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PAGE: 1 of 9

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INDEX DESCRIPTION

PROCEDURES FOR SUPPLIERS OF PRINTED MATERIALS

1.0 Purpose

This document describes the process qualifying printed material suppliers and provides specific process and procedural requirements for suppliers providing printed materials.

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2.0 Applicability

This procedure applies to suppliers providing printed materials to Baxter, Medication Delivery, and Renal general office support operations, functions and units including but not limited to: Baxter locations (, Cleveland, Irvine, Mountain Home, Round Lake Drug Delivery, Round Lake Penicillin, North Cove, Singapore, Tampa, Aibonito, Costa Rica, and Jayuya), Division Purchasing and Global Compliance (i.e. GC). This specification does not apply to printed material subcontractors utilized by Finished Good suppliers.

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3.0 Associated Documents

3.1 Parent

CQP0302003 Supplier Management Process

3.2 Related

CQP0303002 Evaluation and Selection of Suppliers
CQP0303003 Maintenance of Existing Suppliers
CQP0303004 Supplier Quality Audit Procedure
CQP0303005 Supplier Corrective Action Report (SCAR) Procedure
20-01-A Raw Material and Packaging Material Receiving and Handling Procedure
20-01-B Packaging Material Receiving and Inspection Procedure

4.0 Definitions

For definitions, See Baxter Glossary

5.0 Responsibility and Authority

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- A. Applicable responsibilities are established in associated CQP's.
- B. Plant Purchasing will ensure that each supplier for printed material is supplied with the most recent issue of individual item specifications and any applicable general specifications (e.g., 20-01-B). Plant Purchasing (or site requestor role in Global Supplier Quality Trackwise System (GSQTS)) is responsible for the following:
 - a. Generate a material/service evaluation request (manual or GSQTS form)
 - b. Determine the risk of the supplier following CQP0303002.

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ISSUE DATE: 20-OCT-2010
EFFECTIVE DATE: 19-NOV-2010

FOR APPROVALS: 1143067 OWNER CODE: CCS

PAGE: 2 of 9

- C. Supplier will ensure formal written procedures are in place for the management and control of their processes as outlined in section 8.0 of this procedure.
- D. Division Labeling Departments will ensure released artwork (camera-ready or electronic) is supplied to Division Purchasing, local operation or unit, and supplier. This function will also provide overlays to the local operation or unit, as required, by the Labeling Department or supplier. Note: for the Cleveland, MS plant: Alcon provides art and proof approval for Alcon codes.

6.0 General

- A. This procedure defines the elemental process and procedural requirements for:

① Artwork controls and verification	Change control ②	Quantity reconciliation ③
Specification controls and verification	Bar code controls ↓	Gang Printing ↓
Area clearance ↓	Code marking controls	Finished product Packaging and Identification
Material segregation	Print mats and Plate storage	Splice controls
Nonconforming material	Over-bleed controls	Code hole controls
Equipment set-up	Proofreading	Artwork controls and Obsolescence.

- B. This document provides guidelines for conducting an evaluation when a mix is detected in supplier produced printed materials.

7.0 Process/Procedure

- A. Approval Evaluation

1. The approval process is based on the risk score calculated using the Trackwise System or CQP0303002.
2. Minimum approval requirements will be determined from CQP0303002

8.0 GENERAL SUPPLIER REQUIREMENTS

Suppliers must have a process and written procedure controls which cover each of the elements outlined below. Copies of these procedures must be forwarded to Baxter Purchasing and Global Compliance when requested. Baxter Supplier Quality will review the procedures in use when the facility assessment is made. These procedures must be readily available to the employees in the work area.

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DOCUMENT NO: 20-01-10-001
CHANGE NO: CP0387874
ISSUE DATE: 20-OCT-2010
EFFECTIVE DATE: 19-NOV-2010
PAGE: 3 of 9

FOR APPROVALS: 1143067 OWNER CODE: CCS

A. Verification of order specifications.

Prior to producing any order of printed materials, the supplier must verify that:

- a. The artwork and specifications agree with the specification number, revision letter (if applicable) and issue date referenced on the purchase order. Alcon codes require review of the packaging specification provided by Alcon.
- b. The printing plate(s) and any proofs match the artwork provided and are set up according to the requirements of the individual specification and an applicable general specification.

B. Line Clearance.

Line clearance involves the inspection of an individual work area to detect and remove any materials from the previous run. The material for the scheduled run may not be brought into the work area until the inspection has been successfully completed and documented on an appropriate form by a responsible individual. This form becomes part of the permanent job record. Line clearance procedures and documentation must exist for each discrete operation (e.g., press, cutter, slitter, folder, rewind, gluer, packing, labeling, inspection, etc.).

C. Material Segregation.

Printed material segregation is defined as positive methods that ensure that printed materials do not inadvertently become mixed or misplaced. Some examples are: Overwraps, cages, covered bins, banding, straps, etc.; such methods are to be used to provide segregation of Baxter printed material throughout the process. Procedures must exist to assure that materials are properly identified throughout the operation. Once materials are printed they will be segregated from any other job throughout the manufacturing process.

D. Non-conforming Materials.

Printed materials suppliers must have a formal written system to handle non-conforming materials.

E. Equipment Start-Up.

Supplier procedures must require that a responsible individual other than the pressman or operator verify and/or challenge the equipment set-up at each station where mechanical equipment is used.

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DOCUMENT NO: 20-01-10-001
CHANGE NO: CP0387874
ISSUE DATE: 20-OCT-2010
EFFECTIVE DATE: 19-NOV-2010
PAGE: 4 of 9

FOR APPROVALS: 1143067 OWNER CODE: CCS

If automated inspection equipment is used in the process, prior to start-up, such equipment must be challenged to ensure correct operation. All inspections must be documented on an appropriate form. This form becomes part of the permanent job record.

F. Artwork, Proofs, Mats, Plates, and Electronic Artwork Files.

1. Artwork. Suppliers must meet the following requirements pertaining to artwork received from Baxter:
 - a. Suppliers must not change or alter artwork or electronic artwork files in any fashion with the exception of crop marks or overbleed outside of the crop marks.
 - b. Camera ready artwork or an electronic artwork file is provided by Baxter. Cut and paste by suppliers is not permitted. For Alcon codes, artwork will be provided by Alcon.
 - c. Baxter will supply artwork or electronic artwork files which have been approved by the division's Labeling Department. The supplier must verify that each piece of artwork or file is approved. For Alcon codes, artwork approval is supplied by Alcon.
 - d. Suppliers must check artwork against the specification for revision, stock numbers and change level for agreement prior to making negative.
 - e. Designated suppliers for Baxter Special Products may be requested to prepare artwork. Supplier prepared artwork for Baxter Special Products must be proofread against the labeling specification prior to making plates or negatives.
 - f. Suppliers must have a written procedure which verifies that when printing more than one (1) color or using more than one (1) plate that the plates identically match the artwork provided by Baxter and that the colors are set up according to specification requirements.
2. Plates.
 - a. Suppliers must provide an orderly system for storage and retrieval of plates.
 - b. When making multiple images of artwork onto plates, supplier will assure that overbleed on artwork will not extend into adjacent designated print areas. For folding cartons overbleeds on glue flaps and tuck/dust flaps are acceptable.

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CHANGE NO: CP0387874
ISSUE DATE: 20-OCT-2010
EFFECTIVE DATE: 19-NOV-2010
PAGE: 5 of 9

FOR APPROVALS: 1143067 OWNER CODE: CCS

3. Proofreading.

If the supplier makes a negative and/or positive proof from the artwork or electronic artwork file provided by Baxter or is given positive proofs, the supplier must proofread the positive proof or negative film or electronic artwork file label copies against the released specification and artwork prior to press set-up.

For All-in-One format labeling, the supplier must also proofread the negative or positive proof that is made after the address/manufacturing location and specification number is cut and pasted into the position indicated on the artwork against the released artwork. Supplier must also verify that address/manufacturing location and specification number on negative or positive proof agrees with the purchase order.

G. Quantity Reconciliation.

Production runs must be processed to specific purchase order quantities. Throughout production, counting practices (manual, mechanical or electronic) must be used to insure that gross commingling has not occurred. The supplier's procedures must also include action to be taken if quantity reconciliation indicates an unacceptable overage or underage. IT IS NOT ACCEPTABLE TO INVENTORY EXCESS PRODUCTION QUANTITIES FOR INCLUSION WITH SUBSEQUENT ORDERS.

H. Over-labeling on Shipping Containers.

Over-labeling, re-labeling or altering a label with the exception of Purchase Order number and quantity packed on corrugated cartons is not acceptable. New corrugated must be used if a label change is required.

I. Gang (Combination) Printing.

Gang printing is not allowed. Gang printing is defined as a printing process in which more than one product code or stock number is printed at the same time on a single printing machine.

J. Splice Control.

In manufacturing operations that include splicing processes, the supplier must have the acceptable procedures in place to ensure proper controls to prevent an occurrence of defective or mixed materials in finished product.

K. HIBC or UPN Bar Coded Artwork and Film Master Handling.

1. If the typeset artwork does not include the HIBC or UPN bar code, the printing supplier will be provided with released typeset artwork containing the human

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DOCUMENT TYPE: PROCEDURE SPECIFICATION

DOCUMENT NO: 20-01-10-001
CHANGE NO: CP0387874
ISSUE DATE: 20-OCT-2010
EFFECTIVE DATE: 19-NOV-2010
PAGE: 6 of 9

FOR APPROVALS: 1143067 OWNER CODE: CCS

readable information below position box that indicates the location of the bar code, or inside the position box (UPC only). The supplier is responsible for obtaining HIBC bar code (code 39 symbology) or UPN bar code (UPC and UCC/EAN 128 symbology) film masters to be stripped into the negative of the artwork to ensure greater reproduction accuracy.

For non UPC bar codes, the supplier is to strip the bar code ONLY into the artwork and position the bar code above the typeset human readable information, as indicated by the position box on the artwork. For UPC bar codes, the supplier is to strip the bar code and the human readable information into the artwork and position the bar code and human readable as indicated by the position box on the artwork.

2. If the typeset artwork does include the bar code, the printing supplier will be provided with released typeset artwork containing the human readable information below the bar code (code 39, code 128, code UCC/EAN 128, or UPC symbology). The supplier may obtain bar code film masters to be stripped into the negative of the artwork to ensure greater reproduction accuracy if necessary.

For non UPC bar codes, the supplier is to strip the bar code ONLY into the artwork and position the bar code above the typeset human readable information, as indicated by the location of the bar code position on the artwork. For UPC bar codes, the supplier is to strip the bar code and the human readable information into the artwork and position the bar code and human readable as indicated by the location of the bar code position on the artwork.

3. The supplier is responsible for ensuring that the bar code obtained is the correct size, that it is correctly encoded (matches the human readable information on the artwork), and that it is properly positioned.

NOTE: The typeset artwork takes precedence over this specification for location of the human readable copy.

Because the separate film master loses the human readable information after it is stripped in, THE SUPPLIER IS REQUIRED TO HAVE A WRITTEN PROCEDURE IN PLACE to ensure and document that the stripped-in bar code matches the human readable information on the released artwork and is properly oriented. It is then the supplier's responsibility to assure that the film master is appropriately stored and verified at every subsequent usage. All such verifications are to be documented.

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DOCUMENT NO: 20-01-10-001
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ISSUE DATE: 20-OCT-2010
EFFECTIVE DATE: 19-NOV-2010
PAGE: 7 of 9

FOR APPROVALS: 1143067 OWNER CODE: CCS

L. Code Holes.

Some labels are supplied with code holes placed in specified locations to enable the using plant to verify correct label usage by means of a photoelectric eye mechanism on the labeling machines. Suppliers of labels with code holes must ensure that the hole punching operation is an integral operation of the printing machine printing the label. Under no circumstances can punching be performed as a separate operation on a different machine.

M. Code Marks.

Some labels are supplied with code marks placed in specified locations to enable the using plant to verify correct label usage by means of a photoelectric eye mechanism on the labeling machines. Suppliers of labels with code marks must ensure that the code marking operation is an integral operation of the printing machine printing the label. Under no circumstances can the code marking operation be performed as a separate operation on a different machine.

N. Control of Obsolete Materials

The supplier must have a process in place to document the destruction and disposition of any plates, artwork, or other documents related to Baxter obsolete part numbers/product codes. This process must include a formal system for handling and documenting the destruction of materials designated as obsolete by Baxter.

10.0 MIX EVALUATIONS

In the event any Baxter personnel detects a mix in supplier produced printed materials, the following procedure must be followed:

- A. Perform and document a failure investigation (i.e. Supplier Corrective Action Report). Communicate incident to Corporate Compliance Services (CCS) and supplier immediately.
- B. Investigation must be comprehensive to determine the scope and the impact of the nonconformity. The table below provides guidance for gathering specific information and identifying responsibilities:

Information Required	(Responsibility)	
	Baxter	Supplier
Code and labeling specification running.	X	
Code and labeling specification found	X	
Where found (e.g., Receiving Inspection, Production, before line or on line).	X	
Where in shipment (e.g., beginning, middle, end, scattered	X	
Quantity of incorrect items found	X	

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CHANGE NO: CP0387874
ISSUE DATE: 20-OCT-2010
EFFECTIVE DATE: 19-NOV-2010
PAGE: 8 of 9

FOR APPROVALS: 1143067 OWNER CODE: CCS

① All information from shipping carton (label, stamps and other markings).	X	
Supplier markings on printed material, if any (e.g., die position number on individual cartons).	X	
How the mix occurred (at what station and due to what action, or lack of action).		X
What additional Baxter material was in production at the same time as the errant shipment or may be subject to the same problem.		X
What corrective action has been or will be taken (include target dates, as applicable).		X
Formal Documented Investigation	X	X

- C. An audit of the supplier's facility will be coordinated to investigate the occurrence if deemed necessary by Baxter. Copies of the investigation will be forwarded to Global Compliance.
- D. Supplier Quality or Global Compliance may require that supplier's management meet with Supplier Quality, Global Compliance and/or Purchasing management to discuss the mix (cause, resolution, etc.)

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EFFECTIVE DATE: 19-NOV-2010
PAGE: 9 of 9

FOR APPROVALS: 1143067 OWNER CODE: CCS

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