
Audit 4

- 1) **Audit Title**
Is there a mechanism for record keeping and retrospective analysis of accidental or unintended medical exposures?
- 2) **Standard against which the audit topic is to be compared**
European Council Directive
- 3) **Source of standard**
Council Directive 2013/59/Euratom, Article 63
- 4) **Type of Audit - Clinical, regulatory**
Compulsory. Legal requirement.
- 5) **Target / compliance percentage to be achieved**
100 % (Such a resource must exist)
- 6) **Item or variable to be audited**
Formal record of accidental or unintended exposures
- 7) **Method**
Retrospective / prospective
- 8) **Data or information to be collected**
Review of components of formal record of accidental or unintended medical exposures
Number of incidents
Patient demographics
Date, time and nature of incidents
Corrective measures taken and timings, dissemination of learning points
- 9) **Sample details**
One year review of formal record of accidental or unintended medical exposures
- 10) **Target achieved**
Yes / no
- 11) **Action to be taken if the target is not met**
Creation of a detailed formal record of accidental or unintended medical exposures
Are mechanisms in place to disseminate learning information from accidental or unintended exposures to relevant parties
- 12) **Timing for re-audit**
One year, or sooner if target not met