

Procedure: Change Management

1. SUMMARY

- 1.1. The purpose of this procedure is to define the methods for managing changes to processes and other aspects of the management system in a controlled manner.
- 1.2. Where this document discusses changes to processes, this shall be understood to mean the top-level processes identified in the **Management Systems Manual**.
- 1.3. The Director is responsible for implementation and management of this procedure.

2. REVISION AND APPROVAL

[Click here for version control details](#)

3. DEFINITIONS

- 3.1. "Process Output" – the result of any process; these are typically defined in the Process Definition for each top-level process.

4. CHANGES TO PROCESSES

- 4.1. Management system processes will undergo changes, typically when:
 - 4.1.1. Improvement opportunities have been identified, typically to improve process effectiveness
 - 4.1.2. Nonconformities within a process are identified and require corrective action
 - 4.1.3. Conditions in the industry or company change, requiring a process to be updated
 - 4.1.4. New processes are added which impact on existing processes, requiring changes
 - 4.1.5. Customer requirements result in a need to change processes
 - 4.1.6. Any other reason determined by management
- 4.2. In such cases, the process must be changed in a controlled manner to ensure proper authorization and implementation of the changes.
- 4.3. At a minimum, process changes shall include the steps herein:
 - 4.3.1. The request for a process change shall be documented, typically in a CAPA form per the procedure **Corrective and Preventive Action**. The justification for the change shall be recorded.
 - 4.3.2. The change shall be reviewed by appropriate management, including the senior most manager responsible for the process. Changes must be approved prior to implementation.
 - 4.3.3. The appropriate **Process Definition** will be updated to reflect the change. This document will undergo review and approval per the procedure **Control of Documents**. The revision indicator of the **Process Definition** will be incremented, and the nature of the change recorded.

- 4.3.4. The follow-up verification step of the CAR process shall seek to ensure the change has had the intended effect, and/or has improved the process. If not, the change may be rolled back or a new change made to correct any new issues that arise as a result of the change.

5. CHANGES TO PROCESS OUTPUTS

- 5.1. The methods for changing process outputs are typically defined in the **Process Definition**. Where a process output is a document, the rules for changing documents above shall apply.
- 5.2. Formal changes to process outputs will be used when the change is significant. Minor changes may be made without formal control, however the decision on what constitutes a significant vs minor change must be agreed upon by those involved in the change. If a customer indicates a change is significant, this will trump any internal decision.

6. CHANGES TO DOCUMENTATION

- 6.1. Management system documents undergo changes when there is a need to revise them.
- 6.2. Changes to documentation are done in accordance with the procedure **Control of Documents**.

7. CHANGES TO ORDERS OR CONTRACTS

- 7.1. Changes to active orders or contracts may occur when the customer changes the requirements after the work has begun, or may be initiated by ICAH when unforeseen circumstances are encountered.
- 7.2. When changes are initiated by the customer, the new requirements will undergo the same review and acceptance per the procedure Quoting and Order Acceptance. If the changes cannot be accepted by ICAH, a satisfactory solution will be negotiated with the customer.
- 7.3. When changes are initiated by ICAH, the Director will notify the customer and negotiate a resolution.
- 7.4. In all cases, when changes are agreed upon, they shall be initiated as follows:
 - 7.4.1. Posted notifications by email or memo.