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| Reviewed on (Date):  Reviewed by: | Reviewed on (Date):  Reviewed by: | Reviewed on (Date):  Reviewed by: | Reviewed on (Date):  Reviewed by: |
| Approved on (Date):  Approved by: | Approved on (Date):  Approved by: | Approved on (Date):  Approved by: | Approved on (Date):  Approved by: |

### Purpose:

Effective implementation of Process Approach and Risk Based Thinking at all processes of Packages Convertors Ltd

### Scope:

This procedure is applicable for all processes of PCL needed for Quality Management System. List of these processes is approved by PCL Management Team.

### Activities and Responsibilities:

PCL management team approves list of processes needed for PCL Quality Management System. This list can be updated whenever a new process is introduced at PCL in addition to annual review (Management Review). Processes in this list will be ranked as A, B and C.

* Process whose outputs directly go to final customer/consumer without further checking of all properties by any other process will be ranked as “A”.
* If a process feeds to internal customer who verifies all product properties while utilizing the product will be ranked as “B”.
* Processes that do not have direct impact on external customer (through product / service quality) will be categorized as “C”.

PCL will complete process mapping and risk assessment for A & B rank processes initially; C rank processes can be dealt later on.

Interaction of each process with other processes will be described by identifying all inputs, suppliers (internal/external), expectations from suppliers; outputs, customers (internal/external) and expectations of customers from process & its outputs.

## Suppliers

Internal / External

# Inputs utputs

## Customers

Internal / External

## Expectations from suppliers

**O**



**Process**

Expectations of Customers

A team comprising of 3 – 5 persons relevant to process under consideration will work on process mapping and risk assessment of each process. Team members can be from different departments because usually a process involves more than one department. In such case process custodian will interact with relevant department representatives and get nominees for process mapping and risk assessment.

Each process will be mapped using standard flow chart symbols. All process steps will be defined in correct sequence showing flow of materials and information.

Serial numbers can be assigned to each process step and a brief description of process step (function, method etc) will also be mentioned.

Criteria of performance acceptance/rejection will be defined for each process step along with key performance indicators of overall process.

Team will also identify risks & opportunities at each process step having potential impact (positive/negative) on product/service quality and on-time delivery to customer (internal/external).

For each risk RRN (risk rating number) will be calculated by multiplying severity, likelihood and

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detectability numbers from the table mentioned below.

### Risk Rating Number (RRN) = Severity \* Likelihood \* Detectability

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**Severity, Likelihood of Occurrence and Detectability Scale**

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| --- | --- | --- | --- |
|  | **Severity (S)** | **Likelihood of Occurrence (L)** | **Detectability (D)** |
| **1** | Defect is not critical for customer. Product fitness for use will not be compromised.  Will not have any impact on product,  system or subsequent process performance. | Highly unlikely to occur (almost impossible).  Less than 1 per 5000. | Defect/problem will be surely detected immediately.  Existing controls will  prevent cause of variation and isolate the product. |
| **2** | Not critical but MAY have slight impact on usage.  May have slight impact on product, service, system or subsequent process performance. | Likelihood is low but possible in extreme conditions.  Less than 1 per 400. | Will be detected but later on within same process. Controls will not prevent cause of failure but failure will be spotted. |
| **3** | Important for customer; it is part of specification. Product fitness for use will be compromised.  Defect/failure will cause some dissatisfaction; can result in poor  performance of product, service, system or subsequent process. | Can occur even in normal circumstances.  Less than 1 per 100. | Will be detected by subsequent process. |
| **4** | Critical. Product will not work at customer end resulting in complaint. Will result in serious disruption of product, service, system or subsequent process performance. | High chance of occurrence. Failure rate will be in between 1% - 10%. | Will be detected till dispatch. |
| **5** | Critical. Can result in claim or business loss.  Product will fail totally or violation of a legal requirement will occur. | Certain (almost sure).  Failure rate will be more than 10%. | No chance of detection. Will go to final customer. |

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Risks with RRN equal to 4 or below will be considered acceptable however if possible team should try to keep it as low as reasonably possible.

High Risk 7-9

Medium Risk 4-6

**Acceptable** Low Risk **1-3**

Additional actions will be necessary if risk rating number (RRN) is above 4. In order to eliminate/reduce the risk level, team will propose actions (additional controls). Proposed actions will be discussed with process custodian and responsibilities for implementation will be defined with his/her consent.

High risks will be addressed on priority followed by medium risks and low risks

Risk level will be considered as acceptable if RRN is 4 or below however if possible team can plan actions to reduce RRN as low as possible. Risk can also be considered as acceptable if consequences are agreed by the customer. In such cases written information from customer should be available.

Process custodian will ensure provision of necessary resources for implementation of agreed actions.

After implementation of defined actions, effectiveness of actions will be assessed by calculating RRN again. This practice will continue until RRN is 4 or below.

Risk Assessment will be recorded on PCL Risk Assessment form

Team will also identify opportunities (areas of quality / service improvement) in addition to risks. Opportunities will be recorded on and team will propose actions to tap opportunities.

Team will discuss proposed actions with process custodian and where practical, resources will be provided to implement agreed actions.

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Implemented actions (for risks and opportunities) will be integrated with relevant documents for example work instructions/SOPs/ quality plan, inspection checklists etc. to ensure sustainability of these actions.

### Review/Revision of Process Mapping & Risk Assessment:

Process mapping and risk assessment of each process will be reviewed or revised whenever any unplanned change occurs (that can impact consistent provision of quality products to customer).

In case of planned changes (customer specifications change, process modification etc) process mapping and risk assessment should be reviewed / revised before execution of such changes.

Even if there is no change in the process, mapping and risk assessment will be reviewed at least annually.

Process custodians are responsible for said reviews of process mapping and risk assessment.

**Note:** changes can be related to materials, equipment, building/infrastructure, product requirement(s) and/or people responsible to conduct process activities.