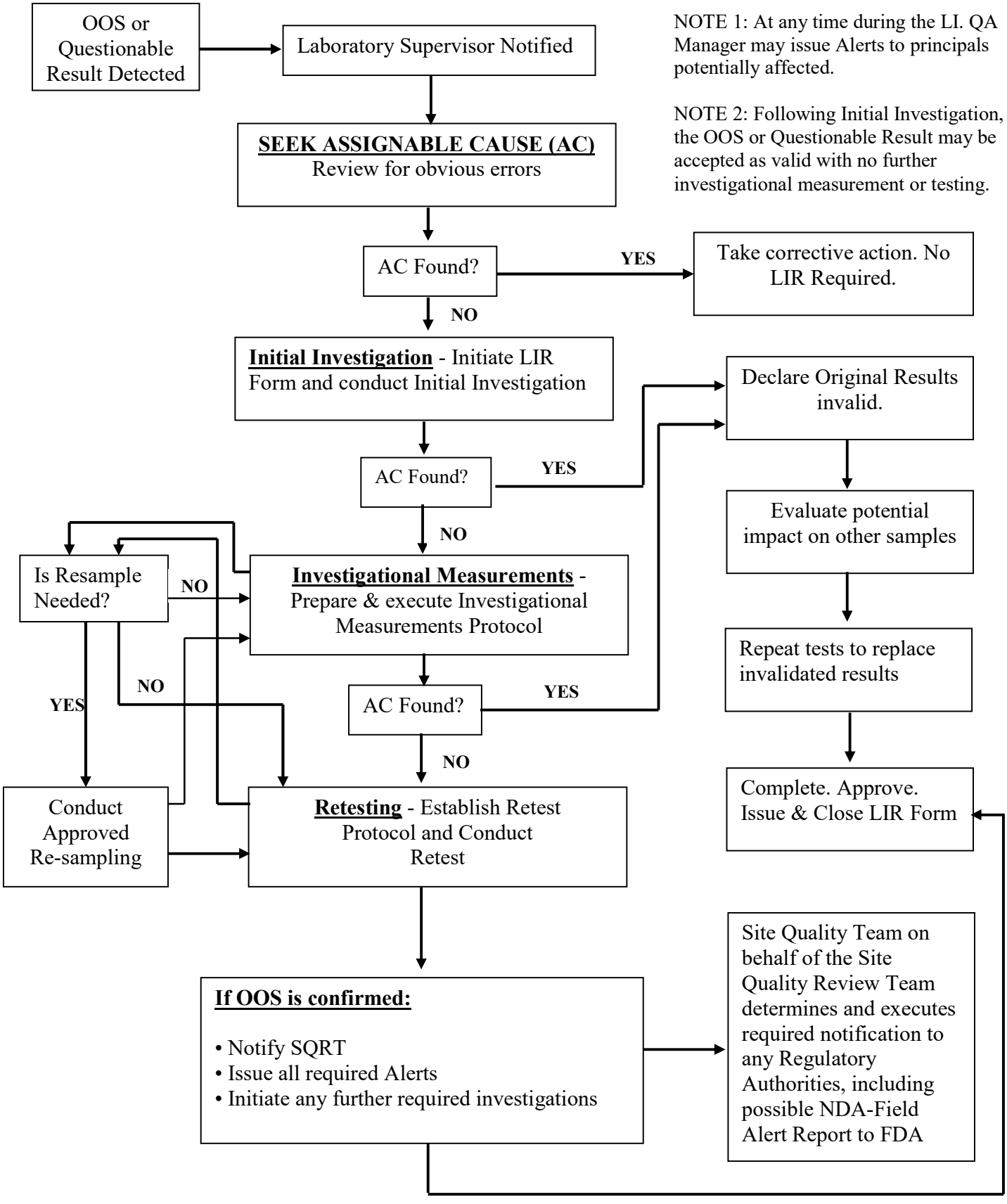
**Practice 005:**

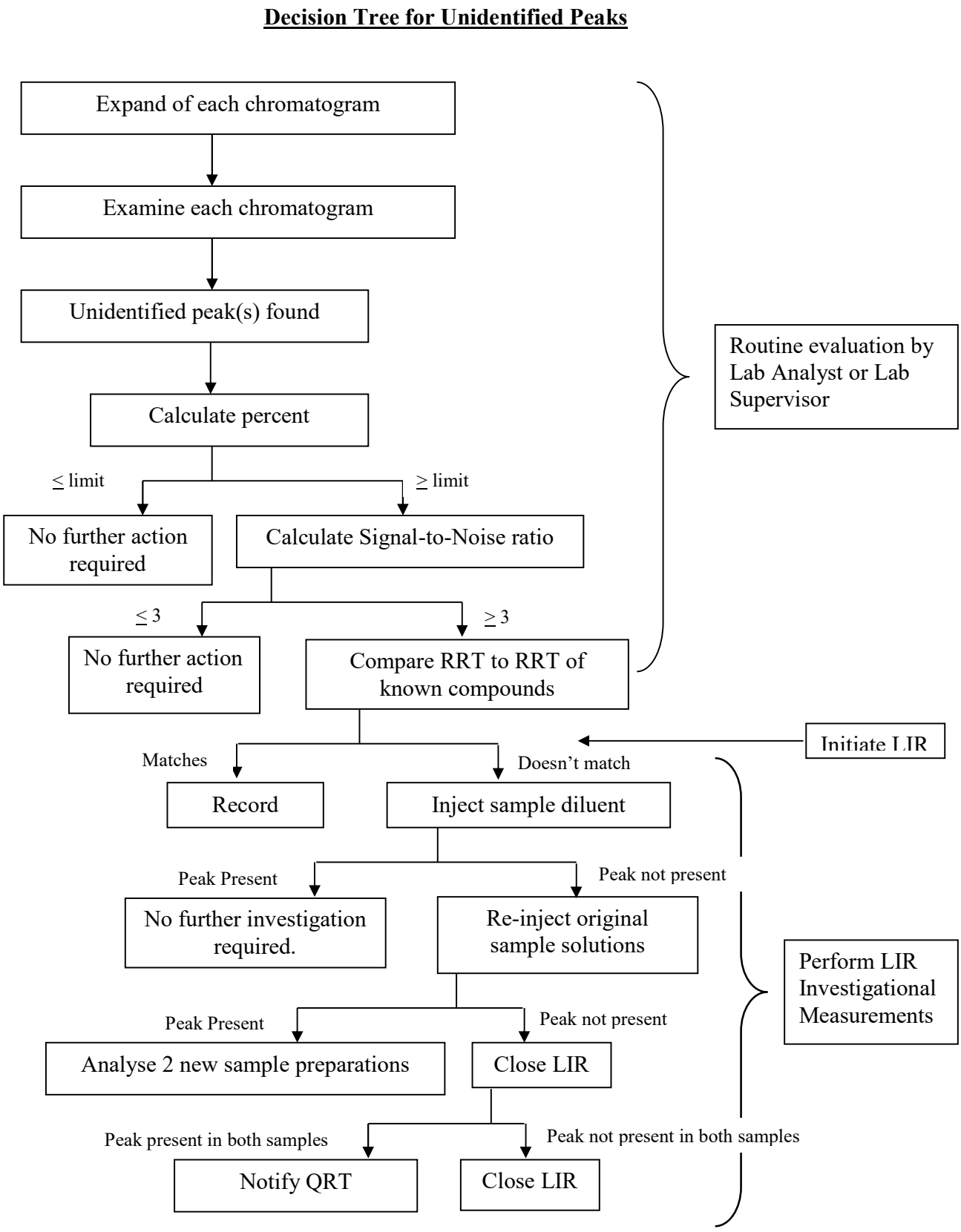
## Figure 1: Laboratory Investigation (LI) Process Flowchart




NOTE 1: At any time during the LI. QA Manager may issue Alerts to principals potentially affected.

NOTE 2: Following Initial Investigation, the OOS or Questionable Result may be accepted as valid with no further investigational measurement or testing.

**Figure 2:**


Decision Tree for Unidentified Peaks
Expand of each chromatogram
Examine each chromatogram
Unidentified peak(s) found
Calculate percent
≤ limit
≥ limit
No further action required
Calculate Signal-to-Noise ratio
≤ 3
≥ 3
No further action required
Compare RRT to RRT of known compounds
Routine evaluation by Lab Analyst or Lab Supervisor
Initiate LIR
Matches
Doesn't match
Record
Inject sample diluent
Peak Present
Peak not present
No further investigation required.
Re-inject original sample solutions
Peak Present
Peak not present
Analyse 2 new sample preparations
Close LIR
Peak present in both samples
Peak not present in both samples
Notify QRT
Close LIR
Perform LIR Investigational Measurements