

Standard Operating Procedure



SOP# **GM0-015**

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Revision: C

Revision Date: 31Mar22

Document Change Notice (DCN): <None>

Approvals:

Director of Quality Assurance

Initial	Date
KWB	31MAR22

Title: Label Control

Purpose:

Maintain control and Security of customer's labels

Designation of Responsibilities:

Managers, Supervisors and designated label control staff

Materials Needed:

Form GM0-015F1 Label Request Form

Process / Procedure:

- 1) Storage / Location
 - A. Labels are to be kept in a secure area that is organized.
 - B. Access to the label area will have limited access.
 - C. Labels are to be kept clean and organized.
 - D. Do not mix labels in the same storage container.
- 2) Labels Control
 - A. Only the label being used may be removed from storage.
 - B. Only labels that are being used can be in the packaging area. All other labels need to be removed.
 - C. A sample label is attached to the production paperwork or folder. The attached sample is then signed in such a manner that the signature crosses the edge of the label to the production paperwork.
 - D. If production stops for a prolonged time such as overnight or for scheduling in which the line will be idle for more than 5 hours. The labels will need to be reconciled and returned to the storage location.
 - E. Labels being returned will be inventoried before returning it back to the storage location. Label balance needs to be reconciled on Section 5 of the batch record (reference MP0-005) at the end of each production shift.

Title: Label Control

File Name:GM0-015C LABEL CONTROL

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- F. Damaged labels must be counted and noted in Shift Reconciliation of the batch record.

Reference Documents:

GM004 Line Clearance
MP005 Batch Record Procedure

Revision History:

Revision	Date	Description for Change	DCN#
B	10AUG15	Added Clarification of Label Storage	N/A
C	3/31	Added Reference to MP0-005 and added clarity of labels in the packaging area.	N//A

End SOP: SOP No: GM0-015 Title: Label Control

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