

QA Sys Op Investigation Report How-To

Accession Number	Use the system-assigned accession number.
1. Consequent (Discovery) Code	<p>From left to right:</p> <ol style="list-style-type: none"> The first space is used to record the event type (misadventure, no harm event, near miss) The two middle spaces are for the consequent process code (where the event was discovered) The remaining three spaces are for the sub-process code that further describes the event.
2. Antecedent (1 st Occurrence) Code	<p>From left to right:</p> <ol style="list-style-type: none"> The first two spaces are for the antecedent (1st Occurrence) process code (where in the process did the event first occurred). The remaining three spaces are for the sub-process code that further describes the initial antecedent event.
3. Significant Antecedent (Occurrence) Code	<p>This code describes the antecedent event the QA Sys Op feels is most amenable to a system improvement.</p> <p>From left to right:</p> <ol style="list-style-type: none"> The first two spaces are for the antecedent process code. The remaining three spaces are for the sub-process code that further describes the antecedent event.
4. Additional description of the event:	This area is used to add key descriptors about the event not contained in A.7 or A.8 on the Event Discovery Report.
5. Risk Assessment:	Indicate one estimate each for QES and QEP.
6. Organizational Risk:	Indicate whether the event has the potential for high, low or no (N/A) organizational risk.
7. Final RAI	<p>This is a calculation that either the QA Sys Op or the system can calculate.</p> <ol style="list-style-type: none"> Multiply the QES and QEP risk values. (QA Sys Op Investigation Report #5). This is the initial Risk Index. Refer to the event type (QA Sys Op Investigation Report #1, a number (1-4) on far left). If the event is a near miss,

	<p>unplanned recovery (3), then add 0.1 to the initial risk index.</p> <p>c. Refer to 'Was product issued?' (Event Discovery Report, B.7). If the product was issued, add 0.2 to the initial risk index.</p> <p>d. The Final RAI is the initial risk assessment, plus b and c above.</p>
<p>8. Follow up:</p>	<p>Based on the results of the Final RAI (see above) select a recommended action(s). Further directions for choosing propose change, consider change and/or monitor are on the RAI tool.</p> <p>External report indicates that the event was discussed /formally reported to another department or organization.</p> <p>FDA Reportable is selected if the event meets the criteria for a report to the FDA.</p>
<p>9. If appropriate, describe the long-term preventive action to be taken:</p>	<p>MERS-TM encourages preventive actions based on aggregate data rather than an individual event. However, occasionally there will be a very simple preventive action that can be easily implemented without assessing the effects of the change. This area is for the description of such a preventive action.</p> <p>Please limit the description to four lines.</p>
<p>10. What type of investigation will this event receive?</p>	<p>An expanded investigation is recommended in the following circumstances:</p> <ul style="list-style-type: none"> • events with a Final RAI of greater than or equal to 0.5. • a high Organizational Risk estimate. • If in the QA Sys Ops expert opinion, the benefit of doing an expanded investigation outweighs the cost. <p>The investigation decision may be changed in either direction based on information obtained from the software tools in Database Functions.</p>

Rough or Linked?	<p>Fill this field out only if the event is undergoing a routine investigation.</p> <p>Enter an 'R' if the following root cause code fields contain estimated root cause codes. The event has neither undergone an expanded investigation nor is it linked to a previous event that did undergo an expanded investigation.</p> <p>Enter an 'L' if:</p> <ul style="list-style-type: none"> • the event has been found to be similar to previous events by the software tools in Database Functions, and • the event has been linked to one of the previous events that has undergone an expanded investigation. The 'L' indicates the root cause codes listed in this section have been transcribed from root cause analysis of the previous event.
Rough / Linked Causal Codes 1-4	<p>Enter up to 4 root cause codes included in the Eindhoven Classification Model – Medical Version.</p> <p>Rough root cause codes are estimates of the causes based on the QA Sys Ops expert knowledge of their system. The event does not warrant a root cause analysis, but they have an idea of what caused the event.</p> <p>Linked root cause codes are transcribed to the current event from a previous event that has had a root cause analysis.</p>
Link to Accession Number:	<p>If the current event undergoing a routine investigation and it is to be linked to a previous event that has had an expanded investigation, then the accession number of the previous event should be recorded here.</p>
Cause Codes 1-8 (FDA Reportable)	<p>If the event has undergone an expanded investigation and is FDA Reportable, transcribe up to eight (8) root cause codes from the Root Cause Analysis Report form to this area.</p>
Notes:	<p>This area is for other comments about the event not included in previous narrative fields.</p>