



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Procedure Title
Quality Records
Procedure

Procedure No. 306

	Print Name	Title	Date
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1. Purpose

To define the control of records.

2. Scope

The Organisation have established this procedure to control all records generated by the Quality Management System. Records can be in any form or any type of media such as hard copy or electronic copy.

3. Reference

Quality Manual section 4.2.4.

4. Definitions

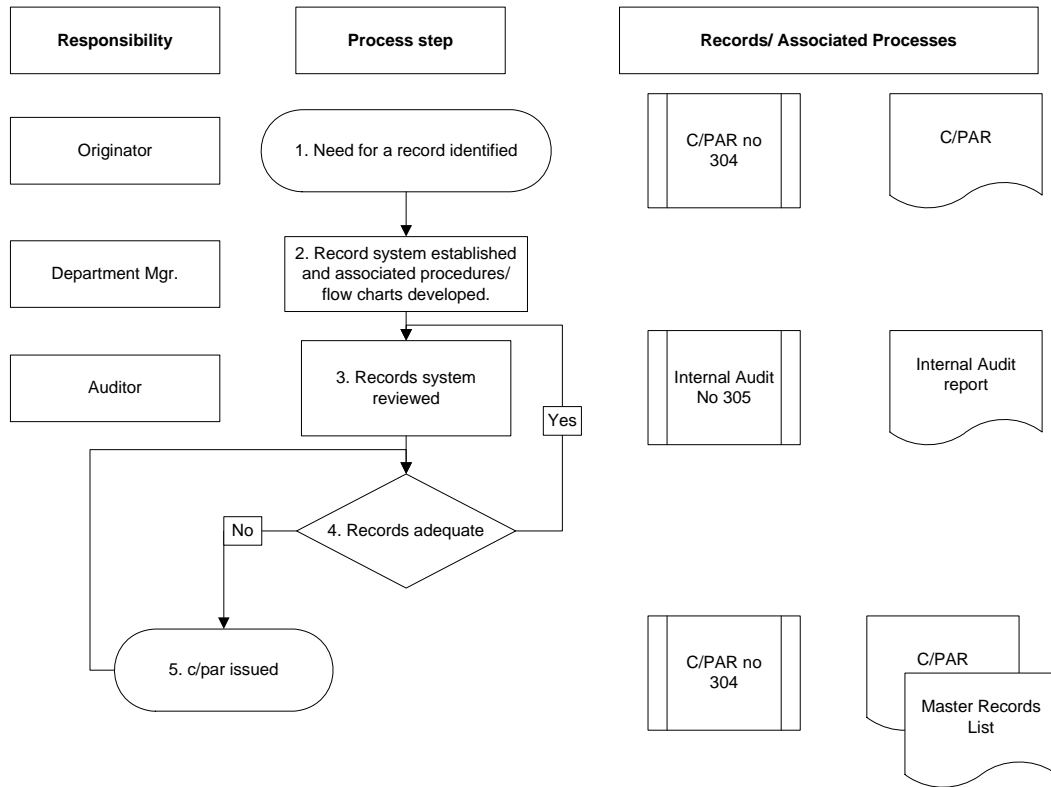
Record: Document stating results achieved or providing evidence of activities performed.

5. Authority and Responsibility

All Staff in Estates Department..

6. Process activities/ steps (flow chart)

The following flow chart provides an overview of the control of records generated in the Organisation.



7. Process Notes

- a. Records required by the Organisation and the QMS are identified developed, implemented and maintained by relevant functions and/ or authorities within the Organisation. Records are available to view through the relevant Department Managers.
- b. Master Standard forms are maintained in the relevant master folders.
- c. If the layout of a standard form is revised, amended or made obsolete, a C/PAR is raised and the amended version is approved by relevant staff members, and placed in the relevant master file. The old version is marked as obsolete. All obsolete blank record forms are stored in an obsolete document folder by the relevant Manager.
- d. The corrective and preventative action system is the mechanism employed for exercising control over records. The individual person responsible for the corrective and preventative action item will ensure that blank record sheets are approved for adequacy prior to being issued.
- e. Internal audits, external assessments and employee, supplier and customer suggestions are used to review the adequacy of existing records.
- f. Inadequacies are documented as a C/PAR. This form is used to review, update, re approve blank record sheets as necessary. Closing the C/PAR indicates that the change details of the record sheet are clearly identified on the C/PAR and that the issue date (revision status) of the record sheet is correct and that the Master Records List has been updated..
- g. Records are maintained to demonstrate conformance to specified requirements, operational processes/ procedures, statutory requirements and effective operation of the QMS.
- h. A master List of records is maintained. This identifies the list of records that comprises the QMS, the individual responsible, retention period and location of records. The Document Controller is responsible for the maintenance of the records list.
- i. All records shall be legible and stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.
- j. For electronically generated and stored records such items are backed-up on a regular basis by the server. It is the responsibility of the record holder identified on the Master List of Records to ensure such controls.
- k. The Organisation retain all records for 7 years minimum.

8. Records/ documentation

- ❖ Master Records List
- ❖ Corrective and Preventative Action Procedure
- ❖ Internal Audit Procedure
- ❖ Computer Server.