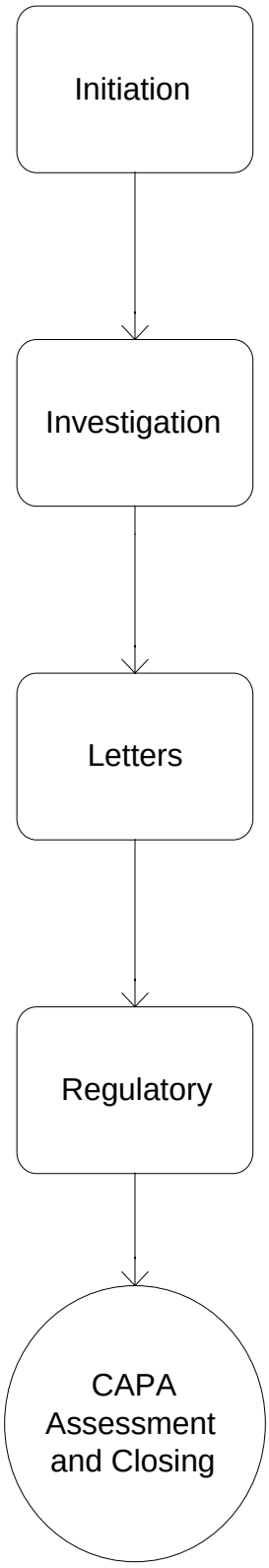
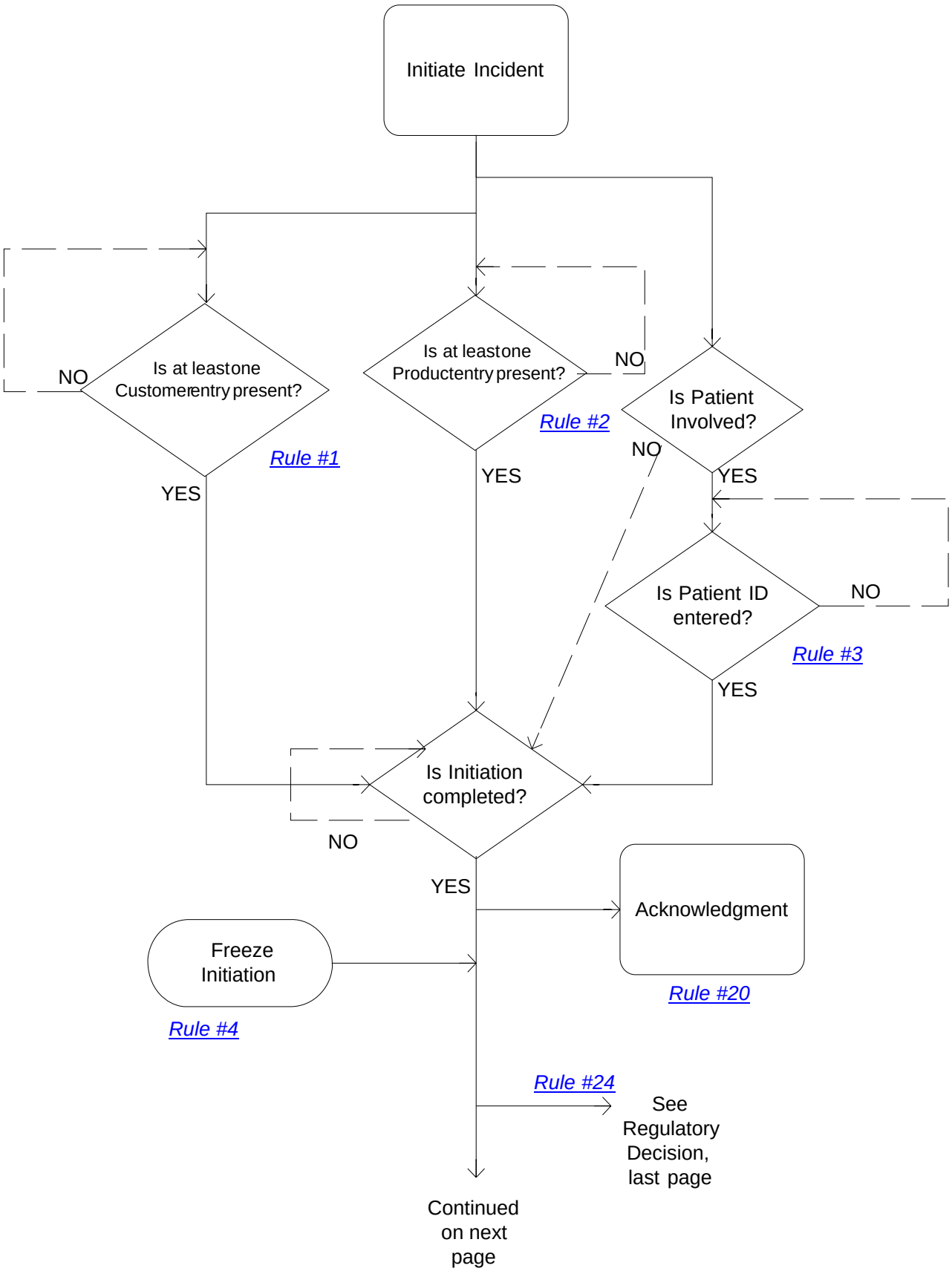
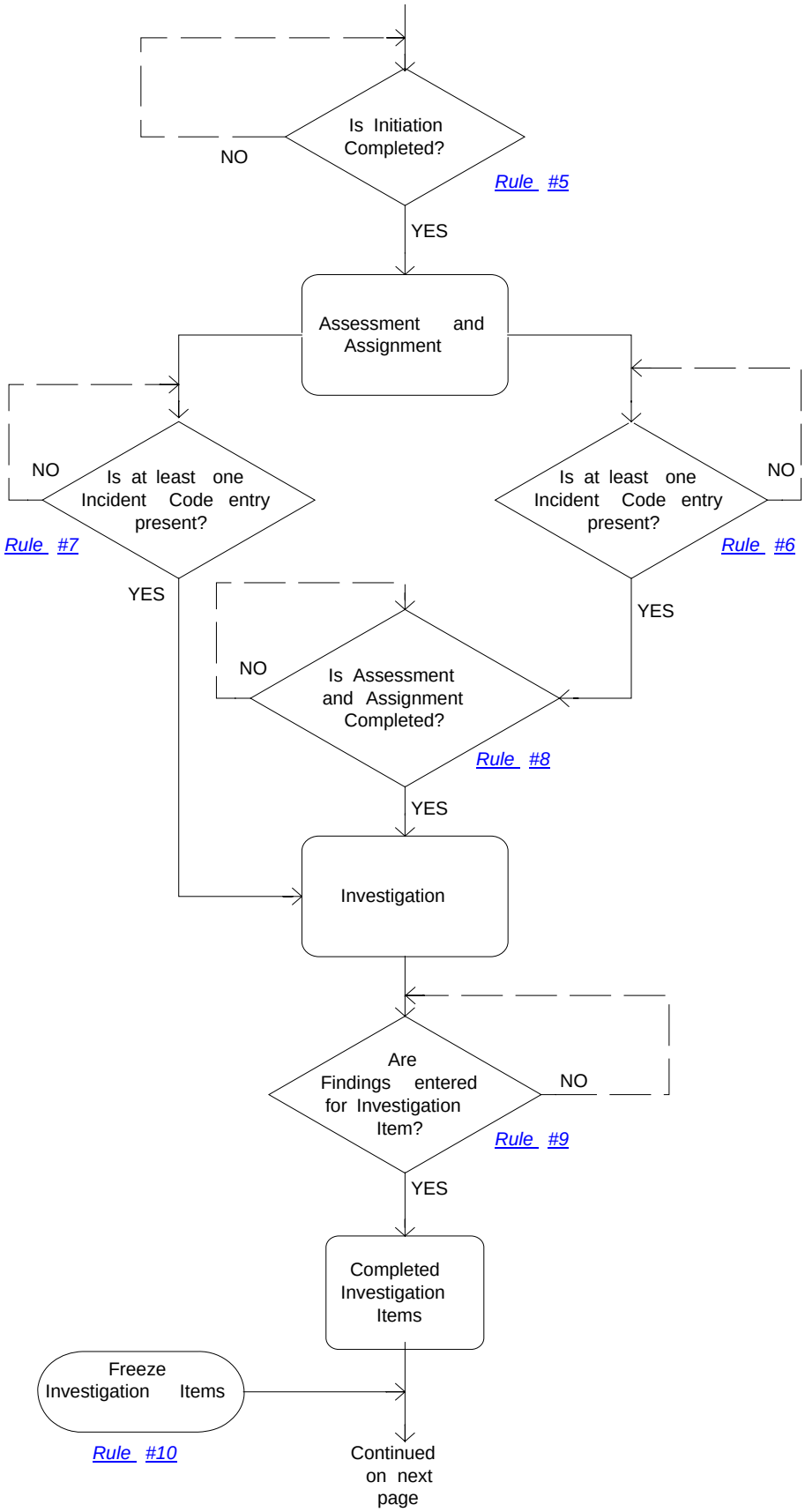
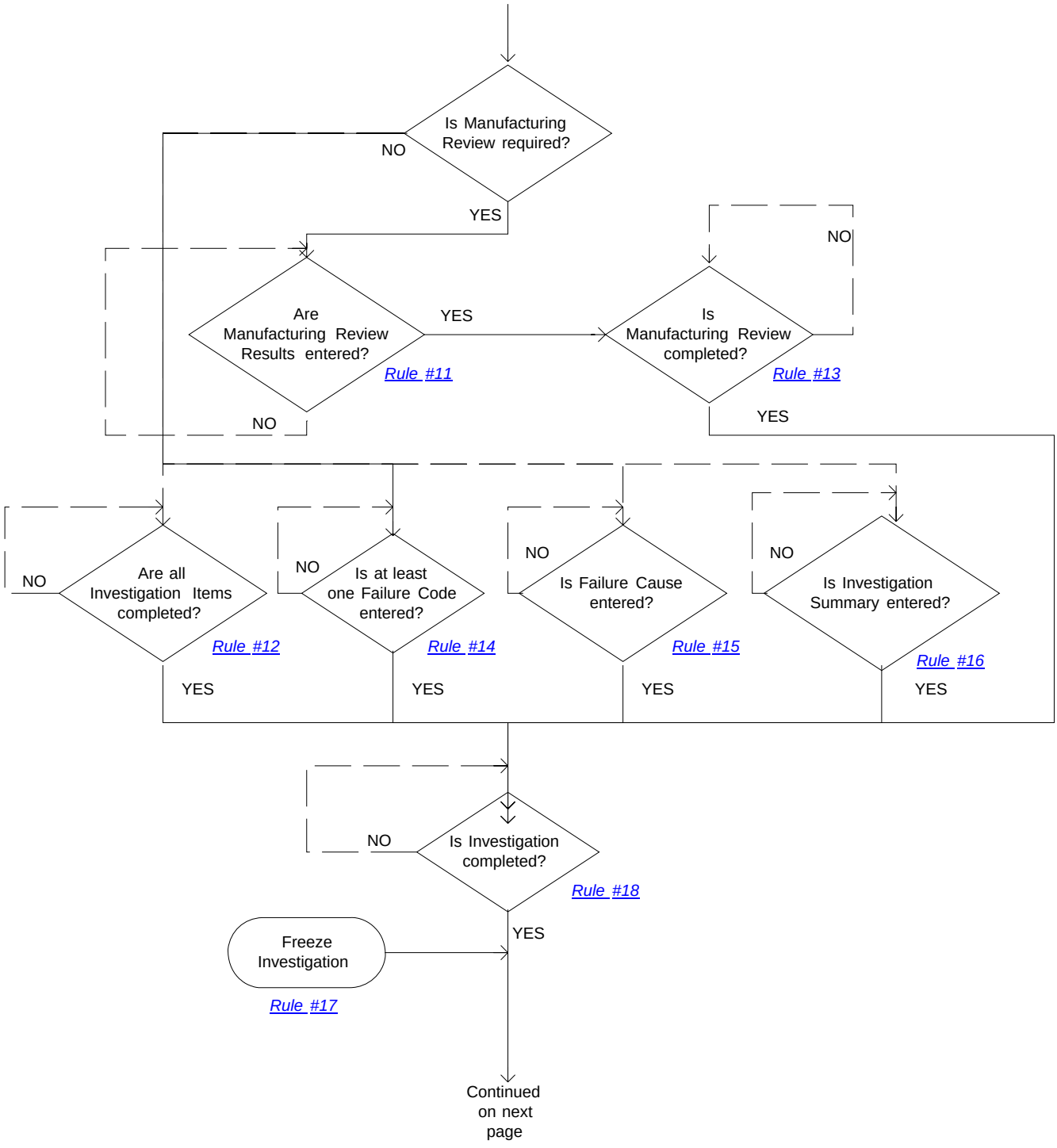
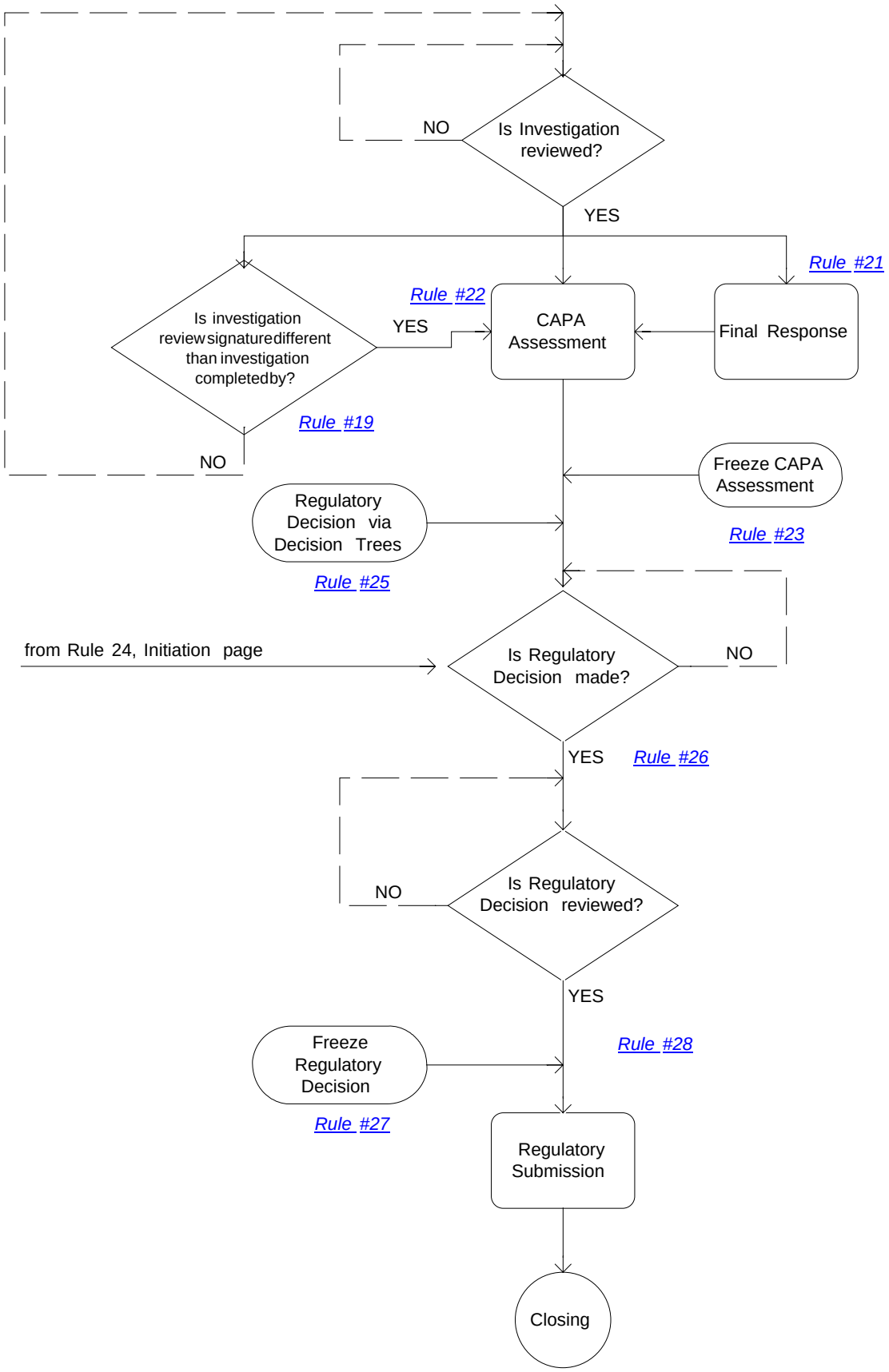
# Appendix A – Incident Flow Diagram




Initiate Incident
Is at least one Customer entry present?
NO
YES
Rule #1
Is at least one Product entry present?
NO
YES
Rule #2
Is Patient Involved?
NO
YES
Is Patient ID entered?
NO
YES
Rule #3
Is Initiation completed?
NO
YES
Acknowledgment
Rule #20
Freeze Initiation
Rule #4
Rule #24
See Regulatory Decision, last page
Continued on next page


Is Initiation Completed?
NO
Rule #5
YES
Assessment and Assignment
NO
Is at least one Incident Code entry present?
Rule #7
YES
Is at least one Incident Code entry present?
NO
Rule #6
YES
NO
Is Assessment and Assignment Completed?
Rule #8
YES
Investigation
Are Findings entered for Investigation Item?
NO
Rule #9
YES
Completed Investigation Items
Freeze Investigation Items
Rule #10
Continued on next page


Is Manufacturing Review required?
NO
YES
Are Manufacturing Review Results entered?
Rule #11
YES
NO
Is Manufacturing Review completed?
Rule #13
NO
YES
Are all Investigation Items completed?
Rule #12
NO
YES
Is at least one Failure Code entered?
Rule #14
NO
YES
Is Failure Cause entered?
Rule #15
NO
YES
Is Investigation Summary entered?
Rule #16
NO
YES
Is Investigation completed?
Rule #18
NO
YES
Freeze Investigation
Rule #17
Continued on next page


NO
Is Investigation reviewed?
YES
Rule #21
Rule #22
Is investigation review signature different than investigation completed by?
YES
CAPA Assessment
Final Response
Rule #19
NO
Freeze CAPA Assessment
Regulatory Decision via Decision Trees
Rule #23
Rule #25
from Rule 24, Initiation page
Is Regulatory Decision made?
NO
YES
Rule #26
NO
Is Regulatory Decision reviewed?
YES
Rule #28
Freeze Regulatory Decision
Rule #27
Regulatory Submission
Closing