
Audit 14

- 1) **Audit Title**
Is there a written protocol for who may be responsible for justification of CT studies?
- 2) **Standard against which the audit topic is to be compared**
BSSD
- 3) **Source of standard**
National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 57
- 4) **Type of Audit - regulatory**
- 5) **Target / compliance percentage to be achieved**
100 %
- 6) **Item or variable to be audited**
Local rules: written protocol for identification of those with responsibility for the justification of CT studies
- 7) **Method**
prospective/retrospective
- 8) **Data or information to be collected**
Written protocol for identification of those with responsibility for the justification of CT studies
Criteria for inclusion
Correlation with request forms/order comms
Percentage correctly completed, signed, dated
- 9) **Sample details**
One month as above
- 10) **Target achieved**
Yes/no
- 11) **Action to be taken if the target is not met**
Establishment of a written protocol for responsibility for the justification of CT studies
Education of staff, staff training
- 12) **Timing for re-audit**
One year, or sooner if target not met