



Quality Manual

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Policy Statement

RASIRC Inc.'s objective is to supply quality products, systems, and services that meet or exceed the standards required by our customers and applicable laws and regulations. We are committed to efficiently delivering safe and reliable products, systems, and services within our scope of operations. This Quality Manual aims to implement and maintain our commitment to these objectives through an active Quality Management System based on the ISO 9001 standard.

There are no exceptions to this commitment. Every employee operating under the guidance of this Quality Manual, including the *Top Management*, is expected to understand and work towards our quality commitment. Success means satisfied customers. This quality management system reflects the company's total commitment to meeting the needs of our customers efficiently and safely. In addition to meeting contract requirements and quality objectives, our commitment is proactively improving our processes and offering increased performance, value, and safety of our products, systems, and services to our customers. We have established measurable quality objectives and performance standards for the current operating environment. Each year, we also identify continuous improvement initiatives that will be implemented throughout the year to address any emerging market requirements, changes in the environment, new customer objectives, and general improvements to increase customer satisfaction. In each of our Quality System processes, we have defined quality/performance objectives and standards, methods for measuring the results, and, as applicable, any continuous improvement initiatives associated with a given process.

President and founder

RASIRC Inc.,

Jeff Spiegelman



Quality Policy

We deliver innovative solutions that meet or exceed all requirements and customer expectations, including performance, reliability, value, ease of use, and totality of purpose through continuous improvement of our processes, products, and services.

Our Quality Policy ensures we are:

- Customer Focused
- Quality Driven
- Performance Based



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1 SCOPE

RASIRC, Inc. ("RASIRC") is headquartered in San Diego, California. The main products are ultra-pure fluid delivery, purification, and chemical generation systems. The main objective of the RASIRC Quality Management System ("QMS") is to ensure that company activities comply with ISO 9001:2015 ("ISO 9001") standards.

The QMS shall include:

- a) clear responsibilities for each activity and task;
- b) confirmation that each activity is defined and controlled;
- c) confirmation that staff are trained to the requirements;
- d) confirmation that compliance with the processes and procedures is maintained;
- e) confirmation that corrective action is taken whenever necessary;
- f) and confirmation that the quality processes and operating procedures are regularly reviewed and audited.

In cases of non-compliance, an investigation and corrective action shall be performed by the functional area manager.

1.1 Responsibility for QMS

The President of RASIRC has appointed the *Head of Quality* responsible for implementing and maintaining the QMS. The *Head of Quality* has the responsibility and independent authority to ensure that adequate processes, procedures, plans, and work instructions are drawn up to provide a common approach to quality assurance throughout RASIRC and that its QMS is continually monitored and improved.

1.2 Quality Manual

This Quality Manual ("QM") has been issued on the authority of the RASIRC President for the use of all staff, clients, or regulatory bodies to whom RASIRC may be required to provide such information. It defines:

- a) The quality policy developed and implemented;
- b) The documentation has been designed to enable RASIRC to carry out that policy.

Subsequent sections of this QM are modeled and structured after ISO 9001. They describe the arrangements or systems established to meet this standard's requirements.

Changes in RASIRC or the environment in which it operates may necessitate modifications, amendments, insertions, and deletions to the overall QMS and its associated documentation. The contents of this QM may be altered as required. Changes shall be deemed operational and published in a revision of this QM following approval by the *Head of Quality*.

2 NORMATIVE REFERENCES

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. The document's latest edition (including any amendments) applies for undated references.

- ISO 9000:2015, Quality management systems – Fundamentals and vocabulary

3 TERMS AND DEFINITIONS

This QM uses the same internationally recognized terms, vocabulary, and definitions in ISO 9000:2015.

The following terms are contextually defined within the scope of RASIRC and this QM:

Head of ~: The 'Head of' a department or function is defined as the person currently assigned top responsibility for that department or functional area. 'Head of' is not herein defined as a title—only as an assignment of responsibility. These assignments will be changed as needed to meet the organization's needs.

Top Management: The President/CEO and all department heads who report directly to the President/CEO.



4 CONTEXT OF THE ORGANIZATION

4.1 Understanding the organization and its context

RASIRC is an entrepreneurial organization established in 2005 to provide innovative solutions by developing products that purify and deliver ultra-pure liquids and gases. RASIRC products are critical for many applications, including semiconductor and microelectronics, solar, and nanotechnology.

RASIRC is agile and flexible and responds quickly to customer requirements and needs. RASIRC strongly believes that every customer, irrespective of size, is essential and ensures every project has visibility at the highest level of *Top Management*.

With its main corporate office in San Diego, California, USA, RASIRC can provide its products, services, and after-sales support worldwide through the Customer Service department and strategic external partners.

RASIRC controls and conducts its business following the QMS requirements and recommendations specified by ISO 9001. RASIRC shall determine, monitor, and review external and internal issues relevant to its purpose and strategic direction that affect its ability to achieve the intended result(s) of its QMS.

4.1.1 Organization Chart

The RASIRC organization chart is available to all employees on its human resources information system (HRIS) hosted on the RASIRC intranet. The company organization and chart are updated to meet RASIRC's needs and objectives.

4.2 Understanding the needs and expectations of interested parties

Due to their potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, RASIRC shall determine the following:

- The interested parties that are relevant to its QMS;
- The requirements and expectations of these interested parties are pertinent to its QMS.

Table 1 Issues of Interested Parties

Internal Issues	External Issues
Market share	Customers & suppliers
Employees	Markets & competition
Performance	Regulatory & statutory
Capacity	Economic backdrop
Values & culture	Technological
Innovation & knowledge	Cultural & social

To address these issues, RASIRC shall organize itself so that the technical, administrative, and human factors affecting the quality of RASIRC products and services will always be controlled within the scope of the QMS.

This control must be orientated to reducing, eliminating, and preventing quality deficiencies. To accomplish these objectives, the QMS must be developed, implemented, and monitored.

4.3 Determining the scope of the quality management system

The QMS is the organized structure of responsibilities, activities, resources, and events that together provide procedures and methods of implementation to ensure the capability of RASIRC to meet the quality, technical, and contractual requirements of our customers.

The scope of the QMS includes the design, manufacture, and sales of ultra-pure fluid delivery, purification, and chemical generation systems.

RASIRC determined the boundaries and applicability of the quality management system to establish its scope. RASIRC considered:

- a) the external and internal issues referred to in 4.1
- b) the requirements of relevant interested parties referred to in 4.2
- c) the products and services of the organization.

RASIRC applies the requirements of ISO 9001 as relevant to the scope of its operations.

The scope of RASIRC's quality management system shall be maintained as documented information. The scope shall state the types of products and services covered and justify any requirement of ISO 9001 that the organization

determines does not apply to its scope.



Figure 1 Leadership PDCA Cycle

4.4 Quality management system and its processes

RASIRC shall define and manage the processes necessary to ensure that all products and services meet all requirements. RASIRC has established a QMS that follows ISO 9001 standards to achieve continual performance improvement. This QMS shall be implemented, maintained, and continually improved and will have the full support of *Top Management*. These shall include:

- Core Business Processes and Supporting Processes;
- Operating Procedures for Core Business and Supporting Processes;

RASIRC shall establish, implement, maintain, and

continually improve a quality management system, including the processes needed and their interactions, following the requirements of ISO 9001.

RASIRC shall determine the processes needed for the quality management system and their application throughout the organization and shall:

- determine the inputs required and the outputs expected from these processes;
- determine the sequence and interaction of these processes;
- determine and apply the criteria and methods needed to ensure the effective operation and control of these processes;
- determine the resources necessary for these processes and ensure their availability;
- assign the responsibilities and authorities for these processes;
- address the risks and opportunities as determined per the requirements of 6.1;
- evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
- improve the processes and the quality management system.

The organization shall:

- maintain documented information to support the operation of its processes;
- retain documented information to have confidence that the processes are being carried out as planned.

5 LEADERSHIP

5.1 Leadership and commitment

5.1.1 General

RASIRC's leadership is responsible for implementing the QMS, which includes developing and deploying the quality policy, quality objectives, and customer-focused product/project-specific plans.

Top Management provides the leadership and governance of all activities related to product lifecycle processes, including defining strategic direction, responsibility, authority, and communication to ensure safe and effective



performance.

RASIRC's leadership structure provides the necessary support for creating and establishing appropriate processes integral to maintaining and achieving our quality objectives and policies. In addition, RASIRC is committed to systemic verification of QMS effectiveness through internal audits and analysis of performance data. Management reviews ensure that our quality management system is effective and proficient and that any necessary adjustments are made.

Top Management is committed to implementing and developing the quality management system. Our policies and objectives define this commitment. RASIRC ensures that our policies are understood, implemented, and maintained throughout all levels of the organization through distributing our policy statements and periodic management review of the policy statements and improvement objectives. RASIRC communicates our mission, vision, strategy, policies, and processes to all employees to:

- a) Create and sustain shared values of fairness and ethical behavior;
- b) Establish a culture of trust and integrity;
- c) Encourage commitment to quality;
- d) Provide people with the required resources, training, and authority to act with accountability;
- e) Inspire, encourage, and recognize contributions.

In addition, RASIRC communicates its policies, objectives, and targets through individual performance objectives, which are established and discussed during employee performance reviews.

5.1.1.1 Customer focus

RASIRC strives to identify current and future customer needs, meet their requirements, and exceed expectations.

Top Management also ensures that customer requirements are understood and met. Customer requirements are understood, converted into internal requirements, and communicated to appropriate organizational personnel.

Top Management ensures that the focus on improving customer satisfaction is maintained by setting and reviewing objectives related to customer satisfaction at management review meetings. Customer complaints and other customer feedback are continually monitored and measured to identify opportunities for improvement.

5.2 Policy

5.2.1 Establishing the quality policy

The quality policy provides the direction and framework for establishing key performance measures with related objectives and targets. *Top Management* ensures that the policies are established, documented, and available to all interested parties.

The *Head of Quality* is responsible for defining, documenting, implementing, and reviewing our quality policy in consultation with *Top Management*. The policy is reviewed as part of the *Top Management* review or at a frequency determined by:

- a) The changing needs and expectations of relevant interested parties (see 4.2)
- b) The risks and opportunities that are presented through the risk management process (see 6.1)

5.2.2 Communicating the quality policy

The quality policy is communicated to all employees within the organization through its posting throughout the facility, during new employee orientation, training, and regular internal communications. Employee understanding of our policies and objectives is determined during internal audits.

5.3 Organizational roles, responsibilities, and authorities

Our organizational structure is defined in an organizational chart (see 4.1). The chart shows the interrelation of personnel within RASIRC. Job descriptions define the responsibilities and authorities of each role. *Top Management* reviews and approves the job descriptions and organizational structure for adequacy as determined by the changing needs and expectations of the interested parties identified in 4.2 and any risks and opportunities presented through the risk management process, 6.1.

Members of *Top Management* are ultimately accountable for the quality of RASIRC products and services. *Top Management* is responsible for business planning, development, and the communication of policies, quality planning, establishing and deploying objectives, providing resources needed to implement and improve the quality management system, and undertaking management reviews. *Top Management* has assigned the responsibility and authority to the management teams and departments to:

- a) Ensure that QMS processes are delivering their intended outcomes;
- b) Report on the operation of the QMS and identify any opportunities;
- c) Ensure that improvement is taking place;
- d) Ensure that customer focus is promoted throughout the organization;
- e) Ensure the integrity of the system is maintained during changes;
- f) Ensure that responsibilities and authorities relating to the QMS are communicated and understood.

All managers demonstrate their commitment to developing and improving the quality management system through the provision of necessary resources, their involvement in the internal audit process, and proactive involvement in continual improvement activities. Emphasis is placed on improving the effectiveness and efficiency of crucial system processes.

All managers are responsible for executing the business plan and implementing the policies, processes, and systems described in this manual. They are also responsible for planning and controlling the management system processes within their responsibility, including establishing and deploying operational-level objectives

and providing the resources needed to implement and improve these processes.

All employees are responsible for the quality of their work and for implementing the policies and procedures applicable to their processes. Employees are encouraged to identify and report any known or potential problems



Figure 2 Risk & Opportunities PDCA Cycle

and to recommend related solutions to aid the corrective and preventive action process.

6 PLANNING

6.1 Actions to address risks and opportunities

Risk and opportunity management within RASIRC aims to



ensure that organizational capabilities and resources are employed efficiently and effectively to take advantage of opportunities and mitigate risks.

Top Management is responsible for instilling risk-based thinking into RASIRC's culture. This thinking includes the establishment of risk management policies and targets to ensure the effective implementation of opportunity and risk management principles and activities by:

- a) Providing sufficient resources to carry out risk and opportunity management activities;
- b) Assigning responsibilities and authorities for risk and opportunity management activities;
- c) Reviewing information and results from audits and risk and opportunity management activities.

The scope of RASIRC's risk and opportunity management process includes assessing the internal and external issues identified in 4.1 and assessing the needs and expectations of any interested parties identified in 4.2. Risk and opportunity management is undertaken as part of RASIRC's operations and is captured in the following hierarchies:

- a) Strategic level;
- b) Program level;
- c) Department level;
- d) Process level

Establishing such a hierarchy to capture risk and opportunity ensures that each is managed appropriately within the organization. Categories are assigned to each level in the hierarchy, as shown in Table 2.

RASIRC has classified its 'risk appetite' as the amount of risk that it is willing to accept in pursuit of an opportunity or the avoidance of risk where each pertains to product and system conformity, and which reflects the following considerations:

- a) Risk management philosophy per product or process
- b) Capacity to take on or mitigate risk
- c) Objectives, business plans, and respective stakeholder demands
- d) Evolving industry and market considerations
- e) Tolerance for failures

RASIRC uses records to assess, respond, review, report, monitor, and plan for relevant risks and opportunities. These records allow our organization to methodically evaluate each risk and study each opportunity associated with our organizational context and the needs and

expectations of our interested parties. The records control and treat risks and opportunities, preserving this knowledge as documented information.

6.2 Quality objectives and planning to achieve them

RASIRC sets its objectives and targets regularly within the *Top Management* review, where details of program dates and responsibilities are defined and communicated through email, memo, or verbally. Improvements in quality and performance are incremental and in keeping with the organization's size and complexity.

When setting objectives and targets, RASIRC ensures that they are consistent with the needs and expectations of interested parties, as defined in 4.2, and with company policies. In addition, technological options and financial, operational, and business requirements are considered.

To determine whether objectives and targets are being met, they are measured and reported as key performance indicators (KPIs). KPIs allow progress to be monitored as metrics are gathered and data is analyzed. *Top Management* documents and discusses the KPIs and objectives for RASIRC.

Table 2 Risk / Opportunity Hierarchy

Business Hierarchy Level	Risk/Opportunity
Strategic	Budgets and profitability
Program	Performance and efficiency
Department	Resources and targets
Process	Evaluation and assurance

Based on the quality policies set and in connection with the application of the ISO 9001 quality management principles, RASIRC sets quality objectives specified in the objectives' record. All employees are responsible for fulfilling the quality policies and subsequent objectives. Managers of all departments must develop company objectives into goals for their departments and employees.



6.3 Planning of changes

The quality management system is planned and implemented to meet the objectives and requirements of ISO 9001. Planning involves establishing and communicating our policies, goals, and operational procedures.

This QM outlines the plan for establishing, maintaining, and improving the quality management system. For each instance of management system planning, the output is documented and retained accordingly, and changes are controlled. The management review and internal audit processes ensure that the integrity of the QMS is maintained when significant changes are planned that may affect critical processes.

Whenever quality management system changes are planned, *Top Management* ensures that all personnel are made aware of any changes that affect their process and that subsequent monitoring is undertaken to ensure that QMS changes are effectively implemented.

7 SUPPORT

7.1 Resources

7.1.1 General

Resources at RASIRC include human resources and specialized skills, infrastructure, technology, work environment, and financial resources. The resources necessary for the implementation, Management, control, and continual improvement of the quality management system and activities required to enhance customer satisfaction are defined in operational procedures, work instructions, and the following sections of this QMS manual:

- a) Planning;
- b) Management review;
- c) People;
- d) Infrastructure;
- e) Environment for the operation of processes;
- f) Operational planning and control;
- g) Requirements for products and services

7.1.2 People

Job descriptions identify and ensure the personnel qualifications, competence, and responsibilities required for each position that affect product and system conformity.

Qualifications include desired requirements for education, skills, and experience. Appropriate qualifications and provisions for any required training provide the competence needed for each position.

Qualifications are reviewed before hiring and when an employee changes positions or the requirements for a position change. Human Resources maintains records of employee qualifications. If any differences between an employee's qualifications and job requirements are found, training or other action is taken to ensure the employee is competent in the role. The training results are then evaluated to determine the actions' effectiveness.

All employees are made aware of the relevance and importance of their activities and how they contribute to achieving RASIRC's policies and objectives. The organization operates a formal system to ensure that all employees are sufficiently trained to perform their assigned duties.

Staff training records are maintained to demonstrate competency. Human Resources maintains and reviews the training records to ensure completeness and to identify possible future training needs. Training records include, at minimum, copies of certificates for any training undertaken to date, current job description, and curriculum vitae.

7.1.3 Infrastructure

RASIRC shall determine, provide, and maintain the infrastructure necessary for the operation of its processes and to achieve conformity with its products and services.

Infrastructure can include:

- a) building and associated utilities;
- b) equipment, including hardware and software;
- c) transportation resources;
- d) information and communication technology.

7.1.4 Environment for the operation of processes

RASIRC ensures that our facilities comply with relevant health and safety regulations. The Safety Committee



conducts regular compliance audits to maintain appropriate standards and reports findings to *Top Management*. *Top Management* is committed to providing:

- a) A place of work that is safe, including all equipment and methods of work;
- b) Training, instruction, information, and supervision for employees;
- c) A means of safe handling, storage, use, and transportation of equipment, materials, and chemicals;
- d) Safe working environment with good lighting, ventilation, safe passageways, stairs and corridors.

7.1.5 Monitoring and Measuring Resources

Production calibration is outsourced to accredited calibration houses.

7.1.5.1 General

RASIRC shall determine and provide the resources needed to ensure valid and reliable results when monitoring and measuring are used to verify the conformity of products and services to requirements.

RASIRC shall ensure that the resources provided:

- a) are suitable for the specific type of monitoring and measurement activities being undertaken;
- b) are maintained to ensure their continuing fitness for their purpose.

RASIRC shall retain appropriate documented information as evidence of fitness for the monitoring and measurement resources.

7.1.5.2 Measurement traceability

When measurement traceability is a requirement or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

- a) Calibrated or verified, at specific intervals, or before use, against measurement standards traceable to international or national measurement standards, the basis used for calibration and verification shall be retained as documented information;

- b) Uniquely identified to determine status;
- c) safeguarded from adjustments, damage, or deterioration.

RASIRC shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found unfit for its intended purpose and shall take appropriate action as necessary.

7.1.6 Organizational knowledge

RASIRC shall determine the knowledge necessary to operate its processes and achieve product and service conformity.

This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

RASIRC shall:

- a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
- b) ensure that these persons are competent based on appropriate education, training, or experience;
- c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- d) retain appropriate documented information as evidence of competence.

7.3 Awareness

7.3.1 Policies and Objectives

RASIRC shall ensure that persons doing work under the organization's control are aware of the following:

- a) the quality policy;
- b) relevant quality objectives;
- c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;



- d) the implications of not conforming with the quality management system requirements.

7.4 Communication

RASIRC shall determine the internal and external communications relevant to the quality management system and ensure that appropriate communication processes are established, including:

- a) what it will communicate;
- b) when to communicate;
- c) with whom to communicate;
- d) how to communicate;
- e) who communicates.

7.5 Documented information

7.5.1 General

RASIRC's quality management system shall include the following:

- a) documented information required by ISO 9001;
- b) documented information determined by RASIRC as being necessary for the effectiveness of the quality management system.

7.5.2 Creating and updating

When creating and updating documented information, RASIRC ensures appropriate:

- a) identification and description;
- b) format and media;
- c) review and approval for suitability and adequacy.

7.5.3 Control of documented information

Documented information required by RASIRC's quality management system and by ISO 9001 is controlled to ensure:

- a) it is available and suitable for use where and when it is needed;
- b) it is adequately protected

For the control of documented information, RASIRC addresses the following activities:

- a) distribution;
- b) storage and preservation, including preservation

- of legibility;
- c) control of changes;
- d) retention and disposition.

Documented information of external origin determined by RASIRC to be necessary for the planning and operation of its quality management system is identified as appropriate and controlled.

Documented information retained as evidence of conformity shall be protected from unintended alterations.

8 OPERATION

8.1 Operational planning and control

RASIRC establishes and implements documented plans and procedures that describe the processes and the controls required to provide services in awareness of the objectives, the potential for planned or unintended change, and the risks and opportunities. During this planning phase, Management or other responsible personnel identify the following parameters:

- a) Objectives and requirements for the service;
- b) Verification, validation, monitoring, inspection, and test requirements;
- c) Document information to demonstrate conformity;
- d) Document information to demonstrate process effectiveness;
- e) Necessary resources or outsourced processes and their controls;
- f) Criteria for process performance and product/service acceptance;
- g) Potential consequences and mitigation to change affecting input requirements;
- h) Resources necessary to support the ongoing operation of the service.

The output of planning activities includes documented plans, resource schedules, processes, requirements, and procedures.



8.2 Requirements for products and services

8.2.1 Customer communication

Communication with customers shall include the following:

- a) providing information relating to products and services;
- b) handling inquiries, contracts, or orders, including changes;
- c) obtaining customer feedback relating to products and services, including customer complaints;
- d) handling or controlling customer property;
- e) Establish specific requirements for contingency actions when they are relevant.

8.2.2 Determining the requirements for products and services

When determining the requirements for the products and services to be offered to customers, RASIRC shall ensure that:

- a) The requirements for the products and services are defined, including:
 - any applicable statutory and regulatory requirements;
 - those considered necessary by the organization;
- b) the organization can meet the claims for the products and services it offers.

8.2.3 Review of the requirements for products and services

Before committing to a customer, RASIRC ensures and confirms our capacity to supply the required product or service. Pre-acceptance reviews are conducted to ensure that:

- a) Product requirements are defined and are appropriate;
- b) Any additional requirements determined by RASIRC, or their customers are appropriate;
- c) Contract or order requirements differing from those previously expressed are resolved;
- d) RASIRC can meet the defined requirements;
- e) Documented information is retained and maintained, showing the results of the review.

Customer requirements are confirmed before acceptance

by the exchange of contracts or purchase orders.

8.2.4 Changes to requirements for products and services

RASIRC ensures that all relevant documented information relating to changes in product or service requirements is authorized and amended where necessary and that all appropriate personnel are made aware of the documented changes.

8.3 Design and development of products and services

8.3.1 General

RASIRC shall establish, implement, and maintain an appropriate design and development process to ensure the subsequent provision of products and services.

8.3.2 Design and development planning

In determining the stages and controls for design and development, RASIRC shall consider the following:

- a) the nature, duration, and complexity of the design and development activities;
- b) the required process stages with schedule and milestones, including applicable design and development reviews;
- c) the necessary development and design verification and validation activities;
- d) the responsibilities and authorities involved in the design and development process;
- e) the internal and external resource needs for the design and development of products and services;
- f) the need to govern interfaces between persons involved in the design and development process;
- g) the need for involvement of customers and users in the design and development process;
- h) the requirements for subsequent provision of products and services;
- i) the level of control expected for the design and development process by customers and other relevant interested parties;
- j) The documented information is needed to demonstrate that design and development requirements have been met.



8.3.3 Design and development inputs

RASIRC shall determine the requirements for specific products and services to be designed and developed. RASIRC shall consider:

- a) functional and performance requirements;
- b) target for product quality, life, reliability, durability, maintainability, timing and cost;
- c) potential consequences of failure due to the nature of the products and services;
- d) information derived from previous similar design and development activities;
- e) statutory and regulatory requirements;
- f) standards or codes of practice that the organization has committed to implementing.

Inputs for design and development purposes shall be complete and unambiguous.

Conflicting design and development inputs shall be resolved.

RASIRC shall retain documented information on design and development inputs.

8.3.4 Design and development controls

RASIRC shall apply controls to the design and development process to ensure that:

- a) the results to be achieved are defined;
- b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
- c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;
- d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
- e) any necessary actions are taken on problems determined during the reviews or verification and validation activities;
- f) documented information on these activities is retained.

8.3.5 Design and development outputs

RASIRC shall ensure that design and development outputs:

- a) meet the input requirements;

- b) are adequate for the subsequent processes for the provision of products and services;
- c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
- d) specify the characteristics of the products and services for their intended purpose and their safe and proper provision.

RASIRC shall retain documented information on design and development outputs.

8.3.6 Design and development changes

RASIRC shall identify, review, and control changes made during or after the design and development of products and services to the extent necessary to ensure that they do not adversely impact conformity to requirements.

RASIRC shall retain documented information on the following:

- a) design and development changes;
- b) the results of reviews;
- c) the authorization of the changes;
- d) the actions taken to prevent adverse impacts.

8.4 Control of externally provided processes, products, and services

8.4.1 External Provider Evaluation Process

The purchasing process is essential to RASIRC's ability to provide our customers with products and services that meet their requirements. RASIRC ensures that all purchased products or services incorporated into our final products conform to our specified requirements.

RASIRC accomplishes this by closely working with a network of external clients. Performance and capability are continually assessed through periodic 2nd party audits, performance data analysis, and inspection or verification of the supplied services.

The type and extent of control applied to our suppliers and purchased services depend on the effect the outsourced service may have on our final service. The following considerations are considered:

- a) Ensuring that we understand the capabilities and competencies
- b) Ensuring that we communicate the roles and



- responsibilities
- c) Defining the quality requirements for the outsourced activity
- d) Selecting and qualifying appropriate suppliers

The *Head of Procurement* and the *Head of Quality* jointly evaluate and select suppliers based on their ability to supply services per specified requirements. Other internal resources may be called upon to assist as required.

8.4.2 Type and Extent of Control

Purchased items are checked against the purchase order to confirm identity and quantity. If an item is rejected on receipt, a Non-Conforming Material Report is made, and the supplier is contacted to arrange replacement or credit. RASIRC has established and implemented a process of inspection to ensure that purchased products conform to:

- a) Purchase orders and delivery notes;
- b) Product specifications;
- c) National or international standards.

8.4.3 Information for external providers

RASIRC shall ensure the adequacy of requirements before their communication to the external provider.

RASIRC shall communicate to external providers its requirements for the following:

- a) The processes, products, and services to be provided;
- b) The approval of:
 - products and services;
 - methods, processes, and equipment;
 - the release of products and services;
- c) competence, including any required qualification of persons;
- d) the external providers' interactions with the organization;
- e) control and monitoring of the external providers' performance to be applied;
- f) Verification or validation activities that the organization or its customer intends to perform at the external provider's premises.

8.5 Production and service provision

8.5.1 Control of production and service provision

RASIRC shall implement production and service provision under controlled conditions.

Controlled conditions shall include, as applicable:

- a) The availability of documented information that defines:
 - the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
 - the results to be achieved;
- b) the availability and use of suitable monitoring and measuring resources;
- c) the implementation of monitoring and measuring activities at appropriate stages to verify that criteria for control and processes or outputs, and acceptance criteria for products and services, have been met;
- d) the use of suitable infrastructure and environment for the operation of processes;
- e) the appointment of competent persons, including any required qualification;
- f) Validating and periodically revalidating processes is crucial to ensure planned results are achieved, especially when output cannot be verified later. Deficiencies might only become apparent after the product is in use or the service is delivered;
- g) the implementation of actions to prevent human error;
- h) the implementation of release, delivery, and post-delivery activities.

8.5.2 Product Identification and Traceability

RASIRC shall use suitable means to identify outputs when necessary to ensure the conformity of products and services.

RASIRC shall identify the status of outputs concerning monitoring and measurement requirements throughout production and service provision.

When traceability is a requirement, RASIRC shall control the unique identification of the outputs and retain the documented information necessary to enable traceability.



8.5.3 Customer or external provider property

RASIRC shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

RASIRC shall identify, verify, protect, and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When a customer's or external provider's property is lost, damaged, or otherwise found unsuitable, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

8.5.4 Preservation of Product

RASIRC shall preserve the outputs during production and service provision to the extent necessary to ensure conformity to requirements.

8.5.5 Post-delivery activities

RASIRC shall meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, RASIRC shall consider:

- a) statutory and regulatory requirements;
- b) the potential undesired consequences associated with its products and services;
- c) the nature, use, and intended lifetime of its products and services;
- d) customer requirements;
- e) customer feedback.

8.5.6 Control of changes

RASIRC shall review and control changes for production and service provision to the extent necessary to ensure continuing conformity with requirements.

RASIRC shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Monitoring and measurement of the product

RASIRC shall implement planned arrangements at

appropriate stages to verify that the product and service requirements have been met.

The release of products and services to the customer shall only proceed once the planned arrangements have been satisfactorily completed unless otherwise approved by a relevant authority and, as applicable, by the customer.

RASIRC shall retain documented information on the release of products and services. The documented information shall include:

- a) evidence of conformity with the acceptance criteria;
- b) traceability to the person(s) authorizing the release.

8.7 Control of non-conforming outputs

RASIRC shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent unintended use or delivery.

RASIRC shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. These actions shall also apply to non-conforming products and services detected after delivery of products, during or after the provision of services.

RASIRC shall deal with non-conforming outputs in one or more of the following ways:

- a) correction;
- b) segregation, containment, return, or suspension of the provision of products and services;
- c) informing the customer;
- d) obtaining authorization for acceptance under concession.

Conformity to the requirements shall be verified when non-conforming outputs are corrected.

RASIRC shall retain documented information that:

- a) describes the nonconformity;
- b) describes the actions taken;
- c) describes any concessions obtained;
- d) identifies the authority deciding the action concerning the nonconformity.



9 PERFORMANCE EVALUATION

9.1 Monitoring, measurement, analysis, and evaluation

9.1.1 General

RASIRC shall determine:

- a) what needs to be monitored and measured;
- b) the methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results;
- c) when the monitoring and measuring shall be performed;
- d) when the results from monitoring and measuring shall be analyzed and evaluated.

RASIRC shall evaluate the performance and the effectiveness of the quality management system.

RASIRC shall retain appropriate documented information as evidence of the results.

9.1.2 Customer satisfaction

RASIRC shall monitor customer feedback on how their needs and expectations have been fulfilled and determine the methods for obtaining, monitoring, and reviewing this information.

9.1.3 Analysis and evaluation

RASIRC shall analyze and evaluate appropriate data and information arising from monitoring and measurement.

The results of the analysis shall be used to evaluate:

- a) conformity of products and services;
- b) the degree of customer satisfaction;
- c) the performance and effectiveness of the quality management system;
- d) if planning has been implemented effectively;
- e) the effectiveness of actions taken to address risks and opportunities;
- f) the performance of external providers;
- g) the need for improvements to the quality management system.

9.2 Internal Audit

RASIRC shall conduct internal audits at planned intervals to provide information on whether the quality management system:

- a) Conforms to:
 - RASIRC's requirements for its quality management system;
 - the requirements of ISO 9001;
- b) is effectively implemented and maintained.

RASIRC shall:

- a) plan, establish, implement, and maintain an audit program, including the frequency, methods, responsibilities, planning requirements, and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
- b) define the audit criteria and scope for each audit;
- c) select auditors and conduct audits to ensure objectivity and impartiality of the audit process;
- d) ensure that the results of the audits are reported to relevant Management;
- e) take appropriate correction and corrective actions without undue delay;
- f) retain documented information as evidence of the implementation of the audit program and the audit results.

9.3 Management review

9.3.1 General

Top Management shall review the organization's quality management system at planned intervals to ensure its suitability, adequacy, effectiveness, and alignment with its strategic direction.

9.3.2 Management review inputs

The management review shall be planned and carried out taking into consideration the following:

- a) the status of actions from previous management reviews;
- b) changes in external and internal issues that are relevant to the quality management system;



- c) Information on the performance and effectiveness of the quality management systems, including trends in:
 - customer satisfaction and feedback from relevant interested parties;
 - the extent to which quality objectives have been met;
 - process performance and conformity of products and services;
 - nonconformities and corrective actions;
 - monitoring and measurement results;
 - audit results;
 - the performance of external providers;
- d) the adequacy of resources;
- e) the effectiveness of actions taken to address risks and opportunities (see 6.1);
- f) opportunities for improvement.

9.3.3 Management review outputs

The output from the management review shall include any decisions and actions related to the following:

- a) opportunities for improvement;
- b) any need for changes to the quality management system;
- c) resource needs.

RASIRC reviews and evaluates outputs and the need for continuous improvement during Management Reviews.

10 IMPROVEMENT

10.1 General

RASIRC drives improvement by analyzing relevant data to determine and select opportunities for improvement, implementing any necessary actions to meet the requirements of customers and relevant interested parties, and enhancing customer satisfaction. The data inputs for the improvement process include:

- a) Risk and opportunity evaluations
- b) Assessment of the changing needs and expectations of interested parties
- c) The conformity of existing products and services
- d) The effectiveness of our QMS
- e) Supplier performance

- f) Levels of customer satisfaction, including complaints and feedback
- g) Internal and external audit results
- h) Corrective action and non-conformance rates

RASIRC also ensures that the *Head of Quality* evaluates opportunities for improvement. These opportunities are typically implemented through the corrective action system. Opportunities for improvement from analyzing longer-term data and trends are evaluated and implemented through the management review process and prioritized by their relevance to achieving our quality objectives.

The overall effectiveness of the continual improvement program is assessed through our management review process.

10.2 Nonconformity and corrective action

10.2.1 Occurrence and action

When a nonconformity occurs, including any arising from complaints, RASIRC shall:

- a) React to the nonconformity and, as applicable:
 - act to control and correct it;
 - address the ramifications;
- b) Evaluate the need for action to eliminate the cause(s) of the nonconformity, such that it does not recur or occur elsewhere, by:
 - reviewing and analyzing the nonconformity;
 - determining the causes of the nonconformity;
 - determining if similar nonconformities exist or could potentially happen;
- c) implement any action needed;
- d) review the effectiveness of any corrective action taken;
- e) update risks and opportunities determined during planning, if necessary;
- f) make changes to the quality management system, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

10.2.2 Records

RASIRC shall retain documented information as evidence



of the following:

- a) the nature of the nonconformities and any subsequent actions taken;
- b) the results of any corrective action.

10.3 Continual improvement

RASIRC continually improves the effectiveness of its quality management system by applying policies and objectives, auditing, data analysis, corrective and preventive actions, and management reviews.

The continual improvement process begins with establishing the organization's policies and objectives for improvement. These are based on the business plan's

objectives, customer targets, and goals. Customer satisfaction, internal audit data, process and product performance data, and the cost of poor quality or risk control are compared against objectives or KPIs to identify additional opportunities for improvement.

Our management review process assesses the overall effectiveness of the continual improvement program, including the corrective actions taken and the overall progress toward achieving organizational improvement objectives, to ensure that RASIRC is committed to continually improving.

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