

Datix Guidance Document

Regulatory reporting

The provision of health and social care is independently regulated in England. Registered providers of regulated activities have a legal duty to notify the regulators about certain changes, events and incidents that affect their services or the people who use it.

Failure to notify in line with the regulations could potentially lead to a fine being imposed on Primary Care 24 (PC24) or prosecution.

It is therefore very important that incidents are reported on Datix within 1 working day of the incident occurring and reviewed and managed within a further 2 working days.

Identifying a Notifiable Incident

reporting to the CQC regulator. For instance, if an incident is reported with “serious injury to person” or the “absence of a registered person” identified specialist leads in the organisation will be automatically notified by email that a potential regulatory incident has been reported, and requires their review.

Reg No.	Essential Standards	Table of Statutory Notifications under Health & Social Care Act 2008.
12	15	Changes to the provider’s statement of purpose.
14	27	Absence (and return from absence) of registered persons.
15	28	Changes affecting a registered person.
16	18	Death of a Person who uses the service.
17	19	Deaths and unauthorised absences of people who are detained or liable to be detained under the Mental Health Act 1983.
18	20	Serious injuries to people who use the service.
18	20	Application to deprive a person of their liberty (under the Mental Capacity Act), including its outcome.
18	20	Abuse and allegations of abuse involving people who use the service.
18	20	Events that prevent or threaten to prevent the provider from carrying on regulated activities safely and properly.
18	20	Incidents reported to or investigated by the police.
18	n/a	Placement of children or young people on an adult psychiatric ward.
20	n/a	Death of a woman after termination of a pregnancy.
21	n/a	Death of a service provider (including a personal representative’s plans for a service following the death of a provider).
22	n/a	Appointment of liquidators.
18	n/a	Other incidents.

NOTE: This list is a summary. Please see the Essential Standards Document and the guidance on the NHS, Primary Care or independent healthcare for full details of what must be notified:
[CQC Guidance on Statutory Notifications](#) (Ctrl+click link)

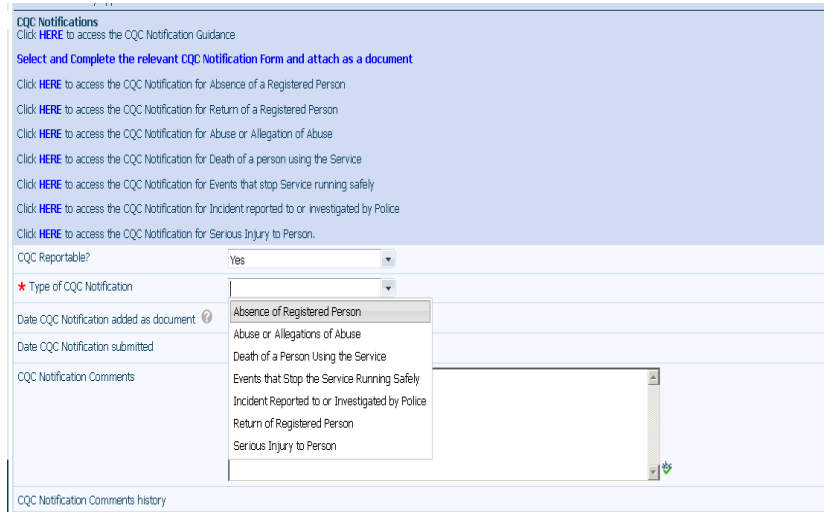
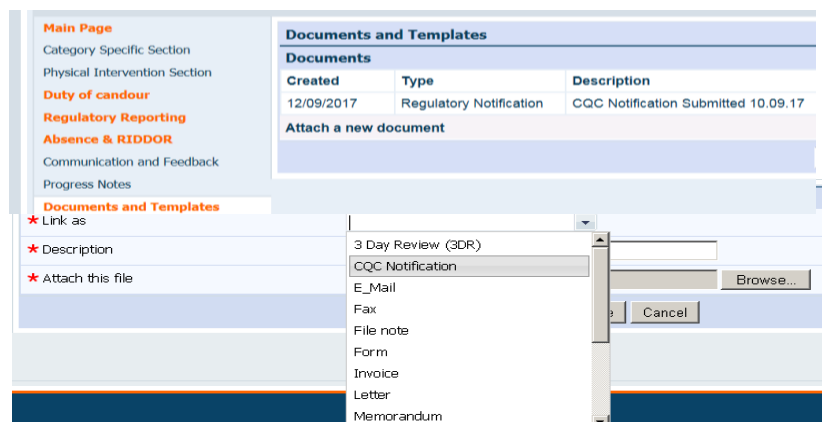
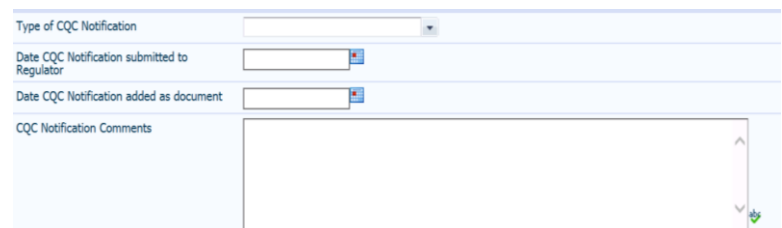
Regulatory Reporting Section (Specialist Lead)

identified and the relevant notification section within **Regulatory Reporting** ticked as “yes”.

An external reporting section is available for the Specialist lead to review the incident and confirm whether the incident needs reporting to the CQC. Once reviewed the lead will either report the incident and include details of this within the form, or will record that reporting was not required and provide a rationale.

There are links to the CQC regulator Notification forms in blue text in the relevant section header (see screenshot below):

- If a notification is required, select the regulator in: **Type of Regulator Notification**. If the Specialist Lead decides that the incident is NOT notifiable, a rationale should be added to the **Notification Comments** field.
- Once the form is completed in **FULL** then go to 'File' and 'Save As' and save the file within your local drive on your own computer.
- Attach the completed Notification Form to the Incident record as follows:
- Click on the **Documents & Templates Section** in the left-hand panel
- Click **Attach a new document**:
- Select the relevant document type from the **Link as** drop-down menu
- Enter a **Description** to name your Document
- To attach your file:
 - **Browse** to your local folder
 - Locate the file to be attached
- Click **Save**
- Complete the remaining fields in the Regulatory Reporting section:
- Select the **Date Notification added as a document**
- Select the **Date Notification submitted to Regulator**
- Add any **Regulator Notification comments**

For clarity or guidance in relation to Regulatory Reporting please contact the Quality & Governance Team. For assistance with Datix, please contact the Datix Helpdesk within PC24
E-mail: datix@pc24.nhs.uk

CQC (England) Reporting Requirements

Table of Statutory Notifications under the Health and Social Care Act 2008.

Regulation No.	Essential Standards Outcome	Notification
12	15	Changes to the provider's statement of purpose.
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18	20	Events that prevent or threaten to prevent the provider from carrying on regulated activities safely and properly.
18	20	Incidents reported to or investigated by the police.
18	n/a	Placement of children or young people on an adult psychiatric ward.
20	n/a	Death of a woman after termination of a pregnancy.
21	n/a	Death of a service provider (including a personal representative's plans for a service following the death of a provider).
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