Quality Assurance Plan for MediSmarts

	Name	Position	Date
Written By	**Laurence Kaplan**	**Project Manager**	
Checked By	**David Elgad**	**Q.A. Manager**	
Authorized By	**Tazhi Mazor**	**Head of Dept**	

Modifications:

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1 Definitions and acronyms

The following alphabetical contractions appear within the text of this document:

CDR - Critical Design Review
Dev. – Development
Man. – Management
P.C. - Personal Computer, IBM compatible.
PDR - Preliminary Design Review
SDP – Software Development Plan
SQAP - Software Quality Assurance Plan
SRR - Software Requirements Review
SRS - Software Requirements Specifications
UDF - Unit Development Folder
SCR – Software change Requirement

2 Purpose

ROTEM's MediSmarts system is a Modular comprehensive real time on-line radiation monitoring system, which provides solutions to regulatory, health physics safety and production monitoring in Cyclotron Facilities The MediSmarts system is a user friendly, fully automated system, that can be tailored with the following block modules for the specific needs of each site.
Stack monitoring
Area monitoring
Production Monitoring
Comprehensive Radiation analysis software
Site safety control

This document will cover the MediSmarts software for the life cycle period as described in the table below:

2.1 Hardware and software life cycle

	Stage	Yield	Documents to UDF
1	Define preliminary demands	Definition of Demands - SRR	Dev. folder – SRR Man. folder - SDP
2	Contract Review	Firmware configuration requirements	Dev. folder - SRS
3	Preliminary Design Review PDR	Preliminary firmware configuration Updating of timetable	Dev. folder - Preliminary SDD
4	Critical Design Review CDR	Final Firmware configuration Updating of timetable	Dev. folder - Test results
5	Firmware Verification and Validation plan SVVP	Version Declaration	Test Results and Upgrades
6	Version Declaration	Backup and user's manuals	
7	Installation and Training	Training kit and customer authorization of installation	
8	Backup and Service		Man. folder – Version documentation - Distribution documentation - Malfunction documentation

3 Reference documents

Software Quality Assurance Plans	IEEE Std 730-1989
Israeli standard	2000.3
Documentation Cataloging	RGWI9401.DOC
Firmware quality assurance	QGWI9601.DOC
Definition of software demands	QGWI9604.DOC
Software demands checklist form	QGWI9604.01
Software yield test procedure	QGWI9605.DOC
Software writing procedure	QGWI9606.DOC
Software testing procedure	QGWI9607.DOC
Software documentation procedure	QGWI9608.DOC
Product management procedure	QGWI9609.DOC
Activity list for development projects	QGQA9621.DOC

4 Management

The Rotem project team:

Project Manager – Tzahi Mazor - Nuclear Instrumentation manager.
Laurence Kaplan - Project Manager / Documentation
Alon Osovitski - System analyst.
Baruch Ashkenazi - Senior programmer.
David Elgad - Q.A. Manager

4.1 Organization

4.1.1 Planned activities in the hardware and software life cycle

Project folder

Upon acceptance of the contract a Product folder will be opened by the Product Manager.

The Product Manager will work according to the firmware life cycle as described in section 2.1 of this document excluding a detailed Q.A. plan. In this case the Q.A. manager will prepare an SQAP document.

Control of the format will be done according to Format control procedures. QGWI9609.DOC - Format Control, Management of Versions and upgrades, Customer follow-up etc.

Each controlled document relating to the project will be written by the Project Manager and will be controlled by the Q.C. Manager and authorized by the Head of Department.

4.1.2 Auditing end of stage

Following the conclusion of a certain stage in the firmware life cycle, it is necessary to confirm the conclusion of the stage. Confirmation of conclusion shall be performed by checking the existence of the format that was previously defined. Conclusion of a stage which is regarded as a milestone depends on the release of a written summary and it’s distribution.

Summary of the audit shall include :

Examination of the subjects and remarks that were received.
Summary of the decisions including a list of directives defining responsibilities and timetable for completion.

The Project Manager is responsible for checking that the directives are followed and executed by the team.
An audit, which is not completed stops progress to the next stage
A closed stage is defined as a stage where all the demands have been fulfilled.
Following the testing of the system a final audit will be taken whereby, at the successful conclusion, a firmware version will be released.

Installation and maintenance.

Following the release of the software, it is necessary to check the existence of up-to date installation and operation instructions. Also it is necessary to check the existence of a folder containing a division, relating to the follow-up and upgrading as well as lists of faults, according to Format control procedures described in QGWI9609.DOC

Responsibility

The responsibility of applying this procedure is bestowed to the Department heads as well as the Project Manager and includes the firmware development.

4.2 Tasks and Responsibilities

4.2.1 General

This section covers all the required activities of the Q.A. department starting from the operational demands stage, pre-programming activities, the prototype planning and production, testing and approval, production of a model, the testing of the approval, production of the series, acceptance testing, and finally packaging and shipping to the end-user.

The section describes the procedures, work orders, forms, resources and responsibilities of the Q.A. department in regard to the product's hardware and firmware life cycle.

4.2.2 Purpose

The purpose of this section is to describe the required activities in order to stand by the demands of the Q.A. department as described in the specification.

4.2.3 The Methodology

4.2.3.1 General

The Electronic control and instrumentation unit of Rotem Industries conforms with ISO9001 standards and works according to Q.A. procedures for development, production and maintenance which are defined in a list of procedures including the following :

1. Periodic checks
2. Periodic managerial analysis
3. Content Control - Program analysis, document control and upgrading.
4. Purchasing Control - acceptance procedure checks, merchant rights granted.
5. Control of production procedure.

6. Final Quality control tests.
7. Periodic calibration of test equipment.

4.2.3.2 Constant Quality Assurance activities in the project

Activity of the constant Q.A. department will take place along the entire life cycle of the project starting from the *operational demand* stage and will include:

1. Documentation and following of changes and problems in development, production and maintenance.
2. Documentation and following of changes of firmware versions in development.
3. Documentation control - The firmware package will be supplied to the end-user accompanied with the required documentation as specified in the development order.
4. Documentation control according to the Q.A. department procedure appendix 3.2 and 3.3
5. Follow of timetable and resources in the development and production procedures.
6. Work procedures will take place according to the production folder and according to signed and authorized work orders.

4.2.3.3 Quality Assurance activities in the development stage.

1. Contract review - a contract review will take place according to procedure 939.03.01. with the purpose of checking the scope of work involved and the capability of Rotem Industries to stand up to the demands of the operational demands, and also to setup clear development instructions which are comprehensible to both the developers and the customers.
2. Technical specification sheet. - Preparation of a technical spec. sheet and amendments continuously until the stage that format development has been frozen, and written according to development instructions.
3. Preliminary design reviews (PDR) will take place with the purpose of selecting and authorizing the technical solution to be used.
4. A Critical design review (CDR) will take place to authorize the software package design, and will result in the format being frozen. The CDR will include an integrity appraisal out of a forecasted accuracy procedure, and Failure mode effect and critical analysis (FMECA) procedure.
5. Production requirements review (P.R.R.) A review of the readiness of production, production folders, Q.A involvement in the production routine procedures and authorization of the production line.

6. The design reviews will take place according to procedures, in cooperation with the end-user or customer and experts, according to requirements and will be summarized into a list of tasks, including ranges of responsibilities and timetables for operations.

7. Tests and Reports - during the course of development a number of key tests will take place, each test will culminate in a key report. The report will include the following:

   i. Test program - Purpose of the test, test condition, test equipment, measuring equipment, analysis of the results, conclusions and recommendations.
   ii. Authorization test - will be performed according to the authorization test which will answer the demands of the project according to the specifications listed in the T.B.D. The test could take place in-house as well as in outside laboratories.
   iii. Acceptance tests - will take place according to standard acceptance test procedures.

4.2.3.3.1 Maintenance

A maintenance policy will be defined according to different levels of authority, the program will include: maintenance times for each level of authority, recommended timetable to perform periodical calibration, lists of test equipment, lists of measuring equipment, lists of tools needed to perform maintenance and lists of spare parts needed to perform maintenance.

4.2.3.4 Quality Assurance activities in the production stage.

The requirement of the software is to interface with existing hardware, manufactured by Rotem Industries using sub-contractors. It is therefore necessary to set out the guidelines for Q.A. activities regarding the hardware.

1. Reception testing for purchased items and sub-contractors.
2. Component orders for the project will take place according to the standard no 939.06.01 and according to attachment 'a' – standard Q.A demands checklist form.
3. Components required for the project will undergo an acceptance review before they are accepted into the production line, according to order no' 9401IWGS.NIE. acceptance test of materials into the warehouse.

4.2.3.4.1 Sub-contractors

Certain sub-assemblies of the product could be sent to sub-contractors only after they have been screened and accepted as registered sub-contractors of Rotem Industries according to standard no' 939.06.03 authorization of merchants and contractors.

The sub-assemblies sent to the sub-contractors will be accompanied by production folders and technical specifications.

4.2.3.4.2 Testing procedures during production.

Testing and measuring equipment - The testing during the different production stages and final testing will take place using test equipment that has been calibrated and authorized according to standard no' 939.11.00 Testing and calibrating equipment.

Control during the production - will take place according to standard no' 939.09.01 Control during production sequence using *operation performed* forms called "production accompanying form" . existing in the manufacturing facilities or similar forms prepared for this project.

Treatment of malfunctions and corrections - For every mistake or irregularity found a form will be filled in. According to the type of irregularity it may be decided to distribute a form calling for a change to be made to the original specifications. For insignificant changes a MRB committee will be convened, according to standard no' 939.14.01, and the decision will be taken as to methods of rectifying the situation.

4.2.3.4.3. Screening of electronic cards

The electronic cards will undergo screening test according to environment factors, (temperature and vibrations) according to specification " Screening according to environment factors".

4.2.3.4.3 Final testing

1. 100% testing of electronic boards and mechanical assemblies.
2. Frontal finish test, assembly and wiring for every piece of equipment.
3. Functional tests for every piece of equipment.
4. ATP/ATL tests following environmental tests

5. Calibration tests for each piece of equipment according to the specific test specifications specified.
6. Acceptance tests according to acceptance test procedure.

4.2.4 Training

The Q.A. team foundation in the factory includes:

Q.A. personnel. each assigned, approved and valid according to standard no' 939.18.02 training, validation and appointment of Q.A. personnel.
Production workers - trained in wiring and soldering, assembly and modifying in a "training" factory environment of the aircraft industries and tre also exists a continuous review of the training status of employees.
Heads of departments and sections have been authorized as Q.A. personnel and are responsible for the testing and authorization of activities in their departments

4.2.5 Responsibilities

The project manager is responsible to apply the Q.A. plan
The Q.A. manager and personnel are responsible in helping the project manager in applying the tasks defined in this section.

Table of activities of Q.A. personnel in the project

	Serial No Paragraph Activity	Assurance Responsibility
Q.C.1	Preliminary document - reference to Q.A. demands	Q.A. Dept
Q.C.2	Reference to defining the firmware demands – filling in form "checklist of firmware demands" attachment "a" of standard QGWI9604.DOC	Product Manager
Q.C.3	Contract review - according to Contract review standard Product Manager no' 939.03.01 attachment "c" Checklist for contract review	
Q.C.4	Preparation of Firmware Quality Assurance Plan	Q.A. Dept
Q.C.5	Reference to acceptance test procedure	Prod. Man. & QA
Q.C.6	Reference to authorization test procedure	Prod. Man. & QA
Q.C.7	Preparation for Preliminary Design Review - Parts count method	Prod. Man. & QA
Q.C.8	Preliminary Design Review - preparation and distribution of written material to the parties involved	Product Manager
Q.C.9	Analysis of failure FMECA	Prod. Man. & QA
Q.C.10	Analysis of integrity	Prod. Man. & QA
Q.C.11	Critical Design Review - preparation and distribution of written material to the parties involved	Product Manager
Q.C.12	Ordering L.L.I. components.	Product Manager
Q.C. 13	Updating production folder according to Development folder and according to standards	Product Manager Q.A. Dev. team
Q.C.14	Controlled ordering of parts according to the project. Product Manager according to standard no' 939.06.01	Purchasing Dept
Q.C.15	Production of Hardware and acceptance tests	
Q.C.16	Wiring Production - Subcontractors, on-site check authorization of Dealers	
Q.C.17	Hardware construction - Instructions & prod	Product Manager

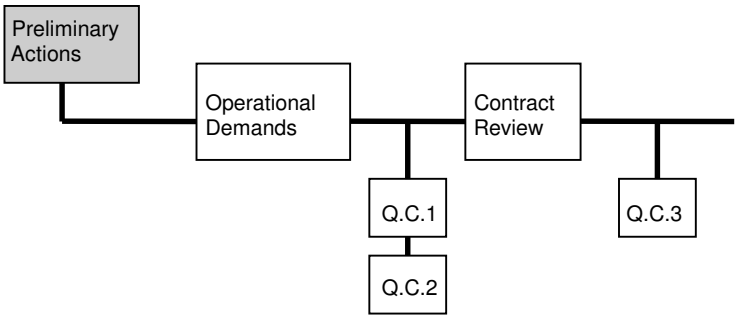
	accompanying form	Q.A. Dev. team
Q.C.18	Testing Instructions and Results form	Product Manager

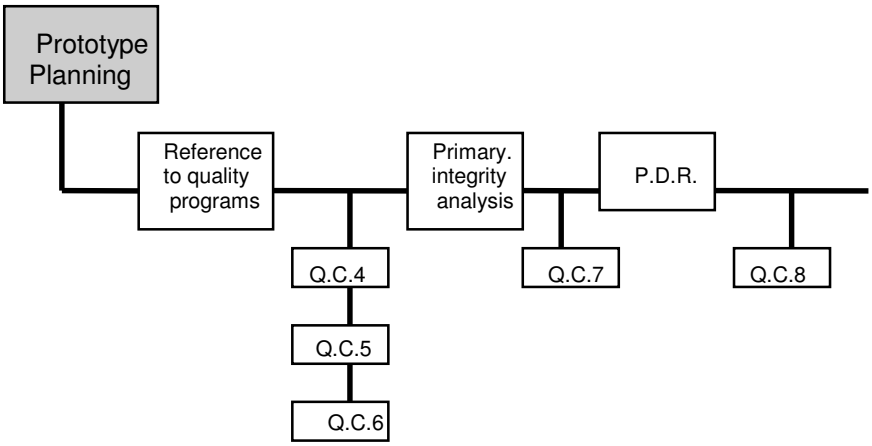
Table of activities of Q.A. personnel in the project (contd.)

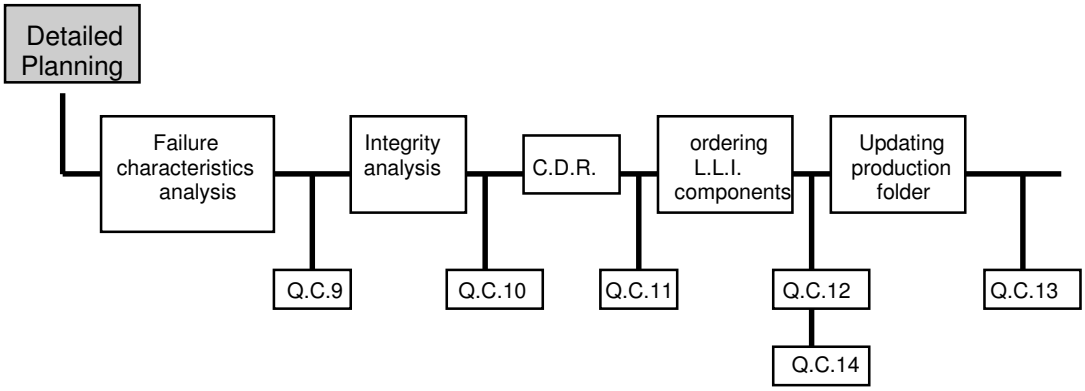
Q.C.19	Testing of hardware & Firmware , Testing programs Results sheets ATP/ATL & Result form	Product Manager Final Testing Dept
Q.C.20	Testing program environment conditions, result sheets Result form from environment conditions	Q.A. Dev. Team Final Testing Dept
Q.C.21	Conclusive report results and tests including results against demand	Product Manager
Q.C.22	Updating production folder against results, non conforming results sheets & changes	Product Manager Q.A. Dev. team
Q.C.23	Production of hardware for sample authorization according to up-to-date production folder	Dev. Team
Q.C.24	Preparation and authorization of *authorization testing plan* perform authorization test plan	Product Manager Q.A. Dept
Q.C.25	Report results of authorization testing plan	Product Manager
Q.C.26	Perform Production requirements review (PRR)	Product Manager
Q.C.27	Preparation of manuals - Operating , maintenance and calibration manuals	Product Manager
Q.C.28	Final testing - Instructions for final testing procedure	Product Manager
Q.C.29	Perform program for acceptance testing program Result forms	Product Manager

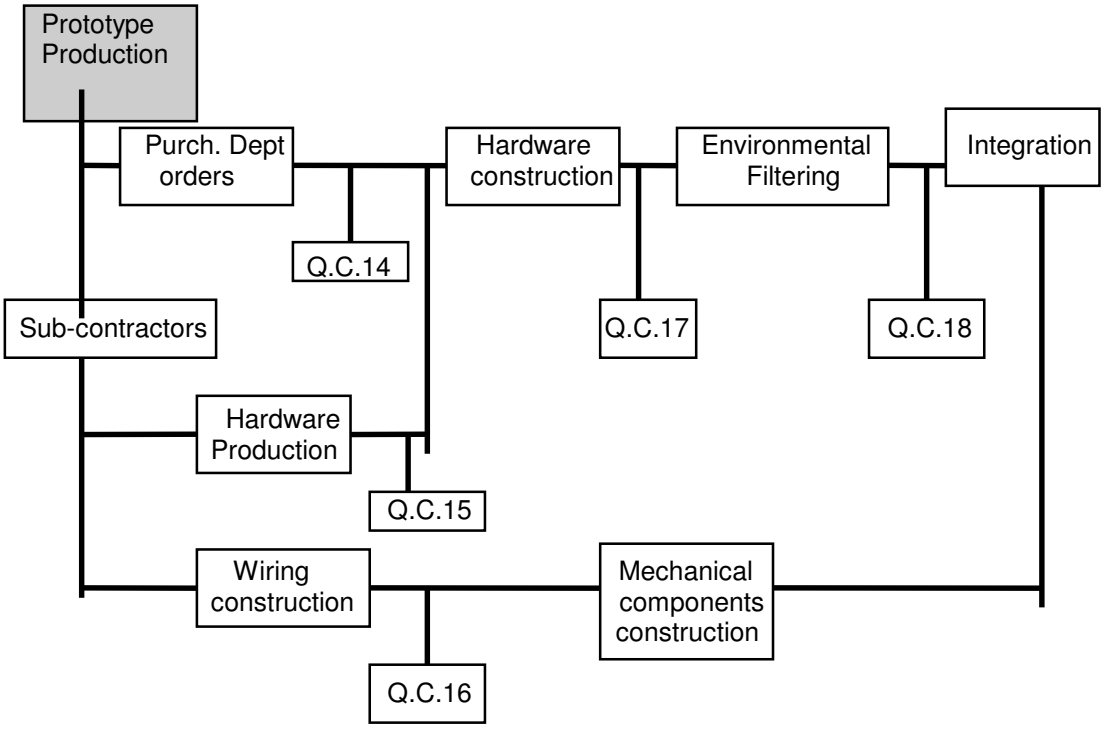
4.2.6 Block diagram

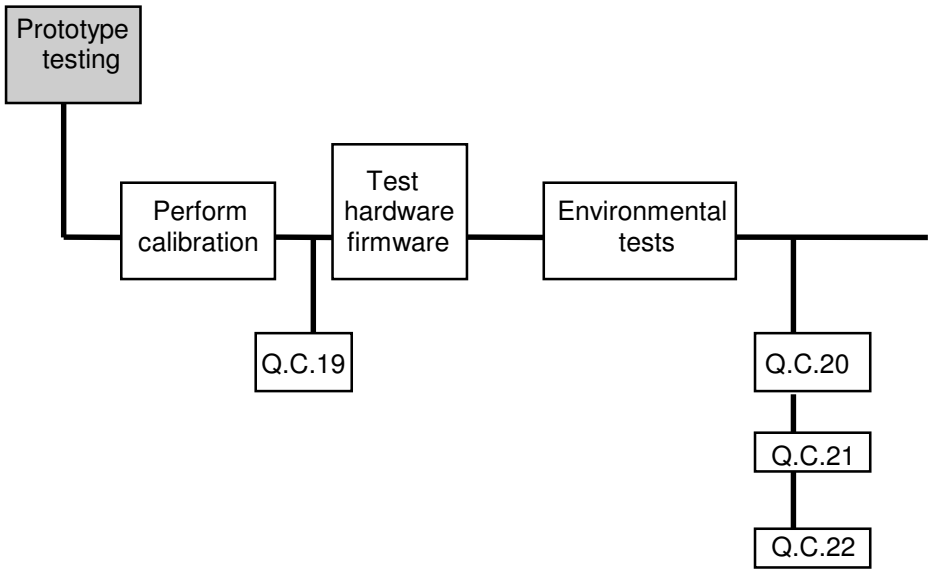
The following block diagram describes the activities of the Q.C. and Q.A. departments during the development, production and maintenance stages of the project.

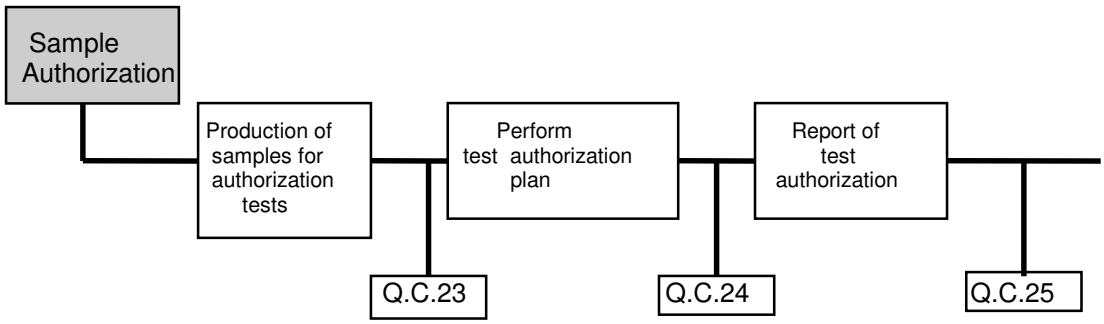


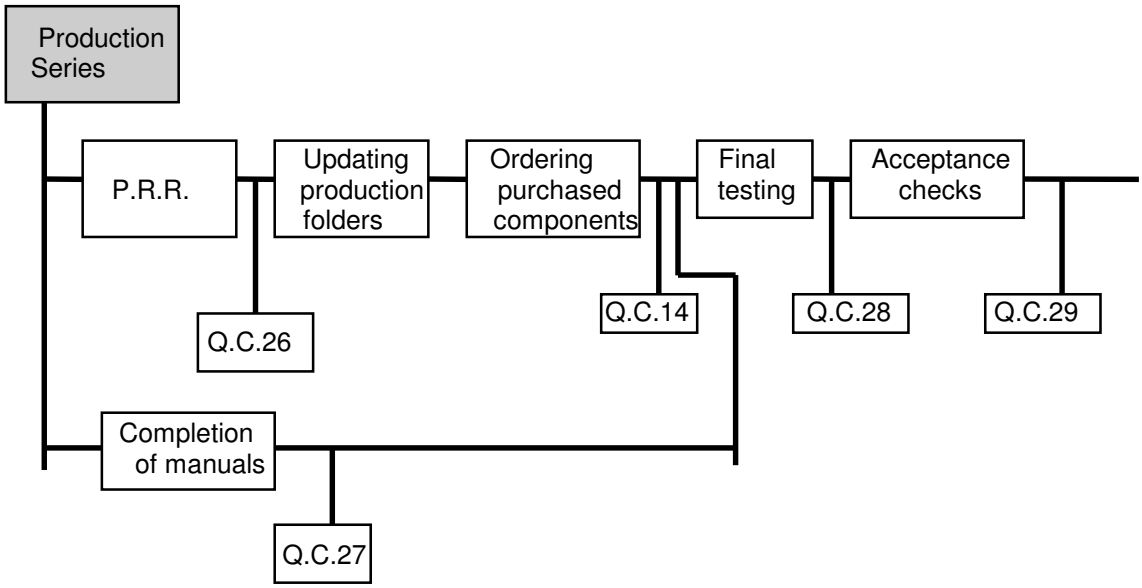

Prototype Planning
Reference to quality programs
Primary. integrity analysis
P.D.R.
Q.C.4
Q.C.7
Q.C.8
Q.C.5
Q.C.6


Detailed Planning
Failure characteristics analysis
Integrity analysis
C.D.R.
ordering L.L.I. components
Updating production folder
Q.C.9
Q.C.10
Q.C.11
Q.C.12
Q.C.13
Q.C.14


Prototype Production
Purch. Dept orders
Hardware construction
Environmental Filtering
Integration
Q.C.14
Sub-contractors
Q.C.17
Q.C.18
Hardware Production
Q.C.15
Wiring construction
Mechanical components construction
Q.C.16


Prototype testing
Perform calibration
Test hardware firmware
Environmental tests
Q.C.19
Q.C.20
Q.C.21
Q.C.22


Sample Authorization
Production of samples for authorization tests
Perform test authorization plan
Report of test authorization
Q.C.23
Q.C.24
Q.C.25


Production Series
P.R.R.
Updating production folders
Ordering purchased components
Final testing
Acceptance checks
Q.C.26
Q.C.14
Q.C.28
Q.C.29
Completion of manuals
Q.C.27

5 Documentation

5.1 Software Requirements Specifications.

5.1.1 Purpose

The MediSmarts system (hardware and firmware) is used in many cyclotron sites and Nuclear Power Plants in the USA and around the world. The firmware and is being continuously upgraded due to either customer requirements or anomalies found during operation. We have installed the system at MSU and other sites we have continuous communication via PCANYWHERE with the BETA site.

Having the direct communication with the customer helps a lot in defining the Specifications required but the following guidelines still apply before applying any of the required modifications.

5.1.1.1 Applied standards

Standard name	number	edition
Firmware quality assurance	QGWI9601.DOC	4
Documentation Cataloging	RGWI9401.DOC	3
Firmware yield test procedure	QGWI9605.DOC	1
Firmware testing procedure	QGWI9607.DOC	1
Firmware demands checklist form	QGWI9604.DOC	1

5.1.1.2 The method

It is possible to divide the definition of requirements into Primary definition requirements (operational requirements) and detailed definition requirements called Requirements Specifications.

5.1.1.2.1. Primary Definition requirements

There is no necessity to write the operational requirements, but it will facilitate the writing of the requirements specification. The operational requirements should include:

1. Description of the entire system, including block diagrams explaining the different authorities.
2. Description of the environmental conditions that the software package will be used in.
3. A general description of the functional requirements of the firmware package, ie. What the system will do
4. A general description of how the software will be used.

5.1.1.2.2. Requirements Specifications

The Requirements Specifications will be based on the Primary definition requirements (if it exists), and will include reference to all the subjects related to the firmware package, excluding the internal structure. The requirements specifications will include reference to the following subjects:

1. A detailed description of the software functions.
2. Development tools and language.
3. Types of equipment, including configuration and peripheral equipment. eg. Disk, display, memory etc.

4. Block diagram of the layout of the system.
5. The flow of parameters in the system.
6. Databases
7. Reactions to all possible developments.
8. Treatment of mistakes.
9. Input/output facilities including display, screens, menus, dialog boxes
10. Definition of the interfaces.
11. Definition of documentation.
12. Tutoring requirements required to perform the work.

5.2 Software Version Control

5.2.1 The SCR form

During the software life cycle there will be the need to upgrade or modify the program according to new customer requirements or anomalies. The decision to modify the program will be taken by either the software team, in the case of an anomaly, or Project Manager, if the request comes from a customer. The procedure for modifying the program must include a SCR form (see example below) and the modification must be listed in the software release form.

He SCR form should be sent to the customer before approval before any work commences. This is a valuable tool for checking that both the customer and software writer understand the modifications required and that the customer understands the scope of work, cost and delivery time. The SCR also limits the customer to specific requirements which have been laid out and authorized and therefore limits the scope of work.

The SCR should include at least two paragraphs: Current situation and Customer Requirement

Current situation – Describes the current situation
Customer Requirements – Describes the customer's requirement and what modifications should be made to the software. If this is very detailed, it should be broken down to a third section called Modifications Required.

Software Change Request

SCR Number: 029	Page 1 of 2	Submitted by L. Kaplan
Department: Mirvach	Phone: 6564781	Date: 14/11/2006
Project: MediSmarts	System/Product: MediSmarts	Current Release: 4.2.2

Reasons for Change	Change Request:
✓ Improvement ☐ Adaptation ☐ Bug ✓ Distributor request	Display Total Activity Release

Change Description

See Next Page

Estimated working time	Calendar Time	Schedule Impact
16 hours		

Estimate approved by (name)	Signature	Date
Baruch Ashkenazi		20/11/2006

Approval (Yes/No Yes	By (Name and Position)	Signature	Date
	Laurence Kaplan Project Manager		20/11/2006

Reasons or Decision	Documented Affected
☐ The next release ☑ The next version _____ ☐ Not authorized	✓ Code ☐ Specifications ✓ Tests ☐ Adjustment ☐ Maintenance ✓ Operation ✓ Other: Manuals

5.2.2 The Software Release Form

The Software Release Form will include each version and the items that were modified/upgraded. The responsibility of maintaining this form falls on the software team leader, and will be checked periodically by the Project Manager. The software release form will serve as a basis for producing a list of upgrades, which will be published with each release of a new version.

5.2.3 Version Number Control

At any time during the software life cycle there will be two versions under control; The Released Version and the Development Version. This is in order to maintain a fully operational software package while development takes place in-house. The released version will be modified only if a fatal anomaly is found and a new, temporary, intermediate version will be created in order to allow the customer to continue using the software. The Development version will be modified to accept the new update. In most cases, following a customer complaint, the customer will be urged to wait for the next release.

The decision to create a new version or sub version will depend largely on the modifications made to the software compared to the last released version.

If a new window, feature or command line is added to the software package, a new version will be created.
If anomalies were corrected or commands were added/modified within a small number of internal screens, a new sub-version will be created.

The MediSmarts application consists of a number of supporting programs; TeleSetup.exe, TelePop.exe, TeleComm.exe, MediWrite.exe….

Upon a version release it has been decided not to update the version number of each supporting program unless the supporting program has been updated. This allows for tighter software control, customer support and maintenance issues.