

SYSTEM OPERATION PROCEDURE		REVISION NO. 01
TITLE : VOYAGER : QUALITY PLAN		REVISED DATE : 04/06/98
ORIGINATOR :	CHOW KWONG MENG	PAGE : 1 OF 7

REVIEWED BY :		APPROVED BY :	
SIGNATURE :		SIGNATURE :	

1.0 PURPOSE

To define a quality plan for the manufacture of Voyager product.

2.0 SCOPE

It covers the quality requirements for order receipt and processing, materials receipt, incoming inspection, manufacturing control, finished product audit, shipping and documentation.

3.0 DEFINITION

RSO - Radiation Safety Officer.
ECD - Electron Capture Detector.

4.0 REFERENCE DOCUMENT

QM-04-02 Quality System.
QM-04-09 Process Control.

5.0 APPLICABLE DOCUMENT

950373	ECD Wipe Test /Assembly Orientation Figure.
QMS-006-00	Record Retention.
QMS-010-00	Process Quality Assessment.
QMS-011-00	Incoming Quality Verification.
MAT-001-00	Contract Review.
MAT-002-00	Production and Materials Planning.
MAT-004-00	Purchase of Direct Materials.
MAT-006-00	Receiving of Local Materials.
MAT-007-00	Receiving of Overseas Materials.

SYSTEM OPERATION PROCEDURE		DOCUMENT NO. QMS-014-00
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MAT-008-00	Shipping.
MFG-002-00	Control of Inspection, Measuring & Test Equipment.
MFG-011-00	Manufacturing Process of Voyager
MFG-015-00	Retrieval of ECD Cell.
QMS-015-00	Inspection of ECD Cell.
Attachment 1	List of Items Requiring Certificate of Compliance (COC) or Performance Data Sheet Upon Receipt.

6.0 PROCEDURE

6.1 Order Receipt and Processing

Responsibility

- | | | |
|-------|---|-------------------------------------|
| 6.1.1 | Review customer order by verifying against production capacity and incorporate requirements into master production plan per MAT-001-00. | Buyer /Planner
Materials Manager |
| 6.1.2 | Identify materials requirements and initiate procurement per MAT-004-00. | Buyer/ Planner |
| 6.1.3 | Schedule production, based on requirements in master production plan. | Buyer/ Planner |
| 6.1.4 | Release work order to manufacturing in order to meet committed delivery per MAT-002-00. | Buyer/ Planner |

6.2 Materials Receipt and Inspection

- | | | |
|-------|--|--------------|
| 6.2.1 | Receive purchased materials per MAT-006-00 and MAT-007-00. | Storekeeper |
| 6.2.2 | Segregate materials requiring incoming inspection and inform Quality Assurance as per QMS-011-00. Segregate ECD cells for inspection by Quality as per MAT-007-00. | Store Keeper |

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Responsibility

- 6.2.3 Perform incoming inspection on materials according to inspection and sampling plans in QMS-0011-00.

QA Technician

Note: Items requiring a Certificate of Compliance (COC) or a performance data sheet upon receipt is listed in Attachment 1.

- 6.2.4 Perform radioactive contamination check on packaging of ECD cell per QMS-015-00.

QA Technician

- 6.2.5 Perform a wipe test on areas of ECD cell as specified in drawing 950373.

QA Technician

- 6.2.6 Sent wiped swabs to an accredited laboratory for determination of radiation level per QMS-015-00.

QA Technician

- 6.2.7 Review result of wipe test from laboratory and record wipe expiration date in ECD log per QMS-015-00.

QA Technician

- 6.2.8 Store ECD cells that passed wipe test in designated cabinet as per requirement in QMS-015-00.

QA Technician

6.3 In-Process Manufacturing Control

- 6.3.1 Receive work order and prepare for Voyager production per MFG-011-00.

Product Leader /
Production Technician

- 6.3.2 Draw out ECD cell if required and update ECD log accordingly per MFG-015-00.

Operator /
Production Technician

Note: Expiration date is six-month from date of test. A retest need to be performed per MFG-015-00.

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Responsibility

- 6.3.3 Build sub-assemblies as per relevant work instructions and update travel log per MFG-011-00.

Operator /
Production Technician

- 6.3.4 Test sub-assemblies and record all test data as specified in MFG-011-00.

Operator /
Production Technician

Note : Sub-assemblies that requires testing is as listed in table :

Assembly no.	Assembly Description
200158	Voyager IS Body 'A' Assembly
200159	Voyager IS Body 'B' Assembly
200160	Voyager EX Body 'A' Assembly
200161	Voyager EX Body 'B' Assembly
200156	Voyager IS/EX Chassis 'A' Assembly
200157	Voyager IS/EX Chassis 'B' Assembly
301201	Voyager Analytical Engine 'A' Assembly
301204	Voyager Analytical Engine 'B' Assembly
301203	Voyager Computer Board
301209	Voyager Key/Display Board
301215	Voyager PID Power Board
301218	Voyager Valve Driver Board
301220	Voyager Charger Board
301205	Voyager Carrier Supplier Assembly
301213	Voyager PID Detector Assembly
301261	Voyager ECD Negative Converter Board
301262	Voyager ECD Amplifier Board
380314	Voyager IS 5Ahr Battery Pack
380315	Voyager IS 7Ahr Battery Pack
380359	Voyager EX 5Ahr Battery Pack
380360	Voyager EX 7Ahr Battery Pack

Responsibility

- 6.3.5 Perform random audit on manufacturing process and sub-assemblies as per QMS-010-00.

Quality Technician

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6.3.7 Configure Voyager unit to required assays as indicated in work order per relevant work instructions.

Operator /
Production Technician

6.3.8 Pack configured units with required accessories per packing list in MFG-011-00.

Operator /
Production Technician

Note : The inspection & test equipment used for manufacturing the above assemblies are maintained and calibrated under MFG-002-00.

6.4 Finished Product Audit and Shipping Control

6.4.1 Perform random audits on finished / packaged units and record audit results per QMS-010-00.

QA Technician

6.4.2 Transfer finished products to Store per MFG-011-00

Operator /
Production Technician

6.4.3 Review purchased order for Voyager unit and prepare shipment per MAT-008-00.

Logistic Executive/
Storekeeper

Note : Perkin-Elmer Singapore does not ship Voyager unit (with ECD) to end customer. All products are shipped to distribution centers which are responsible for customer License agreement.

6.5 Documentation

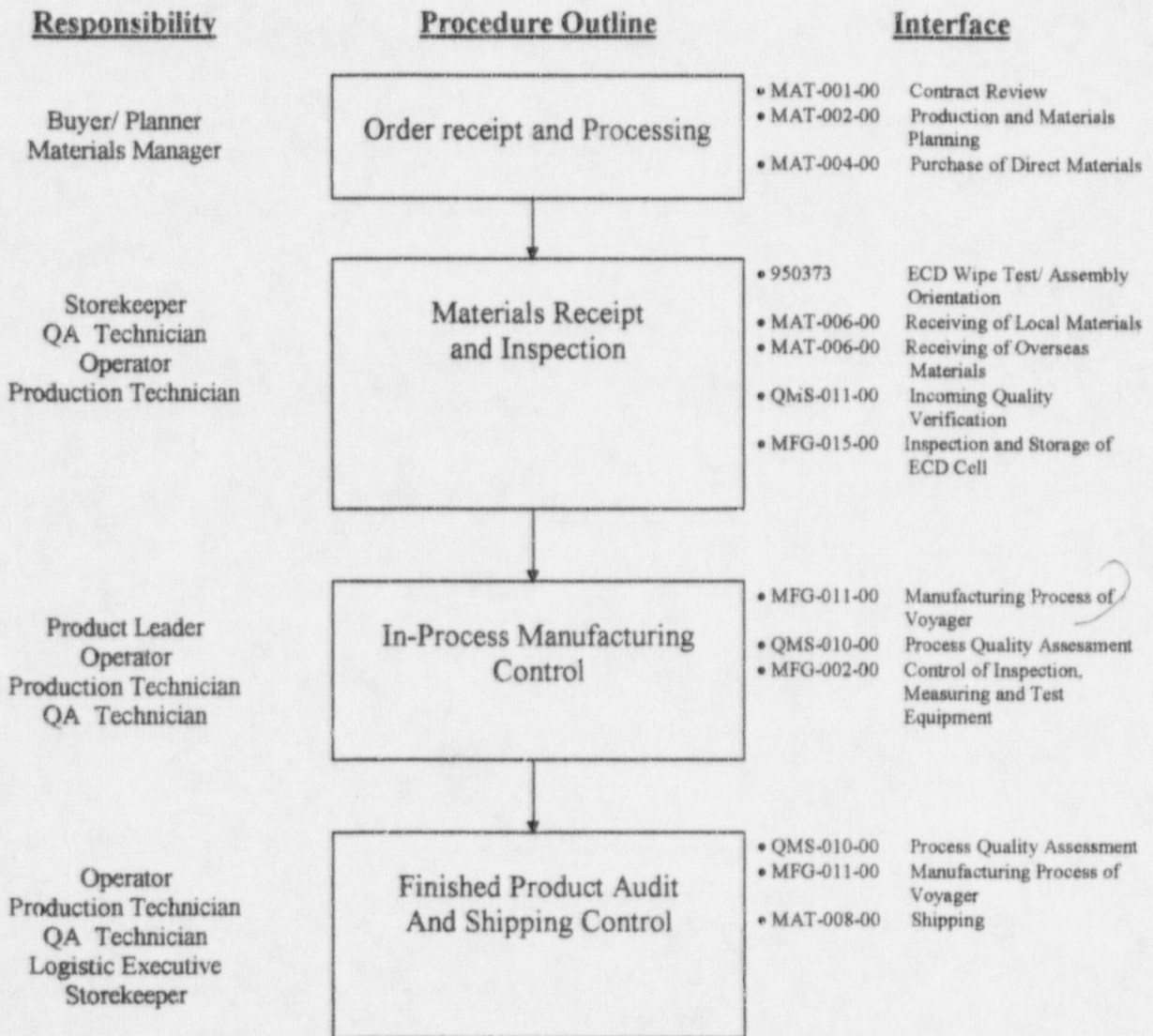
6.5.5 Provide to RSO a list of distribution centers that have ordered Voyagers (with ECD) on a quarterly basis

Logistic Executive

6.5.6 File records and test data generated from the above steps per Record Retention procedure QMS-006-00.

All

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REVISION RECORD PAGE

REVISION NUMBER	REVISED DATE	DESCRIPTION	CHANGE REQUEST NUMBER
00	18/05/98	Written & Released	DC00139
01	04/6/98	Renamed MFG-015-00 to Retrieval of ECD Cell. Insert QMS-015-00: Inspection of ECD Cell in section 5.0. Re-written procedures in section 6.2. All attachments remain unchanged. Revised by Chow Kwong Meng.	DC00140

Attachment 1 : List of items requiring Certificate of Compliance (COC) or performance data sheet upon receipt

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Assembly No. or Part No.	Item Description
301203	Voyager Computer Board
301209	Voyager Key/Display Board
301215	Voyager PID Power Board
301218	Voyager Valve Driver Board
301220	Voyager Charger Board
301221	Voyager D-cell Battery Pack
301222	Voyager F-cell Battery Pack
301261	Voyager ECD Negative Converter Board
301262	Voyager ECD Amplifier Board
501516	R22 Valve Array Driver Fitting Plate
501517	R22 Valve Array Bottom Driver Plate
501518	R22 Valve Array Bottom Seat Plate
501519	R22 Valve Array Fitting Plate
501520	R22 Valve Array Top Seat Plate
501521	R22 Valve Array Top Driver Plate
501522	R22 Valve Array Bolt Plate
501523	R22 Valve Array Clamping Screw
501533	INJECTION PORT RETAINER
501534	INJECTION PORT BODY
501535	R22 Valve Array Foil
501544	PID CELL
501545	PID SPACER
501546	ANTENNA FORMER
501548	HV ELECTRODE
501549	COLLECTOR
501550	PID HOUSING
501554	REGULATOR PISTON
501555	REGULATOR SEAT
501559	FILTER HOUSING
501571	CHASSIS
501573	OVEN FLOOR
501599	LAMP HOUSING
501600	COLUMN TRAY LID
501601	DETECTOR HEATING STRAP
501603	ENGINE BONNET FOAM
501614	THERMAL CUTOFFS ASSY

Attachment 1 : List of items requiring Certificate of Compliance (COC) or performance data sheet upon receipt

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Assembly No. or Part No.	Item Description
501620	DETECTOR INSULATION
501635	CIRCULAR INSULATION
501646	SET A, MID-RANGE COLUMN (Column B)
501647	SET A, LIGHTS COLUMN (Column C)
501648	SET B, MID-RANGE COLUMN (Column B)
501649	SET B, LIGHTS COLUMN (Column C)
501650	SETS A/B, BLANK COLUMN (Column A)
501651	SET A, HEAVIES COLUMN (Pre-Column)
501652	SET B, HEAVIES COLUMN (Pre-Column)
501678	ECD PLUG FOAM
501679	ECD BOTTOM FOAM
501680	ECD CENTER FOAM
501681	ECD TOP FOAM