Handout: Desk Review 4-55

**ISO 15189:2012 4.3 Document control**

The laboratory shall control documents required by the quality management system and shall ensure that unintended use of any obsolete document is prevented.

**NOTE 1** Documents that should be considered for document control are those that may vary based on changes in versions or time. Examples include policy statements, instructions for use, flow charts, procedures, specifications,

forms, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software documentation, drawings, plans, agreements, and documents of external origin such as regulations, standards and text books from which examination procedures are taken.

**NOTE 2** Records contain information from a particular point in time stating results achieved or providing evidence of activities performed and are maintained according to the requirements given in 4.13, Control of records.

The laboratory shall have a documented procedure to ensure that the following conditions are met.

**a)** All documents, including those maintained in a computerized system, issued as part of the quality management system are reviewed and approved by authorized personnel before issue.

**b)** All documents are identified to include:

— a title;

— a unique identifier on each page;

— the date of the current edition and/or edition number;

— page number to total number of pages (e.g. “Page 1 of 5,” “Page 2 of 5,”);

— authority for issue.

NOTE ‘Edition’ is used to mean one of a number of printings issued at separate times that incorporates alterations and amendments. ‘Edition’ can be regarded as synonymous with ‘revision or version’.

**c)** Current authorized editions and their distribution are identified by means of a list (e.g. document register, log or master index).

**d)** Only current, authorized editions of applicable documents are available at points of use.

**e)** Where a laboratory’s document control system allows for the amendment of documents by hand, pending the re-issue of documents, the procedures and authorities for such amendments are defined, amendments are clearly marked, initialed and dated, and a revised document is issued within a specified time period.

**f)** Changes to documents are identified.

**g)** Documents remain legible.

**h)** Documents are periodically reviewed and updated at a frequency that ensures that they remain fit for purpose.

**i)** Obsolete controlled documents are dated and marked as obsolete.

**j)** At least one copy of an obsolete controlled document is retained for a specified time period or in accordance with applicable specified requirements

4.3 **Document Control**

CCHL creates and controls all documents and information (from internal and external sources) that form its quality documentation so that all authorized users only work from current and approved documents. Laboratory personnel are expected to follow these documented processes and procedures as written without personal deviations.

1. All documents, once identified, are created, reviewed, and then approved by the HoD prior to use according to *Document Control Management Process* [QGen\_DocCon\_Pr001]. The approval signature is kept on file with the master copy.
2. All CCHL internal documents are uniquely identified by laboratory name, a title, document number on each page, effective date, revision number, page number (in x of y format) and control copy number (authority for issue). External documents are dated, on its cover page, when the document is placed into service and the date it is archived. Any external document (i.e. donated equipment procedure manuals) received in a language that is not commonly understood between the staff must be translated to the extent that is deemed sufficient by the Technical Supervisor and Head of Section

The filename path naming convention for internal documents and, where appropriate, external documents are applied according to the template chosen.

Document Numbering System Table

|  |  |  |
| --- | --- | --- |
| QMS = Quality Manual  QGen = General Quality, applicable to all areas and staff  Recp = Reception and Phlebotomy Sections  Hist = Histology Section  Cyto = Cytology Section  Txn = Blood Bank and Transfusion Services  Heme – Hematology Section  Chem = Clinical Chemistry Section  Mole = Molecular Biology Section  Sero = Serology Section  Micr = Microbiology and Virology Section  Info = Information System  POCT = Point-of-Care  Ext = External Source Documents | Additional descriptor, if required | M = manual  Pl= Policy  Pr = Process  P = Procedure  Ja = Job Aid  F = Form, Tag, Label, or Table |

1. All authorized documents (internal and external) are listed on the *Documents Master File Index Form* [QGen\_DocCon\_F001] which remains in the custody of the Quality Manager. This form is maintained by the document control coordinator to identify the current valid revisions, and their distributions.
2. Only current authorized versions of appropriate documents are available for active use at relevant locations. Original copies are to be retained in a master file and a soft version back-up in a hard drive by the Quality Manager. Originals copies in the master file shall be used to make controlled copies for use by all authorized CCHL personnel.

CCHL personnel may make uncontrolled copies of documents for training, short-term use (less than 30 days), audits, or proposed revisions with the authority from the Quality Manager by completing *Uncontrolled Copy Authorization Form* [QGen\_DocCon\_F002]. These copies are to be discarded after use. Uncontrolled copies of quality system documents, including manuals may be issued to organizations, customers, consultants, and suppliers at the discretion of the Quality Manager. These copies are to be stamped "UNCONTROLLED COPY, CURRENT WHEN ISSUED". The recipient shall not receive subsequent revisions.

1. CCHL allows amendments of documents by hand pending the re-issue of documents. The *Document Change Control Procedure* [QGen\_DocCon\_P002] specifies how these amendments are made and authorized. The revised document is then issued within the next review date.
2. Documents are revised using *Document Change Control Procedure* [QGen\_DocCon\_P002] to ensure that only authorized changes are made to approved documents, all changes are reviewed and approved before use, and all copies of the documents in use reflect the change. The nature of changes within revised documents shall be clearly indicated in the section entitled *Document Revision Log*. For the quality and safety manuals, this log is located at the end.
3. All documents must be prepared using the appropriate template as specified in the *Applying the Appropriate* *Documentation Template Procedure* [QGen\_DocCon\_P003]. All documents are prepared using a word processor (i.e. Microsoft Word) to ensure legibility. CCHL documents are reviewed annually, revised when necessary, and approved by authorized personnel. Additionally, revision of all documents is done when a need arises (major changes in the document, or recommendation from corrective/preventive actions, management reviews).

All personnel are responsible for notifying the Quality Manager if there is a need to update procedures or whenever actual procedures are permanently changed from documented procedures. The change is initiated using a *Document Management Form* [QGen\_DocCon\_F005].

1. CCHL documents are reviewed annually, revised when necessary, and approved by authorized personnel. Additionally, revision of all documents is done when a need arises (major changes in the document, or recommendation from corrective/preventive actions, management reviews).

All personnel are responsible for notifying the Quality Manager if there is a need to update procedures or whenever actual procedures are permanently changed from documented procedures. The change is initiated using a *Document Management Form* [QGen\_DocCon\_F005].

1. All obsolete documents are promptly removed from all points of use using the *Document Archival and Destruction Procedure* [QGen\_DocCon\_P004]*.* Themaster copy of all superseded documents is dated and marked *Obsolete*, then archived for reference according to the *Document and Record Retention Procedure*’s [QGen\_DocCon\_P005] embedded table. Any copies of invalid documents are promptly shredded, with the original marked *Invalid* and attached to its accompanying NCE reporting form.
2. Each document has a master file that contains the current (master document) and all previous versions of the document. When a document is changed, the new version becomes the new master document and the previous version is marked with *OBSOLETE*, along with the dateon the upper right hand corner of the header, and archived in the master file. Included with the master file are the forms for all author, reviewer, and approval signatures for each version, as well as the attestation sheets.
   1. **Service agreement**
      1. **Establishment of Service Agreements**

The accepted request form, IPMS or paper, constitutes the basis for an agreement between laboratory and customers to perform tests. Verbal requests are accepted, but results will not be released until a written request is made. All test requests are reviewed against CCHL resources and agreements to provide medical laboratory services taking into account factors affecting the request, the examination and the report generated. CCHL has made available the list of tests performed including referral tests to customers through the *Specimen Collection Manual CCHL-QMS-M-002*. The procedure for *Review of Service Agreements CCHL-QMS-P-012* details the conditions that are to be met when CCHL enters into an agreement to provide service and these includes ensuring that;

1. The requirements of the customer and users, and that of CCHL including the examination processes to be used, are defined, documented and understood;
2. The laboratory has the capacity and resources to process requests. Once the request has been accepted by the laboratory, it is understood that the laboratory has the capacity *(*Machinery, Methods, Manpower, Materials and Milieu (environment)) to be able to carry out the test or has adequate options to refer the test;

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1. **Purpose / Applicability**
   1. **Purpose**

The purpose of this procedure is to provide guidelines for the timely revision, review, and approval of formerly approved documents.

* 1. **Scope/Application**

This procedure applies to all internal or external quality systems documents within Cape Clinic Hospital Laboratory.

1. **Definitions and Terms**
   1. **Definitions**
      1. **Document** - Information and its supporting medium (manual, procedures, forms and books).
      2. **Master List** – A list of all quality management system documents identifying the current valid revisions in Cape Clinic Hospital Laboratory
      3. **Obsolete Documents** - Documents superseded by a new revision
      4. **Abbreviations**
      5. **CCHL** -Cape Clinic Hospital Laboratory
      6. **HoD** – Head of Department
      7. **HoS** - Head of Section
      8. **QM** - Quality Manager.
2. **Responsibility**
   1. All CCHL staff members are responsible for the effective implementation of this procedure.
   2. Individual responsibilities are explained under 4.0.
3. **Procedure**

**4.1 Establishing the need for revision**

*Responsible staff: Change Requester*

**4.1.1** Complete a *Document Management Form.*

**4.1.2** Forward the completed form to your HoS.

**4.1.3** ……….

*Please note: For the sake of brevity for this SLMTA 2 activity, you only received the first page of one SOP. Back at your site, ensure you obtain all applicable documentation to perform an adequate review.*

**Document Management Form**

|  |  |
| --- | --- |
| **Document Name:** | |
| **Document Number:** | **Requestor** |
| **Version Number:** | **Date:** |

**Check one: € New Document € Change Document € Retire Document**

**Description of Document:**

**Rationale for new, changed, or retired document:**

**Are any related documents affected? \_\_\_\_\_ YES \_\_\_\_\_ NO**

**If yes, list here. Prepare additional *Document Management Forms*, if needed.**

**Is process validation affected? \_\_\_\_\_ Yes \_\_\_\_\_ NO**

**Why or why not?**

|  |  |  |
| --- | --- | --- |
| **Approvals:** | **Signatures** | **Date** |
| **Document Author** |  |  |
| **Head of Section** |  |  |
| **Quality Manager** |  |  |
| **Laboratory Director** |  |  |
|  | **Issue Date for Training** |  |
|  | **Effective Date for Use** |  |

|  |  |  |
| --- | --- | --- |
| **Retirement:** |  |  |
| **Reason** | **Signature** | **Date** |
|  |  |  |

**Document Reviewer Checklist**

|  |  |  |  |
| --- | --- | --- | --- |
| **Format Review** | | **YES** | **NO with Comment** |
| **All**  **Document**  **Types** | Is the correct information in the header and footer? |  |  |
| Has the correct template been used for the document type? |  |  |
| Is the document type in the title? |  |  |
| Is the correct font size and type used per the template? |  |  |
| Is the document legible? |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Content Review** | | **YES** | **NO with Comment** |
| **Process**  **Document** | Based on the information presented, can this process be successfully completed? |  |  |
| Are all associated procedures current and correct? |  |  |
|  |  |  |  |
| **Procedure Document** | Does every step begin with an action verb? |  |  |
| Is the action described understandable? |  |  |
| Are all formulas and their example calculations correct? |  |  |
| Are people referred to by job title rather than by name? |  |  |
| Are all actions present for successful completion of the process or procedure? |  |  |
| Is the content accurate? |  |  |
|  |  |  |  |
| **Job Aid Document** | Does the title of the job aid link it to the source procedure? |  |  |
| Does the job aid follow the procedure’s steps exactly? |  |  |

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| --- | --- | --- | --- |
| **Content Review** | | **YES** | **NO with Comment** |
| **Form Document** | Is it clear to which procedure the form is connected with? |  |  |
| Are directions for completion of the form included on the form or in the source document? |  |  |
| Do the places to record information flow in the same sequence as the information is generated from the source procedure? |  |  |
| Is there sufficient space to record the needed results and information generated from performing the procedure? |  |  |

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| --- | --- | --- |
| **Is the document acceptable as written?** | | |
|  | YES - send to quality manager | Signature: |
|  | NO - return to author for revision to the draft | Date: |

**Attestation Record**

**Document Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

€ Laboratory-wide Document € Section-specific Document

Section: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

All employees responsible for this document must read and sign below.

Your signature indicates the following:

* You have read the document
* You understand the document’s contents
* You have asked questions for clarification, as needed
* You will follow the document without personal deviations
* You will report any problems with the document to your Head of Section (HoS)

A signed copy of this page will be maintained with the Master Document listed above.

|  |  |  |
| --- | --- | --- |
| **Name of Employee (please print)** | **Signature** | **Date** |
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