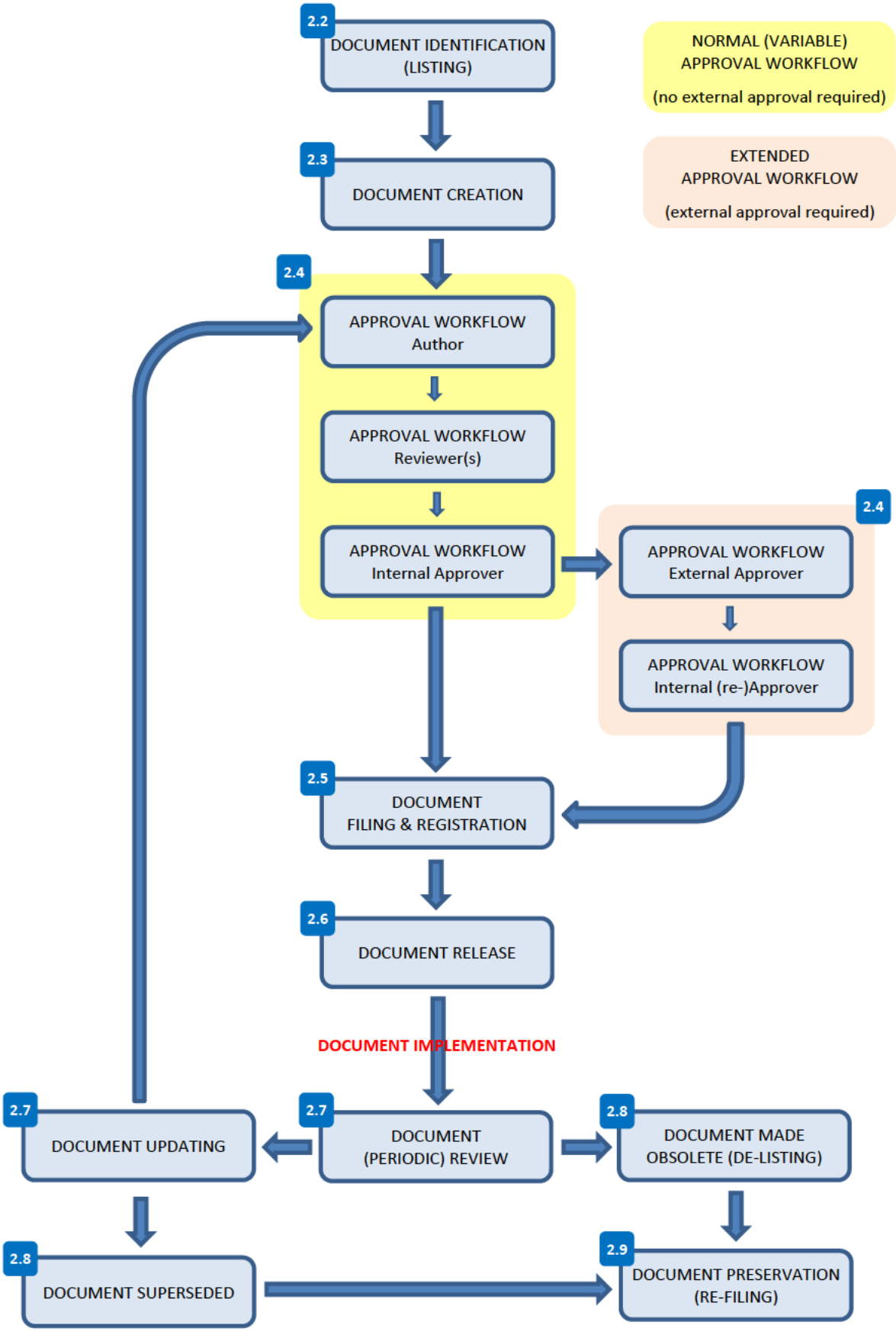

Figure 1: IMS document life-cycle.

The IMS document naming convention comprises 6 elements (see Annex B for more details):[5]

- IMS (fixed);
- applicability (variable);
- related process (variable) (cf, Ref. [10]);
- document type (variable – see Annexes A and B);
- number (variable);
- language (optional if the language is English, otherwise mandatory);

Regarding different languages:

- Additional language versions of the same document must:
  - bear the same values for the naming convention elements with the exception of the language;
  - have the same version number for the same document contents across different languages;
  - indicate if the language version is derived from a master language document (i.e. master language has precedence over other languages).
- In cases where a single document is multi-lingual (e.g. English and German), the document is defined as English and the languages indicated in the title (e.g. DE/EN) using the language codes defined in Annex B.

As regards versioning:

- the versioning for all IMS documents other than lists and registers is numeric, with the first approved and released version usually being 1.0 (number is not part of the IMS document identifier);[6]
- the versioning of lists and registers may be either as above or the date and time of the document's approval.

The IMS documents list is part of the Document Control application in IMSIS.[7]

2.3 Creating an IMS document

2.3.1 Authoring the document

The author must ensure that interested parties other than process staff are, where necessary, involved in the creation of a new document or when an existing document undergoes a major update.

The metadata for different document types which must appear on the cover page and on other pages in the document is defined in Annex C.

Unless stated on the first page of the document, any paper copy of an IMS document is uncontrolled. A statement to this effect must appear on the first page of the document such as that used in this procedure.

Wherever practical, the author must specify in the document how records created as a result of implementing the document are to be managed. In the case of records resulting from the use of templates

[5] The document may also bear a second (non-IMS) identifier on the title page if this will facilitate users during the transition towards the IMS or if there is some over-riding need approved by the Process Owner (cf. Annex C).

[6] During the transition to IMS documents, a higher initial IMS document version is permitted taking into account the current version of the non-IMS document.

[7] Until the IMSIS Document Control application is operational, an IMS documents list based on MS Excel is maintained by the IMS Manager in the folder P:\IMS\IMS documents list.

and forms, their subsequent management is defined in the IMS document (typically a procedure or work instruction) which governs the template or form.

Some recommended practices for authoring documents are given in Annex D.

2.4 Implementing the approval workflow of an IMS document

2.4.1 General

Part of the control for an IMS document is its approval workflow which potentially involves four roles of actor: author, contents reviewer, form reviewer; approver (always internal and additional external if needed).

The minimum approval workflows for IMS documents are presented in Table 2. The approval workflow always commences with the author and ends with the internal approver, even if the workflow also requires an external approver.

Table 2: Minimum approval workflows for the most common IMS documents.[1]

<table>
<tr><th>Document type[2]</th><th colspan="2">Approval workflow actors[3]</th></tr>
<tr><td>Manual</td><td colspan="2" rowspan="4">Author
Reviewer(s) – content
Reviewer – form
Approver</td></tr>
<tr><td>Process description</td></tr>
<tr><td>Procedure</td></tr>
<tr><td>Work instruction</td></tr>
<tr><td>Form</td><td rowspan="2">Minor update[4]
Author = Approver</td><td rowspan="2">First release or a major update[4]
Author
Reviewer – form (first release only)
Approver</td></tr>
<tr><td>Template</td></tr>
<tr><td>List</td><td colspan="2">Author = Approver</td></tr>
<tr><td>IMS policy</td><td colspan="2" rowspan="3">Author
Approver (if needed after a positive opinion from the Directoire)</td></tr>
<tr><td>IMS process map</td></tr>
<tr><td>IMS organisational chart</td></tr>
<tr><td>Documents not identified above</td><td colspan="2">Author
Approver</td></tr>
</table>

1 Excluding any necessary external approver.

2 For more information on the document type, see Annex A.

3 Further requirements and recommendations regarding workflow actors are discussed in §2.4.4.

4 For more information on minor and major updates, see §2.7.

Where necessary, the above minimum workflow approval requirements are complemented by work instructions at a JRC or local level.

Actors in the approval workflow cannot have dual roles except:

- when the author is an IMS responsible, the same person may also have a form reviewer role;
- the approver may be one of the reviewers;
- in the case of a form or template undergoing a minor update, the author and approver may be the same person.

When launching the workflow, the author must identify:

- whether controlled paper copies are foreseen (cf. §2.3.1);
- if the document is subject to approval by an external authority and, if so, by which authority.

The approval workflow always commences with the author and ends with the internal approver (or internal re-approver if the workflow also requires an external approver).

Any actor in the workflow other than the author may:

- accept a draft document;
- reject a draft document with comments;
- reject a draft document and provide an edited update of the draft document;

with rejection meaning that the workflow returns to the author.

The following is applicable for signing an IMS document:

- electronically sign in IMSIS:[8]
  - for a document with only internal workflow actors
  - for a document involving an external approver who does not require an original paper document to be manually signed by internal actors;
- manually sign:
  - for a document involving an external approver who requires an original paper document to be manually signed by internal actors.[9]

2.4.2 Review of an IMS document's contents

Where necessary, the author must envisage a review of the document's contents. One or more reviewers may be selected to verify that the document satisfies the intended purpose taking into account typical users of the document and any complementary documents and/or supporting tools. Given this, a reviewer should not have significantly contributed to authoring the document and must have the necessary competence and access to pertinent background information upon which to base his/her review.

When there is more than one contents reviewer, no prioritisation is usually foreseen (i.e. parallel workflow).

Where there are multiple contents reviewers acting in a collective capacity (e.g. as with the present document), a lead reviewer acts on behalf of such multiple reviewers in the approval workflow.

2.4.3 Review of an IMS document's form

After all of the document contents reviewers have accepted the document, a reviewer to verify the form of the document may be necessary. Such a reviewer is an IMS responsible usually at a unit or directorate level, most often the IMS Responsible supporting the Process Owner for JRC-level documents or, for local documents, the organisational entity where the document is applicable.

[8] Until the IMSIS document control application is operational, the document should be electronically signed in ARES.

[9] Manual signing will require that the storing and subsequent management of the original paper document be stipulated.

2.4.4 Internal approval of an IMS document

After all the reviewers have accepted the document, the approver approves the document for release and distribution or, in exceptional cases, approves the document in anticipation of its external approval and subsequent internal re-approval.

For some documents, the approver may be required to have a specific job function. This requirement must be identified in the approval workflow applicable to the document.

The approver depends on the type of document to be approved:

- for process related documentation, the approver is usually the Process Owner for documents applicable at a JRC level (less so for templates and forms), and a Director, HoU, site manager or facility manager for documents applicable at a local level;
- for a policy, the approver is normally the Director-General or a Director depending on the scope of the policy, although ISO/IEC 17025 driven policies may be approved by a HoU;
- for the JRC process map, the approver is the Director-General;
- for the JRC organisational chart, the approver is the Director-General.

2.4.5 External approval of an IMS document

Very occasionally, an IMS document requires external approval (e.g. a document governed by a nuclear license). In such instances, an extended workflow is used to confirm that external approval of the internally approved document has been received.

Since an external approver does not have access to IMSIS, this person usually is represented in the information system by an internal approver who re-approves the document and provides objective evidence (e.g. references the external approver's approval filed and registered in ARES) when re-approving the document. If the external approver rejects or demands changes to the document, the unacceptable document (neither registered nor filed) must be appropriately preserved and, where necessary, a modified document re-submitted for external approval.

2.5 Registering and filing an IMS document

After the document is internally approved or re-approved where applicable, it must be registered and filed in ARES where all IMS documents are stored except for any documents which have an EU security classification[10]. Details regarding the associated ARES files can be found in Annex E.

The ARES process sub-file in which the document is located depends on:[11]

- the process to which the document belongs;
- any limitation on the document's access (public sub-file for no limitation or a specific restricted sub-file for a pre-defined limited access).

[10] Restricted, confidential, secret and top secret.

[11] Until the Document Control application of IMSIS is operational, the IMS documents list maintained by the IMS Manager includes the correspondence table between IMS processes and ARES sub-files.

Filing a document in the ARES process sub-file implies that the document can be released and may be automatic or manual:

- No external approver: internally approved document automatically registered and filed in the ARES process sub-file;[12]
- External approver: internally and externally approved document manually or automatically filed in the ARES process sub-file, this partially depending on whether the filed document must bear real rather than electronic signatures.

2.6 Releasing an IMS document

An IMS document can only be released by IMSIS (published, distributed where necessary and the awareness of process staff and other interested parties raised) after the document's approval (and re-approval where necessary). The general release of IMS documents is shown in Table 3.

Table 3: General release of IMS documents.[1]

	Real (physical) IMS document[2]		Virtual IMS document
Document type	IMS documents other than forms and templates	IMS forms & templates	IMS forms
Publication	Published on Connected as a link to the ARES pdf of the native document registered in ARES.[2]	Published on Connected as a link to the native document registered in ARES.[2]	Made available as an integral part of an information system.[3]
Access	ARES public sub-file: access unlimited. ARES restricted sub-file: access limited.		Access determined by information system.

1 For a document requiring controlled paper copies (e g. individually stamped and numbered, use of distribution receipt), this aspect of document control is governed by local practices.

2 The IMS Manager regularly updates on Connected a list of IMS documents (excluding those with an EU security classification) together with the associated ARES links (cf. §2.5), this complementing the publication on behalf of the Process Owner of a document in any Connected spaces specific to a process or group of processes.

3 For example, the standard order form within JIPSY (JRC Integrated Process System).

It is the responsibility of the author to ensure that the link on Connected directs the user to the correct document and its latest approved version (e.g. by opening the link on the JRC intranet).

In some cases, it may be necessary to distribute the document by targeting specific interested parties. Whatever communication means are employed, the distributed document must be the same as that published.

The author should, where appropriate, complement the use of Connected with other communication channels (e.g. networks, specific training, direct contact) to raise the awareness of process interested parties with regard to a new or updated document.

[12] Until the IMSIS Document Control application is operational, IMS documents must be registered and filed manually.

2.7 Reviewing and updating an IMS document

It is necessary to periodically review and, where necessary, update and re-approve each IMS document. The review period, unless otherwise stipulated, is taken as 3 years from the date of approval.

For a document whose periodic review does not lead to any document update, its review is recorded in IMSIS.

The updating of a document involves similar controls as when preparing a document.

The revision history of each IMS document is recorded in IMSIS. Also, wherever practical, significant changes to the previous version must be indicated in the document's history that is an integral part of the document, and may exceptionally be complemented with a detailed revision history which outlines the changes made to specific sections, paragraphs, sentences, etc., at the end of a document's main body.

The approval workflow for updating a document is usually the same as for the previous version of the document unless the document is a form or template (workflow variable).

The version number of the updated document depends on whether the update is considered minor or major. For instance, if the previous version was 1.0, the next version is 1.1 for a document which has undergone a minor (insubstantial) update, and 2.0 for a document that has substantially changed (major update). A minor update fulfils two criteria: it does not change the original intent of the content and it is not large in size relative to the document. For example, a formatting or grammatical change, the correction of a typographical error, minor word changes to standardise language or remove ambiguities and/or improve clarity are all minor updates. Updates which fail to fulfil these criteria or which are large in size relative to the document are major.

As for the first release (cf. §2.2), the versioning of lists and registers may utilise the approach discussed above or may be the date and time of the approved update.

2.8 Managing superseded and obsolete IMS documents

An IMS document is superseded when a new version of the document is released, while a document is made obsolete when it is no longer required and no new document version is released.

In general, the management of superseded and obsolete documents is the responsibility of the author supported by the relevant IMS responsible.

If a version of a document is superseded:

- IMSIS modifies any link from Connected to ARES via the information system (native document or associated pdf) from the superseded to current version.[13] For this reason, only ARES links rather than documents should be uploaded on Connected; and
- process staff and other interested parties must be informed of the document's updating.

If a document is to be made obsolete:

- the workflow for rendering a document obsolete comprises:
  - the author of the document;
  - the approver of the document; and
  - the PO (if not the approver of the document).

[13] Until the Document Control application of IMSIS is operational, the management of such links must be performed manually.

- the document must be identified as obsolete in the IMS documents list;
- the existing link to the document on Connected must be removed and any complementary text adjusted;
- process staff and other interested parties must be informed of the document's obsolescence.

The management of a superseded or obsolete document made available as a controlled paper copy is governed by local practices.

2.9 Preserving an IMS document

2.9.1.1 The preserving and subsequent actions with respect to all IMS documents must be undertaken in conformance with applicable rules, particularly the Commission's CRL [13]. This substantially means:

- re-filing the superseded or obsolete document in the ARES file for superseded and obsolete IMS documents by an IMS responsible;
- annually closing by the IMS Manager and DMO the ARES file for obsolete IMS documents.

The ARES file for superseded and obsolete IMS documents is:

- File title: IMS – Superseded and obsolete controlled internal documents - <yyyy>
- File code: JRC.yyyy/IMS.DOCS.INTREC.yyyy
- Heading : 09.01.53.060.990 IMS - Preservation of obsolete controlled documents
- CRL Category: 12.10.1.

2.10 Controlling other documents necessary for planning and operating the IMS

Documents other than IMS documents which are necessary for planning and operating the IMS (i.e. standards and legal requirements) must be appropriately controlled (e.g. listed).

Table 4: Storing and listing of documents others than IMS documents.

Origin	Document	Storage	Listing	List Responsible
Internal	Ad-hoc documents	Defined by the Process Owner	List (listing is often short term) with cross-reference to impacted IMS documents.	Process Owner
External[1]	Ad-hoc documents	Defined by the Process Owner	List (listing is often long term) with cross-reference to impacted IMS documents.	Process Owner
	Standards	ARES	List of standards for the IMS based on input from JRC staff.	IMS Manager

1 A similar approach to storing and listing standards can be foreseen for regulatory and statutory documents (e.g. Register of legal requirements).

In addition, for documents subject to updates, the List Responsible as defined in Table 4 must ensure the availability of the correct version together with any necessary awareness raising of and distribution to interested parties. Similar actions are likewise required when such documents are made obsolete.

2.11 Managing records

Records (i.e. documents stating results achieved or providing evidence of activities performed) must also be appropriately managed but as their required management is so varied, only generalities can be given in the present document. IMS documents whose implementation leads to records must stipulate how records will be managed. In the case of forms and templates, this control is usually defined in the procedure or work instruction which governs the form or template.

3 LINKS TO OTHER DOCUMENTS

3.1 Reference documents setting out document management requirements

[1] European Commission, *Simplified and Reduced Internal Control Requirements*, ARES(2014)1329924.

[2] ISO 9001:2015, *Quality management systems – Requirements*.

[3] ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*.

[4] ISO/IEC 17043:2010, *Conformity assessment - General requirements for proficiency testing*.

[5] ISO Guide 34:2009, *General requirements for the competence of reference material producers*.

[6] OECD GLP (1997), *Principles of Good Laboratory Practice*.

[7] ISO 14001:2015, *Environmental management systems - Requirements with guidance for use*.

[8] EU, *Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/E.*

[9] OHSAS 18001:2007, *Occupational Health and Safety Management Systems – Requirements*.

[10] IMS document IMS-JRC-M1.2-WIN-0001, *Instructions and recommendations for Process Owners* (latest version).

[11] IMS document IMS-JRC-M1.2-PMP-0001, *JRC Integrated Management System Process Map* (latest version).

[12] ISO 9000:2015, *Quality management systems - Fundamentals and vocabulary*.

[13] European Commission, *Common Commission-level retention list for European Commission files – First revision*, SEC(2012)713, ARES(2012)1501883.

[14] ISO/TR 10013, *Guidelines for quality management system documentation*, (2001).

[15] ISO/TC 176/SC 2/N 525R2, *ISO 9000 Introduction and support package: Guidance on the documentation requirements of ISO 9001:2008*, (2008).

[16] ISO/TC 176/SC 2/N 544R3, *ISO 9000 introduction and support package: Guidance on the concept and use of the process approach for management systems*, (2008)

[17] European Commission, *Document management in the Commission: Collected decisions and implementing rules*. ISBN 978-92-79-12965-0 (2010).

3.2 Associated documents

The following documents are associated with this procedure:

- IMS-JRC-M1.2-TMP-0001: Process description.
- IMS-JRC-M1.2-TMP-0002: Procedure.
- IMS-JRC-M4.1-LST-0001: IMS documents list.
- IMS-JRC-M4.1-LST-0002: List of standards for the IMS.

4 DOCUMENT MANAGEMENT

4.1 Control of this document

This is a controlled document and the organisational entity identified on the cover page as document owner is responsible for maintaining the document. This includes keeping the document up-to-date, making the latest version available to users, and informing users of any updates as necessary.

Any user of this procedure or of the associated documents who identifies an inaccuracy, error, ambiguity or potential improvement need is requested to contact the document owner.

4.2 Records management

Although not records in the conventional sense, each year a snapshot is taken of the lists as identified in §3.2, and is systematically managed as defined below[14].

Standard file type:	IMS Lists and Registers
File title:	IMS Lists and Registers
File identifier:	B01.<yyyy>/IMS.COORD.RGS.<yyyy>
Common Nomenclature:	09.01.53.060.020.010 (IMS - Management System Control – Coordination)
CRL category:	12.10.1
Lead Department:	JRC.B.1
Access - filing:	IMS Manager
- read:	JRC
Registration repositories:	ARES
Comment:	-

List of records						
Name	Mandatory /Optional	Repository	Identifier	Approval Method	Preservation Medium	Other
List of IMS documents	M	ARES	IMS ID + yyyy	Not applicable	Electronic	-
List of standards for the IMS	M	ARES	IMS ID + yyyy	Not applicable	Electronic	-

[14] How to define the Content of Files (COF)", IMS-JRC-M4.1-WIN-0003 (previously JRC-IMS-M4.1-WI003).

ANNEX A: DEFINITIONS

1.1. Acronyms

ARES Advanced Records System (of the Commission)

BS British Standard

CRL Common Retention List (of the Commission)

DMO Document Management Officer (of the JRC)

GLP Good Laboratory Practice (of the OECD)

ICS Internal Control Standard (of the Commission)

IMS Integrated Management System (of the JRC)

IMSIS IMS Information System

ISO International Organization for Standardization

OECD Organisation for Economic Co-operation and Development

OHSAS Occupational Health and Safety Standard

1.2. Terms

The definition of terms in this procedure is given below. Those terms with an * indicate a document type.

**Betriebsreglement (operating regulation)*	*A top-level document which provides a complete overview of how the organisation complies with the technical, safety and security rules set out by the competent authorities in Germany.*
Controlled document	An internal or external document that forms part of the IMS and is controlled in accordance with clause 7.5.3 of ISO 9001:2015.
Date of document approval	The date when the IMS document is internally approved (or re-approved after any mandatory external approval).
Date of document version	The date associated with the version of the form or template and mainly used for reference purposes. The version date should be close to, but cannot be after the date of the document approval.
Document	Information and the medium on which it is contained (clause 3.8.5 of ISO 9000:2015). A documented procedure as defined by ISO 9001:2008 is documented information to be maintained (Annex A.6 of ISO 9001:2015).
Document applicability	The document applicability identifies the organisational entity (whole of the JRC, site, directorate including specific units and facilities managed by that directorate) to which the document is applicable. A document is at a JRC level when applicable throughout the organisation or at two or more sites or directorates, and at a local level when applicable to a single site or directorate (including specific units and/or facilities managed by that directorate).
Document approver	The person who internally approves the document. There is only one internal approver.

Document author	The person, competent in the subject matter of the document, who takes the lead role in creating, reviewing/updating the document and who ensures the document is appropriately filed, published, distributed and preserved.
Document life-cycle	All the stages in the life of a document from its creation until it is transferred to the Commission's historical archives and/or opened to the public or until it is destroyed according to applicable rules.
Document owner	The organisational entity responsible for managing the document in compliance with applicable requirements.
Document review period	The maximum period allowed before a controlled IMS document must be reviewed and, if necessary, updated and re-approved.
Document reviewer(s) – content	The person(s), competent in the subject matter of the document, who verifies (verify) that the document satisfies the intended purpose. There may be one or more reviewers of the document's content.
Document reviewer – form	The person, competent in the management of documented information of the IMS, who verifies that the form of the document is consistent with applicable requirements set out in the IMS. There is only one reviewer of the document's form.
Document type	The type of document (e.g. procedure, form) that forms part of the IMS (developed from clause 2.7.2 of ISO 9000:2005).
Documented information	Information to be controlled and maintained by an organisation and the medium on which it is contained (clause 3.8.6 of ISO 9000:2015).
External document	A document of an external origin (i.e. not created by the JRC) which is required for the correct functioning of the IMS. Such documents are typically regulatory or statutory in nature. An external document required for the correct functioning of the IMS must be controlled (sub-clause 7.5.3.2 of ISO 9001:2015).
*Form	A non-configurable document which, when filled-in, becomes a record (developed from clause3.2 of ISO/TR 10013:2001).
*Guideline	A document stating recommendations or suggestions (clause 2.7.2 of ISO 9000:2005). Guidelines complement other IMS documents and cannot include any requirements.
IMS document	A document created by the JRC which is required for the correct functioning of the IMS and which bears a unique IMS ID.
*List	A list, the contents of which depend on the scope of the list (but see also register).
*Manual	A document specifying the management system of an organisation, facility, etc. Not to be confused with a user manual for say an information system, this type of manual being categorised as a work instruction.
*Norm	A technical document establishing criteria, methods and practices to achieve specific goals.
*Ordnung (Ordinance)	*A document describing how the organisation complies with specific technical, safety and security requirements in specific areas regulated by external authorities.*
*Organisational chart	A document providing a schematic overview of the principal functions and lines of authority in the organisation.
*Policy	A document stating the overall intentions and direction of the organisation as formally expressed by senior management (clause 3.5.8 of ISO 9000:2015).

*Procedure	A specified way to carry out an activity or a process (clause 3.4.5 of ISO 9000:2015). A procedure may be documented or not (clause 3.4.5 of ISO 9000:2015).
*Process description	A document providing a general description of how to plan and implement the process activities, and how to monitor/measure and improve a process.
*Process map	A document providing a schematic overview of the processes in the management system.
Process Owner	The person responsible for ensuring the implementation, maintenance and improvement of a process and its interactions. (clause 5.1.5 of ISO/TC 176/SC 2/N 544R3).
Record	Documented information retained to provide evidence of conformity with requirements (Annex A.6 of ISO 9001:2015, see also clause 4.2.4 of ISO 9001:2008). A document stating results achieved or providing evidence of activities performed. Generally records are not under revision control (clause 3.8.10 of ISO 9000:2015).
*Register	A list, the term typically applying to contents of a regulatory nature.
*Template	A configurable document whose use leads to a new document or record. Templates are used to promote standardisation of specific documents and records (developed from the definition of a form).
Uncontrolled document	An internal or external document that does not form part of the IMS or a paper copy of a controlled document, the copy not being controlled in accordance with clause 7.5.3 of ISO 9001:2015.
Version (of a document)	The revision level of the document. The first approved and issued version is usually 1.0, and if subsequently updated, the approved and issued next version is 1.1 for a document which has undergone a minor (insubstantial) update, and 2.0 for a document that has substantially changed (major update). Lists and registers may also use the date and time for versioning purposes.
Virtual document	Document which is an integral part of an information system rather than a stand-alone physical document.
*Work instruction	A detailed description of how to perform and record tasks (clause 3.1 of ISO/TR 10013:2001).
*Workflow	A document (usually a single page) proving a concise overview of a flow (work, waste, transport, etc.).
Certificate (record)	Certificate, e.g. of certified reference material
Plan (record)	A record providing details regarding, for instance, sequential steps, responsibilities, acceptance criteria, records, for quality, inspections, testing, etc.
Validation report (record)	Validation report.

ANNEX B: ELEMENTS OF IMS DOCUMENT NAMING CONVENTION

1 IMS DOCUMENT NAMING CONVENTION

1.1. Naming convention element 1: IMS

This denotes that the document is an IMS document.

1.2. Naming convention element 2: Applicability

A document can either be applicable at the level of the organisation, a single site or a single directorate (facility). For consistency, codes are those used in Sysper wherever practical.

Table B1: Applicability naming convention codes.

Code	Applicability		Code	Applicability		Code	Applicability
JRC	Throughout the JRC [1]		SVQ	Sevilla site		JRC.E	JRC.E
BRU	Brussels site		JRC.DG [2]	DG – DDG		JRC.F	JRC.F
GEE	Geel site		JRC.A	JRC.A		JRC.G	JRC.G
IPR	Ispra site		JRC.B	JRC.B		JRC.H	JRC.H
KRU	Karlsruhe site		JRC.C	JRC.C		JRC.I	JRC.I
PTT	Petten site		JRC.D	JRC.D		JRC.J	JRC.J

1 Implies applicability at two or more sites or directorates.

2 Not defined in Sysper.

1.3. Naming convention element 3: Related process

This element of the naming convention identifies to which process the IMS document belongs with reference to the IMS Process Map [10]. In determining the process, the following is used:

- Management System level Manuals belong to process M4.1 Management System Control;
- Precedence is given to a process which is specifically targeted by the document rather than to the topic of the document (e.g. a training work instruction supporting procurement belongs to process S3.1 Procurement, while a general training work instruction is part of the process S4.2 Learning and Development).

In case of doubt, the author should contact his/her Directorate Quality Manager.

1.4. Naming convention element 4: Document type

A document type is identified by three letters, the codes being identified below.

Table B2: Document type codes.

Code	Document type	JRC level	Local level	Notes
BRM	Betriebsreglement	×	✓	Only KRU
FRM	Form	✓	✓	-
GUI	Guideline	✓	✓	-
LST	List	✓	✓	-
MAN	Manual[1]	✓	✓	-
NOR	Norm	×	✓	Only IPR
ORD	Ordnung	×	✓	Only KRU
ORG	Organisational chart	✓	✓	-
PDE	Process description	✓	×	-
PMP	Process map	✓	×	-
POL	Policy	✓	✓	-
PRO	Procedure	✓	✓	-
RGS	Register	✓	✓	-
TMP	Template	✓	✓	-
WIN	Work instruction	✓	✓	-
WFL	Workflow	✓	✓	-
CER[2]	Certificate	×	✓	This is a record.
PLN[2]	Plan	✓	✓	This is a record.
VAL[2]	Validation report	×	✓	This is a record.

1 A manual for a management system, facility, etc., and not to be confused with a user manual which falls under the classification of a work instruction.

2 Included in the list to harmonise the naming convention of specific records with IMS documents.

1.5. Naming convention element 5: Number

Four digit number with leading zeros (e.g. 0012).

1.6. Naming convention element 6: Language (optional for English)

A two letter code.

In cases where a single document is multi-lingual, the document is defined as English.[15]

[15] It is assumed that all multi-lingual documents include English as one of the languages.

Table B4: Language codes.

Bulgarian	BG		Estonian	ET		Irish	GA		Portuguese	PT
Croatian	HR		Finnish	FI		Italian	IT		Romanian	RO
Czech	CS		French	FR		Latvian	LV		Slovak	SK
Danish	DA		German	DE		Lithuanian	LT		Slovenian	SL
Dutch	NL		Greek	EL		Maltese	MT		Spanish	ES
English	EN[1]		Hungarian	HU		Polish	PL		Swedish	SV

1 Default language – code is optional and normally not used.

1.7. Examples

An example of the naming convention:

IMS-JRC-C4.1-PRO-0013

denotes an IMS procedure belonging to process C4.1, applicable throughout the JRC (or at least two directorates/sites), which is drafted in English and bears the number 0013.

Another example:

IMS-KRU-S6.5-WIN-0193-DE

denotes an IMS work instruction belonging to process S6.5, applicable only at the Karlsruhe site, which is drafted in German and bears the number 0193.

A final example is:

IMS-KRU-S6.5-WIN-0193

denotes the English version of the second example (note the same first five naming elements of the German version with no specific language for the sixth element indicating English).

ANNEX C: MANDATORY DATA FOR IMS DOCUMENTS AND SPECIFIC RECORDS

Table C1. Mandatory data on the pages of IMS documents and specific records.

Document	IMS documents												Specific IMS records		
	Virtual	Real (physical)													
	FRM	FRM	GUI	MAN	ORG	PDE	PMP	POL	PRO	TMP	WIN	Other	CER	PLN	VAL
	(A)	(B)	(C)	(C)	(C)	(C)	(C)	(C)	(C)	(B)	(C)	(C)	(C)	(C)	(C)
ALL PAGES															
Title	✓	✓[1]	✓	✓	✓	✓	✓	✓	✓	✓[1]	✓	✓	✓	✓	✓
English title (if document is not in English)	✓	✓[1]	✓	✓	✓	✓	✓	✓	✓	✓[1]	✓	✓	✓	✓	✓
Unique IMS identifier[2]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Page number of total page numbers	[3]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Version	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Date (of version)	-	✓	-	-	-	-	-	-	-	✓	-	-	-	-	-
TITLE PAGE															
Document owner (organizational entity)	-	✓[1]	✓[1]	✓	✓[1]	✓	✓	✓	✓	✓[1]	✓[1]	✓[1]	✓	✓	✓
Author	-	-	✓[1]	✓	-	✓	-	-	✓	-	✓[1]	✓[1]	-	-	-
Related main and other IMS processes	-	-	✓[1]	✓	-	✓	-	-	✓	-	✓[1]	-	-	-	-
Keywords	-	-	✓[1]	✓	-	✓	-	-	✓	-	✓[1]	-	-	-	-
Reviewers(s) - content	-	-	✓[1]	✓	-	✓	-	-	✓	-	✓[1]	-	-	-	-
Reviewer – form	-	-	✓[1]	✓	-	✓	-	-	✓	-	✓[1]	-	-	-	-
Approver	-	-	✓[1]	✓	-	✓	-	-	✓	-	✓[1]	✓[1]	-	-	-
Disclaimer regarding uncontrolled document	-	-	✓[1]	✓	-	✓	-	-	✓	-	✓[1]	-	-	-	-

(A) Form which is purely created within an information system.

(B) Form made available to users as a native document of the type MS Word, MS Excel, etc.

(C) Document or record made available to users in the pdf bearing the ARES registration number.

1 But optional if either the document or the record originating from the document is destined for interested parties external to the JRC.

2 The document may also bear a second (non-IMS) identifier on the title page if this will facilitate users during the transition towards the IMS or if there is some over-riding need approved by the Process Owner.

3 Only if envisaged to be printed and is cost-effective.

ANNEX D: SOME RECOMMENDED PRACTICES FOR IMS DOCUMENTS

1.1. Recommended practices for IMS documents

For implementing recommended practices for IMS documents:

a) Particular attention should be paid to verbal forms:
- must, will, shall indicate a requirement;
- should indicates a recommendation;
- may indicates a permission;
- can indicates a possibility or a capability.

b) Headings in the main body and in annexes should be numbered, and the main body and each annex should commence from 1.

c) Body text may be numbered (as the present document) or unnumbered, the choice primarily depending on the complexity of the document, and if a detailed revision history is to be included in the document.

d) It is recommended that annexes be uniquely identified with, for example, A, B, C and so on.

e) Text in annexes should be readily distinguishable from body text such as by indicating the page as an annex (as with this document) or by preceding the numbering of annex headings with the annex identifier.

f) The numbering of pages in the document (main body and any annexes) should be continuous.

g) The recommended page numbering format is n/N where:
- n is the sequential number of pages;
- N is the total number of pages in the document (inclusive of any annexes).

h) Concerning languages:
- any master language document should make a clear statement to this effect, preferably on its title page;
- for a document not in English, the English translation of the title should also be given (preferably on the title page).

Turning specifically to forms and templates, the following is also recommended:

a) Form and templates should be designed so that the input of information follows a logical sequence with respect to process steps.

b) When there are multiple users having different process functions in the same form or template, the document should be designed to allow each user to provide his/her input without being obliged to overwrite the input of previous users.

c) Forms and templates serving similar purposes within the same process and even across processes should, where practical, have the same style and functionalities rather than presenting themselves differently and/or reaching the same objective by fundamentally different routes.

d) It may be desirable and cost-beneficial to include some intelligence in form and templates. Automatic copying of information within such documents, automatic dating, simple drop-down lists, dependent drop-down lists, conditional formatting for warning, as well as macro instructions are examples of functionalities that may be considered to facilitate the user.

ANNEX E: ARES FILING PLAN FOR IMS DOCUMENTS AND EXTERNAL STANDARDS

1 CURRENT IMS DOCUMENTS

Standard file type:	IMS document
File title:	<Process code> - <Process name>
File identifier:	JRC.yyyy/IMS.DOCS.<Process code>
Common Nomenclature:	(09.01.53.060.010) IMS - Controlled documents
CRL category:	12.10.1
Lead Department:	Organisational entity of the Process Owner
Access - filing:	IMSIS and IMS responsibles
- read:	JRC
Registration repositories:	ARES
Comment:	Each process has one public sub-file and one or more limited access sub-files.

All ARES files and sub-files for IMS documents are created and deleted by the JRC DMO on request of the IMS Manager.

2 SUPERSEDED AND OBSOLETE IMS DOCUMENTS

Standard file type:	IMS document
File title:	IMS: Superseded and obsolete controlled internal documents - <yyyy>
File identifier:	JRC.yyyy/IMS.DOCS.INTREC.yyyy
Common Nomenclature:	(09.01.53.060.990) IMS - Superseded and obsolete controlled documents
CRL category:	12.10.1
Lead Department:	JRC.B.1
Access - filing:	IMS responsibles
- read:	JRC
Registration repositories:	ARES
Comment:	One file per year.

3 EXTERNAL STANDARDS FOR THE IMS

Standard file type:	External standard for the IMS
File title:	IMS: Reference external standards
File identifier:	B01.yyyy/IMS.DOCS.STANDARDS
Common Nomenclature:	(09.01.53.060.010) IMS - Controlled documents
CRL category:	12.10.1
Lead Department:	JRC.B.1
Access - filing:	IMS Manager
- read:	JRC
Registration repositories:	ARES
Comment:	Only for standards provided by DG GROW for internal Commission use.

4 SUPERSEDED AND OBSOLETE EXTERNAL STANDARDS FOR THE IMS

Standard file type:	External standard for the IMS
File title:	IMS: Superseded and obsolete applicable external standards
File identifier:	JRC.yyyy/IMS.DOCS.INTREC.yyyy
Common Nomenclature:	(09.01.53.060.990) IMS - Superseded and obsolete controlled documents
CRL category:	12.12.4
Lead Department:	JRC.B.1
Access - filing:	IMS Manager
- read:	JRC
Registration repositories:	ARES
Comment:	Only for standards provided by DG GROW for internal Commission use. Documents to be eliminated.