

Requirements	Look At	Look For	Objective Evidence
7 Product Realization			
7.1 Planning for product realization			
<p>1. Is planning of the organization's product realization consistent with the requirements of the other processes of the quality management system?</p> <p>2. Are the following being determined when planning the product realization:</p> <p>a) Quality objectives and requirements for the product?</p> <p>b) The need to establish processes, documents, and provide resources specific to the product?</p>	<p>Planning for product/service realization</p>	<ul style="list-style-type: none"> * <u>Quality objectives</u> for the product/project/contract (5.4.1) * Documentation: <ul style="list-style-type: none"> - Procedures/Work Instructions (4.2.3) - Identification and communication of significant features of the process * The <u>resources</u> necessary to the product (6.1) * Acceptance criteria for the product 	<p>Manufacturing works to work instructions and checklists. Manufacturing gets involved in the NPDP process during stage 2. They work with engineering</p> <p>Parts are issued a serial number once they get to the first main assembly</p> <p>Acceptance criteria is documented on checklists and work instructions.</p>
<p>c) Required verification, validation, monitoring, inspection and test activities specific to the product and criteria for product acceptance?</p> <p>d) Records needed to provide evidence that the realization processes and resulting product fulfill requirements?</p> <p>3. Is the planning output in a form that is suitable for the organization's method of operation?</p>	<p>Appropriate output of planning</p>	<ul style="list-style-type: none"> * Methods of: <ul style="list-style-type: none"> - Verification - Validation - Monitoring - Inspection - Testing * Analysis, review and improvement of the processes (7.5.2) * Objective evidence/records that realization processes and resulting product meet the stated requirements (4.2.4) * Quality Plan/Control Plan by product/ contract/ product family or process * FMEA * Reliability predictions * Other risk analysis tools 	<p>Manufacturing employees can make improvement suggestions to manufacturing engineering at any time. Manufacturing engineering reviews the idea validates and tests it. If the new process is validated the work instruction will be changed and re-released.</p>
7.2 Production and service provision			
7.5.1 Control of Production and Service provision			
<p>44. Are the production and service provision planned and carried out under controlled conditions including:</p> <p>a) Availability of information that describes the product characteristics?</p> <p>b) Availability of work instructions, as necessary?</p> <p>c) Use of suitable equipment?</p> <p>d) Availability and use of monitoring and measuring devices?</p> <p>e) Implementation of monitoring and measurement?</p> <p>f) Implementation of release, delivery and post-delivery activities?</p>	<p>Realization carried out under controlled conditions</p>	<p>a. Product characteristics information available to production</p> <p>b. Work instructions if necessary</p> <p>c. Suitable equipment</p> <ul style="list-style-type: none"> - Maintenance * Control of NC programs and other software <p>d. Available monitoring and measuring devices and instructions:</p> <ul style="list-style-type: none"> - Process sheets - Inspection instructions - Shop travelers - Test procedures - Standard operating sheets <p>e. Implementation of monitoring and measurements</p>	<p>Manufacturing works to work instructions and checklists. Manufacturing gets involved in the NPDP process during stage 2. They work with engineering to develop processes and testing methods. Once processes are created they are verified and checked by someone other than the creator.</p>

		f. Release, delivery and post-delivery activities.	
7.5.2 Validation of processes for production and service provision			
45. Have processes where deficiencies may become apparent only after the product is in use or the service has been delivered been validated?	The validation methods used to ensure that the processes can achieve planned results. (Including "Special" processes)	* Process documentation and records	Planned results are assured through the work instructions and checklists.
46. Do the results of validation demonstrate the ability of the processes to achieve planned results?		- Use of run charts	
47. Where applicable, have the arrangements been established for:		- Capability [Process Capability Analysis]	
a) Defining criteria for review and approval of processes?		* Criteria for review and approval of processes	
b) Approval of equipment and qualification of personnel?		* Approval of equipment	
c) Use of specific methods and procedures?	* Qualification of personnel	There are also training records of all employees.	
d) Requirements for records?	* Specific methods and procedures	Folders are kept for each serial number. Reachback scans in the folders for computer accessibility.	
e) Re-validation?	* Records, as required		
	* Planned revalidation of processes		
7.5.3 Identification and traceability			
48. Is the product identified by suitable means throughout product realization?	Identification of the product throughout the realization process	* Documentation:	Products are accompanied by a folder including all required checklists and a serial number. Reviewed a folder, it had checklist and a serial number.
49. Is the product status identified with respect to monitoring and measurement requirements?		- Move tickets	
50. When traceability is a requirement, is the product uniquely identified and controlled?	- Identification labels		
51. Is the unique identification maintained as a record?	- Location identification		
	Identification of product status	Documentation: - HOLD tickets Records: - Completed test forms, logs - Completed operation tickets	
	Traceability requirements	* Lot locations * Lot control * Lot orientated picking lists * Customer/regulatory requirements	
7.5.4 Customer property			
52. Does the organization exercise care with customer property while it is under the organization's control or being used by the organization?	Care of customer property, including intellectual property and tooling	* Copyright protection	NA
53. Is customer property identified, verified, protected, and safeguarded?		* Identification	
54. If lost, damaged or otherwise found to be unsuitable for use, is condition recorded, reported to the customer and maintained as a record?		* Verification	
	Notification to customer in the event of loss or damage or	* Safeguarding/protecting * Customer notifications, reports, logs * Records	
7.5.5 Preservation of product			
55. Is conformity of product preserved during internal processing and delivery to the intended destination?	Methods to preserve the conformity of the product (including constituent parts) during internal processing and delivery)	* Identification	All parts are properly identified. All employees are trained in proper handling, such as the ESD training
56. Does preservation activities include:		* Handling	
a) Identification?		* Packaging	
b) Handling?		* Storage	
c) Packaging?	* Protection		
d) Storage?			

e) Protection?

57. Are preservation activities applied to constituent parts of a product?

8 Measurement, Analysis and Improvement

8.2 Monitoring and measuring

8.2.4 Monitoring and measuring of product

16. Are product characteristics monitored and measured to verify that product requirements are met?

17. Is monitoring and measurement of product characteristics carried out at appropriate stages of the product realization process in accordance with the planned arrangements?

18. Is evidence of conformity with the acceptance criteria documented and maintained?

19. Are records maintained to indicate the person(s) authorizing release of product?

20. Unless otherwise approved by a relevant authority or where applicable, the customer, are all planned arrangements satisfactorily completed prior to proceeding with release?

Verification that product meets requirements

Evidence of conformity with the acceptance criteria

Authority for release of product

Product release

* Measurement characteristics of the product
* Verification at suitable stages in the process according to the quality plan (7.1)

* Check sheets
* Test logs
* Final test certificates

* Record
* Authorization

* All aspects of the quality plan satisfied.
* If not, approval by relevant authority or customer

Products are tested. These test are documented thru checklists and files maintained on the system.

Requirements	Look At	Look For	Objective Evidence
INTRODUCTION			
8.2.2 Internal Audit			
<p>5. Are internal audits conducted at planned intervals to determine whether the quality management system:</p> <p>a) Conforms to planned arrangements, requirements of ISO 9001 and the quality management system?</p> <p>b) Is effectively implemented and maintained?</p> <p>6. Are the audit programs planned taking into consideration the status and importance of the processes and areas to be-audited, as well as the results of previous audits?</p> <p>7. Is the audit criteria, scope, frequency and method defined?</p> <p>8. Do auditor selection and conduct of audits ensure objectivity and impartiality of the audit process?</p> <p>9. Is it ensured that auditors do not audit their own work?</p>	<p>Effective Internal Audit process (ISO 19011)</p>	<ul style="list-style-type: none"> * Planned * Audits the complete qms * Schedule based upon importance and status * Audit reports and results of audits * Definition of audit scope, criteria, frequency, strategy * Trained internal audit team * Impartiality and objectivity of the audit process * A system that precludes auditors from auditing their own work: <ul style="list-style-type: none"> - Not related to the process owner - Have no responsibility for the bottom line of the area - Does not take work instructions from the process owner 	<p>Audit was completed by a third party auditor. Third party auditor reviewed and audited each section of the quality management system.</p>
<p>10. Has a documented procedure been established to define responsibilities and requirements for planning and conducting audits, reporting results, and maintaining records?</p> <p>11. Have management responsible for the area being audited ensured that actions have been taken without undue delay to eliminate detected nonconformities and their causes?</p> <p>12. Do follow-up activities include the verification of the actions taken, and the reporting of the verification results?</p>	<p>Documented responsibilities and requirements for planning and conducting audits and for reporting results and retaining records</p>	<p>A documented procedure:</p> <ul style="list-style-type: none"> * Defined management responsibility * Timely corrective action * Follow up verification of the corrective action and reporting of the corrective action. 	<p>A process exists for internal auditing. The process is not presently being followed. Follow-up of audits are being completed through the Corrective action Process not QMF 03.</p>
	Records	Detected nonconformities and their causes	

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Quality and Procedures Manuals

Smiths Detection

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Danbury, CT 06810
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Quality Manual

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**Valid Only:
1/20/2011**

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This document is approved for use _____

SMITHS DETECTION

Copy Holder

Copy Holder: Quality System Management Representative

Copy Number: 1

This Quality Manual covers the activities and functions performed by operating areas included in the service scope definition:

The design, development, manufacture and service of monitoring and detection systems for hazardous chemical, biological and gaseous systems.

The Quality Management System is designed to meet the requirements of

ISO 9001: 2008

CA

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SMITHS DETECTION

Distribution

Quality Manual

Copy Number 1 – SMITHS DETECTION (Electronic read only)

Copy Number 2 – SMITHS DETECTION (QMR Master)

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SMITHS DETECTION

Manual Contents

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SMITHS DETECTION

Amendments

All copies of this Quality Manual must be kept under strict control to prevent the system from becoming unreliable. The following procedures will ensure that the system remains current and valid.

- 1) All copies of the Quality Manual will be clearly numbered and the holder recorded.
- 2) Each page in the Quality Manual will carry its own number.
- 3) The Quality Management Representative will be responsible for all revisions and additions being recorded.
- 4) Changes can be suggested by any employee, but must receive signed approval before being entered into the Quality Manual.
- 5) Proposed changes to the Quality Manual will be referred to the Management Review Meeting for approval.
- 6) All changes must be recorded on the Amendments List (QM 04, Page 5 of 17) and appropriate pages in each Quality Manual changed.
- 7) The Quality Manual is not distributed in its controlled form to any other location, but may be issued in uncontrolled form to any location. Any uncontrolled copy shall be distributed as "UNCONTROLLED – VALID ONLY", followed by the date. No records need to be maintained on the issuance of uncontrolled copies of the Quality Manual.

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Table of Amendments - Quality Manual					
Document Number	Page Number	Issue	Date	Description of Change	Authorization
QM07	8	2	3/11/2009	Added New Org Charts	G. Genna
QM06	7	2	3/11/2009	Changed Incorrect QM Number	G. Genna
QM04	5	2	3/11/2009	Rev Table of Contents after changes	G. Genna
QM07	8	3	4/2/2009	Added New Org Charts	G. Genna
QM04	5	3	4/2/2009	Rev Table of Contents after changes	G. Genna
QM07	8	4	5/26/2009	Added New Org Charts	G. Genna
QM04	5	4	5/26/2009	Rev Table of Contents after changes	G. Genna
QM06	7	3	5/28/2009	Updated Policy	G. Genna
QM04	5	5	5/28/2009	Rev Table of Contents after changes	G. Genna
QM01	1	2	6/10/2009	Updated Scope	G. Genna
QM08	17	2	6/10/2009	Added reference to procedures	G. Genna
QM04	5	6	6/10/2009	Rev Table of Contents after changes	G. Genna
QM07	8	5	6/25/2008	Added new org charts	G. Genna
QM04	6	7	6/25/2009	Rev Table of Contents after changes	G. Genna
QM07	8	6	4/23/2010	Added new org charts	G. Genna
QM04	6	8	4/23/2010	Rev Table of Contents after changes	G. Genna
QM06	7	4	5/11/2010	Change QMR	J. Davis
QM04	6	9	5/11/2010	Rev Table of Contents after changes	J. Davis
QM07	8	7	7/1/2010	Removed Date of Org chart	J. Davis
QM04	6	10	7/1/2010	Rev Table of Contents after changes	J. Davis

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SMITHS DETECTION

Organization Profile

SMITHS DETECTION ("The Organization"), part of the Smiths Group, offers security solutions based on trace detection equipment, X-ray screening systems and other proven and developing technologies. The organizations detection equipment is used by military forces and public service workers who need to be equipped for chemical agent detection and biological warfare agent identification; by staff responsible for airport security, transportation security and critical infrastructure security; by customs officers responsible for contraband detection and cargo security (based on x-ray screening), and by the emergency services. Related products service the life sciences, veterinary and food manufacturing industries.

Smiths Detection is a world leader in transportation security, notably airport x-ray systems used in the search for illegal and dangerous items or for explosives detection in checked baggage, hand-baggage or on passengers themselves. The Organizations specialist software supply business allows the management of large sensor and video surveillance networks.

Smiths Detection is proud of its record of providing and maintaining high quality in both product and service to its customers. This is accomplished through a tight product quality assurance program to guarantee specification, conformance and reliability. The quality program is controlled from receipt, production, inspection and distribution of their product to agreed delivery schedules.

The Organization's use of experienced customer service and product specialists to evaluate customer requirements across a range of supply and manufacturing options often leads to improved product specification at reduced prices. The Organization's ability to customize further enables a solution to be value engineered and cost effective, without sacrificing quality and fitness for the intended application.

Smiths Detection support's their service capability by a strong partnership with selected product, component & service providers enabling a complete auditable service where application performance, delivery and product cost can be matched to each application.

An essential requirement of the Organization's objective to continually improve its customer service performance is the installation of a quality system registered to ISO 9001:2008.

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SMITHS DETECTION
Quality Policy

Smiths Detection Inc. recognize that the disciplines of quality, health/safety and environmental management are an integral part of its management function. The Organization views these as primary responsibilities and as keys to good business in adopting appropriate quality standards.

The Organization's quality policy calls for continual improvement in its quality management activities and business will be conducted according to the following principals.

The Organization will:

- Comply with all applicable laws, regulations and requirements.
- Follow a concept of continual improvement and make best use of our management resources in all quality matters.
- Communicate our quality objectives and performance against these objectives throughout the Organization and to interested parties.
- Take due care to ensure that activities are safe for employees, customers, suppliers and any others who come into contact with our work.
- Work closely with our customers and suppliers to establish the highest quality standards.
- Adopt a forward-looking view on future business decisions that may affect quality.
- Train our staff in the needs and responsibilities of quality management.

It is Smiths Detection aim that with the total involvement of all staff through the implementation and ongoing development of a documented Quality Management System meeting the ISO 9001:2008 standard we will exceed the expectations of our customers, staff and investors.

Signed: _____
 Bob Bohn, General Manager

Signed: _____
 Joy Davis, Quality Management Representative

Date: 5/11/2010

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Smiths Detection
Organization and Responsibilities

See Organizational Charts As Attached

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Quality Management System Requirements

4.0 Quality Management System (PRM01, PRM09)

4.1 General

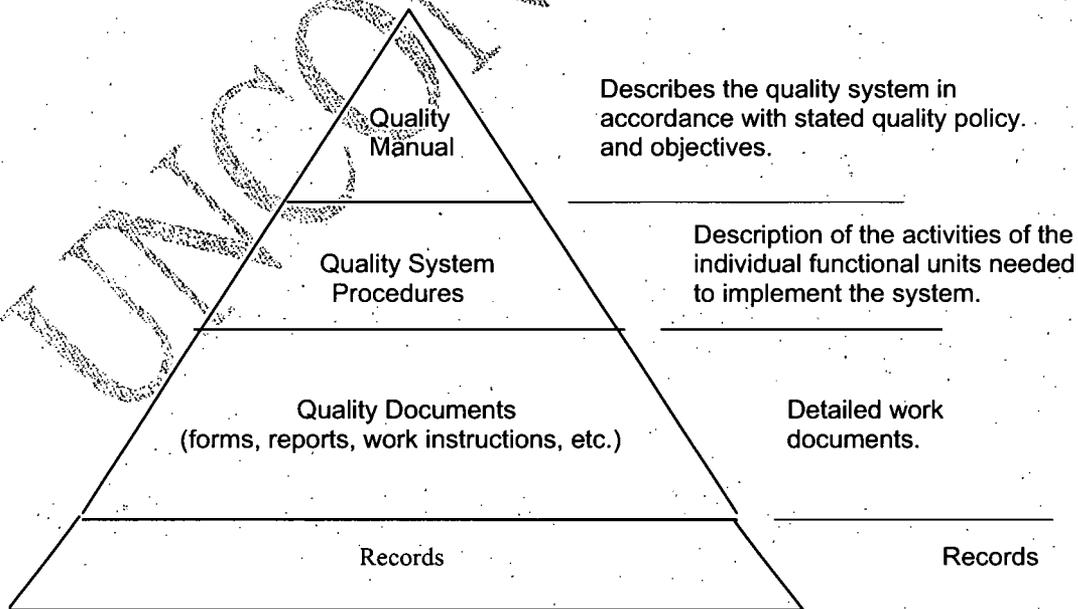
Smiths Detection Inc. are committed to maintaining an effective quality management system.

This manual has been prepared to satisfy the requirements of ISO 9001:2008 for quality management systems for the activities carried out at the site.

Wherever possible, quality controls have been integrated into existing systems (environment, health and safety) and cross-referenced for ease of interpretation.

The effective implementation of the quality management system will be verified by regular inspections, reviews and audits that will compare management practice against the requirements of the written procedures for quality management system standards. Corrective action will be taken where necessary and will be subsequently reviewed for effectiveness.

The system is structured as below



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Quality Management System Requirements

4.2 Documentation (PRM 02)

- 4.2.1 The Organization has written its quality policy and procedures as appropriate for its size, type and complexity. The quality policy is available to all employees.
- 4.2.2 The Organization has prepared and maintains a controlled quality manual that defines the scope of its activities supported by documented procedures.
- 4.2.3 A documented procedure ensures that all relevant quality documentation is controlled, reviewed, updated and approved as necessary. The Organization ensures that quality documentation is legible and retrievable, and located where necessary. The status of quality documents is identified; obsolete quality documents are clearly identified to prevent unintended use. Where quality documents originate from outside the Organization, these documents are identified and controlled.
- 4.2.4 Procedures are in place for the identification, storage, retrieval, protection, retention and disposition of quality records.

5.0 Management Responsibility (PRM 03)

5.1 Commitment

Top management of the Organization will ensure that all employees and subcontractors are aware of the need to meet customer and regulatory requirements and that the necessary resources are available. Quality policy and objectives are kept up-to-date via regular management review.

5.2 Customer Focus

Top management ensures that its customer needs and expectations are properly determined and fulfilled so the Organization can achieve customer satisfaction. Due consideration is also given to product, service and regulatory/ legal requirements.

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Quality Management System Requirements

5.3 Policy

The Organization has established, through its quality policy, the need to meet customer requirements and continually improve its products and services. Quality objectives are reviewed for continuing suitability and communicated as appropriate throughout the organization.

5.4 Planning

The Organization has ensured that all relevant functions and levels within the organization have clear, measurable quality objectives that are consistent with the Organization's quality policy and product requirements. Adequate resources are available and output is planned in a controlled manner as required by its quality management system, being mindful of the need for continual process improvement.

5.5 Administration

5.5.1 Details of the Organization's quality management system are documented. Elements of the quality management system have been defined and communicated wherever quality is affected.

5.5.2 Representatives have been appointed who have the authority and responsibility to ensure that the quality management system is established and maintained, and that reports on the performance of the system (and on any need for improvement) are made available to the Quality Management Representative. The significance of meeting customer requirements is understood.

5.5.3 Communication between all levels and functions are set to ensure the effectiveness of the processes of the quality management system.

5.6 Management Review

5.6.1 The complete quality management system is reviewed at planned intervals to evaluate the need for change and ensure its continuing suitability, adequacy and effectiveness.

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Quality Management System Requirements

5.6 Management Review (continued)

5.6.2 The review includes the evaluation of current performance and improvement opportunities based on quality audits, customer feedback, process improvement, product performance, follow-up from previous meetings, and any changes that could effect product or service quality.

5.6.3 All results of management review activity are recorded.

6.0 Resource Management (PRM 04)

6.1 Provision of Resources

The Organization has ensured that the necessary resources needed to implement and improve the quality management system and to address customer satisfaction are available.

6.2 Human Resources

6.2.1 Where personnel are assigned quality responsibilities, the Organization has ensured that they are competent on the basis of applicable education, training, skills and experience.

6.2.2 The Organization has identified the training needs for quality related activities and provides training to satisfy these needs. Performance is evaluated, and appropriate training records are maintained.

6.3 Facilities

Suitably equipped workplaces with appropriate hardware/ software and supporting services are provided.

6.4 Work Environment

All aspects of the human and physical factors of the work environment that affect the conformity of product or service have been identified and are managed.

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Quality Management System Requirements

7.0 Product Realization (PRM 05, PRM 06, PRM 07, PRM 08, PRM 13)

7.1 Planning of Realization Process

The production process for the Organization's products and services is planned and documented as defined in the quality management system. Quality objectives, resources, processes and documentation needs are stated, and acceptable criteria for verification and validation are defined. Records appropriate to the level of confidence required for the process (and the product or service) are maintained.

7.2 Customer Related Processes (PRM 05)

7.2.1 The needs of the customer with regard to availability, delivery and support are considered along with the product's intended use. In addition, regulatory and legal requirements are determined and satisfied.

7.2.2 The Organization reviews its customers' requirements and determines any additional requirements for each contract or order. Where no customer requirements are documented, details are confirmed before acceptance of the order or contract. Any changes to contracts or quotations are resolved before proceeding, and the Organization's ability to meet the defined requirements is confirmed.

7.2.3 The customer is kept informed of product information, inquiries, order changes/ amendments and progress on customer complaints.

7.3 Design and / or development (PRM 13)

7.3.1 When the Organization is not working to pre existing design, the Organization's product is designed and developed through a formal design, development, and change order process.

7.3.2 The customer's requirements, past design experience and statutory and regulatory requirements appropriate to the intended destination of the product are inputs into the design process.

7.3.3. Appropriate level of design approval from the customer is a requirement of the design process.

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Design and development (continued)

7.3.4. The Organization insures control over designs through a structured part document numbering and document storage system, structured revision control and engineering change process.

7.3.5. All designs are assembled and tested prior to release to the customer. Final testing may occur at the customers premises.

7.4 Purchasing (PRM 07)

7.4.1 The Organization controls its purchasing function to ensure that the purchased product conforms to requirements. Suppliers are selected against defined criteria and are subject to planned review and evaluation. The results of evaluations and follow up actions are recorded.

7.4.2 Purchasing documents are reviewed before release for the adequacy of information on product, procedures, processes, equipment and personnel.

7.4.3 The Organization verifies its purchased products.

7.5 Production and Service Provisions (PRM 06)

7.5.1 Production and service operations are planned and controlled through procedures, product specifications, work instructions, suitable equipment and proper maintenance. Measuring and monitoring activities, final inspection and delivery processes are defined in procedures and instructions.

7.5.2 Where verification of product or service cannot be ensured during the process by measuring and monitoring, control is exercised by qualification of the process, equipment and personnel through defined methods, procedures, records and re-validation if required.

7.5.3 Where appropriate, the Organization identifies the product throughout the production and service activities and identifies its status with respect to measuring and monitoring activity. Where traceability is required, the unique identification of the product is controlled and recorded.

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7.5 Production and Service Provisions (continued)

7.5.4 Where customer property for inclusion in the product comes within the Organization's control, it is identified, verified, maintained and protected with details of adverse condition reported to the customer.

7.5.5 The Organization preserves the conformity of the product or service from receipt of order to delivery.

7.6 Control of Measuring and Monitoring Devices (PRM 08)

Measuring and monitoring devices are identified throughout the Organization where quality is affected, and the devices used are controlled to appropriate standards for consistency. The devices are protected against random adjustments, damage and deterioration, and the results of calibrations are recorded.

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Quality Management System Requirements

8.0 Measurement, Analysis and Improvement (PRM 10, PRM 11, PRM 12, PRM 14)

8.1 Planning

The requirement for defining methods and equipment for measurement and monitoring products and processes has been recognized. The procedures for utilizing such methods and equipment have been determined.

8.2 Measurement and Monitoring (PRM 12)

8.2.1 Clear methods have been established to audit customer satisfaction and identify any failures to meet Organization standards.

8.2.2 Suitably trained personnel conduct periodic independent internal audits on a planned basis. All aspects of internal audits are recorded and reviewed, and corrective action taken where necessary.

8.2.3 Processes effecting customer requirements are periodically reviewed to ensure that the requirements are being met.

8.2.4 Measuring and monitoring of the product throughout the process is designed to ensure that the finished product meets specifications and authorized personnel control its release for delivery.

8.3 Control of Non-conformity (PRM 10)

Documented procedures are in place to identify and isolate non-conforming products, and before the corrected or accepted non-conforming item is returned to the process, it is re-checked. In the event non-conforming product mistakenly reaches the customer, appropriate corrective action is taken.

8.4 Analysis of Data (PRM 11, PRM 12, PRM 14)

Data referring to product quality problems are collected and analyzed, and where changes to the quality management system offer improvements, these changes are introduced. Areas for attention are customer complaints, meeting the customer's needs, product characteristics and supplier performance.

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Quality Management System Requirements

8.5 Improvements (PRM 12)

8.5.1 The quality management system is managed in a manner to offer continual improvement, consistent with the quality policy, quality objectives, audit results, data analysis, corrective/preventive actions and management review.

8.5.2 Appropriate action is taken to rectify faults/weaknesses and prevent their recurrence. Any actions involving procedural changes, are documented. Requirements for identifying faults, determining their cause and developing appropriate corrective action is covered and recorded, with the results reviewed.

8.5.3 The Organization identifies preventive actions to preclude the recurrence of non-conformities and problems. The processes to develop/implement preventive actions are set out in procedures, and the results of such actions are recorded and reviewed for effectiveness.

9.0 Procedure Reference

PRM 00	Control Documentation
PRM 01	Quality Management System
PRM 02	Document Control and Records
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Procedures Manual

Smiths Detection

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CONTROL DOCUMENTATION (ISO 9001:2008. Clause 4.2.3)

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Distribution

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Amendments

All copies of this Procedures Manual must be kept under strict control to prevent the system from becoming unreliable. The following procedures will ensure that the system remains current and valid.

1. All copies of the Procedures Manual will be clearly numbered and the holder recorded.
2. Each page in the Procedures Manual will carry its own number.
3. The Quality Management Representative will be responsible for all revisions and additions being recorded.
4. Changes can be suggested by any Employee, but must receive signed approval before being entered into the Procedures Manual.
5. Proposed changes to the Procedures Manual will be referred to the management review meeting for approval.
6. All changes must be recorded on the relevant Amendments List (PRM 00, Pages 05 of 07 and 06 of 07) and the appropriate pages or documents in the Procedures Manual changed.
7. The Procedures Manual is not distributed in its controlled form to any other locations, but may be issued in uncontrolled form to any location. Any Uncontrolled copy shall be distributed as "UNCONTROLLED". No records need to be maintained of the issue of uncontrolled copies of the Procedures Manual.

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PRM 00	Control Documentation
PRM 00A	Forms List
PRM 01	Quality Management System
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PRM 06	Process Control
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Table of Amendments - Procedures Manual					
Document Number	Page Number	Issue	Date	Description of Change	Authorization
PRM05	1	2	3/17/09	Change National Sales Manager to BU Manager, Remove "TOM" System references, Update procedure for QMF08a, Change verbiage In 4.3.1.1, update process in 4.3.1.4	G. Genna
PRM00	5	2	3/17/09	Issue Update for Revisions	G. Genna
PRM00	6, 7, 8	3	4/13/09	Issue Update for Revisions	G. Genna
PRM00	6, 7, 8	4	4/14/09	Issue Update for Revisions	G. Genna
PRM07	5-6	2	4/21/09	Update/ Correct Flow Charts	G. Genna
PRM00	4-5	5	4/21/09	Issue Update for Revisions	G. Genna
PRM00	5-9	6	4/22/09	Issue Update for Revisions	G. Genna
PRM01	2,4	2	5/11/09	Added 4 th level of pyramid, Updated and corrected interaction matrix	G. Genna
PRM00	5, 7, 8	7	5/11/09	Issue Update for Revisions	G. Genna
PRM02	2-3	2	5/11/09	Added Document Control Matrix	G. Genna
PRM05	7	3	5/12/09	Removed 4.4.5, 4.4.6, 4.4.7	G. Genna
PRM11	1-4	2	5/12/09	Changed procedure to reflect corrective action and removed Preventative action to make new procedure (PRM14)	G. Genna
PRM00	5	8	5/12/09	Issue Update for Revisions	G. Genna
PRM14	ALL	1	5/13/09	Initial Release New Procedure	G. Genna
PRM04	ALL	2	5/13/09	Updated procedure to reflect current practice	G. Genna
PRM10	ALL	2	5/20/09	Updated procedure to reflect current practice and clear audit non-conform	G. Genna
PRM07	ALL	3	5/20/09	Update procedure to reflect current Practice and clear audit non-conform	G. Genna
PRM06	ALL	2	5/21/09	Update procedure to reflect current Practice and clear audit non-conform	G. Genna
PRM00	ALL	9	5/22/09	Issue Update for Revisions	G. Genna
PRM07	ALL	4	6/9/09	Updated Procedure to reflect current Practice.	G. Genna
PRM00	ALL	10	6/9/09	Issue Update for Revisions	G. Genna
PRM01	ALL	3	6/11/09	Update Interaction Matrix	G. Genna
PRM08	ALL	2	6/11/09	Updated procedure	G. Genna
PRM00	ALL	11	6/11/09	Issue Update for Revisions	G. Genna
PRM00	10	12	6/23/09	Added New Form	G. Genna
PRM06	ALL	3	6/25/09	Added Haz WI Numbers	G. Genna
PRM00	ALL	13	6/25/09	Issue Update for Revisions	G. Genna

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PRM 00	ALL	14	9/2/09	Various Form Updates	G. Genna
PRM00	ALL	15	4/23/10	Various Form Updates	G. Genna
PRM00	ALL	16	5/4/10	Updated Forms and Table of Content Issue numbers	J. Davis
PRM00	ALL	17	5/10/10	Updated Forms and Table of Content Issue numbers	J. Davis
PRM00	ALL	18	5/13/10	Updated Forms and Table of Content Issue numbers	J. Davis
PRM07	ALL	5	5/14/10	Updated to reflect corporate procurement	J. Davis
PRM00	ALL	19	5/14/10	Updated Table of Content Issue numbers	J. Davis
PRM00	ALL	20	5/18/10	Updated Forms and Table of Content Issue numbers	J. Davis
PRM00	ALL	21	5/20/10	Updated Forms and Table of Content Issue numbers	J. Davis
PRM00	ALL	22	5/26/10	Updated Forms and Table of Content Issue numbers	J. Davis
PRM00	ALL	23	5/28/10	Updated Forms and Table of Content Issue numbers	J. Davis
PRM10	ALL	3	5/28/10	Updated Process to Reflect New forms	J. Davis
PRM00	ALL	24	6/3/10	Updated Forms and Table of Content Issue numbers	J. Davis
PRM00	ALL	25	6/8/10	Updated Forms and Table of Content Issue numbers	J. Davis
PRM 07	ALL	6	6/10/10	Updated Supplier Approval Process	J. Davis
PRM 06	ALL	4	6/10/10	Removed WI made Appendix	J. Davis
PRM00	ALL	26	6/10/10	Updated Forms and Table of Content Issue numbers	J. Davis
PRM00	All	27	6/17/10	Updated Forms and Table of Content Issue numbers	J. Davis
PRM03	All	2	6/17/10	Removed reference to QMF03 and QMF19	J. Davis
PRM09	All	2	6/17/10	Removed reference to QMF03 added reference to QMF04a	J. Davis
PRM11	All	3	6/17/10	Removed reference to QMF19	J. Davis
PRM14	All	2	6/17/10	Removed reference to QMF19	J. Davis
PRM02	All	3	6/17/10	Removed QMF20 Referred to the global policy	J. Davis
PRM00	All	28	6/29/10	Updated Forms and Table of Content Issue numbers	J. Davis
PRM00	All	29	7/13/10	Separated Procedures, Added Amendments to each procedure, Changed forms to be Procedure PRM00A	J. Davis

Quality Assurance Master Form and Document Register

<u>Document</u>	<u>Description</u>	<u>Date</u>	<u>Issue No.</u>
QMF 01	New Hire Checklist	03.10.09	1
QMF 01A	Training Matrix (Example)	03.10.09	1
QMF 02	Internal Quality Audit Programme	06.29.10	3
QMF 03	Open		
QMF 04	Complaints/ Non-conformance Register	11.01.10	3
QMF 04A	QCAR Report	11.01.10	2
QMF 05	Measuring and Monitoring Equipment Register	05.20.10	4
QMF 05A	Maintenance Log	03.10.09	1
QMF 06	Management Review Agenda	06.08.10	2
QMF 07	Customer Questionnaire	03.10.09	1
QMF 08	Sales Logix "Opportunity" Record (Example)	03.17.09	2
QMF 08a	Sales Order Entry Checklist	03.23.09	3
QMF 09	Quotation (Example)	03.17.09	2
QMF 10	SAP Order Confirmation (Example)	03.31.08	1
QMF 10a	SAP Delivery Document	03.31.08	1
QMF 10b	SAP Purchase Order (Example)	03.31.08	1
QMF 11	Open Sales Order Report (Example)	03.23.09	2
QMF 11a	Daily Operations Meetings	06.03.10	5
QMF 12	Bill of Materials (BOM) (Example)	03.10.09	1
QMF 13	Non-Conforming Material Request	09.02.10	4
QMF 13A	Non-Conforming Material Supplier Request	09.02.10	2
QMF 14	Hazmat ID Performance Test Log	03.10.09	3
QMF 14A	Performance Test Plan for HazMatID Units	11.18.10	5
QMF 14B	HazMatID 360 Shipping Check List	11.22.10	1
QMF 14C	HazMat ID Checklist	08.17.10	3
QMF 14D	Performance Validation (Example)	03.10.09	1
QMF 14E	IdentifyIR/TravellIR II Performance Test Log	11.17.10	1
QMF 14F	HazMat ID Shipping Checklist	09.09.10	8
QMF 14G	DoD HazMat ID Shipping Checklist	11.18.10	9
QMF 14H	International HazMat ID Shipping Checklist	09.09.10	10
QMF 14I	International HazMat ID Shipping Checklist	09.09.10	7
QMF 14J	DoD Command System HazMat ID Shipping Checklist	10.26.10	9

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QMF 14K	Command System HazMat ID System Check List	10.26.10	9
QMF 14L	DoD Extended Package HazMatID Shipping Checklist	10.26.10	9
QMF 14M	Extended Package HazMatID Shipping Checklist	10.26.10	9
QMF 14N	RepeatIR Shipping Checklist	03.10.09	1
QMF 14O	Performance Test Plan for GasID Units	08.17.10	3
QMF 14P	GasID Performance Test Log	03.10.09	1
QMF 14Q	GasID Checklist	09.30.10	3
QMF 14R	GasID Basic System Shipping Checklist	06.08.10	4
QMF 14S	GasID Partnership Package Shipping Checklist	06.08.10	4
QMF 14T	GasID International System Shipping Checklist	07.23.10	5
QMF 14U	GasID International System Shipping Checklist	12.15.09	3
QMF 14V	IdentifyIR/TravellIR II Checklist	11.17.10	1
QMF 14W	Responder Performance Validation Report	06.10.10	2
QMF 14X	Responder Performance Validation Report (Comm)	06.10.10	2
QMF 14Y	HGVI Manufacturing and Quality Database Form	03.10.09	1
QMF 14Z	HazMat ID TM Checklist	03.20.09	2
QMF 14AA	Responder QC Checklist	09.02.09	2
QMF 14AB	HazMatID TM Shipping Checklist - 1011	09.09.10	3
QMF 14AC	HazMatID TM Shipping Checklist - 1015	09.09.10	4
QMF 14AD	Ranger Packing List 026-1005	05.13.10	1
QMF 14AE	Ranger Test Sheet	11.09.10	2
QMF 14AF	Ranger – Manufacturing and Specification Test Sheet	03.25.09	1
QMF 14AG	Responder Checklist	12.28.10	6
QMF 14AH	IdentifyIR Shipping Checklist	11.17.10	1
QMF 14AI	ExtractIR Sample Prep Kit Check List	03.10.09	1
QMF 14AJ	ExtractIR Replacement Kit Check List	03.10.09	1
QMF 14AK	TravellIR II Shipping Checklist	11.17.10	1
QMF 14AL	Responder BLS Packing List	10.27.09	1
QMF 14AM	Ranger Packing List 026-1001	05.13.10	1
QMF 14AN	Ranger Packing List 026-1002	05.13.10	1
QMF 14AO	Command System HazMat ID System Checklist (EOD)	10.26.10	7
QMF 14AP	HGVI Shipping Checklist	06.15.09	1

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QMF 14AQ	Responder Checklist	03.10.09	1
QMF 14AR	Accessories Checklist	07.14.09	1
QMF 14AS	Performance Validation Report	05.13.10	1
QMF 14AT	HGVI Shipping Checklists	11.22.10	1
QMF 14AU	HGVI LinX Shipping Checklist	11.22.10	1
QMF 14AV	360 Upgrade Checklist	01.07.11	1
QMF 15	Preferred Supplier Register	10.12.10	7
QMF 15A	Supplier Self Assessment	06.10.10	1
QMF 15B	Supplier Classification Worksheet	06.10.10	1
QMF 15C	Supplier Assessment Audit	06.10.10	1
QMF 16	SAP Purchase Order (Example)	03.31.09	1
QMF 17	SAP RMA (Example)	03.31.09	1
QMF 17A	SAP Certificate of Decontamination (Example)	03.31.09	1
QMF 18	Shipping Request Form	10.12.10	1
QMF 19	Open		
QMF 20	Open		
QMF 21	Work Instruction Format	06.08.10	1
QMF 22	Document History Form	05.21.09	1
QMF 24	SAP Service Notification (Example)	03.31.09	1
QMF 25	Personnel Grounding Devices Monitoring Log	09.02.09	1

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PRM00A Amendments

QMF	Issue	Description of Change	Authorized By	Date
14F	2	Add PC Anywhere to Checklist	G. Genna	4/6/2009
14G	2	Add PC Anywhere to Checklist	G. Genna	4/6/2009
14H	2	Add PC Anywhere to Checklist	G. Genna	4/6/2009
14I	2	Add PC Anywhere to Checklist	G. Genna	4/6/2009
14J	2	Add PC Anywhere to Checklist	G. Genna	4/6/2009
14K	2	Add PC Anywhere to Checklist	G. Genna	4/6/2009
14L	2	Add PC Anywhere to Checklist	G. Genna	4/6/2009
14M	2	Add PC Anywhere to Checklist	G. Genna	4/6/2009
11A	2	Added Ranger	G. Genna	4/7/2009
14AB	2	Change 3.1 Software and added warranty card. Updated part numbers	G. Genna	4/8/2009
14AC	2	Change 3.1 Software and added warranty card. Updated part numbers	G. Genna	4/9/2009
11A	3	Added Ranger Ship Details	G. Genna	4/13/2009
11A	4	Changed Haz Titles	G. Genna	4/14/2009
14AA	1	Duplicate Form - Removed	G. Genna	4/22/2009
14Y	2	Duplicate Form - Fixed	G. Genna	4/22/2009
14B	2	Update Step 7	G. Genna	4/22/2009
21	1	Added New Form	G. Genna	5/20/2009
15	2	Updated Supplier Register	G. Genna	5/20/2009
14O & P	1	Removed Forms from system	G. Genna	5/21/2009
22	1	Added New Form	G. Genna	5/21/2009
14AO&AP	1	Added New Forms	G. Genna	6/23/2009
15	3	Updated Supplier Register	G. Genna	6/25/2009
14AR	1	Added New Form	G. Genna	9/2/2009
14R-U	2	Removed Item from Checklist	G. Genna	9/2/2009
14AM, 14AN, 14AL, 14AD	1	Removed Forms From System	G. Genna	9/2/2009
25	1	Added New Form	G. Genna	9/2/2009
14AA	2	Updated Form	G. Genna	9/2/2009

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14C	2	Updated Form with specification changes.	G. Genna	10/1/2009
14AL	1	Added New Form (BLS)	G. Genna	10/27/2009
14AO	2	Updated form for new software version	G. Genna	12/7/2009
14F - M	3	Updated form for new software version	G. Genna	12/7/2009
14R - U	3	Updated form for new software version	G. Genna	12/15/2009
14AG, 14AH, 14AK	2	Updated form for BLS	G. Genna	1/26/2010
14AG, 14AH, 14AK	3	Removed Interlok Harness	G. Genna	3/12/2010
14AG, 14AH, 14AK	4	Changed 2GB to 4GB	G. Genna	4/23/2010
23		Obsolete	J. Davis	5/4/2010
05	2	Updated Calibrations	J. Davis	5/10/2010
14AM, 14AN, 14AD, 14AS	1	Added Forms	J. Davis	5/13/2010
05	3	Updated Calibrations	J. Davis	5/18/2010
05	4	Updated Calibration Form	J. Davis	5/20/2010
14F, 14G, 14H, 14I, 14J, 14K, 14L, 14M,	4	Changed Rev on HazMatID to L, Added Bluetooth on 14J, 14K, 14L, 14M	J. Davis	5/26/2010
04	2	Changed Procedure to Reference Number Procedure/Vendor	J. Davis	5/26/2010
13	3	Changed to an Access Form Consolidated QMF 21 and 13	J. Davis	5/28/2010
13A	1	New release	J. Davis	5/28/2010
11A	5	Updated Form	J. Davis	6/3/2010
02	2	Recorded 2010 Audits	J. Davis	6/8/2010
06	2	Updated Format	J. Davis	6/8/2010
21	1	Created Work Instruction Format	J. Davis	6/8/2010
14J, 14K, 4L, 4M, 14F, 14G, 14H	5	Added Libraries	J. Davis	6/8/2010
14R, 14S, 14T,	4	Added Libraries	J. Davis	6/8/2010
14AO	3	Added Libraries	J. Davis	6/8/2010

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15	4	Updated Suppliers	J. Davis	6/10/2010
15A, 15B, 15C	1	New Forms	J. Davis	6/10/2010
14X, 14W	2	Added Bluetooth Firmware Ver.	J. Davis	6/10/2010
15	5	Removed suppliers	J. Davis	6/17/2010
14h	6	Added Configuration	J. Davis	6/21/2010
02	3	Added Junes Auditing	J. Davis	6/29/2010
14M	6	Removed RerpeatIR	J. Davis	7/6/2010
PRM00A	1	Removed forms from PRM00	J. Davis	7/13/2010
14T	5	Added Chinese and Japanese	J. Davis	7/23/2010
14H	7	Added Chinese and Japanese	J. Davis	7/23/2010
15	6	Updated list	J. Davis	7/27/2010
14b, 14e, 14v		Obsolete	J. Davis	8/17/2010
14O, 14C	3	Consolidated Sheets	J. Davis	8/17/2010
14Q	2	Consolidated Sheets	J. Davis	8/17/2010
14A	4	Consolidated Sheets	J. Davis	8/17/2010
14AO	4	Changed HazMatID Rev to M	J. Davis	8/17/2010
14I	5	Changed HazMatID Rev to M	J. Davis	8/17/2010
14F, 14J, 14K, 14G, 14L	6	Changed HazMatID Rev to M	J. Davis	8/17/2010
14H	8	Changed HazMatID Rev to M	J. Davis	8/17/2010
14J, 14K, 14L, 14F, 14G	7	Removed IlluminatIR	J. Davis	8/20/2010
14AO	5	Removed IlluminatIR	J. Davis	8/20/2010
14H	9	Removed IlluminatIR	J. Davis	8/20/2010
14I	6	Removed IlluminatIR	J. Davis	8/20/2010
13A	2	Removed Short Description	J. Davis	9/9/2010
13	4	Changed Short Description to Reason Code	J. Davis	9/9/2010
14h	10	Removed Press and checkboxes for accessories	J. Davis	9/9/2010
14f, 14m, 14l, 14k, 14j, 14g,	8	Removed Press and checkboxes for accessories	J. Davis	9/9/2010
14ab	3	Removed Press and checkboxes for accessories	J. Davis	9/9/2010
14ac	4	Removed Press and checkboxes for accessories	J. Davis	9/9/2010

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14ao	6	Removed Press and checkboxes for accessories	J. Davis	9/9/2010
14i	7	Removed Press and checkboxes for accessories	J. Davis	9/9/2010
14AG	5	Consolidated AG, AH, and AK	J. Davis	9/30/2010
14Q	3	Removed Bluetooth	J. Davis	9/30/2010
15	7	Updated per quarterly review	J. Davis	10/12/2010
18	1	Released New Form	J. Davis	10/12/2010
14M, 14L, 14K, 14J	9	Changed Laptop Part Number	J. Davis	10/26/2010
14AO	7	Changed Laptop Part Number	J. Davis	10/26/2010
04	3	Changed to a Database	J. Davis	11/1/2010
04A	2	Changed to a Database	J. Davis	11/1/2010
14AE	2	Added IP addresses/MAC Codes	J. Davis	11/9/2010
14AK, 14AH, 14V	1	Re-released Checklists for TravellIR, IdentifyIR	J. Davis	11/17/2010
14G	9	Changed Ref CD to 023-0018	J. Davis	11/18/2010
14A	5	Added Long and short performance validation	J. Davis	11/18/2010
14AT, 14AU	1	New Release	J. Davis	11/22/2010
14B	1	New Release	J. Davis	11/22/2010
14AG	6	Changed checks to check boxes and added configurations	J. Davis	12/28/2010
14AV	1	New Release	J. Davis	1/7/2011

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Quality Management System (ISO 9001:2008. Clause 4)

4 Introduction

The Organisation has defined, documented and maintained a Quality System that will ensure that its requirements for Quality will be met.

2.0 Scope

This procedure describes the mechanism and responsibilities used by the Organisation to ensure its products and services conform to the specified requirements.

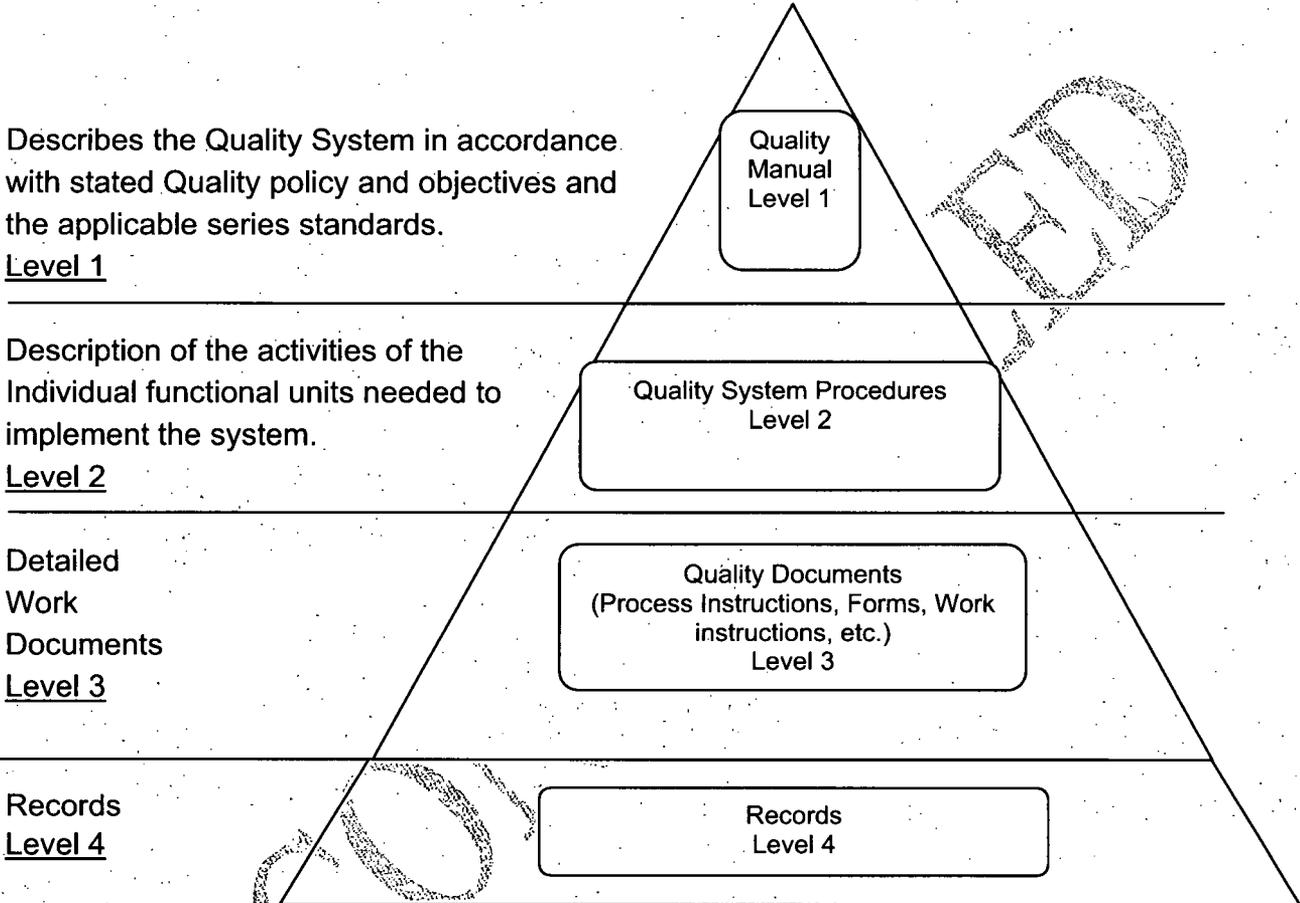
3.0 Responsibilities

The Quality System Management Representative is responsible for ensuring that the Quality System is effectively implemented and maintained in all areas of the Organisation.

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4.0 Procedure

4.1.1 The system is structured as below:



4.1.2 The Organisation has prepared, implemented and will maintain a controlled Quality Manual; Quality Procedures Manual and where required, clear instructions for specific jobs in the form of Work / Inspection Instructions, Method Statements etc.

4.1.3 The appropriate resources for order production, inspection, dispatch and maintenance will be employed to meet the Quality requirements.

4.1.4 Where appropriate to the operation or process being undertaken or service being performed, clearly defined acceptance and rejection criteria have been established and are applied.

4.1.5 Personnel employed will be trained to meet the stated Quality needs of the service or function undertaken by them.

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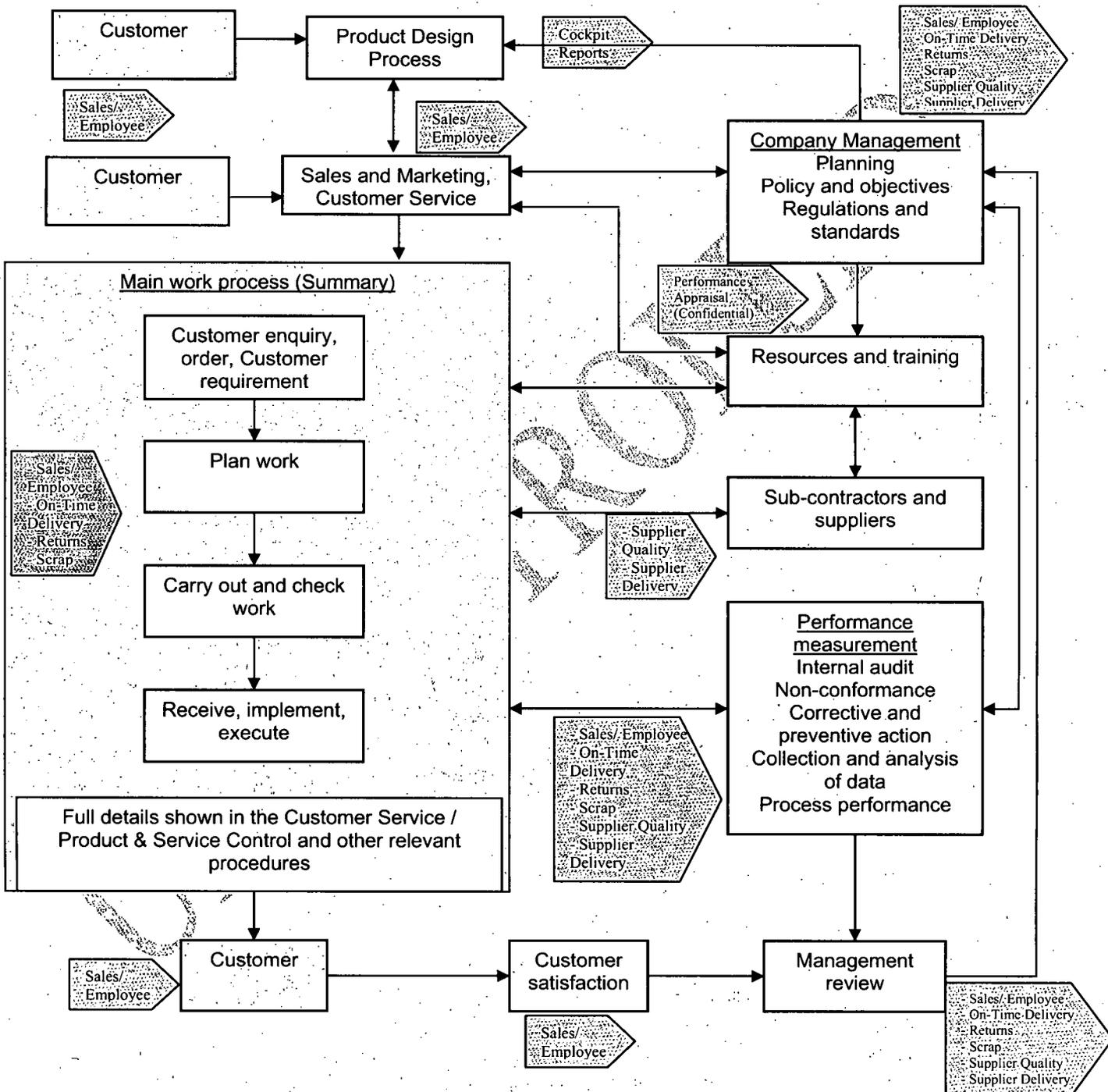
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- 4.1.6 Appropriate verification of Quality records are made and retained.
- 4.1.7 The Quality System extends to all employees and is not limited to Quality Control Personnel.

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Flow Chart of Interaction between the Processes of the Quality Management System



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PRM01 Amendments

Page Number	Issue	Date	Description	Authorization
2,4		25/11/09	Added 4th level of pyramid, Updated and corrected interaction matrix	G. Genna
ALL		36/11/09	Update Interaction Matrix	G. Genna
All		47/13/10	Added Amendments to the last page	J. Davis

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DOCUMENT CONTROL AND RECORDS. (ISO 9001:2008. Clause 4.2.1, 4.2.2, 4.2.3 and 4.2.4)

1.0 INTRODUCTION

To demonstrate that the Organization's stated quality objectives have been satisfied, a detailed system of control for quality related documentation and records needs to be maintained.

2.0 SCOPE

The Organization will produce and maintain adequate documentation to detail the requirements of the quality management system and to ensure that the requirements of the customer can be satisfied. Adequate records must be maintained for this purpose.

This procedure also applies to all records generated under the other procedures in the quality management system.

3.0 RESPONSIBILITY

It is the responsibility of the Quality Management Representative to ensure that:

- The Quality Management System is adequately documented.
- Documents are properly controlled and approved and are readily available to those personnel that need to use them.
- Sufficient records are maintained and these are legible and readily accessible.

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4.0 PROCEDURE

4.1 Document and Data Control

4.1.1 All quality and procedures manual documentation must carry a unique identification number, an issue number and the date from which the document becomes effective.

4.1.2 Documents must be formally approved for use. Any changes to documentation will require re-approval of the document. The review of quality documents will take place on at least an annual basis and re-approval is required when any changes take place.

4.1.3 Other quality documents must be clearly identified by their title or other reference, traceable from the document master register.

4.1.4 A master register will be available and must carry the current issue of each document. The master register will be the only source of copies.

4.1.5 External documentation must be adequately controlled to ensure that it is not damaged or lost.

4.1.6 Any changes required to the Quality Policy will be reviewed at the Management Review Meeting.

4.1.7 Whenever a change takes place to any section of the manual the revision status of the procedure must be updated.

4.1.8 Whenever a change takes place to any form, the revision status of the document must be updated.

4.1 Document and Data Control (continued)

4.1.9 The Quality Management Representative shall be responsible for ensuring that changed sections or documents are introduced into all controlled copies of the manual.

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4.1.10 Obsolete documents will be withdrawn from the system and marked '**Obsolete**' if retained.

4.2 Records

4.2.1 All completed quality documentation and records must be retained for at least seven years unless otherwise stated by the Organization or specified in other regulations or by government legislation.

4.2.2 Records must be correctly filed under suitable headings, in files, in folders etc., so that they are readily retrievable. Adequate security must be maintained to ensure that records are not lost or damaged.

4.2.3 Records must be legible.

4.2.4 Customer documents will be held in a master file. When a revised document is received any previous computer file will be deleted or electronically marked "**Obsolete**" and moved to the Obsolete folder. The electronic copy of the "**Obsolete**" document will be retained in the Obsolete Folder. Obsolete hard copies shall be destroyed.

4.2.5 Records kept on computer or on other electronic media must be backed up on a regular basis such that the information can be recovered if necessary.

4.2.6 Hard copies of documents will be stored per Smiths Detection Record & Information Management Policy.

4.2.7 Hard copies will be retained for the minimum required retention time as outlined in Smiths Detection Record & Information Management Policy. Records will be destroyed at the end of the retention period as per Smiths Detection Record & Information Management Policy.

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PRM02 Amendments

Page Number	Issue	Date	Description	Authorization
2-3	2	5/11/09	Added Document Control Matrix	G. Genna
All	3	6/17/10	Removed QMF20 Referred to the global policy	J. Davis
All	4	7/13/10	Added Amendments to the last page	J. Davis

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MANAGEMENT REVIEW (ISO 9001:2008 Clause 5.6)

1.0 INTRODUCTION

The Quality Management System needs periodic review to ensure that it is kept up-to-date and meets the requirements with regard to policy, objectives, effectiveness, resources and planning.

2.0 SCOPE

The Management Review must cover the operation of the Quality Management System throughout the Organization.

3.0 RESPONSIBILITY

It is the responsibility of the Management Representative to ensure that:

- The quality management system is reviewed at least annually to ensure its continued suitability and effectiveness.
- The minutes of the meeting are recorded.
- Any actions are identified and implemented.
- Opportunities for improvement are identified and implemented.

4.0 PROCEDURE

4.1 Management Reviews must be held at least twice per year (target is 4 times per year) to address all parts of the Organization's quality management system:

- To determine whether it is operating effectively to the benefit of the Organization.
- To identify opportunities for improvement.

4.1 (continued)

- To determine whether the Organization is continuing to meet customer requirements.

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- To prevent non-conformity.

4.2 The Management Representative, senior management and other staff as appropriate must attend the meeting.

4.3 A Management Review Agenda (QMF 06) will be prepared for each meeting, which must include the following:

- Actions from previous meeting - The aim is to ensure that any actions authorized from the previous meeting have been taken/ implemented.
- Review of the Quality Policy and quality objectives - The Quality Policy must be reviewed to check that it is still suitable for the Organization. Any quality objectives must be reviewed to check whether they are still appropriate and are being achieved. New objectives must be set where necessary.
- Improvement - The meeting must address methods of improvement to the system. Where areas for improvement are identified, appropriate objectives and methods of monitoring will be established. Any of the topics addressed during the meeting may be considered for improvement initiatives.
- Non-conformance and customer complaints - Non-conformances (of materials finished products, procedures, etc.) and customer complaints must be reviewed to check that the underlying cause has been addressed. His effect on customer satisfaction must be evaluated.
- Corrective and preventive action - Corrective and preventive actions must be reviewed to check that they have been effective in achieving an improvement in the quality system.
- Internal and external audits - Audit results must be reviewed to check that any non-conformance was corrected within an acceptable timeframe. The frequency of auditing may be reviewed based on the audit results.

4.3 (continued)

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- Planning and future resource requirements (long term planning) - Any changes to the business that could affect the customer or the quality management system should be addressed. This should include changes related to personnel, equipment or other resources.
- Training - Training needs must be reviewed together with any proposals for carrying out training.
- Supplier performance - Any need for changes to the suppliers used by the Organization must be addressed.
- Customer satisfaction - The meeting must address whether the Organization is meeting or if possible exceeding, the customers' requirements and expectations. Where complete customer satisfaction is not being achieved the Organization must plan and allocate suitable resources to resolve the problem.
- Any other business - This may include any initiatives for improvement, reduction in rework or waste, etc.

4.4 At a minimum, the review must cover the period since the last Management Review.

4.5 The person responsible for any actions identified at the meeting must be recorded together with target dates for completion where appropriate. The Organization must allocate the necessary personnel and resources for these corrective actions.

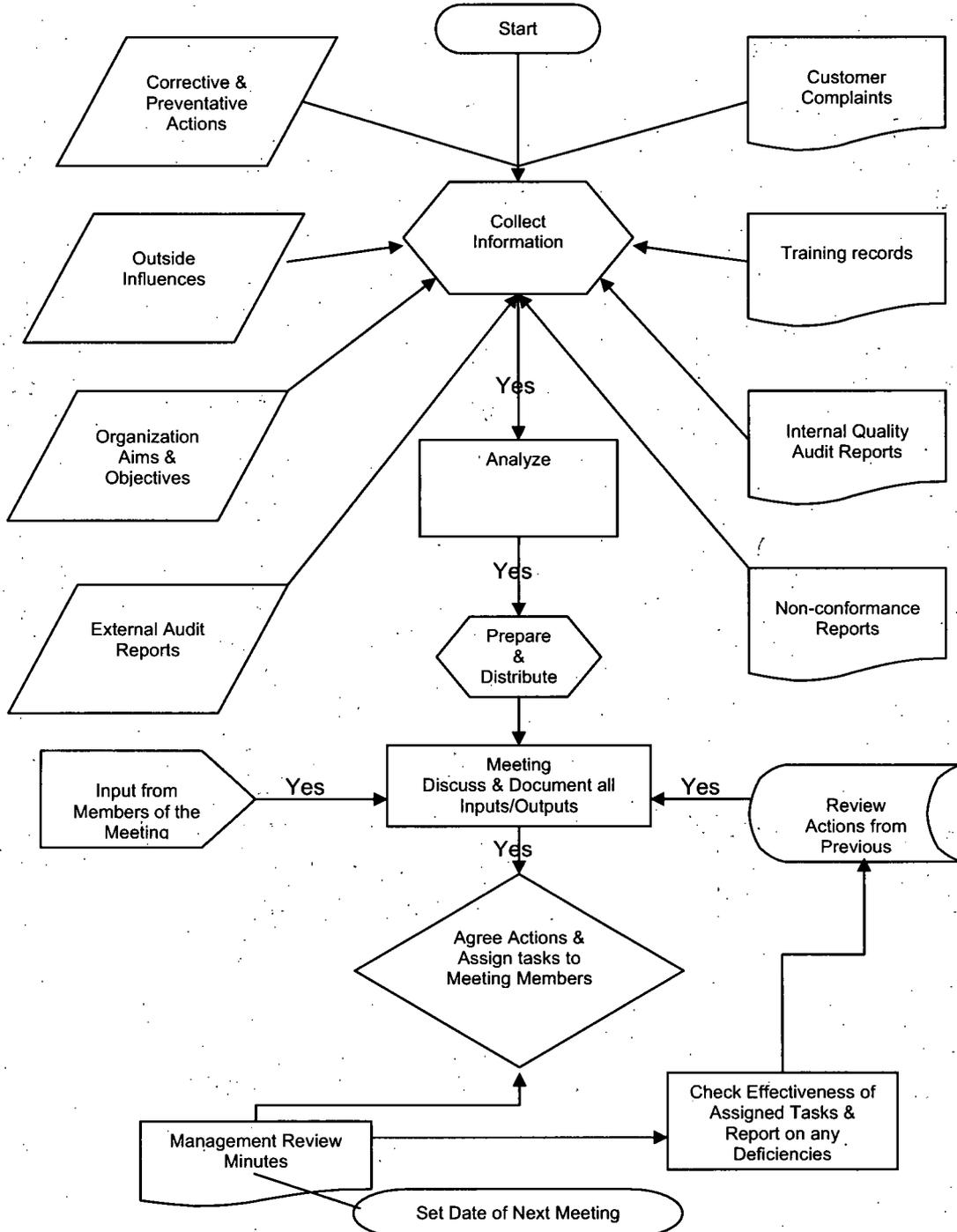
4.6 Inputs to the Management Review must include:

- Non-conformance/ Complaints Records (QMF 04/ 04A).
- SAP Service Notification (QMF 24)
- Training Records (QMF01, QMF01A).
- Non-Conforming Material Request (QMF 13)

4.7 The minutes of the meeting must be recorded and copies of those minutes must be provided to all personnel who attended the meeting together with those who have action plans to carry out as a result of the meeting.

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Reference Documents - Management Review

- QMF 01 New Hire Checklist
- QMF 01A Training Matrix
- QMF 04 Non-conformance/Complaints Register
- QMF 04A Non-conformance/Complaints Registration Form
- QMF 13 Non-Conforming Material Report
- QMF 24 SAP Service Notification
- QMF 06 Management Meeting Agenda

PRM03 Amendments

Page Number	Issue	Date	Description	Authorization
All		26/17/10	Removed reference to QMF03 and QMF19	J. Davis
All		37/13/10	Added Amendments to the last page	J. Davis

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RESOURCES (ISO 9001:2008 Clause 6.1, 6.2.1, 6.2.2, 6.3 and 6.4)

1.0 INTRODUCTION

To meet the requirements of the customer, the Organization ensures that there are adequate resources in the form of personnel, plant and equipment. This may include additional resources from outside the Organization where necessary.

2.0 SCOPE

This procedure covers the systems and operations necessary to ensure that the Organization has adequate resources to meet the requirements of its customers and operates the business in an efficient and safe manner.

3.0 RESPONSIBILITY

It is the responsibility of the Functional Area Manager to ensure that:

- The Organization's resource requirements are reviewed on a regular basis.
- Training needs are identified.
- Suitable training is carried out and reviewed for effectiveness.

4.0 PROCEDURE

4.1 General

4.1.1 The review of resources status (i.e. open positions, new hires, etc) is carried out as part of the management review process, but is also part of the day-to-day management of the Organization. See PRM 03 Management Review.

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4.1 General (continued)

4.1.2 Records associated with personnel and training are maintained in accordance with PRM 02 Document Control and Records.

4.2 Human Resources

4.2.1 As part of the general planning and management process, the Organization must identify the personnel needed to ensure that it operates effectively. The general structure of the Organization is shown in the organisation chart in the Quality Manual. Specific responsibilities are defined in the organisation chart and documented in the relevant parts of the Procedures Manual.

4.2.2 The Organization personnel will make recommendations for additional recruitment. Final authorization to hire will be given by Headquarters, as appropriate.

4.2.3 New Personnel including sub contract or temporary staff will be selected by interview (usually two people e.g. Line manager and Technician), and skill test or review of references. The Organization's policy of recruiting and procuring personnel with the required level of skills, experience and education is reviewed in the light of labor availability and changes in the nature of the Organization's work.

4.2.4 All personnel must be given induction training, including an explanation of the quality management system and the health/ safety requirements when they start work with the Organization. A New Hire Checklist (QMF 01) will be completed for all new employees.

4.2.5 The training and experience of each employee will be assessed against defined objectives (and any changes that have taken place or are about to take place) to ensure that personnel are adequately trained and experienced to carry out his duties.

4.2 Human Resources (continued)

4.2.6 The "On the Job" (OTJ) training needs of all personnel will be identified by the relevant manager on an ongoing basis by observation. Where possible, measurable objectives will be set to assist in continual improvement. A Training Matrix (QMF 01A) is generated per product line.

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4.2.7 Where a specific training need is identified, the training must be arranged by the responsible manager or supervisor and included on the Training Matrix (QMF 01A).

4.2.8 Training will generally occur by means of in-house training but can be by formal courses.

4.2.9 Where additional training outside of OTJ training is undertaken, the details and results will be recorded and stored on the talent management database.

4.2.10 All training must be assessed by the responsible manager to determine that it was effective through the performance evaluation process.

4.2.11 Personnel records must be maintained to show all qualifications, experience and training relevant to the ability of the employee to perform tasks affecting the quality of the product or service. Copies of certificates or other evidence (i.e. sign-in sheets) to show that training has been carried out will be maintained.

4.3 Facilities and Equipment

4.3.1 Recommendations for additional plant and equipment will generally be prepared by the Organization personnel and authorized by the General Manager as appropriate.

4.3 Facilities and Equipment (continued)

4.3.2 The Facilities Supervisor (c/o Operations Director) must ensure that all plant and equipment and buildings are regularly maintained in accordance with manufacturer's recommendations or recognized good practice.

4.3.3 The operating personnel undertake routine maintenance, including general cleaning daily and annually as required.

4.3.4 Records of maintenance will be maintained. Where appropriate, copies of certificates or other evidence of work will be retained in hard copy form.

4.3.5 Parts or subcontract maintenance/repair services are purchased in accordance with the requirements of the purchasing procedure.

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4.4 Work Environment

4.4.1 All personnel must maintain a good standard of housekeeping within the work area.

4.4.2 Waste materials must be cleared away regularly to maintain a safe working environment.

4.4.3 Any faulty plant or equipment must be reported to the Facilities Supervisor for attention.

4.4.4 The Organization will comply with the Health and Safety (OSHA), MSDS and all other hazardous materials regulations as and where applicable.

Reference Documents - Management Review

QMF01 New Hire Checklist
 QMF01A Training Matrix (Example)

PRM04 Amendments

Page Number	Issue	Date	Description	Authorization
ALL	2	5/13/09	Updated procedure to reflect current practice	G. Genna
All	3	7/13/10	Added Amendments to the last page	J. Davis

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CUSTOMER REQUIREMENTS (ISO 9001:2008 Clause 7.1, 7.2.1, 7.2.2 and 7.2.3)

1.0 INTRODUCTION

Meeting the customers' requirements is the principal objective of the Organization. The needs of the customer must be fully understood and accepted, and the Organization must establish that it is in a position to meet these requirements in an effective manner.

2.0 SCOPE

The Organization's business is mainly the design, development, manufacture, and distribution of trace element detection equipment and related services in conformance with specifications, instructions and samples received but can involve the development of products or services to meet market or customer requirements. (PRM 12 design and development refers)

The scope of this procedure includes:

- Identification and documentation of the customer requirements.
- Review of these requirements.
- Methods of communication with the customer.
- Outline planning of the work.

3.0 RESPONSIBILITY

It is the responsibility of the Business Unit Manager to ensure that:

- All verbal or written inquiries for quotation and orders are reviewed to ensure that the requirements, together with any changes, are adequately defined and understood by both parties.
- These requirements, together with any changes, are adequately documented.

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3.0 RESPONSIBILITY (continued)

- Adequate planning is carried out to ensure that the Organization has or can obtain the necessary resources to fulfil the order or contract.
- Effective lines of communication are set up between the customer and the Organization.
- Sufficient records are kept to show that the above requirements have been satisfied.

4.0 PROCEDURE

4.1 General

4.1.1 Customer requirements will be dealt with in three stages:

- Receipt and understanding of the customer requirements.
- Review of the Organization's capability to meet these requirements.
- Confirmation of acceptance to the customer.

4.1.2 Inquiries for quotation and orders are generally received by e mail or telephone but can be by mail, fax, web site or sales visit.

4.1.3 Records related to dealing with Customer inquiries will be kept in Sales Logix CRM system and electronic email folders. (Customer Quotations are attached by Customer sales opportunity in Sales Logix).

4.1.4 Records related to dealing with Customer orders will be kept in open Customer order files, closed accounts receivable files, Manufacturing Customer files and electronically on in email folders, 'SAP' Financial and Manufacturing Business System, 'Sales Logix' (CRM) Customer files.

4.1.5 When the Organization is unable to meet the customer's requirements the customer is advised through verbal, electronic or written communication.

4.1.6 The Organization's products and services are as described by the web site, (www.smithdetection.com) and sales brochures.

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4.2 Customer Requirements – Inquiries

4.2.1 Inquiry Receipt

4.2.1.1 All verbal or written inquiries, requests for quotation, invitation to tender etc. will be handled by Sales (may be screened and redirected by the Sales and Marketing administration).

4.2.1.2 Details of the inquiry for quotation will be recorded and must include as appropriate:

- Date of inquiry, Customer contact name.
- Customer telephone number, fax number or e-mail address.
- Customer inquiry number (if provided by the customer).
- Details of requirements.
- Shipping details, where stated.
- Any customer supplied documents (specifications, samples, etc.).
- Regulatory or legislative requirements (i.e. CE, RoHs, WEEE)
- Any special requirements for product validation or verification. (i.e. test on customer supplied sample).
- Any special documentation required (certificates of compliance, material certificates etc.)
- Service Contract, Service Contract requirements

4.2.1.3 The details will be logged by Customer sales opportunity into Sales Logix "Opportunity" Record (QMF 08) but may initially be recorded as part the written Customer inquiry or on any hard format available.

4.2.2 Inquiry Review

4.2.2.1 When the details of the customer's requirements have been clearly identified, the Organization's ability to carry out the work must be formally reviewed by Sales. Where an inquiry is of a simple or routine nature, for example a repeat order or order extension, a full review will not be required.

4.2.2 Inquiry Review (continued)

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4.2.2.2 The review must be based on the documents or other information provided by the customer or the Organization's own documentation defining the requirements.

4.2.2.3 The review of the Organization's capability for carrying out the work must address the following:

- Can the Organization carry out the work in accordance with the customer's requirements without any additional resources or changes to normal Organization operations?
- Is the inquiry from a new or existing customer?
- Is there a need for additional investigation or research?
- Is any additional staff training needed?
- What materials, supplies or services need to be obtained from outside suppliers?
- Does the work involve any special process not usually carried out by the Organization?
- Are there any special legal or regulatory requirements? E.g. health and safety etc.
- Are there any quality requirements, e.g. national/international standards, Industry standards (i.e. CE, UL, RoHs, WEEE).
- Is specific documentation needed, e.g. First Article Inspection, C of C, material certificates etc.?
- Can the design requirements be met (for requirements involving design [PRM 12 refers])

4.2.2.4 When any questions are developed during this review process, they must be resolved with the customer by the Sales department.

4.2.2.5 Where the inquiry is from a new customer no specific action is taken before quoting other than setting up a profile in Sales Logix and checking the inquirers web site (by exception).

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4.2.2.6 Confirmation that the Organization can meet the customer's requirements will be by reading back the order or by the preparation and submission of a Quotation (QMF 09).

4.2.2.7 Each quotation will confirm details as reviewed in 4.2.1.2, is given a unique reference (e.g. date, initials, variation no.) and stored electronically in Sales Logix. Price list/ repeat order related inquiries are still confirmed by a Quotation.

4.2.2.8 When a specification has been provided by the customer to assist in the preparation of a quotation, it will be identified with the customer name and/or a product reference.

4.3 Customer Requirements – Orders

4.3.1 Order Receipt

4.3.1.1 Customer orders will generally be handled initially by Sales Staff and then passed to the Sales Administration person handling the inquiry.

Each customer order must be identified by the customer name and order number.

Where an order is received without a quotation the details shall be recorded in accordance with Section 4.2.1 Inquiry receipt, paragraph 4.2.1.2 of this procedure.

Note: where the order includes a service contract; when the order has been despatched a copy of the invoice is sent to reception to be scanned electronically into the server. Upon delivery of the unit to the customer, a copy of the invoice is sent to the service department as a record of order receipt and the start of the service availability.

4.3.2 Order Review

4.3.2.1 When the details of the customer's requirements have been clearly identified, the Organization's ability to carry out the work must be formally reviewed, ensuring the information originally checked in 4.2.2.3 remains current. Where an order is of a simple or routine nature, for example a repeat order or order extension, a full review would not be required.

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4.3.2.2 When an order is received without a prior quotation, the details will be reviewed in accordance with Section 4.2.2 Inquiry Review, Paragraphs 4.2.2.2 & 4.2.2.3 of this procedure.

4.3.2.3 The Customer order details must be checked against a Sales Order Entry Checklist (QMF 08a) by the Sales Person who dealt with the original enquiry or a designated representative, and then entered into the SAP Financial and Manufacturing system. Order details entry into SAP enables a SAP Order Confirmation (QMF 10) or Purchase Order (QMF10b) for intercompany orders and an SAP Delivery Document (QMF 10a). Copies are sent to manufacturing and retained by Sales in customer files.

4.3.2.4 When the order is from a new customer the order will be processed once credit references or advance payment i.e. credit card payment has been received.

4.3.2.5 Confirmation that the Organisation can meet the Customer's requirements will be in the form of reading back the order or sending an acknowledgement if specifically requested.

4.4 Communication

4.4.1 Clear lines of communication must be established and maintained between the customer and the Organization. This will be by means of, email and telephone plus fax, letter, and sales visit when appropriate.

4.4.2 Verbal quotations may be given where the customer has clearly defined requirements at the time of the inquiry and the customer is known and established or where the quotation is a 'ball park' or standard price. Verbal quotations will be confirmed in writing.

4.4 Communication (continued)

4.4.3 Quotations (QMF 09) will be prepared in response to all clearly defined requirements. Signing the quote (i.e. electronic signature) confirms the formal review of the customer's requirements.

4.4.4 Customer orders should be in writing with an order number. If a written order/ number is not received, it will be requested.

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4.4.5 Where a sample or specification reference change has been implemented a replacement will be requested from the customer before the order is processed.

4.4.6 Changes to an order required by the customer, shall be confirmed in writing. Where confirmation of a change is not received from the customer and where the change is significant or the customer has made a specific request, the organisation will confirm the change in writing to the customer. This confirmation will include any changes to the contract due to the requested change, e.g. price and delivery.

4.4.7 Communication within the organisation will generally be verbal with relevant paperwork created where necessary.

4.4.8 All communications which could significantly affect the Organization's ability to fulfil the order or contract must be recorded.

4.4.9 Any customer complaints must be dealt with in accordance with procedure PRM 11 and PRM 12.

4.5 Planning

4.5.1 As part of the process of review of the customer's requirements, the order will be reviewed at the daily planning meeting to plan how the work is to be carried out. This is to ensure that sufficient resources are available to achieve the specified requirements and quality.

4.5.2 Planning will take into account:

- The customer's delivery or other critical dates.
- Any specific product verification or inspection requirements.
- Availability of resources (including staff, materials and equipment).

4.5.3 Any longer term planning will be dealt with at the management review meeting where the Quality Management Representative will ask for and provide feedback where problems have arisen with a view to improvement in the quality system.

4.5.4 The method of checking or verifying that the product meets the specified requirements will be addressed in the Process Control Procedure (PRM 06).

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Reference Documents – Customer Requirement

- QMF 08 Sales Logix "Opportunity" Record (example)
- QMF 08a Sales Order Entry Checklist
- QMF 09 Quotation (Example)
- QMF 10 SAP Order Confirmation (Example)
- QMF 10a SAP Delivery Document (Example)
- QMF 10b SAP Purchase Order (Example)

PRM05 Amendments

Page Number	Issue	Date	Description	Authorization
1		23/17/09	Change National Sales Manager to BU Manager, Remove "TOM" System references, Update procedure for QMF08a, Change verbiage In 4.3.1.1, update process in 4.3.1.4	G. Genna
7		35/12/09	Removed 4.4.5, 4.4.6, 4.4.7	G. Genna
All		47/13/10	Added Amendments to the last page	J. Davis

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PROCESS CONTROL (ISO 9001:2008 Clause 7.1, 7.5.1, 7.5.2, 7.5.3, 7.5.4, 7.5.5 and 8.2.4)

1.0 INTRODUCTION

Work carried out by the Organization shall be adequately controlled to ensure that it meets the requirements of the customer. This shall be achieved by good planning, the provision of adequate resources, properly trained and experienced personnel, clearly defined standards and methods of working, and correct monitoring and product verification.

2.0 SCOPE

The Organization's business is mainly the design, manufacture, and distribution of on-site FT-IR Spectroscopy analysis machines as a own brand or OEM machine or machine driver and related services in conformance with specifications, instructions and samples received but can involve the production of products or services to meet market or customer requirements. (PRM 13 design and development)

The scope of this procedure includes:

- Planning of the work process.
- Control of the work process.
- Validation of the work.
- Identification and traceability.
- Customer Property
- Control of associated activities including handling, packing, storage, preservation, and delivery.

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3.0 RESPONSIBILITY

It is the responsibility of the Director of Operations or a designated representative to ensure that:

- All work carried out by the Organization is adequately defined and controlled.
- Appropriate instructions are provided, maintained (and readily available) to ensure that the quality of work is satisfactory.
- Standards of workmanship and criteria for acceptance are defined.
- Suitable personnel are assigned for the work process and for product verification and checking activities.
- Adequate resources are provided in the form of personnel, equipment, and a suitable workplace.

The following personnel are responsible for product verification activities and the maintenance of the associated records.

Received product verification	Manufacturing Personnel
In process product verification	Manufacturing Personnel
Final product verification	Independent manufacturing Personnel

It is the responsibility of all personnel to comply with this procedure and seek guidance from their manager or supervisor where clarification is required.

4.0 PROCEDURE

4.1 General

4.1.1 Technical planning of the work will include creating the Shop Packet i.e. Order Confirmation (QMF 10) (External Orders) or Purchase Order (QMF10b) (Inter-Company Orders), Open Sales Order Report (QMF11), drawings, work instructions, etc.

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4.1 General (continued)

4.1.2 All work carried out by the Organization must take into account any applicable health and safety requirements, including government regulations. Good standards of housekeeping will be maintained.

4.1.3 All records associated with the work process will be in accordance with PRM 02, Document Control and Records.

4.1.4 All personnel carrying out work will be suitably trained and experienced in accordance with PRM 05, Resources.

4.1.5 Measuring equipment is to be controlled in accordance with PRM 08, Measuring and Monitoring Equipment.

4.1.6 All equipment will be maintained regularly in accordance with the manufacturer's or supplier's instructions.

4.1.7 Process capability will be addressed in accordance with Measurement and Improvement Procedure (PRM 12).

4.2 Planning

4.2.1 Work will be planned and controlled using a Open Order Report (QMF 11), (and a customers shipment schedule when and if provided as part of QMF 11) and planning boards. Review of planned work takes place informally as required and formally in Daily Operations Meetings (QMF 11a) at least once a week.

4.2.2 Planning must take into consideration the following:

- Allocation of responsibilities.
- Resources required.
- Validation of the process and analysis of any risks.
- Legal or regulatory requirements.
- Procurement of materials or services.
- Procedures, methods, and work instructions.
- Deadlines for the completion of the work.
- Records.
- Other requirements as appropriate to meet the quality objectives.

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4.3 Work Control

4.3.1 The specification of characteristics of the work must be clearly defined by the Operations Director. Using the Open Sales Order (QMF 11) report annotated from the weekly planning meeting. A SAP Delivery Document (QMF 10) or SAP Purchase Order (QMF 10b) (Inter-company orders) and if appropriate a Bill of Materials (QMF 12) is printed.

4.3.2 As appropriate to skills and experience of the manufacturing personnel taken in conjunction with the complexity, frequency of production and age of the build item; the Bill of Materials (referenced from the Sales Order/ Open Order report), Build specification Book, process build chart, drawings and specifications as appropriate together with any verbal or written instructions provide all of the information necessary for the trained and experienced operations personnel to complete the job to the required quality standard. *Note: where legacy products have been built over the course of several years the Sales Order and experience of the build personnel might be sufficient to achieve the required quality standard prior to Testing.*

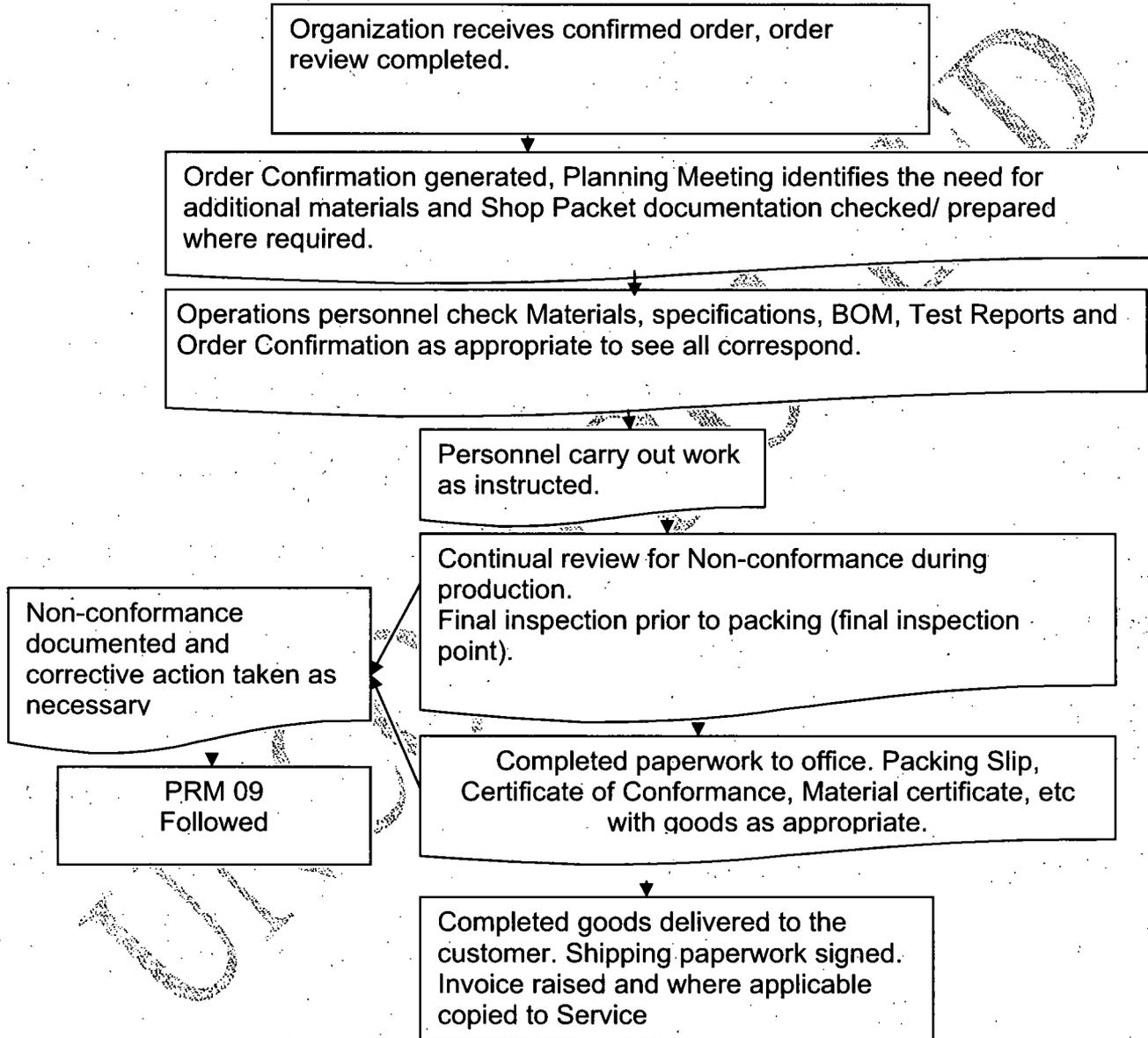
4.3.3 Work instructions listed in **Appendix A** are to be followed for the production of units. The last approved revisions level will be used.

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Manufacturing Work Control Process Flow Diagram



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4.3 Work Control (continued)

4.3.4 Where sub contract operations are required, these will be arranged in accordance with the purchasing procedure. The items are packaged as required and details are noted on the SAP Order Confirmation (QMF 10) or SAP Purchase Order (QMF 11b) (Inter-company orders).

4.3.5 Should the customer wish to return the product e.g. under a service contract, every effort will be made to resolve the issue prior to following the RMA Process and raising/processing an RMA form (QMF 17) and Certificate of Decontamination (QMF 17a) accordingly.

4.3.6 RMA goods received are identified within SAP for any service agreement basis; goods are assessed and repaired per the SAP RMA (QMF 17) and results are entered into SAP manufacturing and financial system. If under a warranty or service agreement or a proposal for repair is raised in SAP and the customer requirement process followed as outlined in PRM 05. Work would be carried out referencing the SAP RMA (QMF 17).

4.3.7 The means of checking and product validation will be in accordance with Section 4.4 of this procedure.

4.3.8 The work will be carried out with plant and equipment specific to the Organization. This will be regularly maintained in accordance with the manufacturer's or vendor's instructions. Appropriately trained and qualified personnel will operate all equipment.

4.4 Validation/Inspection

4.4.1 The procedure for incoming material inspection is detailed in the Purchasing Procedure (PRM 07).

4.4 Validation/Inspection (continued)

4.4.2 In-process and final service inspection must be carried out in accordance with the specified requirements detailed in the relevant documentation. (May include BOM, Order Confirmation, Work instructions and Test Reports and Specifications created during the design process (see PRM 12)). All products are subject to

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inspection, visually and by calibrated instruments and equipment as specified in the relevant documentation.

Final Inspection is performed at the packing stage by an independent operations personnel member and confirmed by stamp/signature on the Testing Report Documents.

4.4.3 If and where formally required by contract, specific inspection documentation and protocol will be developed, documented and required by the Order Confirmation (QMF 10).

4.4.4 After development is approaching completion a first prototype will be prepared as required by PRM12, (engineering will generate the prototype), second prototype will involve manufacturing, (effectively pre- production build), then production can commence use specifications instructions etc. issued by engineering & the BOM to generate a first item for inspection. Inspection is performed by R&D/ Product Management/ Quality Assurance.

4.4.5 As appropriate, on acceptance of the first piece/batch using the appropriate gages and measuring equipment where quality would be affected, the Test Data (QMF 14) is printed then signed/ stamped as approved and full production can commence.

4.4.6 Product verification records will be in the form of the signed/stamped test sheets, test data, as appropriate. Additionally, where contractually required, customer stage/final release inspection records either on site or remote will be maintained. Test Data is maintained as a hard copy (QMF 14) in a manufacturing customer files etc.)

4.4.7 Product will not be delivered to the customer unless all testing and product validation is complete to customer specifications or a formal deviation is signed by the customer.

4.4.8 Non-conforming product will be dealt with in accordance with PRM 10 Control of Non-conforming Product.

4.5.1 All products and materials delivered to the Organization must carry identification from the supplier unless this is obvious by appearance. If there is a specific requirement for traceability this will be maintained throughout the work process.

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4.5.2 Materials will be identified in the storage area by location item number, and material as appropriate. Work in progress must be identified at all stages by location or associated paperwork, e.g. the BOM (QMF 11).

4.5.3 Product verification status will be shown by the materials or item location or associated documents including the Test Reports (QMF 14-14AQ). Finished Goods will be identified with a product reference and serial number.

4.5.4 Any rejected product will be identified with a Non-Conforming Material Request (QMF 13) and removed to the Non-Conforming area where required.

4.5.5 When traceability is a requirement specified in the order, the details will be made clear to purchasing, who will ensure that purchased items meet the traceability requirements. Where unique identification is required, details will be specified on the Order Confirmation (QMF 10).

4.6 Customer Property

4.6.1 The customer's own material, products or property, i.e. intellectual property, will be looked after with care whilst on the Organization's premises.

4.6.2 Customer's property will be clearly identified and stored in a designated area. i.e. All customers' specifications are to be filed by the relevant order or inquiry/ref.

4.6.3 The Organization undertakes to advise the Customer of any changes in the condition of the supplied product and treat it as though it was their own while it is in their possession.

4.7 Associated Activities

4.7.1 Handling

4.7.1.1 Goods and materials will be handled in a manner that does not cause any damage or deterioration.

4.7.1.2 When necessary, mechanical handling equipment will be used (e.g. for heavy loads).

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4.7.1.3 Due consideration will be given to health and safety requirements for manual handling or for hazardous goods and materials.

4.7.2 Storage and Preservation

4.7.2.1 Storage will be within designated areas where conditions are appropriate for the products and materials. Inventory is maintained on SAP and is taken as the need for parts is identified and annually (fiscal).

4.7.2.2 The general condition of stored items is checked during normal operations and any defective products shall be removed to a quarantine area where authorized personnel shall decide on the disposition of the defective product.

4.7.3 Packing

4.7.3.1 Goods and materials must be packed in a manner that ensures that they are not damaged during storage or transport.

4.7.3.2 Storage areas will be checked periodically to ensure that no changes have occurred that may affect the goods or materials. Inventory is taken as required but annually as a minimum.

4.7.3.3 Generally it is not needed to carry out any specific preservation/ packing treatments to finished products. However where preservation/ packing has been specified by the customer these details will be noted on the Order Confirmation (QMF 10) and followed.

4.7.4 Transport and Shipping

4.7.4.1 Finished Product will be generally shipped by carrier but can be by courier, customer collection or own transport.

4.7.4.2 When carriers are used the product will be packed to specifications developed by the Organization unless already specified by the customer to ensure safe transit.

4.7.4.3 Goods will be labelled to indicate destination and contents, tracking information and transit care requirements as appropriate.

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4.7.4.4 If and where Goods are shipped to a sub contractor for processing (e.g. infra-red coating) they will be supplied with a copy of the SAP Purchase Order (QMF 16).

4.7.4.5 When goods are to be shipped to the Customer, SAP Order Confirmation (QMF 10) specifies what is to be shipped. If goods are to be picked up by the customer a signature to confirm satisfactory receipt is required.

4.7.4.6 When a courier is used the courier documentation will be completed and signed as required.

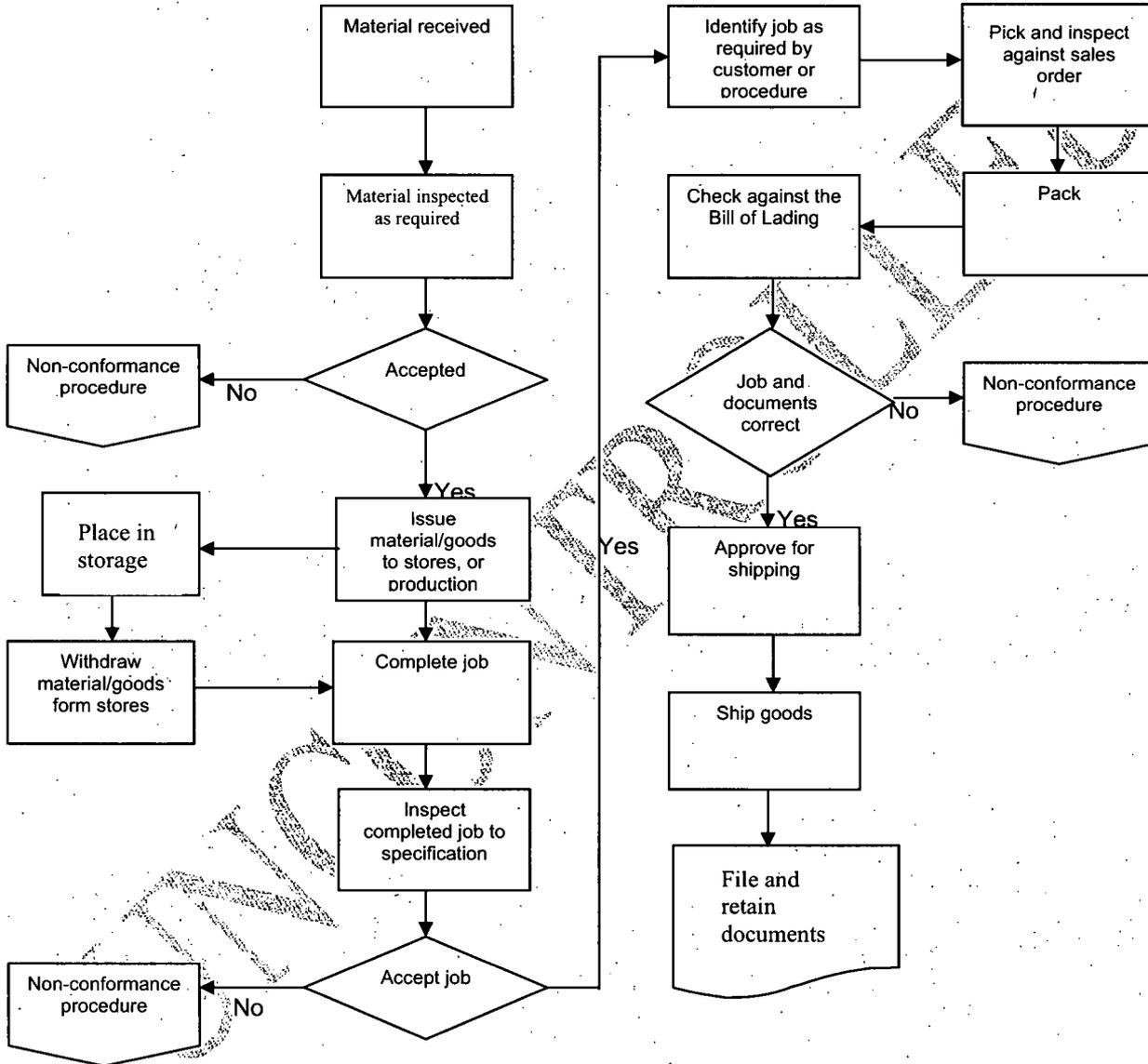
4.8 Associated Documents

4.8.1 Certificate of Origin, Bills of Lading, Packing Slip, Certificates of Compliance, Material Certificates etc. will be supplied as appropriate to the nature of the goods and contract.

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Flow Chart – Verification/Validation**



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Reference Documents – Process Control

- QMF 10 SAP Order Confirmation
- QMF 10A SAP Delivery Document
- QMF 10B SAP Purchase Order
- QMF 11 Open Order Report
- QMF 11A Daily Operations Meetings
- QMF 12 Bill of Materials (BOM)
- QMF 13 Non-Conforming Material Report
- QMF 14-14AQ Test Reports and Checklists
- QMF 15 Preferred Supplier Register
- QMF 16 SAP Purchase Order
- QMF 17 SAP RMA
- QMF 17a SAP Certificate of Decontamination

PRM06 Amendments

Page Number	Issue	Date	Description	Authorization
ALL		2/5/21/09	Update procedure to reflect current Practice and clear audit non-conform	G. Genna
ALL		3/6/25/09	Added Haz WI Numbers	G. Genna
ALL		4/6/10/10	Removed WI made Appendix	J. Davis
All		5/7/13/10	Added Amendments to the last page	J. Davis

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PURCHASING (ISO 9001:2008 Clause 7.4.1, 7.4.2 and 7.4.3)

1.0 INTRODUCTION

To ensure the quality of the Organization's products and services is maintained, it is essential that material and services purchased for use in the organizations products meet quality objectives. Suppliers will be selected on their ability to consistently meet the Organization's quality objectives.

2.0 SCOPE

All purchased products and services used within the Organization's products fall within the scope of this procedure.

3.0 RESPONSIBILITY

It is the responsibility of the Master Scheduler/Approving Manager to ensure that:

- The requirements for purchased products or services are clearly defined.
- Purchased products or services are inspected or checked.
- Suppliers are formally assessed to confirm that they can meet the Organization's quality objectives.

4.0 PROCEDURE

4.1 Supplier Approval

4.1.1 Supplier Selection is based on a required need as follows:

- New Product Development Process (NPDP)
- Engineering Change Process (ECN Process)

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- 4.1.1 Supplier Selection (continued)
- Failure of current supplier to meet delivery, pricing or quality requirements.
- 4.1.2 Suppliers of products and service are chosen as Approved Suppliers by one or more of the following criteria:
- Past History or Performance.
 - Evaluation of a trial order, samples, or activity.
 - Comparative test results with the same or similar products.
 - Recommendations or references from other users or suppliers.
 - Product verification up to one hundred percent (100%) of all services/products from supplier.
 - Supplier financial viability.
 - Specified by Engineering or Product Management.
 - Supplier Assessment Audit.
- 4.1.3 The list of approved suppliers will be included on the Preferred Supplier Register (QMF 15).
- 4.1.4 The list of approved suppliers must be reviewed at least once per year. Approved suppliers will remain on the list based on their performance with On-Time Delivery and Quality Yield. This information is reviewed as part of the management review.
- 4.1.5 All supplier issues must be investigated. If an issue with the supplier cannot be satisfactorily resolved, the supplier may be removed from the approved supplier list. Final removal will be evaluated by Operations, Quality Manager and/or Director of Operations.
- 4.1.6 There may be suppliers that are sole or single source for supplies or services which achieve a below standard supplier rating. In such cases, Operations and/ or Quality Manager will monitor corrective action.

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4.2 Purchasing

4.2.1 Items incorporated into Organization products or services must be purchased from the suppliers listed in the Preferred Supplier Register (QMF 15). The Quality Manager, Operations Manager, or delegate must authorize purchases made from suppliers not on the Preferred Suppliers Register.

4.2.2 Purchase orders must clearly define the product or service required; they will address:

- Product or service required.
- Any relevant standards or regulations that are applicable.
- Shipping requirements, including due date for delivery to the Organization.
- Any documentation to be supplied (e.g. material/compliance certificates).
- Price

4.2.3 Purchase requirements will be detailed on a Purchase Order (QMF 16). Each Purchase Order will be identified with a unique reference, then reviewed and electronically signed.

4.2.4 All suppliers are required to comply with the specifications, quantity, price, delivery, and terms as shown on the purchase order.

4.2.6 When a purchase order change is required, the Master Scheduler will contact the supplier to re-negotiate the required changes. The changes will then be reiterated to the Edgewood Facility to update the PO.

4.3 Verification/Inspection

4.3.1 When purchased items are delivered, the items are verified against the supplier's packing list.

4.3.2 If a packing list is not included, the supplier is contacted and the items are set aside until a copy of the packing list is received via fax or e-mail.

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4.3.3 Contents are inspected for proper count and, as best possible, for correctness (i.e. proper vendor part number on package is the same as part number on packing list).

4.3.4 A good receipt is generated electronically for accounts receivable. A Goods Receipt Slip is issued and attached to the supplier's packing list for file.

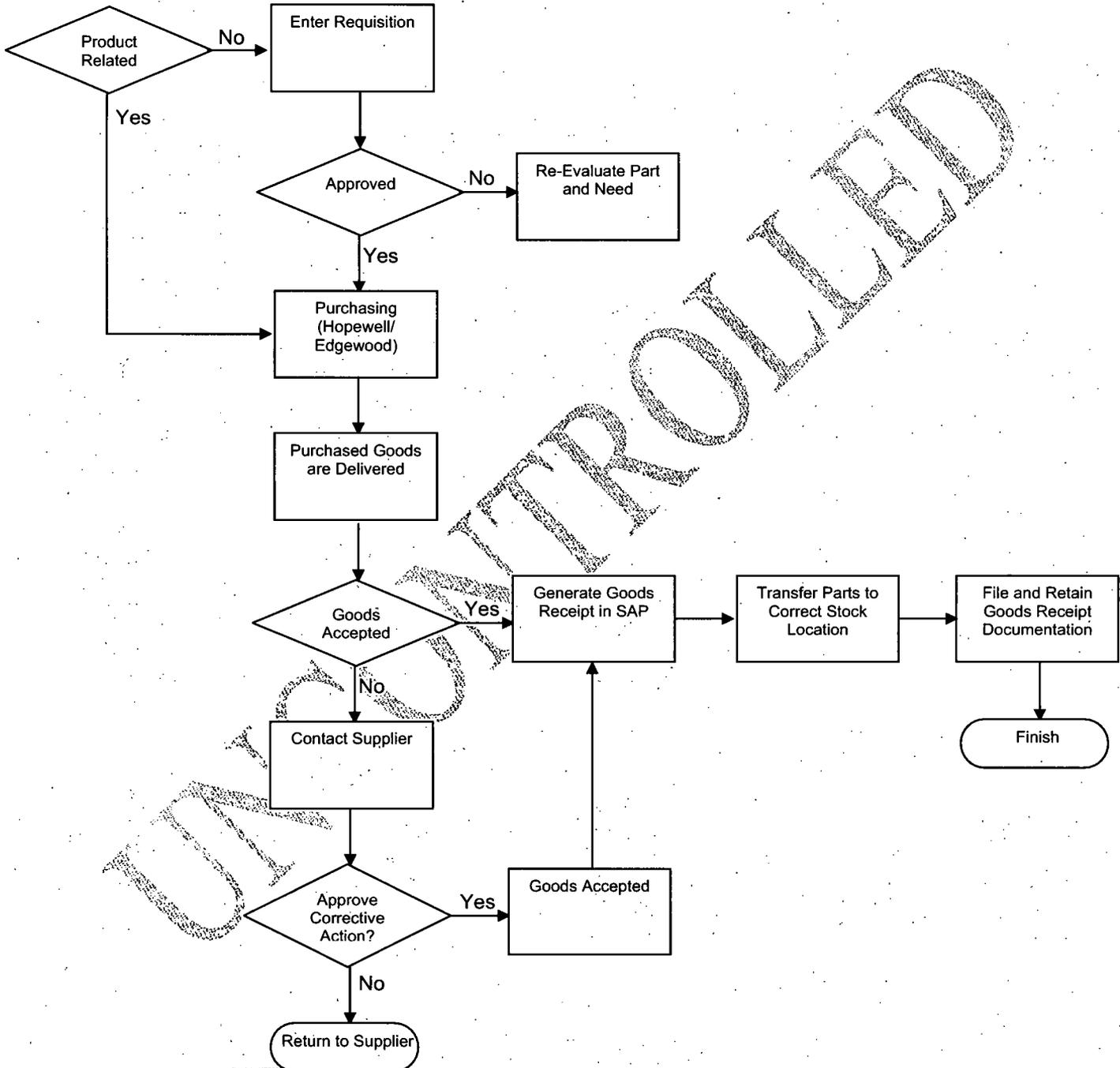
4.3.5 Any discrepancies will be resolved with the supplier prior to a goods receipt being generated.

4.3.6 When incoming inspection is required, a quality inspection plan will be created and material will be inspected against the criteria listed.

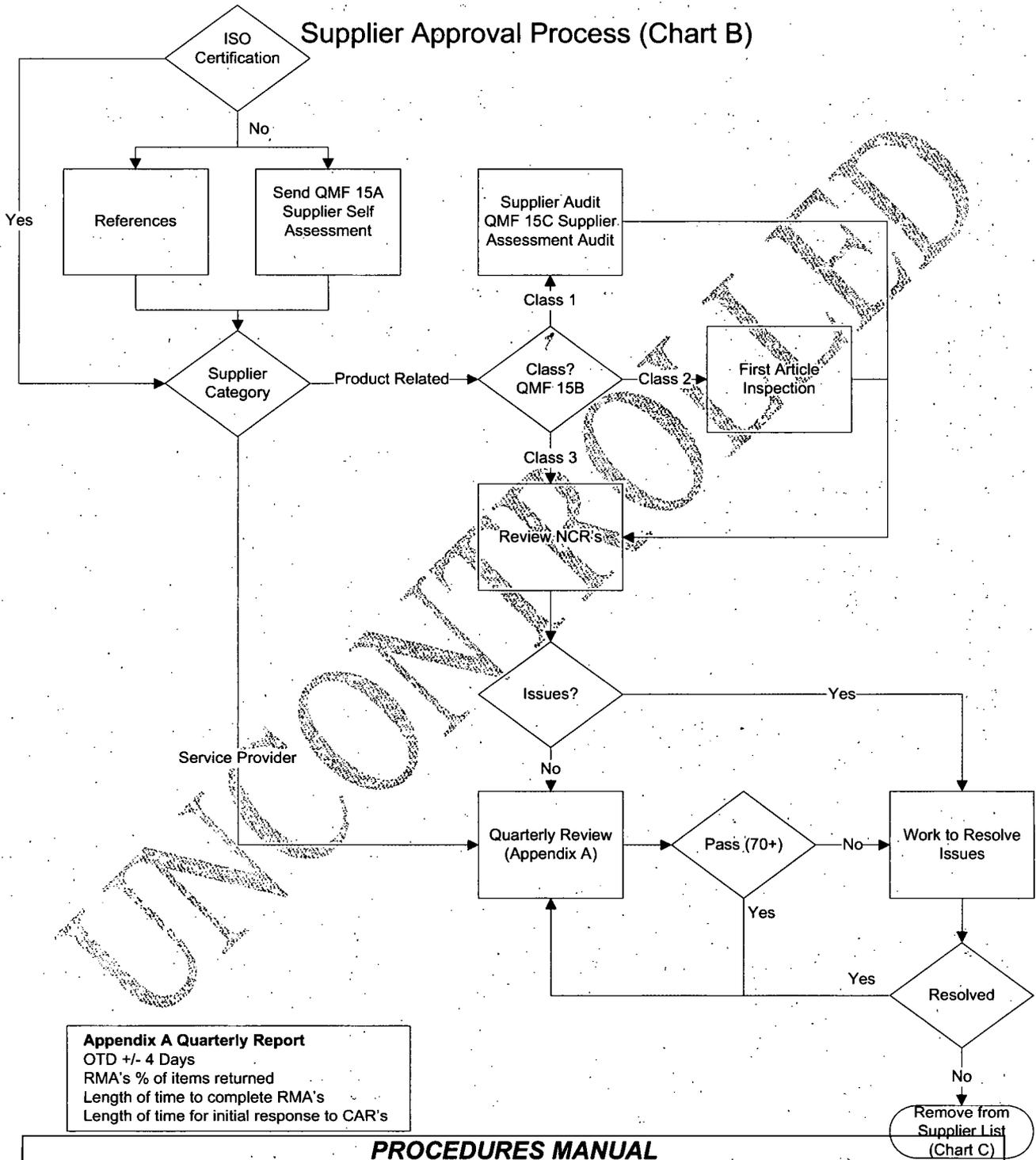
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Flow Chart – Purchasing (Chart A)

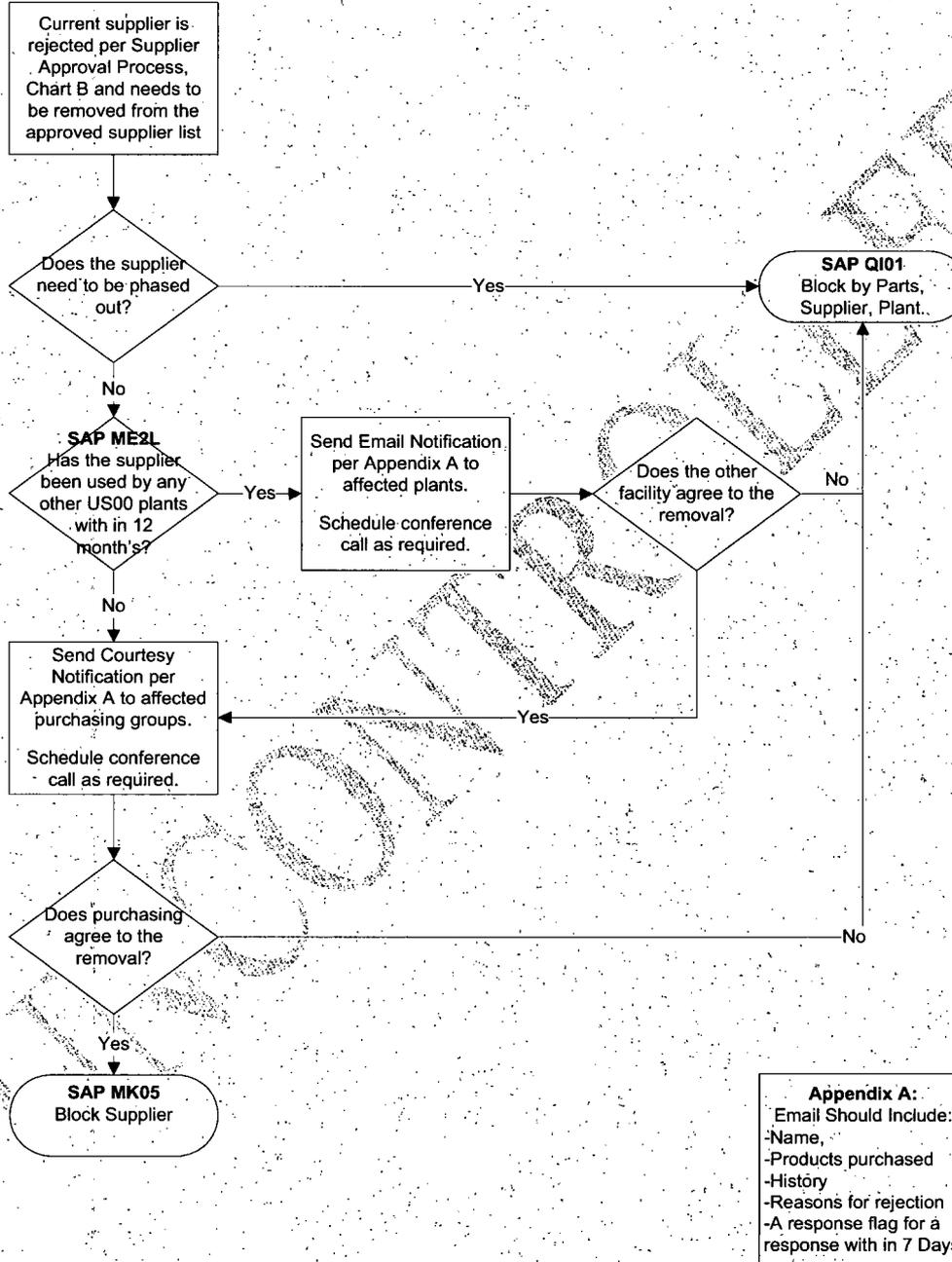


Supplier Approval Process (Chart B)



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Supplier Removal Process (Chart C)



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Reference Documents – Purchasing

- QMF 15 Preferred Supplier Register
- QMF 16 Purchase Order
- QMF 15A Supplier Self Assessment
- QMF 15B Supplier Classification Worksheet
- QMF 15C Supplier Assessment Audit

PRM07 Amendments

Page Number	Issue	Date	Description	Authorization
5-6		2/4/21/09	Update/ Correct Flow Charts	G. Genna
ALL		3/5/20/09	Update procedure to reflect current Practice and clear audit non-conform	G. Genna
ALL		4/6/9/09	Updated Procedure to reflect current Practice.	G. Genna
ALL		5/5/14/10	Updated to reflect corporate procurement	J. Davis
ALL		6/6/10/10	Updated Supplier Approval Process	J. Davis
All		7/7/13/10	Added Amendments to the last page	J. Davis
All		8/12/16/10	Added chart 3 Supplier Removal Process	J. Davis

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MEASURING AND MONITORING EQUIPMENT (ISO 9001:2008 Clause 7:6)

1.0 INTRODUCTION

When equipment is used to check that product meets the customer's requirements, that equipment shall be properly controlled and maintained. The equipment must be capable of making the required measurements to the specified accuracy. Where test software is used, it should be checked before initial use and rechecked at specific intervals.

2.0 SCOPE

This procedure covers all product verification, and measuring equipment used by the Organization whether owned by the Organization, leased/rented, on loan, owned by employees or provided by a customer. It also covers test hardware and software.

3.0 RESPONSIBILITY

It is the responsibility of the Quality Management Representative to:

- Identify the equipment to be used for the measurement and tests to be carried out together with the accuracy required.
- Ensure that all measuring, test and product verification equipment is identified, maintained, controlled, and checked or calibrated at defined intervals.
- Ensure that test software is validated to ensure its capabilities and accuracy, and is released in a controlled manner.
- Maintain adequate records.

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4.0 PROCEDURE

- 4.1 Measuring and test equipment, used during the manufacturing process and essential to product quality characteristics, shall be identified and logged in the Measuring and Monitoring Equipment Log (QMF 05).
- 4.2 Equipment which it is not practical to calibrate such as Steel rules and steel tapes will be subject to visual inspection by the user and replaced when deterioration is noted.
- 4.3 All measuring and product validation equipment detailed in the Measuring and Monitoring Equipment Log (QMF 05) will have a calibration record, noting acceptance criteria, identification marking, location, checking frequency, calibration dates and results.
- 4.4 The method of calibration will be identified (e.g. by a calibration laboratory or in-house traceable to national or international standards).
- 4.5 The details of equipment calibrated or checked in-house will be recorded on a Maintenance Log (QMF 05A).
- 4.6 Where measuring equipment is on loan or leased/rented, a certificate of calibration will be received for each such piece of equipment calibrated and retained on file by the Organization. Where an outside testing service calibrates any measuring equipment, the outside testing service shall provide the Organization with a certificate of calibration, which will be retained on file.
- 4.7 Equipment failing to meet the required standard must be identified for repair or discarded, and removed from the working area. Equipment can be marked as limited calibration if performance passes within calibration range. All equipment cleared for limited calibration will be clearly marked.

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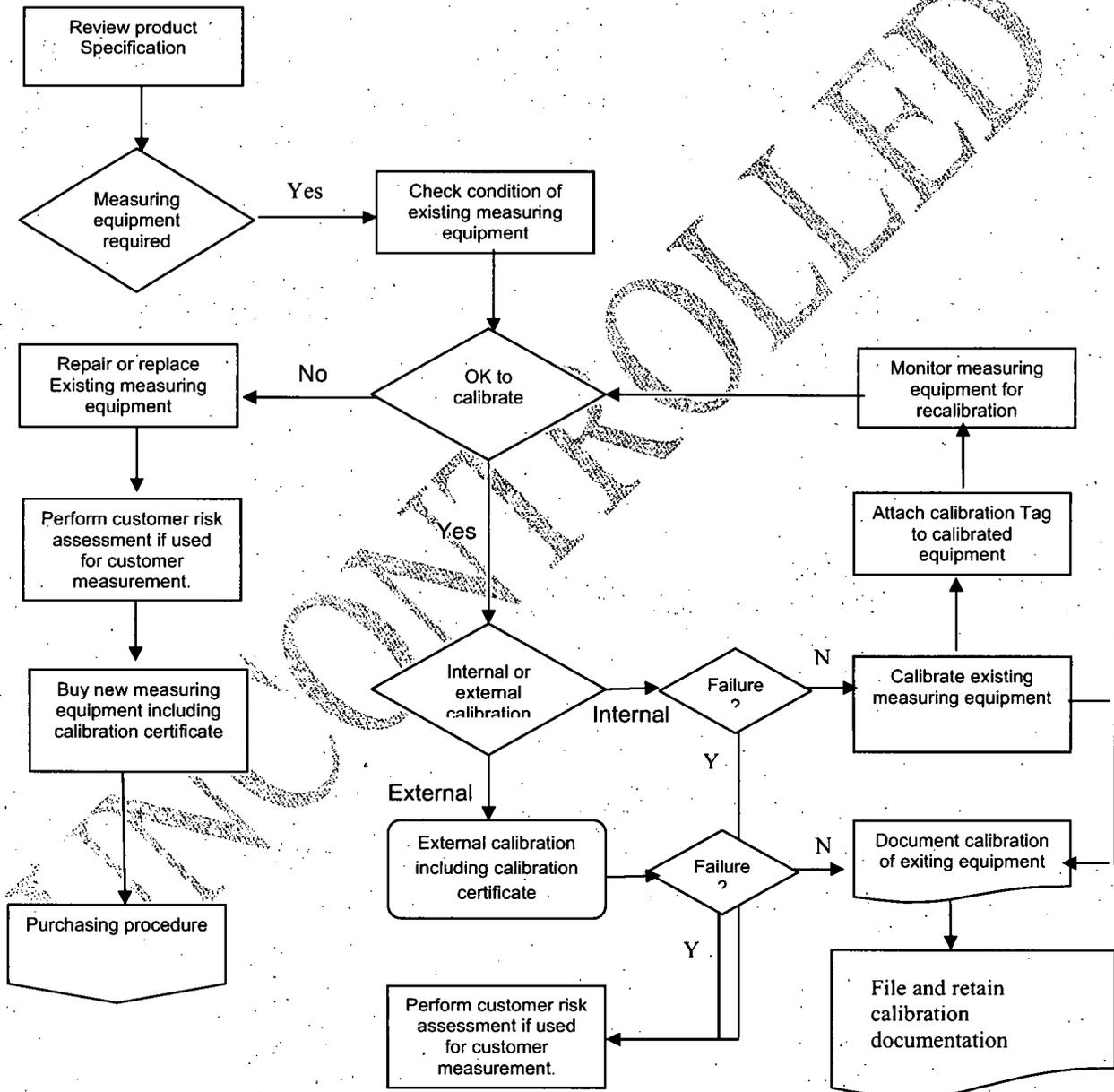
- 4.8 New equipment will be checked or calibrated before issue and the calibration record updated as necessary.
- 4.9 After completion of the calibration, the details will be recorded on the calibration tag or label on the equipment. Calibration records will be stored as per the PRM02. Hard copies are stored on QMR's office.
- 4.10 All measuring and product verification equipment used will be stored in conditions to ensure accuracy and fitness for use.
- 4.11 If a unit is found to be out of calibration, an assessment will be performed to determine the degree of risk for customer units. Action to mitigate customer risk will be determined based on the nature and level of risk.

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Flow Chart – Measuring and Monitoring Equipment



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Reference Documents – Measuring and Monitoring Equipment

- QMF 05 Measuring and Monitoring Equipment Log
- QMF 05A Maintenance Log

PRM08 Amendments

Page Number	Issue	Date	Description	Authorization
ALL		26/11/09	Updated procedure	G. Genna
All		37/13/10	Added Amendments to the last page	J. Davis

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INTERNAL AUDIT (ISO 9001:2008 Clause 8.2.2)

1.0 INTRODUCTION

The Organization's Quality Management System needs to be audited on a regular basis to ensure that the Quality Management System standards are being met in practice.

2.0 SCOPE

This procedure details the method of planning and carrying out the internal audit to verify that the Organization's procedures are being followed.

3.0 RESPONSIBILITY

It is the responsibility of the Quality Management Representative to ensure that:

- An internal audit program is prepared to review all aspects of the quality management system.
- Suitable personnel are trained and dedicated to carry out the internal quality audits.

It is the responsibility of the personnel performing the audits to identify any non-conformance and follow up to ensure completion of corrective and preventive actions.

4.0 PROCEDURE

4.1 Planning

4.1.1 An Internal Quality Audit Program (QMF 02) must be prepared covering all aspects of the Quality Management System. The audit program will be developed in such a manner as to ensure that each quality procedure is audited at least annually.

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4.1. Planning (continued)

4.1.2 Suitably trained auditors must be assigned to carry out the audit of each aspect of the system. The auditor should be independent of the work or area being audited.

4.1.3 Additional audits may be scheduled where problems or deficiencies are identified.

4.2 Conducting the Audit

4.2.1 The internal auditor(s) will carry out audits in accordance with the audit program.

4.2.2 Each element in the Quality Management System will be checked to ensure that its requirements are being met and that the overall objective of the system is being met.

4.2.3 Written notes on variances, non-conformance and omissions will be recorded through a Quality Corrective Action Request (QMF 04A) and circulated for action to appropriate personnel.

4.2.4 Supplementary notes will be taken of supporting information and records checked (e.g. job numbers, purchase orders, etc.).

4.3 Reporting and Closing Out Non-conformance

4.3.1 The internal auditor will be responsible for following up on designated actions and for providing information on incomplete items available for review at the Management Meeting.

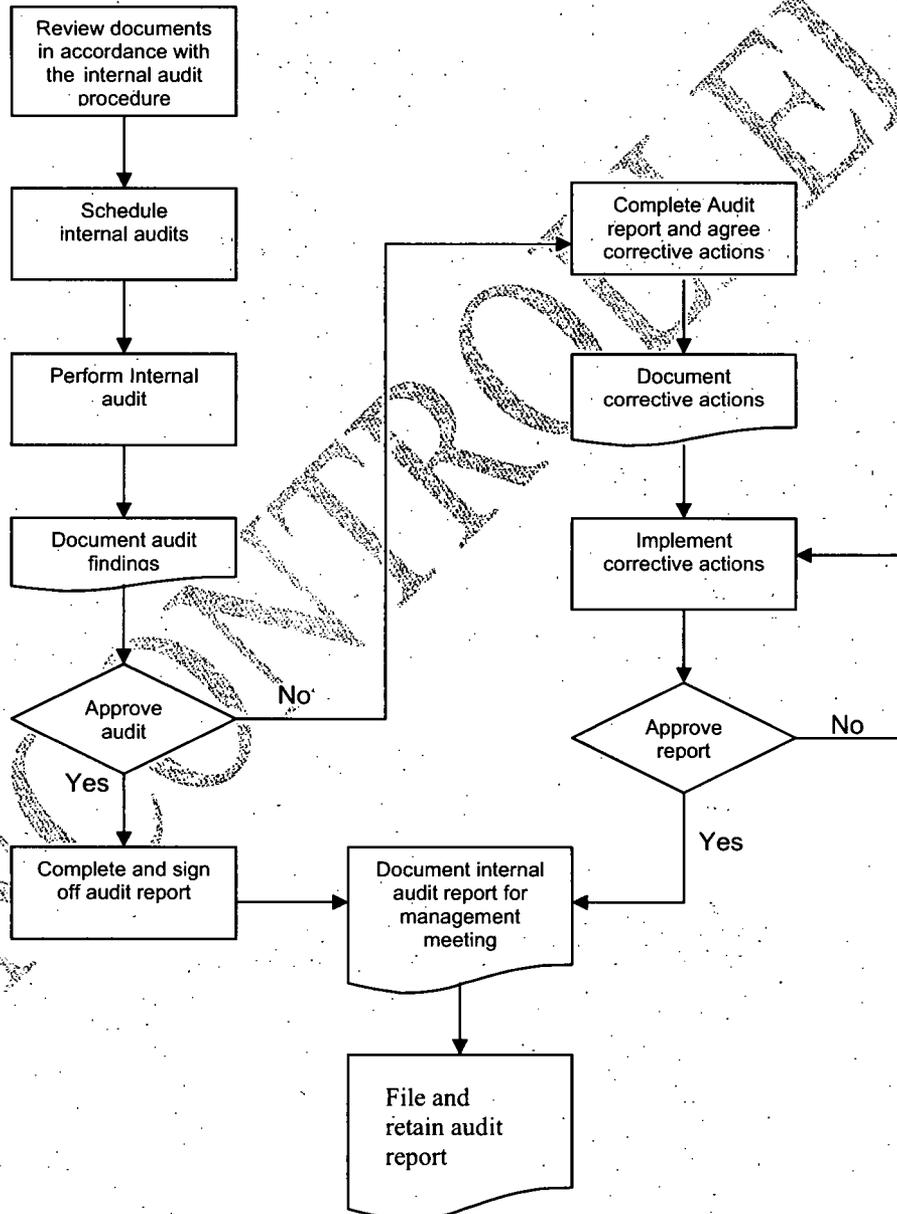
4.3 Reporting and Closing Out Non-conformance (continued)

4.3.2 If the internal auditor believes any procedure or method of the Quality Management System is not meeting its intended objectives, the procedure/method could be improved upon or further information is required, it will be discussed with the appropriate manager and corrective/preventive action will be taken. This will be reported at the Management Meeting.

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Flow Chart – Internal Audit



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Reference Documents – Internal Audit

QMF 02 Internal Quality Audit Program
QMF 04A Quality Corrective Action Request

PRM09 Amendments

Page Number	Issue	Date	Description	Authorization
All	2	6/17/10	Removed reference to QMF03 added reference to QMF04a	J. Davis
All	3	7/13/10	Added Amendments to the last page	J. Davis

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CONTROL OF NON-CONFORMING PRODUCT (ISO 9001:2008 Clause 8.3)

1.0 INTRODUCTION

When defective or substandard items are produced, the non-conforming product or service needs to be identified and corrected to prevent customer complaints. The causes of the non-conformance need to be identified and corrected to prevent recurrence, if possible.

2.0 SCOPE

This procedure addresses non-conforming products and services at all stages in the Organization's work process.

3.0 RESPONSIBILITY

It is the responsibility of the following personnel to ensure that the causes of the non-conformance are identified and corrected, and the necessary records are maintained.

- Customer complaints General Manager/ Service Manager
- Product/ Service non-conformances Operations Director
- Supplier non-conformances Materials Manager
- Quality system non-conformances Management Quality Representative

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4.0 PROCEDURE

4.1 General

4.1.1 Inspection of products during receipt, at all stages of the work process and prior to shipping should be aimed at identifying any non-conforming or defective products. All personnel must report non-conformances.

4.1.2 Non-conforming or defective product must be identified with a Non-Conforming Material Request (QMF 13) and moved to a quarantine area, if practicable.

4.1.3 All non-conforming or defective products/services must be dealt with promptly to prevent additional problems.

4.1.4 Non-conformance will be corrected by the most appropriate and cost effective method. This may include one or more of the following:

- Returning materials or goods to the supplier.
- Requesting a deviation from the customer.
- Modifying the production process.
- Rework the item.
- Scrap (i.e. dispose of) the item.

4.1.5 Non-conformance must be recorded together with the corrective /preventive actions taken.

4.2 Supplier Non-conformance

4.2.1 When a supplier's product is identified as non-conforming, it will be marked with a Non-Conforming Material Request (QMF 13). The non-conforming product will be subject to further investigation by the Organization and the supplier, if required.

4.2.2 When a non-conformance identified during a work process can be traced to a supplier, the product will be removed from the work area and handled in accordance with paragraph 4.2.1.

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4.2.3 When products received from a supplier are rejected, the parts are identified with a Non-Conforming Material Request (QMF 13) and moved to a quarantine area, if practicable

4.2.4 The inventory control specialist or their designee will be involved in making arrangements with the supplier regarding the inspection, return and credit, or disposal of the non-conforming product.

4.3 In Process Non-conformance

4.3.1 When a non-conforming work-in-process component or assembly cannot be corrected immediately the component or assembly will be identified with a Non-Conforming Report (QMF 13) and placed in a designated quarantine area (if practical).

4.3.2 If the material is set aside for further evaluation using the Non-Conforming Material Request (QMF 13), the material placed in the designated area to await evaluation and final disposition. A copy of the Non-Conforming Material Request (QMF 13) must also remain with the material in the designated area. The original form will be given to the inventory control specialist or their designee for processing.

4.3.2.1 Once the material is evaluated it need to be dispositioned in one of the following ways:

- If deemed usable, the material is to be returned to stock.
- If deemed unusable, the material is to be scrapped.
- If deemed unusable but can be repaired by vendor, the material will be returned to vendor using the Non-Conforming Material Supplier Request (QMF 13A).

4.3.2.2 The disposition is to be recorded by completing the disposition section on the copy of the original Non-Conforming Material Request (QMF 13) and kept with the material. The Inventory Control Specialist or designee will process the disposition accordingly.

4.3.3 If the material is identified with a Non-Conforming Material Request (QMF 13), then the material should be process in accordance with section 4.2 Supplier Non-Conformance.

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4.4 Customer Complaints

4.4.1 When a defect is identified by a customer, the Organization will record a complaint in the SAP System and log details into an SAP Service Notification (QMF 24).

4.4.2 When made to order goods are returned to the Organization by a customer, details will be recorded on a SAP Service Notification (QMF 24).

4.5 Follow-up Action

4.5.1 Customer complaint reports, associated correspondence and non-conformance reports will be retained for review and analysis.

4.5.2 Where required the Customer Non-conformance/ Corrective action report may be completed and supplied to the customer.

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Reference Documents – Control of Non-Conforming Product

- QMF 04 Complaints/Non-conformance Log
- QMF 04A Complaints/Non-conformance Form
- QMF13 Non-Conforming Material Request
- QMF13A Non-Conforming Material Supplier Request
- QMF 24 SAP Service Notification

PRM10 Amendments

Page Number	Issue	Date	Description	Authorization
ALL		2/5/20/09	Updated procedure to reflect current practice and clear audit non-conform	G. Genna
ALL		3/5/28/10	Updated Process to Reflect New forms	J. Davis
All		4/7/13/10	Added Amendments to the last page	J. Davis

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CORRECTIVE ACTION (ISO 9001:2008 Clause 8.5.2)

1.0 INTRODUCTION

A procedure shall be established and maintained to ensure that non-conforming products/services are identified and corrected. It is also important that the causes of such non-conformances are determined and that corrective actions are taken to reduce or eliminate the possibility of a recurrence.

2.0 SCOPE

This procedure details the method of dealing with corrective actions in order to correct or prevent future non-conformances and customer complaints.

3.0 RESPONSIBILITY

It is the responsibility of the following personnel to ensure that non-conformance and customer complaints are corrected and prevent reoccurrence:

- | | |
|------------------------------------|------------------------------------|
| • Customer complaints | General Manager/ Service Manager |
| • Product/service non-conformances | Operations Director |
| • Supplier non-conformances | Materials Manager/Purchasing Agent |
| • Quality system non-conformances | Management Quality Representative |

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4.0 PROCEDURE

4.1 General

4.1.1 The time, effort and cost to implement a corrective action shall be balanced against the significance of the non-conformance. The potential impact on the product/service, the process, the customer and safety must be balanced against the impact of a corrective/preventive action.

4.1.2 Sources of information for corrective action will include customer complaints/Non-conformance records, management review, and other management system records (i.e. internal audits, customer satisfaction records and process measurements).

4.1.3 Records will be maintained to document the non-conformance, the action planned, the corrective action taken, and the effectiveness of the action taken.

4.2 Corrective Action

4.2.1 The root cause of non-conformance must be determined and suitable corrective action must be taken to eliminate the cause of the non-conformance.

4.2.3 Follow up must be performed to ensure that the corrective action was effective and has eliminated or reduced the risk of the non-conformance occurring again.

4.2.4 There are generally 4 types of non-conformances that may occur:

1. Customer Complaint/ Non-Conformance
2. External Non-Conformance (i.e. Vendor Non-conformance)
3. Internal Non-Conformance
4. QMS Non-Conformance

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4.3 Customer Complaints and Non-conformances

4.3.1 Upon receipt of a customer complaint or non-conformance, the details of the complaint will be recorded in the SAP system on a SAP Service Notification (QMF 24), and appropriate action taken to resolve complaint.

4.3.2 All details (cause, action and follow-up) to correct a complaint/non-conformance will be detailed in the SAP Service Notification (QMF 24).

4.3.3 Non-conformances that are discovered to have a large customer impact will be addressed and be resolved using appropriate process (i.e. EC, TDD, RMA).

4.3.4 The review of large scale non-conformances and their efforts will be handled on a conducted on a weekly basis at the "EC Meeting". The EC meeting is conducted by the QMR.

4.4 External/ Internal Non-conformances

4.4.1 Upon identification of supplier or internal non-conformance, the non-conformance will be handled in accordance with PRM10.

4.5 QMS Non-Conformances

4.5.1 Quality Complaints/ Non-Conformances will be handled in accordance with PRM 10.

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Reference Documents – Corrective and Preventive Action

QMF 04 Non-conformance/ Complaints Log
 QMF 04A QCAR Form
 QMF 13 Non-Conforming Material Report
 QMF 24 SAP Service Notification

PRM11 Amendments

Page Number	Issue	Date	Description	Authorization
1-4		25/12/09	Changed procedure to reflect corrective action and removed Preventative action to make new procedure (PRM14)	G. Genna
All		36/17/10	Removed reference to QMF19	J. Davis
All		47/13/10	Added Amendments to the last page	J. Davis

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MEASUREMENT AND IMPROVEMENT (ISO 9001:2008 Clause 5.2, 8.1, 8.2.1, 8.2.3, 8.4 and 8.5.1)

1.0 INTRODUCTION

The Quality Management System shall be periodically reviewed to ensure that high quality standards are maintained and improved. The Organization needs to monitor its work processes to ensure that customer requirements and expectations are met. Measurement is aimed at achieving an "added value" benefit to the customer and the Organization. This process is Organization-wide and involves all personnel.

2.0 SCOPE

The scope of this procedure includes:

- Planning and control of all processes.
- Collection and analysis of data and information.
- Measurement of customer satisfaction.
- Monitoring and improvement of process capability.
- Continual improvement.

3.0 RESPONSIBILITY

It is the responsibility of the Quality Management Representative to ensure:

- The Quality Management System is in place to measure the Organization's performance.
- The Quality Management System is continually improved.
- Customer satisfaction is measured.

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4.0 PROCEDURE

4.1 General

- 4.1.1 The measurement and improvement process will include:
- Setting priorities and objectives.
 - Determining the methods used to collect data.
 - Allocating resources.
 - Carrying out the measurements.
 - Collection and analysis of data and information.
 - Communicating the results to the appropriate parties in a manner that is clearly understood.
 - Implementing the appropriate action.
 - Verifying that opportunities for improvement have been implemented.
- 4.1.2 Communication and information gathering will be through discussion with appropriate personnel, bulletin boards, and Management Meetings.
- 4.1.3 Other sources of information for the improvement process are covered in:
- PRM 03 Management Review
 - PRM 09 Internal Audit
 - PRM 10 Control of Non-conforming Product
 - PRM 11 Corrective and Preventive Action
- 4.1.4 The main resource for this process will be the Management Meeting.

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4.2 Collection and Analysis of Data

4.2.1 In order to measure quality performance, data and information need to be collected. This will address:

- Meeting customer requirements and measurement of customer satisfaction.
- Performance of suppliers.
- Assessment of the quality process and product characteristics and trends.

4.2.2 The Organization will determine what data is needed, the specific methodology to be used to collect data, and the frequency of the data collection. This may include the use of statistical techniques showing trends and variations.

4.2.3 Other sources of information detailed in section 4.1.2 may be used as necessary.

4.2.4 The goal is to improve the efficiency and performance of the Organization.

4.3 Customer Satisfaction

4.3.1 Customer satisfaction will be measured to ensure that:

- The product or service meets customer requirements.
- The price is competitive.
- The shipping process is timely.

4.3.2 Customer satisfaction will be measured through the following measures:

- On-Time Delivery
- Sales/ Employee
 - Other measures that may be used include:
 - Feedback from customer complaints.
 - Feedback from the customer during sales and ordering activities.
 - Formal or Informal, direct communication with the customer during the course of business.

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4.3.2 Customer Satisfaction (continued)

- Returns and repairs (i.e. non-conformances).

4.3.3 The information obtained must be analyzed and the appropriate action taken to improve customer satisfaction.

4.4 Monitoring the Process

4.4.1 The work process must be monitored to ensure that it is effective and to identify areas for improvement. This will include review of new equipment or processes, reject and rework rates, monitoring the achievement of targets, and reduction in equipment down-time and costs.

4.5 Monitoring of Suppliers

4.5.1 The performance of suppliers will be monitored for on-time delivery and the ability to meet the Organization's requirements.

4.6 Planning for Continual Improvement

4.6.1 The overall Quality Management System will be improved by:

- Setting objectives.
- Monitoring these by means of audits, analysis of corrective/preventive action, and customer complaint information.
- Evaluation of the effectiveness of each process.
- Taking the appropriate corrective action.

4.6.2 The improvement process will be reviewed and monitored at the Management Meeting.

4.6.3 New objectives will be set when the current objectives have been achieved.

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PRM12 Amendments

Page Number	Issue	Date	Description	Authorization
All	2	7/13/10	Added Amendments to the last page	J. Davis

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DESIGN CONTROL (ISO 9001:2008 Clause 7.3)

1.0 Introduction

The process of design or development of the product where user requirements rather than adequate specifications and samples are given, needs to be planned, controlled and clearly documented to ensure the product functions as intended and meets all of the user requirements. All aspects of the design need to be reviewed to ensure that the output meets the design brief including any other statutory or legal requirements.

2.0 Scope

The scope of this procedure includes:

- Planning and control of the design process including the control of changes.
- Translation of the design brief into a design that meets all of the input requirements.
- Modifications to existing design.
- Review of the design at appropriate stages.
- Verification and validation that the design is satisfactory and will perform as intended.

3.0 Responsibility

It is the responsibility of the General Manager through Engineering to ensure:

- The Development design process is properly planned and controlled.
- The Customers or users needs are understood and are translated into a clear design specification.
- The design meets all the specified requirements.
- The design is reviewed to check that it will work as intended.

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3.0 Responsibility (continued)

- Design verification and validation is carried out in accordance with the planned arrangements

4.0 Procedure

4.1 General

4.1.1 All personnel carrying out design activities will be suitably qualified and experienced in accordance with PRM 03 Resources.

4.1.2 The results of design reviews, verification and validation activities, and any changes and follow up action will be recorded on the documentation contained in the New Product Development Process (NPDP), Software Release Procedure and the ECN process.

4.1.3 The responsibilities and interfaces between all personnel involved in the design process must be clearly defined. e.g. design, production, purchasing etc.

4.1.4 Measuring and test equipment used for verification or validation will be controlled in accordance with PRM 08 Measuring and Monitoring Equipment.

4.2 Design and development planning

4.2.1 The design process must be planned and controlled such that appropriate resources are available when required.

4.2.2 Planning will include the identification of points when design reviews, verification, and validation need to be carried out. Design plans or schedules will define all key stages.

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4.2 Design and development planning (continued)

4.2.3 The interfaces between those involved in the design must be defined together with their responsibilities.

4.2.4 Design planning will also address the control of subcontracted parts of the work, reliability, safety and environmental aspects.

4.3 Design and development inputs.

4.3.1 The design input (specification) must take into account all of the Customer or user requirements and define the functional performance requirements as clearly as possible.

4.3.2 Legal and statutory requirements for the appropriate market must be identified.

4.3.3 Other essential information will be collected, including any information from previous similar designs. The intended use and the need for maintenance, disposal requirements, budgetary control and value engineering will be taken into consideration.

4.3.4 The form of input will be in the form of Customer and Company generated samples and specifications as appropriate.

4.3.5 Testing and verification requirements will be identified including any Customer involvement. When samples form part of the design, the verification and validation requirements will also be clearly defined.

4.3.6 The input data will be reviewed for missing information and any deficiencies will be resolved.

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4.4 Design and development outputs

- 4.4.1 The design will be documented in a Development File, including but not limited to; Rough Notes, Meeting Records, SOP's, instructions, specifications, and samples.
- 4.4.2 The design will be verified or checked to ensure that it meets all of the input requirements.
- 4.4.3 All designs will be formally reviewed before release to the user or for manufacture.
- 4.4.4 The acceptance criteria for the design must be clearly defined.
- 4.4.5 Adequate operation and maintenance information will be provided together with any training requirements for the user.
- 4.4.6 Any safety characteristics or procedures for safe use must be clearly identified.
- 4.4.7 Other items to be considered as appropriate to the particular Development :
- Stages in design. Conceptual design, final design, subcontracted design etc.
 - Purchasing.
 - Consequence of failure.
 - Workmanship standards.
 - Identification of critical features.

4.5 Design and development review

- 4.5.1 The design will be periodically reviewed in accordance with the NPDP, Software Release Process or ECN process to confirm the ability to meet all of the requirements and meet the needs of the Customer/ User.

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4.5 Design and development review (continued)

4.5.2 All parties involved in the design review will be identified.

4.5.3 The review will evaluate potential problems together with the consequence of any failure. Safety, reliability, and environmental aspects of the design will be taken into consideration.

4.5.4 Meetings to further the development will occur within the NPDP, Software Release Process or ECN process. The findings will be summarized and actions required will be listed and responsibility allocated. Findings will be circulated as necessary.

4.5.5 Requests for clarification or the resolution of questions will be submitted and/or recorded formally on letter headed hard format.

Other items to be considered as appropriate to the particular Development:

- Potential delays
- Costs
- Document status
- Regulatory or legal requirements
- Purchasing requirements
- Opportunities for improvement in design and the overall process
- Review of test, verification and validation requirements and data

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4.6 Design and development verification

- 4.6.1 Before the design is released for use or manufacture it must be thoroughly checked and tested against the specified requirements. This will be to prove that the design is capable of meeting or exceeding all of the requirements of the design input together with any other regulatory or legal requirements.
- 4.6.2 These tests must be at least as stringent as the design would be expected to withstand in use
- 4.6.3 The method of verification will be by documented completion of Performance Test Criteria
- 4.6.4 Details of verification will be recorded within the NPDP, Software Release Process or ECN process.
- 4.6.5 Any changes carried out as a result of this process will be re-tested

4.7 Design and development validation

- 4.7.1 The product will be checked to ensure that it meets its intended purpose. All significant characteristics of the design will be checked.
- 4.7.2 The conditions for validation must be defined.
- 4.7.3 Validation may be carried out before delivery to the Customer or user if possible. The validation process will be completed in conjunction with possible third-party testing.
- 4.7.4 Any problems with the design will be fed back into the design review process.

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4.8 Design and development changes

- 4.8.1 All changes that effect design after release must be clearly identified and will be controlled to the same standard as original information.
- 4.8.2 Changes must be documented on a NPDP, Software Release Process or ECN process and formally approved before being passed on to the appropriate personnel for implementation.
- 4.8.3 The effect of any changes on the overall design will be evaluated and the resulting design will be rechecked and validated.
- 4.8.4 All changes will be detailed, defining the original design point, the new design point, reason for change, and referring to any supporting specifications, or calculations. Any consequent changes to the contract arrangements including, price, delivery, or performance will also be documented or referenced.

4.9 Engineering Waiver

- 4.9.1 Where a temporary deviation from a company specification for a particular job is required this will be requested using the Temporary Development Deviation (TDD) process.
- 4.9.2 The engineering deviation will be submitted to the Engineering Manager(s) who will approve the request as appropriate. Further approvals may be necessary. A record of the approval will be recorded on the TDD form.
- 4.9.3 A Log is retained recording all waivers submitted to the Engineering Manager. This log is retained and a copy of the TDD is kept in the Instrument File.

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4.10 Engineering Change

4.10.1 If a change to an existing design is requested the requesting department will complete an ECN form and submit it to Engineering Manager. The change request will be reviewed and, if approved, and where required, any new specifications, Inspection Documentation or Production Reports will be raised at the new revision level. The details of the change will be recorded in the ECN Files.

PRM13 Amendments

Page Number	Issue	Date	Description	Authorization
All	2	7/13/10	Added Amendments to the last page	J. Davis

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PREVENTATIVE ACTION (ISO 9001:2008 Clause 8.5.3)

1.0 INTRODUCTION

A procedure shall be established and maintained to ensure prevention of non-conformances. It is also important that the causes of such non-conformances are determined and that preventative actions are taken to reduce or eliminate the possibility of an occurrence.

2.0 SCOPE

This procedure details the method of dealing with preventative actions in order to prevent future non-conformances and customer complaints.

3.0 RESPONSIBILITY

It is the responsibility of the following personnel to ensure that the organization focuses on the prevention of non-conformances:

- | | |
|------------------------------------|------------------------------------|
| • Customer complaints | General Manager/ Service Manager |
| • Product/service non-conformances | Operations Director |
| • Supplier non-conformances | Materials Manager/Purchasing Agent |
| • Quality system non-conformances | Management Quality Representative |

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4.0 PROCEDURE

4.1 General

4.1.1 The time, effort and cost to implement a preventative action shall be balanced against the significance of the potential non-conformance. The potential impact on the product/service, the process, the customer and safety must be balanced against the impact of a preventive action.

4.1.2 Review of process and/or work operation records and procedures may indicate a potential area of concern that could be addressed prior to it becoming a non-conformance that needs correcting. Sources of information for preventative action will include customer complaints/Non-conformance records, management review, and other management system records (i.e. internal audits, customer satisfaction records and process measurements).

4.1.3 Records will be maintained to document the action planned, the action taken, and the effectiveness of the action taken. Actions will be tracked in the minutes of the Sustaining Engineering Meetings (i.e. EC Meeting), Management Review Meeting, Ad-Hoc product meetings, EC folders,

4.2 Preventive Action

4.2.1 Preventative Action review occurs in planned and "as needed" intervals. Examples of planned review include Daily Operations Meetings, New Product Development Process (NPDP) and Engineering Change (EC) Process.

4.2.2 When a potential condition is identified that compromises customer products, process or the quality system, it will reviewed as part of meeting such as sustaining and engineering meetings, Daily Operations Meeting or Management Review.

- Examples of sources of data that will drive preventative action include:
 - KPI Metrics
 - Customer Feedback through SAP service notifications (QMF24)
 - Vendor Non-Conforming Process (PRM10 & QMF13)
 - NPDP Process

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- EC Process
- QCAR results from Internal Audits (QMF04a)

4.2.3 Documentation of Need, Action, Results and Review will occur within the appropriate process (NPDP process, EC process, Management Review, Meetings, etc...)

4.2.4 Examples of Implemented Preventative Action Include:

1. Sales Order Checklist
2. Packing Checklists
3. NPDP Risk Assessments
4. Specific EC's (i.e. Pre-Amp)

Reference Documents – Corrective and Preventive Action

QMF 04 Non-conformance/ Complaints Log
 QMF 04A QCAR Form
 QMF 13 Non-Conforming Material Report
 QMF 24 SAP Service Notification

PRM14 Amendments

Page Number	Issue	Date	Description	Authorization
ALL	1	5/13/09	Initial Release New Procedure	G. Genna
All	2	6/17/10	Removed reference to QMF19	J. Davis
All	3	7/13/10	Added Amendments to the last page	J. Davis

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THIS DETECTOR CONTAINS
RADIOACTIVE MATERIAL
THE PURCHASER IS EXEMPT
FROM ANY REGULATORY
REQUIREMENTS

Radionuclide: Na-22
Activity: 0.016uCi

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MODEL	RADSEEKER D	SERIAL	XXXXX
PART #	4822400HHB	CAGE	35471
VOLTS	15VDC	AMPS	1.6



3547 4822400HHB XXXXX

CAUTION: RADIOACTIVE MATERIAL

ISOTOPE: Na-22 AMOUNT: .005 μ Ci



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RadSeeker™ DL

Operator's Manual

Draft Document, Revision A3, November 2010
Part Number: 6822403

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Welcome

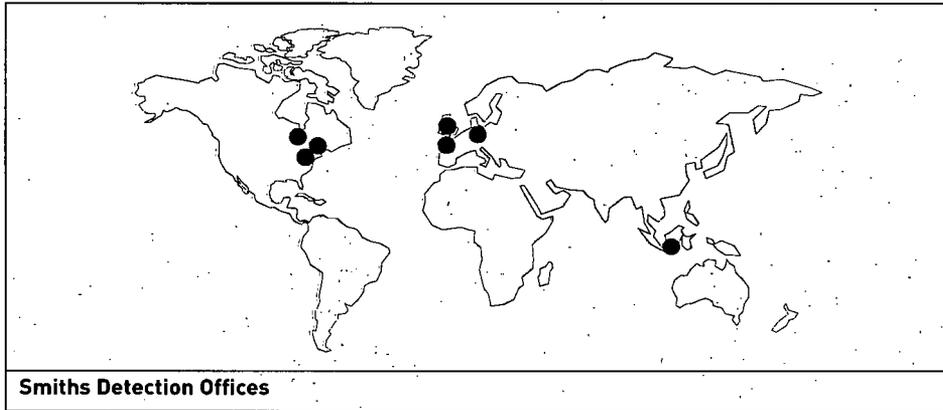
The RadSeeker DL employs new radiation detector technologies to accurately and rapidly identify and report threat material.

RadSeeker DL is ideally suited for a large number of Scanning applications such as:

- Ports and borders security inspection
- Use in emergency response and force protection area inspections
- Mass transit passenger Scanning
- Critical Infrastructure

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<p>Smiths Detection EUROPE SARL 36, rue Charles Heller 94400 Vitry sur Seine FRANCE Telephone: +33 (1) 55.53.55.55 Fax: +33 (1) 46.80.34.99</p>	<p>Smiths Detection Im Herzen 4 65205 Wiesbaden GERMANY Telephone: +49 (611) 9412-0 Fax: +49 (611) 9412-229</p>
<p>Smiths Detection ASIA PACIFIC 100 Beach Road #20-06 Shaw Towers SINGAPORE 189702 Telephone: +65 6466 1700 Fax: +65 6469 2506</p>	

Warranty

All equipment sold by Smiths Detection, which is manufactured by them, is warranted against defects in material and workmanship under normal operation and following manufacturer's instructions for a period of twelve (12) months from the date of delivery. For equipment other than that manufactured by Smiths Detection and sold in connection with Smiths Detection equipment, the original manufacturer's warranty shall apply to the extent any such warranty is assignable by Smiths Detection. Equipment and parts subject to consumption and normal wear and tear are not covered by this warranty.

Smiths Detection's responsibility under this warranty is limited to the repair or replacement, at Smiths Detection's option, of defective parts FOB Smiths Detection's plant, provided that prompt notice of any defect is given by Purchaser to Smiths Detection in writing within the applicable warranty period and that upon the Purchaser's return of the defective equipment or parts to Smiths Detection, properly packed and with transportation charges prepaid by Purchaser, inspection thereof shall reveal to Smiths Detection's satisfaction that Purchaser's claim is valid under the terms of this warranty.

The delivery of repair or replacement parts shall not interrupt or prolong the term of the warranty. Smiths Detection's warranty ceases to be effective if Purchaser fails to operate and use the equipment sold hereunder in a safe and reasonable manner and in accordance with Smiths Detection's written instructions.

Notwithstanding anything in this warranty to the contrary, Smiths Detection shall not in any event be liable to Purchaser or any other person for any liability, claim, loss, damage or expense of any nature whatsoever caused directly or indirectly by the equipment or any inadequacy thereof for any purpose, or any deficiency or defect therein, or the use or maintenance thereof, or any delay in providing or failure to provide servicing or adjustments thereto, or any interruption or loss of service or use thereof, or any loss of business, or any incidental or consequential damages (including loss of profit), whatsoever or howsoever caused.

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smiths detection

RadSeeker™ DL

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Chapter 1 Safety

1.1 Introduction

This document provides guidance regarding the safe and proper use of the RadSeeker DL high performance radionuclide identification system. It is important that the information herein is followed at all times. Where they exist, relevant local and national regulations, codes of practice, and transport regulations must be applied.

The primary purpose of the RadSeeker™ DL is to detect and identify radioactive material and identify small signals from the energy profiles of isotopes. This is not a safety device or a personal safety monitor.

1.2 General Radiation Safety and Review



Radioactive Material. This product contains a Na-22, 0.016uCi radioactive source. Do not attempt to access or remove this source. Attempting to tamper with the radioactive source will void the warranty on the product.

To avoid danger it is essential that these instructions are strictly observed:

- a. This product is distributed under 10 CFR 32.14. The user is exempt from any regulatory requirement.
- b. This unit has been approved by the US NRC as an exempt device. Leak testing is not required.
- c. Storage:
The unit should be stored at room temperature (22°C) to ensure that the source integrity is maintained. Humidity should also be kept as low as reasonably possible.

d. Transfer

Should the unit require disposal or no longer be required for use, attach a IATA label, UN2911, with a text description marked "Fragile."

Return the prepaid system to:

Smiths Detection
ReachBack
21 Commerce Drive
Danbury, CT 06810
USA

e. Disposal

NOTE: According to US NRC Regulations this device may be disposed of as ordinary refuse. Please be advised that this device may contain other hazardous substances, which must be disposed of in accordance with federal, state, and local requirements. Contact Smiths Detection for disposal instructions.

The following items must be returned to Smiths Detection Canada for disposal, refer to mailing instructions above.

- The Gamma Detector assembly
- The Neutron Detector assembly

The end user is not subject to any regulatory requirement. The remaining parts of the unit may be disposed of as ordinary waste, such as:

- Aluminum – housings, chassis, various assemblies and components
- PC boards –Charger, Display and Processor, etc.
- Copper wiring – wiring harnesses, point to point wiring
- Various plastics – Teflon®, nylon, Delrin®, ABS, polycarbonate, etc.
- Hardware – zinc plated steel screws, nuts, bolts, washers, spacers, stainless steel screws, nuts and washers

Refer to Federal, State and local regulations and Bylaws concerning disposal of non-radioactive waste. Consult the MSDS for further information.

1.2.1 Emergency Response

1. Do not operate the unit if it is damaged or damage is suspected. Pack the unit in a heavy-duty cardboard box with enough fill to ensure safe transport of the unit. Send the unit back to Smiths Detection for servicing.
2. If the unit is involved in a fire or explosion, the immediate area must be secured. Contact your local control agency IMMEDIATELY for radiological removal assistance.
3. If the unit is lost, the Radiation Safety Officer must be informed. Records of any investigation taken to locate the lost material must be kept for an appropriate period.

For additional information concerning the disposal of the instrument, contact the Radiation Safety Officer at Smiths Detection: (1) 203 207 9700.

1.3 International Regulatory Information

Before using the radioactive device, the customer must take all actions necessary to ensure that they are complying with their national or state regulations which apply to the use of a sealed nuclear device.

In most countries, regulations are closely related to the International Atomic Energy Agency (IAEA) regulations, standards, and codes of practice. If the devices have to be transported, it is necessary to comply with the current IAEA "Safety Regulations for the Safe Transport of Radioactive Material," Safety Requirements no. TS-R-1, 2005 edition, which can be found at the following link:

<http://www-ns.iaea.org/standards/documents/default.asp?sub=200>

1.4 US Radiological Safety Information

This unit has been approved by the US NRC as an exempt device. The end user is not subject to any regulatory requirement. It may be disposed of as ordinary waste.

Should the unit require disposal or no longer be required for use, attach a UN2911 label and return the system to Smiths Detection for radioactive source removal.

For additional information concerning the disposal of the instrument, contact the Radiation Safety Officer at Smiths Detection:

- United States, (1) 203 207 9700
- Canada, (1) 905-817-5990

1.4.1 Packaging Instructions for the Return of the Device

The Gamma Detector and Neutron Detector assemblies can be returned as part of the whole system or individually in a shock resistant container with styrofoam packing with a minimum thickness of 6 inches. If the Gamma Detector and Neutron Detector assemblies are returned as a part of the RadSeeker system, then the system should be returned in its original container.

- a. The packaging must be so designed that the package can be easily handled and can be properly secured in the aircraft during transport.
- b. A package must be provided with means of manual handling.
- c. The outer layer of packaging must be so designed as to avoid, as far as practicable, the collection and retention of water.
- d. Any feature added to the package at the time of transport which is not a part of the package must not reduce the safety of the package.
- e. A label marked "Fragile" and an International Air Transportation Association (IATA) UN2911 label should be placed on the outside packaging as well as on the unit.
- f. Shipped under the UN code 2911- RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - ARTICLES.
- g. The accompanying shipping papers should contain exactly the following: "Radioactive Material, Excepted Package - Instrument".

NOTE: The procedures described in this section are sufficient for the preparation of the device for shipping; no additional instructions are necessary. In addition to the regular shipping documents.

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RadSeeker™ DL

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Chapter 2 RadSeeker DL Overview

The RadSeeker DL is designed to:

- Detect unauthorized nuclear materials at border crossings and seaports
- Rapidly and reliably discriminate between Innocent and Threat sources such as Special Nuclear Materials (SNM) and Radiological Dispersal Devices (RDD), as described in ANSI N42.34
- Locate and identify potentially dangerous nuclear radiological materials in unsuspected locations

The principal operational environments are:

- Searching for radiological and nuclear material at ports of entry and checkpoints, including:
 - Custom and Border Protection operations
 - Line-up Scanning of specific objects identified by other means, such as; primary detectors or intelligence information
 - Scanning of people, cars, trucks, containers, railcars, and other conveyances
 - Scanning wide areas such as accident scenes, special events, buildings, ships, public/open areas, container/yard checkpoint areas, piers, aircraft, etc.
- Emergency responders and force protection (Hazmat or Defence response teams)

2.1 RadSeeker DL Main Features

The portable RadSeeker DL has an operational capacity of 8(+) hours on a fully-charged battery. The display is a high-contrast, high-resolution color Organic Light Emitting Diode (OLED) that displays color coded backgrounds and messages, which provide all relevant data for the Operator.

The operator can also connect the RadSeeker DL to a PC for data viewing and programming using the RadSeeker DL Detector Controller software to offload files and upgrade SW/FW.

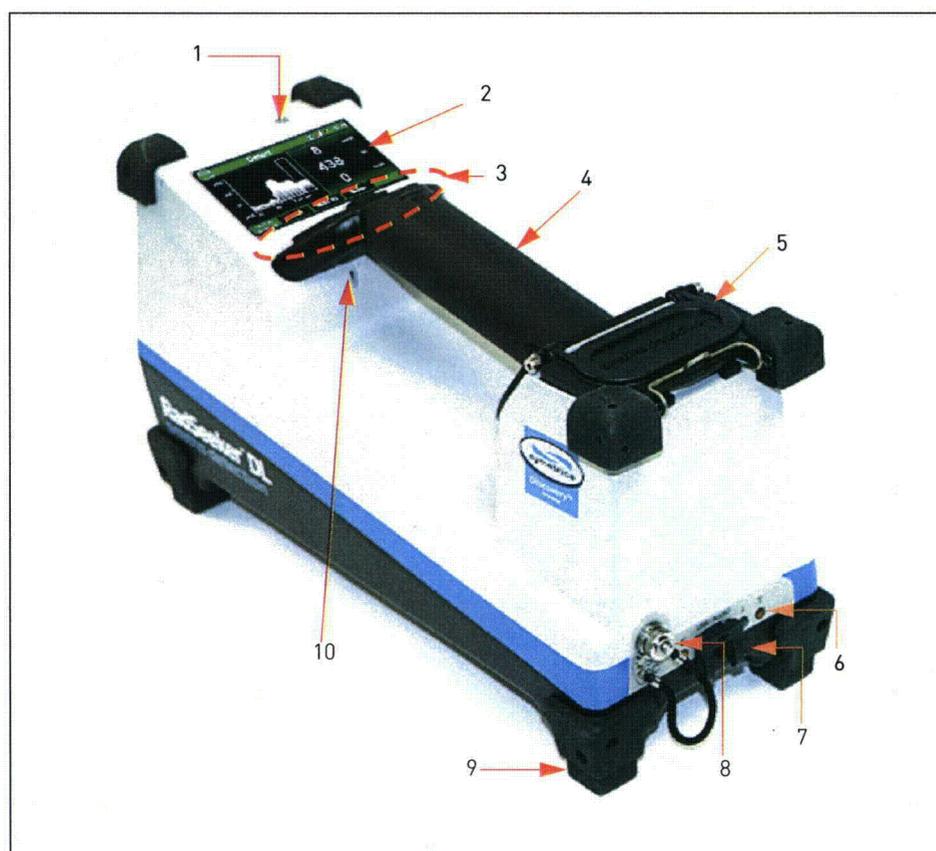


Figure 2-1 RadSeeker DL

1. Sensor for Automatic Light Adjustment 2. OLED Display 3. Key Pad 4. Tactile Alert 5. Battery Cover 6. LED Alarms 7. USB/Audio Connections 8. External Power Connection 9. Bumpers 10. Beeper

2.1.1 OLED Display

The OLED display has many advantages, including temperature range, high-contrast (10,000:1), wide viewing range, and the ability to run in low power. The display is in landscape format with a resolution of 480 pixels wide by 272 pixels high.

The OLED display is composed of three main sections: Mode and Status, Data Display and Message area. Refer also to [Table 2-1 on page 2-4](#) for icon descriptions.

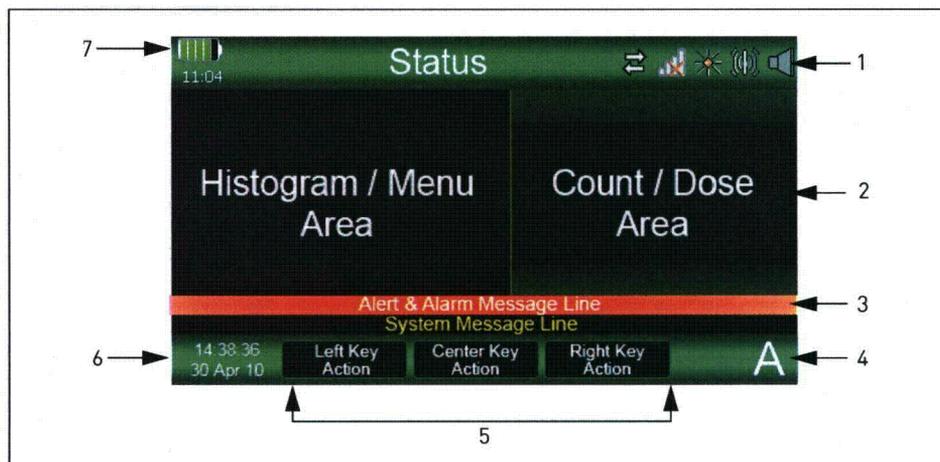


Figure 2-2 OLED Display Sections (Typical)

- 1. Mode/Status and Icon Area
- 2. Histogram Menu - Data Display Area
- 3. Message Area
- 4. Advanced/Service Indicator
- 5. Function Keys
- 6. Date and Time
- 7. Battery

Screen Display	Description
Mode and Status	Displays the current operational mode and status indications (Refer to Table 2-1 on page 2-4).
Histogram - Data Display	Menu Area: Shows the gamma dose rate, history, menus or alarm messages. Count / Dose Area: Shows the current gamma dose rate, gamma gross count rate, and neutron gross count rate.
Message	Displays context sensitive instructions and messages.
Advanced/Service Indicator	 When the user is in Advanced mode, the letter A appears in the bottom-right corner.  When the user is in Service mode, the letter S appears in the bottom-right corner. NOTE: The area remains empty when user is in Normal mode.

Screen Display	Description
Function Keys	<ul style="list-style-type: none"> Select, scroll up or down, increase figure amount or move to next field (i.e. when entering a password), go back to previous menu or screen (Refer to Table 2-2 on page 2-6).
Date and Time	Displayed on the unit

2.1.1.1 Display Icons

The display includes several icons. These icons include communication status, alert/ alarm annunciator status and battery capacity.

Table 2-1 Display Icons and Descriptions

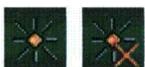
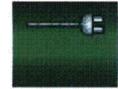
Icon	Description
	Audible sound is enabled or disabled (red X).
	The data transfer icon indicates if the communication ports are enabled or disabled (red X).
	Alert / Alarm LEDs enabled or disabled (red X).
	Vibration in handle is enabled or disabled (red X).
	The Wi-Fi icon indicates if a connection to an access point has been established and the signal strength when a connection has been established. A red X indicates the Wi-Fi is disabled.
	Indicates how much battery charge remains in hours and minutes. NOTE: This is the factory default setting.
	Indicates how much battery charge remains when the Battery Format is set to percent. Refer to "Basic System Configuration" on page 3-16 .
	Indicates that the unit is plugged into AC power and the battery is charging. NOTE: When set to Time the remaining charge indicator does not display when plugged into AC power.
	Indicates that the unit is plugged into AC power and the battery is charging when the Battery Format is set to percent.

Table 2-1 Display Icons and Descriptions (Continued)

Icon	Description
	Indicates the unit is connected to AC power and that the battery is fully charged. NOTE: When set to Time, the remaining charge indicator does not display when plugged into AC power.
	Indicates the unit is connected to AC power and that the battery is fully charged when the Battery Format is set to percent.
	Indicates that the unit is plugged into AC power and that no battery is present.
	Based on the type of Radio Signal Strength Indicated (RSSI) one of the following icons displays: <ul style="list-style-type: none"> A Looking glass over the RSSI bars indicates the radio is not associated or authenticated to a Wi-Fi access point.
	<ul style="list-style-type: none"> One blue bar indicates the RSSI for the current access point (to which the radio is associated) is -90 dBm or weaker. This indicates that a 802.11b/g radio will operate at 802.11b data rates only.
	<ul style="list-style-type: none"> Two blue bars indicates the RSSI for the current access point is stronger than -90 dBm, but not stronger than -70 dBm. This indicates that a radio will operate at 802.11g or 802.11a data rates that are less than 54 Mbps.
	<ul style="list-style-type: none"> Three blue bars indicates the RSSI for the current access point is stronger than -70 dBm, but not stronger than -50 dBm. This indicates that a radio should operate consistently at 54 Mbps.
	<ul style="list-style-type: none"> Four blue bars indicate the RSSI for the current access point is stronger than -50 dBm.
	Scroll up a one line at a time or used when setting a value.
	Scroll down the display one line at a time.
	Scroll up the display one screen at a time.
	Scroll down the display one screen at a time.
	"Select" key. Used to acknowledge a command, select a feature/item or Power key.

2.1.2 Keypad

The keypad consists of three buttons.



Figure 2-3 Keypad

Table 2-2 Keypad Description

Button	Function
	<p>Press to activate the selected menu option</p> <ul style="list-style-type: none">• Acknowledge an alarm• Back (only from System Information, Health, and Log menus)• Cancel• Toggle options On and Off
	<ul style="list-style-type: none">• Scroll up through some menu options• Increase value on display
	<ul style="list-style-type: none">• Scroll down through the menu options• Move to next field (i.e. when entering a password)

2.1.3 Connections

The RadSeeker DL also features connection points for:

- USB cables
- Audio (Ear Phones) via USB to audio adapter cable
- External Power Supply

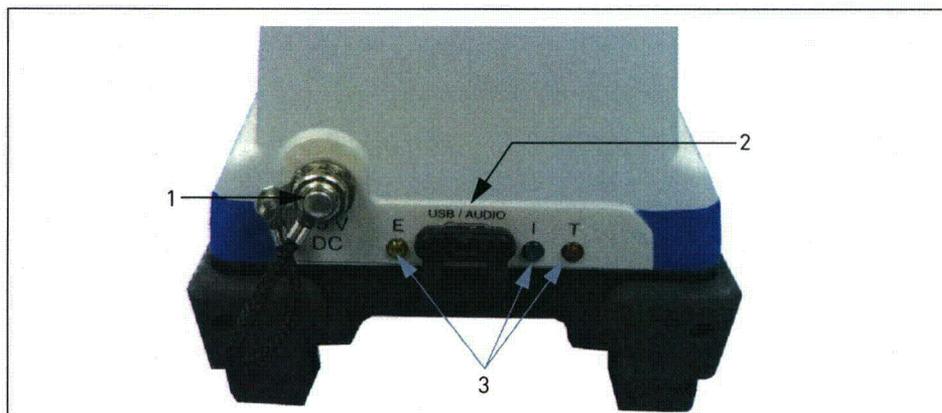


Figure 2-4 RadSeeker DL Connections

1. External Power Connection 2. USB/Audio Connection 3. LED Alarms

2.1.4 Audio Indicators

The alert and alarm audio indicators come from two sources:

- A beeper located underneath the front of the handle
The operator is able to turn On or Off the beeper source. Refer to ["Basic System Configuration"](#) on page 4-8.
- Connecting a USB-capable headset to the USB connector enables audio through the USB port. Refer to [Figure 2-4](#).

The beeper alert and alarm sounds are defined in the following table:

Event	Pitch	On	Off	Notes
System Error Alarm	Low	100ms	200ms	
Gamma Gross Count / SNM Alert	High	100ms	100ms	Variable Pulse rate, dependent on proximity to source
Innocent Isotope ID Alarm	Low	50ms	50ms	Repeat 4 times with a 350ms delay
Gamma Count Alert	High	50ms	30ms	Repeat sequence 8 times with a 400ms delay
Threat Isotope ID Alarm	Low	50ms	50ms	Repeat sequence continuously with a 400ms delay between each sequence
	High	50ms	50ms	
	Low	50ms	50ms	
Gamma Dose / Neutron Count Alarm	High	1000ms	0ms	Repeat sequence continuously with a 1000ms delay between each sequence
	Low	100ms	0ms	

2.1.5 Tactile Indicator

The tactile indicator (vibrator) automatically turns On when an alert or alarm occurs and remains On until the user acknowledges the alarm, at which point the tactile sensor turns Off.

2.1.6 LED Indicators

Three LEDs (Figure 2-4) are used to indicate alert and alarm states. The table below lists the various alert/alarm states and the LED status for each of these:

Alert / Alarm Condition		LED State
Gamma Detection Alert	Alert	All Off
Gamma Dose	Alarm	All Flashing
Innocent Identification	Alarm	Green On
Threat Identification	Alarm	Red On
Neutron Detect	Alarm	Red On
System Error	Alarm	Amber On

Each of the LED indicators can be disabled. Refer to "Basic System Configuration" on page 4-8. When the LEDs are disabled, the display provides the only visual indication of an alert or alarm condition. The user must confirm the disabling of the LEDs with a second acknowledgement.

2.1.7 Data Transfer to PC

The RadSeeker DL has two means of connecting to a PC to transfer data. More information is available in "Data Transfer Using Detector Controller" on page 3-19.

2.1.7.1 Wired Communications

The RadSeeker DL transfers data via a USB cable connected to a PC.

2.1.8 Battery

The RadSeeker DL uses a Lithium Ion rechargeable battery with a typical operational capacity of 8(+) hours.

2.1.8.1 Disposal

Refer to local regulations for requirements on battery disposal, as regulations may vary for different countries.

2.1.8.2 Storage

Store in a cool, dry, and well-ventilated area.

The battery should be stored in an environment with low humidity, free from corrosive gas, at a recommended temperature range <21°C (70°F) and a minimum allowable storage temperature for battery -20°C (-4°F). Extended exposure to temperatures above 45°C (113°F) could degrade battery performance and life.

2.1.8.3 General Handling Precautions

- Avoid shorting the battery
- Do not immerse in water
- Do not disassemble or deform the battery
- Do not dispose of the battery in or expose the battery to fire
- Avoid excessive physical shock or vibration
- Never use a battery that appears to have been damaged

2.1.9 Battery Charger

The dual bay desktop battery charger can recharge two batteries at the same time. Included with the battery charger package is the AC adaptor. The battery requires approximately 2.5 hours to fully recharge. Refer also to [“Charging the Battery” on page 3-32.](#)



Figure 2-5 Battery Charger

2.1.9.1 Cleaning the Battery Charger

Use a cloth dampened with Isopropyl Alcohol to wipe down the charger.

2.1.9.2 Storage

The battery charger should be stored in temperatures between -20°C to +70°C (-4°F to 158°F).

2.2 Technical Specifications

The RadSeeker DL will operate under most environmental conditions normally encountered in common operations, such as airports, public buildings (including outdoor events), mass transit systems, borders, etc.

CAUTION!

Do not cover the unit or restrict air flow, as the system may shut down if the ambient temperature is too high.

NOTE: In the event the RadSeeker DL is dropped or otherwise subjected to strong shock, it is recommended that the system be rebooted and that a self-test be initiated by the operator as described in "System Self-Test" on page 4-15.

Refer to Table 2-3 for operation requirements and performance specifications. For additional information, please contact your local Smiths Detection office.

Table 2-3 RadSeeker DL Specifications

Name	Specification
Input Voltage	15 VDC
Operation time of batteries	8+ hour capacity
Dimensions (L x H x W)	13.6" x 8.2" x 6.4" (35.5 cm x 20.8 cm x 16.3 cm)
Water and Dust	IP65
Weight	5 lbs (2.27 kg)
Environmental:	
Temperature	-25°F (-32°C) after warm up, to 122°F (50°C)
Humidity	3 to 98% relative humidity, non-condensing at 95°F (35°C)

2.2.1 Over-range Indicators

Neutron saturation: indicated when neutron count rate exceeds the neutron detector's saturation level of 30,000 counts per second. The neutron count will display as 1.8 million counts per minute (30,000 cps) when the count is at or above this rate.

Gamma saturation: indicated when gamma count rate exceeds the detector's saturation level of 500,000 counts per second. The system will power down the detectors, both gamma and neutron, to prevent damage to the instrument when the gamma saturation level of 500,000 cps is reached. The operator should move to an area of decreased radiation, and can then re-enable the detectors.

2.2.2 Dose Rate Range

The minimum gamma dose rate reading is 1 $\mu\text{Rem/hr}$ or 0.1 $\mu\text{Sv/hr}$, depending on the setting of dose rate units (Rem or Sievert).

The maximum dose rate displayed is limited by the gamma saturation count rate level (see "Over-range Indicators" on page 2-11). Beyond this count rate, the detectors will shut off.

The following table illustrates approximate sample dose rates that will occur for the indicated source at the saturation rate of 500,000 cps.

Table 2-4 Dose Rate Range

Source	Maximum Dose ($\mu\text{Sv/hr}$)	Maximum Dose (mRem/hr)
Am-241	30	3
Cs-137	200	20
Co-60	370	37

Photon energy range; 25keV – 3MeV

2.2.3 Units

The Smiths Detection RadSeeker DL reports gamma dose equivalent rate in Sv/hr or rem/hr.

ANSI N42.34 provides instructions for converting exposure rate (R/h) to dose equivalent rate (Sv/hr or rem/hr). Applicable conversion factors are found in ISO 4037.

The following conversions will be used to correct exposure rates from ^{137}Cs sources to dose equivalent rate.

$$\text{Deep Dose Equivalent (rem/hr)} = \text{Exposure Rate (R/hr)} * C_k * C_x$$

Where:

$$C_k = 1.21 \text{ rem/rad for } ^{137}\text{Cs, } H_p(10) \text{ (ISO 4037 Table 33)}$$

$$C_x = 0.878 \text{ rad/R}$$

This yields:

$$1 \text{ rem/hr} = 1.06 \text{ R/h}$$

2.2.4 Isotope Library

The following table lists the standard isotopes programmed into the unit. Additional isotopes can easily be programmed into the RadSeeker DL.

Table 2-5 Detectable Isotopes

Category	Isotope
Special Nuclear Material (SNM)	Plutonium (²³⁸ Pu, ²³⁹ Pu, ²⁴¹ Pu) Highly Enriched Uranium (²³³ U, ²³⁵ U) Neptunium (²³⁷ Np)
Weapons Indicating (WI)	Uranium (²³² U, ²³⁸ U) Americium (²⁴¹ Am)
Medical (MED)	Fluorine (¹⁸ F) Sodium (²² Na) Chromium (⁵¹ Cr) Cobalt (⁵⁷ Co) Gallium (⁶⁷ Ga) Selenium (⁷⁵ Se) Strontium (⁸⁹ Sr) Molybdenum (⁹⁹ Mo) Technetium (^{99m} Tc) Palladium (¹⁰³ Pd) Indium (¹¹¹ In) Iodine (¹²³ I, ¹²⁵ I and ¹³¹ I) Cesium (¹³¹ Cs) Xenon (¹³³ Xe) Europium (¹⁵² Eu) Samarium (¹⁵³ Sm) Thallium (²⁰¹ Tl)
Naturally Occurring Radioactive Material (NORM)	Potassium (⁴⁰ K) Radium (²²⁶ Ra) and daughters Thorium (²²⁸ Th, ²³² Th) and daughters Lanthanum (¹³⁸ La)
Industrial (IND)	Manganese (⁵⁴ Mn) Cobalt (⁶⁰ Co) Yttrium (⁸⁸ Y) Strontium (⁹⁰ Sr/ ⁹⁰ Y) identified as Beta Emitter only Barium (¹³³ Ba) Cesium (¹³⁷ Cs) Iridium (¹⁹² Ir) Thallium (²⁰⁴ Tl)

2.3 Normal Mode Menu Tree

This is the first screen where the user can start navigating through the menu structure.

- On all menus that have modifiable parameters, the Back, Select/Toggle, and Scroll options may appear.
- The Back option saves the changes made, if any, and returns to the previous menu.

Main Menu
Collect New Background
Adjust Brightness
Adjust Volume
Adjust Basic System Config
View System Status
Satellite Phone Data Transfer
Enter Advanced Mode
Back

Menu Options	
Starts Background Collection Process	
Adjust Brightness	High
	Medium
	Low
	Auto
	Back
Adjust Volume	High
	Medium
	Low
	Back
Adjust Basic System Configuration	LEDs
	Beeper
	Vibration
	Wi-Fi
	Battery Format
	Back
View System Status	System Information
	System Health
	Battery Information
	System Log
	Network Information
	Self-Test
	Back
Satellite Phone Data Transfer	Most Recent Event
	All Events
	Event Number Range
	Back
Enter Advanced Mode	Refer to Chapter 6 – Advanced Mode
Back	Returns to Detect screen

2.4 Advanced Mode Menu Tree

In Advance Mode, the display shows an "A" in the lower right corner, and the Advanced Mode menu is available without the need for re-entering the password.

Main Menu
Adjust Thresholds
Background Options
Advanced System Configuration
Satellite Phone Configuration
Manual Identification
Update Software
Factory Reset
Enter Service Mode (see Note)
Exit Advanced Mode
Back

Note: The "Enter Service Mode" menu is only visible if the user enters the Service Mode password when prompted on the "Enter Advanced Mode" login screen.

Menu Options	
Adjust Thresholds	High Gamma Dose Rate
	Gamma Alert Level
	Neutron Alarm Level
	Hysteresis Time
	Back
Background Options	Manual Collection Time
	Active Interval
	Background Subtraction
	Active Background
	View Background Spectrum
	Back
Advanced System Configuration	Brightness Low
	Brightness Medium
	Brightness High
	Audio Low
	Audio Medium
	Audio High
	Beeper Low
	Beeper Medium
	Beeper High
	Battery Low Threshold
	Battery Critical Threshold
	Storage Low Threshold
	Storage Critical Threshold
	Default Data Collection Time
	Standby Power Mode
	Standby Idle Time
	Auto Off Power Mode
	Auto Off Idle Time
	Gamma Dose Rate Units
	Back
Satellite Phone Configuration	Phone Number
	Number of Tries
	Back
Manual ID	Refer to "Manual ID" on page 6-14

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RadSeeker™ DL

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