

Material Status Indication

- Rejected material should be removed within twenty-four (24) hours of status assignment to a dedicated material status area and provided visible status indication; and
 - Quarantine-HOLD material should be removed within twenty-four (24) hours of status assignment to an isolated Quarantine-HOLD area and provided visible status indication.
Rejected and Quarantine-Hold materials may remain within an automated warehouse where status indication of racked materials is controlled by barcodes and validated computerized systems when the following special conditions are met:
 - Visible status indication is applied as soon as rejected materials leave the automated warehouse for on-site disposal or waiting to be shipped for off-site destruction;
 - If only a portion of the lot is rejected then the status label should be applied within twenty-four (24) hours of status designation;
 - Extra security measures are applied through a combination of programming and administrative controls that isolate Rejected and Quarantine-Hold material from normal warehouse transactions and authorize only a limited number of qualified individuals to move such materials; and
 - All extra security measures are clearly identified in procedures, validated, and approved by the Quality Team.
10. When Status of a Material is Changed, the quantity of material being assigned to a status should be documented.
11. R&D Materials, when stored in non-R&D (Research & Development) areas, should follow the same status indication standards. When such materials are in areas that also contain production materials, additional color-coded status labels (e.g., “*Research & Development Material*”) may be used alongside the standard status labels for additional status indication. Alternatively, R&D materials should be totally isolated.