



Procedure: Control of Documents

1. SUMMARY

- 1.1. This procedure defines the requirements for the creation, review, approval, distribution, use and revision of ICAH quality management system documents.
- 1.2. This procedure applies only to documents which instruct ICAH staff on how to carry out activities and tasks; this includes manuals, procedures, forms and instructional sheets or posters. Documents outside of this scope do not require control.

2. REVISION AND APPROVAL

This procedure is released and approved as follows.

Rev.	Date	Nature of Changes	Approved By
1.0.0.0	01/07/2017	Original issue.	Patrik Hutzal

3. PROCEDURE

3.1. Creation of Documents

- 3.1.1. Documents are created by an appropriate subject matter expert.
- 3.1.2. All internal documents are created as soft files (MS Word®, etc.); it is recommended that files of a similar type follow the format of other documents in that type.
- 3.1.3. Draft versions must then be sent to the appropriate approver(s) for review and approval.
- 3.1.4. Original releases of documents are given a revision indicator of 1.0.0.0
- 3.1.5. Intensive Care at Home documents sent externally must be in pdf format.

3.2. Review and Approval

- 3.2.1. The **Management Quality Systems Manual** may only be approved by the Director. Other documents are to be approved by the original author, and the Management Review Committee (MRC). A quorum of approval will be considered as $\frac{2}{3}$ of the MRC. Once a policy is sent out for approval, MRC members should strive to respond within 7 days.
- 3.2.2. Draft files may be sent to the approver(s) via hardcopy or email.
- 3.2.3. The reviewer will resolve any issues with the original author to achieve a satisfactory document.
- 3.2.4. The reviewer will indicate approval of the document by the version control stamp on the document.



3.2.5. The approved document shall then be sent to web support for publishing and distributed to relevant staff.

3.2.6. The Quality Manager will maintain a computer folder, on the company server, for the latest soft copy versions of document. This fileset must be on a server subject to data backup. The Director will place new or revised documents into that folder, setting each file's permission to READ ONLY, or converting the released versions to a non-editable file format.

3.2.7. Any previous soft versions are then moved to a separate folder identified for obsolete documents which are kept for historical purposes.

3.2.8. The directory of official released documents shall act as a "master list" of documents, indicating the current versions of all documents. No other master list is required.

3.3. Distribution of Documents

3.3.1. Controlled documents will be available via the intranet for all employees. Employees receive training on the file and folder locations for most current documents.

3.3.2. 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. The only exception to this rule is for Forms (see below.)

3.3.3. Controlled hardcopies may not be photocopied, unless for the purposes of sending to a recipient who is authorized to receive uncontrolled versions of ICAH documents (i.e., a vendor or customer). The only exception to this rule is for Forms (see below.)

3.4. Re-Evaluation

3.4.1. Documents must be reviewed by the original author or another subject matter expert or top manager every two years.

3.4.2. The Quality Manager will ensure re-evaluation is conducted and that documents are updated if required, and will maintain a record of document re-evaluations, to identify when documents are due for re-evaluation.

3.4.3. If a document is determined to require updating, the changes shall be made and a new version issued per the rules below.

3.4.4. If a document is determined not to require updating, no action on the document is necessary.

3.5. Revising Documents

3.5.1. Changes to documents go through the same steps as the original issue, except that their revision level is advanced upon approval.

3.5.2. Only authorized personnel may change documents, although any employee can request a change to their Manager, or by filing a CAR form. Wherever possible, the document shall include a change history table within its text. Forms do not require a revision history table.



3.5.3. Any changes to documents that require customer or regulatory authority review and approval shall be submitted accordingly, and not implemented until such approval is obtained.

3.5.4. If document changes require customer or regulatory approval prior to implementation, this will be obtained in writing. When processes are changed, the appropriate documentation shall be updated, with a change history updated to reflect the reason for the change.

3.5.5. Re-evaluation, inspection (where applicable) and internal auditing will confirm the effectiveness of changes.

3.6. Controlling Documents of External Origin

3.6.1. For external documents such as standards or third party specifications which are referenced in a customer purchase order or contract, these documents may be maintained without control, provided that the revision of the document on file matches the revision indicated by the customer. Where the customer provides no revision number, the latest (most recent) revision shall be assumed.

3.6.2. For external documents such as standards or third party specifications which are not referenced in a customer purchase order or contract, these must be controlled. Such control requires that the Director or responsible manager obtain the latest version of the document, and maintain it on the company server (for electronic versions) or in a binder of controlled external documents (for hardcopies). Like other controlled documents, these may not be edited or copied.

3.6.3. Third party specifications and prints, including those of the customer, are controlled per the configuration management requirements set forth in the ICAH **Management Systems Manual**.

3.6.4. External documents for non-critical use, such as user manuals, reference books, marketing materials, and supplier directories are not controlled.

3.7. Forms

3.7.1. Forms are a special kind of document that may be photocopied as needed. Furthermore, forms do not require an approval signature; department managers are responsible for creating and using forms in their areas.

3.7.2. A softcopy of each approved form must be sent to the Director for inclusion in the document control area on the intranet, and for inclusion in the **Document Master List**.