manufacture, date of release or date of Production/testing depending on the type of document.

3.2. Documents must be disposed of by shredding or incineration.

3.3. In the event of a third party contractor being used to dispose of documents, this contractor's activities should have been inspected by QA personnel in order to determine acceptance or suitability.

4. Retention and Disposal of Laboratory Documentation

The Laboratory produces a large quantity of documentation which must be clearly labelled, stored and accounted for at all times for the duration of the documents retention period (minimum 13 years).

Documents are stored in either in laboratory safes or in the numbered well boxes with detailed reference.

4.1. Archiving system is predominantly a manually hand recorded system for recording of documentation and can only be traced by manually looking through logbooks to find information.

4.2. All Analytical Laboratory documentation is to be kept for a minimum of 13 years (unless otherwise stated). If in doubt about what documents must be retained, ask the Laboratory Manager or the QA Manager.

5. Laboratory Documentation Systems

5.1. Faulty/Rejected Material Reports

The Laboratory keep a copy of all Faulty/Rejected Material Reports (Raw Material Chemicals; Raw Material Packaging Materials/Components; Finished Good Rejected Product; Expired Product) that were sent to the Laboratory for signing.

5.2. Finished Good Certificates of Analysis

Manufactured Finished Goods are assigned a Certificate of Analysis, which is generated from an entry in the Finished Good Register (**Form-250**). Each batch is assigned a pre numbered Certificates of Analysis known as Lab number. All tests and results are to be printed on the Certificate of Analysis. Export Certificates of Analysis are created from these certificates of analysis using the data recorded on each. Trend cards (**Form-265,260**) are filled in prior to the Certificate of Analysis being filed. All of these certificates of analysis are to be archived into numbers well boxes for long-term storage. If results are required from any of these certificates of analysis, check the Trend cards first before retrieving the actual document.

5.3. Finished Good Register

All manufactured Finished Good products are entered into the finished good register. These register records the following information: Lab No. (pre-printed number on the top of the finished good Certificate of Analysis), BPN no., Product Name, Code No., Manufacture Date, Container, Batch Size, Comments, Goods Booking Slip no, QA Signature and Date of when product was passed.

5.4. Raw Material Certificates of Analysis

Incoming Raw Materials are all assigned a Certificate of Analysis, which was generated from an entry in the Raw Material Register **(Form-255)**. Each batch was assigned Laboratory Batch Number as soon as it is received by warehouse (see SOP **WAR-005**). All tests and

