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SUPERSEDES: N/A	<b>DOCUMENT TYPE</b> Standard Operating Procedure	<b>DOCUMENT OWNER:</b> SCA-Head of CIS
OBSOLETES: N/A	<b>DOCUMENT TITLE</b> <b>Notification of Incidents to the State Claims Agency Clinical Indemnity Scheme (CIS) by participating enterprises</b>	<b>EFFECTIVE DATE:</b> August 2009

### 1.0 PURPOSE

To describe the notification requirements of the Clinical Indemnity Scheme of Patient Safety Incidents by participating enterprises

### 2.0 SCOPE

All enterprises covered by the CIS have a statutory duty to;

- Report all adverse incidents to the SCA.
- Furnish relevant information when requested to do so.
- Preserve relevant evidence.
- Permit and facilitate SCA investigation to include furnishing when requested to do so by the SCA, complete and properly ordered medical records.

This applies to all enterprises covered by the Clinical Indemnity Scheme as listed in S.I. No. 63 of 2003 *National Treasury Management Agency (Delegation of Functions) Order 2003* (Appendix 1) and *National Treasury Management Agency (Delegation of Functions)(Amendment) Order 2007*



### 3.0 RESPONSIBLE PERSON

Risk Advisor/Manager or other HSE designated person

### 4.0 PROCEDURE:

Any patient safety incident directly related to service user treatment or care which did or could have resulted in an adverse outcome must be reported to the CIS via the STARSWeb system, by those enterprises that are “live” on the system, and by paper notification for all other enterprises awaiting access to the live system.

- The patient safety incident is reported to the local Quality & Risk department or local designated office responsible for managing incident reporting in accordance with the HSE Incident Management Policy and Procedure (2008).
- The incident reports are reviewed by the local Risk Adviser or other designated person. Any follow up action is taken, any further information required is sought and the

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information, including the incident risk rating, is entered on the STARSWeb Clinical Incident Reporting Database within 4 weeks of incident occurrence.



- Serious patient safety incidents/complaints (see attached) or those considered likely to result in a claim should be notified to the CIS Clinical Risk Adviser within **48 hours** of their occurrence in tandem with routine notification on the STARSWeb System
- The incident report should include a factual description of what happened; details of any equipment involved or medication; the initial assessment of the impact and outcome on the individual, the affected part of the body and any ameliorating action taken. This information should be entered on the STARSWeb system
- To protect the anonymity of the patient/client/resident ensure that the name of the patient/client/resident is not inadvertently used in the “Further Details of Event” field or in any document/note attached as an “Attachment”, or in any other free text field on STARSWeb
- Any subsequent additional information relating to the patient safety incident is to be entered as an attachment to the Incident on STARSWeb.
- When corresponding with the CIS always quote the STARSWeb reference number. Do not send any documentation, (other than original solicitor’s letter of claim) to the CIS, whether records request, complaint letter, medical records etc, unless specifically requested by the CIS.
- When a review of a serious patient safety incident has been carried out by an enterprise, a copy of the report should be attached to the incident on STARSWeb and a notification email sent directly to the relevant CIS Clinical Risk Adviser.

## 5.0 RESOURCES:

STARSWeb incident reporting system

## 6.0 DOCUMENTATION:

- The State Claims Agency Clinical Indemnity Scheme Incident Notification Requirements.
- [OQR006 HSE Incident Management Policy & Procedure](#)



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- [OQR008 Toolkit of Documentation to Support HSE Incident Management.pdf \(size 662.7 KB\)](#)
- Final Technical Report for The Conceptual Framework for the International Classification for Patient Safety v.11
- Rapid Notification of Serious Adverse Clinical Event.

## 7.0 TERMS AND CONCEPTS:

In order to ensure that definitions are in line with internationally agreed definitions, the World Healthcare Organisation Final Technical Report for The Conceptual Framework for the International Classification for Patient Safety v.11 has been adopted where possible.



- **Safety:** the reduction of risk of unnecessary **harm** to an acceptable minimum.
- **Hazard:** a **circumstance, agent** or action with the potential to cause harm.
- **Event:** something that happens to or involves a **patient**.
- **Patient Safety:** the reduction of risk of unnecessary **harm** associated with **healthcare** to an acceptable minimum.
- **Healthcare-associated harm:** **harm** arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying **disease** or **injury**.
- **Patient safety incident:** an **event** or **circumstance** which could have resulted, or did result, in unnecessary **harm** to a **patient**.
- **Risk:** the probability that an **incident** will occur.
- **Harmful incident (adverse event):** an **incident** which resulted in **harm** to a patient.
- **Harm:** impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes **disease, injury, suffering, disability** and death.
- **Contributing Factor:** a **circumstance**, action or influence which is thought to have played a part in the origin or development of an **incident** or to increase the **risk** of an **incident**.
- **Incident type:** a descriptive term for a category made up of incidents of a common nature, grouped because of shared, agreed features.
- **Adverse reaction:** unexpected harm resulting from a justified action where the correct process was followed for the context in which the event occurred.
- **Side effect:** a known effect, other than that primarily intended, related to the pharmacological properties of a medication.

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- **Preventable:** accepted by the community as avoidable in the particular set of circumstances.
- **Detection:** an action or **circumstance** that results in the discovery of an **incident**.
- **Mitigating factor:** an action or **circumstance** which prevents or moderates the progression of an **incident** towards harming a **patient**.
- **Patient outcome:** the impact upon a patient which is wholly or partially attributable to an **incident**.
- **Degree of harm:** the severity and duration of harm, and any treatment implications, that results from an **incident**.
- **Ameliorating action:** an action taken or **circumstances** altered to make better or compensate any **harm** after an **incident**.
- **Actions taken to reduce risk:** actions taken to reduce, manage or control any future harm, or probability of **harm**, associated with an **incident**.
- **Accountable:** being held responsible
- **System failure:** a fault, breakdown or dysfunction within an organization's operational methods, processes or infrastructure.
- **System improvement:** the result or outcome of the culture, processes, and structures that are directed toward the prevention of **system failure** and the improvement of **safety** and **quality**.
- **Root cause analysis:** a systematic iterative process whereby the factors which contribute to an **incident** are identified by reconstructing the sequence of events and repeatedly asking why? Until the underlying root causes have been elucidated.
- **STARSWeb:** A web-based IT system for the purposes of notification of incidents that links enterprises to the CIS central database that is held in the SCA

## 8.0 RELEVANT CONTACT NAMES & NO'S:

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