

## Guidance 070 Receipt, Approval and Use of Labels and Labeling

- received from the label or labeling printer (e.g., corrugated containers) should never be reused.
7. A Packaging Batch Order, Verified Against the Master Packaging Order, should be issued for each batch to be labeled.
  8. Incorrect (Foreign) Labels or Incorrectly Labeled Product should be investigated. The person who discovers the error should immediately report the incident to the responsible Area Supervisor.
  9. Actual Yield Calculations of Labels and Labeling Used for a Lot/Batch should be performed by one person from Site Production Team and verified by second person. Yield calculations should be verified by Site Quality Team as part of Batch Record review. Yield calculations should compare the number of product units labeled against the quantity issued, less the quantity returned to stock (where permitted). Yield calculations and results should be kept with the Packaging Batch Records.
  10. Acceptability Limits for Reconciliation (e.g., 98 Percent -102 Percent) and Yield (e.g., 95 percent -102 percent) should be listed or specified in the Packaging Batch Order. Limits should be based on operation lot size and historical data.
  11. If Labels and Labeling are needed for Packaging Equipment Set Up, then the labels and labeling materials that are specified on the Packaging Batch Order for the current lot or batch to be packaged in the packaging area should be used. The same issuance and verification, and receipt and verification controls should be applied to all labels and labeling materials used for packaging equipment set up as used for the remainder of the lot or batch.
  12. Labeled Products Removed from the Line or Conveyor but not from the Production Module (e.g., for equipment disruption) should be temporarily stored so as to preserve container/closure integrity and product cleanliness. Control of the products removed from the line should be defined in a Site SOP 13. When Complete Labels or Labeling are Printed On-Line, the first and last units completing the packaging/labeling operation should be proofread by a qualified person against the approved copy of the master label or labeling and approved by Site Quality Team.
  14. For Contract Vendors, all labeling controls should be performed either by the site or by the contract vendor. The contract that defines Good Manufacturing Practices (GMP) responsibility should define which labeling controls are being performed by the site and which are being performed by the contract vendor.