1.2. The purpose of reconciliation is to ensure that all materials have been accounted for and no mix-up occurred. Reconciliation is carried out on printed and/or coded components and the finished product. The limits outlined in this procedure should help detect errors at the time of manufacture and avoid release of a non-conforming product.

1.3. Reconciliation should be performed at the end of each stage, especially if the goods are moved from one location to another. Final reconciliation should cover the whole process.

1.4. The reconciliation calculation should be based on real figures. Estimate is allowed in relation to materials that can be lost during the process.

1.5. It is of prime importance that all products are correctly identified (labelled). A series of systems - defined by batch documents and SOP's - exist to ensure components are correctly labelled, e.g.

- Unique component Material and version number
- Bar code checks
- Reconciliations after pre-coding
- Line Clearance/Opening/Cleaning Procedures
- Security storage
- Sampling of all printed and/or coded materials

2. Procedure

2.1. At the end of each specific packing of a batch or part-batch, the printed components and product will be tallied by the Machine Operator, e.g. labels, cartons, leaflets, tablets, etc.

2.2. These components will be reconciled as a % yield, comparing the number at the start with the number at the end of the process including all waste that occurred during the process.

2.3. \[ \text{% yield} = \frac{\text{No. of Goods produced at the end of process} + \text{Rejects} + \text{Samples} + \text{Returned}}{\text{No. of goods received at the start of process}} \times 100 \]

2.4. All components and products should reconcile 100%, however, allowances are made (Tolerance limits) to allow for counting error and/or minor inconsistencies.

ANY UNUSUAL situation and out-of-tolerance tally must be investigated immediately on checking the reconciliation.

In the case of the out of the range result a recount must be done and the entries corrected. If the % yield is still outside the allowable limits a thorough investigation must take place to ensure the cause of such a deviation to establish that no mix up has occurred.

2.5. Yields outside the set tolerances must be explained in a Deviation Report (DR). See SOP QMS-035.

3. Example-Allowable Tolerances for Printed Components

<table>
<thead>
<tr>
<th>Batch Size (Packs)</th>
<th>0 - 50,000 Packs</th>
<th>Over 50,000 Packs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cartons used on packs</td>
<td>99 - 101%</td>
<td>99.5 - 100.5%</td>
</tr>
<tr>
<td>Leaflets used on units</td>
<td>99 - 101%</td>
<td>99.5 - 100.5%</td>
</tr>
<tr>
<td>Labels used on units</td>
<td>99 - 101%</td>
<td>99.5 - 100.5%</td>
</tr>
</tbody>
</table>

Note:
The number of leaflets received on the line should be taken as the amount specified on the manufacturer's label, or in the case of partial boxes, the number written on the partial sticker.