**REDIMED**

**ISO 9001:2008**

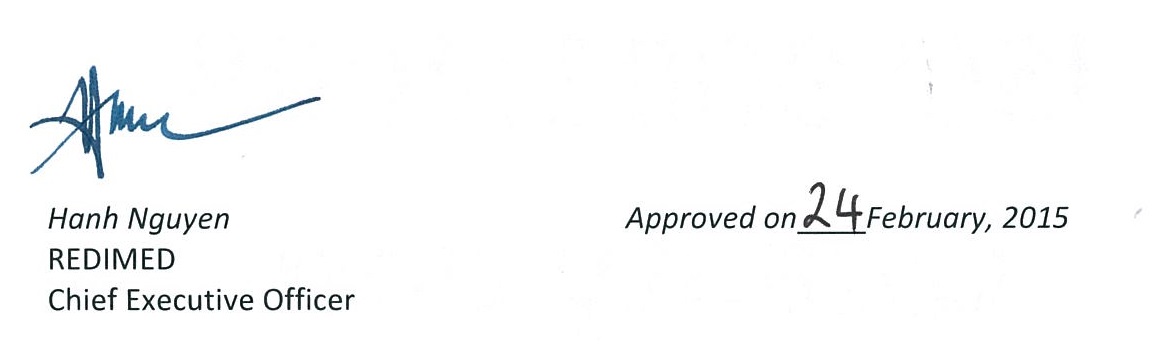
**Quality and Procedures**

**Manual**

# Approval

This ISO 9001 Quality and Procedures Manual has been approved for use throughout REDIMED Pty Ltd:

Version 5.2:

**

This ISO 9001 Quality and Procedures Manual has been written and published by Derrick Chan of REDIMED Pty Ltd. Please contact Derrick Chan at derrick.chan@REDIMED.com.au with questions, comments and improvement suggestions.

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# Introduction

## The ISO 9001 Quality and Procedures Manual

This ISO 9001 Quality and Procedures Manual contains the requirements of our quality management system.

**Intended audience:** All management, employees and contractors of REDIMED.

**Use:** As training material and as a guide for workplace protocols.

**Purpose:** Guidance in the implementation and maintenance of our ISO 9001 compliant quality management system.

**Structure:** The manual is structured according to key company processes. The following figure illustrates the interaction of our key processes and their interface with the customer.



*The ISO 9001 Quality and Procedures Manual follows our key processes.*

**Management Principles:** Our quality management system is based on the following seven management principles:

* **Customer focus**  
  At REDiMED we work closely with our clients and patients to provide the highest quality Health Care services and outcomes.

In order to deliver, and indeed exceed client service expectations, and to continue to offer services that are cutting edge and desired by clients both now and into the future, it is essential to drive a customer service focus across all levels of our company.

A thorough examination of client feedback combined with analysis of current and future market trends will enable REDIMED to deliver and anticipate current and future customer needs. REDIMED leaders build enthusiastic teams and create an environment where people can’t imagine working anywhere else.

Our leaders involve their teams to establish and achieve compelling goals and outcomes that align with the united purpose and direction and desired outcomes of the company. Through staff engagement they create and maintain an internal environment in which people can become fully united in working to achieve the company’s objectives.

* **Involvement of people**

REDIMED is successful when every individual within our organisation is accountable for clear outcomes and displays ownership for improved results.

When we never lose sight of our individual and company goals, we are fully committed to achieving positive outcomes both at an individual and company level.

When we each take ownership of the problems we discover and are accountable for making sure they are resolved, encouraging open communication and involvement, together with our colleagues, suppliers and clients, we build relationships and outcomes to make REDIMED a great place to work and enable us to work effectively and efficiently throughout our company.

* **Process approach**A desired result is achieved more efficiently when projects, daily duties, services and related resources are managed and directed through a structured process.
* **System approach to Management**Identifying, understanding and managing interrelated processes as a system contributes to the company’s effectiveness and efficiency in achieving its objectives.
* **Continuous improvement**REDIMED is committed to the continuous improvement of the company’s overall service delivery, growth and performance.
* **Factual approach to decision making**Effective decisions are based on the analysis of data and information.
* **Mutually beneficial supplier relationships (Efficiency Focused)**We are successful when the business has a culture committed to efficient outcomes, aligning every person’s role to delivering maximum value to our clients and return for our company.

Building long term relationships, particularly with suppliers- can maximise negotiation power and achieve better business outcomes.A company and its suppliers are interdependent, and a mutually beneficial relationship enhances the ability of both to create value.

## Vision and Mission

REDIMED is a company which provides a comprehensive, quality and professional service for workplace injuries aimed at prevention, treatment, rehabilitation and returning the injured worker to work in the optimum time.

**Our Vision**

The Vision of REDiMED

To offer the highest quality total injury management service and be the provider of first choice for Western Australian industry.

**Our Mission**

The Mission of REDiMED

Our ultimate goal is deliver the highest Quality Health Care Outcomes, and to exceed Client expectations.

**Goal**

To provide comprehensive injury management services to ensure industrial injuries are minimised and when injury occurs the injured worker receives optimum care to ensure the best possible outcome and return to work.

**Objectives**

To ensure that the worker is medically and functionally fit for the work they undertake in industry.

To ensure the injured worker receives rapid access to specialist treatment 24 hours a day to minimise the impact of the injury and ensure their optimum physical and mental recovery and wellbeing.

To provide coordinated and comprehensive rehabilitation services to ensure optimum recovery of the injured worker.

To work in close association with industry representatives to ensure a consistent and coordinated approach to injury management and optimum return to work of the injured worker.

To provide a 24 hour emergency support service to industry including provision of advice and facilitating the injured workers access to emergency care

To provide education and training in injury management to industry employees and other health professional to provide assistance to industry in the preparation and planning for disasters.

To plan the expansion of the company to meet the requirements of industry throughout Australia and in the long run internationally.

To offer a specialist consultation and treatment service to areas in Western Australia that the Company is based.

To work in close association with general practitioners and other primary care providers.

# General Requirements

## Quality Management System and Management Representatives

**Purpose:**

Maintain the Quality Management System with the assistance of Management Representatives.

**Scope:**

Every site has Management Representatives who are responsible for their department in the Quality Management System.

**Responsibility:**

Senior Management will be responsible for appointing the Site Management Representatives.

**Quality Management System**

REDiMED maintains an integrated system of policies, procedures and work instructions that lay the fundamentals of our business activities, and that meet the requirements of ISO 9001. We call this our **Quality Management System**. The Quality Management System is implemented consistently across the entire company.

**Management Representatives**

Management will be responsible for appointing a **Management Representative** at all company or office locations who are responsible for ISO 9001 at that location (Note that the role of Management Representative is an additional responsibility, and that one Management Representative may be responsible for more than one location).

**Key responsibilities of the Management Representative:**

* Ensure that the ISO 9001 system is implemented and remains maintained throughout the areas and sites of the business for which the Management Representative is responsible.
* To interface with auditors and communicate audit results to the relevant functions and ensure proper follow up; ensure that the lead auditor is notified of how the business unit plans to address audit findings.
* Monitor the quality management system (e.g. through audit reports) to ensure that it is effectively implemented and maintained.
* Report to Management on the performance of the ISO 9001 system and any need for improvement.
* Ensure that the awareness for customer requirements is promoted throughout the company.
* Report to Management on the performance of the Quality Management System.
* Make suggestions on how to improve the Quality Management System.

The Quality Manager is the **Management Representative for the entire company**, and as such he is responsible for the corporate quality management system. The Quality Manager coordinates all company Management Representatives.

**During times of change…**

The Quality Coordinator and Management Representatives are accountable for ensuring the integrity of the Quality Management System.

The Quality Manager strives to ensure that the integrity of the Quality Management System is maintained when changes are planned and implemented and will direct the Quality Coordinator who will be the custodian of the Quality Management System.

## Documentation Structure

**Purpose:**

To explain the flexibility within the documentation structure.

**Scope:**

To ensure there is a standard document framework, font, header and structure implemented which is adhered to across all levels of REDIMED.

**Responsibility:**

All management, employees and contractors of REDiMED.

**How is our quality management system documented?**

The following documents are the backbone of our quality management system:

* This ISO 9001 Quality and Procedures Manual, which consists of the corporate policies and procedures.
* Additional procedures, work instructions and other documents used throughout the company.
* Records required by ISO 9001:2008.

**Much More Flexibility**

In order to allow each office enough operating flexibility, the ISO 9001 Quality and Procedures Manual includes only top-level corporate procedures.

Management have the flexibility to add more specific requirements to standardise their processes further. However, all such requirements and procedures must meet the requirements set forth in this ISO 9001 Quality and Procedures Manual.



## Document Control

**Purpose:**

To ensure that the right personnel have the current version of the documents they need, while unauthorised persons are prevented from access, editing and/or use as applicable.

**Scope:**

All documents are controlled but the level of control is appropriate to the importance and impact of the document, and the level of access appropriate to the individual.

**Responsibility:**

All employees.

**Procedure**

**Preparation:** The Quality Manager sets up a **Record Retention Guide** that defines for each record or record type the retention period, the filing and archiving location, and the method of destruction. The Record Retention Guide must be accessible to all involved in filing and archiving.



**Summary: Important Document Controls**

**When you write a document…**

* Give it a **title.**
* Add a **date** (don’t use the auto date function!) and a **source** (e.g., your department and your initials). Example: see the footer of the ISO 9001 Quality and Procedures Manual.

**When you make changes…**

* If you make **handwritten** changes, initial and date them.
* If you revise the document, update the **date** in the footer and **inform users of changes** (e.g., revision history, high-lighting of changes).

**If somebody else needs to sign off…**

* If you don’t have the necessary **authority**, get approval first.
* Keep a **record of the approval** (on the document or separate; if separate, record date of approval, date of document, name of approver).

**Note:** Additional requirements apply to **proposals** and **contracts**. See respective chapters for more information.

**When you make the document available to users…**

* Keep a **distribution list** of hard copies (e.g. you can handwrite the location of all hard copies on your “master copy”).
* Make documents **accessible** to intended users, and **protect** them so they remain in an authorised format.
* Save shared documents on the Intranet or on a shared drive, then provide **shortcuts and hyperlinks** pointing to the document rather than emailing the document as an attachment (to prevent outdated, uncontrolled copies).
* Set **permissions** on the Intranet and on shared folders to protect documents from unintended and unauthorised use and / or change.

**Keeping your instructions, forms and similar documents current…**

* **Management** ensures that instructions, forms and similar documents in their area of responsibility remain current.
* **Review** your instructions, forms and similar documents as needed to ensure they remain current. Refer to the QMS procedure “Control of Quality Records” for timeframes
* If necessary, assign a **review by** **date** and then review documents on their review by date.

**Filing…**

* If you retain **obsolete** instructions, forms and similar documents, mark them clearly as obsolete. (How will this be marked- folder or name of document?
* Index and file records so that they can be **easily retrieved** if needed.

**Archiving and Record Retention…**

* Refer to the **Record Retention Guide** for instructions and retention periods.
* Archive boxes with the following information: box number, contents, dates covered, destruction date.
* Keep a **storage log** listing archived records and their location.
* Keep archived records **secure** in a locked area throughout the required retention period.
* Destroy records that are passed their indicated destruction date. Most records must be **shredded**. See the QMS procedure “Control of Quality Records” for.

**Document Destruction…**

* As a rule of thumb, all documents that should not be seen by competitors or outsiders, **they** **must be deposited into the secure document destruction bins**. This includes extra printouts, copies and worksheets.
* See the QMS procedure “Control of Quality Records” for details.

**External documents**

The above requirements on identification and distribution also apply to documents that originate outside of REDIMED. If you modify any such documents (thus making them your own), all of the above requirements apply.

# Leadership

## Responsibilities and Authorities

**Purpose:**

All employees have a clear understanding of their responsibilities and authorities.

**Scope:**

Companywide between all employees and their supervisors, team leaders, management representatives and senior management.

**Responsibility:**

All supervisors.

**Procedure**

**Job descriptions**

1. Human Resources issue job description for a job vacancy and each employee, in conjunction with the supervisor (job descriptions for new employees should be completed prior to hiring).
2. Supervisor and employee sign the job description.
3. A copy is provided to the employee, another copy is sent to the HR Department for their personnel file.

**Company charts**

1. Managers of functional areas maintain a company chart that defines all reporting relationships.
2. Company charts are made available to employees within the functional area.

## Quality Policy

**Purpose:**

Providing top-level quality direction to management and employees.

**Scope:**

All processes and functional areas companywide.

**Responsibility:**

Management.

**Procedure**

Management uses the Quality Policy as a **guide** to the development of objectives and metrics, and for management decisions.

Supervisors **communicate** and explain the Quality Policy to their employees to ensure that everybody is familiar with the policy and its intent.

**Quality Policy**

REDiMED is committed to providing worldwide integrated health services that are reliable, efficient, and timely and of a high standard.

We strive to achieve this by:

* Promoting an understanding of our customers’ needs and expectations, together with a culture of exceeding customer expectations.
* Developing seamless processes by fully integrating the services provided by our suppliers and partners.
* Monitoring our performance through performance metrics in order to continually improve our processes and services.
* Utilising our ISO 9001 Quality Management System for all company processes and work procedures, provides consistence everywhere, every time, without exception.

## Setting Objectives

**Purpose:**

To provide a clear outline of the REDIMED company direction to all employees across all levels of the business. To ensure that resources are focused, and inform and engage individuals across the organization to enable unified prioritisation and decision making work processes in line with the corporate strategies and direction.

**Scope:**

Objectives are set across all departments, sites and levels of the company, ranging from strategic business objectives set at the corporate level through to departmental and individual performance objectives.

**Responsibility:**

All individual in the company.

**Procedure**

REDiMED establishes objectives in order to provide all stakeholders, business units, departments and employees with a clear company direction. Objectives are established on the highest level, and then trickle down through divisions, business units to the individual.

All objectives support the next higher level in order to ensure that the Strategic Objectives of the Organisation, Management and Board of Directors are achieved.

**Implementation**

Management of departments and business units sets their annual business objectives in support of the top-level objectives.

**Business Plans:**

Management makes informed assumptions about the business environment and anticipates future client needs and plans these into their business activities in support of divisional and strategic objectives. Specific objectives are a crucial part of the business plan. See section 4.1 for details.

All objectives should meet the SMART criterion (Specific, Measurable, Attainable, Relevant, and Time-bound).

**Budgets:**

Management prepares a budget for the upcoming year before the end of financial year. Budgets are based on planned business activities, informed assumptions on the market environment, and anticipated client needs (i.e. budgets reflect the business plan). See section 4.1 for details.

**Performance Objectives:**

Supervisors and individuals set specific performance goals and objectives as part of the annual performance review. These performance objectives also support the objectives of the business unit and the overall strategic objectives. See section 4.2 for details.

**Metrics:**

Management uses metrics to track if company objectives are being accomplished. See section 9.3 for more information on metrics.

## Customer Focus

**Purpose:**

Promoting an understanding of our customers’ present and anticipated future needs and expectations, together with a culture of exceeding customer expectations.

**Scope:**

Customer focus is constantly reinforced across the business.

**Responsibility:**

All.

**Procedure**

REDiMED promotes a culture of customer focus so that all employees understand relevant customer service expectations, specific client needs and work towards enhancing customer satisfaction.

* Supervisors help employees understand **who** the customers are (see section 6.1).
* Supervisors communicate with employees about the **needs and expectations** of customers and potential customers (see section 6.2).
* Supervisors establish clear **requirements** that help us meet customer needs and expectations (see sections 3.3 on **objectives**, 8.2 on **control of production and service provision**, and 9.3 on **metrics**).
* Feedback from clients / market and client trend analysis to predict and improve services and client satisfaction.

## Internal Communication

**Purpose:**

To establish good internal communication channels that give employees the information they need to fully support our company goals.

**Scope:**

Internal communication and involvement of people is done constantly and throughout all levels of the company.

**Responsibility:**

Management

**Procedure**

Management establishes internal communication channels and ensures that communication takes place with employees regarding:

* the quality policy and other company policies
* job requirements
* performance objectives and actual performance results and accomplishments

Communication channels *may* include, but are not limited to the following:

* New hire orientations
* Intranet and email
* Company newsletter
* Employee recognitions and awards
* Notice boards and other postings
* Memos and handouts
* Staff meetings, pre-shift meetings, safety talks
* Suggestion boxes and employee surveys and other ways of generating feedback from employees

# Resource Management

## Resource Allocation

**Purpose:**

To provide the resources needed to implement company objectives.

**Scope:**

Company resources are aligned strategically to enable company objectives to be achieved. Resources are allocated during business planning and budgeting, and may be allocated or adjusted as required throughout the year.

**Responsibility:**

Senior Management

**Procedure**

Management of each of the business units determines resource needs, and ensures that the requested resources are appropriate, are presented for final approval and allocated appropriately once approved.

**Business Plan and Budget**

Prior to the beginning of each calendar year, management of each of the departments develop and present a business plan including a budget for the upcoming year.

* The **business plan** is *based* on corporate and division objectives, and on management’s expectations for the business environment and anticipated client needs. It *contains* management’s plan for the operation of the existing business, and their plan for new business activities.
  + It contains plans and informed assumptions about services performed and revenue generated.
  + It also contains plans and informed assumptions on necessary resources, including
    - suppliers,
    - people and training,
    - equipment and devices,
    - materials and supplies,
    - buildings, work environment, and utilities,
    - internal support services, including IT and financial
    - financial resources and their cost, including initial investments and working capital

In order to ensure that all resource needs are identified, management identifies the processes and then the resource requirements for each process.

* The **budget** is based on the business plan. It reflects the planned business revenue and the costs involved in generating that revenue.

**New Opportunities Outside of Business Plan**

As part of the proposal process, management of the business unit projects not only revenue of the new business, but also identifies the resources necessary. The above description of the business plan and budget is intended to serve as a guide.

**Making Resources Available**

Management is responsible for making the resources available. The following sections address Human Resources, Infrastructure, Work Environment and Equipment.

## Human Resources

**Purpose:**

To ensure that the necessary skills and capabilities are available for the effective and efficient operation of the company.

**Scope:**

All positions.

**Responsibility:**

* Managers are responsible to follow the Human Resources process for hiring, termination and performance reviews.
* Human Resources is responsible for supporting Managers in Human Resources issues, and for meeting legislative, industrial and organisational requirements.

**Procedure**

Management aims to ensure that all positions are filled with individuals whose competencies meet the position requirements. This can be achieved through:

1. Internal Reorganisation
2. Training
3. Hiring and Termination
4. Developing potential within the organisation

Performance Reviews are conducted to verify that competencies and achievements meet the position requirements, and to identify opportunities for improvement.

**Training**

Supervisors provide their employees with training that is necessary to meet the skills and task requirements of the position. Training may take many forms, including formal induction, training and educational sessions and formal classes through to on-the-job coaching, training and development.

* **Training Plan**

Supervisors determine appropriate training approaches, with the purpose of aligning staff skills, knowledge and abilities with the identified competence requirements of the specific position. The planning for training is performed whenever new competencies are required, as well as annually as part of the performance review.

* **Training**

Managers ensure that the plan is followed and the training is provided. Once training is complete, **records** are established, and a copy is sent to Human Resources. Human Resources keeps records on all training and provides Managers with access to information on past training.

* **Evaluation**

Managers evaluate the outcome of training to ensure that the training objectives have been met and that the new competencies have been learned and practiced. Where the training outcome is unsatisfactory, Managers may determine additional training needs or they may re-evaluate competence needs. Or follow performance recovery and coaching processes.

The training evaluation is performed as part of the formal induction and end of probation period reviews, as part of the annual performance review, and following the provision of any formal training.

1. Requisition and Job Description:

The hiring Manager provides Human Resources with a signed and authorised requisition form and job description for the vacant position.

1. Posting and Advertising:

Human Resources posts the job opening internally and / or externally to ensure compliance with company requirements and for an affirmative action plan.

1. Initial Review of Applicants:

Human Resources receives applications, reviews them and short lists candidates. All successful candidate resumes are kept on the staff file by Human Resources, unsuccessful candidate applications are kept for 3 months and are then destroyed.

1. Interview:

The hiring manager asks the applicant to fill out an Employment Declaration Form before the interview and interviews the applicant according to Human Resources guidelines. There will be two Managers, or a Manager and a Human Resources representative present at all interviews. The Manager also fills in a log of all interviews (EEO Log) and forwards the log to Human Resources for their records.

1. **Pre-Employment Process:**

* Reference Checks
* Background checks (including education, Registration, Insurance, Current Identification)
* Federal Police Clearance and Working with Children (if required)
* Drug and Alcohol testing
* Current Right to Work Visa (VEVO)

1. Job Offer:

The hiring Manager makes a verbal job offer. All job offers are dependent on the results of background checks.

1. Contract Offer:

The hiring Manager fills out and submits all necessary documents to Human Resources within the required timelines (see “New Hire Check List”). Human Resources creates a contract ready for approval and maintains the records.

1. Orientation:

Human Resources and the hiring Manager provides the new employee with an orientation that is formally signed and acknowledged, and which includes company history and a review of the employee handbook (incl. corporate policies & standards of conduct, and employee benefits).

As with any training, Human Resources keeps a record of the orientation.

T**ermination**

Managers will always check with Human Resources first **before** terminating any employee. Human Resources ensures that all Senior Management and legislative requirements are met, and provides Managers with guidelines and check sheets.

**Performance Review**

Managers evaluate and adjust the performance of their personnel throughout the course of everyday duties and interaction. Formal performance reviews will be performed and recorded annually. Human Resources prompts managers by supplying the performance review form during the month prior to the review. The review form requires:

* **Evaluation of job related qualities**

Managers review the employees current behavior, skills and competency in line with Company expectations, Client care and satisfaction expectations and various job specific requirements. Highlights of strengths, along with identification of opportunities or development are agreed, and goals and objectives are set accordingly.

* Setting performance objectives

Managers guide employees and assist them to determine performance objectives that support the objectives of the department or business unit. When determining these objectives, Managers and Employees also consider how they can measure if the objectives have been met. Performance objectives should meet the SMART criterion: specific, measurable, attainable, relevant and time-bound.

* Evaluation of last year’s performance objectives

Managers and Employees together evaluate if the performance objectives that were set during the last review have been met.

* Planning for training

Managers and Employees identify training and education opportunities, training options and support necessary to meet position requirements. See section on training.

* Evaluation of last year’s training

Managers and Employees evaluate not only if the planned training has been performed, but more importantly if the employee learned/acquired the necessary skills.

Managers strive to perform the performance review **within one month** of the review date. Both employee and manager fill out a review formprior to the review, and then **discuss** each item as part of the review. Refer to the **Supervisor Manual** for details.

Human Resources retains all performance reviews on staff file.

## Infrastructure and Work Environment

**Purpose:**

To ensure that infrastructure and work environment are conducive to meeting customer requirements.

**Scope:**

Ongoing and company-wide.

**Responsibility:**

* Management for providing, managing and maintaining infrastructure and the work environment.
* Senior Management for review and approval of licenses and other corporate documents, and engagement with legal contractors as required.

**Procedure**

Typically, resources for infrastructure and work environment requirements are identified and provided according to section 4.1.

In any case, the Facility Manager strives to **provide**, **manage** and **maintain** the infrastructure and work environment needed to ensure that our services meet customer requirements.

Infrastructure includes:

* Buildings, workspace and utilities
* Equipment (both hardware and software)
* Supporting services (including IT and communications)

Work environment includes:

* Heat, humidity, light and airflow
* Presentation and Hygiene
* Workplace location

**Lease agreements (landlord/tenant)**

*Prior to signing*, the Facility Officer on behalf of REDiMED will forward to Senior Management all lease agreements (REDIMED being tenant, or REDiMED being landlord) for legal review and approval.

*After signing*, Senior Management keeps a copy of all lease agreements on file.

**Equipment lease or sale agreements**

Use a standard contract form. See section 7.4 for more information on standard contract forms.

**Licenses and other Corporate Documents**

*Prior to signing*, the Facility Officer on behalf of REDiMED will forward to Senior Management all licenses, applications for authorities and other corporate documents for legal review and approval.

*After signing*, Senior Management keeps a copy of all corporate documents on file.

## Equipment

**Purpose:**

To ensure that our products/services meet requirements, and to prevent accidents, delays and other costs due to equipment failure.

**Scope:**

All equipment, including measuring equipment, used in the production and service provision.

**Responsibility:**

Management.

**Equipment Maintenance**

In order to prevent breakdowns and malfunctioning of equipment used in the production and service provision, management implements a **maintenance program**.

1. **Setting up the maintenance program**

The Facility Officer establishes a formal equipment maintenance program that includes:

* Defined maintenance **intervals** (e.g., every 6 months,)
* Defined maintenance **activities** (e.g., change engine oil)

1. **Following the program**

The Facility Officer strives to ensure that all maintenance activities are conducted **according to plan**, and that all maintenance **records** are kept.

**Measuring Equipment**

Management strives to ensure that our measurements are correct by:

* **Selecting the right measurement equipment**

The Relevant department Manger determines where measurements are needed and how precise they have to be. Based on these requirements, the Facility Officer locates the appropriate measuring equipment.

* **Measuring accurately**

Management strives to ensure that required measurements are taken properly and in accordance to measuring needs.

* Equipment meets all accreditation/ certification standards TGA (e.g. NATA)
* Measuring equipment e.g. Drug Testing equipment to meet NATA and TGA requirements.
* **Protecting the equipment**

Management works to attain that measuring equipment is protected and safeguarded from adjustments that would invalidate results.

**Calibration**

Management implements a formal **calibration program** for all measuring equipment that can be calibrated.

1. **Setting up the calibration program**

Local management establishes a formal calibration program that includes:

* Defined calibration **intervals** (e.g. once a year, or before use)
* Defined calibration **methods** (if the methods are not an industry standard, the basis for calibration is documented)
* Defined calibration **range** (i.e. the range in which calibration results are supposed to fall)

1. **Following the program**

Management strives to ensure that the measuring equipment is calibrated **according to plan**, that they are **identified** with the **calibration status**, and that all calibration **records** are kept.

1. **If a device is out of calibration**

In case a measuring device is found out of calibration (i.e., calibration results outside the permitted range), local management **evaluates** if previous measurements might have caused our products/services not meeting requirements. Where necessary, local management takes appropriate **action** which may include rework or recall. **Records** of the evaluation of the impact on our products/services and any resulting action are maintained. And finally, the out-of-calibration device is **repaired or replaced**.

**Other Equipment Issues**

* **Equipment leases (our equipment or third party equipment):**

The Leaser will provide a service contract REDiMED to agree or negotiate terms.

# Customer Contracts

## Rate Quotes

**Purpose:**

To ensure that our quotations are correct, well defined, and that we are able to meet our commitments.

**Scope:**

Written service level agreements and other client service contracts.

**Responsibility:**

* Management
* Chief Financial Officer or Financial Controller
* Business Development and Client Liaison

**Procedure**

Senior management establishes **authorities** providing companies quotations. Management also establishes quote and/or confirmation **forms,** as well as **guidelines** that include requirements for profit margins, vendor selection, service delivery KPI’s and other commitments as applicable.

When rate quotes are made **in writing**:

1. Document all verbal customer requirements.
2. Keep these documents available so that a co-worker can continue if necessary.
3. Send the rate quote and other pertinent information. Include standard **terms and conditions**, as approved by Senior Management, with the rate quote.

When rate quotes are made **over the phone**:

1. Document all customer requirements on a standard form.
2. Document the rate quote.
3. Keep these documents available so that a co-worker can continue if necessary.
4. **Written confirmation**:
   1. Where feasible, confirm the rate quote and other pertinent information in writing. Include standard **terms and conditions**, as approved by Senior Management.
   2. Or, if the rate quote was only made verbally, send written confirmation as soon as the customer accepts the quote. Include standard **terms and conditions**, as approved by Senior Management.

## Proposals and Contracts

**Purpose:**

To ensure that our proposals and contracts are correct, well defined, and that we are able to meet our commitments.

**Scope:**

Ensure all proposals and contracts are formally documented, including Request for Proposals.

**Responsibility:**

* Proposal owner (Manager or Client Liaison Officer).
* Executive

**Proposals**

**Formal RFPs**

Forward all formal Request for Proposals to Senior Management for an initial review – this allows Senior Management to filter out those Request for Proposals that are not feasible for the company.

**Proposal Preparation**

As part of the preparation of a customer proposal, the following requirements are determined, taken into consideration and addressed by the proposal owner:

* Requirements specified by the customer, including any requirements for delivery and post-delivery activities
* Implied requirements
* Requirements not stated by the customer but necessary for the customer to gain the specified or intended benefits (where known)
* Customer needs of which the customer may not yet be aware
* Senior Management requirements related to the product/service
* Any additional requirements determined by our company

**Senior Management Note**

The Senior Management Note (below) should be included in any proposal:

“*This proposal is subject to mutual agreement on the terms and conditions of a formal* ***signed*** *contract prior to there being any binding obligation on the part of either party*.”

* If included: You don’t need Senior Management’s review and approval prior to submitting the proposal to the customer.
* If not included: Senior Management reviews any customer proposal in advance since such proposal could create binding obligations for the company.

**Proposal Format**

All proposals are created in accordance with corporate style guides and format set by the Executive Officer.

**Proposal Review**

The proposal owner ensures that proposals are reviewed by various affected parties prior to submission to the customer. Reviews should take place as early as possible in the proposal stage to allow affected parties to contribute.

Who reviews?

* Management of affected operating units
* Chief Financial Officer or Financial Controller
* Senior Management
* Chief Executive Officer (Where relevant)

What is reviewed?

The review helps ensure that

* Product/service requirements are well defined,
* Any changes to previously expressed requirements are resolved,
* The company has the ability to meet the defined requirements,
* That the quoted price and the financial assumptions are correct, and
* That the company is not exposed to any unknown and uncalculated risk and liability.

Records

The proposal owner is also responsible for generating the review records, which include information on:

* Who reviewed
* Date of review
* Subject of review
* Actions based on review

Management maintains the records of review together with the proposal or the resulting signed.

**Written Contracts**

**Contract Preparation**

In the absence of a standardised form, the signing manager submits requests for preparation of a customer contract to Senior Management.

**Contract Review**

All customer contracts are reviewed before their acceptance. The signing manager is also responsible for ensuring that the review is performed and that records of the review are kept.

1. **The Contract was Prepared by Senior Management**

Only signing manager reviews prior to signing.

1. **The Contract was Not Prepared by Senior Management but it is based on a Proposal that was reviewed by Senior Management**

Senior Management and the signing manager review prior to signing.

1. **The Contract varies significantly from the reviewed Proposal**

The interested parties (management of affected operating units, CFO, IT Services), Senior Management, and the signing manager review prior to signing. See above “What is reviewed?” and “Records” for instructions on the review and record keeping.

**Contract Acceptance and Communication**

The **signature** of the manager on the contract or agreement is an acknowledgement that the manager has complied with the requirements for review of the document prior to signature.

Signing management **informs** all affected functions (i.e., the functions that performed the review) as soon as the contract is accepted. The contract or relevant requirements are made available to management of all functions who are directly or indirectly involved in meeting the contract requirements.

**Contract File**

* Signing management keeps a contract file that includes the signed contract as well as records of review.
* A copy of each signed customer contract or other agreement is forwarded to Senior Management for retention in the central filing system of REDIMED.

## Contract Changes and Renewals

**Purpose:**

To ensure that contract changes are correct, well defined, and that we are able to meet our commitments.

**Scope:**

All material contract changes and all contract renewals.

**Responsibility:**

Manager accepting contract changes or renewals.

**Contract Changes**

Changes to contracts undergo similar scrutiny and procedures as the original contract.

**Review**

The Manager accepting the contract change ensures that significant contract changes are reviewed before acceptance according to section 5.2.

**Written Contract Change or Confirmation**

In case the customer’s requirements are only verbal, we provide the customer with a written confirmation. See “Verbal Customer Orders” in section 5.2.

**Communication**

Signing management **informs** all affected functions (i.e. the functions that performed the review) as soon as the contract change is accepted. The contract change or relevant requirements are made available to management of all functions who are directly or indirectly involved in meeting the changed contract requirements.

**Contract File**

1. Signing management keeps a record of the written contract change, or the confirmation in lieu of a signed contract, together with the review record.
2. A copy of the contract change or confirmation is forwarded to Senior Management for retention in the central filing system of REDIMED Pty Ltd.

**Contract Renewals**

**No Review**

Contract renewals do not require a formal review.

**In Writing**

Contract renewals are always put in writing and kept in the local contract file. A copy is forwarded to Senior Management.

**Important Note:** If the renewal contains any contract terms other than the extension, forward to Senior Management for review and approval prior to signing.

# Design and Planning

## Customer Awareness

**Purpose:**

To ensure that all employees contribute to establishing and maintaining customer satisfaction levels.

**Scope:**

Throughout the company and all departments.

**Responsibility:**

Managers and supervisors.

**Procedure**

Managers implement and educate employees to understand REDiMED services, who various direct and indirect customers are, and what REDIMED and client customer service expectations are required.

**Identification of Customers**

Management educates our employees as to who REDIMED customers are, and expected customer service expectations. Potential customers include but are not limited to the following:

External:

* Those who signed our contracts
* Those who pay our bills
* Customers’ customers
* Recipients and beneficiaries of our services
* End-users
* Service Providers

Internal:

* Senior management
* Management to whom our expenses are allocated or billed
* Management and individuals that receive our services
* Each other

**Customer Requirements**

Customer requirements are determined during the marketing and sales process; they are then formalised as part of the contract.

In order to plan for the production and service provision, however, Management reviews market trends, and the **requirements of all identified customer groups** so that all applicable requirements, needs and expectations are taken into consideration.

As part of this evaluation, staff feedback and service improvement initiatives across the organisation are also encouraged and considered.

Management also **communicates** with their employees so that all are aware of what the pertinent customer requirements are.

## Quality Planning

**Purpose:**

To ensure that the processes for new services are efficient, effective, in accordance with the requirements of customers and our quality management system and align with the corporate direction.

**Scope:**

Planning of processes for new services.

**Responsibility:**

Senior management.

**Procedure**

Senior management plans and develops the processes needed for production and service provision, while ensuring that all customer requirements and requirements of the quality management system are met.

In planning for production and service provision, management considers the following:

* **Requirements**

Quality objectives and requirements need to be determined. Many of the requirements come directly from the customer; other requirements and objectives are based on objectives of our company. Focus should be on determining requirements that are measurable.

* **Processes**

Do we need to create any new processes or do the necessary processes already exist somewhere in the company? New processes will probably require:

* + Forms and work instructions
  + Resources including people, skills, equipment, infrastructure, information, etc.

(see section 4).

* **Responsibilities and Authorities**

Define who has responsibilities and authorities for the new processes. You may need to update job descriptions and company charts.

* **Metrics**

Determine the metrics used to evaluate if key requirements are met. Metrics can be used internally to monitor our performance, and externally to give evidence of success to our customers.

* **Establishing Success**

How do we know if we meet all requirements and objectives? What activities are necessary to establish this?

* + **Verification**  
    Verification means to test the new processes and see if the results meet all requirements.
  + **Validation**  
    Validation means to test the new processes in order to see if they can achieve the purpose (asides from meeting the few requirements that were specified).
  + **Monitoring**  
    You may need to determine some monitoring activities that allow you to see in real-time any problems once the processes are working.
  + **Quality Control Inspections**  
    You may want to establish quality control inspections to check if performance meets requirements. Inspections could check all or only samples. See section 8.4.
* **Records**

Consider what records are needed to show evidence that requirements are met. These records may include results of inspections, measurement, monitoring, validation and verification activities. Depending on the processes, records may be necessary to demonstrate conformance to Senior Management and safety requirements.

**Quality Plans**

Senior Management / CEO decides if the outcome of Quality Planning is **formalised in writing or not**. In many cases, written responses to all of the above bullet points are valuable for establishing consistency and best practices, as well as to demonstrate to the customer that quality is well planned.

## Design

**Purpose:**

To ensure that we develop new products in an efficient manner and in accordance with customer requirements.

**Scope:**

Design and development of new, *complex* products. For *less complex* new products and services, only the Quality Planning requirements of section 6.2 apply.

**Responsibility:**

Project Leader

**Procedure**

Wherever we engage in the design of a new, complex product, an appointed project leader plans the design and ensures that design is then performed according to plan.

The **Result of Design** is not only a description of the new product. All of the following are part of the desired design output:

* Plans for purchasing, production and service provision
* Criteria for product/service acceptance and QC activities
* Essential characteristics for safe and proper use
* Metrics
* Documentation and record requirements
* Resource requirements
* Responsibilities and Authorities

In order to achieve the desired results, a few steps have to be followed.

**Step 1: Design Planning**

Management appoints a Project Leader who is responsible for the design process. The project leader plans the design process. During design planning the following are determined:

* Design and development stages
* Review (which includes verification and validation activities as described in Step 3) that is appropriate to each development stage
* Responsibilities and authorities for design
* Possible involvement of suppliers in design activities
* Communication interfaces between different groups involved in the design to achieve effective communication

Design plans are usually documented, often in the form of project plans; they are used to guide the design process.

Design is performed as planned. The following illustration gives an **overview of the** **design process** with its inputs and outputs.



**Step 2: Design Input**

The Project Leader determines all necessary design input, which includes:

* **Functional and performance requirements**

In the case of custom design, these requirements are typically provided by the customer, or determined together with the customer. In other cases, the marketing department may provide them.

* **Applicable business objectives**

Business objectives may be part of the business plan; they often include objectives for profit margins.

* **Quality objectives**

Quality objectives are based on the quality policy; they often include issues related to longevity, reliability, performance, speed etc.

* **Applicable Senior Management requirements**

These are typically requirements of government agencies that relate to the production or service provision and registration, certification (e.g. pollution, safety) as well as to the final product (e.g. product safety).

* **Where available, information from previous similar designs**

Much time and resources can be saved if information and experience from previous designs is available and can be used.

The Project Leader **documents** all necessary design inputs. Then all design inputs are **reviewed** for accuracy and to ensure that the requirements are complete, clear and not in conflict with each other.

**Step 3: Design and Design Review**

The Project Leader ensures that design and design reviews are performed as planned.

**Design reviews** are crucial in ensuring that the final product is provided in the most efficient way and that it satisfies our customers’ needs and expectations. The Project Leader ensures that design is reviewed at planned stages.

**When?**

At suitable stages, systematic reviews of our product design are performed in accordance to plan. A final review usually takes place at completion.

**Who participates?**

Participants include representatives of functions concerned with the design stage(s) being reviewed. Participants may also include customers.

**What is part of the review?**

The design review includes verification and validation activities according to plan (see Step 1):

* Verification:   
  Does the design output meet all of the stated input requirements?
* Validation:   
  Is the resulting product capable of meeting the requirements for the specified application or intended use? Or in short: can the product do what it is supposed to do? This is an important part of the review as not all requirements may have been stated.

**What is the outcome?**

The review outcome is either

* An approval of the design stage, or
* The identification of problems and a proposal of necessary action.

**What records are needed?**

Records of the results of the review (including verification and validation) and any necessary actions are maintained.

**Step 4: Design Release**

The design is released once reviewed and approved, and the design output meets all design input requirements. All outputs as listed above under **Results of Design** are included.

**Design Changes**

Changes to the product design could be originated by the customer or by us internally (e.g. during the review process). The following issues are taken into account in order to control the changes:

* Changes are identified and documented
* Changes are reviewed (see above)
* The effect of the changes on constituent parts and product already delivered are evaluated
* Design changes may cause need for contract changes (see above)

## Customer Communication Channels

**Purpose:**

To establish effective communication.

**Scope:**

Communication channels with external and internal customers, and in both directions.

**Responsibility:**

Management.

**Procedure**

Realising the importance of good customer communication with both external and internal customers, Management strives to establish, maintain and continually improve communication channels as part of all REDiMED business forward planning.

**Contacts on Customers’ Side**

Management establishes effective communication channels in both directions to help us receive all necessary product/service information from customer feedback.

**Points of Contact**

Management determines points of contact and communicates them to the customers:

* Inquiries – who can the customer call with questions on service delivery status, billing, payment etc.
* Customer orders, contracts and order/contract changes
* Feedback and complaints

Points of contact could be names, position titles, phone numbers, email addresses, mailing addresses etc.

**Other Communication Channels**

In addition to points of contact, other communication channels may improve efficiency:

* Website
* Automated electronic reports and updates
* Social media

# Purchasing and Outsourcing

## Supplier Selection and Evaluation

**Purpose:**

To ensure that our suppliers have a positive impact on our services and our bottom line.

**Scope:**

Suppliers of products and services. Building long term relationships, particularly with suppliers- can maximise negotiation power and achieve better business outcomes. The regular evaluation of suppliers’ products and services will have a direct impact on REDIMED performance, service delivery and company revenue.

**Responsibility:**

Those responsible for purchasing of products and services.

**Procedure**

REDiMED selects suppliers based on their ability to provide us with products and services according to our requirements. The extent to which we select, evaluate and re-evaluate our suppliers depends on the impact that their products and services have on our products and services.

Management or other designated personnel selects a supplier through one of the following three options:

1. **Customer-Specified Suppliers**

Wherever our customers specify a particular supplier, we use that supplier.

1. **Established Suppliers**

Depending on the type of supplier and the impact of supplied products/services, a pool of pertinent established suppliers is maintained at the local level or at the corporate level in computer systems, lists, files. Management is encouraged to take advantage of prior evaluations and to leverage our corporate purchasing power through the use of established vendors.

1. **New Suppliers**

If the needed product/service cannot be satisfactorily provided by an established supplier, we **evaluate** new suppliers and maintain **records** of the evaluation and resulting action. Depending on impact and cost of the supplied product or service, we evaluate and compare several suppliers.

**Some Suggested Evaluation Criteria:**

General Criteria:

* The supplier has not been disapproved
* Recommendations from other business units
* Performance history (this is often published by the supplier)
* References, customer base, customer testimonials
* Financial stability
* ISO 9001 or other management systems

Product or Service:

* Price
* Extent to which the offered product or service meets our needs
* Additional benefits of the product or service
* Availability and service delivery timelines

Customer Service:

* Responsiveness
* Support capability

Other:

* Logistics capability

**Standardised Criteria**

Management establishes standardised criteria (rather than deciding on criteria on a case-by-case basis) for those types of suppliers that are frequently evaluated.

**Records**

Records of evaluation include the evaluation criteria (or a reference to them), the evaluation outcome, the date of the evaluation, and the name of the evaluating person.

**Extend of Evaluation**

The **extent** to which we evaluate suppliers and consider the above issues depends on the impact of their products/services on our processes, products and services. If there is only **one possible supplier** (i.e., monopoly), an evaluation is only necessary if we consider changing our processes to avoid that supplier.

## Supplier Maintenance

**Purpose:**

To ensure that only qualified suppliers are used.

**Scope:**

Suppliers of products and services. The extent and level of spend of the supplier evaluation depends on the supplier’s impact on our services and company.

**Responsibility:**

Management responsible for purchasing products and services.

**Procedure**

Management maintains a pool of approved suppliers. This pool of approved suppliers may be in form of lists, databases, or within the computer system.

Management establishes a **process** with the support of forms and work instructions for the following:

* **Adding suppliers**

After evaluation, how can individuals add new, qualified suppliers?

* **Removing suppliers**

How can employees communicate bad experience with suppliers and recommend removal from the pool of approved suppliers? How are disqualified suppliers removed from the pool of established suppliers?

* **Re-evaluation**

Do suppliers periodically need to be re-evaluated? Or are suppliers monitored and kept in the pool of approved suppliers unless they are disqualified for some reason?

* **Communication of changes**

Changes to the pool of approved suppliers (especially disqualified suppliers) need to be communicated to those that use suppliers.

## Supplier Contracts and Insurance

**Purpose:**

To ensure that our supplier relations are adequately defined, and that the suppliers’ insurance adequately protects us.

**Scope:**

* The general requirement to establish proper supplier contracts applies to all locations.
* Supplier insurance requirements only in connection with **services**.

**Responsibility:**

* The Facility Officer manages supplier insurance certificates.
* Management responsible for purchasing products and services is responsible that a proper contract template has been established and proof of insurance has been received ***before*** using suppliers.
* Senior Management is responsible for reviews, approvals and secondary record keeping.
* The Facility officer is responsible for all temporary contracts.

**Supplier Insurance**

Supplier insurance requirements only apply in connection with **services** (i.e. in cases in which the service – not the used parts or materials – are the predominant feature).

The Facility officer strives to ensure that we receive proof of insurance (requirements for coverage and for additional insured apply) from service providers *before* using them (no proof of insurance is required from suppliers of products) A template that includes the requirements for coverage and for listing us as additionally insured.

**Overview:**

1. **Request evidence:** Download the Supplier Insurance Certificate and send to service provider, along with the request to send a copy of their insurance certificate showing coverage at least as on the template, and showing us as additionally insured precisely as on the template.
2. **Maintenance:** The Facility officer reviews submitted insurance certificates, monitors them for expiration, and strives to receive renewals. Insufficient insurance is communicated to the affected business unit.
3. **Exemptions & modifications:** Any exemptions and modifications must be approved in writing by Senior Management.
4. **Records:** The Facility officer maintains records of insurance certificates.

**Supplier Contracts**

Management strives to ensure that:

* A written quote is established with each supplier *before* using the supplier, and that
* The written quote adequately and completely defines the ordered product or service (including, where appropriate, requirements for the approval of the product/service, process or equipment; requirements for the qualification of personnel; and quality management requirements).

The signature of the purchasing Manager on the contract or purchase order is an acknowledgement that the manager has reviewed the order.

**Overview:**

1. **Supplier’s Contract Form:** If you are requested to use the supplier’s form:

=> Get Senior Management’s approval!

1. **Modifications:** If any modifications are requested to be made to REDiMED forms:

=> Get Senior Management’s feedback and approval!

1. **Standard Contract Form:** If there is a Standard Contract Form available:

=> Use it and get Senior Management’s approval is not required

1. **Purchase Order:** If you want to buy goods or services once (or infrequently) from a supplier:

=> Use the Purchase Order. (Senior Management’s approval is required)

**Overview:**

All templates are submitted to and reviewed by Senior Management on a case-by-case basis.

**Note:** see section 4.3 for **landlord / tenant lease agreements**.

**Supplier’s Contract Form**

If you cannot use a purchase order or other standard contract form, and if you have not received a written waiver from Senior Management, follow the following steps *before* the supplier is used:

**Step 1:** Forward unsigned contract to Senior Management for review. Senior Management may reject, modify or approve; Senior Management keeps a record of the review.

**Step 2:** For services: request proof of insurance (see above).

**Step 3:** Once approved by Senior Management and once proof of insurance (if applicable) has been received, you may sign the contract

**Step 4:** Retain original signed contract together with proof of insurance (if applicable), and send copy to Management for record keeping.

**Note on Supplier Forms:** Management *never* signs any form submitted by a supplier (including “sales confirmation” or similar) *without prior written approval* from Senior Management because the signing of such form could override the REDiMED Purchase Order form and processes. If such a form is received, it is retained by Management in the same file as our Purchase Order that was issued. So long as the Supplier’s form is not signed, there is no need to consult with Senior Management prior to receipt of goods and services since our Purchase Order will provide necessary Senior Management protection.

1. **Modifications**

If any modifications are made to the terms of our purchase order, to other standard contract forms, or to a previously approved contract, follow the following steps *before* the supplier is used:

**Step 1:** Forward unsigned contract to Senior Management for review. Senior Management may reject, modify or approve; Senior Management keeps a record of the review.

**Step 2:** Only for services: request proof of insurance (see above).

**Step 3:** Once approved by Senior Management and once proof of insurance (if applicable) has been received, you may sign the contract

**Step 4:** Retain original signed contract together with proof of insurance (if applicable), and send copy to Senior Management for record keeping.

1. **Standard Contract Forms**

Where applicable, standard contract forms should be used instead of the Purchase Order.

* Leasing out company equipment (also if no fee is received)
* Sale of company equipment (also if given away for free)
* Motor transportation
* Supplier services (e.g., janitorial, maintenance)
* Additional forms may be added

**Step 1:** Send unsigned standard contract form, together with request for proof of insurance (only for services; see above) to the supplier.

**Step 2:** Once proof of insurance (if applicable) has been received, you may sign the standard contract form without Senior Management’s approval (depending on your established (through Finance) signing authorities).

**Step 3:** Retain original signed contract together with proof of insurance (if applicable), and send copy to Senior Management for record keeping.

**Important:** Do not sign a supplier’s confirmation order or similar document without approval from Senior Management and finance.

1. **Purchase Order**

The Purchase Order is used for a single order of goods or services. The supplier’s sale or service provision constitutes his acceptance of our purchase order terms and conditions.

**Step 1:** Fill in and sign the Purchase Order.

**Step 2:** Provide the supplier with a Purchase Order, together with a request for proof of insurance (services only).

**Step 3:** You may now receive products from the supplier. Suppliers of services may not provide their services until proof of insurance has been received.

**Step 4:** Retain a copy of the Purchase Order together with proof of insurance (if applicable).

## Receiving Inspection of Purchases

**Purpose:**

To ensure that purchased products and services meet our requirements.

**Scope:**

Products and services that have a significant impact on our products and services, or the efficiency of our processes.

**Responsibility:**

* Recipients of purchased products are responsible for inspections.
* Facility Officer and other Management are responsible for defining inspection processes.

**Procedure**

**Receiving inspections**

Recipients of purchased products inspect and verify that they meet the specified purchase requirements. The type and extent of such inspections depends on the terms of supply, and the impact that the purchased products and services have on our products and services.

**Defined inspection processes**

Purchasing Managers and other Management responsible for frequent receipt of purchased products defines a process and establishes instructions and Standard Operating Procedures (if beneficial, in writing) for the inspection and verification of such products and services that have a significant impact on our products and services, or the efficiency of our processes.

**Reducing inspections**

Inspections may be reduced if a supplier has proven to reliably deliver what was ordered.

**Problems**

Where products and services have been determined as not conforming to purchase requirements, see section 8.5 on what to do and what kind of records to keep.

# Production and Service Provision

## Customer Property

**Purpose:**

To ensure that customer property is cared for, and that problems are properly reported.

**Scope:**

All customer property, including items given to us for shipment or other service provision, packaging materials supplied by the customer, personal data of the customer, and intellectual property of the customer.

**Responsibility:**

Management.

**Procedure**

REDiMED exercises care with all customer property while it is under our control or being used by its staff and contractors. REDiMED applies the following measures to achieve care with customer property:

* Identification
* Verification
* Protection and safeguarding

**Reporting Problems to the Customer**

If, however, any customer property is lost, damaged or otherwise unsuitable for use, we immediately do the following:

* Reporting the loss or damage to the customer
* Maintaining records of the customer notification

See section 8.5 for information on how to treat nonconforming products. See section 9.5 for information on corrective action.

## Control of Production and Service Provision

**Purpose:**

To control all processes in order to achieve the intended results.

**Scope:**

All processes in our production and service provision.

**Responsibility:**

Management.

**Procedure**

Management strives to control processes through the following:

**Identify Key Processes**  
Management **identifies** key processes in production and service provision, including process inputs, outputs and interaction with other processes.

Management **defines**, where beneficial (for example, to show to the customer, or new staff to better manage and control the processes), these processes in form of flowcharts, pictures/photos or otherwise in writing.

**Tip:** Flowcharts are best prepared using Microsoft Visio.

1. **Control**

Management implements the following control mechanisms for key processes:

* **Product or Service Characteristics**

Management gives employees **information** that describes the characteristics of the product or service. These characteristics may include metrics and other objectives (see section 9.3).

* **Work Instructions**

Management makes work instructions available where such instructions are **beneficial** (for example, as reminders for rarely performed tasks, to help ensure that no steps are omitted, to achieve exact conformity for very important tasks, to help ensure consistency, as a training aid for tasks that tend to be performed by frequently changing personnel).

Work instructions are prepared in a **format** that is most useful *for the intended user*. Possible formats include flowcharts, written text, forms, checklists, pictures, drawings, samples, screenshots etc.

* **Qualified Personnel**

Management determines necessary **qualifications** and skills for every job position and works to ensure that personnel are qualified, trained and/ or upskilled to enable the performance of job specific work duties, and that records of all training and qualifications are kept (see section 4.2).

* **Proper Equipment**

Management strives to ensure that the equipment used in the process is suitable, in good condition and well maintained (see section 4.4). This includes **measuring equipment**, for which also calibration activities etc. are determined (see section 4.4).

* **Monitoring and Quality Control Inspections**

Management identifies processes that should be monitored, or whose output should be verified through QC inspections. Management establishes necessary monitoring and QC inspections (see section 8.4). See #3 below for processes that cannot be easily verified through monitoring or QC inspections.

* **Release**

Management determines and establishes any necessary activities for the release, including inspections and proper release documentation.

* **Records**

Management determines which records are necessary or required to be kept by law, or by our customers, to provide evidence that our processes meet requirements.

1. **Special Processes**

There are special processes whose output cannot be easily verified by monitoring or QC inspections. This includes processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Management **validates** such special processes *prior to implementation* to ensure that they achieve planned results through the following, as applicable:

* Review of the process and formal process approval
* Formal approval of equipment
* Formal approval of the necessary qualifications of personnel
* Formal approval of specific methods and procedures
* Determination of necessary record keeping
* Determination if and when the process needs to be revalidated

## Information Flow

**Purpose:**

To aid the management of our internal processes, and to meet customer requirements.

**Scope:**

All shipments and customer property.

**Responsibility:**

Management.

**Procedure**

REDiMED identifies and tracks all shipments and other customer property:

**Identification**   
REDiMED identifies shipments and other customer property by tracking and identification numbers that are standard in the transportation industry, and/or by customer or shipper name.

**Tracking**  
REDiMED tracks the location of shipments and the status of service provision to the level of detail that is appropriate to customer needs and internal requirements. This information is made available to the customer as appropriate.

**Monitoring and Measuring**   
Wherever monitoring and measuring activities are performed, REDiMED identifies the status of such activities. This information is made available to the customer as required by contract or otherwise in accordance with medical storage and patient record storage guidelines.

**Records**  
To the extent that traceability is a requirement, REDiMED maintains records of the above described status information.

## Quality Control Inspection and Release

**Purpose:**

To identify quality problems at an early stage and to prevent quality problems from spreading and unintentionally reaching the customer.

**Scope:**

Quality Control inspections can be performed for key processes in production and service provision.

**Responsibility:**

* Management for setting up Quality Control inspections.
* QC inspectors and other designated employees for conducting QC inspections.

**Procedure**

Setting up QC inspections

Management identifies processes that should be monitored, or where process output should be verified through QC inspections. Reports (from the computer system) are often excellent ways of monitoring processes. Management establishes QC inspections under consideration of the following:

* For **which** **processes** are QC inspections appropriate and helpful? Often, QC inspections are performed for processes that have had errors in the past, for complex processes that have a big impact on the overall product or service (e.g. the cooling capabilities of a newly installed air conditioner), for business critical processes (e.g. invoicing), and as final inspections (before release to the customer).
* **Sample size:** is it necessary to inspect 100% or are samples (e.g. only 10%)
* **Frequency:** how often should QC inspections be performed (e.g. monthly samples, constant monitoring, every afternoon before release of product)? The answer to this question goes hand in hand with the issue of sample size (above).
* **Who** should do the inspections (e.g. a designated and unbiased QC inspector, the Supervisor or responsibility allocated employee).
* In many cases, **checklists** are a useful tool for conducting the QC inspection, for recording the results. Management establishes any necessary checklists or other documentation requirements. Documentation should include the name of the QC Inspector.
* Management establishes what to do in case of **non-conformities** (e.g. put on hold and notification of supervisor, immediate correction). See section 8.5.

Conducting Quality Control inspections

Quality Control inspections are to be carried out. The QC inspections as planned, and the results are recorded (including the name of the inspector).

**Records** are maintained.

## Nonconforming Products and Services

**Purpose:**

To prevent nonconforming products and services from further processing or unintended use, and to ensure that they are addressed properly.

**Scope:**

All nonconforming products and services (i.e. products that differ from what was expected or required). Nonconforming products and services could be detected in receiving inspections, QC inspections, or by chance.

**Responsibility:**

* Management for establishing the process.
* Employees for following the process.

**Procedure**

Management strives to ensure that non-conformities (both products and service non-conformities) are:

1. **Prevented from Unintended Use or from Further Processing**

In order to ensure that **non-conforming products** are held until they are properly addressed, nonconforming products are segregated (e.g., in a marked area or designated room) or otherwise identified (e.g. labeled, or placed on hold in the computer system).

Similarly, non-conformities in the **service provision** lead to an interruption of that process until the non-conformity is addressed (e.g. delay billing for a misrouted shipment until the problem has been addressed; delay release notification to the customer in case a damage is found in the final inspection).

1. **Addressed Properly**

Once identified and put on hold, non-conforming products and services are addressed in one or more of the following ways:

* **Correction**

If there was a QC inspection that was not passed initially, there is a re-inspection after the problem is corrected.

* **Authorisation**

Management and where applicable, the customer, may authorise the use, release or acceptance of a non-conforming product / service. Any such authorisations are documented and **records** are kept on file.

* **Different Application**

Management may decide to use the nonconforming product/service for a different application.

**Written Work Instructions**

Where appropriate, Management establishes written work instructions for dealing with nonconforming products or services that may have a significant effect on the customer or our company.

**What if the nonconformity is detected after use or delivery?**

In case a non-conforming product or service is detected only after delivery or use has started, Management takes action appropriate to the (potential) effects of the non-conformity.

**Records**

Records of the nature of non-conformities and their disposition (including concessions obtained) are maintained.

# Measurement and Analysis

## Customer Satisfaction

**Purpose:**

To monitor the customer’s perception as to whether we have met customer requirements.

**Scope:**

External customers

**Responsibility:**

* Department management is responsible to ensure that customer satisfaction is measured. Management may want to delegate to their Client Liaison function.
* Management is responsible for measuring, recording and reporting customer satisfaction.

**Procedure**

**What is measured?**

We measure how the customer **perceives** our performance.

**How can we measure customer satisfaction?**

There are many methods available. Management decides on the most appropriate method. Examples are:

* + Questionnaires (e.g. mail, web based)
  + Approvals
  + Phone interviews
  + Informal and Formal meetings and entertainment
  + Business analysis
  + Compliments or Complaints
  + Use of specialized subcontractors
  + Incident and first aid reports
  + Entertainment events

**How often?**

Typically customer satisfaction is measured at least once a year.

**Records and communication**

Dependent on the method chosen, customer feedback is recorded and shared with the relevant department as well as senior Management that may be affected.

**Customer complaints are recorded**

* All customer complaints are recorded by the individual who receives the complaint (that is, if the complaint did not come in writing).
* Customer complaints are communicated to, followed up and actions recorded by the management of the affected locations and functions.

**Take action**

Management engages in corrective action in response to customer complaints and other unsatisfactory customer satisfaction results. See section 9.4.

## Audit Program

**Purpose:**

To determine if the quality management system meets the requirements of ISO 9001 and this ISO 9001 Quality and Procedures Manual, and if it is effectively implemented and maintained.

**Scope:**

All processes addressed in the ISO 9001 Quality and Procedures Manual at all ISO 9001 certified locations.

**Responsibility:**

* The Quality Manager/Coordinator is responsible for the planning and conducting of audits.
* Management is responsible for correcting identified nonconformities in a timely manner.

**Procedure**

**Audit methods**

The Quality Manager/Coordinator selects the most appropriate audit method for each audit:

* Physical audit visits
* Phone audits

The audit method depends on the importance of the processes and locations to be audited, the cost of travel, and on the results of the previous audit.

**Audit plan**

* **Frequency:** each location is audited once a year (not counting any audits by the quality registrar), or more frequently if the Quality Manager considers it necessary based on the importance of the location and its processes, or on previous audit results.
* **Audit Schedule:** the Quality Manager/Coordinator schedules the audits together with local management for mutually agreeable dates. Scheduled audits are published on the Audit Schedule on the Intranet.
* **Scope:** typically each audit comprises the entire ISO 9001 Quality and Procedures Manual. If an audit comprises less, the Quality Manager ensures that the missing areas are audited within the year through one of the above methods.

**Auditors**

Audits are performed by the Quality Manager/Coordinator, within the Quality and Risk department trained in ISO 9001 auditing. Auditors may not audit their own work. Audits of the audit function are performed by the Quality Manager/Coordinator, within the Quality and Risk department trained in ISO 9001 auditing.

**Audit**

The auditor(s) perform their audit with the aim of receiving truthful answers to the following questions:

1. Does our Quality Management System conform to the planned arrangements (see 6.2)?
2. Does our Quality Management System conform to the requirements of ISO 9001:2008 (which are also reflected in this ISO 9001 Quality and Procedures Manual)?
3. Does our Quality Management System conform to the requirements established by REDiMED?
4. Is our Quality Management System effectively implemented and maintained?

The auditor conducts the audit by interviewing staff and by probing sample processes and/or records.

A typical audit consists of the following:

* Opening meeting in which the audit process is explained
* Verification of effective correction of previously identified non-compliance (unless already verified)
* Auditing according to plan
* Closing meeting in which the audit findings are presented

**Audit report**

The Quality Manager/Coordinator prepares a report for each audit, listing the audit findings, opportunities for improvement and recommended action. Audit reports are maintained on the QMS and Quality and Risk departments secure folders in compliance with our record keeping requirements.

**Correction**

Management works to attain that timely action is taken to eliminate detected non-compliance and their causes. Correction is usually completed **within 3 months**.

**Verification**

The Quality Manager/Coordinator verifies at the time of the next audit that all non-compliance have been adequately addressed.

## Metrics

**Purpose:**

To measure the performance of processes and the ability of meeting requirements as basis of decision-making. Management uses metrics as a tool for decision-making, as well as to report performance.

**Scope:**

Key processes and departments.

**Responsibility:**

Management on all levels uses metrics within their area of responsibility.

**Procedure**

Management uses metrics as a tool for decision-making, as well as to report performance.

* **Process owners:** Management on all levels uses metrics to measure performance of processes for which they are responsible.
* **Site and department management:** establishes site or departmentally specific sets of metrics in form of balanced scorecards covering the business unit or division.

**Balanced scorecard**

Business unit and division management strives to establish a balanced set of metrics that includes metrics from the following areas:

* + **Financial**

Financial metrics include revenue, gross profit, and receivables.

* + **Quality**

Quality metrics include process performance and areas that are important to the customer (e.g. on-time performance, service consistency). They also include supplier performance.

* + **People Productivity**

These include output per employee and voluntary attrition. Staff development and contribution

* + **Customers**

These metrics include number of service, customer complaints, feedback, client care, medical care and customer satisfaction (see section 9.1).

**Benchmarking**

Management uses metrics for benchmarking and to determine trends. In order to do this, metrics are established in form of ratios.

**Targets**

Management establishes specific targets for all metrics (except for those few metrics that are established to look for improvement opportunities without a specific objective in mind). Targets are typically aggressive though realistic and achievable.

**Keeping metrics relevant**

Management periodically revises its metrics to ensure that they remain relevant in an ever-changing environment.

**Recording and reporting**

All key metrics are recorded in form of scorecards *(monthly or quarterly as applicable- annually for performance reviews, customer feedback etc.)* and kept on file. Management shares relevant metrics with their employees.

**Analysis**

Metrics serve as one of Management’s tools for decision-making. As such, Management analyses metrics in order to evaluate where improvements to the business processes and the quality management system can be made.

The analysis typically includes:

* Comparing actual performance with set goals, objectives and plans
* Trends
* Benchmarking

## Corrective and Preventive Action

**Purpose:**

To prevent problems from occurring or recurring by correcting their root cause.

**Scope:**

Process improvement throughout the company.

**Responsibility:**

Management is responsible for corrective and preventive action in their functional areas.

**Procedure**

Corrective and preventive action refers to the improvement of **processes**.

* **Corrective Action**  
  Corrective action addresses problems that have already occurred by correcting the root cause and, thus, preventing the problem from reoccurring in the future.
* **Preventive Action**  
  Preventive action addresses potential problems and prevents them from happening.



Management engages in a formal corrective and preventive action process in order to achieve continual improvement.

1. An existing or potential problem is identified

The corrective and preventive action process starts with the discovery of an existing or potential problem. Existing or potential problems are identified through various sources, including:

* 1. Employee input
  2. Nonconforming processes, products and services
  3. Customer feedback
  4. Audit results
  5. Metrics and their analysis
  6. Management review

**Existing problem:** existing problems are investigated, alternative solutions are explored and actioned appropriately. Appropriate handling may include the immediate correction or repair of that particular problem (note that this is not corrective action, as corrective action addresses the root cause to prevent future recurrences).

**Potential problem:** potential problems and their causes are determined based on various information sources as described above. Again the potential issues are thoroughly investigated, alternative solutions are explored and actioned appropriately to prevent potential problems eventuating.

1. Root cause analysis

Root cause analysis is the systematic identification of the **underlying cause** of a problem. There are many ways to determine the root cause, one of which is the “5 W Approach”:

Ask “why?” five times (e.g., “why did the nonconformity occur?” – “because of xyz.” – “why did xyz occur?” - and so on).

1. Do we need to do anything?

Once the root cause is determined, management evaluates if any action could prevent the problem from occurring or recurring in the future.

Senior management makes an informed decision in consideration of the potential impact the problem may have on customer satisfaction, client care, the absolute importance of safety, and the impact the problem has or may continue to have on the smooth running and reputation of REDIMED: does the benefit justify the cost of the action?

1. Action plan

If Management decides that action is needed, an action plan is made. The action plan includes:

* **Deliverables**  
  The intended results of the action items are defined.
* **Responsibilities**  
  An individual responsible for the implementation of each action item is defined.
* **Deadlines**Due dates for each action item are defined.

1. Action

Management strives to ensure that action is taken according to plan and by the established deadline.

1. Review

Corrective or preventive action is not complete when the action has been performed but rather when the action has been verified as achieving the intended results. Management always reviews the success of corrective and preventive action before it can be closed out. If the results are deemed unsatisfactory, Management considers further action.

1. Records

Management documents the results of the action taken. This can be done in a variety of ways, including Corrective & Preventive Action Plan forms, lists on the QMS and a collection of other documentation addressing the issue.

## Management Review

**Purpose:**

To ensure that the quality management system continues to be effective and suitable for the company and to identify opportunities for improvement.

**Scope:**

* **Management Review:** Management evaluates the performance of the business processes and quality management system at the local or business unit level.
* **Company Management Review:** company management reviews are designed to evaluate the company-wide quality management system. The corporate management review is an opportunity to step back and look at the system as a whole.

**Responsibility:**

* Management is responsible for reviews.
* The Quality Manager is responsible for company management reviews.

**Management Review**

Management reviews evaluate business processes and the quality management system at the local or business unit level with the purpose of making plans for the improvement of the quality management system, processes, products and services, and for determining resource needs.

**Participants**

Management.

**Frequency**

Management establishes the frequency in which reviews are performed.

**Agenda**

The following items are part of management reviews. Note that not all items are necessarily covered in a single review but can be spread out.

1. **Old Business**
2. **Metrics**
3. **Customer Feedback**

Solicited, unsolicited & complaints; strategic changes

1. **Corrective & Preventive Action**

Status of ongoing action; plans for new action

1. **Audits and Self-Inspections**
2. **Process Nonconformities and Damages**
3. **Suppliers**

Performance and cost evaluation

1. **Injury Reports**

Local injuries and relevant injury reports from other locations

1. **Changes**

Company, Management structure, customers and other

1. **Improvement**

Opportunities for service improvements, best practices, and resource & training requirements

1. **Client care**
2. **Medical Standards**

**Records**

Notes of management reviews are kept.

**Corporate Management Review**

Company Management reviews are designed to allow for the evaluation of the entire, company-wide quality management system with the purpose of making plans for the improvement of the company Quality Management System, processes, service offerings, and for determining resource needs.

**Participants**

Executive management.

**Frequency**

Once a year.

**Agenda**

Review of the suitability, adequacy and effectiveness of the **Quality Policy** and **entire Quality Management System**. The review is based on:

* Audit Summary
* Customer Feedback

Corporate customer surveys and summary of local customer feedback

* Metrics
* Changes that could affect the quality management system
* Recommendations for Improvement

Opportunities for service improvements and best practices

**Records**

Notes of company Management reviews are kept.

# Appendix

## ISO 9001 Cross Reference

*Use this section to find particular ISO 9001:2008 requirements in this Manual*

|  |  |  |  |
| --- | --- | --- | --- |
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## Revisions, Exclusions & Legend

**Revision History**

Please see the Quality Management System for a revision history on this ISO 9001 Quality and Procedures Manual.

**Exclusions**

None of the requirements of ISO 9001:2008, section 7, have been excluded.