The Catholic University of Eastern Africa

TITLE	AUTHOR
PROCEDURE FOR CONTROL OF DOCUMENTED INFORMATION TO BE MAINTAINED (DOCUMENTS) (CUEA/VC/MR/01)	**MANAGEMENT REPRESENTATIVE**
	NO. OF APPENDICES:
	NUMBER

AUTHORIZATION
This Standard Operating Procedure is issued under the authority of:

TITLE	**VICE CHANCELLOR**
SIGNATURE	
DATE	**9 January 2019**
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STAMP CONTROLLED / UNCONTROLLED	CONTROLLED

NOTE:
1. Write amendments on the page provided (Clause 0.2)
2. Controlled copies of this document will be in the **Vice Chancellor's** and the **Directorate of Quality Assurance** office

0. CONTENTS AND RECORD OF CHANGES

0.1 Table of Contents

0.2 Record of Changes

No.	Date	Details of Changes		Authorization
	(dd-mm-yy)	*Page*	*Clause/subclause*	*Title*
1.	**09-01-2019**	**All**	**Review of Procedure as per requirements of ISO 9001:2015**	**MR**

0.3 Distribution / Circulation

This quality management procedure is available at relevant function for authorized users.

1.0 PURPOSE

This procedure sets out CUEA methodology for developing and controlling quality management system documentation in order to ensure effective planning, operation and control of the quality management system.

2.0 SCOPE

This procedure applies to all documentation to be used within the quality management system. The procedure covers the QMS documentation structure, preparation, control, distribution, updating, retrieval, review and authorization of documents. In addition, it describes methods of identification and control of documents of external origin used within the QMS.

3.0 REFERENCES

3.1 Definitions of Terms Used

For the purpose of this procedure the following terms shall apply in addition to those already defined in the CUEA Quality Management Manual.

3.1.1 Documents of external origin

These are documents which are used within the quality management system to ensure correct performance of processes without necessarily making any further detailing. Documents of external origin in most cases may include customer supplied specification, standards, equipment manuals, legislation and regulations (including Acts, legal notices and government circulars/directives), any guidelines and guidance documents.

3.1.2 Policy documents

These are documents that provide specific guidelines and direction for application throughout the organization and maybe either treated as stand-alone or additional procedural adaptation maybe prescribed. These documents may contain requirements not demanding records but general understanding and communication to staff for correct performance of functions and processes and contains enforceable compliance clauses. These documents include but not limited to the quality policy, scheme of service, code of staff regulations, training policy, budgetary and expenditure guidelines, email and internet usage policy, credit policy etc. Policy documents usually have extended life validity, have wider organizational application and demand clear understanding by all staff.

3.1.3 Procedure
This is a document specifying the way to carry out an activity or a process. The word procedure(s) as used within the CUEA quality management system refers to those documents that describe the performance of processes and are referenced within the Quality Management Manual. The term procedure(s) will only be applied with a predicate other than "operating". For example: "Quality Management Procedure" or "Teaching Service Procedure". In case a particular area of the organization using the word procedure in another context such as within laboratory activities, hence "Laboratory Procedure" its use shall define the context and the appropriate level in which the document applies shall be defined.

3.1.4 Process owner
This is the identified and/or designated staff responsible for ensuring the correct control and performance of a process. Within the QMS the process owner responsible in most cases is the Head of function (e.g. Department or Section) and/or any other staff delegated such a responsibility but stated in the relevant documentation.

3.1.5 Work instruction
This is a document that details descriptions of how to perform and record a task. It also refers to those details that describe the performance of a task, for example written descriptions of how to complete a task such as filling out a form or entering details into a workbook/register; and also included are written descriptions of how to carry out routine maintenance of a piece of equipment and may be contained in a checklist.

3.2 Abbreviations and Acronyms
3.2.1 VC Vice Chancellor
3.2.2 MR Management Representative
3.2.3 HOD Heads of Department
3.2.4 QMM Quality Management Manual
3.2.5 QMP Quality Management Procedure(s)
3.2.6 QMS Quality Management System
3.2.7 CUEA The Catholic University of Eastern Africa
3.2.8 DQA Directorate of Quality Assurance
3.2.9 SOPs Standard Operating Procedure(s)
3.2.10 PDS Policy Documents

4.0 DEFINITION OF TERMS

This procedure makes reference to the following documents which form part of the QMS documentation.

4.1 CUEA-QMM, Section 4 (*Sub-clause 4.2.3*)
4.2 ISO 9000:2015, Quality Management Systems –Fundamentals and vocabulary
4.3 ISO 9001:2015, Quality Management Systems –Requirements
4.4 ISO/TR 10013:2001, Guidelines for Quality Management System Documentation

5.0 PRINCIPAL RESPONSIBILITIES

5.1 The MR has the overall responsibilities for ensuring that this procedure remains adequate for its intended purpose.

5.2 The MR/HOD is responsible for application of this procedure including, document needs identification, development and documentation.

5.3 The MR/HOD is responsible for ensuring that staff uses only authorized copies in accordance to this procedure and that relevant documents are available at the points of use.

5.4 The FMR and / or MR is responsible for the approval of changes/amendments to QMS documents, review and final approval of the documents in liaison with the respective functional areas prior to release for issuance.

6.0 METHOD

6.1 QMS Description and Arrangement of Documents

6.1.1 QMS documentation hierarchy

The CUEA-QMM section 4.4.2 describes the general structure and requirement for the application and documentation of the QMS. The arrangement of CUEA documentation is defined in four levels:

6.1.1.1 Level 1: These consist of the CUEA default documentation that describes the system and CUEA policies required to control processes for common observance of the QMS. This Quality Management Manual (CUEA QMM), CUEA Quality Policy, Quality Management Procedures (QMPs) and associated documents of external origin such as regulations, guidelines and standards form this level. It addresses all the requirements of ISO 9001:2015 for the generic application of QMS throughout CUEA. In addition, this

includes policy documents and some documents of external origin. This CUEA QMM adopts a flexible structure for inclusion of other applicable standards to CUEA services.

6.1.1.2 Level 2: This consists of Functional QMS documentation which is function-specific but applicable throughout the organization, irrespective of location. Functional documentation includes Standard Operating Procedures (SOPs) and where relevant work instructions. A function is an entity that performs generic processes and may be structured as a Faculty, department or section, depending on the extent, distribution or level of importance.

6.1.1.3 Level 3: This constitutes area specific documentation derived from the requirements prescribed in the functional documentation or higher level documents but elaborated for the specific area of application. This shall consist of work instructions elaborated to a specific area and/or location. Area specific documentation may relate to a faculty, department or section in a particular campus, or in some cases a section in a functional area in which its activities cannot be fully addressed in the SOPs.

6.1.1.4 Level 4: These are documents and/or records that detail objective evidence of operation of a process or procedures to support the QMS. They may be generated from or demanded by any of the three levels. It consists of forms, work sheets, workbooks, registers, equipments checklists, minutes, etc.

6.1.2 Quality (QMM) and Procedures (QMPs)

6.1.2.1 The QMM and QMP are described as top level QMS documentation and shall be developed as prescribed in line with the requirements stated ISO 9001:2015. QMPs may be developed in cases where it has been deemed necessary for consistent application of a process or processes within CUEA.

6.1.2.2 The identification, content, format and style requirements shall be as stated in clause 4.2.3 of the CUEA-QMM and detailed in this procedure (including the guidance in Appendix B and C).

6.1.2.3 The MR has been delegated the responsibility for development and maintenance of these documents.

6.1.3 Policy Documents (PDs)

6.1.3.1 Policy Documents may be in existence (prior to the implementation of the QMS) or may need to be developed as output guidelines for general staff application and shall form

part of the QMS. Such policy documents shall be considered as part of level one (1) documentation within the QMS.

6.1.3.2 Policy documents currently in existence and where deemed as valid and appropriate in its present form, content and current application may not need to be re-written.

6.1.3.3 Policy documents deemed necessary for the correct application of the QMS and are not in documented form (written print) shall be developed or otherwise documented. The development of a new policy document shall be initiated by the relevant function that identified the necessity for such a policy.

6.1.3.4 The mechanism and process for development of policy document is described in procedures held at the Legal Department. Typically, policy documents require additional approvals and authorization through Top Management and eventual approval and endorsement by the CUEA University Council.

6.1.3.5 Identification and document control requirement for policy documents shall be as described in Clause 6.3 of this procedure.

6.1.4 Functional quality procedures

6.1.4.1 The functional procedures shall be authored and owned by a designated process owner or HOD and shall be authorized by the respective DVC/Director/ Dean.

6.1.5 Records and related documents

6.1.5.1 Records are documents that serve as objective evidence of a process or procedure or work instruction which shall be referred to and form part of the appendices to that specific document. The records referred to in this case are forms, datasheets, worksheets, workbooks, registers, equipments checklists, minutes, etc

6.1.5.2 Records generated or to be generated as a result of a process or procedures or an instruction to support the QMS shall be identified and indexed as described in Appendix B of this procedure.

6.1.5.3 Detailed description on Control of Documented Information to be Retained (Records) is described in the quality management procedure QMP-02 CUEA/VC/MR/02.

6.1.6 Documents of external origin

6.1.6.1 Documents of external origin or documents not created/generated by the QMS but are used in specific process operations shall be referred to in the QMS documentation at the appropriate level.

6.1.6.2 Documents of external origin shall be evaluated for the extent of application within a process. Where practicable, if a document is applicable in its entirety without any need for adaptation or for reference purpose only, the document shall be included and reference in the appropriate document.

6.1.6.3 Where a document of external origin is applicable in its entirety, the process owner or the HOD shall approve the use of such documents for their inclusion in the process operation. The process owner/HOD shall derive a list/register of such documents of external origin including the version in use and/or either given by year of publication. The list/register shall be kept updated when new documents are added or versions of documents of external origin are received, each functional area shall state the frequency and method to be applied in their documentation.

6.1.7 Documents for information purposes only (INF)

6.1.7.1 Documents for information purposes only are documents that are considered as information carriers to customers or users of CUEA services. Such documents are usually created or generated as an output of processes within the QMS. These documents include brochures, service profiles, catalogue of service information, requirement for applicants, price lists, etc targeted to customers while safety sheets, HIV/AIDS brochures, Pension/trustee information, etc would be targeting CUEA staff.

6.1.7.2 Documents for Information shall be identified as such with INF and appropriate version control mechanism defined within the relevant functional area documentation and at the appropriate level.

6.2 Documentation Need Identification and Revision

6.2.1 Document needs identification

6.2.1.1 The need for creation or generation of a document maybe necessitated due to various reasons. In principle, documents created for application of the QMS shall be based on the need to ensure effective planning, consistent operation and control of a process or processes.

6.2.1.2 Each process owner or HOD shall identify the necessary documentation needed based on the requirement for operation of the process (or processes), or as required by a specific standards and/or regulations. The need for a document to exist shall be identified and agreed at relevant level or function.

6.2.1.3 Where the need identified relates to creation of a new document, the process owner shall initiate the drafting process as detailed in sub-clause 6.3.1 below. And where the need relates to inclusion of a document of external origin, this need shall be treated as described in sub-clause 6.1.7 above.

6.2.2 Document revision/amendment needs

6.2.2.1 All documents within the QMS shall be subject to periodic reviews or when there is a necessity. The need for a revision/amendment may result from internal or external audits, process control measures, inconsistent process or service results, staff observations or other need.

6.2.2.2 Periodic review of documents shall be done as described in the relevant documentation to assess the adequacy of the document in question; whether it remains appropriate for its purpose and if the document that is being used clearly describes the process operation or service.

6.2.2.3 Request for revision of any document maybe initiated by any staff related to the process on any need described in 6.2.2.1 above, but approved by the same functions (process owner) that performed the original creation and approval. Details on document revision control process are described in clause 6.5 below.

6.3 Document Preparation and Identification

6.3.1 Preparation of draft documents

6.3.1.1 Once documentation needs have been agreed upon, the process owner or HOD shall designate staff to develop the relevant draft document in accordance to this procedure.

6.3.1.2 Each document to be developed shall be assigned a proposed document identifier. In assigning documents numbers, care should be given to details contained in Appendix B.

6.3.1.3 Each document (draft) under development shall contain all the applicable information elements and layout detailed in sub-clause 6.3.2 and 6.3.5.2 below.

6.3.1.4 Each draft document once ready shall be checked using the word processing tool for spelling and language. Subsequently, proofreading shall be done by the authors and relevant designated staff in the relevant area.

6.3.1.5 Where practicable the draft document shall be circulated to other members of the functional area or department, and additionally submitted to MR for review where such a document shall have a wider application before approval for final issuance.

6.3.1.6 Once a document is approved for final printing, care should be taken that the new document is included in the relevant document master list and updated accordingly as describe in sub-clause 6.4.4 below.

6.3.2 Document form settings and style

6.3.2.1 All documents developed within the QMS shall be produced in the prescribed format and layout. Within the QMS, two types of document form and style are defined:

Type 1: All Manuals, i.e. Quality management Manual

Type2: Procedures and Policy Documents; i.e. Quality management procedures, functional/campus procedures; and Work Instructions

6.3.2.2 Type 1 documents (Manuals) shall be formatted as follows:

Table 1: Document Setting for Manuals

Element	Settings	
a) Paper size	A4	
b) Page margins	From paper edges	
	Left	30 mm
	Right	20mm
	Top	20mm
	Bottom	15 mm

Revision	00		Date	24 – Dec 2010
	Header	10 mm		
	Footer	10 mm		
Tab setting	15mm			
Font type	Times New Roman			
Font size	Body text	11 points		
	Headers and Footers	10 points		
Print per page	Single sided only (one side only)			
Page numbering	Whole document (Page x of XX) in lower top right box of header. Exclude cover page.			
Line spacing	Single			

6.3.2.3 Type 2 documents (Procedures, Policies and Instructions) shall be formatted as follows:

Table 2: Document settings for procedures, policies and instructions

Element	**Settings**	
a) Paper size	A4	
b) Page margins	From paper edges	
	Left	25 mm
	Right	25mm
	Top	20mm
	Bottom	15 mm

evision	00		Date	24 – Dec 2010

	Header
	Footer
Tab setting	15mm
Font type	Times new Roman
Font size	Body text
	Headers and Footers
Print per page	Double sided only (print on both sides)
Page numbering	Whole document including cover page
Line spacing	Single

NOTE: Use of bullets and footnotes is not recommended unless method of identification and control is defined in the appropriate documentation.

6.3.3 Numbering of headings and text within documents

6.3.3.1 Each individual document, both type 1 (each section) and type 2, as a general rule shall be prepared to address where possible a specific process or sub-process, or a specific issue/subject as a complete entity.

6.3.3.2 In the context of type 2 documents (e.g. a procedure), the details maybe split into separate parts under the same subject of the process. The numbering shall be such that each part of a subject falls within the same number. If in specific cases, a document is likely to become too voluminous, then for practical reasons, the subject contents maybe split into portions that are interlinked and each portion cross-referenced as such.

6.3.3.3 The terms for referring to the assignment of numbers and constituent parts, and the numbering format to be applied to all documents shall be done in Arabic Numerals as shown table 3 below:

Table 3: Numbering terms, heading levels and formatting

Term reference	**Heading**	**Numbering**	**Formatting**
Clause	Level 1	Begins with 1. 2. …etc	**MAIN HEADING** (Bold capital body text)
Sub-clause (primary)	Level 2	1.1, 2.1, 3.1, …etc	**Sub Heading 1** (Bold body text, Leading capitals)
Sub-clause (secondary)	Level 3	2.1.1, 3.1.2, …etc	**Sub heading 2** (Bold body text)
Sub-clause (tertiary)	Level 4	3.2.1.1, 4.3.1.2, …etc	**Further Heading** (Body text, underlined)
Others	Level 5	a), b), c), ….etc	Not applicable

Term reference	Heading	Numbering	Formatting
(pointers/counts)		or i), ii), iii), ….etc	
Paragraph	This is an unnumbered subdivision of a clause or subclause(s)		
NOTES	This shall be indented at 15mm, the "**NOTE:**" header given in bold capital body text in font 10point font size and aligned accordingly.		

6.3.3.4 The format and assignment of numbers for Annexes (in the case of Type 1 documents) and Appendices (in the case of type 2 documents), shall be separate from the main text with centred headings as "ANNEX (ES) and APPENDIX (ES) respectively.

NOTE: Type 1 documents (manuals) shall contain an Annex or Annexes and Type 2 documents (procedures/instructions) shall have an Appendix or Appendices.

6.3.3.5 The title of each annex or appendix shall be preceded by letters starting with "A", "B", "C" …and so on. If the contents of an Annex or Appendix has heading and subheading, each heading in the Annex or Appendix shall be numbered in consecutive order, beginning with A1, A2, A2, and so on. Sub-headings shall follow suit with A1.1, B2.1, A2.2, and so on. There shall be no space between the letters "A" or "D" and the first number or a decimal point (dot) between them. The formatting of the various levels of heading shall be as given in table 3 above.

6.3.3.6 Illustrations and Tables (or figures) contained in each type of document shall be numbered according to the section in the case of type 1 documents, and sequentially in the case of type 2 documents. The format of the heading of each table or figure shall be given either above or below, and the font size applied at 10points.

6.3.4 Document layout

6.3.4.1 All documents developed for use within the QMS with exception of QMM shall adopt a consistent layout and presentation. Each type of document layout as a minimum shall present information required as given in table 4 below:

Table 4: Structure and Information Contents

Area	Information Elements		Document	
			Type 1	Type 2
Cover Page	Main face	Organization's Logo	X	X
		Organization's name in full	X	X
		Documenttitle and Number	X	X
		Authorization details	X	X
		Issue Date	X	X
	Footer:	Revision Status		X
		Page numbering		X
Other pages	Header:	CUEA Logo	X	X
		Document Title	X	X
		Section	X	
		Subject	X	
		Document Number	X	X
		Page numbering	X	X
	Footer:	Issue status	X	
		Revision Status	X	X
		Print Date	X	X

NOTE:

(i) "**X**" means the information must be presented.

(ii) Layout and presentation of the other pages of the QMM shall not follow the above format.

6.3.4.2 The layout of information elements for type 1 documents shall be as given in Appendix B, whilst type 2 documents as in Appendix E respectively which gives the general body outline structure (template) for each document.

6.3.5 Identification of Documents

6.3.5.1 Each document within the quality management system shall be uniquely identified both by "name", i.e. the "Title of the Document" and "Code", i.e. "identification numbers" assigned to it. Detailed guidance on indexing of documents is given in Appendix C.

6.3.5.2 Documents under development (Draft) shall contain all the necessary information elements applicable as given in sub-clause 6.3.3, but in place of the print date, the target date for which the document is expected shall be indicated (valid until [dd-mm-yyyy] e.g. valid until 31 Oct 2005). In addition, against the document title, the words "draft" shall be used to identify the document status / stage of development; the revision status shall standard at zero level.

6.4 Control and Distribution of Documents

As indicated in CUEA-QMM sub-clause 4.2.3, two copies of documents are distinguished: "controlled" or "uncontrolled" documents and shall be issued as such.

6.4.1 Controlled copies

6.4.1. These are documents within the QMS "subject to regular amendments"
Controlled documents shall be in electronic version for all users with access rights specified by the IT department and one printed master copy with all approvals retained by the MR.

6.4.1.2 The master copy of a document if photocopied with all approvals on shall be deemed as uncontrolled.

6.4.1.3 Where sections or pages of controlled documents are extracted, abridged or developed otherwise, as clarification of the original documents to be displayed on notice boards, this shall be controlled based on Issued by, signature, Issue date, and reference to the original document quoted. (E.g. organization charts or flowchart etc.).

NOTE: It is recommended that such section of documents are identified and presented in appendices or annexes.

6.4.2 Uncontrolled copies

6.4.2.1 These are copies of QMS documents issued "for information purposes only" upon request. These documents are not subject to regular amendments and are not updated unless requests are made.

6.4.2.2 Any printed copy of the QMS documents from the electronic copy or Master copy shall be deemed to be uncontrolled. While those to be issued for external purposes outside CUEA shall be stamped "copy for information only".

6.4.3 Distribution/Withdrawal of documents (controlled copies only)

6.4.3.1 Each functional area shall define the access rights for distribution of controlled documents in the appropriate documentation.

6.4.3.2 CUEA-QMM and QMPs (Level 1 documents)
All controlled copies of CUEA-QMM and QMPs are distributed by the MR. These shall be distributed to all Top Management staff by way of access rights granted on the electronic QMS documents.

6.4.4 Master list of documents

6.4.4.1 Each process owner or functional area shall maintain a master list of documents in use within the functional area. Appendix E shows the format of the QMS document master list, QMP-01/L1.

6.4.4.2 A copy of the QMS master list shall be submitted by each functional area to the MR or designated FMR. The MR or FMR shall subsequently collate all QMS master lists and prepare the CUEA overall master list detailing all QMS documents in use. Whenever changes are made to update or withdraw or render obsolete any QMS document, a quarterly supplement of the overall master list on revised/withdrawn documents shall be issued by MR and communicated to all staff. The QMS master lists shall be filed appropriately.

6.5 Document Revision and Amendment

6.5.1 Reviews and update of documents

6.5.1.1 All QMS documents shall be subject to periodic reviews or as necessary (e.g. as a result of recent changes in the organization, etc) or as stated in sub-clause 6.2.2, and as a minimum; they shall be revised or updated at least once in two years or otherwise defined in the appropriate documentation.

6.5.1.2 Results document reviews shall be documented in the "Records of Change" section of the relevant document. Similarly, if a review does not necessarily result into a revision of the document, then the "Record of Change" section of the document shall be updated accordingly. This shall act as evidence that the document was seen, and is still fit for purpose.

6.5.2 Revision and amendments control

6.5.2.1 Changes or amendments to QMS documents shall be reviewed and approved by the same functions that performed the original review and approval. Revisions/amendments of documents shall be subject to the following control.

6.5.2.2 Type 1 Document (Quality Management Manual). The Quality Management Manual revisions are controlled by Title page, whereas the record of changes shall indicate the sections and nature of revisions (e.g. Issue 1: Revision 0) as variable. Revision levels are assigned in numeric order, stating Zero (0) for the original issue and increasing by one with each revision:

(a) If a change/amendment is made on **not more than two** pages, the whole page is to be revised and exchanged. The number of Revision is changed accordingly and; **Section: 0** (Contents and Record of changes) is also revised to incorporate identification of changed section/page and to document revision status of the manual. Similarly its revision status is updated.

(b) If changes/amendments are made on more than half of the sections in a manual or there are multiple and/or overlapping amendments to sections all made at once, then the whole manual maybe re-issued. The issue number is then changed accordingly (incrementally) and revision status (number) for all section/pages reverts back to zero.

6.5.2.3 Type 2 Document (Procedures, Policies or Instructions) Type 2 document revisions are controlled only by pages and all pages of the procedure have the same revision level:

(a) If a change is made to any page, the page is to be revised and a complete issue of the procedure shall be made, with the revision status updated, including Section: 0 (Record of changes) also revised.

(b) Where the change is a minor insertion on a single page, then handwritten amendment process shall be followed as defined in sub-clause 6.5.6 below.

6.5.3 Change or amendment request form

6.5.3.1 Request for a change or amendment to be made to any document maybe initiated by any staff related to the process on any need as described in 6.2.2.1 above.

6.5.3.2 Request for changes or amendments to documents shall be submitted to the designated FMR or MR using the Document Change/Amendment Request form, CUEA VC/MR/01/fm 02, given in Appendix F indicating the precise change/amendment and a clear justification for the change/amendment.

6.5.3.3 The designated FMR or MR shall liaise with the relevant function responsible for authorship and evaluate the change/amendment requested, then grant approval or rejection to the request. Where a request is approved, the impact of the change/amendment shall be assessed and noted in the relevant section of the change/amendment request form, including future actions to be taken following the document re-issuance.

NOTE: Future actions may include communication of change for staff awareness or retraining of staff, demonstration of process performance etc.

6.5.4 Change or amendment identification

6.5.4.1 Where changes are made to any document, the changes or amendments to reissued documents shall be identified as such using the word processing software by highlighting on the altered text or new text.

(a) Where such is not possible the use of highlighting marker pens will be acceptable. Grammatical changes are not designated or highlighted.

(b) Change identification shall only be maintained between the current revision and the next revision, in which the text will revert back without highlighting and the next revision changes are identified.

6.5.5 Record of changes

6.5.5.1 All documents issued shall maintain a history of revisions of documents appropriately, and one copy superseded documents under their control. Once another issue of the document is to be issued, the superseded issue shall be withdrawn and archived pending destruction as defined in QMP-02 (CUEA/VC/MR/02).

6.5.6 Hand written changes/amendments

6.5.6.1 Amendment or changes to documents by hand (hand-written entries) is permissible and is only applicable to documents as provided for in CUEA-QMM section 4.2.3, hand-written entries/or changes to documents shall only be done provided that the following requirements are met:

(a) Each entry made shall be reflected or recorded in the record of changes section of the document;

(b) The changes shall be authorized / approved as given in sub-clause 6.6 below;

(c) The changes made shall be updated for all controlled copies of the document.

(d) The revised document shall be formally re-issued as soon as practicable or within a period of not exceeding three months for major changes.

6.6 Authorization and Approval of Documents

6.6.1 As stated in CUEA-QMM section 4.2.3, all documents shall be approved for release or issuance by the authority higher than where the document is intended to applied/used. As a general guide, the following documents shall be approved for issuance as follows:

6.6.1.1 CUEA-QMM, QMPs and PDs
These are level one (1) documents shall be approved by the Vice Chancellor.

6.6.1.2 Functional Procedures (FPs)

These are level 2 documents shall be approved by the respective DVC/Directors/Dean. The MR shall control the release/issuance of these documents accordingly.

6.6.1.3 WIs and all level 3 documents

Each functional area shall define the method of approval for relevant documentation as appropriate.

6.6.2 Approval of all documents shall be made in the appropriate section provide in the cover pages of each document. Indication of approval of a document may not necessary be made on all copies. Only one copy of the document maybe approved by signing and subsequently electronic copies uploaded on the CUEA servers.

NOTE: Approval by signature on the cover page indicates that the entire document is approved inclusive.

6.7 Presentation of QMS Documents

6.7.1 Document presentation Legibility and file storage (Hardcopy)

6.7.1.1 All QMS documents once printed shall be enclosed in a single transparent file pocket. This shall then be filed as a collection of all Manuals procedures or instructions, etc. that related to a functional area in a four-ring binder file.

NOTE: The four-ring binders may accommodate up to 22 procedures on average. Each four-ring binder should be identified appropriately and a table of contents made as the first or top item in the first file pockets.

6.7.1.2 Where a functional area decides to present their documentation in any other way other that the one stated in sub-clause 6.7.2.1 above, the method of presentation and storage shall define appropriately in their documentation.

6.8 Computer Storage of QMS Documents (Electronic storage)

6.8.1 Softcopy document file storage

6.8.1.1 All QMS documents are collected in the "QMS Documentation" folder which is maintained on the "CUEA Server" on the ICT network located at its headquarters. The documents listed under "QMS Documentation" folder on the server are considered to be

the master documents. Access to change/amend these documents is done via the ME only.

6.8.1.2 All softcopy versions of QMS documents shall be named according to title of the procedure and stored in a folder with the department/functions name.

6.8.2 Back-up copies of QMS documentation

6.8.2.1 All QMS documents stored on CUEA servers shall be held secure to ensure integrity, protection from destruction, disclosure, alterations, delays or undesired manipulations.

6.8.2.2 At defined intervals, a backup of the contents of CUEA servers is undertaken by the ICT department. In addition, the MR once quarterly shall makes a compact disk (CD) back-up of all contents of the QMS documentation folder as an additional safeguard of QMS documents. Similarly arrangements have been made for witnessing of testing of the resultant backup made by the ICT department to ensure correct performance. The ICT quality manual and related procedures details CUEA overall arrangements for backups and storage of data.

6.9 Identification and disposal of obsolete documents

6.9.1 Where a document is rendered obsolete but is retained at the function for any other purpose, such document shall be stamped in red ink as "obsolete" and secured at a location specified by the function.

6.9.2 For the electronic copies, the document will be watermarked with the words "OBSOLETE" and transferred to a file folder named obsolete.

7.0 APPENDICES

7.1 Context
7.2 Risks Analysis and Control
7.3 Required Organizational Knowledge
Appendix A: Format, Content and Structure of Quality Manuals (Requirements)
Appendix B: Guidance on Organization Identifiers and Indexing of Documents
Appendix C: Identification and Indexing of Records
Appendix D: Guidance on Information Elements for Procedure/Instructions

Appendix E: QMS Master List
Appendix F: Change/Amendment Request form

7.0 APPENDICES

7.1 CONTEXT

7.1.1 External / Internal Factors

(a)	External Factors	Identified Risk / Opportunity
(i)	Regulatory in regulatory requirements	Cost of conforming to the regulatory requirements
(ii)	Rapid technological advancements	Loss of access to data and information stored in older modes of storage
(iii)	Technological issues leading to loss of data integrity	Loss of information due to cyber attacks such as viruses and hacking
(b)	**Internal Factors**	**Identified Risk / Opportunity**
(i)	Insufficient storage	Loss of information and data integrity
(ii)	Competency in document management	Lack / slow access to documents and records due to poor document / record management
(iii)		

7.1.2 Relevant Interested Parties

	Party	Needs and Expectations
(i)	Students	Access to necessary information to ensure smooth processes
(ii)	Government	Compliance to requirements for document / record management
(iii)	Employees / staff	Prompt access to information to enable smooth running of processes

7.2 RISK ANALYSIS AND CONTROL

No	Risk	Cause	Risk Assessment			Risk Level	Control / Treatment
			Likelihood	Impact	Likelihood / Impact		
1.	High cost of adopting to regulatory requirements	Changes or amendments to regulatory requireemnts	1	2	2	Low	Include contigency in budgets to cater for such changes
2.	Loss of vital data	Technological advancements	1	3	3	Low	Make provisions to transfer data to new technologies
3.	Loss of vital data	Cyber attacks such as hacking and viruses	2	3	6	Medium	Have adequate and regular back ups

7.3 REQUIRED ORGANIZATIONAL KNOWLEDGE

Appendix A

FORMAT, CONTENTS AND STRUCTURE OF QUALITY MANUAL

A1. INFORMATION REQUIRED FOR ALL QUALITY MANUALS

A1.1 Section: Cover Page

- Authorization
- Document control information
  - Issue Date, Revision number
- Author (Issued by, Issued on, Signed)
- Others and applies to all sections
  - Document Title (e.g. CUEA Quality Management Manual)
  - Document number (e.g. CUEA-QMM)
  - Issue Status (e.g. Issue 1Rev 0)

A1.2 Section: 0 (Content and Record of Changes and Introduction)
Sets out the Table of Contents; Record of Changes; Distribution/Circulation; including Acronyms and Abbreviations, Organizational Profile of CUEA and physical and contact addresses.

A1.3 Section: 1 (Description of the Management System)
Presents the scope of the quality management system, purpose of CUEA QMM, description of the coverage of the QMS, permissible exclusions and justifications and approvals – certifications and accreditations held by CUEA.

A1.4 Section: 2 (References)
Makes reference to the documents which form part of the QMS documentation (Normative or Informative:

A1.5 Section: 3 (Terms and Definitions)
Presents the terms and definitions used in the QMM

A1.5 Section: 4 (Quality Policy and Objectives)
Provide the deployment of the quality policy and presents the objective set out to in realization of the policy and how it is deployed at the lower levels.

A1.6 Section: 4 (Organization and Management)
Defines the organization of the function and the responsibilities of each staff within the functional departmental and sections. The follow clauses will apply: - Management System

The overall CUEA quality management system is documented to ISO 9001:2008 as describe in CUEA-QMM which covers all the activities of the organization.

A1.7 Section: 5 (Description of the Functional Processes)
Presents the processes within the functional area and make reference to appendices where necessary on the process description.

A1.8 Section: (Appendices)
The appendices should be listed and may include the following:
Appendix A – list of procedures
Appendix B – list of records
Appendix C – organizational chart
Appendix D – brief description of QMS roles and responsibilities
Appendix E – summary of applicable legal and statutory regulations

Appendix B

GUIDANCE ON ORGANIZATION IDENTIFIERS AND INDEXING OF DOCUMENTS

B1. CUEA ORGANIZATION WIDE IDENTIFIERS

The following is a list of acronyms or prefixes or identifiers that shall be used or referenced in the application of the QMS and applied appropriately in the QMS documentation.

B1.1 Corporate/Divisional Identifiers (4 or 3-letters)

CUEA	The Catholic University of Eastern Africa
OVC	Office of the Vice Chancellor
VC	Vice Chancellor
DVC (XXX)	Deputy Vice Chancellor
DQA	Directorate of Quality Assurance

D	Department/Division
S	Section
ACD	Academic
REG	Registry
ACL	Academic linkages
FCT	Faculty
RPT	Research Project Supervision
EVP	Evening Programme
EXM	Examination
ACP	Academic Programme Development
DOR	Director of Research
FSC	Faculty of Science
LAW	Law
TCH	Teaching
ETP	Educational Teaching Practicum
PUD	Publication Department
FAS	Social Work/ Field Work/ Practice for FASSc students
LIB	Library
ACU	AIDS Control Unit
ALM	Alumni
CTR	Catering
DOS	Dean of Students
GBA	Gaba
HSK	House Keeping
HRM	Human Resource Management
ICT	Information and Communication Technology
INI	Insurance and Immigration
INF	Infirmary
CIR	Communication and Information Technology
SCM	Supply Chain Management
FIN	Finance
AUD	Audit

B1.2 Functional Identifiers (3-letters)

FIN	Finance
HR	Human Resource
ADM	Administration
IAU	Internal Auditing
ICT	Information and Communication Technology
LEG	Legal
MKT	Marketing
CIR	Communication and International Relations

B1.3 Special/Specific Functional Identifiers (3-letters)

ACC	Accounting or Accounts Activities
ADM	Administration Activities
LIB	Library Activities
PUD	Publishing and Printing Activities
SCM	Supply Chain Activities
SEC	Security Activities

The above specific identifiers have been additionally defined based on commonly used acronyms related to functional activities. However, where a functional area chooses to use any other identifiers outside those listed above, it shall define its use in the relevant documentation.

B1.4 Other Campuses Identifiers (3 or 4-letters)

GBA – Gaba Campus

In addition to the campus identifiers, each campus may assign a two-number where there are several offices or stations as applicable in addition to the campus office.

B2. QMS DOCUMENTATION IDENTIFIERS

The following is a list of prefixes or identifiers shall be used to designate documents within the QMS for purposes of correct referencing and traceability and where agreed for general addressing of documentation.

B2.1 QMS Documents Identifiers (General)

B2.1.1 Manuals (application)
The following prefixes shall be used in relation to manuals at the appropriate hierarchy level of the document:

Q Refers to Quality
M Refers to a Manual
QMM Quality Management Manual (Only applied to level 1)

B2.1.2 Procedures and Instructions (application)
Procedures and Instructions shall be indexed as follows or otherwise defined in the appropriate functional documentation:

OP Refers to a Operating Procedure (*see sub-clause 3.1.3*)
WI Refer to a Work Instruction
QMP Quality Management Procedure

B3. INDEXING OF QMS DOCUMENTATION
As given in sub-clause 6.3.5 of this procedure, the documents shall be indexed as follows:

B3.1 Level 1 Documentation

B3.1.1 Quality Management Manual
CUEA Quality Management Manual known as Quality Management Manual shall be indexed as **CUEA-QMM**

CUEA - Short for The Catholic University of Eastern Africa **QMM** - for Quality Management Manual

B3.1.2 Procedures
CUEA level 1 procedures shall be indexed as:
QMP - short for Quality Management Procedures
XX - serial number starting 01, 02, etc (Two digits) Therefore combined as: **QMP-XX**

Example: - *Quality Management Procedure for Control of documents is indexed as:* **QMP-01 CUEA/ VC/DQA/01**

B3.1.3 Policies

Policy documents shall be indexed as
POL - short for policy
XX - serial number starting 01, 02, etc (Two digits) Therefore combined as: **POL-XX**

Example: - *CUEA quality policy could be indexed as:* ***POL-01***

B3.2 Level 2 Documentation - Functional Procedures

This shall consist of functional procedures (SoPs) and shall be indexed as:

YYY - short form for the function as given in A1.2 and A1.3 above **OP** - short for operating procedures
XX - serial number starting 01, 02, etc (Two digits) Therefore combined as: **YYY/OP/XX**

Example: - *Finance procedure for Payment of suppliers is indexed as:* ***FIN/OP/06***

B3.3 Level 3 Documentation
This consists of areas specific documentation which consists of area specific manuals and work Instructions and related documents.

B3.4 SoP specific Work Instructions shall be indexed as:

YYY - short form for the function as given in A1.2 and A1.3 above **AA** (WI/TM) - short for work instructions or test methods **WWW/ZZZ** - short for SoP

XX - serial number starting 01, 02, etc (Two digits) Therefore could be combined as: **YYY/ WWW/AA/XX**

Example: - *Quality Assurance Department Work Instruction applicable to evaluation is indexed as: DQA/SoP/WI/01*

Appendix C

IDENTIFICATION AND INDEXING OF RECORDS

C1. IDENTIFICATION OF RECORDS

C1.1 General Approach

C1.1.1 As stated in QMP-02, records are documents that details the objective evidence for the operation a process or procedures within the QMS. Where a record is demanded or required to be kept in specified form and structure by any QMS document (either a manual, procedure or instruction) it shall be identified appropriately (and as applicable), and it shall be made traceable to the relevant QMS document.

C1.1.2 The types of records (documents) referred to here may include forms or form sheet, data sheets, list, registers, workbooks, etc. These types of documents are used to record data required by the QMS. It should be appreciated that such documents become a record when the required data is entered.

C1.1.3 Each QMS document shall make appropriate reference to or attached in the appendices information supportive to the document including defining the form and structure of type of records to be kept. This records act to provide evidence and demonstrating consistent conformity to the stated needs and/or requirements of the process as documented.

C1.2 Identification Elements (Minimum) or Information

C1.2.1 Each record developed or in existence shall contain the following:

i) A title (including suitable reference to CUEA or the relevant functional area)
ii) An Identification number (see C2 below)
iii) Revision status identifier

C1.2.2 Each record already in existence without a revision status identifier shall be identified by the existing form title or unique number/code. However, when revised, it shall be assigned an identification number (index) as stated in clause C2 below.

C1.2.3 For records which are of legal nature or defined in a regulation or law (e.g. The universities Act), they shall maintain their existing identification numbers. However, if these

records do not require prior printing and are easily created and printed off from a personal computer (PC) and printer, then existing legal identifier shall be maintained. But, in addition an appropriately identification number assigned to it referenced to the applicable document will be generated.

C1.3 Revision of Identification Number Status

C1.3.1 Each record in existence and those developed shall be considered to be at "baseline" or "zero (Rev 0)" revision status, as such, there is no need to re-issue these records to include revision status.

C1.3.2 Once these records are modified, they shall be given a revision status number as "Rev. 1, Rev 2, Rev 3, etc". All subsequent modifications of these records shall be assigned an incremental revision status number.

C2. INDEXING OF RECORDS

C2.1 QMS Records Identifiers (Index)

C2.1.1 As stated above, the records shall be reference to or attached as Appendices to the relevant QMS documents. The identification or indexing shall be indexed depending on the type of record as follows:

F	Refers to a form or a form sheet
L	Refers to a list or Log
R	Refers to a Register or record book
DS	Refers to a data sheet
SL	Refers to a Standard letter or Sample letter
WB/LB	Refers to a Workbook or Log book or Record book
NOTE:	The above listing is not exhaustive.

C2.2 Buildings Addresses (3-letters)

C2.2.1 For addressing of locations in relation to documents or records within CUEA centre the existing building or block numbering/identifiers shall be utilized. The following two letters identify various building:

RH Rugambwa Hall
NH Nsubuga Hall
TH Tzadua Hall
JH Jubilee Hall
KH Kozloweski Hall
OH Otunga Hall
MH Missio Hall
AB Administration Block
MPH Multi- Purpose Hall
BML Bishop MacCathey Library
OSB Old Staff Block
LRC Learning Resource Centre

C2.3 In addition, where it is a requirement to state appropriately the location up to the room address or state floor layout plans, reference should be made to the door/room numbers. For addressing of locations in relation to documents or records within CUEA campuses, each campus shall make use of the campus identifier and/or define the system adopted for addressing in the appropriate documentation.

C2.4 QMS Records indexing structure

C2.4.1 Forms, Data sheets, Register, Lists, Standard/Sample letters, etc

The indexing structure developed adopts a numbering system which shall be derived or generated from the applicable/appropriate QMS document. This shall be done as follows:

RR or R - For the applicable record identifier (see C2.1.1 above) **Z** - For sequential number of type records as given in the Appendix

Examples: Record referred to in a procedure or instruction:

QMP-01 CUEA/VC/DQA 01, Appendix J – Change/Amendment request form is indexed as CUEA/ VC/DQA/01/ fm 02

Or
QMP-03 Appendix D – Complaints register is indexed as ***QMP-03/R1***

C2.4.2 Record/Workbooks, register held in free-form

Record/Work/Log books and any record in free form shall be indexed as applicable:

Name of User/ Equipment/Function or Title of Usage
- For applicable functional areas (3 or 4-letters)
- Applicable area if relevant (maybe in letter or defined numbers)

RR or **R** - for the applicable record type
AAA -Campus or Area identifier (*if applicable*)
RRR - Room number (*if applicable*)
YYYY - Year of Issue
V - Volume Number (1-digit)

Each functional area shall determine and define the most appropriate method for combining the records identifiers within their documentation and as applicable. For example a computer usage log book used in ICT department maybe defined as **ICT/LB/A103/2011/1.**

Appendix D
GUIDANCE ON INFORMATION ELEMENTS FOR PROCEDURES/INSTRUCTIONS
D1. FORMAT OF PROCEDURES/INSTRUCTIONS (ALL APPLICABLE ELEMENTS)

D1.1 Cover Page (Form and Style)

The cover page shall be made/presented or otherwise formatted with all the information elements as given on the next page. This format may not be applicable to test methods or calibration procedures and related technical documents.

NOTE: Where a functional area chooses to deviate for this prescribed format, it shall originate a suitable cover page and derive an appropriate procedure to ensure all the necessary controls and information elements have been taken into account.

D1.2 Headers and Footers form and styling

D1.2.1 Page Headers

All pages (excluding the cover page) shall have a consistently formatted page headers appearing as a table containing the following information elements:

	_____ *[Insert function/area]* Procedure	[Insert Doc No)
Title	_____ [Insert correct title]	Page X of Y

See sub-clause 6.3.2 and 6.3.4 for styling and layout requirements

D1.2.2 Front Page Footer

The front/cover pages shall have its footer formatted to appear as a table containing the following information elements:

Revision	**00**		**Date:**	**dd-mm-yyyy**

D1.2.3 Other Page Footers

D1.3 Page 2 (Contents and Record of Changes)

This shall at all times be the second (2nd) page of the document indicating the main headings of the documents and page numbers. Generically it will be displayed with the following sub-headings as follows (*see page 2 to this procedure*):

	The Catholic University of Eastern Africa

TITLE	AUTHOR
---------- **Insert Doc Title** ---------- **Insert Doc No.**	**(Designation)** NO. OF APPENDICES: **(Total No.)**

AUTHORIZATION
This Standard Operating Procedure is issued under the authority of:

TITLE	**[Insert designation]**
SIGNATURE	
DATE	**9 January 2019**
ISSUE DATE	**9 January 2019**
STAMP CONTROLLED / UNCONTROLLED	

NOTE :
1. Write amendments on the page provided (Clause 0.2)
2. Controlled copies of this document will be in the -------- and the ---------- office

Revision	00	Date	dd mm yyyy

0. Contents and Record of Changes

0.1 Table of Contents

This indicates the page location of the document headings and sub-headings.

0.2 Record of Changes

This section is intended to enable changes/amendments to the document to be inserted without need for a full revision or reprint of the document. In addition, it also used for indicating the review status of the document.

NOTE: Handwritten amendments have been provided for in sub-clause 6.5.6 and will only be accepted if this section has been appropriately filled out.

0.3 Distribution/Circulation

This section indicates who should access the electronic copy of the document.

D2. CONTENTS OF PROCEDURES/INSTRUCTIONS (OPS/WIs/DIs)

The following content description for procedures or instructions is derived based on guidance given in ISO 10013:2001, but contains additional explanatory detail. All procedures and instructions shall be written or documented with the information layout or in accordance with the following structure:

1. PURPOSE

Describes the Purpose of the document, *i.e. what is the intended objective of the Process that the procedure or document addresses.*

2. SCOPE

This section states clearly the Scope: *What area the document is applicable to. This is to enable the user to determine quickly whether the document is likely to be appropriate for the desired use or application.*

3. TERMS AND DEFINITIONS

3.1.1 Definitions of terms used:

Definitions: State any definitions of terms not normally applied as used in the document. Always use ISO or globally accepted definitions where possible. It is important to quote/acknowledge the source using parentheses or brackets. Otherwise, you may define all possible terms and append to the quality manual and make reference as in the following example.

Example: For the purpose of this procedure the following terms shall apply, in addition to those in already defined in the CUEA Quality Manual.

3.2 Abbreviations and Acronyms

State or identify any Abbreviations or Acronyms used in the document. An abbreviation is a shortened form of a compound word or phrase, while an **Acronyms** is a shortened form of a compound term that uses the initial letters of the term to make a pronounceable word.

4. REFERENCES

State all other documents references which give the essential background or fundamental basis to the document or process to be described and those used within the body of the document. Reference should include manuals that define the policy and the need for that document and all documents allied to that document.

Where a reference is made to a publication (books) other than a standard or regulation, it is recommend that the use of CHEMABS format be adopted (see ISO 690:2000), or otherwise state the Document number, the year, then the Title of the document and the clause applicable whichever is applicable.

Example: This procedure makes reference to the following documents which form part of the QMS documentation:

4.1 CUEA-QMM, Section 4 (Clause 4.2.3)

5. PRINCIPAL RESPONSIBILITIES

State the key responsible persons required for the execution of this procedure. Either performance, decision, cooperate or information

Example:

5.1 The MR has the overall responsibilities for ensuring that this procedure remains adequate for its intended purpose.

6. METHOD

Describe in detail the process in sequence of operation. It is important to ensure that what is described is within the scope of document.
Procedure details should describe in a detail way how a process is carried out. This should as much as possible in sequence or order of performance of various process steps, list any records to be kept where relevant and forms to be filled. If possible make reference to table or additional guidance and make them appendices to the procedure.

Example:

6.1 QMS DESCRIPTION

and documentation of the QMS. The CUEA-QMS is defined in four levels: -

7. APPENDICES

7.1 Context
7.2 Risk analysis and control
7.3 Required Organizational Knowledge
7.4 Flow Chart (Optional)
7.5 Associated Documents

Appendix E

THE CATHOLIC UNIVERSITY OF EASTERN AFRICA

QMS MASTER LIST OF DOCUMENTS

#	Document Number	Documents Titles

ISSUE 01 **ISSUED BY MR** **CUEA/VC/MR/01/fm 01**

THE CATHOLIC UNIVERSITY OF EASTERN AFRICA
A.M.E.C.E.A.
Directorate of Quality Assurance
P. O. Box 62157
00200, NAIROBI
Kenya
Telephone: +254 20 8891601-6
Fax: +254 20 891261

CHANGE/AMENDMENT REQUEST FORM

To be completed by officer requesting change

Functional area or Department / Function:		Request No.:	
PART I: CHANGE/AMENDMENT DETAILS			
Requesting Officer:		Designation:	
Document No:		Document Title:	
Document Status			
Issue No:		Revision No:	
Change/Amendment Sought:			
Reason for Change/Amendment:			
Signature:		Date:	

To be completed by Head of Department / Function

PART II: CHANGE/AMENDMENT APPROVAL				
Request Status:	APPROVED or DENIED:		Date:	
If Denied state reason:				
Signature:		Designation:		

Management Representative's Office Only

PART III: FUTURE ACTIONS ON IMPACT OF CHANGE / AMENDMENT				
Actions proposed:				
Completion Date:		Signature:	Designation:	

Issue No: 01 Issued by Management Representative (MR) CUEA/VC/DQA/01/fm 02