
Audit 2

- 1) **Audit Title**
Is there an established mechanism within the department to register and analyse accidental/unintended 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 %
- 6) **Item or variable to be audited**
The existence of a department repository for this information, with agreed mechanisms in place for record keeping and analysis of accidental or unintended exposures
- 7) **Method**
Retrospective / Prospective / Other
- 8) **Data or information to be collected**
The existence of a department repository for this information
The number of cases / year, case outcomes in terms of registration and root cause analysis
- 9) **Sample details**
Confirmation of appropriate resource
Retrospective calculation of the number of cases per year
Circumstances of the exposure in each case, analysis of causes, appropriate policy adjustments made
- 10) **Target achieved**
Yes / no
- 11) **Action to be taken if the target is not met.**
Creation of appropriate resource, review department policies on recording and analysing accidental or unintended exposures of this nature
- 12) **Timing for re-audit**
One year, or sooner if target not met