

Quality Manual



First Release - October 27, 1996



Revision History

Revision	Revised By	Pages Affected	Effective Date	Comments
.1	Originator	All	Sept. 23, 1996	First Draft
.2	Originator	All	Oct. 16, 1996	Second Draft
1.0	Originator	All	Oct 27, 1996	First Release

Document Responsibility

Responsibility	Name	Title	Signature
Originator	Annick Deregnaucourt	Management Representative	Annick Deregnaucourt
Maintainer	Gitti Kealey	Quality Administrator	Gitti Kealey
Approval	Dr. Mariusz Rybak	CEO	Dr. Mariusz Rybak

Direct requests for further information to:

Responsible Person: Annick Deregnaucourt
Title: Manager, ICT
Company: CPAD Technologies Inc.
Address: 66 Slater Street
Ottawa, Ontario
K1P 5H1
Telephone: (613) 230-0609

Copies of this document are available through:

Responsible Person: Gitti Kealey
Title: Administrative Co-ordinator
Company: CPAD Technologies Inc.
Address: 66 Slater Street
Ottawa, Ontario
K1P 5H1
Telephone: (613) 230-0609

© CPAD Technologies Inc. 1996

Control Number:	QM	Revision:	1.0	Page 2
Status:	first release	Effective Date:	October 27, 1996	



Table of Contents

1. Introduction.....	4
2. Purpose.....	4
3. Scope.....	4
4. References and Abbreviations.....	5
4.1. References.....	5
4.2. Abbreviations.....	6
5. Quality Manual Control and Revisions.....	6
6. Quality Policy.....	7
7. Business Description.....	7
7.1. Product Description.....	7
7.2. Organization.....	8
7.3. Authority and Responsibilities.....	9
8. Quality System Elements.....	10
8.1. Management Responsibility.....	12
8.2. Quality System.....	12
8.3. Contract Review.....	13
8.4. Design Control.....	14
8.5. Document and Data Control.....	15
8.6. Purchasing.....	15
8.7. Control of Customer Supplied Product.....	15
8.8. Product Identification and Traceability.....	16
8.9. Process Control.....	17
8.10. Inspection and Testing.....	18
8.11. Control of Inspection, Measuring and Test Equipment.....	19
8.12. Inspection and Test Status.....	20
8.13. Control of Non-conforming Product.....	20
8.14. Corrective and Preventive Action.....	21
8.15. Handling, Storage, Packaging, Preservation and Delivery.....	22
8.16. Control of Quality Records.....	22
8.17. Internal Quality Audits.....	23
8.18. Training.....	23
8.19. Servicing.....	24
8.20. Statistical Techniques.....	24
9. Quality System Maintenance.....	25
9.1. Continuous Improvement.....	25



1. Introduction

CPAD Technologies Inc. ("CPAD") was founded as a private company in 1986 by a multi-disciplinary team of research scientists to develop chemical detection systems. With US and Canadian government and private funding, it developed its own range of products using both licensed-in as well as in-house developed technology. In 1995, following the successful completion of prototype testing by numerous potential commercial and governmental clients, a management team, lead by Dr. Mariusz Rybak, acquired control of the company in order to launch CPAD in the commercial marketplace while continuing to build on its R&D strengths. Dr. Rybak recognized the need for a "systems" approach to meeting client driven applications of its patented technologies, and in February 1996, CPAD acquired control of AGISS Power Technologies Corporation, a leading systems integration and solutions technology company focused on security and military markets. In August 1996, the ORION Plus Trace Explosive Detection System was successfully evaluated and endorsed by the American Federal Aviation Administration (FAA).

In order to meet the requirements of the international market, CPAD launched its ISO 9001 certification initiative in July 1996. This initiative serves not only to establish and document CPAD's quality system in a maintainable and evolving process, but also to meet established quality standards, enable us to compete globally in our respective markets and ensure continuous client satisfaction.

2. Purpose

The purpose of this Quality Manual is to document CPAD's quality policy, quality system and quality practices as they apply in the development, design and production of CPAD's suite of chemical detection products. The focus of this specific quality manual is on the production of the ORION Plus because it serves as the super system for all CPAD's chemical detection products.

3. Scope

This quality manual applies to those parts of CPAD Technologies' organization that affect the quality of the ORION Plus and other related chemical detection products. This manual includes the following:

- CPAD's Quality Policy;
- business description;
- description of the Quality System, and its integration into CPAD's organizational structure; and
- the processes for continuous improvement and monitoring.

Control Number:	QM	Revision:	1.0	Page 4
Status:	first release	Effective Date:	October 27, 1996	



4. References and Abbreviations

4.1. References

The following is a list of all the manuals and procedures that form part of CPAD's quality system:

Document Number	Document Title
QM	CPAD's Quality Manual
Q1	Management Responsibility Procedure
Q2	Quality System Procedure
Q3	Contract Review Quality Procedure
Q4	Design Control Quality Procedure
Q4 - AD	Design Control - Assembly Drawings
Q5	Document and Data Control Quality Procedure
Q5 - OG	ORION Plus Operator's Guide
Q5 - TM	ORION Plus Technical Manual
Q6	Purchasing Quality Procedure
Q7*	Control of Customer Supplied Product Quality Procedure <i>*(currently not in use)</i>
Q8	Product Identification and Traceability Quality Procedure
Q9	Process Control Quality Procedure
Q9 - AP	Process Control Assembly Procedures Manual
Q10	Inspection and Testing Quality Procedure
Q11	Control of Inspection, Measuring and Test Equipment Quality Procedure
Q12	Inspection and Test Status Quality Procedure
Q13	Control of Nonconforming Product Quality Procedure
Q14	Corrective and Preventive Action Quality Procedure
Q15	Handling, Storage, Packaging, Preservation and Delivery Quality Procedure
Q16	Control of Quality Records Quality Procedure
Q17	Internal Quality Audits Quality Procedure
Q18	Training Quality Procedure
Q19	Servicing Quality Procedure
Q20	Statistical Techniques Quality Procedure



4.2. Abbreviations

Abbreviation	Description
FAA	Federal Aviation Administration
GC	Gas Chromatography
ICAO	International Civil Aviation Organization
IMS	Ion Mobility Spectrometry
R&D	Research and Development

5. Quality Manual Control and Revisions

The development, review, update, distribution and overall administration of the Quality Manual is managed by the Quality Management Representative.

The Quality Management Representative, with the assistance of the Quality Administrator, is accountable for:

- managing the distribution of all controlled Quality Manual copies;
- ensuring that a Master Quality Manual Distribution List is established and maintained;
- ensuring the Quality Manual recipients possess the most recent version of the manual;
- ensuring the original issued controlled copies of the Quality Manual are distinguishable from uncontrolled copies;
- establishing and maintaining a Master List identifying the Quality Manual's revision history;
- ensuring that all obsolete controlled versions will be appropriately discarded; and
- retaining the master copies of current and previous Quality Manual versions.

The Quality Manual is made available to customers with appropriate management approval. Customer copies are marked "**Information Only**" and do not require tracking and replacement when updates occur.

The Quality Manual is reviewed twice yearly by the Quality Management Representative to ensure its continuing suitability and effectiveness to the CPAD Technologies Inc. business strategy. Records of such reviews are retained as quality records. If revised, the Quality Manual is updated with its revision history logged.

The Quality Management Representative is:

Responsible Person: Annick Deregnaucourt
Title: Manager, ICT
Telephone: (613) 230-0609

The Quality Administrator is:

Responsible Person: Gitti Kealey
Title: Administrative Services Co-ordinator
Telephone: (613) 230-0609

© CPAD Technologies Inc. 1996

Control Number:	QM	Revision:	1.0	Page 6
Status:	first release	Effective Date:	October 27, 1996	



6. Quality Policy

It is **CPAD Technologies'** commitment to provide, on time and every time, quality products and services that meet or exceed all our customers' expectations in terms of performance, safety and reliability. It is also our commitment to give every employee the empowerment for continuous improvement in everything that they do.

CPAD recognizes that quality is dynamic. Quality is defined by our customers and all our employees are empowered to take responsibility for ensuring that we meet or exceed our customer requirements. At CPAD, quality is everybody's job, and each employee is required to remain vigilant and focused on continually improving quality.

7. Business Description

7.1. Product Description

CPAD Technologies Inc. is responsible for the development, design and production of the patented suite of chemical detection products. The most elaborate or complete product is the ORION Plus, a highly sophisticated analytical instrument, which is based on a unique, patented Gas Chromatography/Ion Mobility Spectrometry (GC/IMS) combination. All the CPAD chemical detection products are subsets of the ORION Plus.

The ORION Plus stand-alone system detects concealed explosives (including EGDN, NG, TNT, AN, PETN, RDX) as well as chemical markers (often referred to as TAGGANTS, which include the following chemicals :EGDN, OMNB, OMNT, PMNT) mandated by the recent International Conference on Air Law of ICAO for the Convention on the Marking of Plastic Explosives for the Purpose of Detection and the US Counter Terrorism legislation for explosives manufacture. Sampling and analysis are completed in one continuous step. CPAD's system is different from its two major competitors who have a separate sampling step prior to detection and analysis, resulting in much slower operation for their systems. As well, CPAD's systems can be fully automated while its competitors need manual intervention. ORION Plus operates in less than 10 seconds total and is therefore best suited to high throughput, high volume areas such as on-board baggage check-in and handling at airports and border crossings. ORION Plus is sensitive down to parts per trillion quantities of explosive material. ORION Plus requires minimal maintenance, has no consumables as part of the system, produces all gases internally required for operation and is self-purging. Finally, a self-contained unit is available on wheels and is easily operated by one person.

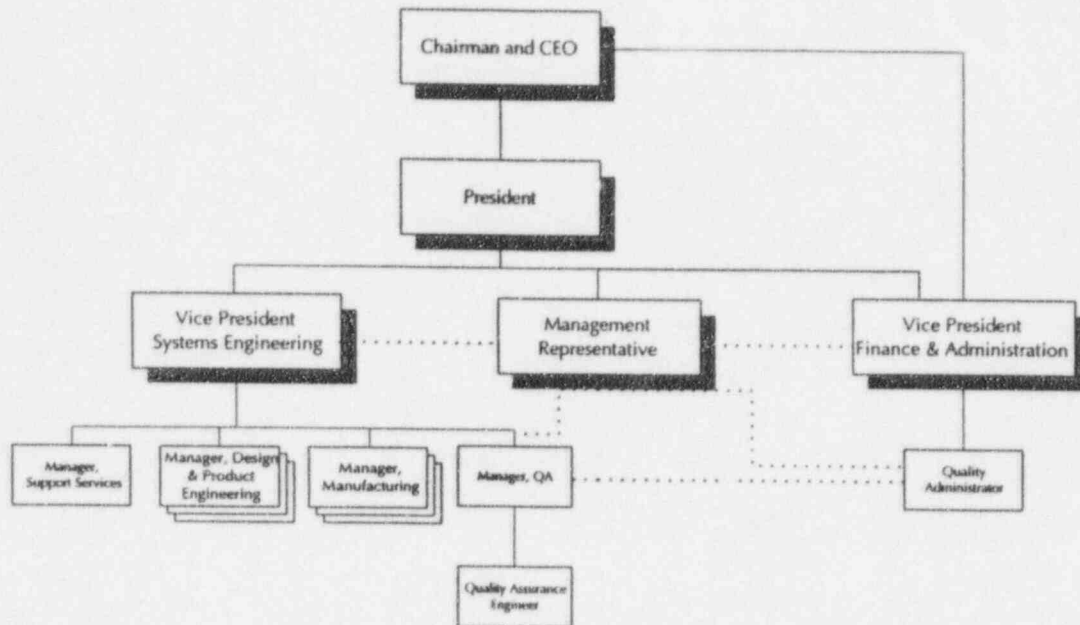
Control Number:	QM	Revision:	1.0	Page 7
Status:	first release	Effective Date:	October 27, 1996	



7.2. Organization

CPAD Technologies - Quality Organization

October 11, 1996



Legend

- The solid lines in the diagram indicate the formal organizational reporting structure.
.... The dotted lines represent the informal implementation team working structure

Title	Person
Chief Executive Officer	Dr. Mariusz Rybak
President and Chief Operations Officer	Scott Feagan
Management Representative	Annick Deregnaucourt
Vice-President, Systems Engineering	Michel Brown
Vice-President, Finance and Administration	Darlene Nielsen-Downey
Manager, Design and Product Engineering	Vic Karpinski
Manager, Manufacturing	Martin Corrigan
Manager, Support Services	Patrick Haussler
Manager, Quality Assurance	Peter Rostant
Quality Administrator	Gitti Kealey

© CPAD Technologies Inc. 1996

Control Number:	QM	Revision:	1.0	Page 8
Status:	first release	Effective Date:	October 27, 1996	



7.3. Authority and Responsibilities

Authority

All CPAD employees have the authority and are encouraged to record product and process quality deficiencies. Likewise, all CPAD employees have the authority and are encouraged to initiate and recommend solutions to perceived or actual product or process quality deficiencies. Each employee is asked to sign a document, indicating the company's quality policy, their own authority and responsibility towards quality and the quality system within CPAD. Further, each employee is personally advised of the procedures to follow to report any perceived or actual product or process quality deficiency and to initiate and recommend solutions.

The Manager, Quality Assurance reviews all the deficiency reports which include suggested recommendations and has the authority to accept, amend or reject the suggestions, or to refer them to more senior managers within the company depending on their scope or impact. The ultimate final authority on quality rests with the Chief Executive Officer.

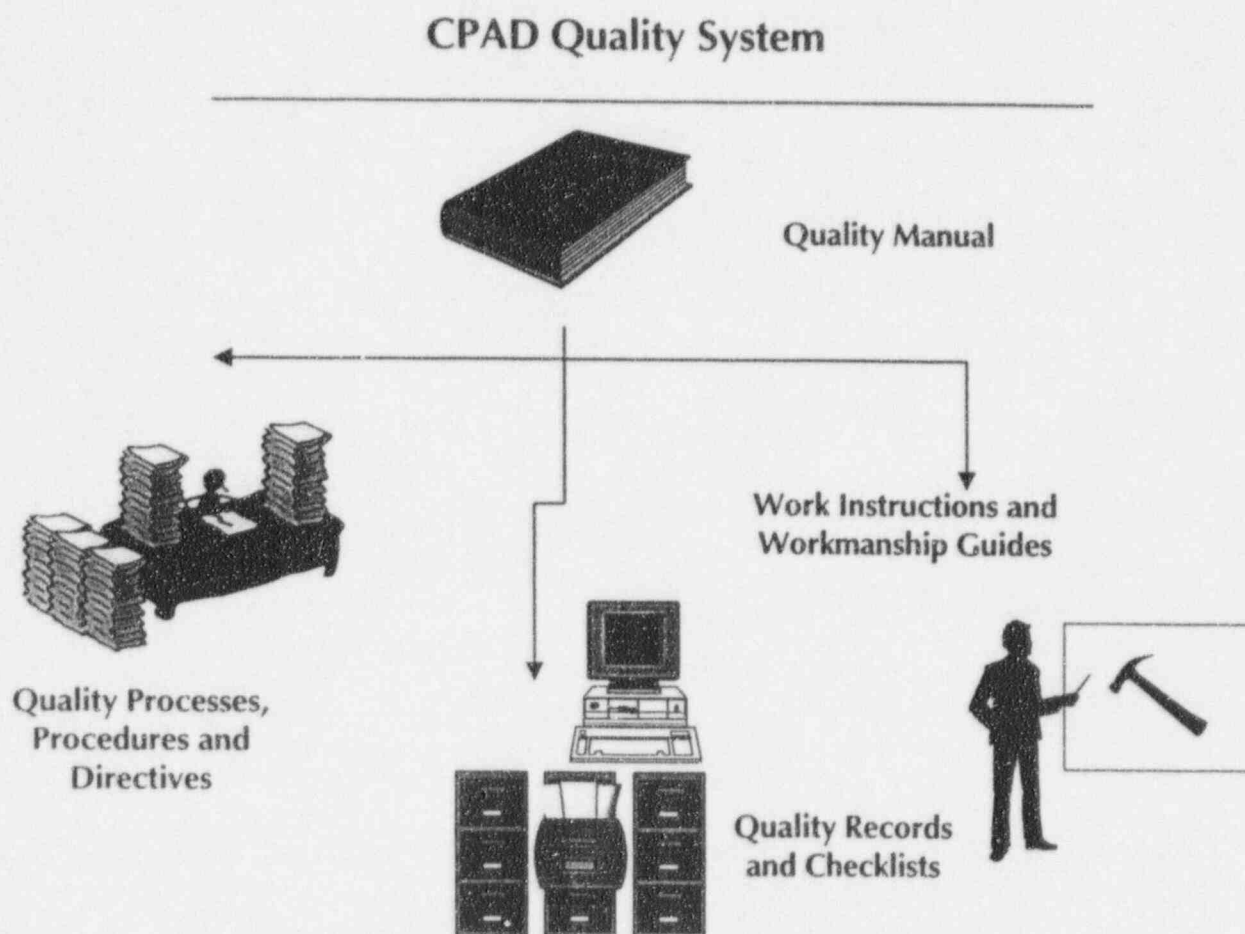
The Management Responsibility Quality Procedure describes which employees within the organizational structure of CPAD have the authority to verify the implementation of solutions, depending on the nature of the original problems. The same procedures describes which employees are authorized to control further processing, delivery or installation of non-conforming products, again based on the nature of the original problem.

Control Number:	QM	Revision:	1.0	Page 9
Status:	first release	Effective Date:	October 27, 1996	



8. Quality System Elements

CPAD's Quality System is composed of the following structure of documentation and processes.



The present Quality Manual defines the elements of the Quality System and gives an overview of the operation of the company within its quality framework. The Quality Processes, Procedures and Directives are documented for each of the Quality System elements under separate cover. Currently, CPAD has two work instruction manuals detailing activities in production and manufacturing - namely **Q4 - AD Design Control - Assembly Drawings** and **Q9 - AP Process Control Assembly Procedures Manual**.

The last part of the Quality System is the quality records and checklists that demonstrate and record the quality activities pertaining to each of the quality elements. These are identified and detailed within each quality element procedure.

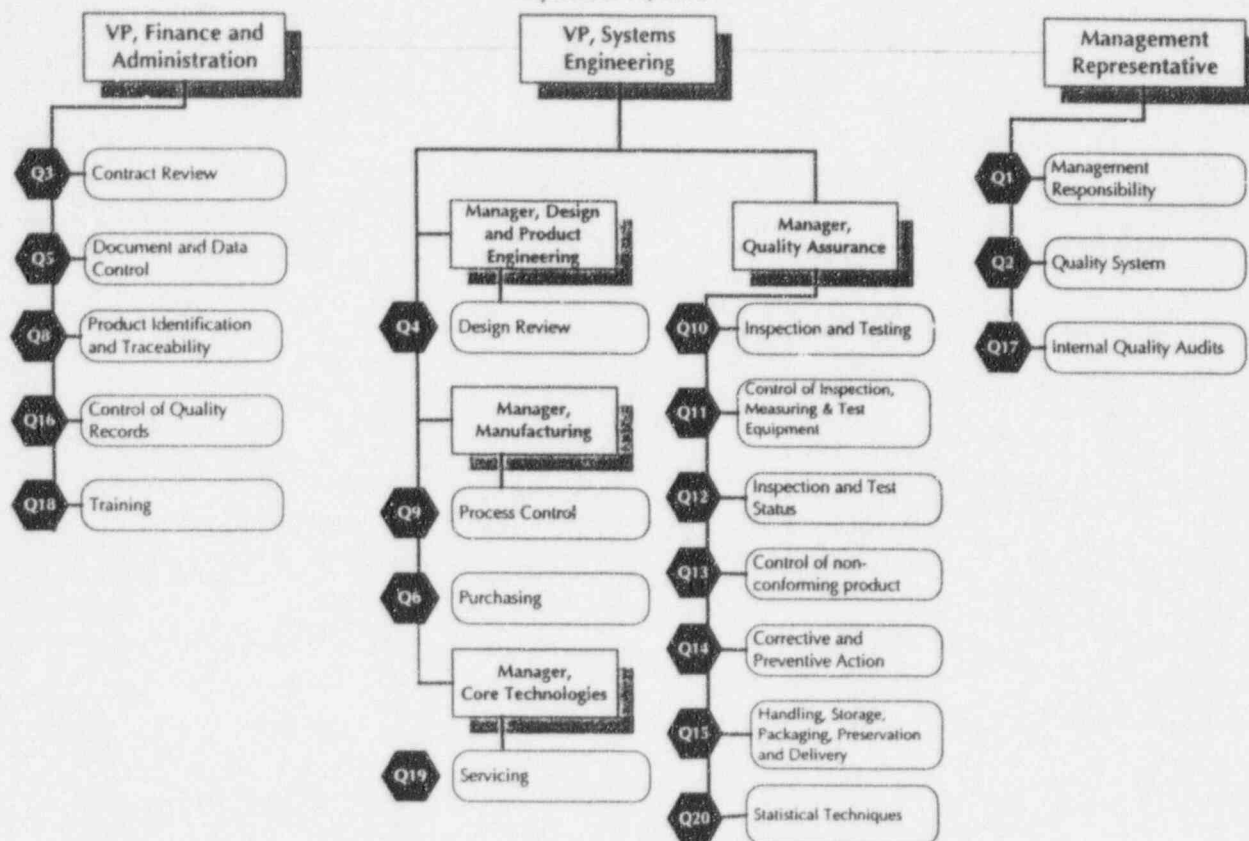
Control Number:	QM	Revision:	1.0	Page 10
Status:	first release	Effective Date:	October 27, 1996	



Each quality procedure within CPAD Technologies Inc. is identified by a document control number and assigned within the organizational responsibility of a senior manager of the company.

Quality Procedures at CPAD Technologies

September 11, 1996



Control Number:	QM	Revision:	1.0	Page 11
Status:	first release	Effective Date:	October 27, 1996	



The following are the quality procedures documented in CPAD Technologies' quality system as they are defined in the ISO 9001 infrastructure.

8.1. Management Responsibility

Scope

The Management Responsibility Procedure defines the input of senior management to CPAD's Quality System for the design, manufacture, production and servicing of the ORION Plus and other related chemical detection products.

Description

The Management Responsibility procedure focuses on:

- CPAD's quality policy;
- CPAD's quality objectives;
- the role of management in communicating the quality policy, quality objectives and the goals of the quality system to all employees within the organization;
- the need to identify the requirements for resources, and to provide the appropriate resources and assign trained personnel for management, performance of work and verification activities including internal quality audits;
- the role of management in ensuring that all employees within the organization are aware of their responsibilities towards quality and that the means and processes are available for each employee to meet his/her responsibilities;
- the management representative; and
- the requirement, scheduling, and frequency of internal management reviews of the quality system held by managers with executive responsibility.

Responsible Person

Document Control Number: Q1
Responsible Person: Annick Deregnacourt
Title: Management Representative

8.2. Quality System

Scope

The Quality System Procedure defines the Quality System in place within CPAD Technologies as it supports the design, manufacturing and production of the ORION Plus and other related chemical detection products. The scope of this procedure encompasses the identification of which employer and/or employee is authorized to perform specific tasks, and how the tasks are executed.



Description

The Quality System procedure identifies what constitutes a quality task or requirement, the persons authorized to perform them, the equipment needed, the quality records which must be retained and maintained and the roles and responsibilities of individuals. As well the Quality System procedure addresses how the requirement for quality is met through the use of quality planning.

Responsible Person

Document Control Number: Q2
Responsible Person: Annick Deregnacourt
Title: Management Representative

8.3. Contract Review

Scope

This element of the CPAD Quality System refers to the review of all contracts related to the design, manufacture, production and servicing of the ORION Plus and other related chemical detection products.

Description

The Contract Review Procedure addresses the following points:

- review of incoming contracts as they relate to the ORION Plus and other related chemical detection products;
- understanding of customer requirements and the contract clauses by all interested parties within CPAD; and
- integration of a checklist which ensures that all questions and comments regarding quality issues are integrated and that a process can be initiated to address the quality issues.

Responsible Person

Document Control Number: Q3
Responsible Person: Darlene Nielsen-Downey
Title: Vice-President, Finance and Administration



8.4. Design Control

Scope

This element of the CPAD Quality System refers to the control and verification of the design against specified requirements. The scope of these procedures are limited to the design of the ORION Plus and other related chemical detection products.

Description

These procedures reflect the necessary steps to ensure:

- adequate planning for design and development activities;
- clear documentation of the design requirements;
- the definition, documentation and review of interfaces between different groups are defined, documented and reviewed;
- designs or drawings adhere to applicable regulations as stated within the requirements and identify any issues that would have an impact on the safe and proper functioning of the product;
- verification of the designs through the most applicable processes;
- validation of the designs to ensure the product conforms to the client requirements;
- adequate control, approvals and documentation of design changes and modifications
- planning and review of design results.

Responsible Person

Document Control Number: Q4
Responsible Person: Vic Karpinski
Title: Manager, Design and Product Engineering



8.5. Document and Data Control

Scope

This element of the CPAD Quality System refers to the control of all documents and data related to the design, manufacture, production and servicing of the ORION Plus and other related chemical detection products.

Description

The Document and Data Control Procedure identifies the necessary steps required to control documents and data media related to CPAD's quality system, review and approve documents and data media related to CPAD's quality system, and ensure the content of procedures are adequate for use within CPAD Technologies Inc.

Responsible Person

Document Control Number: Q5
Responsible Person: Darlene Nielsen-Downey
Title: Vice-President, Finance and Administration

8.6. Purchasing

Scope

This element of the CPAD Quality System refers to ensuring that purchased products in support of the design, manufacture, production and servicing of the ORION Plus and other related chemical detection products meet specified requirements.

Description

The Purchasing procedure describes the assessment of sub-contractors, the type of purchasing data that needs to be captured to ensure requirements are met, and the processes and steps in place to verify the purchased product.

Responsible Person

Document Control Number: Q6
Responsible Person: Martin Corrigan
Title: Manager, Manufacturing

8.7. Control of Customer Supplied Product

CPAD currently does not perform any activity with customer-supplied products, and does not include this element within its Quality System.



8.8. Product Identification and Traceability

Scope

This element of the CPAD Quality System refers to the requirement that the ORION Plus and other related chemical detection products be identified from applicable drawings, specifications and other documents during all stages of production, delivery and installation, as well as for servicing.

Description

This procedure defines how the ORION Plus and other related chemical detection products is identified from applicable drawings and design documents. It also establishes the steps for ensuring that each individual product and its relevant sub-assembled parts have a unique identification number. The procedure also identifies what quality records must be retained and maintained.

Responsible Person

Document Control Number:	Q8
Responsible Person:	Darlene Nielsen-Downey
Title:	Vice-President, Finance and Administration

Control Number:	QM	Revision:	1.0	Page 16
Status:	first release	Effective Date:	October 27, 1996	



8.9. Process Control

Scope

This element of the CPAD Quality System refers to the processes within the production of the ORION Plus and other related chemical detection products which directly affect quality.

Description

The Process Control procedure includes any element that allows the production of the ORION Plus and other related chemical detection products to take place in a controlled environment, such as:

- documented work instructions;
- monitoring and control of process and product characteristics;
- approval of processes and equipment;
- criteria for workmanship.
- the suitability and maintenance of production, installation and servicing equipment,
- the suitability of working environment
- the identification of special processes
- compliance with standards, plans and documented procedures

Responsible Person

Document Control Number: Q9
Responsible Person: Martin Corrigan
Title: Manager, Manufacturing



8.10. Inspection and Testing

Scope

This element of the CPAD Quality System refers to the inspection and testing of parts and products in the manufacturing and production of the ORION Plus and other related chemical detection products.

Description

The Inspection and Testing procedure identifies the steps and processes required to ensure:

- inspection and testing of incoming or receiving products, taking into consideration the amount of control exercised at the subcontractor's premises;
- inspection and testing of products within the production process;
- final inspection and testing of the final ORION Plus and other related chemical detection products.
- positive recall procedures to address urgent production requirements.

The procedure also identifies what quality records must be retained and maintained.

Responsible Person

Document Control Number: Q10
Responsible Person: Peter Rostant
Title: Manager, Quality Assurance



8.11. Control of Inspection, Measuring and Test Equipment

Scope

This element of the CPAD Quality System refers to the control of inspection, measuring and test equipment whether owned by CPAD, borrowed or leased, or provided by a client or supplier, to demonstrate the conformance of the ORION Plus and other related chemical detection products to specified requirements.

Description

This procedure identifies the steps necessary to:

- identify the appropriate measurements and required accuracy, and select the necessary inspection, test and measuring equipment;
- identify, calibrate and adjust inspection, test and measuring equipment, considering the process employed for calibration, the suitability of environmental conditions and the safeguard, handling, preservation and storage of inspection, measuring and test equipment;
- maintain calibration records;
- assess and document the validity of previous test results when the equipment is out of calibration; etc.

The procedure also identifies what quality records must be retained and maintained.

Responsible Person

Document Control Number: Q11
Responsible Person: Peter Rostant
Title: Manager, Quality Assurance



8.12. Inspection and Test Status

Scope

This element of the CPAD Quality System refers to the requirement to identify the inspection and test status of the ORION Plus and other related chemical detection products throughout production and installation.

Description

The Inspection and Test Status procedure identifies the necessary steps required for the control of verification status used for internal processes or for the production of the ORION Plus and other related chemical detection products. The procedure also identifies what quality records must be retained and maintained.

Responsible Person

Document Control Number: Q12
Responsible Person: Peter Rostant
Title: Manager, Quality Assurance

8.13. Control of Non-conforming Product

Scope

This element of the CPAD Quality System refers to the control of components of the ORION Plus and other related chemical detection products that do not conform to specified requirements in order to prevent such parts from inadvertent use or installation.

Description

The Non-conforming Product procedure identifies the steps required to control products or services that do not conform to the internal processes or requirements that must be met during the production of the ORION Plus and other related chemical detection products. This procedure also defines who is responsible for the review and authorized to dispose of the non-conforming product. The procedure also identifies what quality records must be retained and maintained.

Responsible Person

Document Control Number: Q13
Responsible Person: Peter Rostant
Title: Manager, Quality Assurance



8.14. Corrective and Preventive Action

Scope

This element of the CPAD Quality System refers to the requirement to correct and prevent the non-conformance of components of the ORION Plus and other related chemical detection products to the specified requirements.

Description

The Corrective and Preventive Action procedure identifies what tasks are required to:

- analyse the root cause of a non-conformance;
- provide a process to discover potential non-conformances;
- eliminate recurring non-conformances;
- monitor the progress of corrective action; and
- identify the personnel's roles and responsibilities to implement the corrective and preventive action system, including making changes to the documented procedures resulting from the corrective and preventive actions, as well as determining which corrective actions are needed to eliminate the cause of the non-conformities.

The procedure also identifies what quality records must be retained and maintained.

Responsible Person

Document Control Number: Q14
Responsible Person: Peter Rostant
Title: Manager, Quality Assurance



8.15. Handling, Storage, Packaging, Preservation and Delivery

Scope

This element of the CPAD Quality System refers to handling, storage, packaging and delivery of the ORION Plus and other related chemical detection products.

Description

The Handling, Storage, Packaging, Preservation and Delivery procedure identifies the steps required to internally control the handling, storage, packaging, preservation and delivery of product which directly affects the quality of the ORION Plus and other related chemical detection products. The procedure also identifies what quality records must be retained and maintained.

Responsible Person

Document Control Number: Q15
Responsible Person: Peter Rostant
Title: Manager, Quality Assurance

8.16. Control of Quality Records

Scope

This element of the CPAD Quality System refers to the requirement to demonstrate achievement of quality requirements and effective operation of the quality system through the collection and retention of quality records as they relate to the design, production, delivery, installation and servicing of the ORION Plus and other related chemical detection products

Description

The Control of Quality Records procedure identifies what tasks are required to identify and record a quality event, collect, index, and access the record, store the event, maintain the record, identify the retention period for which the document must be controlled, and dispose of the quality records, as well and identify personnel's roles and responsibilities to control quality records.

Responsible Person

Document Control Number: Q16
Responsible Person: Darlene Nielsen-Downey
Title: Vice-President, Finance and Administration



8.17. Internal Quality Audits

Scope

This element of the CPAD Quality System refers to the requirement to regularly audit the Quality System to ensure its evolving and continuing effectiveness.

Description

The Internal Quality Audit procedure identifies what tasks are required to plan an internal audit, document the audit results, provide corrective action against non-compliance, and identify personnel's roles and responsibilities to perform an audit. This procedure also considers the implementation, follow-up and verification of internal audits. The procedure also identifies what quality records must be retained and maintained.

Responsible Person

Document Control Number: Q17
Responsible Person: Annick Deregnaucourt
Title: Management Representative

8.18. Training

Scope

This element of the CPAD Quality System refers to the requirement to identify the training needs and provide training to the personnel performing activities affecting the quality of the ORION Plus and other related chemical detection products.

Description

The Training procedure identifies what tasks are required for developing a training course, documenting the employees course test results, identifying who is authorized to identify what training requirements are required for specific tasks, and identify personnel's roles and responsibilities to control the training process. This procedure also addresses the identification of training needs and the qualification of personnel to perform specific tasks. As well, the procedure also identifies what quality records must be retained and maintained.

Responsible Person

Document Control Number: Q18
Responsible Person: Darlene Nielsen-Downey
Title: Vice-President, Finance and Administration



8.19. Servicing

Scope

This element of the CPAD Quality System refers to servicing the ORION Plus and other related chemical detection products where specified in any contractual arrangements.

Description

The Servicing procedure identifies the necessary steps to ensure:

- that the servicing and verification process meets the contractual requirements;
- what the servicing procedures are;
- what the product recall procedures are; and
- what quality records must be retained and maintained.

Responsible Person

Document Control Number: Q19
Responsible Person: Patrick Haussler
Title: Manager, Support Services

8.20. Statistical Techniques

Scope

This element of the CPAD Quality System refers to the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics of the ORION Plus and other related chemical detection products.

Description

The Statistical Techniques procedure identifies the necessary steps to implement and control the application of the statistical techniques.

Responsible Person

Document Control Number: Q20
Responsible Person: Peter Rostant
Title: Quality Manager



9. Quality System Maintenance

9.1. Continuous Improvement

CPAD recognizes that for our Quality System to be effective:

- senior management must be committed and involved;
- all staff have been involved and know what is expected of them and how to do it;
- the right equipment, processes and tools are available in the proper sequence to do the job properly;
- the right information reaches the right people at the right time; and
- there is a system of management and control.

In order to identify any deficiency in the system outside of the scheduled internal reviews and compliance audits, CPAD has advertised and distributed a Quality Improvement Form to all staff. The purpose of this form is to serve as a formal vehicle for communication on quality issues, and to continually request feedback on how we can keep on improving our Quality System. Once completed, the Quality Improvement Form is routed to the Manager, Quality Assurance.

Control Number:	QM	Revision:	1.0	Page 25
Status:	first release	Effective Date:	October 27, 1996	

WE HAVE MOVED, PLEASE CHECK OUR NEW ADDRESS!

FACSIMILE



FACSIMILE

Date & Time: Thursday, October 24, 1996 11:53 AM

Pages To Follow: 2

Send To

Name: Brian Smith
Company: NRC Headquarters

FAX: 301-415-5369
Phone: 301-415-5723

From

Name: Al McEachern
Address: CPAD Technologies Inc.
66 Slater Street, 6th Floor
Ottawa, Ontario K1P 5H1

Phone: (613) 230-0609
FAX: (613) 230-3805

cc:

Subject: NRC DEVICE REVIEW

Notes: This fax contains a letter that has been put in the mail to Mr. Baggett. If you require new copies of the applicable drawings, please advise and I will provide.

I have also included an amended version of the label that will be affixed to the Analytical Unit. The change includes the model and serial numbers.

Thanks for your support.

Sincerely,

A handwritten signature in dark ink, appearing to read "A.L. McEachern", is written over the typed name.

A.L. McEachern
Director, Business Development

WE HAVE MOVED, PLEASE CHECK OUR NEW ADDRESS!

WARNING!

This CPAD Technologies Inc. transmission is intended for the addressee. It may contain privileged or confidential information, any unauthorized disclosure is strictly prohibited by law. If you have received this transmission in error, please notify us immediately so that we may correct our transmission. Please then destroy the original. Thank you.



October 24, 1996

Mr. Steven L. Baggett, Section Leader
Sealed Source Safety Section
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial Safety
Office of Nuclear Material Safety
and Safeguards

Dear Mr. Baggett:

In reply to your letter of October 18, 1996, I have discussed the matter with the inventor and have determined that although we would like to protect the distribution of the two drawings in question, the importance of completing the process outweighs the need for protection. We will rely on the protection offered by our patents to safeguard our trade secrets. The restriction that was initially placed on drawing numbers IM-B-035 and IM-B-037, together with the parts lists, is hereby lifted.

My staff is in constant contact with Mr. Brian Smith and will send a copy of this letter by fax to him for his immediate action. I will take this opportunity to mention that Mr. Smith has been most helpful and very responsive in the exchange of information that will hopefully allow our license to be approved. We have been in contact with the FAA on numerous occasions since their evaluation of our system; they have been asking about the status of the license.

Thank you for your continued support.

Sincerely,

A handwritten signature in dark ink, appearing to read "M. Rybak", is written over a faint, circular embossed seal or watermark.

Mariusz Rybak
Chief Executive Officer
CPAD Technologies Inc.

A handwritten signature in dark ink, appearing to read "M. Rybak", is written over a faint, circular embossed seal or watermark.
CPAD Technologies Inc.

WARNING - CONTAINS RADIOACTIVE MATERIAL

THIS ANALYTICAL UNIT (MODEL NUMBER _____ SERIAL
NUMBER _____) CONTAINS A DETECTION SYSTEM THAT HAS AS PART OF
ITS SYSTEM A "DEVICE" THAT CONTAINS A RADIOACTIVE NICKEL - 63 SOURCE AT
3.3 MILLICURIES. IT HAS BEEN MANUFACTURED BY CPAD TECHNOLOGIES INC. OF
OTTAWA CANADA, IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.27.
THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.

WE HAVE MOVED, PLEASE CHECK OUR NEW ADDRESS!

FACSIMILE



FACSIMILE

Date & Time: Friday, October 25, 1996 1:35 PM

Pages To Follow: 1

Send To

Name: Brian Smith
Company: NRC Headquarters

FAX: 301-415-5369
Phone: 301-415-5723

From

Name: Al McEachern
Address: CPAD Technologies Inc.
66 Slater Street, 6th Floor
Ottawa, Ontario K1P 5H1

Phone: (613) 230-0609
FAX: (613) 230-3805

cc:

Subject: NRC DEVICE REVIEW

Notes: I want to tell you that I just received the reference material that arrived by International Express Mail.

This fax also includes a copy of the labels as per our earlier discussion; I want to make sure I understood you correctly before we go the expense of preparing labels.

Thanks for your support and have a good week end.

Sincerely,

A handwritten signature in cursive script, appearing to read "Al McEachern", is written over a vertical line that extends from the signature area down towards the bottom of the page.

WE HAVE MOVED, PLEASE CHECK OUR NEW ADDRESS!

WARNING!

This CPAD Technologies Inc. transmission is intended for the addressee. It may contain privileged or confidential information, any unauthorized disclosure is strictly prohibited by law. If you have received this transmission in error, please notify us immediately so that we may correct our transmission. Please then destroy the original. Thank you.

REQUESTED CHANGES

2. The label attached to the device itself and the point of sale package must identify the holder of the registration certificate - Galson Corporation. This can be accomplished by adding Galson Corporation or their license number to the label. Please provide the wording for the labels.

Reply:

The label on the device will include "U.S. LICENSE # 2260-3047" which is the Galson Corporation license number.

Change

Further to our telephone conversation on this date, the above statement is changed to read as follows:

The label on the device will include "U.S. LICENSE # XXXX-XXXX" which will be the license number granted by the NRC To CPAD Technologies Inc..

Change

THIS CRATE CONTAINS A DETECTION SYSTEM THAT HAS AS PART OF ITS SYSTEM A "DEVICE" THAT CONTAINS A RADIOACTIVE NICKEL - 63 SOURCE AT 3.3 MILLICURIES. IT HAS BEEN MANUFACTURED BY CPAD TECHNOLOGIES INC., IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.

Change

WARNING - CONTAINS RADIOACTIVE MATERIAL

THIS ANALYTICAL UNIT (MODEL NUMBER _____ SERIAL NUMBER _____) CONTAINS A DETECTION SYSTEM THAT HAS AS PART OF ITS SYSTEM A "DEVICE" THAT CONTAINS A RADIOACTIVE NICKEL - 63 SOURCE AT 3.3 MILLICURIES. IT HAS BEEN MANUFACTURED BY CPAD TECHNOLOGIES INC., IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.