Health and Safety Change Control Procedure

Procedure Objective

To define methods and responsibilities for the control of change (e.g. engineering, technical, process, and/or material changes) for any activities carried out by Soloarte Limited.

To ensure that changes are competently assessed and implemented so that they will have no unforeseen effects on:

• the performance of products when handled or used by customers;

• the health and safety of employees and contractors working under Soloarte Limited's control;

• the environment; or

• the equipment and processes

Scope

This procedure applies to all changes or modifications controlled by Soloarte Limited's personnel, or other permanent site personnel, that could impact the activities carried out, products produced, or services supplied by Soloarte Limited.

The scope of this procedure covers any change that is not "like for like", and includes such things as:

- changes to equipment;
- changes to raw materials (specification or supply source);
- changes to operating and maintenance procedures;
- changes to automated process control sequences or logic;
- changes to operating parameters.

Definitions

Change

- Any significant change to a method of operation, process, or maintenance procedure. The approved method should already be set down in the area instructions, operating manuals, standard operating procedures, etc.
- Any change in the specification or supply source of a raw material, packaging component, or outsourced material processing service.
- Any alteration which is not "like for like", whether temporary or permanent, to hardware or a component thereof.

Changes specifically excluded from this definition are:

- process changes within the design intent, within the range of acceptable limits laid down in authorized operating manuals or standard operating procedures
- changes to controlled documents within the management system

Responsibilities

It is the responsibility of Soloarte Limited's Top Management; DiagramX and/or DiagramPlus to:

- ensure that this procedure is implemented, and any resources required are made available; and
- monitor the effectiveness of this procedure and report the results at management reviews.

It is the responsibility of the change "Proposer" to:

- lead and manage the implementation of a proposed change; and
- ensure that any temporary changes are reversed before the approved date.

Procedure

Proposing a change

All proposed changes, whether permanent or temporary, shall be recorded and ensure a systematic approach to the consideration and execution of the change.

Where the need for a change is identified, a "Proposer" must provide the following information:

- A description of the change including reference to any supporting drawings, material specifications, equipment specifications, service specifications, technical assessment reports, CAPA reports, customer complaints, etc;
- A justification for the change including reference to any supporting drawings, material specifications, equipment specifications, service specifications, technical assessment reports, CAPA reports, customer complaints, etc;
- Impact of the change on equipment, products, IT hardware, IT software, site infrastructure, maintenance schedules, process controls, operating procedures, and/or site layout;
- Estimated cost including reference to any CAPEX proposals, project proposals, or supplier quotations;
- Planned start date and finished date for implementing the change;
- Change lifetime (Permanent or Temporary – including date that it will be reversed on if temporary);
- Change Type;
- Risk identified and planned control measures;
- Modifications required to controlled documents;
- Process verification and validation tests required (where applicable);
- Customer approvals required (where applicable);
- Training requirements; and
- Upload of any documentation to support the description, justification, cost estimate, and risk controls for the change, and links of that documentation to the change request

Reviewing a change

The Authorized Persons meet with Proposers to review changes that have been Raised, Implemented, Canceled, and Validated.

Proposed changes must be reviewed by Authorized persons.

For each change proposed, the relevant Authorized Person(s) will review the information and approve the change if:

- the description, justification, and cost are satisfactory,
- the risk controls are specified, and residual risks are acceptable
- the customer approvals are correctly identified (where applicable)
- the controlled documentation modifications and training plans are correct

OR the relevant Authorized Person(s) will:

- Reject the change and specify the reasons for the rejection

OR the relevant Authorized Person(s) will:

- Action the Proposer to update the information

Implementing Changes

The Proposer must ensure that all relevant controls specified in the risk assessments are in place, controlled documents have been updated, process verification and validation tests completed (including recording of results and sign-off), customer approvals granted, and training plans are completed, before the change is made live.

Validating Changes

All implemented changes must be validated to confirm that:

- they have been implemented (or reversed for Temporary changes) as specified;
- all controls specified in risk assessments are in place;
- customer authorizations have been received;
- controlled documentation has been updated; and
- training plans have been completed.

Validation of changes must be completed by the person assigned by an Authorized Person (the “Validator”) within 1 week of a change going live.

If a Validator identifies any actions not completed, then they must record these in their assessment and notify the Authorized Person(s) and the Proposer of this outcome. Once outstanding actions are completed, a re-validation must be undertaken by the Validator.

If a Validator is satisfied that all actions have been completed, then they must identify this in their assessment and notify the Authorized Person(s) and the Proposer of this outcome.