Procedure for development and update of ALS controlled documents

Change History

<table>
<thead>
<tr>
<th>Version number</th>
<th>Effective date</th>
<th>Description of changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>12/04/2024</td>
<td>Reverting to version 1 due to changes in responsibilities</td>
</tr>
<tr>
<td>2</td>
<td>12/05/2023</td>
<td>Members take on former responsibilities of the Management Committee for type B documents. Global Director approves type A documents. Technical Manager position no longer exists, the Global Director approves type O documents.</td>
</tr>
<tr>
<td>1</td>
<td>04/02/2022</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Associated Documentation

<table>
<thead>
<tr>
<th>Document Reference</th>
<th>Document Type</th>
<th>Document Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
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1. **Purpose and Scope**
   This document defines the responsibilities and methods for development, revision, control, and release of ALS controlled documents.

2. **Procedure**

   2.1 **General notes**
   
   2.1.1. Each ALS document is categorised using one of the three types (A, B, O) in the table below:
   
   2.1.2. The process for development or revision for each type is specified in this procedure.
2.1.3. Revision of documents follows the same steps as the original development, except that the publication and/or approval date is updated upon approval.

2.1.4. All ALS documents shall be controlled by the requirements of this procedure.

2.1.5. Editorial changes such as the design of a document are not considered under this procedure.

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
<th>Process</th>
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</table>
| A    | Documents that concern the functioning of the ALS, but which do not need a wider consultation process. | - Drafted by HCVN Secretariat staff or consultant
- Management Committee (MC) inputs/advice
- Production of final version
- Approval by MC |
| B    | Documents that concern the functioning of the ALS, where the purpose and content need stakeholder buy-in for them to be effective and credible. These documents govern procedures and requirements for individuals and organisations other than HCVN and its employees. | - Drafted by HCVN Secretariat staff or consultant – may include participation of external partners
- Consultation (to include as relevant e.g., licensed assessors, QP members, training providers, external partners, public, etc.)
- Approval by MC and external partner if relevant |
| O    | Forms and templates that are based on approved content from other documents (from types A & B). | - Drafted by HCVN Secretariat staff or consultant –
- Inputs may be received from HCVN staff and/or external partners as relevant
- Approval by HCVN Technical Manager or Global Director |

2.2. **Trigger for the document development/revision process**
2.2.1. Development and/or revision of a controlled document is initiated because of:

- **A new policy decision** which requires a new document or revision of an existing document.
- **Scheduled revisions**: ALS Controlled documents will be revised (if needed) at least once every five years. Scheduled revisions shall consider information directly related to the ALS and ALS controlled documents, registered in the ALS issue log.

### ALS Issue Log

Upon publication of this procedure, the HCVN Secretariat will manage an ALS issue log. The ALS issue log is an excel file where Secretariat staff document the following information directly related to the ALS and ALS controlled documents:

- Comments received from external stakeholders and ALS participants
- Results of internal reviews
- Results of independent reviews
- Management Committee recommendations

Comments and recommendations will be assigned to the following categories:

- An existing document if relevant
- An existing topic (if a document does not yet exist)
- A new topic to be created as needed

Comments and recommendations for the development or revision of ALS controlled documents may be submitted at any time. The issue log shall identify the issue to be addressed or the document to be created or revised. It also states the urgency of the revision (whether it can wait for a scheduled revision or should be made sooner).

- **Extraordinary revisions**: Extraordinary revisions will be conducted if review of the ALS issue log shows that a revision of an existing document is needed sooner than the document revision schedule would require.

### Rationale for the development or revision of ALS controlled documents

Based on these possible triggers, the Technical Manager or Global Director for type O documents and the MC for types A and B documents, may approve or reject a proposal for the development or revision of a controlled document.
The rationale for a new or revised document shall be documented in the ALS issue log.

If the document is to be revised, HCVN Secretariat shall prepare a draft that takes into consideration the record in the issue log related to the document.

2.3. Drafting

Based on the proposal for a new or revised controlled document, the drafter shall prepare a first draft of the document using the controlled document template. All controlled documents are created as electronic files. The document format shall follow that of other documents of that type. For example, there is a generic controlled document template and a generic template for procedures.

Controlled documents are created or revised by an authorised and appropriate subject matter expert. This could be HCVN Secretariat staff or consultants.

Development and/or revision of controlled documents may include engagement with relevant stakeholders through ad-hoc working groups and/or stakeholder consultation (see 2.5).

2.4. Review

The first draft shall be submitted to the reviewer(s), as defined in the ALS controlled documents list (e.g., HCVN Secretariat staff, external consultant). After review, the drafter shall address comments and prepare a revised draft. The drafter will resolve any issues with the reviewer to achieve a satisfactory draft document.

2.5. Consultation (type B)

Documents classified as type B go through consultation with external parties. This may include e.g., licensed assessors, QP members, external partners, the public, etc. The decision of which parties will be consulted is taken by the MC.

The consultation process will be aligned with HCVN generic principles for consultation.

For public consultations, HCVN Secretariat will post announcements on the HCVN website and send notices to interested and affected groups (e.g. licensed assessors, QP members, and others as relevant):

a) Inviting comment on the draft document.

b) Setting a deadline for submission of comments.
The drafter shall compile all the comments received during the consultation stage and note how each comment was:

- addressed
- resolved
- left outstanding, noting the reasons

The written synopsis of received comments shall be saved in an approvals folder by the Controlled Documents Lead.

A second round of consultation on a revised version may be conducted, if decided by the Global Director.

Tests such as field trials can be carried out to assess the feasibility and applicability of the requirements (e.g., in a procedure, manual, etc.), if deemed necessary and subject to funding availability.

A final revision of the document shall be prepared and submitted for approval by the MC.

2.6. **Input and advice (type O)**

Type A documents will be shared for inputs and advice with the MC.

Type O documents will be shared for inputs and advice with HCVN staff and/or external partners as relevant and with HCVN Technical Manager or Global Director.

A final revision of the document shall be prepared and submitted for approval.

2.7. **Approval**

Requests for approval are to be made by the Controlled Documents Lead in writing, either by hardcopy or electronic communication, and copies of these written requests shall be saved in an approvals folder by the Controlled Documents Lead.

The approver may:

- approve the final draft as submitted,
- ask for a second round of consultation (for type B) or for a second round of inputs/advice (type A and O), or
- reject the final draft.

If approved, the Controlled Documents Lead shall

- Ensure the date is correct
- Ensure the document reference number is correct
- Include a summary of each change in the Change History section of the revised document (as done for this document) and update the document’s associated documentation, if relevant.
- Manage any design and/or translation requirements of the document.
- Save the new or revised document to the controlled document folder on the server. This includes both word and pdf version (as relevant) of the document and any translations.
- If a new document, add it to the list of ALS controlled documents.
- If an existing document is reviewed, modify the ALS controlled documents list as appropriate.
- Update the ALS controlled documents list on the server with:
  o the name of the approver
  o date of approval
- Send the document for publication to the HCVN Website if relevant.

2.8. **Record Keeping**

The Controlled Document Lead will maintain a folder, on Egnyte, for the current electronic versions of all documents. This file set must be on a server subject to data backup.

The version with the latest date of approval is the governing version.

Superseded versions shall be archived and then removed from the list of controlled documents (ALS_01_G).

The ALS controlled document list shall serve as the “master list” of documents, indicating the current versions of all documents. No other master list shall be maintained.

2.9. **Control of hardcopies**

Controlled hardcopies may not be altered or modified by users and must remain legible and readily identifiable. This includes hand mark-ups by unauthorized personnel.

Controlled hardcopies may not be photocopied, unless for the purposes of sending to a recipient who is authorized to receive uncontrolled versions of HCVN documents (i.e., a vendor or customer).

2.10. **Communication and Publication**
The new or revised document shall be published by HCVN Secretariat along with a statement of the date on which the new version will be put into effect if relevant.

If necessary, HCVN may publish a process for the transition to the new or revised document that may include how the transition may be managed and phased deadlines for the transition.

All ALS controlled documents shall be published in English. Translations will be produced where relevant in the following languages: Spanish, Bahasa Indonesia, Portuguese and French.

In case of any inconsistency between different versions of the same document, the English version stands as the official one.