| VOP | | | |
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| Viamed Operating sub Process | | | |
| **Process Monitoring, System Reviews, Audits, Management Reviews and Analysis Data** | | | |
| Created: | 27/03/06 | VOP 13 | |
| | | See the Route Map for related ISO Standards. | **Page 1 of 5** |
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## SCOPE

This procedure defines the system in operation at the companies for carrying out planned internal audits, and / or reviews, necessary to verify compliance with all aspects of the defined quality program. It is used in conjunction with the individual sub procedures, which show the relevant information necessary.

## RESPONSIBILITIES

It is the responsibility of the Managing Director, to ensure that the contents of this procedure, and related procedures, are adhered to. To oversee all requirements of this procedure, with delegated nominees adding to the audit team if and where necessary.

## DATA AND INFORMATION ANALYSIS

See VOP 15 data and information analysis.

## OBJECTIVES

It is the Objective of this VOP to demonstrate the Process Monitoring, System Reviews, Audits, Rolling Tasks and Mini Audits, Management Reviews and Analysis Data. How they are used, the information processed and reviewed throughout the companies.

## INTERNAL AUDITS

Intrastats generates Issues when an audit is due, it will be carried out within 2 months of being generated and the completed checklist will be uploaded to the issue, by the person responsible for carrying out the audit. Any non conformance's or corrective actions shall be tracked by related Issues to the original Audit Issue. Any areas, that the auditor feels they cannot audit due to a conflict of interests, will be delegated to another experienced member of staff.

### Review of the Audits and Audit Calendar

The review of Audits is carried out by Audit 21, the Audit of Audits. Each section of the company's system, as described in the manual, is audited at least once per annum. Further audits are dependant upon previous results. Previous Audit results are reviewed in the Management Review Meeting and any outstanding issues are reviewed as part of the next years Audit.

The Audit Calendar is review as part of the Management Review Meeting. At this time, the next years Audits and Audit calendar is agreed up on.
The audit calendar can be view in Intrastats ISO → Route Map → VOP / Audit QC 17 Audit Calender.

All Audits will have the checklist, the sections of the Route Map they relate to and a list of the current years rolling tasks and Mini Audits.

For products we are actively placing on the market, product audits will also be performed as dictated by company and regulatory needs. The auditor will diligently check that the procedures in operation are being complied with, and are suitable and effective. Checklists may be generated for use in the audit, and would therefore form the basis of the audit records, cognisance of previous audit results is taken when generating any checklists.

Where corrective actions are needed as a result of audits, Create a follow up / related Issue linked to the primary audit, which includes a Time for Completion, Immediate Action Plan, Corrective Action Plan, Corrective Action, Confirmation of Resolution. If its a major / critical non conformance complete form QC 21. Carry out a risk assessment for any changes that need to be made to make sure they do not adversely affect the systems, products or company.

Reviews of these Subsequent follow-ups will take place within one week of these effective dates, to assess compliance. The auditor will complete the audit after having been assured that follow-up actions have been satisfactorily completed. All results will are recorded in the issue's and linked issues. Final Audit closer is the responsibility of the Managing Director.

**Mini Audit**
Each underlying process / task, depending on the risk and type of process, can be allocated a Rolling Audit Issue. As each process has an allocated employee, any other employee can perform a mini audit. Most Mini Audits contain instructions on carrying out the audit, within the issue, generated.

Weekly Management review, of rolling Tasks and Audits, will either close the Mini Audit, or generate further actions if required. Further action Issues, are linked to the original audit Issue, and tracked until completion.
History of a Mini Audits / associated tasks are linked to every mini audit, and available from the related Issues.
On completion of the weekly management review, the Task / Audit completion history screen is displayed, where any outstanding Issues from previous tasks / audits are highlighted for re-review.

At this time if any areas of risk become apparent a risk assessment will be carried out.

**Review of the Mini-audits**
Review of audit issues shall be carried out by management before being completed.
History of audits can be retrieved by pulling up the history of the Rolling Issue, or the appropriate header in intrastats.

Procedures will be periodically assessed for possible changes needed. Significant Changes will need approval of Assessment Body.

## BOARD MEETING MANAGEMENT REVIEW

Process 7846, Rolling Task 746. Senior management at the official Management Review Meeting / Board Meetings, together with other management staff, as deemed appropriate, will review the System and its processes at least once every year +/- 2 Months. The review will consist of analysis of intrastats data reports, and where possible using statistical techniques.

The review agenda will constitute, as a minimum, the following points:

a. Follow-up actions from previous reviews.
b. Customer feedback
c. Results of internal audits
d. Process and product performance
e. Preventive and corrective actions
f. Possible system changes.
g. Regulator Changes
h. Recommendations or improvement
i. Any other business

In addition, each of the following points, as a minimum, will be addressed and an objective included where appropriate:

1. Contract review, Picking, Packing and Despatch
2. Purchasing controls
3. Supplier, subcontractor performance
4. Storage and Stock control
5. Customer complaints
6. Calibration
7. Documentation and records
8. Training
9. Internal audits and corrective actions
10. Review of responsibilities
11. Resources required
12. New products etc.
13. Quality planning
14. Achievement of Quality Policy
15. Advisory notices and recalls
16. Vigilance system (Complaints, Repair levels, Surveillance)
17. Changes to the Management system
18. Changes to CE marked products
19. Risk and any changes to risks.

Before any changes are made a risk analysis will be carried out to make sure the change doesn't adversely affect the process.

The review will be minuted, a plan of action, in the form of issues will be generated from it. Activities undertaken in the plan of action will be timely, and subsequently verified by the Managing Director.

Areas that require it will be agreed during the meeting including and limited to signing off the Audits and agreeing the next years audit calendar and agreeing the current organisation chat etc.

**Weekly Management Reviews**

Where possible a weekly review of all tasks and audits, across all departments and areas is undertaken, but never more than 3 weeks apart in special circumstances.
As per Mini Audits above.
Weekly Management review of rolling Tasks and Audits will either close the Mini Audit, or generate further actions if required, further action Issues are linked to the original audit issue, and tracked until completion.
History of a Mini Audit / associated tasks are linked to every mini audit, and available from the related Issues.
On completion of the weekly management review, the Task / Audit completion history screen is displayed, where any outstanding Issues from previous tasks / audits are highlighted for re-review.

**Product Reviews Post Market Surveillance**

Our previously manufactured products, that have now been discontinued but need to be supported for their lifespan – Each range shall be reviewed once per year +/- 12 months depending on the timing of the triggering Issue, to perform the Product review (Task ID 50)

Each discontinued product type will have a post market surveillance report created, as per VM3COP18 and a risk assessment as per VM3COP27.11. Until the end of its life span.
Stock References will be confirmed, as included in the review:

- All related suppliers will be confirmed, and checked that the supplier review is up to date, where we still actively purchase from them.
- Sales Information will reviewed. For discontinued products, there will not be any new sales data.
- Country Sales will be reviewed. For discontinued products, there will not be any new country sales data.
- Returns and QA Failures will be reviewed. (Note due to the size and quantity of information within the Returns and QA reviews, a summary is listed, in the Final Post Market surveillance report).
- Any design changes will be reviewed. For discontinued products, there will not be any new changes.
- Instruction manual changes will be reviewed. For discontinued products, there will not be any new changes.
- Labels will be reviewed. For discontinued products, there will not be any new changes.
- Other Documentation changes will be reviewed. For discontinued products, there will not be any new data or changes.

All internal Issues relating to the product ranges will be reviewed, (again due to the quantity of information contained within the Issue review, only the ID and subject will be listed in the Final Post Market surveillance – however during the review and afterwards the entire issue history is available). For discontinued products, there will not be any new changes.
A web search for Clinical / FDA reports will be performed to see if there are any unknown risks (maybe with competitors products) or if the technology is outdated.

Issues created during the review will be evaluated to see if the Risk file requires updating.

**MDR Considerations**

As of 2019 Viamed no longer places any manufactured products of its own onto the market.
Spares and basic repairs / servicing is still available for the lifetime of the products place on the market Pre-2019.
Tom Thumb Range, the last product change was pre 2004.
Microstim Range, the last product change was 2006.
There has now been 15+ years track record of safety with these devices since the last product change. There have been Zero adverse incidents with either range of devices in over 15 years so we do not perform a PMCF at this time. Products will be re-evaluated to contain a PMCF should any new feedback from the current PMS warrant it.

In the unlikely event of a reportable incident occurring. Current modern methods of reporting and risk assessing will be carried out. We will refer to Article 120 of the MDR and the current version of 14971:2019.

**Management Product Reviews General**

Rolling Issues to review the 'New Repair Code' information across all products supplied. Both in house produced items or those supplied by other manufacturers will appear on this list.
The report screen displays any new type of fault as discovered by QA / Returns engineers.
During the review, the repair code is either linked to a clean code, or a new clean code is produced.
If its an in house product, and there is a new clean code, an entry into the Risk file is made (now automatically), for further investigation to evaluate the potential new risk presented.
Rolling Task ID 750, Rolling Audit 751.

QA Reviews rolling task 727 Rolling Audit 729. All the previous months QA is reviewed, when there is a high percentage of failures a non conformance issue is raised to examine further the potential problem.

**Effectiveness of the systems**

Effectiveness of the systems is assessed by regular meetings with supervisory staff, in the form of office and warehouse reviews. Discussing requirements and performance of the system. Review of issues pertaining to the system and their effectiveness within the company errors and issues. Which refer to gaps or areas that may not be fully effective. The systems are discussed in the Management Review and Board meetings. Any areas that need update or change a risk assessment will be carried out to make sure it does not adversely affect the system or process.

Effectiveness of staff is assessed by regular meetings with supervisory staff, in the form of office and warehouse reviews. Review of issues pertaining to staff and their effectiveness within the company and the processes they use and are part of. Including the non conformance review of errors and issues. Annual appraisals when possible (Covid 19 Issues). Management Review and Board meetings.

Effectiveness of training is assessed by regular meetings with supervisory staff, in the form of office and warehouse reviews. Discussing requirements and performance where relevant. Review of issues pertaining to staff and their effectiveness within the company and the, which refer to training gaps or training that may not have been fully effective. Training is discussed in the Annual appraisals when possible (Covid 19 Issues). The Effectiveness of training is reviewed in the Management Review and Board meetings.

For Sub Processes Linked to VOP 13 please refer to the Document Index admin page.