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QUALITY MANUAL

RWANDA MEDICAL SUPPLY Ltd

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Approved On 9th September 2025 by



Claire ILIBAGIZA
Acting Chairperson
Board of Directors

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Abbreviations

HR: Human Resource
 ISO: International Organization for Standardization
 RMS Ltd: Rwanda Medical Supply Limited
 QA/QC: Quality Assurance and Quality Control
 QMS: Quality Management System
 QP: Quality Policy
 SOP: Standard Operating Procedures
 RBC: Rwanda Biomedical Centre
 MPPD: Medical Procurement and Production Division
 GSP: Good Storage Practice
 RFDA: Rwanda Food and Drug Authority

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Introduction

Rwanda Medical Supply Limited is autonomous private company created and owned by the Government of Rwanda. It was established by Cabinet Resolutions of August 14th 2020 by merging the Rwanda Biomedical Centre/Medical Procurement and Production Division (RBC/MPPD) with 30 districts pharmacies.

RMS Ltd was created to address the procurement challenges and other supply chain related issues faced by the former RBC/MPPD that used to delay availability processes of health commodities.

Mandate

RMS Ltd is mandated to manage the end-to-end health supply chain for Rwanda by quantifying, procuring, storing, and distribution essential and program health commodities (on behalf of donors) to public health facilities.

Vision

Thriving Rwanda where everyone has the health resources they need to live a long and fulfilling life.

Mission

To be the leading health supply chain institution in Africa which ensures availability and affordability of quality assured health commodities by 2030.

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1. SCOPE

This manual describes the Quality Management System (QMS) of RMS based on ISO 9001:2015 which applies to all activities contributing its services. It covers quality policy, quality objectives and processes of RMS Ltd to ensure continual improvement in service delivery to meet customer expectations and comply with statutory and regulatory requirements.

In line with Clause 4.3, all the requirements of ISO 9001:2015 are applicable excluding Clause 8.3 – Design and Development of Products and Services. RMS does not engage in the design or development of products or services. All medical supplies, laboratory commodities and pharmaceutical products are procured based on established national and international specifications and guidelines.

RMS Ltd operate countrywide with 27 RMS regional warehouses and all operations are led from its Kigali Headquarter at KN 8 Ave, Kigali.

The scope of certification of ISO 9001:2015 strictly limited to operations conducted at RMS Ltd Headquarters. The services provided under scope of this document are quantification, procurement, warehousing, sales and distribution, finance and administration.

2. NORMATIVE REFERENCES

ISO 9001: 2015, Quality Management systems – Requirements

ISO 9002:2016, Quality Management Systems – Guidelines for the application

3. TERMS AND DEFINITIONS

The terms and definitions given in RS ISO 9000: 2015 Quality management systems — Fundamentals and Vocabulary, RS ISO 9001:2015 Quality management system, and RS ISO 19011 Auditing apply for purposes of this Manual.

4. CONTEXT OF THE ORGANIZATION

4.1. Organization and the context of RMS Ltd

RMS Ltd determines the external and internal issues relevant to its purpose and strategic direction which negatively or positively affect its ability to achieve the intended results of the QMS. This is done through regular Senior Management meetings, unit meeting, and management review meeting and documented in the RMS ISS.6.01.02 external and internal issues.

4.2. Needs and expectations of interested parties

RMS Ltd identifies the needs and expectations of the relevant interested parties and determine associated risks and opportunities guided by the strategy through regular senior management meetings.

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RMS Ltd top management ensures that the needs and expectations of identified interested parties are monitored, reviewed, updated, and maintained as per RMS INP 6.01.02 Interested parties.

4.3. Scope of the quality management systems

In order to continuously provide products and services that meet customer requirements, RS ISO 9001:2015 based QMS is applied within RMS Ltd and covers quantification, procurement, warehouse, sales and distribution, quality assurance and quality control, finance, IT and administration. While determining the scope of RMS Ltd, this scope considers the internal and external issues affecting RMS (Clause 4.1) in response to the needs and expectations of its interested parties (Clause 4.2).

In line with Clause 4.3, all the requirements of ISO 9001:2015 are applicable excluding Clause 8.3 – Design and Development of Products and Services. RMS does not engage in the design or development of products or services. All medical supplies, laboratory commodities and pharmaceutical products are procured based on established national and international specifications and guidelines.

4.4. Quality Management System and its processes

4.4.1 RMS Ltd has established and implemented a QMS which includes inputs and outputs of each process and their interactions. The required resources, risk and opportunities for each process are defined as per RMS RISK REGISTER. QMS is maintained and continually improved according to the requirements of the ISO 9001:2015 standard.

4.4.2 RMS Ltd maintains documented information to support its operations and keeps records as evidence for implementation. The operational processes are regularly monitored for effectiveness and improved through Risk based thinking approach.

5. LEADERSHIP

5.1 Leadership and Commitment

5.1.1 General

RMS Ltd top management demonstrate leadership commitment in regard to QMS by considering the following:

1. The effectiveness of QMS implementation in the organization by providing the required resources.
2. Establishment of quality policy and quality objective.
3. Ensure the integration of QMS requirements in RMS Ltd processes.
4. Ensure the use of process approach and risk-based thinking for decision making.

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5. Communicating the importance of effective quality management and conforming to the quality management system requirements.
6. Engagement, directing, supporting personnel contributing in the effectiveness of QMS.
7. Ensure that QMS reaches the intended results and promote continual improvement.
8. Support other relevant managers to demonstrate their leadership as it applies to their areas of responsibility, role and authority.

5.1.2 Customer Focus

RMS Ltd Top management demonstrate leadership and commitment required to ensure the customer focus by:

1. Considering the customer requirements, statutory and regulatory requirements are determined, understood and are consistently met.
2. Determining and addressing the risks and opportunities that can affect conformity of products and services
3. Ensuring the ability to enhance the customer expectations are determined and addressed.

5.2 Policy

5.2.1 Establishing the quality policy

RMS Ltd Top management establish, implement, and maintain the quality policy RMS/QMS/POL/02 by addressing the following:

- 5.2.1.1. The quality policy responds to the purpose and context of RMS Ltd.
- 5.2.1.2. The framework for setting quality objectives
- 5.2.1.3. Commitment to satisfy applicable QMS requirements
- 5.2.1.4. Commitment to continual improvement of the QMS

5.2.2 Communicating the quality policy

RMS Ltd Top management ensures that quality policy is available, maintained as documented information, communicated, understood, applied, and availed to all interested parties as detailed in the RMS Communication policy RMS/QMS/COP/03.

1. RMS Ltd internal meeting/unit meeting/QMS meeting
2. Internal Emails and shared drive
3. Displayed as framed posters at RMS Ltd premises
4. Quality policy is uploaded on the website

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5.3 Organisational roles, responsibilities and authorities

RMS Ltd top management ensures that the qualified personnel are assigned with their roles and responsibilities as documented in the RMS Job description RMS/QMS/RSP/01.

Top management assigned the QMS core team with responsibilities of ensuring that:

1. QMS conforms to the requirements of the standard
2. Reports on the performance of the QMS
3. The integrity of the QMS is maintained when changes to the QMS are planned and implemented.
4. The customer focus is promoted throughout organisation.
5. The processes at organization are delivering the intended outputs.

6. PLANNING

6.1 Actions to address risks and opportunities

RMS Ltd considers the risk and opportunities related to its context and processes. The identified risks and actions to address them are maintained and monitored as per RMS RISK REGISTER.

6.2 Quality objectives and planning to achieve them

RMS Ltd have established quality objectives that are Specific, Measurable, Achievable, Realistic and Time bound (SMART). These are consistent with the quality policy and consider statutory and regulatory requirements. The quality objectives are relevant to conformity of products and services and enhance customer satisfaction as per RMS/QMS/QOB/02.

6.3 Planning of changes

RMS Ltd determines the need for changes to the QMS as per SOP 6.18.03 Change Management, and address them in a risk based thinking approach by considering:

1. The purpose of the changes and their potential consequences.
2. The integrity of the quality management system.
3. The availability of resources required for implementation of plan.
4. The allocation and reallocation of responsibilities and authorities.

7. SUPPORT

RMS Ltd determines and provides the necessary resources and for the establishment, implementation, maintenance and continual improvement of QMS to meet the customer requirements.

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7.1 Resources

7.1.1 General

RMS Ltd determines and provides necessary resources for the establishment, implementation, maintenance, and continual improvement of the QMS as per fiscal year annual budget. The process takes into consideration any budgetary constraints and the need to obtain additional resources from external providers were necessary. The resources support the operation of all processes and are critical for ensuring effective and efficient performance.

7.1.2 People

RMS Ltd determines and provides the competent personnel for the effectiveness of its QMS and for the operations and control of its processes as per RMS Competence matrix MAT 8.01.01.

7.1.3 Infrastructure

RMS Ltd determines, provides, and maintains safe infrastructure necessary for the operation of its processes to achieve conformity of products and services. The infrastructures are managed and recorded in the RMS Assets register RMS/ASR/01.

7.1.4 Environment for operation of the processes

RMS Ltd determines and provides a safe working environment for human resource involved in operation of its processes aiming to achieve products and services conformity as per Ministerial Order No 02/MIFOTRA/23 of the 01/08/2023 and GSP-RFDA.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

RMS Ltd provides all necessary resources needed for measuring and monitoring the conformity of products and services which is monitored through the established control measures at determined time as per FOM.6.24.01 Calibration program.

7.1.5.2 Measurement traceability

RMS Ltd traces and measures its necessary resources through competent body as documented in calibration and verification file as per RMS Assets register RMS/ASR/01.

7.1.6 Organizational knowledge

RMS Ltd determines, shares, and maintains the available current knowledge necessary to all relevant interested parties for the operation of its processes and to achieve conformity of products and services as per RMS/HR FILES and RMS Master file MAS 6.01.01.

7.2 Competence

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RMS Ltd determines necessary competence of its personnel that affects the performance and effectiveness of the quality management system.

Staff competence is established on the basis of appropriate education, training, skills and experience. Where necessary, appropriate measures are taken to upgrade staff competence, an assessment is carried out to identify gaps for the actions be taken to ensure effectiveness of staff competence as per SOP 06.26.03 Competence and Training.

7.3 Awareness

RMS Ltd disseminates and ensures that all staff are aware of the quality policy, quality objective and how they affect the effectiveness of the quality management system and customer requirements. This will be found in the training reports.

7.4 Communication

RMS Ltd determines the internal and external communications relevant to the quality management system, as detailed in RMS/QMS/COM/01 Communication matrix.

7.5 Documented Information

RMS Ltd considers documented information required by the ISO 9001:2015 standard, puts in place documents determined by the institution, identify and control external documents which affect the RMS Ltd management system as indicated in RMS Ltd master list RMS/QMS/MAST/01 and document control procedure SOP 6.15.04 Control of Doc Information.

8. OPERATION

8.1 Operational planning and control

RMS Ltd plans, implements and controls the processes clauses 4.4, 6, and 8.4 needed to meet the requirements for the provisions of products and services.

8.2 Requirements for products and services

8.2.1 Customer Communication

RMS Ltd ensures that information related to product and service requirements, handling of customer feedback including complaints and management of customer property are communicated to the customers. Details on customer communication are elaborated in the SOP 8.01.01 RMS communication.

8.2.2 Determining the requirements for products and services

RMS Ltd ensures that requirements for the products and services to be delivered to the customer are determined and reviewed to conform to the statutory and regulatory requirements to enhance customer satisfaction.

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When determining requirements of products and services to be offered to the customers, RMS Ltd considers the customer requirements, statutory and regulatory requirements and other necessary requirements.

RMS Ltd also is committed to handle all claims and complaints related to the products and services as per SOP 6.09.03 Complaints Management and Incident Management.

8.2.3 Review of the requirements for products and services

RMS Ltd ensures the review of the requirements of products and services stated and the reference is provided in SOP 3.04.03 Issue invitation to tender up to contract award.

8.2.4 Changes to requirements of products and services

The relevant documentation for requirements of products and services information is amended whenever there are changes.

8.3 Design and development of products and services

NA

8.4 Control of externally provided processes, products and services

RMS Ltd establishes controls for processes of selection and qualifying the outsourced products and services as per FOM.4.02.01 Technical and Financial bid evaluation.

8.5 Production and service provision

8.5.1 Control of production and service provision

Provision of RMS Ltd products and services is controlled through subsequent steps as defined in documented information at functional level.

8.5.2 Identification and traceability

RMS Ltd establishes means of identifying, controlling, monitoring, measurement, and traceability of its outputs to ensure the conformity of products and services as per RMS/ASR/01 Assets register and FOM.6.18.01 on Calibration program.

8.5.3 Property belonging to customers or external providers

RMS Ltd defines means to identify, verify, protect, and safeguard customer properties provided for use or incorporated into the products and services as per FOM.6.12.01 for customer products, equipment and vehicle handling form.

8.5.4 Preservation

RMS Ltd determines the outputs which can deteriorate or degrade and affect conformity of the products or service. Appropriate preservation methods have been implemented to ensure integrity, identification and security of products and services. This is implement in

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respect to the Rwanda FDA Guidelines for Good Storage and Distribution Practices of Medical Products.

8.5.5 Post-delivery activities

RMS Ltd conducts post-delivery activities to meet customer requirement and statutory/regulatory requirements as per documented FOM.6.10.01 Customer complaint & handling form, surveys. RMS Ltd determines and acts on its contractual responsibilities such as maintenance and supplementary services like recycling or waste disposal.

8.5.6 Control of changes

RMS Ltd reviews and controls changes for production or service provision to ensure continuing conformity with requirements as per documented information (minutes of the review activities, verification, and validation results, change description documents) describing the results of review of changes, the person authorizing the change, any necessary actions arising from the review is retained at departmental levels.

8.6 Release of products and services

RMS Ltd implements planned arrangements at appropriate stages to verify that the products requirements have been met before release to customers as per documented information FOM.6.19.01 Reception of products checklist and is retained at functional levels.

8.7 Control of nonconforming outputs

8.7.1 RMS Ltd ensures that nonconforming outputs are identified and do not progress to the next stage or released to the customer. This is done to prevent their unintended use or delivery. RMS Ltd handles nonconforming outputs in accordance with as per FOM.6.03.01 about Non conformity corrective action recording form.

8.7.2 RMS Ltd retains documented information that describes the non-conformity, actions taken, concession obtained and the authority deciding action taken in respect to the nonconformity as per SOP 6.10.03 OOS and Non-Conformance Management and they are monitoring using the Non-Conformity Management System(NCMS) Tracker.

9. PERFORMANCE EVALUATION

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

RMS Ltd determines, monitors and measures all its processes to evaluate the performance and the effectiveness of the QMS and retains appropriate documented information as evidence of the results, using file RMS Monitoring and Evaluation report.

9.1.2 Customer Satisfaction

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RMS Ltd obtains feedback from its customers to determine whether needs and expectations have been met. Customer satisfaction and perception is monitored through use of FOM.6.11.01 Customer Feedback forms, FOM.6.10.01 Customer Complaint Forms, Customer handling forms, Public Perception Survey, Stakeholders' meetings, Feedback from RMS Ltd social media platforms and website.

9.1.3 Analysis and Evaluation

RMS Ltd analyses and evaluates data from the results of monitoring and measurement in order to determine whether processes and services meet requirements. Where necessary, statistical techniques (tools used) are used for analysis.

The results of analysis are used to evaluate level of customer satisfaction, Conformity of products and services, Whether the organization is meeting plans, performance of the QMS, how external providers are performing, the effectiveness of actions taken to address risks and opportunities, the need for improvements to the QMS as per SOP 6.19.03 Continual Improvement.

Results for monitoring and measurement are analysed, reported, and presented at the Quality Management Review meeting.

9.2 Internal audit

RMS Ltd regularly plans and conducts internal audit to determine whether the management system is effectively implemented and maintained in accordance with SOP 6.16.04 Internal audit and recorded in the FOM 6.01.01 Audit plan.

9.3 Management review

RMS Ltd Top Management conducts management review at planned intervals to check of its QMS continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of RMS Ltd as referred to management review documented information.

10. IMPROVEMENT

10.1 General

RMS Ltd determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhances customer satisfaction by improving the performance and effectiveness of the QMS as per SOP 6.19.03 on Continual Improvement.

10.2 Nonconformity and corrective action

When a nonconformity occurs, including complaints, RMS Ltd record, analyse, investigate the root cause and propose the corrective action to prevent the occurrence of the similar non conformity as per Non-Conformity Management System(NCMS) Tracker.

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10.3 Continual Improvement

RMS Ltd continually improves the suitability, adequacy and effectiveness of its QMS through the outputs of Management reviews.

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