

Supplier Product/Process Change Notification (PCN) Requirements



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1.0 Introduction and Purpose

This policy document expands on the contents of the Ballard Supplier Manual (MAN5100058) by laying out requirements for Ballard's suppliers with respect to supplier product/process change and end-of-life notifications.

In order to maintain security and integrity of the supply chain and to achieve the quality and reliability standards that Ballard expects of its products, Ballard requires that its suppliers provide notification of, and seek approval for product or process changes prior to their implementation. This document clarifies which types of changes approval is required for, and describes the process of notification and approval.

2.0 Acronyms and Terminology

CHANGE

An alteration to a product or process.

PROCESS

A combination of people, procedures, methods, machines, materials, measurement equipment, and/or environment for specific work activities to produce a given product or service.

PCN

Product/Process Change Notification - a document sent to Ballard describing a proposed product or process change, the reasons for the change, and the projected impact of the change. Ballard may accept or reject the proposed change.

EOL

End-of-Life. The point at which a product or component or subcomponent is discontinued or becomes obsolete and unavailable, requiring that a substitution be made.

3.0 General Requirements

3.1 Change Management System

The supplier shall have a formally documented change management system in place that reviews, verifies and validates change proposals before implementation. This system shall include customer notification as outlined in section 5 "Communication of a Proposed Change".

If a change is approved, the supplier shall ensure that all associated documents and records are updated to formally deploy the change within their organization including, but not limited to:

- Procedures, work instructions, drawings and specifications
- Process FMEAs, process flowcharts and process control plans
- Floor layouts
- Measurement system analysis

- SPC charts and capability studies
- Preventive maintenance instructions
- Training instructions and records
- Approved supplier list
- Environmental, health and safety impacts
- Qualification plans and reports

3.2 Change Approval

The supplier shall not make changes to their products or processes without prior written consent and approval from Ballard. These include changes to, or additional:

- Locations
- Facilities
- Manufacturing process
- Manufacturing equipment
- Test or measurement process
- Test or measurement equipment
- Supplier or sub supplier
- Components or subcomponents
- Raw material
- Product design

This also includes any other change that may affect product form, fit, function, or appearance, or adversely affect reliability, quality or safety. For further guidance with respect to what types of changes require notification and approval, please refer to Appendix A.

3.3 Review Period

Ballard does not accept or acknowledge a time window or time limit to approve a proposed change. The supplier shall not deploy a change unless Ballard has communicated its final approval. Ballard is committed to providing a response within a reasonable amount of time.

3.4 PCN Policy Communication and Cascade

Requirements set forth in this specification shall be communicated to all affected personnel within the supplier's organization. Supplier shall also cascade these requirements to their suppliers and sub-suppliers.

4.0 Communication of a Proposed Change

Ballard may require 6 to 12 months advanced notice of a change in order to evaluate and mitigate any potential negative effects of the change. The supplier shall provide 12 months advanced notice wherever possible.

Supplier shall utilize FRM5100416 "Supplier Product / Process Change Request (PCN)" to request that Ballard review and approve a proposed change. The completed form shall be signed and scanned, with supporting information attached to

the PDF document. The document shall be forwarded to the Ballard Supplier Quality Engineer via email (supplier.pcn@ballard.com) and shall include the following:

- PCN tracking number (Date mmddyyyy followed by 4 digit vendor ID found on PO)
- Notification date
- Proposed first ship date for change
- Description and scope of change
 - Effect(s) of NOT making proposed change
 - A statement confirming that no other change, besides the one outlined in the PCN, is included in the submission
- Products affected
 - If the change involves an EOL component or product, provide recommended equivalent replacement component or product
- Parameters that may be affected
- Method for identifying changed product
- Reason for change
 - Anticipated (positive and negative) impact on form, fit, function, reliability, quality or safety
- Qualification plan summary and results
- Launch plan
- Description of attached, supporting documentation
- Date when qualification samples are available
- Last date of manufacture of the unchanged product
- Name, address, telephone and e-mail of supplier contact

If a submitted PCN does not have a direct effect on a Ballard production released product, Ballard may elect not to act on the submission.

5.0 Change Qualification

The supplier shall take all necessary steps to fully characterize and qualify the proposed change and provide quantitative evidence indicating that the change would have no detrimental effect on form, fit, function, reliability, quality or safety. Ballard may elect to conduct its own characterization and/or qualification activities to further corroborate the data.

6.0 End -of-Life and Last Time Buy

Supplier shall notify Ballard a minimum of twelve months prior to the discontinuation of a product and shall allow Ballard to perform a last time buy in order to qualify and phase in the recommended replacement. Suppliers shall continue to support field returns and failure analysis for their product for a minimum time frame of the product's warranty period beyond the last time ship deadline.

7.0 Change Approval / Rejection

The supplier must receive written approval (e.g. email or letter) from Ballard Supplier Quality Engineer before proceeding with the launch plan. Verbal approvals are not admissible. If the change is denied, the supplier will be expected to continue

providing products or services using the current production approved process and/or design.

Suppliers will be held accountable for changes made to their process without prior notification and approval that adversely impact form, fit, function, reliability, quality or safety of Ballard's or our customer's products. Supplier will reimburse Ballard for all additional costs, reasonably incurred including but not limited to scrap, rework, testing, repair, replacement, shipping and/or labor costs.

8.0 Related Ballard References

MAN5100058 BALLARD Supplier Manual
FRM5100416 Supplier Product / Process Change Request (PCN) Form
FRM5100105: Supplier Profile

APPENDIX A: Further Guidance on Types of Changes Requiring Notification and Approval

Change Category	Example	Ballard Approval Needed	Ballard Approval Not Needed; Control changes within QMS
Plant/Environment	Change to or addition of production plants/sites that will manufacture Ballard products	X	
	Changes in the work environment that could affect the mfg or storage condition of Ballard products (ex: high temps and humidity)	X	
	Changes in the work environment that do not affect Ballard's materials (ex: lighting)		X
Manufacturing Processes, Equipment & Tooling	Change of production line layouts (ex: physically moving a compression molding press)	X	
	Change of production methods (ex: cell mfg to batch mfg)	X	
	Change manufacturing of a Ballard product from one piece of equipment to another (ex: line A to line B)	X	
	Maintenance of work standards/PM's		X
	Shift Changes		X
	Adding/Deleting/Changing to/from automated mfg processes	X	
	Addition/Modification/Repair/Transfer of jigs/tools/fixtures	X	
	Changes to processing conditions or methods (Ex: speed, temperature, drying time...)	X	
	Adding new equipment (that will be used to run Ballard product)	X	
Materials/Supply Base	Change/addition of supplier, sub-tier supplier/outside or contract manufacturer	X	
	Any change that will affect the fit, form, function, cleanliness or appearance of a material <i>that is or is not specified in a drawing</i>	X	
	Requesting to use recycled materials or changing mixing ratios/times, etc...	X	

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Change Category	Example	Ballard Approval Needed	Ballard Approval Not Needed; Control changes within QMS
Inspection/ Calibrated Devices	Changes to the in-process or raw material sampling methods, # of inspection points, inspection items or inspection ratios		X
	Changes to final inspection sampling plans, # of inspection points, inspection items or ratios	X	
	Changes to or inability to recalibrate gages/equipment used to perform outgoing inspections on Ballard products	X	
Packaging/Warehouse conditions	Changes to "internal" packaging components (ex: bags, trays, cores)	X	
	Changes to "external" packaging components/configurations (ex: carton boxes to plastic bags, bulk packaging)	X	
	Requests to change transportation methods (freight forwarders, air vs. sea shipment, etc...)	X	
	Changes to packaging quantities (relative to the originally agreed upon specifications or those deviating from current packaging practice)	X	
	Changes in the warehouse environment that could affect the mfg or storage condition of Ballard products (ex: high temp and humidity)	X	
	Physical location change of warehouse/storage area	X	