QUALITY MANAGEMENT SYSTEM BASED ON ISO 9001:2015

MANDATORY PROCEDURE MANUAL

RU/QMR/MPM/003

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PROCEDURE NUMBER 1: DOCUMENT CONTROL

1.0 GENERAL

1.1 PURPOSE

The purpose of this procedure is to ensure effective and efficient control of documents at Rongo University.

1.2 SCOPE

This procedure applies to all documents at Rongo University.

1.3 REFERENCES

a) Quality Manual – RU/QMR/QMR/002
b) ISO 9001:2015

1.4 TERMS, ABBREVIATIONS AND DEFINITIONS

a) VC– Vice-Chancellor.
b) DVC - AFP – Deputy Vice-Chancellor Administration, Finance and Planning.
c) HoD – Head of Department.
d) QMR – Quality Management Representative.
e) ICT – Information Communication Technology.
f) QMS – Quality Management System.

1.5 RESPONSIBILITY

a) The VC is responsible for the supervision of this procedure.
b) The QMR is responsible for the implementation and adherence to this procedure.

2.0 PROCESS INPUTS

a) Documents review form
b) Documents issuance form

3.0 METHOD

3.1 Document generation and approval

3.1.1 This procedure shall start with process owners developing draft QMS documents relevant to their units and submitting to QMR.

3.1.2 The QMR shall process the draft QMS documents and submit to VC for approval and authorization.

3.2 Document Identification

The QMR shall ensure that all documents are indexed as follows:

3.2.1. The first part shall be ‘RU’ denoting that the document belongs to Rongo University followed by a forward slash (/).

3.2.2. The second part shall be initials of the Division from which the document originates followed by a forward slash (/) and;

3.2.3. The third part shall be assigned the initials of the document type followed by a forward slash (/).

3.2.4. The fourth part shall be allocated a unique number depending on the documents originating from the unit/division starting from 001.

Example: The Finance Procedures Manual shall be indexed as follows: RU/AFP/FPM/004(1).

3.3 Document Packaging

All QMS documents shall be packaged into Policies, Manuals, Procedures, and Procedure Manuals where applicable.

3.4 Document Issuance and Circulation

3.4.1 The QMR shall be responsible for printing and issuance of documents.

3.4.2 Printed copies of all documents developed shall be kept in the Vice-Chancellor's and QMR's offices while process owners shall maintain copies related to their respective areas.

3.4.3 The QMS Policy shall be signed and displayed at strategic locations within the University.

3.4.4 The QMR shall convert all documents into read-only formats and ensure they are uploaded on to the University's intranet.

3.4.5 Each process owner and staff shall fill and sign a QMS document circulation form when issued with the documents (RU/AFP/QMR/001).

3.4.6 The QMR shall maintain a distribution list of all documents issued.

3.5 Document Review, Updating and Re-approval

3.5.1 Any member of staff may initiate review and up-dating of any QMS documents by filling in a Document Review Request Form. (RU/AFP/QMR/002) and submitting to respective process owner.

3.5.2 The process owner shall verify the need for review and submit the request form to QMR.

3.5.3 The QMR shall process and submit the request to the VC for approval.

3.5.4 The QMR will make the approved changes.

3.5.5 Changes made to any document shall be tracked through the Document Change History form attached at the end of each procedure, and the Master Documents Register, maintained by the QMR and updated appropriately.

3.5.6 Where changes are made, the document shall be re-issued as the subsequent revision starting Revision 1 unless such changes represent a significant shift in operations where the document shall be re-issued as the subsequent version starting from version B. This shall be captured in the footer section of the document.

3.5.7 When the new version is re-issued the old versions shall be withdrawn.

3.5.8 Re-approval of the documents shall proceed as per clause 3.1.3 – 3.1.5 in this procedure.

3.6 Identification and Control of Documents of External Origin

3.6.1 All documents of external origin deemed to be necessary by the process owners for the effective operation of the QMS shall be identified through the title given by the author;

3.6.2 The respective process owners shall maintain an inventory and a distribution list of all documents of external origin.

3.7 Control of Obsolete Documents

The Process owners shall identify documents that are no longer in use, mark them as obsolete and archive them.

3.8 Document Protection

All editable versions of the QMS documents shall be maintained by the QMR and backed up as per the backup procedure Number 3 in the ICT Procedure Manual.

4.0 PROCESS OUTPUTS

a) Controlled documents
b) Documents review records.
c) Inventory of documents of external origin.
d) Document distribution list.
e) Memos.

5.0 DOCUMENT CHANGE HISTORY

Supersedes Revision	Revision – (Clause & Details)	Current Version / Rev.	Reviewer's name	Date

PROCEDURE NUMBER 2: RECORD CONTROL

1.0 GENERAL

1.1 PURPOSE

The purpose of this procedure is to ensure effectiveness and efficiency in the control of records at RU.

1.2 SCOPE

This procedure is applicable to all records at RU.

1.3 REFERENCES

a) RU Quality Manual RU/QMR/QM/002
b) ISO 9001:2015
c) Kenya National Archives and Documentation Act (Cap 19).

1.4 TERMS, ABBREVIATIONS AND DEFINITIONS

a) RU – Rongo University.
b) QMR – Quality Management Representative.
c) HoD – Head of Department.

1.5 RESPONSIBILITY

a) The VC is responsible for the supervision of this procedure.
b) The QMR is responsible for the implementation and adherence to this procedure.

2.0 PROCESS INPUTS

d) Files
e) Cabinets, filing racks or safes.
f) Records

3.0 METHOD

3.1 General

Records at RU shall be categorized into forms and registers. Each of these categories shall be identified as in 3.2 below.

3.2 Identification of Records

3.2.1 Identification of Forms and Registers

3.2.1.1 All forms shall be identified using the University name and logo and name of the form.

3.2.1.2 The form shall be indexed as follows:-

a) The first part shall be assigned the initials of the University followed by a slash (/).

b) The second part shall be assigned the initials of the originating Division followed by a slash (/)

c) The third part shall be assigned the initials of the originating Section followed by a slash (/)

d) The second part shall be assigned a serial number starting with number of the respective Division followed by number of the respective form

Example: RU/ADM/HS/201.

3.2.1.3 All registers used in the University shall be identified through indexing as follows:

a) The first part shall be assigned the initials RU to denote Rongo University followed by a slash (/)

b) The second part shall be assigned the initials of the originating Unit followed by a slash (/)

c) The third part shall be assigned a serial number starting with R 001 followed by a slash (/)

d) The fourth part shall be assigned the volume of the register starting with VOL. 1.

3.2.1.4 The officer in charge of the Unit where the form/register originates shall be the custodian of the forms and registers.

3.2.2 Identification of Systems Generated Records

Systems generated records shall be identified by the unique numbers allocated by the application system.

3.3 Filing and Storage

3.3.1 Records shall be filed as per the records management procedure in the Administration Procedure Manual.

3.3.2 Soft copy records shall be maintained in computer folders and back-up of the same maintained as per the Backup procedure Number 3 in the ICT Procedure Manual.

3.3.3 Files containing hard copy records shall be stored in cabinets, filing racks or safes.

3.4 Protection

3.4.1 All records shall be protected from potential hazards.

3.5 Retrieval

3.5.1 Soft copy records shall be maintained in clearly labeled folders for ease of retrieval and shall be availed on request.

3.5.2 Hard copy records shall be stored in clearly labeled storage facilities and shall be availed on request.

3.6 Records Retention and Disposal

3.6.1 The retention period for records shall be as per the provisions of the University Records Retention and Disposal Schedule.

3.6.2 All records owners shall ensure that their records are appraised and those due for disposal, are disposed as per the provisions of the University Records Retention and Disposal Schedule.

4.0 PROCESS OUTPUTS

a) Controlled records
b) Record movement register.
c) Record retention schedule.
d) Disposal records.

5.0 DOCUMENT CHANGE HISTORY

Supersedes Revision	Revision – (Clause & Details)	Current Version / Rev.	Reviewer's name	Date

PROCEDURE NUMBER 3: INTERNAL QMS AUDITS

1.0 GENERAL

1.1 PURPOSE

The purpose of this procedure is to ensure effectiveness and efficiency in QMS internal audits.

1.2 SCOPE

This procedure includes planning, execution, reporting and follow–up of QMS internal audits and applies to all units and sections in the University.

1.3 REFERENCES

a) Quality Manual – RU/QMR/QM/002.
b) ISO 9001:2015 Clause 9.1.2.
c) ISO 19011:2018.

1.4 TERMS ABBREVIATIONS AND DEFINITIONS

a) VC – Vice-Chancellor.
b) QMR – Quality Management Representative.
c) QMS – Quality Management System
d) Corrective Action - Action taken to eliminate the causes of nonconformity.
e) CAR – Corrective Action Request Plan Forms.

1.5 RESPONSIBILITY

a) The VC is responsible for the supervision of this procedure.
b) The QMR is responsible for the implementation and adherence to this procedure.

2.0 PROCESS INPUTS

a) Audit Criteria documents
b) Audit documentation/forms
c) Relevant reference documents

3.0 METHOD

3.1 Planning and Preparing the Audit

3.1.1 The QMR shall at the beginning of every financial year prepare an annual QMS internal audit programme, provided that there will be auditing at least once a year or as the need arises.

3.1.2 The QMR shall then submit the audit programme to the VC for approval

3.1.3 The QMR shall issue a general audit notification to the units to be audited at least a month to an audit.

3.1.4 At least a month to the audit date, the QMR shall appoint an audit team leader and a team of auditors to undertake the audit.

3.1.5 The Audit Team Leader shall prepare an audit plan (RU/AFP/QMR/003) and circulate it to the auditees at least a week to the audit. The plan shall include: (Specify in the RU/AFP/QMR/003)

a) Audit objective, scope and criteria;
b) Units/Divisions to be audited and responsible individuals in charge;
c) Audit team members; and
d) Date, place, time of the audit.
e) Resources required

3.2 Pre-Audit Meeting

At least a day to the audit date, the audit team leader shall convene a meeting with the audit team to prepare for the audit.

3.3 Opening meeting

There shall be an open audit meeting between the audit team and the auditees to document agreed objectives and scope (Opening Meeting Attendance Form Ref. RU/AFP/QMR/004).

3.4 Audit Execution

3.4.1 The auditors shall perform the internal audit using the checklists (RU/AFP/QMR/005) and record the audit findings in the Audit Findings Forms (RU/AFP/QMR/006)

3.5 Auditors' Meeting

3.5.1 The audit team leader shall convene an auditors' meeting after the audit to analyse and consolidate the findings and prepare a report and submit to QMR.

3.5.2 The agenda shall include:

a) Review and analysis of findings;
b) Consolidation of all findings including grouping and tabulation;
c) Classification of findings; and
d) Preparation of recommendation and audit conclusion.

3.5.3 The audit team shall review all of their findings whether they are to be reported as positive, as areas of improvement or as non-conformities.

3.5.4 The classification of findings shall be as follows:

a) **Positive findings** – Findings that pertain to processes and/or systems that are as required by audit criteria document.

b) **Areas of Improvement** – A hint for improvement which may or may not be implemented by the auditee.

c) **Minor nonconformity** – A minor deficiency. One or more elements of the QMS is/are only partially complied with.

d) **Major nonconformity** – This pertains to a major deficiency in the QMS. A major non-conformity also pertains to one or more element of the audit criteria document not being implemented.

All nonconformities shall be recorded in the CAR forms (RU/AFP/QMR/007) and classified as minor or major.

3.6 **Closing Meeting**

3.6.1 There shall be QMS Audit closing meeting chaired by audit team leader attended by the audit team and the auditees.

3.6.2 The auditors shall report their findings and observations.

3.6.3 The auditee shall acknowledge the findings by signing the Audit Findings Form.

3.7 **Audit Reporting**

3.7.1 The audit team leader shall consolidate all the audit findings for the preparation of the audit report.

3.7.2 The audit team leader shall prepare a standard internal audit report containing the following information:

a) Audit Number;

b) Date of Audit;

c) Area audited /Process Name;

d) Name of Auditee and auditors;

e) Statement of findings (all nonconformities found);

f) Reference to the Quality management system requirements and standard;

g) Corrective and Preventive Actions with completion date; and

h) Follow-up actions for non conformities;

Notes:

a) The report should be concise but factual and presented in a constructive manner;

b) The findings should be within the scope of audit and evidence based.

3.7.3 The audit team leader shall, within seven working days, issue a formal Audit Report to the QMR and all auditees.

3.7.4 The QMR shall process and submit the audit report to the VC.

3.7.5 The internal audit report shall be maintained and controlled by the QMR**.**

3.8 **Audit Follow-Up**

3.8.1 The auditees shall carry out corrective actions on non-conformities.

3.8.2 The audit team shall follow-up on the implementation of corrective actions as stated on the CAR forms.

3.8.3 The audit team shall close out the CAR form if a corrective action(s) are implemented to the satisfaction of the audit team and submit report to QMR.

4.0 PROCESS OUTPUTS

a) Audit programme.
b) Auditor's appointment letters.
c) Audit notification.
d) Audit plan.
e) Audit checklists.
f) Audit findings report.
g) Corrective action report.
h) Attendance register.
i) Audit Report

5.0 DOCUMENT CHANGE HISTORY

Supersedes Revision	Revision – (Clause & Details)	Current Version / Rev.	Reviewer's name	Date

PROCEDURE NUMBER 4: CONTROL OF NON-CONFORMING PRODUCTS AND SERVICES

1.0 GENERAL

1.1 PURPOSE

The purpose of this procedure is to ensure effectiveness and efficiency in controlling nonconforming products and services.

1.2 SCOPE

This procedure applies to the control of all nonconforming products and services identified in the University.

1.3 REFERENCES

a) Quality Manual – RU/QMR/QM/002
b) ISO 9001:2015

1.4 TERMS AND DEFINITIONS

a) QMR – Quality Management Representative.
b) HoD – Head of Department

1.5 RESPONSIBILITY

a) The VC is responsible for the supervision of this procedure.
b) The QMR is responsible for the implementation and adherence to this procedure.

2.0 PROCESS INPUTS

a) Nonconforming products and services

3.0 METHOD

3.1 The procedure shall start with member of staff completing and submitting the Corrective Action Notice form to the process owner on identifying a nonconforming product/service in the course of product/service provision, or receiving information on a nonconforming product from a customer.

3.2 The process owner shall determine the nature and extent of the nonconformity.

3.3 The process owner shall carry out corrective action and inform the customer(s) of the action taken to address the nonconformity.

3.4 The process owner shall maintain records of the nature of nonconforming products or services and the action(s) taken to address them.

4.0 PROCESS OUTPUTS

a) Conforming products and services
b) Records of Nonconformity and actions taken.

c) Memos and letters.

5.0 DOCUMENT CHANGE HISTORY

Supersedes Revision	Revision – (Clause & Details)	Current Version / Rev.	Reviewer's name	Date

PROCEDURE NUMBER 5: CORRECTIVE ACTION

1.0 GENERAL

1.1 PURPOSE

The purpose of this procedure is to ensure effective and efficient elimination of causes of nonconformities.

1.2 SCOPE

This procedure is applicable to all corrective actions identified within the University.

1.3 TERMS AND DEFINITIONS

a) VC – Vice Chancellor.
b) HoD – Head of Department.
c) QMR – Quality Management Representative
d) CAN – Corrective Action Notice.
e) QMS – Quality Management Systems
f) CAR – Corrective Action Request Form.
g) Process non-conformity: Non-conformities related to process deviations.
h) Product non-conformity: a deviation or error on the output of a process thereby compromising integrity.
i) Customer complaints: valid complaints coming from customers.

1.4 REFERENCES

a) Quality Manual – RU/QMR/QM/002
b) ISO 9001:2015

1.5 RESPONSIBILITY

a) The VC is responsible for the supervision of this procedure.
b) The QMR is responsible for the implementation and adherence to this procedure.

2.0 PROCESS INPUTS

a) Records of nonconformities
b) CAN Record

3.0 METHOD

3.1 Identification of nonconformities

3.1.1 This shall start with an internal auditor or any member of staff identifying a non-conformity and its effects or extent.

3.1.2 The member of staff or auditor shall complete and submit a Corrective Action Notice (CAN) (RU/AFP/QMR/009) to the process owner.

3.1.3 The process owner shall apply an immediate or containment action to correct non-conformity.

3.2 Evaluating the Need for Action

3.2.1 The process owner shall within a week of receipt of the Corrective Action Notice evaluate the need for a corrective action to ensure that nonconformities do not recur.

3.3 Implementing Action Needed

3.3.1 The process owner shall determine the corrective action to deal with the causes, fill the CAR form and forward it to the internal auditor as appropriate for verification.

3.3.2 If the corrective action is sufficient, the internal auditor shall endorse it enter the details in the CAR form

3.3.3 After the corrective action is endorsed, the process owner shall implement the agreed corrective action.

3.3.4 The internal auditor shall monitor CAR forms on a regular basis to verify pending non-conformities and ensure timeliness of follow-up audits.

3.4 Follow up on Implementation of Corrective Actions

3.4.1 An auditor shall follow-up to check the implementation of corrective actions as stated in the CAR form.

3.4.2 In the event that corrective action has not been implemented, the auditor shall remark in the CAR form and report to the QMR for further action.

3.5 Reviewing Effectiveness of the Corrective Action Taken

3.5.1 An internal auditor shall review effectiveness of the corrective action taken during subsequent internal audits.

3.5.2 In the event that the actions taken are not effective, the auditor shall issue a new CAR form to the process owner.

3.5.3 If the action taken is effective, the auditor shall close out the non-conformity and forward the completed CAR form to the QMR for filing.

4.0 PROCESS OUTPUTS

a) Effectively implemented corrective actions
b) CAR records.
c) Preventive Action Notice.

5.0 DOCUMENT CHANGE HISTORY

Supersedes Revision	Revision – (Clause & Details)	Current Version / Rev.	Reviewer's name	Date

APPLICABLE FORMS

RONGO UNIVERSITY

DOCUMENT CIRCULATION FORM

Date	Document Reference	Name of Receiving officer	Signature

DOCUMENT REVIEW FORM

Date:.....

Name of the requesting officer:.....

Title of Document to be reviewed:.....

Suggested Review:.....
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.....
.....

Objective of the Review:.....
.....
.....
.....

Signed:.....

Comments by the Process owner:.....
.....
.....
.....

Signed:.....

QMR Comments:……...

Signed:……

VC comments:…….

Signed:…….

OPENING MEETING ATTENDANCE FORM

Date:.....

SN	Name	Designation	Signature

QMS INTERNAL AUDIT FINDINGS FORM

S/N	Findings	Relevant Clause	Name and Signature of Auditee Rep

CORRECTIVE ACTION REQUEST FORM

Audit date:	Audit No:	CAR No: ____ of____
Area audited:	Clause of criteria document:	
Requirement: Nonconformity: Category: ☐ Major ☐ Minor Signed: Auditor_____ Auditee_____		
Root Cause: _____ _____ _____ _____ _____		
Correction (as applicable) _____ _____ _____ _____ _____		
Corrective action (as applicable) _____ _____ _____		

Date of completion:_____Signed: Auditee_____ Auditor_____

Follow up action (to filled by the auditor

Action fully completed ☐

Action partially completed ☐

No action taken ☐

Reason

Details:

Auditor Name:_____ Signature:_____ Date: _____

Auditee Name:_____ Signature:_____ Date: _____

Effectiveness of corrective action (***to be completed during the next audit by auditor***)

Was corrective action taken effective? ☐ **Yes** ☐ **No**

Details (as necessary)**:**

Auditors Name:_____ Signature: _____ Date:_____

CLOSING MEETING ATTENDANCE FORM

Date:.....

SN	Name	Designation	Signature

CORRECTIVE ACTION NOTICE FORM

Date:.....

Staff issuing notice:.....

Nature of nonconformity:.....

.....

Sign:.....

Name of concerned staff:.....

Comments by respective HoD:.....

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Sign:.....

Comments by QMR as applicable:.....

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Sign:.....

Timeframe for undertaking action:.....

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Effectiveness of action taken:.....

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Comments:.....

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Sign:.....