Internal Audit Check list

CORRECTIVE ACTIONS

Created:	17/May 1995	**Audit No 14**	VM3/COP 06,09 VOP19
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Audit Date	5-9-16	Auditor Helen Lowe	ISO 8.5.2

QUESTION:	**RESPONSE:**	**Y/N**
Verify that all are reviewed regularly. This can be done by checking the management meeting minutes,issues.& actions	ID (88)	Y
Check that customer complaints & non-conformities are reviewed regularly at management meetings	Intrastats	
Check that these reviews assess the cause of the non-conformities.	Intrastats	
Verify that action is taken to ensure that stated non-conformities do not recur.	ID(283)	Y
Verify that records of these actions are retained.	Intrastats	
Check that corrective actions taken are reviewed.	Intrastats	
Check that reviews are undertaken to assess potential cause of non-conformities.	Intrastats	
Verify that the need for action to prevent these occurrences is evaluated.	non Con Review Issues	Y
Check that any action deemed necessary has been undertaken and records retained.	Issues	
Check that preventive action taken is reviewed.	ID(283)	Y
Check that the appropriate authority undertakes regular update reviews.i.e management meeting minutes		
Verify that reviews are presented to the annual management review.	agenda Board meet	Y
Are Customer complaints properly recorded Hard copy & Intrasasts		Y
Is the complaint Index completed correctly Hard copy		Y
Is the complaint Report completed correctly Hard copy		Y
Are reports/correspondence filed in the customer file	Don't do GM/Intrastats	
Has corrective action been taken and recorded	None	

· Host meeting - History cust complaints all meetings.

add to telephone log - customer complaint tick box "needs to say "please include Comprehensive notes relating to this complaint"

Customer Complaints and Vigilance

VM3/COP/10

RESPONSIBILITIES

It is the responsibility of the Managing Director, or a designated person, and senior management to ensure that the requirements of this procedure are strictly adhered to, and that the relevant documentation is fully completed.

DEFINITION

A Complaint is defined as any report, written or oral, with or without a return product, expressing Customer dissatisfaction with:

Device identity: labeling errors
Reliability: Inability to perform in a consistent manner throughout the warranty period or specified service period.
Safety: Possible harm to patient or operator.
Effectiveness: Inability to perform as intended.
Performance: Inability to perform in compliance with the published specifications.
Durability: Inability to perform throughout warranty period or specified service period.

Definition Exceptions:

Routine calibration, product maintenance, technical inquiries, product updating to current approved revision levels, customer suggestions for more product features, credit inquiries, etc., are not considered complaints

REFERENCE DOCUMENTS

Customer Complaint Report (QC12)
Customer Complaint Report Index (QC11)
Service Repair Note (QC09).
Risk assessment for MDD Notification (QC44)

TELEPHONE COMPLAINTS

Note name and address in diary (daily telephone log).
If the complaint cannot be answered pass the complaint to the Managing Director or Financial Controller or Technical Staff for investigation.
If the complaint cannot be answered i.e. Not a user associated problem request the instrument or accessory be returned Generate a Returns number from Intrastats and quote the number to the customer.
Record details of complaint in the SRS Fields.

If the complaint warrants immediate action, raise an Issue in intrastats under Customer Complaints and 'Issue To' a director.

Customer Complaints and Vigilance

VM3/COP/10

GOODS RETURNED TO VIAMED placed in product

Upon receipt, the product will be ~~boxed~~ and a service repair form, Intrastats SRS raised by ~~the office staff~~ with supply date referenced on it. ~~If a repair it is logged to the Repairs Book~~. (Ref procedure VM/COP/09 Section 4.1.2).

Goods in or after

~~the goods~~ records goods in Stock

Pass to Engineers for examination with a copy of any accompanying paperwork, the complaint report and the SRS. If repaired the procedure will be as in VM/COP/09.

Copy of complaint to be sent to the Managing Director, who will investigate those problems associated with damaged goods or failure to meet specification in spite of QA Inspection Corrective Action, will be recorded.

If the complaint is a failure to comply with a specification, a repeated failure, or a premature failure (e.g. sensors), then the substance of the complaint and preferably the written complaint should be copied to the original manufacturer (See procedure VM/COP/06).

If the complaint is common or has a known explanation a letter should be sent explaining the current position and the action being taken by ourselves and/or the original supplier.

If the problem has no present solution the complaint should be filed in the CURRENT COMPLAINTS file with the SRS, and all the relevant copies of the paperwork until an answer is found. The customer is contacted and informed of the position, and the ~~Office Manager~~ team leader reviews progress with the person responsible for investigating the problem. The Quality Engineer will review progress with the investigator.

The Complaint Report is filed in the complaints file and ~~the Hospital/customer file~~ attached to contact in Intrastat.

VIGILANCE SYSTEM

Should the complaint escalate to withdrawal of suspected product or require advisory notices – QC11 Paper file index will be added to / Refer back to the intrastats Issue number and the QC44 Risk assessment form started. End user

All correspondence regarding the complaint shall be logged against the original customer complaint issue number,
All ~~Emails~~ / forms can be scanned and linked to the Issue number

Vigilance system will be carried out in accordance with the current MEDDEV 2.12.-1, See Document index. Version of MEDDEV 2.12-1 is check for version control once per calender year.

WITHDRAWAL OF SUSPECT PRODUCT OR NOTICE FROM SUPPLIER

Substantiated complaints which could be dangerous or harmful will require notification to the relevant Competent Authority. In this situation a complete list of users or locations should be assembled, see VM3/COP/10.02.

If appropriate the Managing Director will arrange to withdraw remaining items from stock.

Sub Distributors must also keep records of destinations of products distributed and have in existence recall methods.

RECALL OF SUSPECT PRODUCT

See VM3/COP/10.02 For product recall process.

REPAIR OF SUSPECT PRODUCT

Repairs will be in accordance with VM/COP/09
Customer complaint Report QC12 will be raised for the duration of the recall

FORMAT OF ADVISORY NOTICE Email

Users will be contacted by letter , Fax , or Telephone followed by a letter notifying them of the problem. The information in the letter should contain a clear description of the problem and its possible effects. A solution if available. Advice on how to circumnavigate the problem if a method exists. Copies of the Original manufacturers information should be enclosed. Information on Order No: Invoice Number: Date of purchase: Equipment type and Equipment Serial number should be included where available
A list of users/purchasers can be obtained as in VM3/COP/10.02
EBME and/or engineering departments should be informed.
Incidents as defined in the MDD will be reported on form Appendix 3 (MDD) and CMDCAS guidance documents.

Response will be immediate and instant referral to the MDD guidelines following the Incident Action plan on Appendix 4 .Risk assessment to determine MDD notification is carried out on (QC44)

The Notified Body and any other National body requiring notification will be informed at the same time as the MDD
Notification of incidents will be indicated on Customer Complaint Report Index (QC11) & (QC12).

NOTIFICATION OF NOTIFIED BODIES.

Where it is identified that product has been shipped abroad while following VM3/COP/10.02.
Any external notified bodies / medical authorities will be informed of the recall / advisory notice,

eg.

Sales to U.K. - M.H.R.A
Sales to Canada – Canada Health will be informed following CMDCAS Guidance Documents
Sales to Taiwan – Food and Drug administration, ministry of health and welfare, TFDA.

BSI Technical Manager shall be Emailed, and BSI's current reporting process carried out.

TIME SCALE OF REPORTING

The following time lines apply in a case of:
Serious public health threat: IMMEDIATELY (without any delay that could not be justified) but not later than 2 calendar days after awareness.

Death or UNANTICIPATED serious deterioration in state of health: IMMEDIATELY (without any delay that could not be justified) after the link between the device and the event but not later than 10 elapsed calendar days following the date of awareness of the event.

Others: IMMEDIATELY (without any delay that could not be justified) after the link between the device and the event but not later than 30 elapsed calendar days following the date of awareness of the event. If after becoming aware of a potentially reportable INCIDENT there is still uncertainty about whether the event is reportable, the report must be submitted within the time frame required for that type of INCIDENT.

1. Where appropriate, or where required by such as Customer Complaints, Internal problems etc., corrective actions will be addressed and implemented.
2. Where the Sales team or other personnel highlight potential problems, then these will be reviewed and analysed for their possible impact on products or services. QC21
3. When a problem is highlighted, the General Director will be informed as to all possible scenarios so that all the relevant information is available to enable the correct decision to be made.
4. The decision made may be one that has a direct bearing on the design of the product or on the integrity of the service provided. Where this is the case then all relevant personnel will input to the problem.
5. Should the actions taken, whether corrective or preventive, have impacts on Customer satisfaction, then the Customer will be immediately informed and actions followed-up to ensure full satisfaction. Subsequent actions such as design modifications will be entered into the design file (CE file where appropriate) and all records amended.

need an addition relating to.
internal non conformance review.
write one.

Internal Non conformace reveiw

Error logging ~~or~~ per invoice/ ORD
is to be filled in ~~when~~ as Errors
are found and corrected. Also when credits
are processed.

if you discover an error or mistake and it
goes beyond the error ~~reporting~~ logging
a non Conformance issue should be coded
to the HR ~~Finance~~ Director. this is a private
issue so ~~you can be~~ no one can read it

Every ~~month~~ 3 months a non Conformace is done
to detail any problems and list details of error logging