INTERNAL AUDITS

This procedure defines the system in operation at the company for carrying out planned internal audits, and / or reviews, necessary to verify compliance with all aspects of the defined quality program. It is the responsibility of the Quality Engineer to oversee all requirements of this procedure, with delegated nominees adding to the audit team if and where necessary. Personnel performing audits must be aware of notes in the Quality Guidance document. QGD01

Audits will be performed in accordance with the flexi-chart matrix (and alarmed in Goldmine), maintained by the Quality Engineer. Prior to any audit being performed, the responsible department head will have been notified in advance.

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. 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 the audit, they will be detailed and the corrective action / completion date agreed. Subsequent follow-up audits will take place within one week of these effective dates, to assess compliance. The auditor will formally close out the audit after having been assured that follow-up actions have been satisfactorily completed. All results will be recorded in the "Lotus" database and the matrix will then be up-dated. A copy of the report will be filed for reference.
Procedures will be periodically assessed for possible changes needed
NB may need approval of Assessment body

MANAGEMENT REVIEW

Senior Management, together with other management staff as deemed appropriate, will review the System and its processes at least once every year. 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. Recommendations or improvement.
h. Any other business

In addition, each of the following points, as a minimum, will be addressed:

1. Contract review / Picking, Packing & Despatch
2. Purchasing controls
3. Supplier / subcontractor performance
4. Storage & Stock control
5. Customer complaints
6. Calibration
7. Documentation & records
8. Training
9. Int. audits & corrective actions
10. Review of responsibilities
11. Resources required
12. New products etc.
13. Quality planning
14. Achievement of Quality Policy
15. Advisory notices & recalls

16. Vigilance system (Complaints, Repair levels, Surveillance reply cards)
17. Changes to the Management system 18. Changes to CE marked products

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