2.4. Biological Assay Test Samples - (if required)

When collecting Bacterial Endotoxin Samples please record the information on the Sterile Area Sample Identification Checklist (**Form 625**).

2.5. **Sterilisation Charts**

All charts that are generated from the steaming of the sterile preparation machines and transfer lines are to include the following details:

- Machine Number
- Shipper Label to be signed and dated by Operator
- The details of BPN, Material Code, User ID, Product Type are to be entered onto the chart at the header section.

The chart is to be checked before the commencement of filling of product. Once the chart has been checked, it is to be signed and dated by the Operator.

If, for any reason a machine is not steamed (because of filling a product of the same Code and there has been no break in sterility of the line), It is still require the header section of the chart to include all details and a signed and dated Shipper Label. If no Shipper label has been generated for the BPN, or the machine does not require steaming, **the Operator still needs to send a completed copy of Form 630 to the Micro. Lab**., to enable Micro. Lab. personnel to enter the steaming details into the steaming log. Include the information that the machine has not been steamed, (i.e. N/A for Steaming).

If at the start of filling a batch, the machine does not require steaming, but during the filling of the batch it does require steaming, due to a break in sterility, then a **Deviation Report (DR)** is to be raised. The DR number is to be written onto the chart.

All sterile preparation and transfer machine chart records are to be inspected before delivery to the Micro. Lab. Sample Cabinets. The charts are to be logged into the Chart Logbook (FM 0635).
Micro. Lab. staff is responsible for the daily collection of the charts from the Sample Cabinets and the checking of the charts.

2.6. **Settle Plate (Fallout plate)**

2.6.1. Each Filling Machine is required to have exposed at least one Settle plate (Fallout) for 4hours **+ or -** 15minutes/ per shift/ per BPN/ per number of days of filling, (i.e. if filling over 3 shifts then you are required to have at least 3 Settle plates). If for some reason the exposure time is less due to the batch finishing on that shift or due to breaks, major stoppage then indicate this on Settle plate. Settle plates are not to be exposed for longer than 4hours **+ or -** 15minutes due to the possibility of the plates becoming dehydrated. **NOTE:** If a batch has only just started or about to end on a shift and the exposure time is less than 4hours **+ or -** 15minutes, then the plate should be identified with start and end of batch to avoid a deviation being raised for insufficient exposure time on that individual shift of manufacturing.

2.6.2. **Nutrient Agar plates** are exposed to sample the air quality during filling. Written details required on the plate are as follows:

- BPN
- Material Code Number
- Date of Filling
- Sterile Preparation Machine number
- Start time of Exposure
- Finish time of Exposure
- Position on machine, i.e. Left, Right side.

2.6.3. Plates are to be available from the production or Micro Lab. fridges.