



QA SysOp Investigation Report (worksheet)

Report Accession Number: _____

Event Codes:

1. Consequent (discovery) Code: 2. Initial antecedent (1st occurrence) Code: 3. Significant antecedent (occurrence) Code:

* _____

*Enter 1-4 on the first line: 1=No recovery, harm 2=No recovery, no harm 3=Near miss, unplanned recovery 4=Near miss, planned recovery

4. Additional description of event (optional):

5. Risk Assessment:

Final RAI: _____

6. Organizational Risk:

QES: .99 .90 .75 .50 .25 .10

High Low N/A

QEP: .99 .90 .75 .50 .25 .10

7. Follow up:

Propose action Consider action Monitor External report to other dept/org FDA Reportable

8. If appropriate, describe the long-term preventive action to be taken:

9. What type of investigation will this event receive? Routine Investigation Expanded Investigation

Complete this section only if this event is undergoing a routine investigation.

Rough or Linked?	Rough/Link Cause Code 1	Rough/Link Cause Code 2	Rough/Link Cause Code 3	Rough/Link Cause Code 4	Link to Accession Number
_____	_____	_____	_____	_____	_____

Notes:

