i. **AUDITS**,

1. Audits will be carried out by the Managing Director or Nominee but the nominee cannot be the department representative. V13/3.1
2. Relevant sections of the Quality System will be audited according to the Audit programme (Form QC17) as follows:
3. Check conformance to the statements in the Quality Manual and procedures manual. Audit questionnaires will be used as a guide.
4. As part of the procedure, samples of documents used will be taken and checked for correct entering and use.
5. Departures from conformance to procedure will be recorded, and will be examined in order to establish the reason for the non-conformance.
6. When the reasons for non-conformance have been established, corrective action will be considered, this may include:

a. Returning to the original procedure
b. Modifying the original procedure in the light of the reasons for non-conformance
c. Preparing a completely new procedure

7. During 1.3 and 1.4 above, the opinions of, and suggestions from those operating the procedure will be sought and corrective action established as necessary.
8. The results of the Audit will be recorded on the System Audit Record (Form QC18) stating the corrective action and the time scale for its completion.
9. If it is necessary for the Quality Manual to be revised, the pages in question must be held for approval by the Assessment Body. The approved revised page(s) will be incorporated in the master manual and copies circulated to all holders of Controlled Copies of the Manual.
10. If the revision is of a procedure only, it will be revised and circulated in accordance with the amendment control procedure.

ii. **MANAGEMENT REVIEW**

1. The Managing Director or nominee will carry out a Complete System Review at intervals of not more than a year.
2. He will use an Agenda, Appendix A and the results of Audits and effectiveness of corrective action to carry our the review.
3. The whole of this Review will be minuted and the Managing Director will verify that corrective actions are effective.

2. 3.**RECORDS**

_Copies of the minutes of Management Reviews and Audits will be filed as a Record of the

a. Viamed Quality System for inspection by the assessing body.

3. Appendix A

i. Contract Review/Picking, Packing and Despatch
ii. Purchasing Controls
iii. Supplier/Sub-contractor Performance
iv. Storage and Stock Control
v. Customer Complaints
vi. Calibration
vii. Documentation and Records
viii. Training
ix. InternalQuality Audits-
1. Corrective Actions
x. Review of Responsibilities
xi. Resources required
xii. . New products
1. New services
2. Space
3. Test Equipment
xiii. Training
xiv. Quality Planing
xv. Achievement of Quality Policy
xvi. Advisory notices & recalls
xvii. Vigilance System
1. Complaints
2. Repair levels
3. Surveillance reply cards
xviii. Changes to the Quality Management System
xix. Changes to CE marked products