Procedure

Change Management

Contents

1. Scope

1.1 This procedure applies to all activities within the scope of the Thanet Health CIC Management System.

2. Purpose

2.1 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 so as to maintain the integrity of the system and the organisation's ability to continue to provide conforming products / services during the change.

3. Responsibilities

3.1 The Quality Department is responsible for the communication, operation and maintenance of this procedure.

3.2 Process owners are responsible for the effective implementation of this procedure.

3.3 Any individual process user can take responsibility for raising change requests if they believe there are requirements for change.

4. Definitions

4.1 **Minor Change:** To correct spelling or grammatical problems, where the change does not alter the meaning of a sentence, paragraph or phrase.

4.2 **Significant Change:** Any change that is not a minor change.

5. Associated documents

5.1 All associated documents referred to in this procedure are highlighted in bold and underlined.

6. Change Management

6.1 Any proposed changes shall be managed by application of a risk-based approach to help avoid negative consequences such as reduced quality of products / services. This procedure can also result in positive consequences such as reduction in nonconforming outputs or reduced incidents of human error.

6.2 Typically, changes may be required when:

- 6.2.1 Improvement opportunities have been identified to improve process effectiveness.
- 6.2.2 Nonconformities within a process are identified and require corrective action.
- 6.2.3 The operating environment of the organisation changes, requiring a process to be updated.
- 6.2.4 New processes are added which impact existing processes, requiring changes.
- 6.2.5 Customer, statutory or regulatory requirements change resulting in a need to change processes.

6.3 When cases arise, the process must be changed in a controlled manner to ensure proper authorisation and implementation of the changes as per Appendix A.

6.4 Formal changes will be made when the change is significant. Minor changes may be made without formal control, but the decision on what constitutes significant or minor change must be agreed upon by those involved in the change. Changes mandated by customer, statutory or regulatory must be classed as significant.

6.5 Prior to approval of any change, the following must be verified:

- 6.5.1 All necessary technical, security, safety and environmental reviews are completed.
- 6.5.2 Risks and consequences identified during the review of processes are addressed.
- 6.5.3 Proposed changes comply with customer, statutory and regulatory requirements.

6.5.4 Wherever necessary, approvals are obtained from customers, regulatory and / or legal authorities.

7. Changes Not Approved

7.1 If the proposed change is not approved, a re-evaluation of the concern must be carried out.

7.2 If a new change is proposed, this procedure shall be followed again.

8. Changes Approved

8.1 If the proposed change is approved, the following must be verified:

8.1.1 The proposed change is implemented as intended.

8.1.2 All related documents reflect the change.

8.1.3 The change is communicated.

8.1.4 All affected personnel are adequately trained where necessary.

9. Logging Change Requests

9.1 Change requests shall be logged on the Thanet Health CIC – **Risks and Opportunities Register**.

9.2 Details of the proposed change shall be entered onto the register and it shall be either approved or not approved.

9.3 If approved, details of the proposed change and an implementation plan shall be recorded on a **Change Management Plan** form.

Appendix A: Change Management Process Flow