

Guidance 068 Material Status Indication

- If space limitations prohibit the pallet-width separation, barriers must be used that physically prevent movement of any containers into or out of the dedicated area.
3. All Status Labels should be placed on containers in a manner that is readily visible, and should never be applied to pallets or to container lids. Approved status labels should not be required to be used on finished drug products, finished APIs, finished medical devices, in-process materials or intermediates.

In lieu of labeling each container, status labels should be applied to at least two sides of the unitized pallet containing the drums/containers. The unitized pallet should be shrink wrapped or covered with a shroud such that individual containers cannot be removed.

4. All Status Label Sizes and Shapes should be square or rectangular and the same size except for sampled status labels, which may be smaller. Alternative measures for use of status labels, except for Rejected and Sample status labels may be used. Additional points regarding use of status labels, include:
 - Standard size may vary from Site-to-Site;
 - Print size may vary, but must clearly display status;
 - Validated bar-coding systems can be used to augment status labeling, as long as status is clear and visible;
 - Approved status labels are not recommended for finished API packaging or drug product or medical device shippers; the action would require peelable labels, which tend to fall off containers. In addition, when materials are transferred to another Site, such status becomes misleading; and Label entries are made prior to application, unless otherwise authorized by the responsible Quality Team.
5. Newly Received Material should be inspected, have all status indication labels or labeling immediately defaced or removed, and promptly provided new status indication/protection. The quantity of material received and assigned to a status should be recorded.
6. Labels Marked “*Sampled*” should be used to identify each container that has been sampled. The container should be numbered to identify from which container each sample was taken. Bar-coding with human-readable text may be used.
7. Rejected Material should be physically isolated in dedicated materials status areas, and its status clearly identified by label.
8. Status Labels Signifying Rejected Status should be applied to each container of the lot involved within twenty-four (24) hours after the material status has been defined. Such status labels should be of non-peelable stock. If the Rejected status label cannot be applied within twenty-four (24) hours, an acceptable temporary [less than twenty-four (24) hours] alternative is the use of suitable shrouds (e.g., shrouds labeled Rejected).