Audit 4:

1. Audit Title
   What is the mechanism for record keeping and retrospective analysis of adverse incidents?

2. Standard against which the audit topic is to be compared.
   EU Directive

3. Source of standard
   EU 2013 /59

4. Importance
   Compulsory. Legal requirement.

5. Target/compliance percentage to be achieved
   100% (Such a resource must exist)

6. Item or variable to be audited
   Adverse incident repository (AIR)

7. Method: Retrospective /Prospective /Other
   Retrospective

8. Data or information to be collected
   Review of AIR components
   Number of incidents
   Patient demographics
   Date time and nature of incidents

9. Sample details
   One year review of AIR

10. Target achieved
    Yes /no/ not applicable
    If no: actual result......................

11. Action to be taken if the target is not met.
    Creation of a detailed AIR

12. Timing for re-audit
    One year