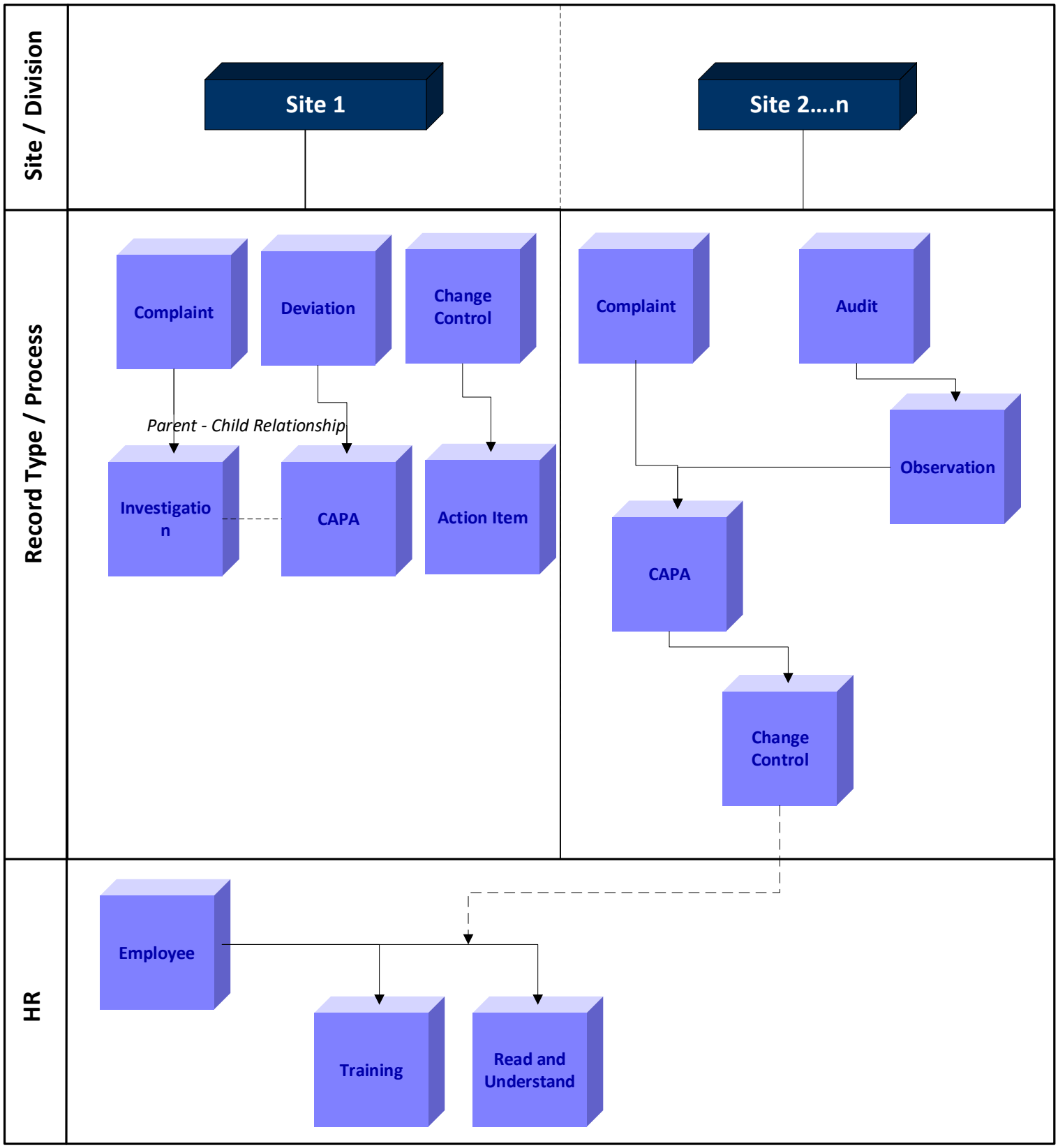
NOTES

- **Unlimited Sites can be created**
- **Unlimited Projects can be created within each Site**
- **Each Site can share workflows, forms, notification rules, escalations, etc. OR can have individual / separate rules for its Projects**
- **User membership and permissions are assigned based on Project. For example Joe Smith may have ability to initiate deviations in India but not in America**

Configuration Overview



NOTES

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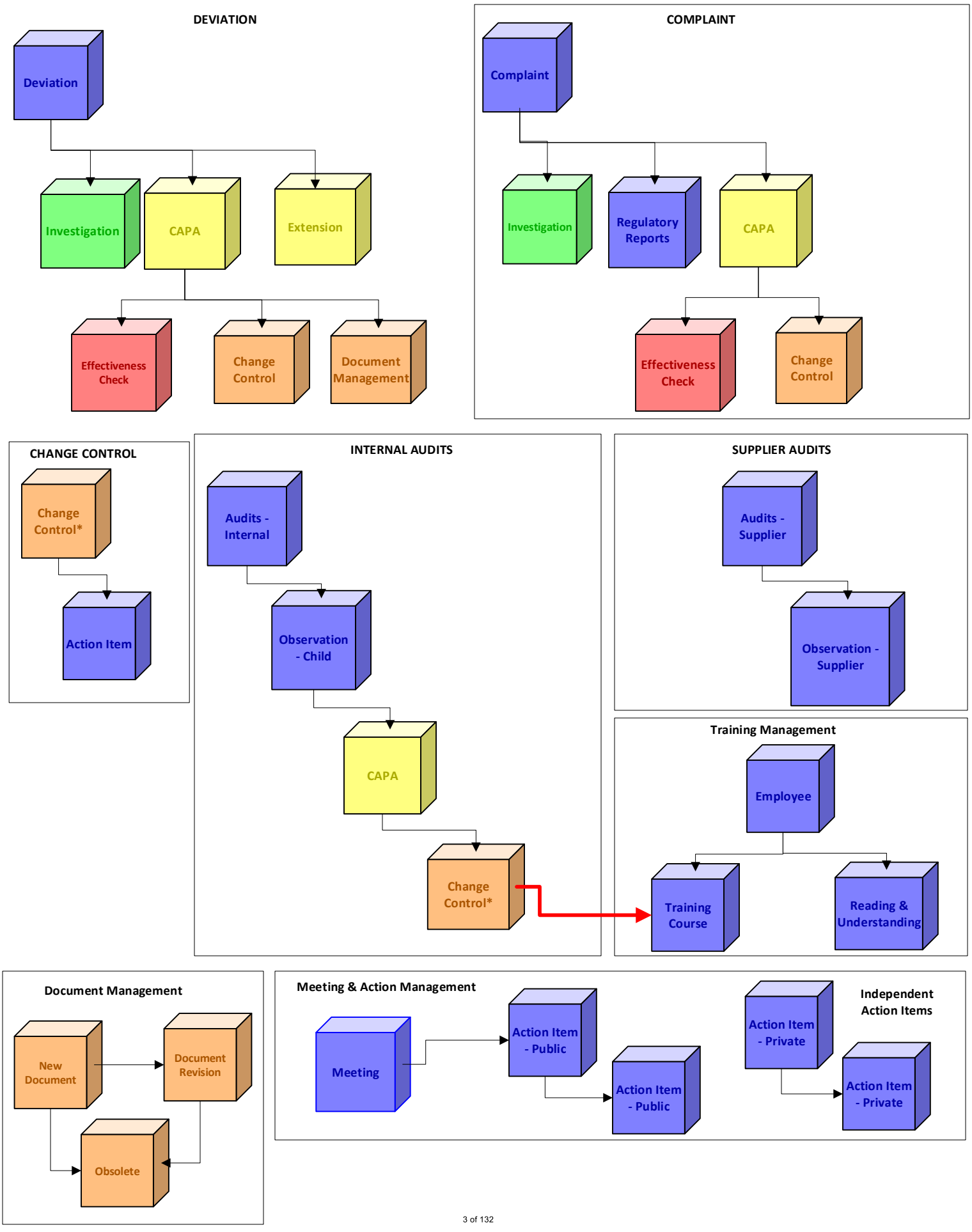
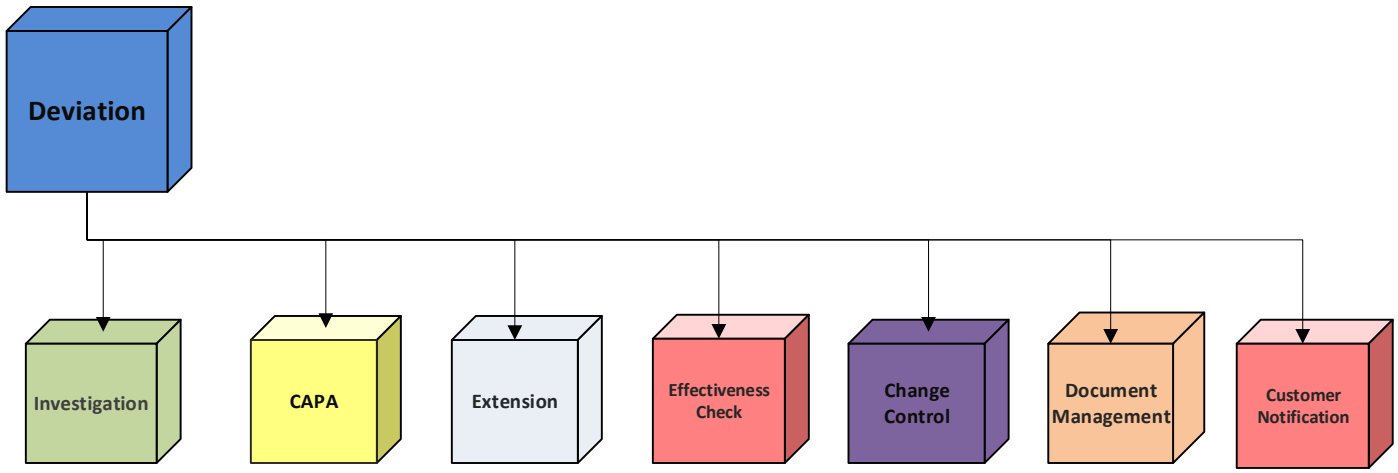
Parent Child Relationships

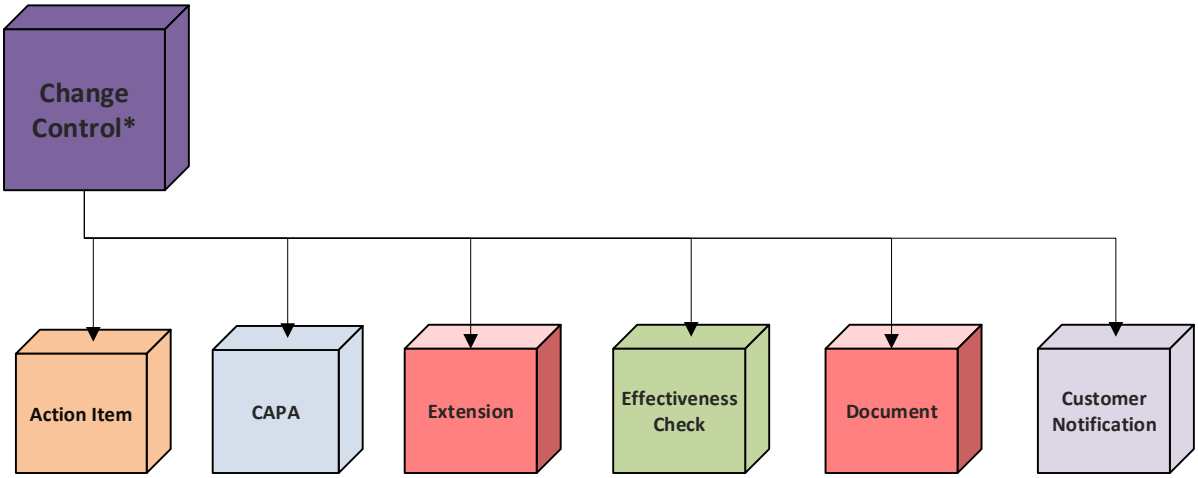


Parent Child Relationships

DEVIATION FAMILY

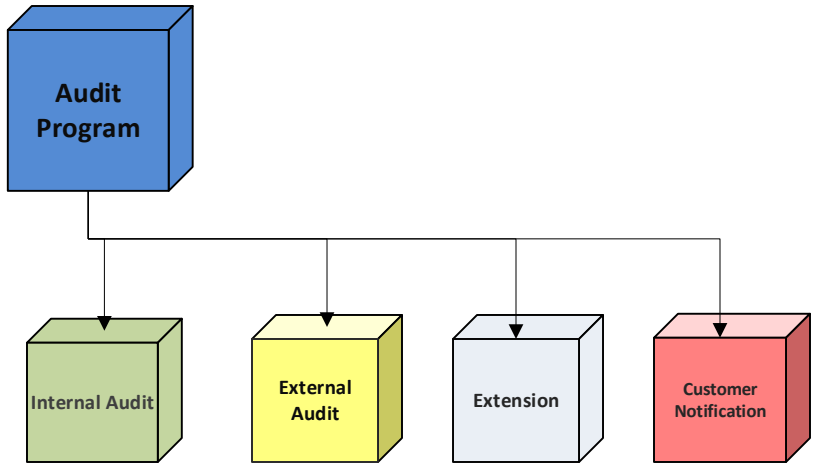


Change Control

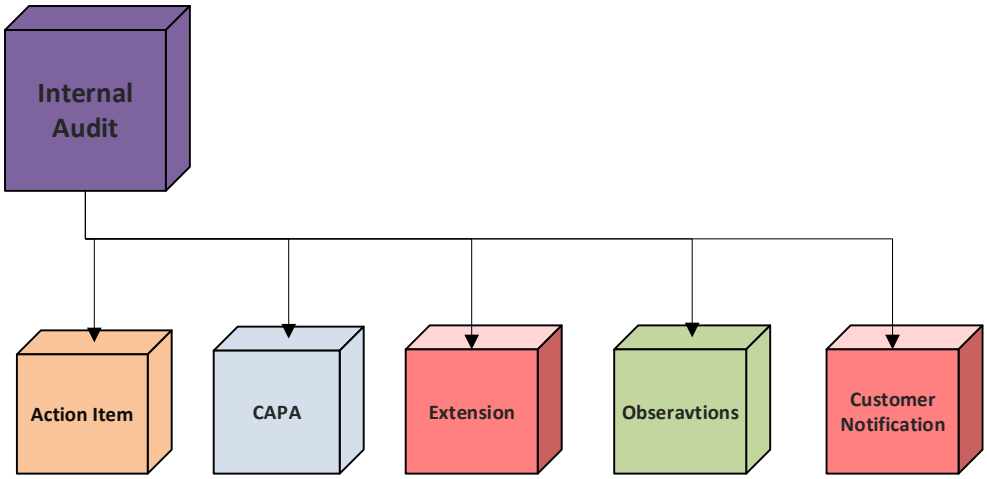


Parent Child Relationships

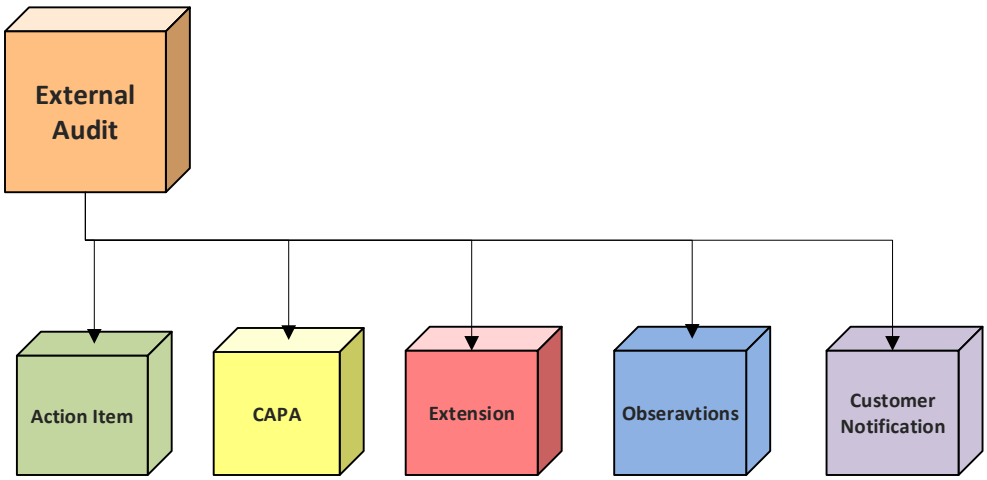
Audit Program



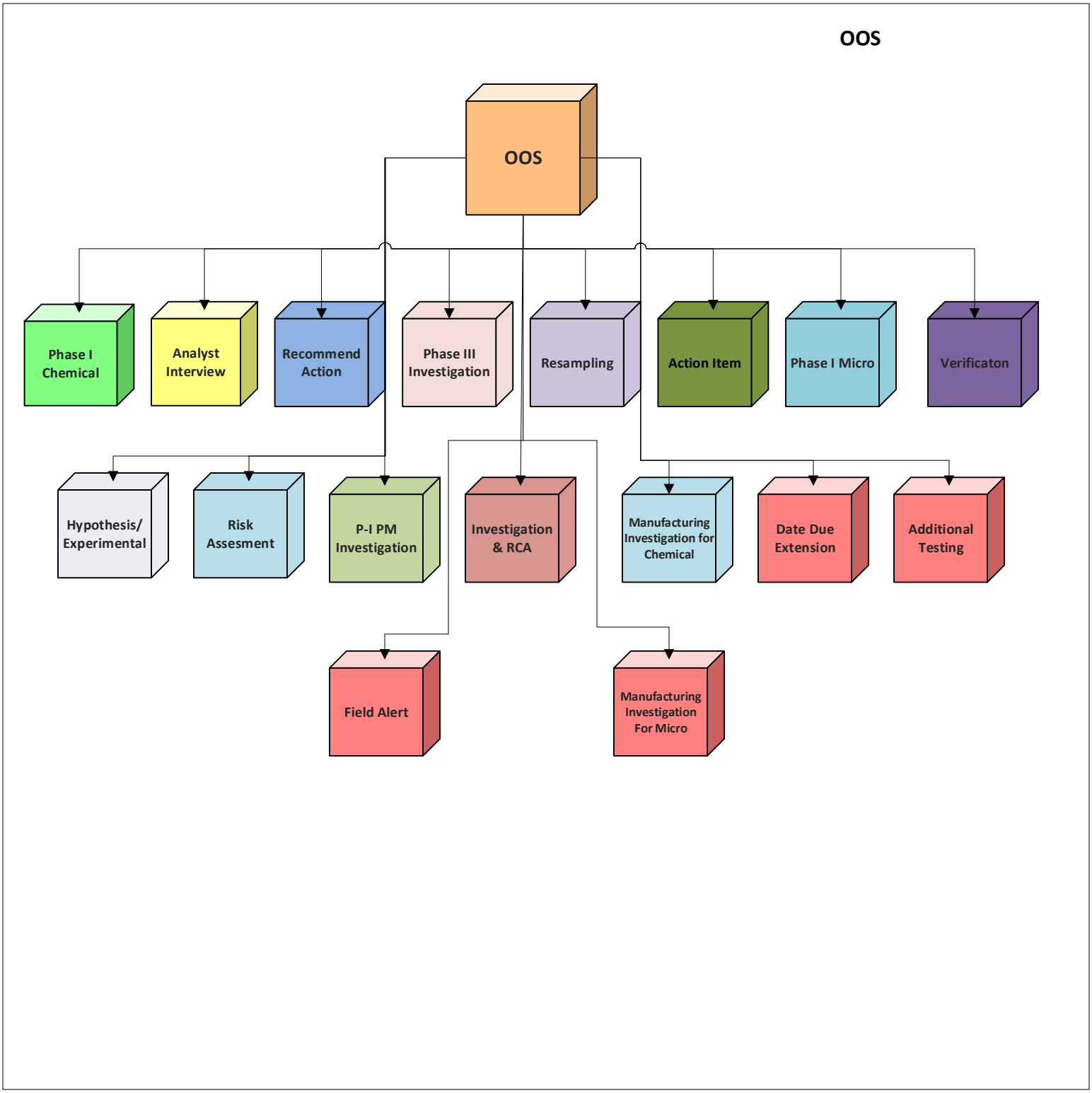
Internal Audit



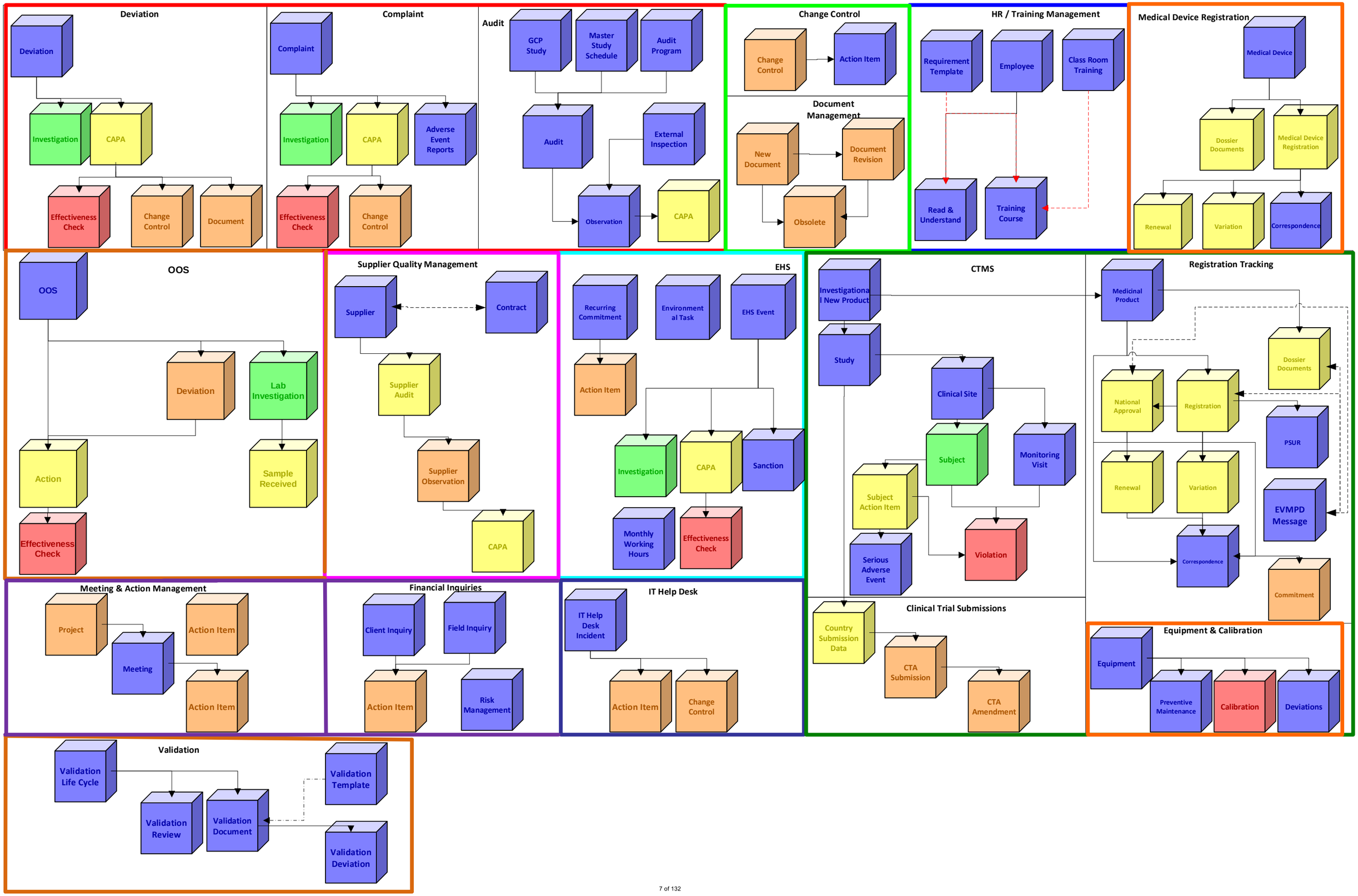
External Audit



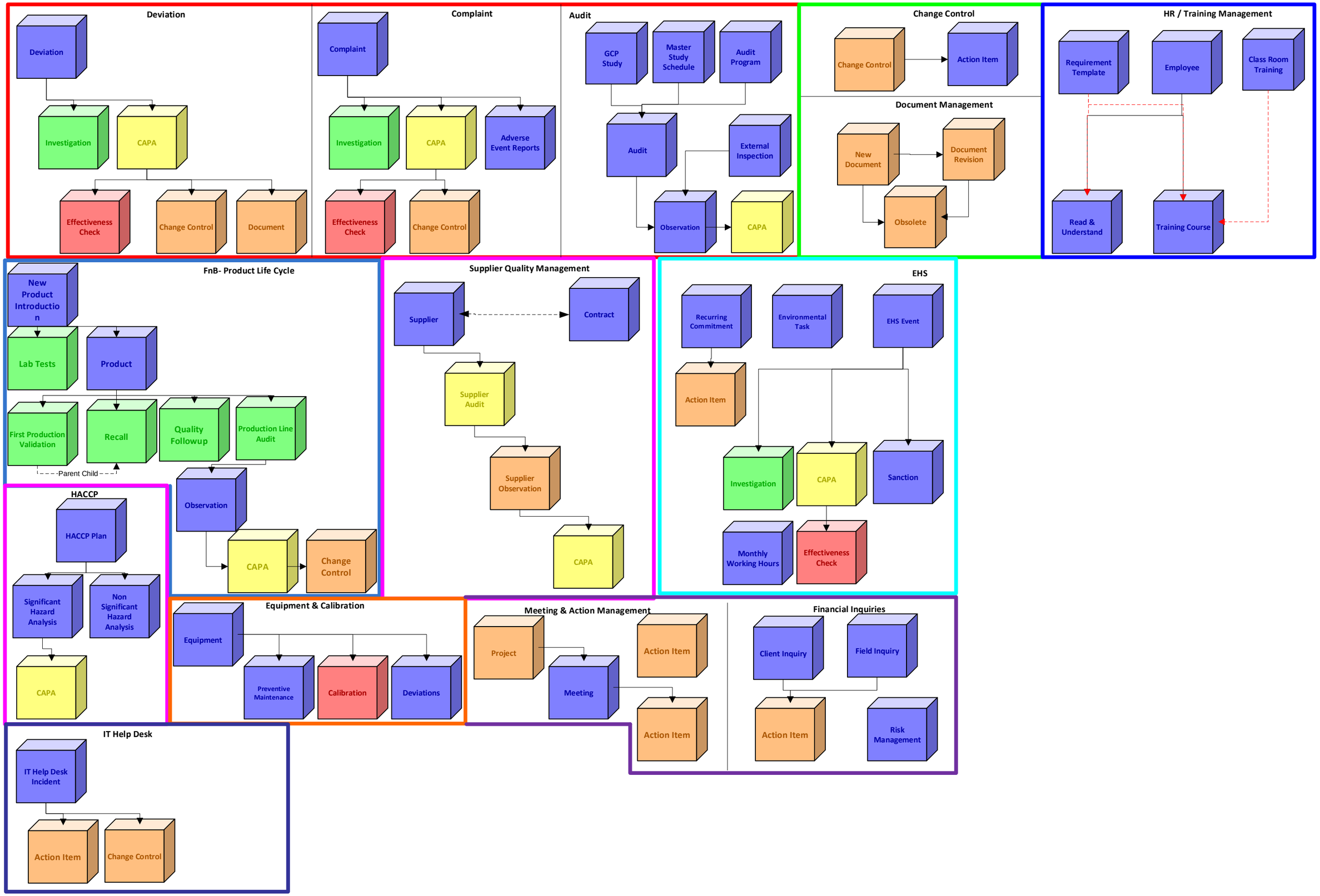
Parent Child Relationships



Life science-Preconfigured Solution



None Life science Preconfigured Solution



The Nirvana Core

Configurable Workflow with Granular Role Based Security

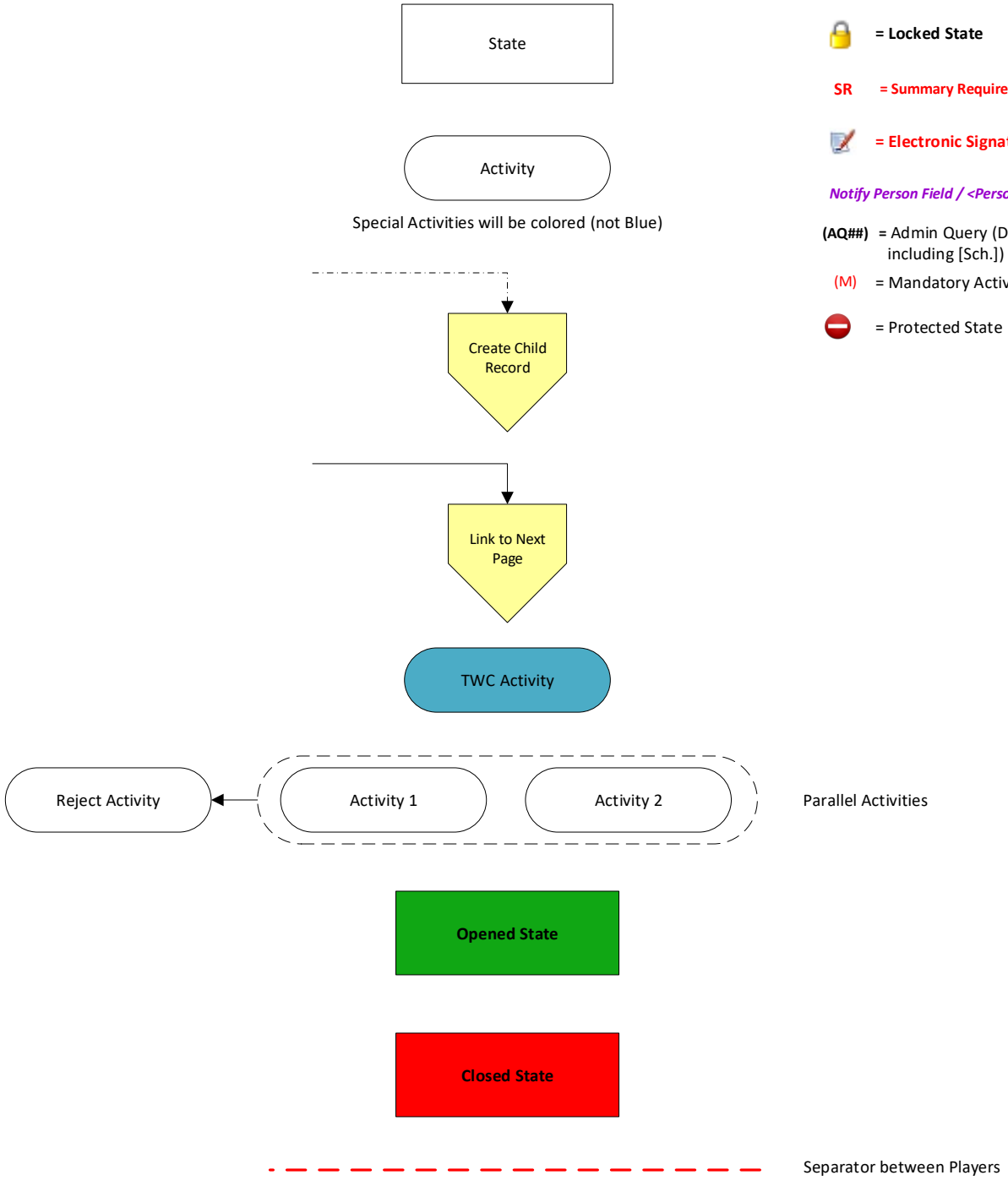
Core Component

Configurable Data Entry Forms with Granular Field Level Security

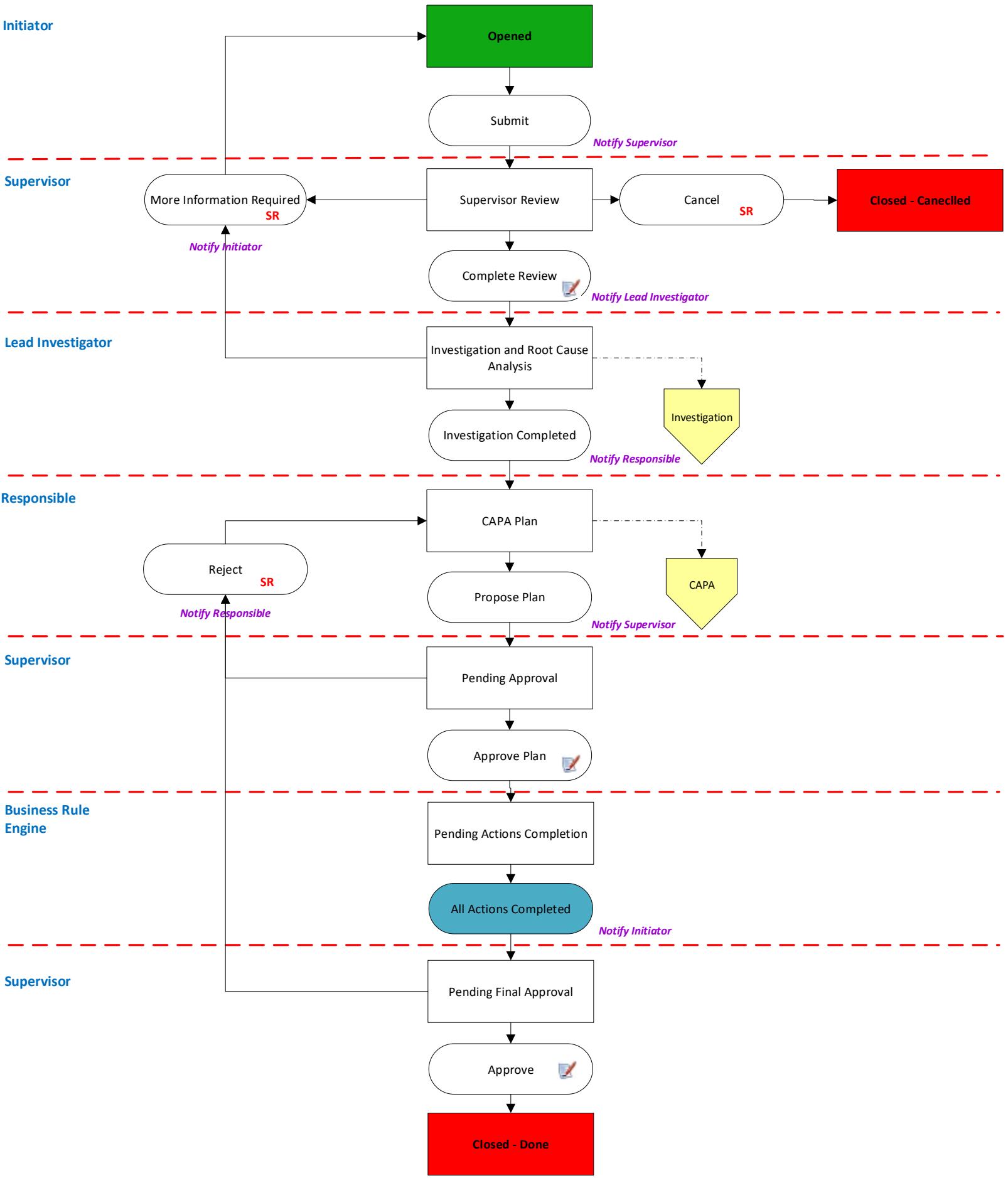
Patented Configurable Business Rules Engine to Enforce & Automate SOPs

Legend

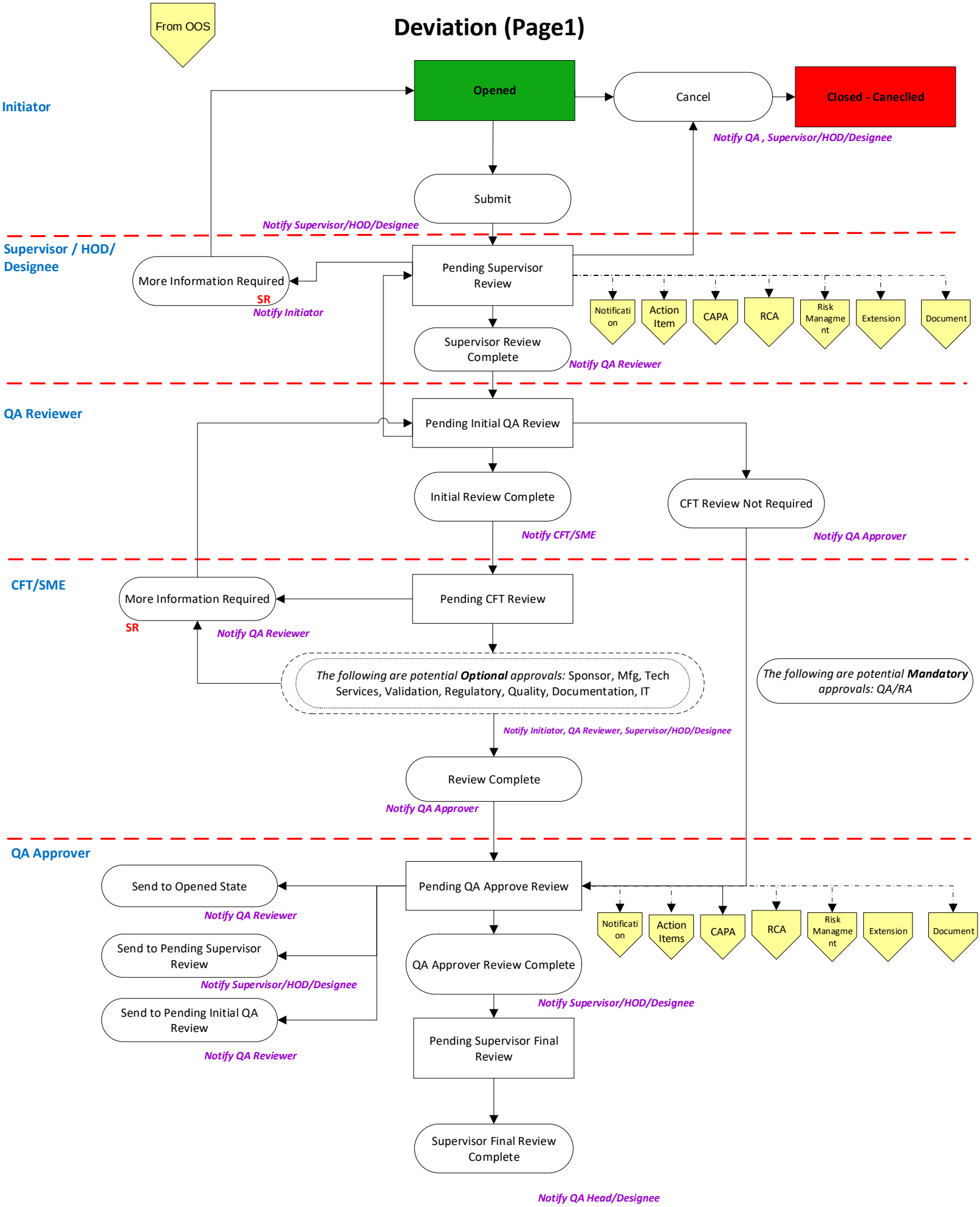
Player

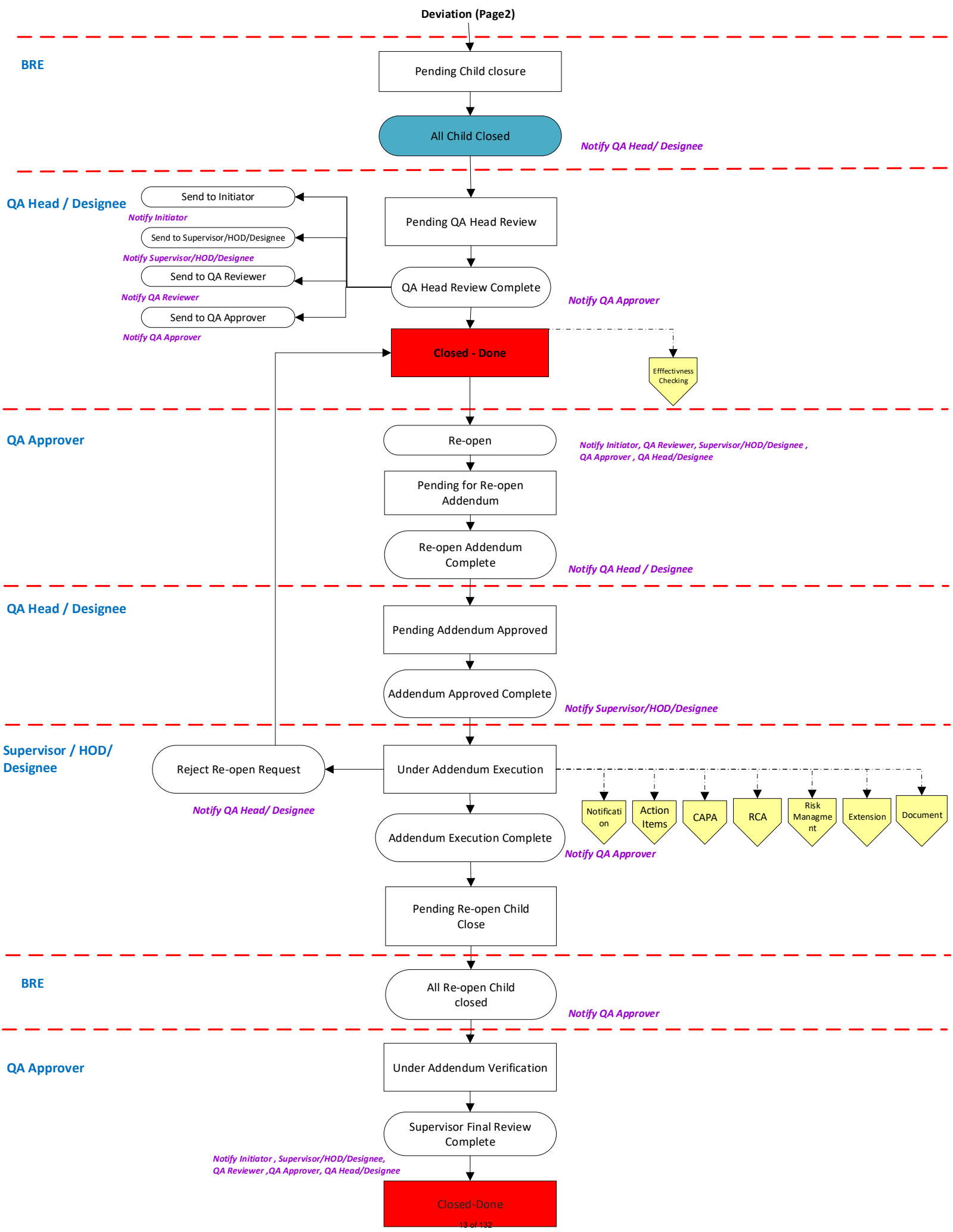


Deviation

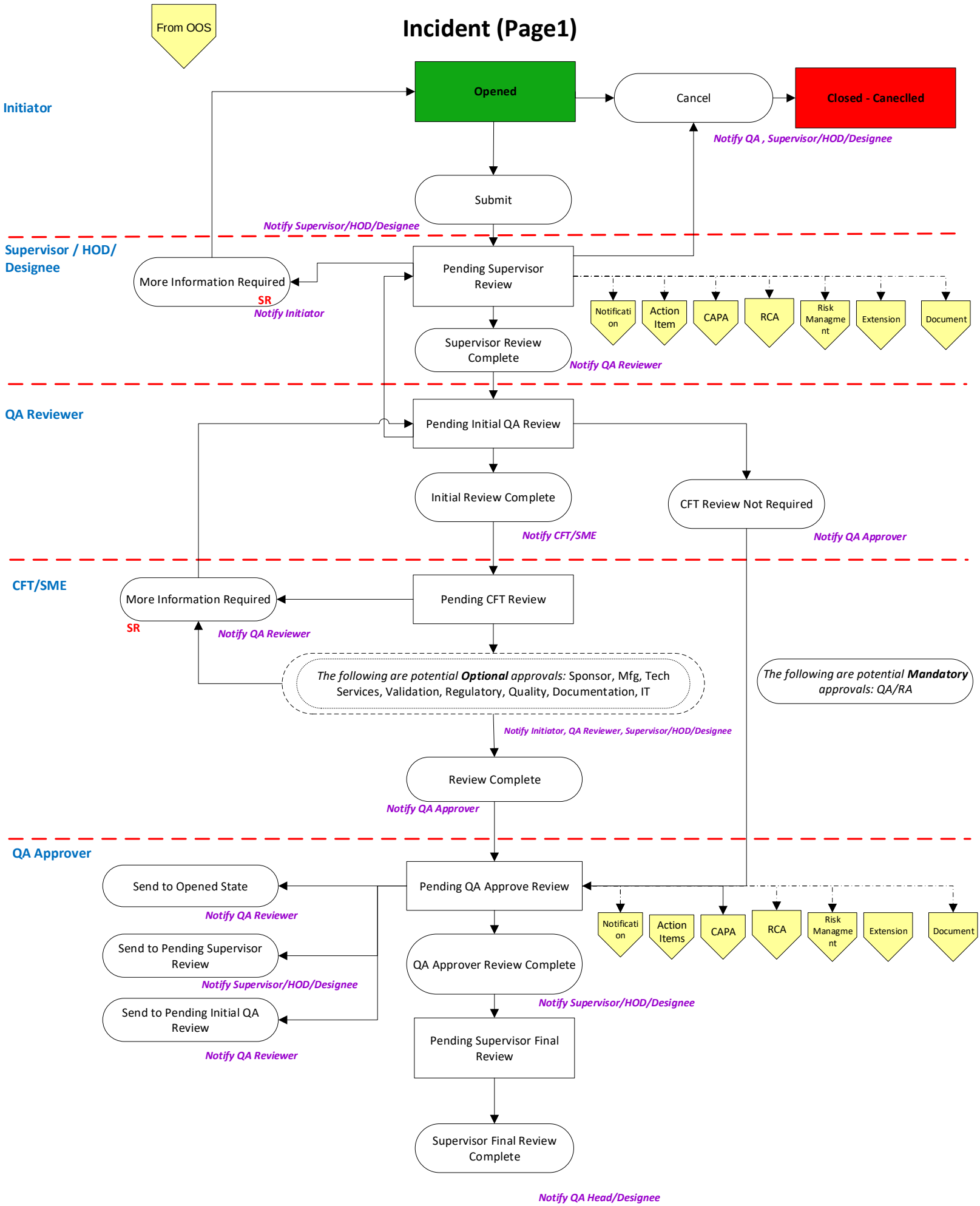

Compliance Task
From OOS
Initiator
Opened
Submit
Notify Supervisor
Supervisor
More Information Required
SR
Supervisor Review
Cancel
SR
Closed - Canecled
Notify Initiator
Complete Review
Notify Lead Investigator
Lead Investigator
Investigation and Root Cause Analysis
Investigation
Investigation Completed
Notify Responsible
Responsible
CAPA Plan
Reject
SR
CAPA
Propose Plan
Notify Responsible
Notify Supervisor
Supervisor
Pending Approval
Approve Plan
Business Rule Engine
Pending Actions Completion
All Actions Completed
Notify Initiator
Supervisor
Pending Final Approval
Approve
Closed - Done

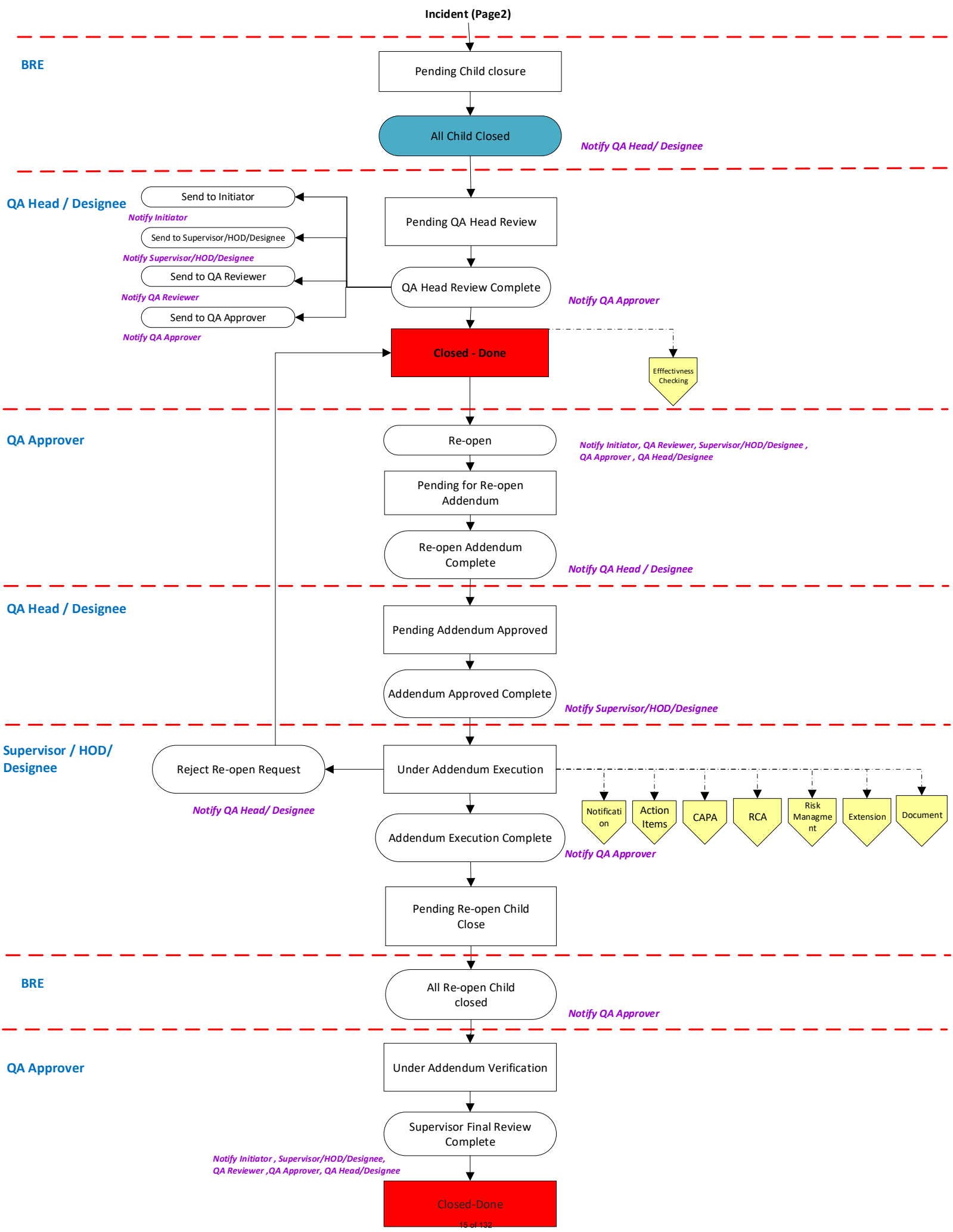
Deviation (Page1)



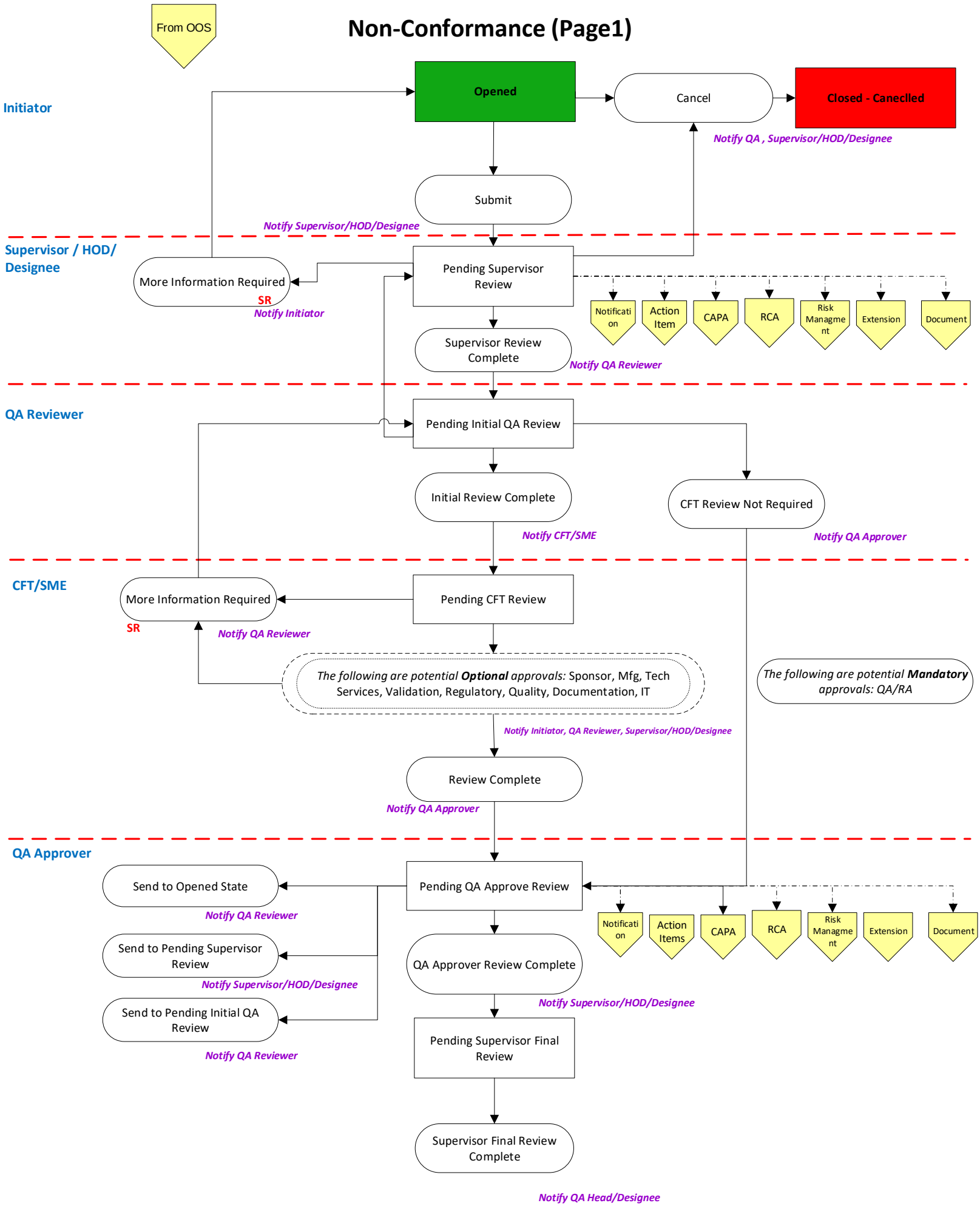

Deviation (Page2)
BRE
Pending Child closure
All Child Closed
Notify QA Head/ Designee
QA Head / Designee
Send to Initiator
Notify Initiator
Send to Supervisor/HOD/Designee
Notify Supervisor/HOD/Designee
Send to QA Reviewer
Notify QA Reviewer
Send to QA Approver
Notify QA Approver
Pending QA Head Review
QA Head Review Complete
Notify QA Approver
Closed - Done
Efffectivness Checking
QA Approver
Re-open
Notify Initiator, QA Reviewer, Supervisor/HOD/Designee , QA Approver , QA Head/Designee
Pending for Re-open Addendum
Re-open Addendum Complete
Notify QA Head / Designee
QA Head / Designee
Pending Addendum Approved
Addendum Approved Complete
Notify Supervisor/HOD/Designee
Supervisor / HOD/ Designee
Reject Re-open Request
Notify QA Head/ Designee
Under Addendum Execution
Notificati on
Action Items
CAPA
RCA
Risk Managme nt
Extension
Document
Addendum Execution Complete
Notify QA Approver
Pending Re-open Child Close
BRE
All Re-open Child closed
Notify QA Approver
QA Approver
Under Addendum Verification
Supervisor Final Review Complete
Notify Initiator , Supervisor/HOD/Designee, QA Reviewer ,QA Approver, QA Head/Designee
Closed-Done

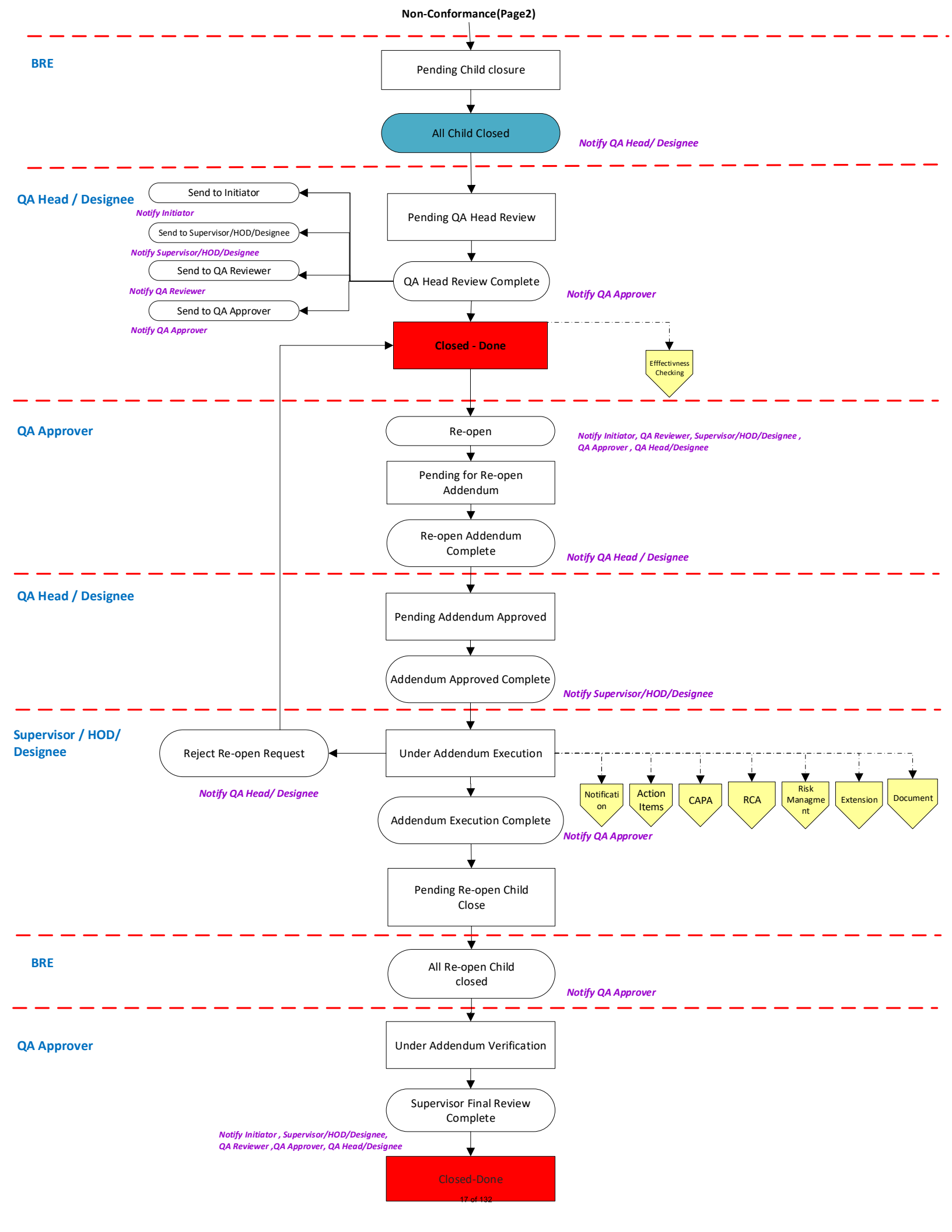
Incident (Page1)



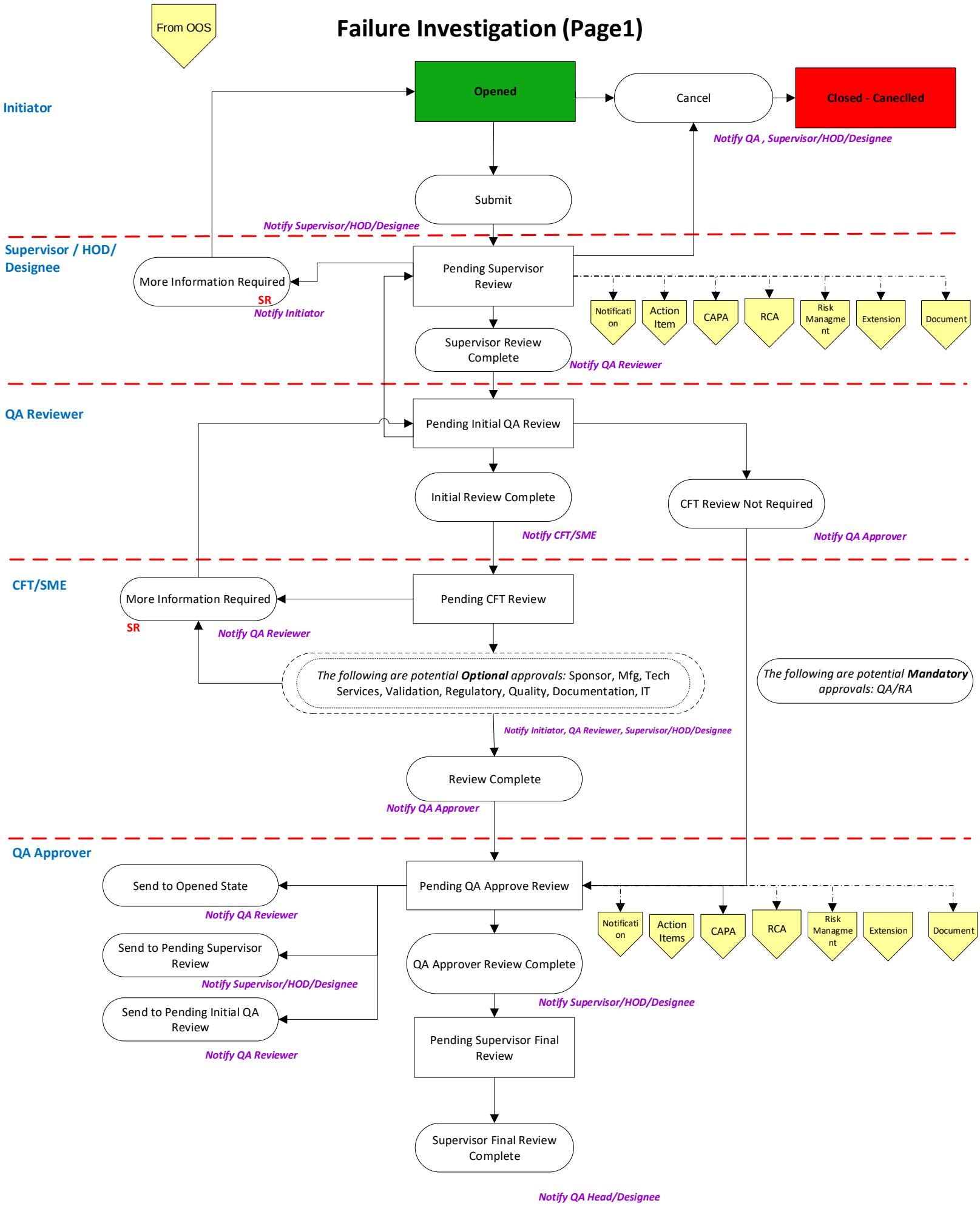

Incident (Page2)
BRE
Pending Child closure
All Child Closed
Notify QA Head/ Designee
QA Head / Designee
Send to Initiator
Notify Initiator
Send to Supervisor/HOD/Designee
Notify Supervisor/HOD/Designee
Send to QA Reviewer
Notify QA Reviewer
Send to QA Approver
Notify QA Approver
Pending QA Head Review
QA Head Review Complete
Notify QA Approver
Closed - Done
Efffectivness Checking
QA Approver
Re-open
Notify Initiator, QA Reviewer, Supervisor/HOD/Designee , QA Approver , QA Head/Designee
Pending for Re-open Addendum
Re-open Addendum Complete
Notify QA Head / Designee
QA Head / Designee
Pending Addendum Approved
Addendum Approved Complete
Notify Supervisor/HOD/Designee
Supervisor / HOD/ Designee
Reject Re-open Request
Notify QA Head/ Designee
Under Addendum Execution
Notificati on
Action Items
CAPA
RCA
Risk Managme nt
Extension
Document
Addendum Execution Complete
Notify QA Approver
Pending Re-open Child Close
BRE
All Re-open Child closed
Notify QA Approver
QA Approver
Under Addendum Verification
Supervisor Final Review Complete
Notify Initiator , Supervisor/HOD/Designee, QA Reviewer ,QA Approver, QA Head/Designee
Closed-Done

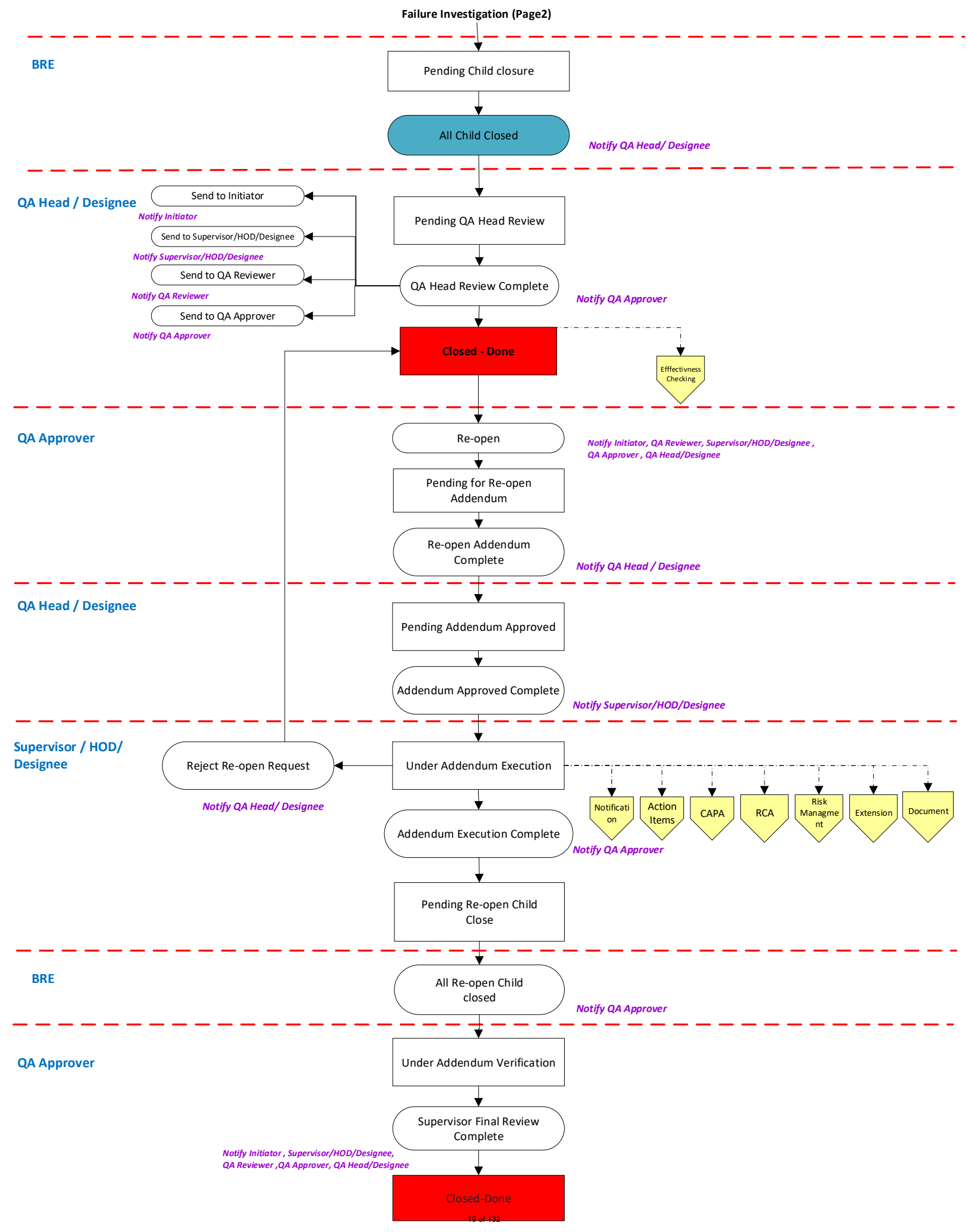
Non-Conformance (Page1)




Non-Conformance(Page2)
BRE
Pending Child closure
All Child Closed
Notify QA Head/ Designee
QA Head / Designee
Send to Initiator
Notify Initiator
Send to Supervisor/HOD/Designee
Notify Supervisor/HOD/Designee
Send to QA Reviewer
Notify QA Reviewer
Send to QA Approver
Notify QA Approver
Pending QA Head Review
QA Head Review Complete
Notify QA Approver
Closed - Done
Efffectivness Checking
QA Approver
Re-open
Notify Initiator, QA Reviewer, Supervisor/HOD/Designee , QA Approver , QA Head/Designee
Pending for Re-open Addendum
Re-open Addendum Complete
Notify QA Head / Designee
QA Head / Designee
Pending Addendum Approved
Addendum Approved Complete
Notify Supervisor/HOD/Designee
Supervisor / HOD/ Designee
Reject Re-open Request
Notify QA Head/ Designee
Under Addendum Execution
Notificati on
Action Items
CAPA
RCA
Risk Managme nt
Extension
Document
Addendum Execution Complete
Notify QA Approver
Pending Re-open Child Close
BRE
All Re-open Child closed
Notify QA Approver
QA Approver
Under Addendum Verification
Supervisor Final Review Complete
Notify Initiator , Supervisor/HOD/Designee, QA Reviewer ,QA Approver, QA Head/Designee
Closed-Done

Failure Investigation (Page1)




Failure Investigation (Page2)
BRE
Pending Child closure
All Child Closed
Notify QA Head/ Designee
QA Head / Designee
Send to Initiator
Notify Initiator
Send to Supervisor/HOD/Designee
Notify Supervisor/HOD/Designee
Send to QA Reviewer
Notify QA Reviewer
Send to QA Approver
Notify QA Approver
Pending QA Head Review
QA Head Review Complete
Notify QA Approver
Closed - Done
Efffectivness Checking
QA Approver
Re-open
Notify Initiator, QA Reviewer, Supervisor/HOD/Designee , QA Approver , QA Head/Designee
Pending for Re-open Addendum
Re-open Addendum Complete
Notify QA Head / Designee
QA Head / Designee
Pending Addendum Approved
Addendum Approved Complete
Notify Supervisor/HOD/Designee
Supervisor / HOD/ Designee
Reject Re-open Request
Notify QA Head/ Designee
Under Addendum Execution
Notificati on
Action Items
CAPA
RCA
Risk Managme nt
Extension
Document
Addendum Execution Complete
Notify QA Approver
Pending Re-open Child Close
BRE
All Re-open Child closed
Notify QA Approver
QA Approver
Under Addendum Verification
Supervisor Final Review Complete
Notify Initiator , Supervisor/HOD/Designee, QA Reviewer ,QA Approver, QA Head/Designee
Closed-Done

Change Control

Compliance Task

From Help Desk

From CAPA

Originator

Opened

Submit

Notify Supervisor/HOD

Supervisor/HOD

More Info Required SR

Notify Originator

Impact/Risk Analysis

Cancel SR

Closed – Cancelled

Complete Analysis

Notify QA Reveiwer

QA Reveiwer

More Info Required SR

Notify Originator

Quality Review Complete

Cancel SR

Closed – Cancelled

Complete Analysis

Notify Implementer

Implementer

Pending Change Plan

Complete Change Plan

Notify CFT/SME

Action Items

New Document/ Document Revision

Due Date Extension

CFT/SME

Parallel Approval

Pending Plan Approval

Reject Change Plan SR

Notify Implementer

*The following are potential **Optional** approvals:* Sponsor, Mfg, Tech Services, Validation, Regulatory, Quality, Documentation, IT

*The following are potential **Mandatory** approvals: QA/RA*

Notify QA Head

QA Head/ Designee

Pending QA Plan Approval

QA Plan Approval

Business Rule Engine

Pending Change

All Actions Completed

Notify Quality

Quality

Reject Actions SR

Notify Action Owner

Pending QA Approval

QA Approval

Closed – Done

Efffectiveness Check

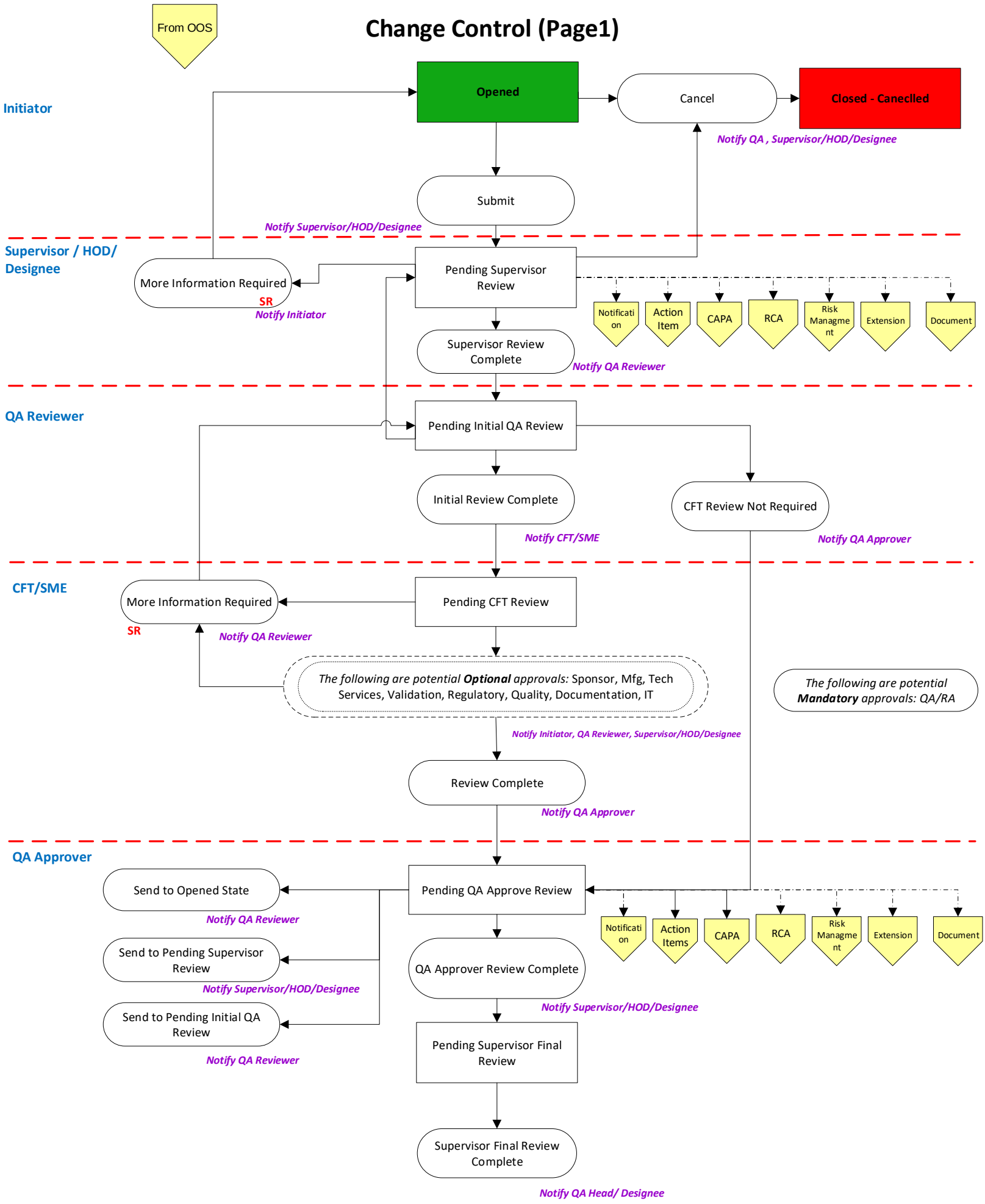
Re-Open for Addendum SR

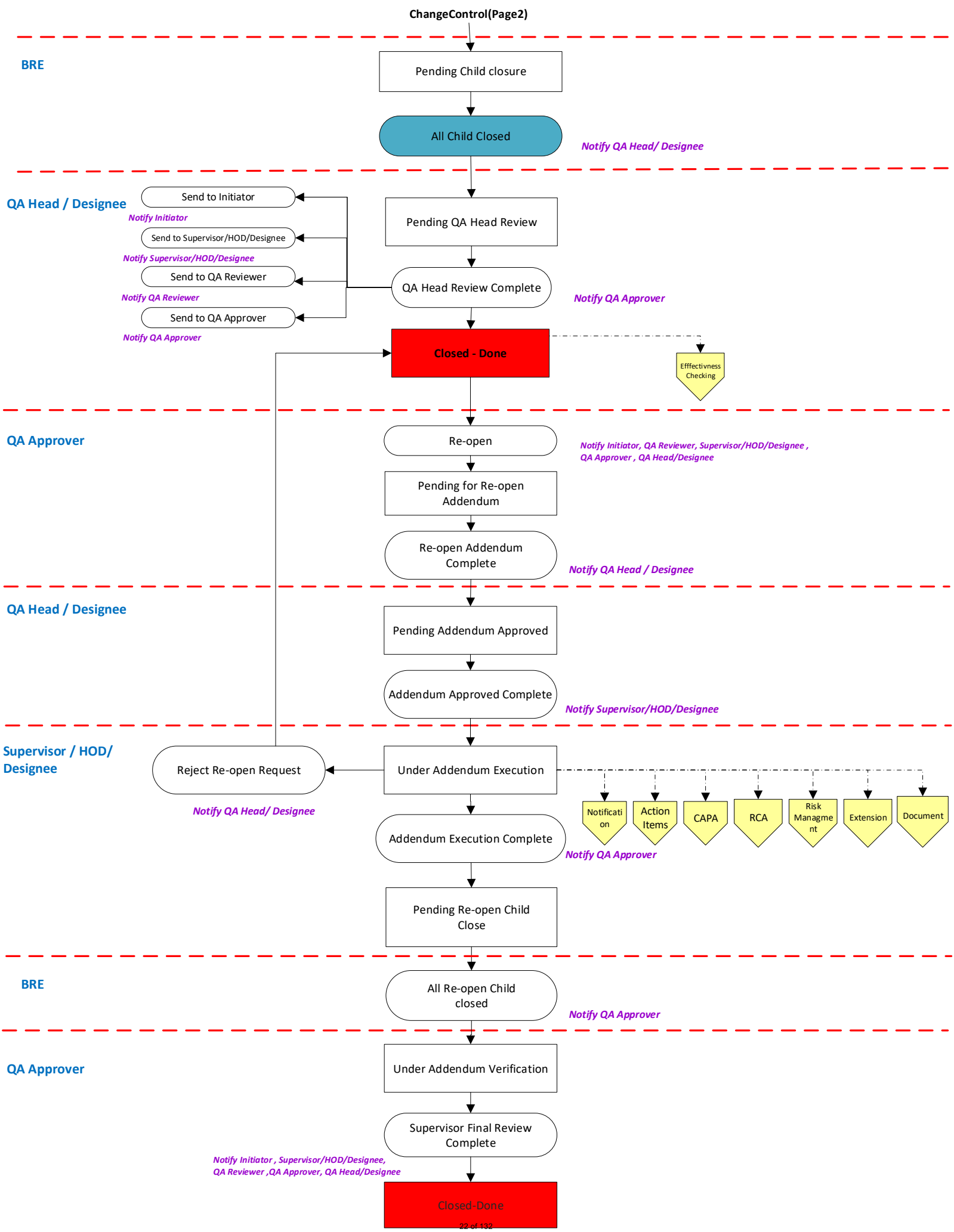
Pending For Addendum

Addendum Complete

Quality Reviewer, Supervisor, Assignee, Originator

Change Control (Page1)




ChangeControl(Page2)
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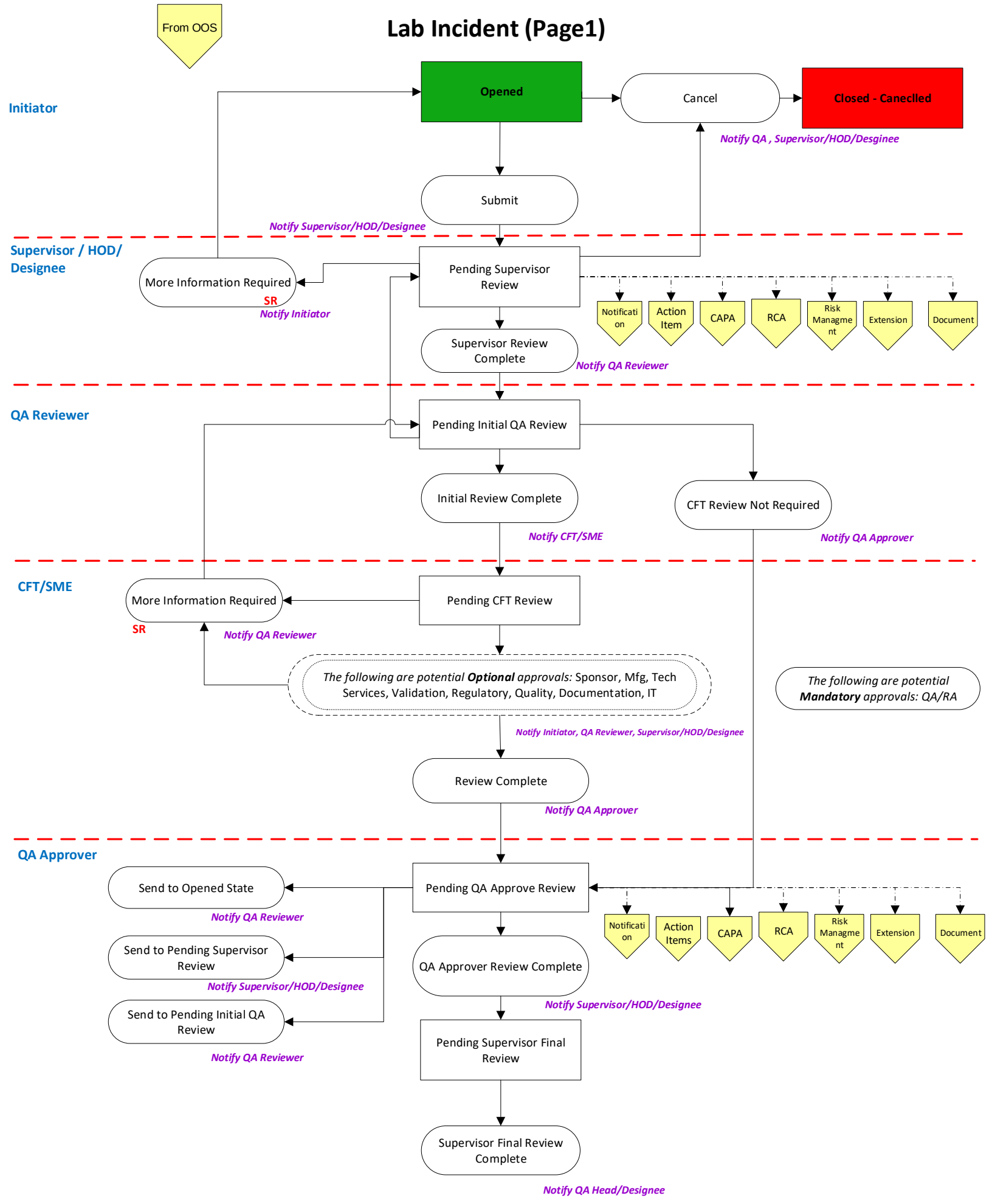
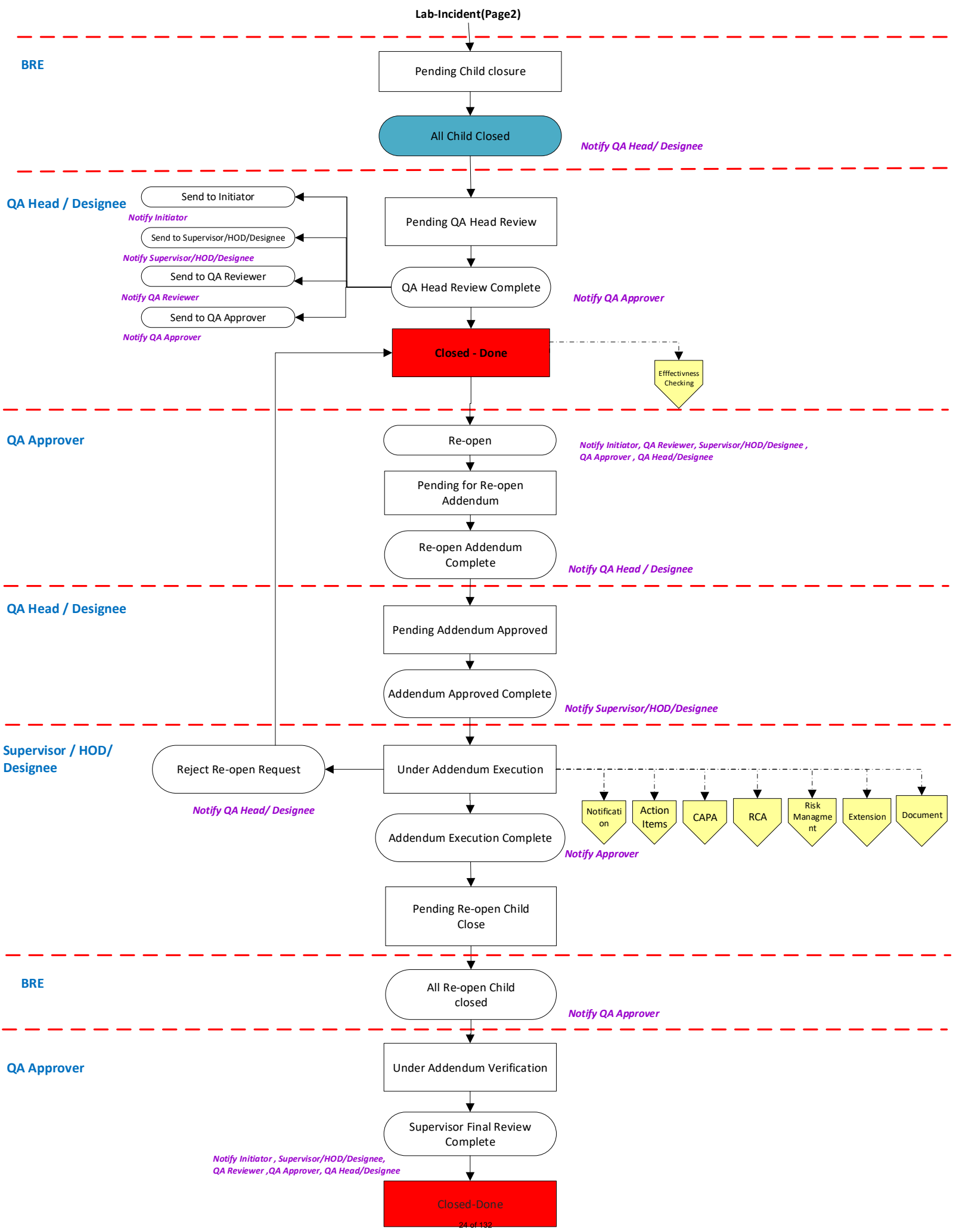
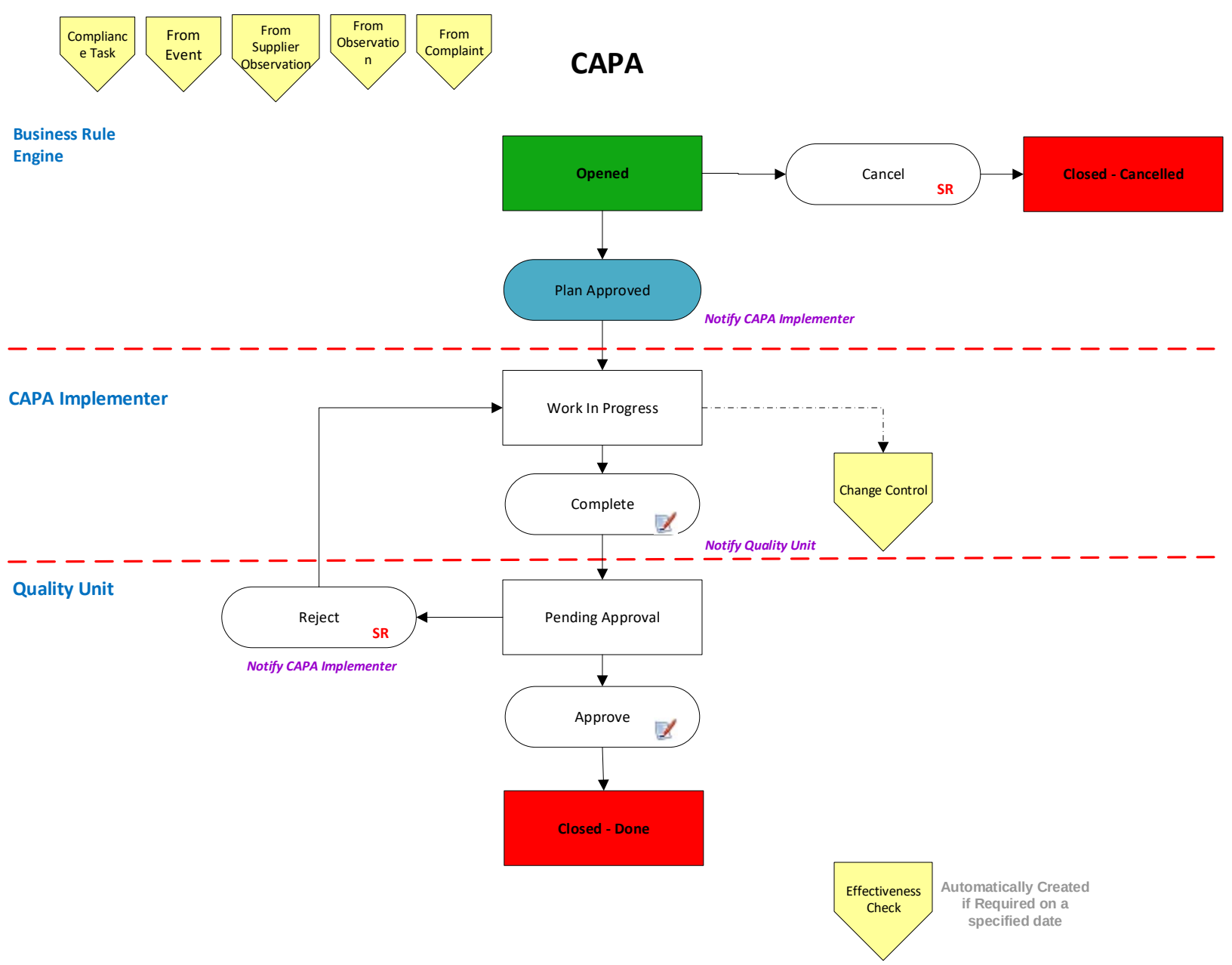
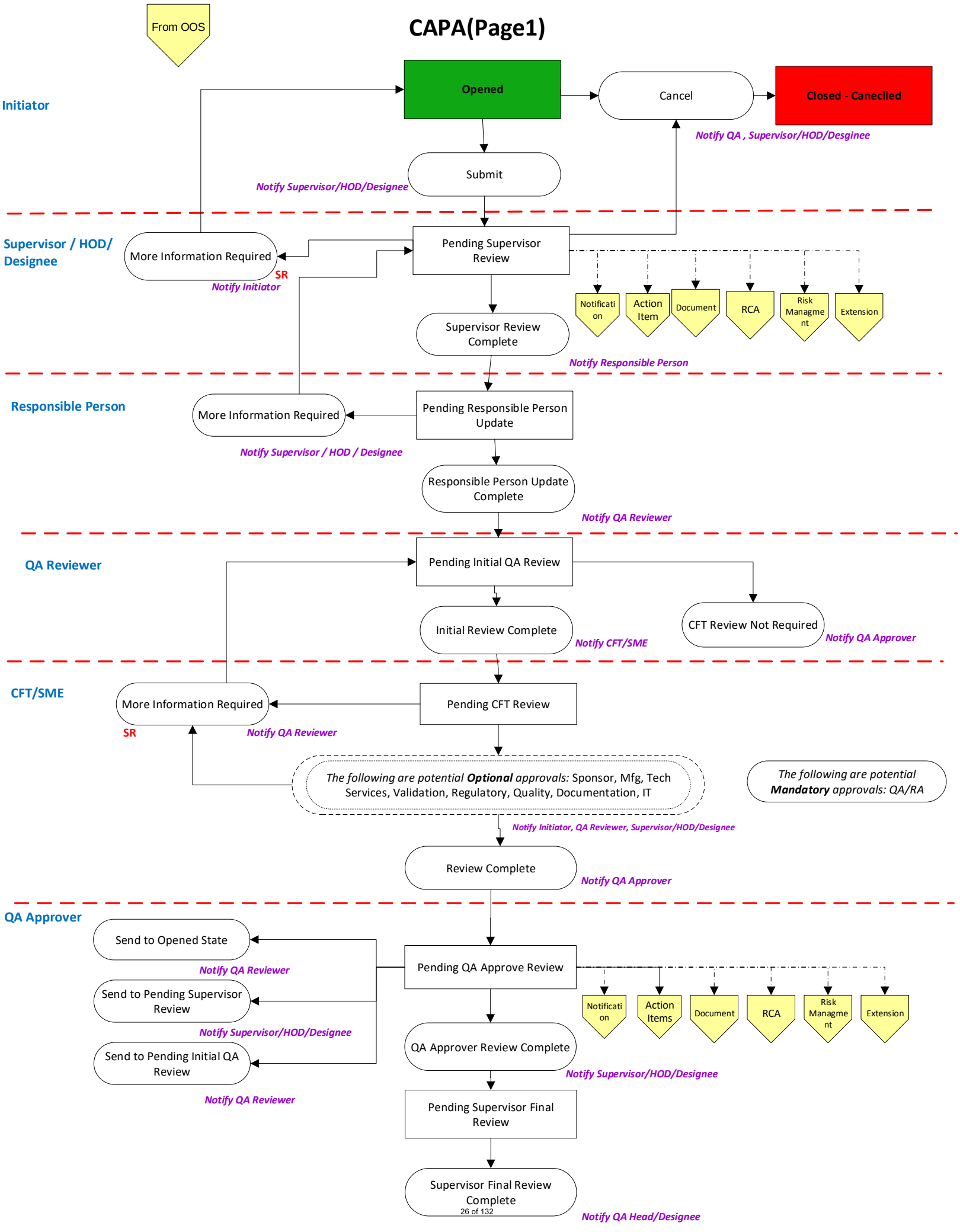
Pending Child closure
All Child Closed
Notify QA Head/ Designee
QA Head / Designee
Send to Initiator
Notify Initiator
Send to Supervisor/HOD/Designee
Notify Supervisor/HOD/Designee
Send to QA Reviewer
Notify QA Reviewer
Send to QA Approver
Notify QA Approver
Pending QA Head Review
QA Head Review Complete
Notify QA Approver
Closed - Done
Efffectivness Checking
QA Approver
Re-open
Notify Initiator, QA Reviewer, Supervisor/HOD/Designee , QA Approver , QA Head/Designee
Pending for Re-open Addendum
Re-open Addendum Complete
Notify QA Head / Designee
QA Head / Designee
Pending Addendum Approved
Addendum Approved Complete
Notify Supervisor/HOD/Designee
Supervisor / HOD/ Designee
Reject Re-open Request
Notify QA Head/ Designee
Under Addendum Execution
Notificati on
Action Items
CAPA
RCA
Risk Managme nt
Extension
Document
Addendum Execution Complete
Notify QA Approver
Pending Re-open Child Close
BRE
All Re-open Child closed
Notify QA Approver
QA Approver
Under Addendum Verification
Supervisor Final Review Complete
Notify Initiator , Supervisor/HOD/Designee, QA Reviewer ,QA Approver, QA Head/Designee
Closed-Done

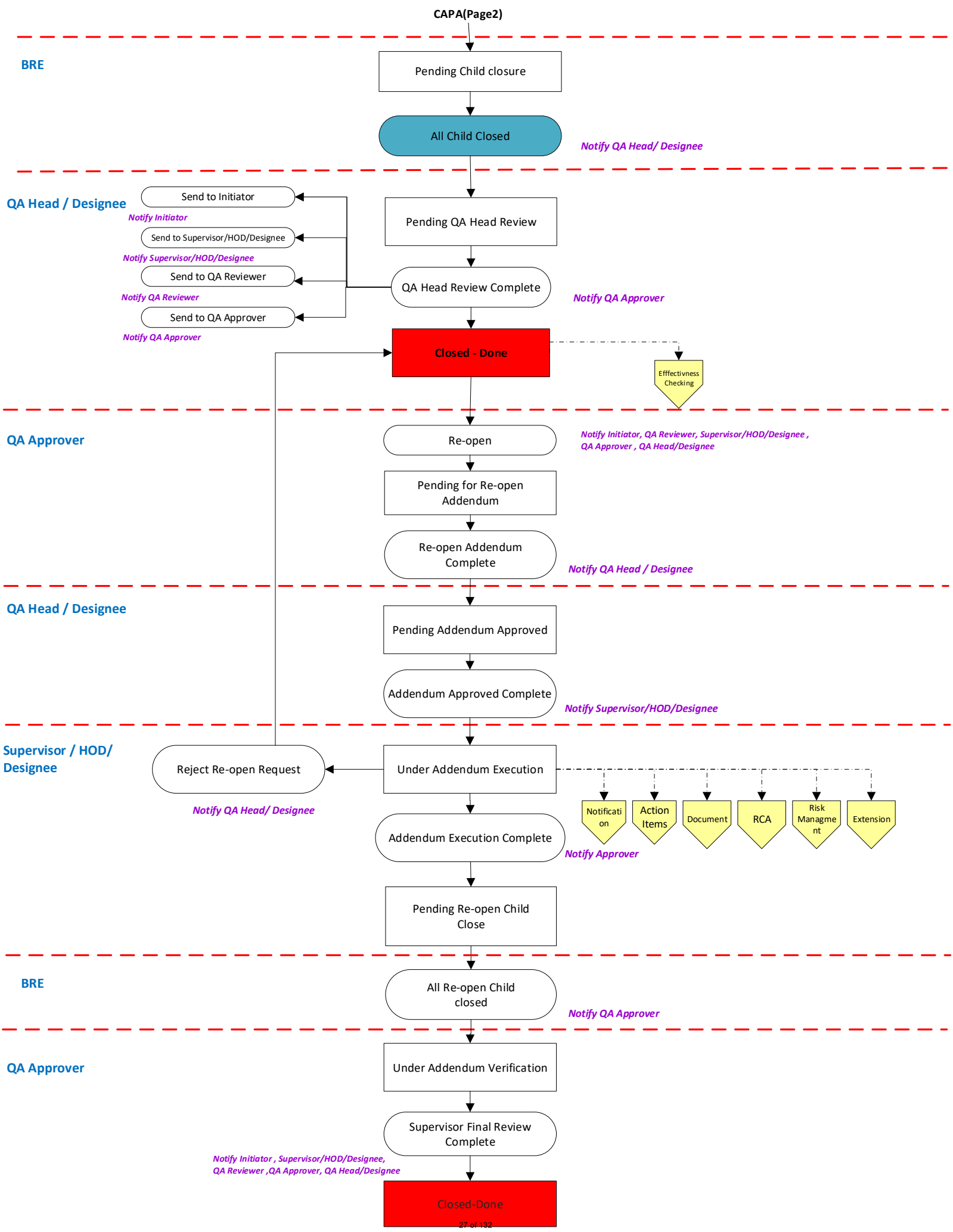
Lab Incident (Page1)



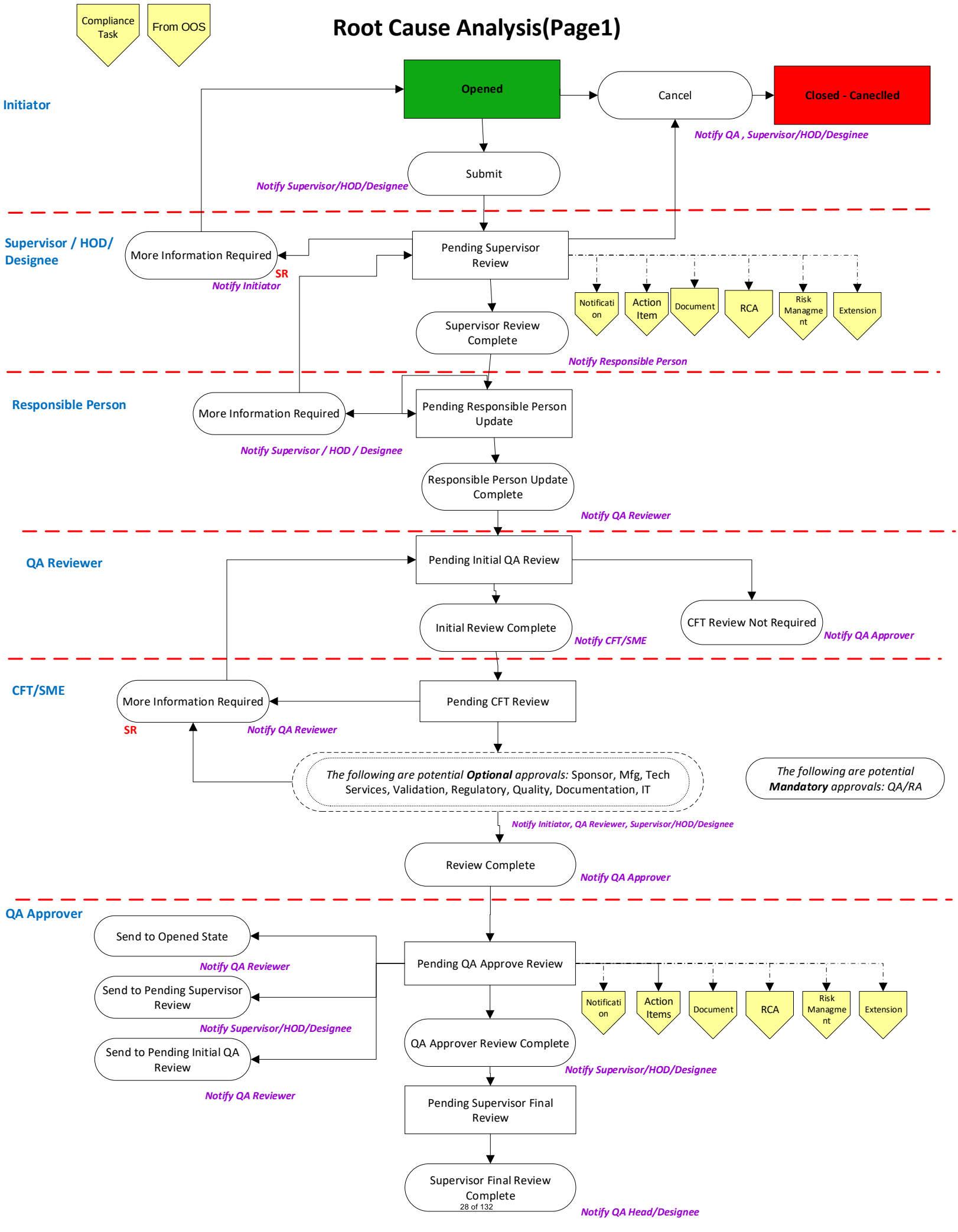

Lab-Incident(Page2)
BRE
Pending Child closure
All Child Closed
Notify QA Head/ Designee
QA Head / Designee
Send to Initiator
Notify Initiator
Send to Supervisor/HOD/Designee
Notify Supervisor/HOD/Designee
Send to QA Reviewer
Notify QA Reviewer
Send to QA Approver
Notify QA Approver
Pending QA Head Review
QA Head Review Complete
Notify QA Approver
Closed - Done
Efffectivness Checking
QA Approver
Re-open
Notify Initiator, QA Reviewer, Supervisor/HOD/Designee , QA Approver , QA Head/Designee
Pending for Re-open Addendum
Re-open Addendum Complete
Notify QA Head / Designee
QA Head / Designee
Pending Addendum Approved
Addendum Approved Complete
Notify Supervisor/HOD/Designee
Supervisor / HOD/ Designee
Reject Re-open Request
Notify QA Head/ Designee
Under Addendum Execution
Notificati on
Action Items
CAPA
RCA
Risk Managme nt
Extension
Document
Addendum Execution Complete
Notify Approver
Pending Re-open Child Close
BRE
All Re-open Child closed
Notify QA Approver
QA Approver
Under Addendum Verification
Supervisor Final Review Complete
Notify Initiator , Supervisor/HOD/Designee, QA Reviewer ,QA Approver, QA Head/Designee
Closed-Done

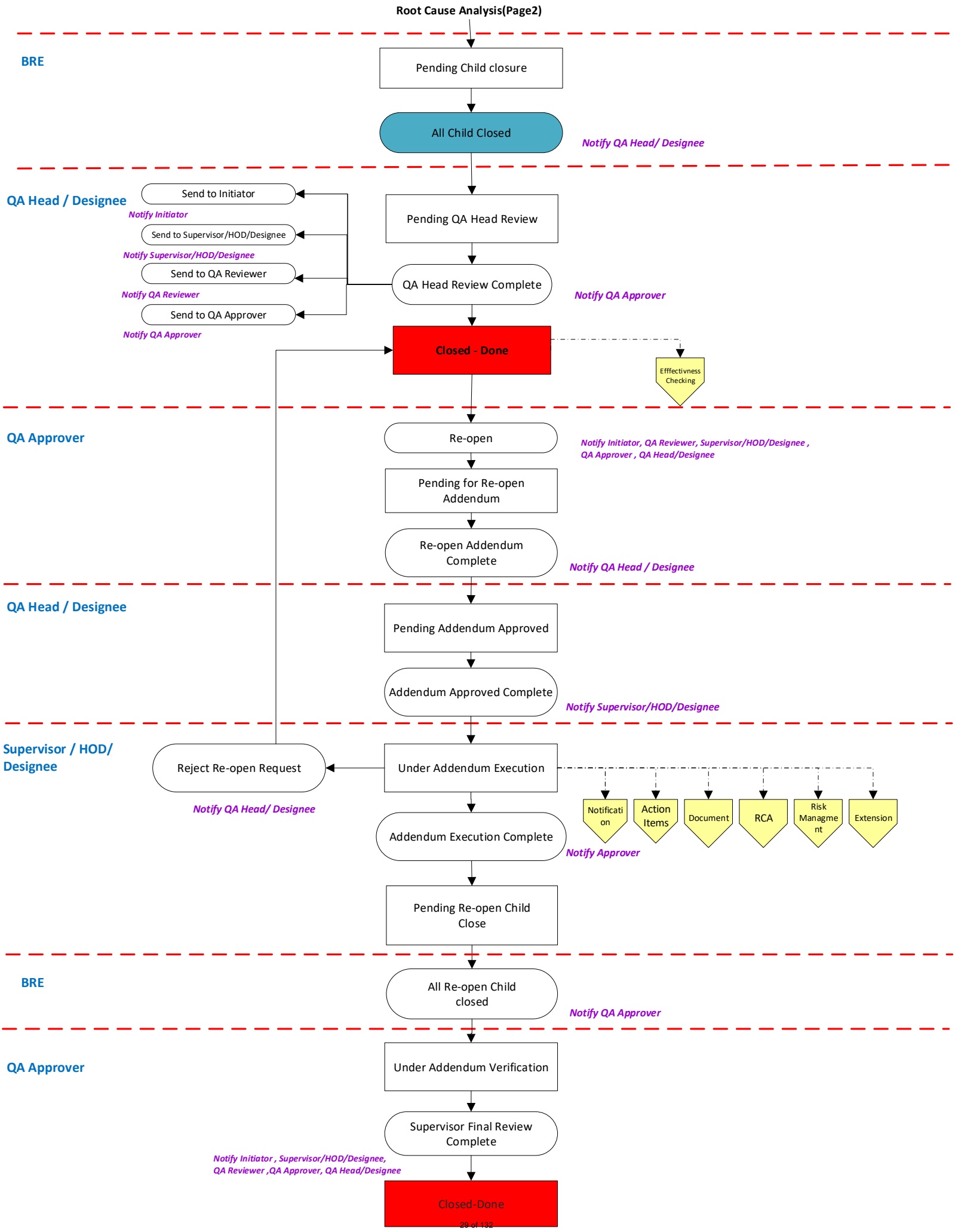

Compliance Task
From Event
From Supplier Observation
From Observation
From Complaint
CAPA
Business Rule Engine
Opened
Cancel
SR
Closed - Cancelled
Plan Approved
Notify CAPA Implementer
CAPA Implementer
Work In Progress
Change Control
Complete
Notify Quality Unit
Quality Unit
Reject
SR
Notify CAPA Implementer
Pending Approval
Approve
Closed - Done
Effectiveness Check
Automatically Created if Required on a specified date


From OOS
CAPA(Page1)
Initiator
Opened
Cancel
Closed - Caneclled
Notify QA , Supervisor/HOD/Desginee
Submit
Notify Supervisor/HOD/Designee
Supervisor / HOD/ Designee
More Information Required
SR
Notify Initiator
Pending Supervisor Review
Notificati on
Action Item
Document
RCA
Risk Managme nt
Extension
Supervisor Review Complete
Notify Responsible Person
Responsible Person
More Information Required
Pending Responsible Person Update
Notify Supervisor / HOD / Designee
Responsible Person Update Complete
Notify QA Reviewer
QA Reviewer
Pending Initial QA Review
Initial Review Complete
Notify CFT/SME
CFT Review Not Required
Notify QA Approver
CFT/SME
More Information Required
SR
Notify QA Reviewer
Pending CFT Review
The following are potential Optional approvals: Sponsor, Mfg, Tech Services, Validation, Regulatory, Quality, Documentation, IT
The following are potential Mandatory approvals: QA/RA
Notify Initiator, QA Reviewer, Supervisor/HOD/Designee
Review Complete
Notify QA Approver
QA Approver
Send to Opened State
Notify QA Reviewer
Send to Pending Supervisor Review
Notify Supervisor/HOD/Designee
Send to Pending Initial QA Review
Notify QA Reviewer
Pending QA Approve Review
Notificati on
Action Items
Document
RCA
Risk Managme nt
Extension
QA Approver Review Complete
Notify Supervisor/HOD/Designee
Pending Supervisor Final Review
Supervisor Final Review Complete
Notify QA Head/Designee

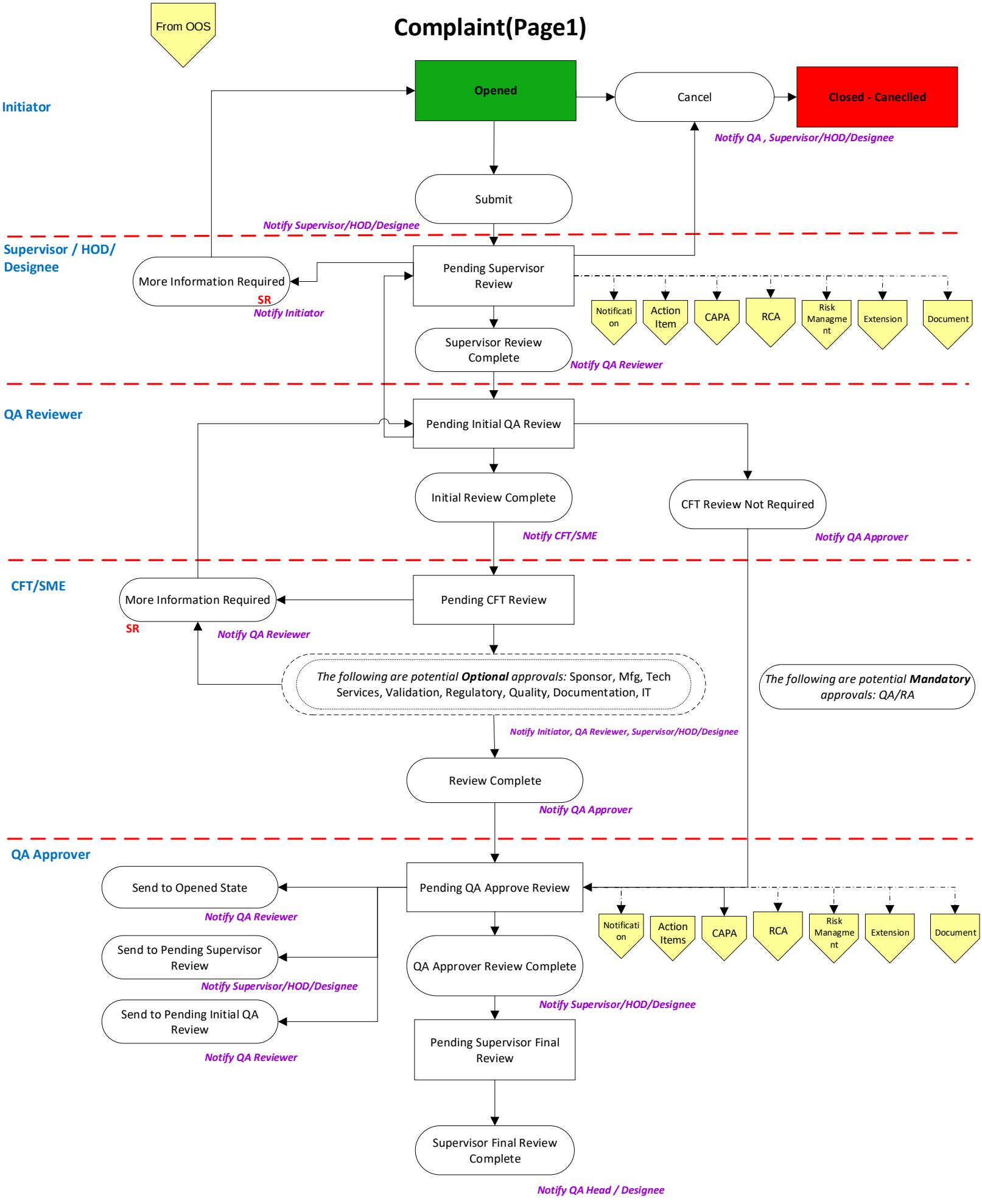

CAPA(Page2)
BRE
Pending Child closure
All Child Closed
Notify QA Head/ Designee
QA Head / Designee
Send to Initiator
Notify Initiator
Send to Supervisor/HOD/Designee
Notify Supervisor/HOD/Designee
Send to QA Reviewer
Notify QA Reviewer
Send to QA Approver
Notify QA Approver
Pending QA Head Review
QA Head Review Complete
Notify QA Approver
Closed - Done
Efffectivness Checking
QA Approver
Re-open
Notify Initiator, QA Reviewer, Supervisor/HOD/Designee , QA Approver , QA Head/Designee
Pending for Re-open Addendum
Re-open Addendum Complete
Notify QA Head / Designee
QA Head / Designee
Pending Addendum Approved
Addendum Approved Complete
Notify Supervisor/HOD/Designee
Supervisor / HOD/ Designee
Reject Re-open Request
Notify QA Head/ Designee
Under Addendum Execution
Notificati on
Action Items
Document
RCA
Risk Managme nt
Extension
Addendum Execution Complete
Notify Approver
Pending Re-open Child Close
BRE
All Re-open Child closed
Notify QA Approver
QA Approver
Under Addendum Verification
Supervisor Final Review Complete
Notify Initiator , Supervisor/HOD/Designee, QA Reviewer ,QA Approver, QA Head/Designee
Closed-Done

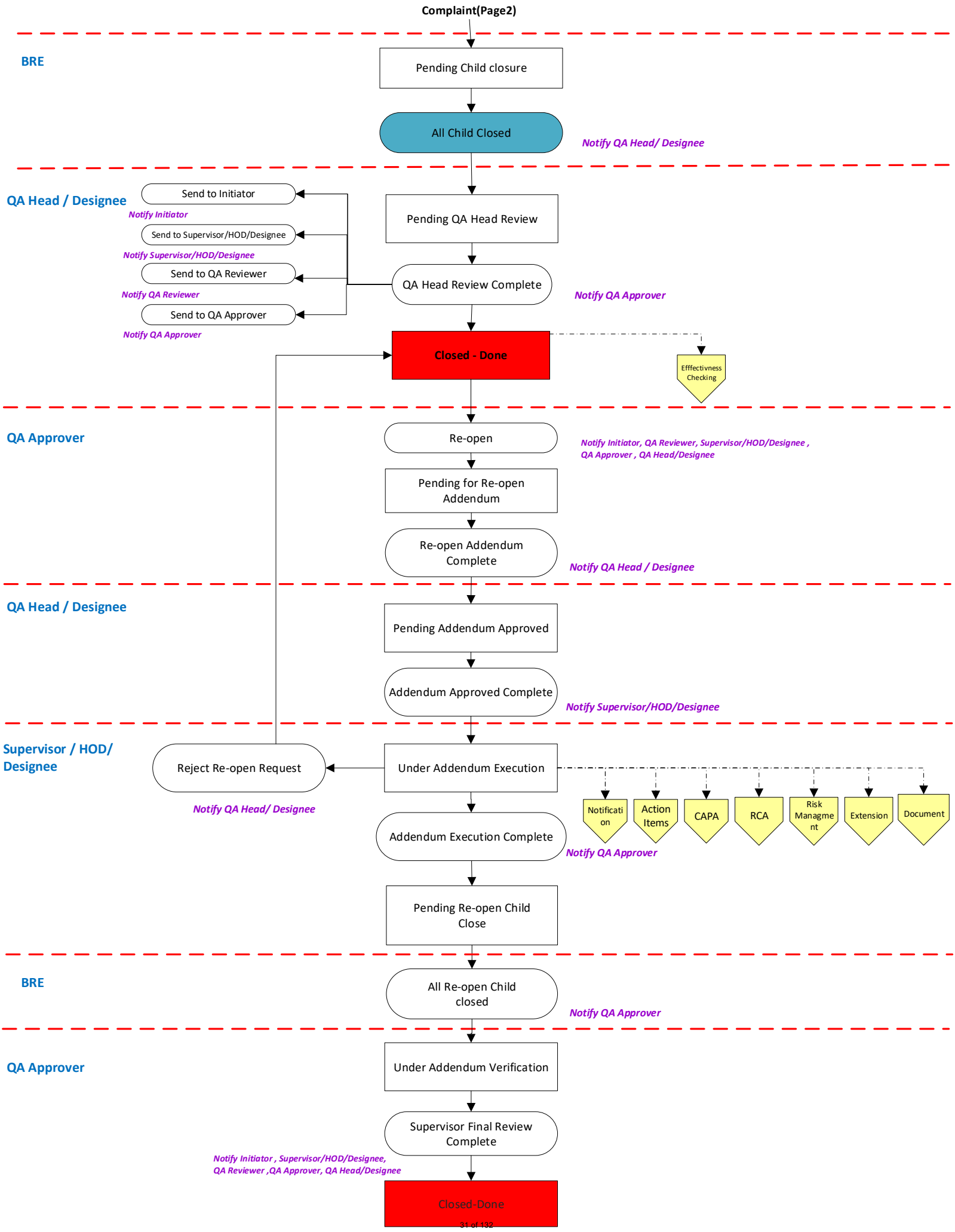
Root Cause Analysis(Page1)



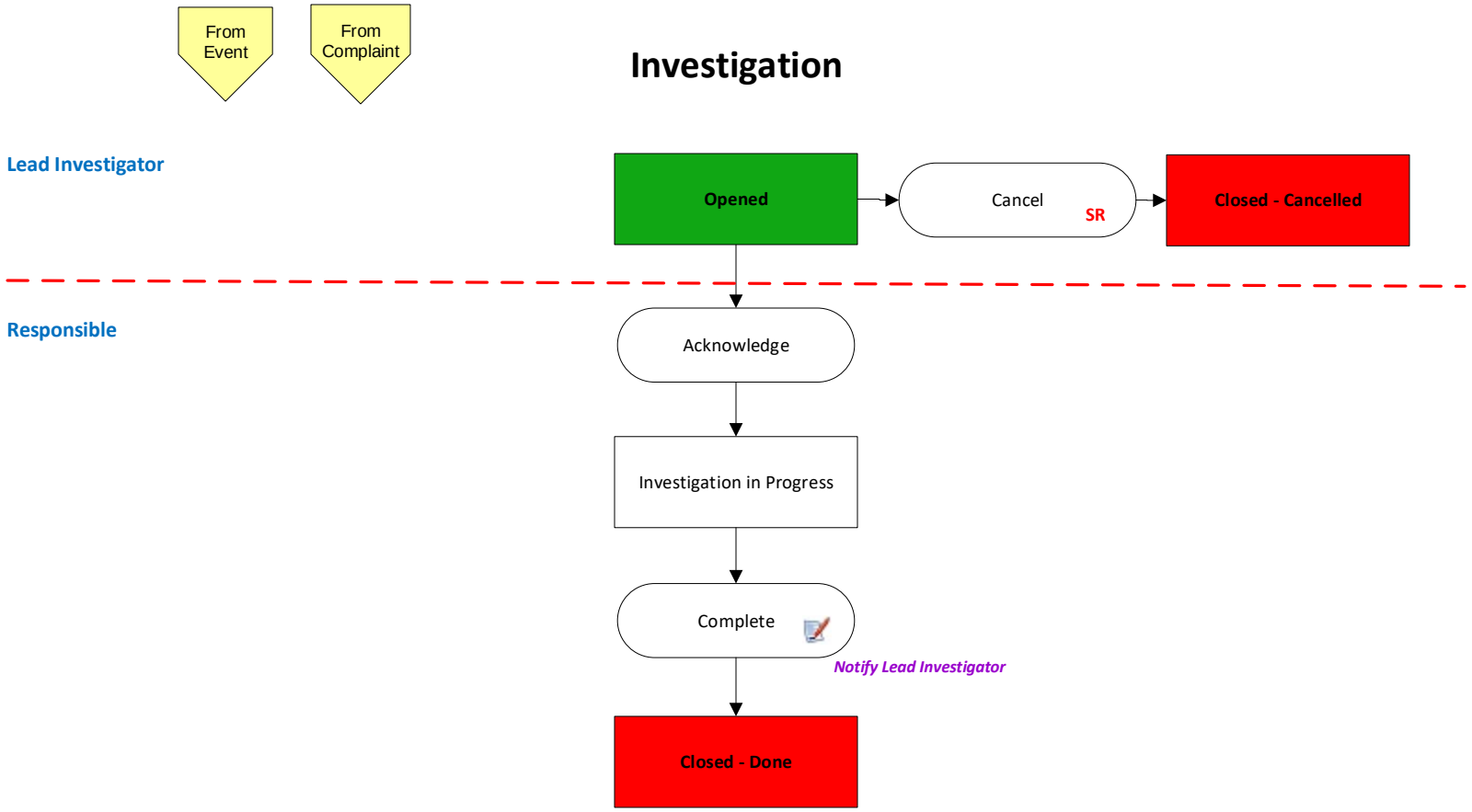

Root Cause Analysis(Page2)
BRE
Pending Child closure
All Child Closed
Notify QA Head/ Designee
QA Head / Designee
Send to Initiator
Notify Initiator
Send to Supervisor/HOD/Designee
Notify Supervisor/HOD/Designee
Send to QA Reviewer
Notify QA Reviewer
Send to QA Approver
Notify QA Approver
Pending QA Head Review
QA Head Review Complete
Notify QA Approver
Closed - Done
Efffectivness Checking
QA Approver
Re-open
Notify Initiator, QA Reviewer, Supervisor/HOD/Designee , QA Approver , QA Head/Designee
Pending for Re-open Addendum
Re-open Addendum Complete
Notify QA Head / Designee
QA Head / Designee
Pending Addendum Approved
Addendum Approved Complete
Notify Supervisor/HOD/Designee
Supervisor / HOD/ Designee
Reject Re-open Request
Notify QA Head/ Designee
Under Addendum Execution
Notificati on
Action Items
Document
RCA
Risk Managme nt
Extension
Addendum Execution Complete
Notify Approver
Pending Re-open Child Close
BRE
All Re-open Child closed
Notify QA Approver
QA Approver
Under Addendum Verification
Supervisor Final Review Complete
Notify Initiator , Supervisor/HOD/Designee, QA Reviewer ,QA Approver, QA Head/Designee
Closed-Done

Complaint(Page1)




Complaint(Page2)
BRE
Pending Child closure
All Child Closed
Notify QA Head/ Designee
QA Head / Designee
Send to Initiator
Notify Initiator
Send to Supervisor/HOD/Designee
Notify Supervisor/HOD/Designee
Send to QA Reviewer
Notify QA Reviewer
Send to QA Approver
Notify QA Approver
Pending QA Head Review
QA Head Review Complete
Notify QA Approver
Closed - Done
Efffectivness Checking
QA Approver
Re-open
Notify Initiator, QA Reviewer, Supervisor/HOD/Designee , QA Approver , QA Head/Designee
Pending for Re-open Addendum
Re-open Addendum Complete
Notify QA Head / Designee
QA Head / Designee
Pending Addendum Approved
Addendum Approved Complete
Notify Supervisor/HOD/Designee
Supervisor / HOD/ Designee
Reject Re-open Request
Notify QA Head/ Designee
Under Addendum Execution
Notificati on
Action Items
CAPA
RCA
Risk Managme nt
Extension
Document
Addendum Execution Complete
Notify QA Approver
Pending Re-open Child Close
BRE
All Re-open Child closed
Notify QA Approver
QA Approver
Under Addendum Verification
Supervisor Final Review Complete
Notify Initiator , Supervisor/HOD/Designee, QA Reviewer ,QA Approver, QA Head/Designee
Closed-Done

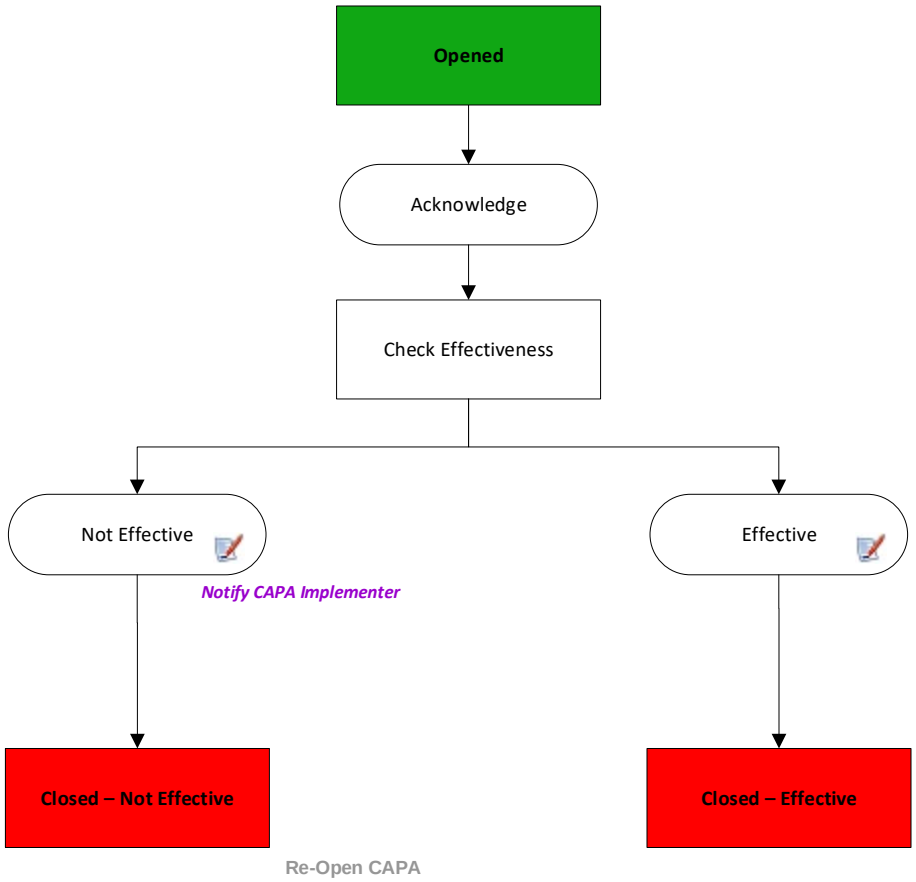
Investigation



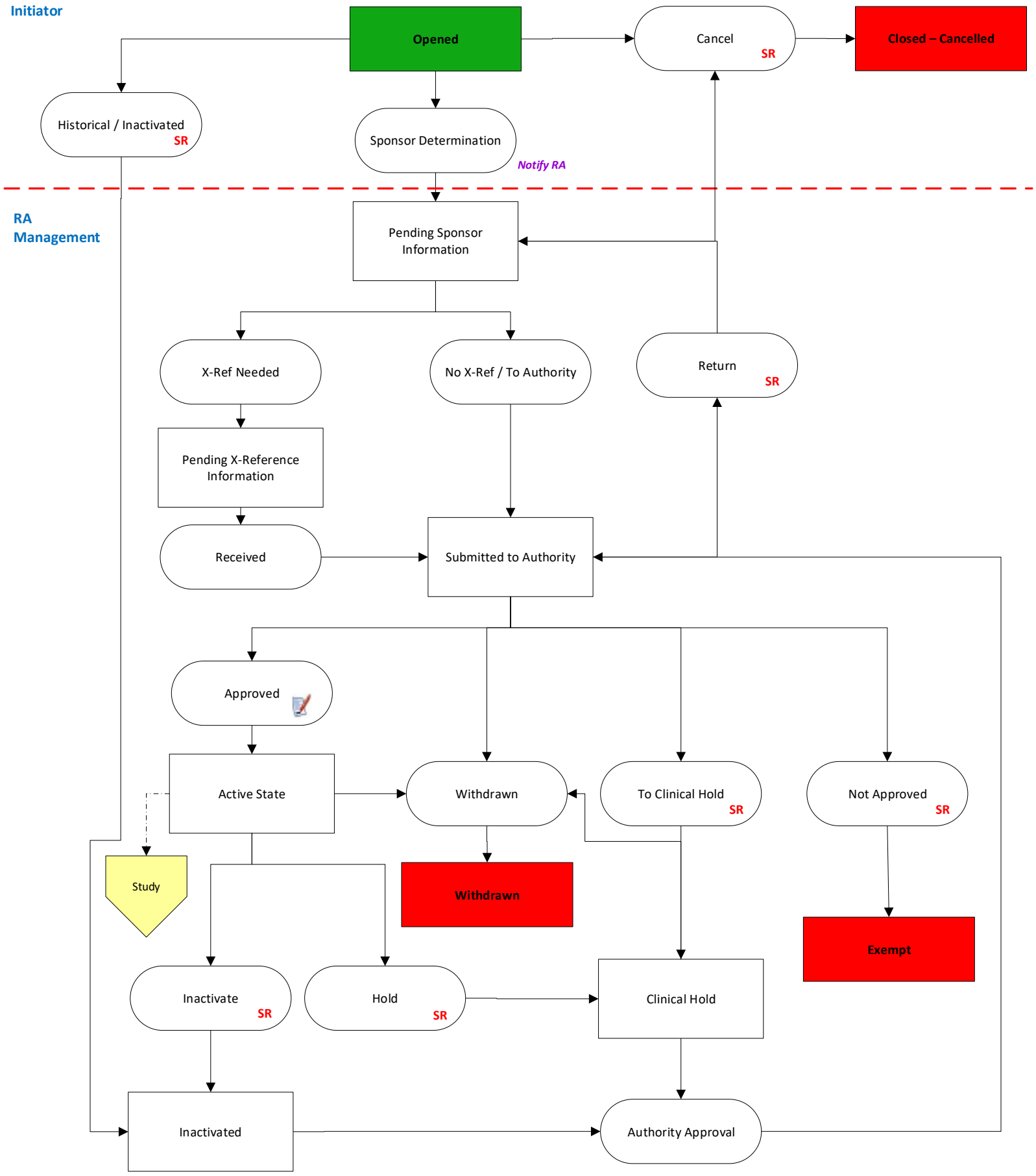
From CAPA

Effectiveness Check

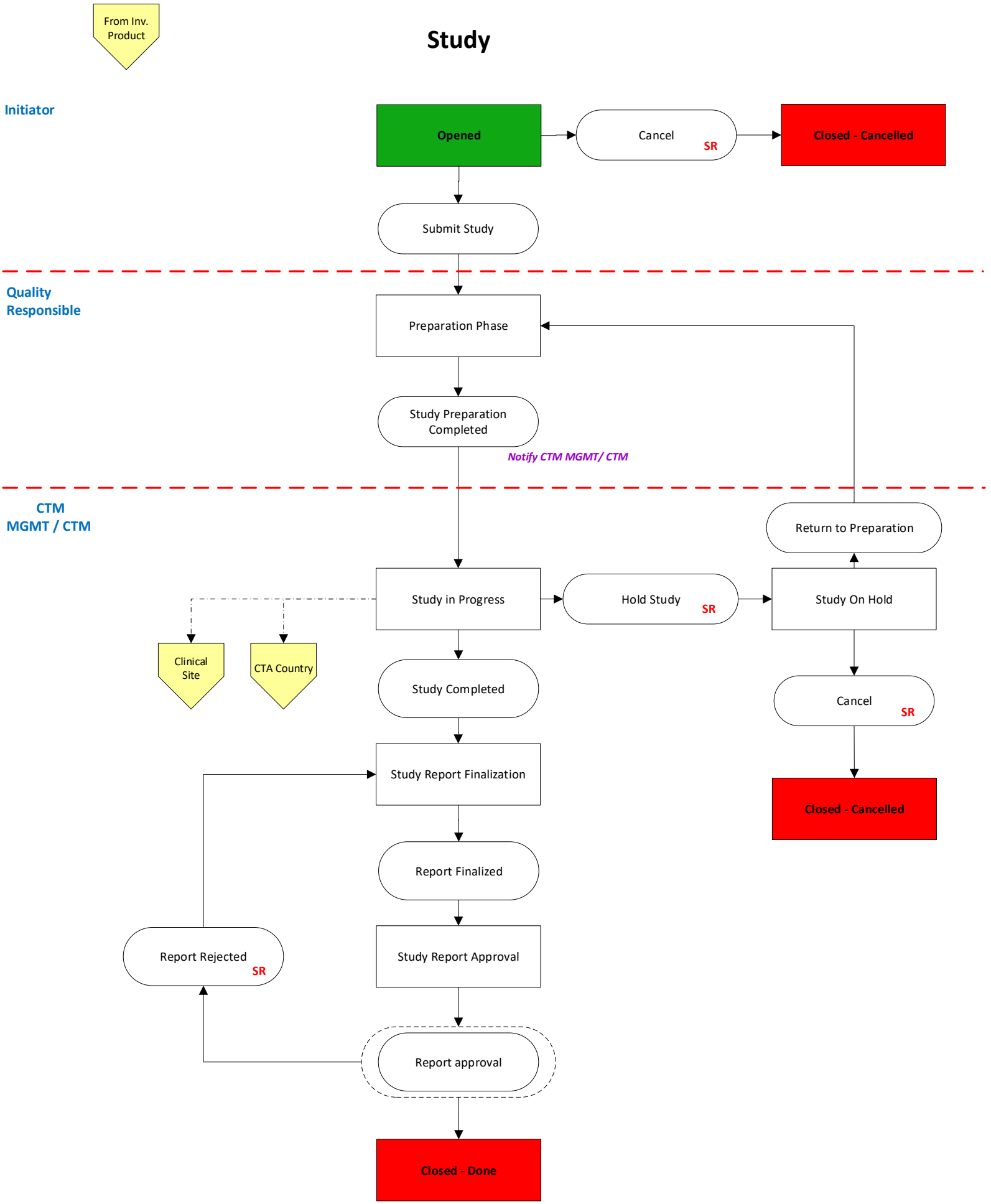
Responsible



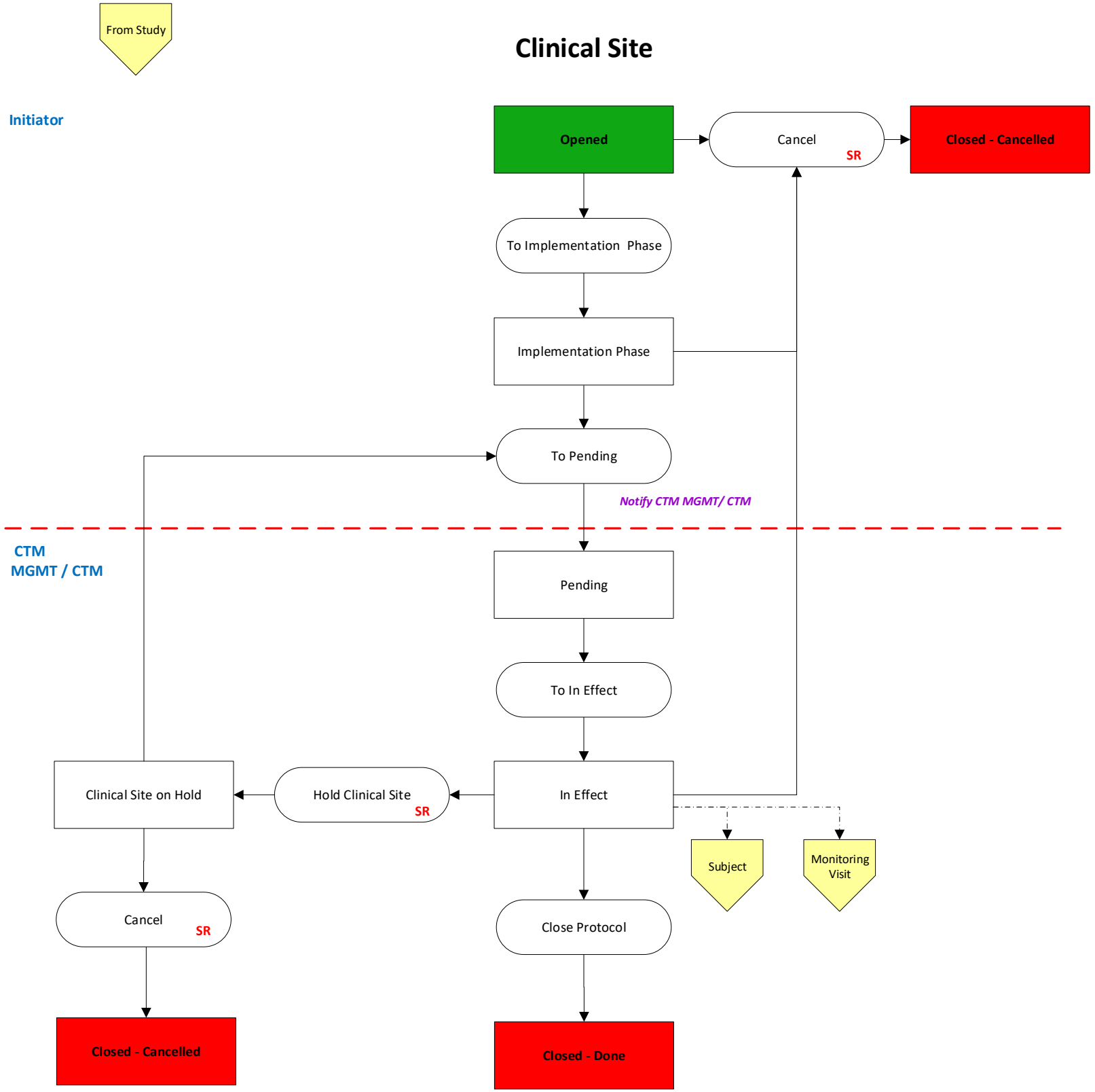
Investigational Product



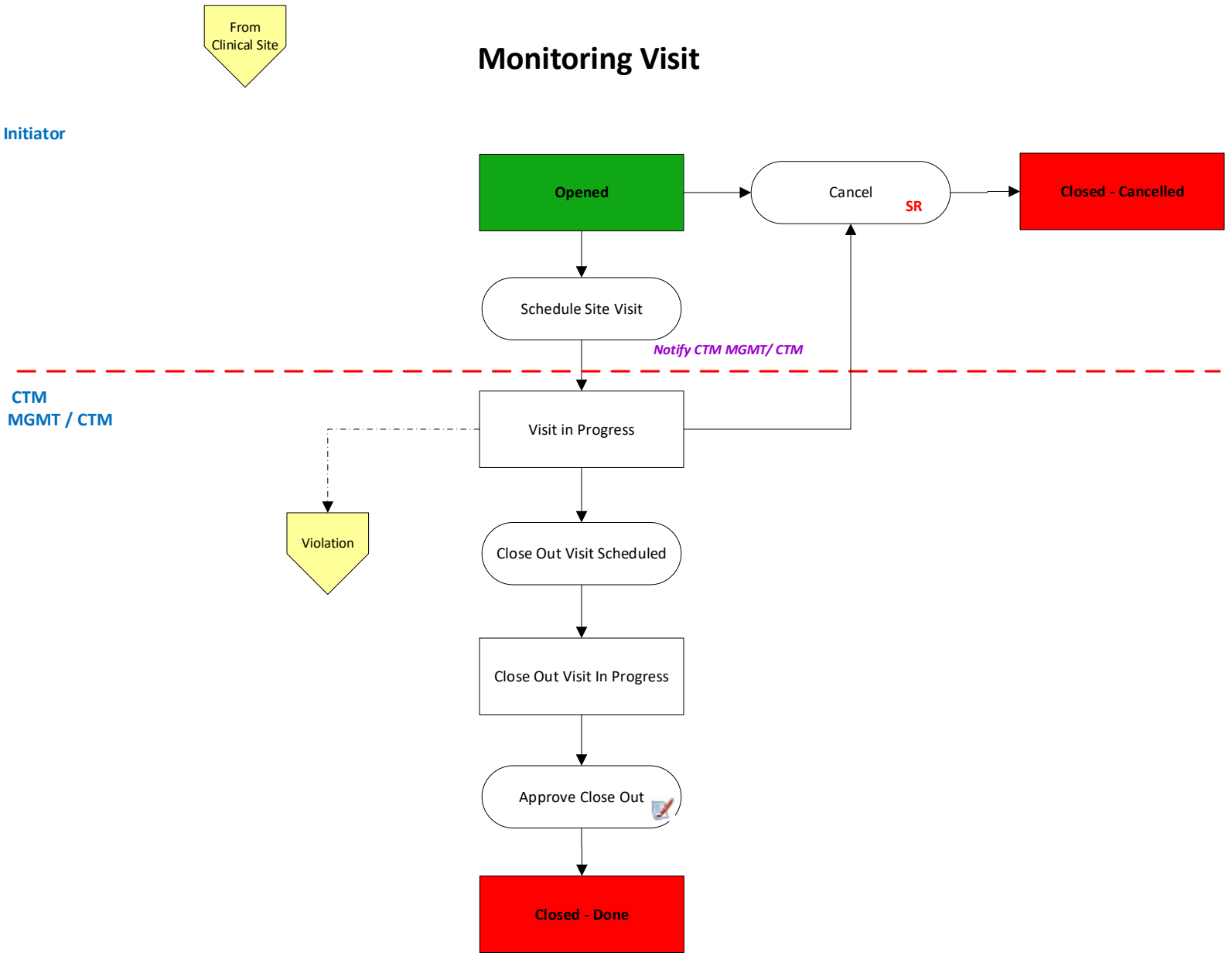
Study


From Inv. Product
Initiator
Opened
Cancel
SR
Closed - Cancelled
Submit Study
Quality Responsible
Preparation Phase
Study Preparation Completed
Notify CTM MGMT/ CTM
CTM MGMT / CTM
Return to Preparation
Study in Progress
Hold Study
SR
Study On Hold
Clinical Site
CTA Country
Study Completed
Cancel
SR
Study Report Finalization
Closed - Cancelled
Report Finalized
Report Rejected
SR
Study Report Approval
Report approval
Closed - Done

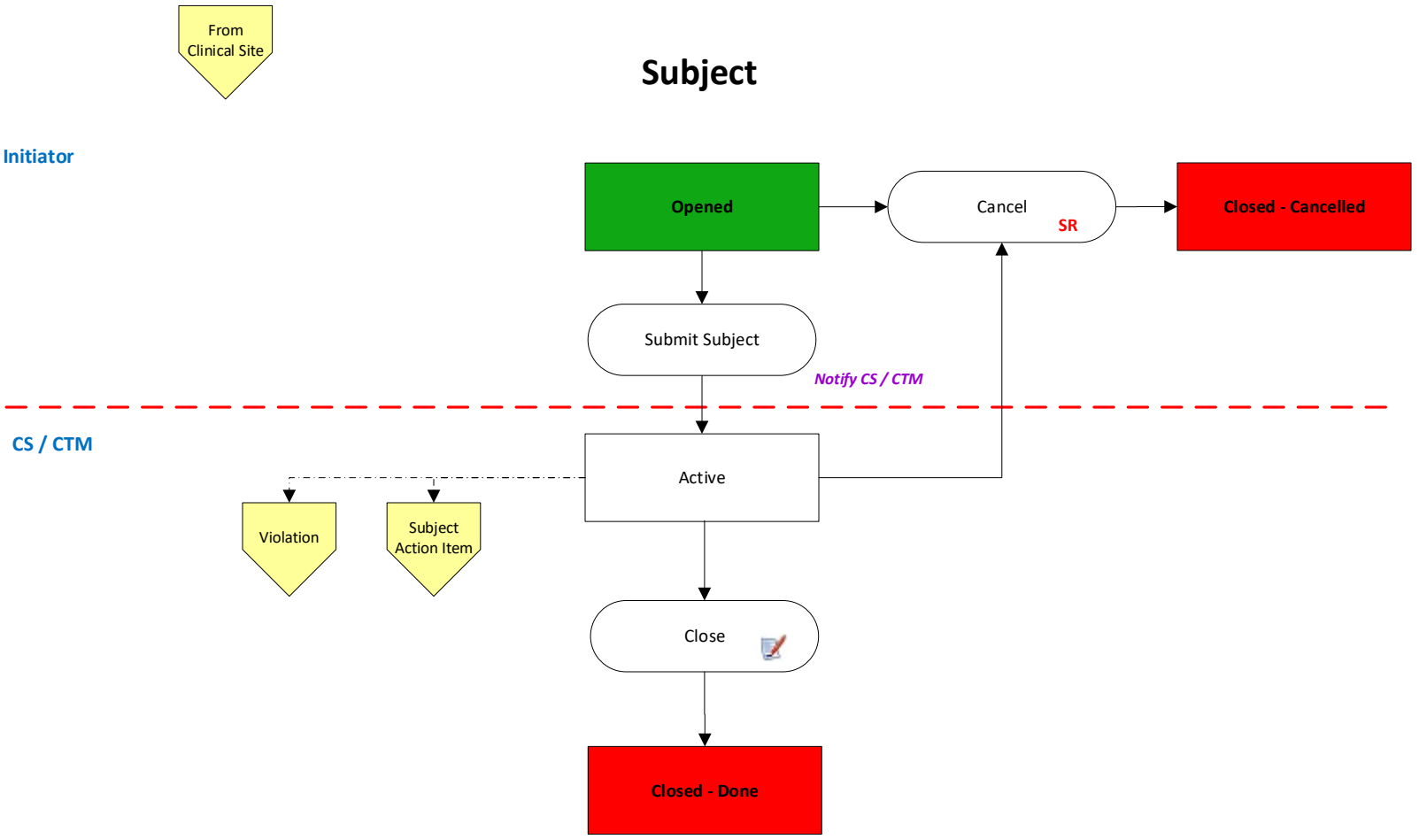
Clinical Site

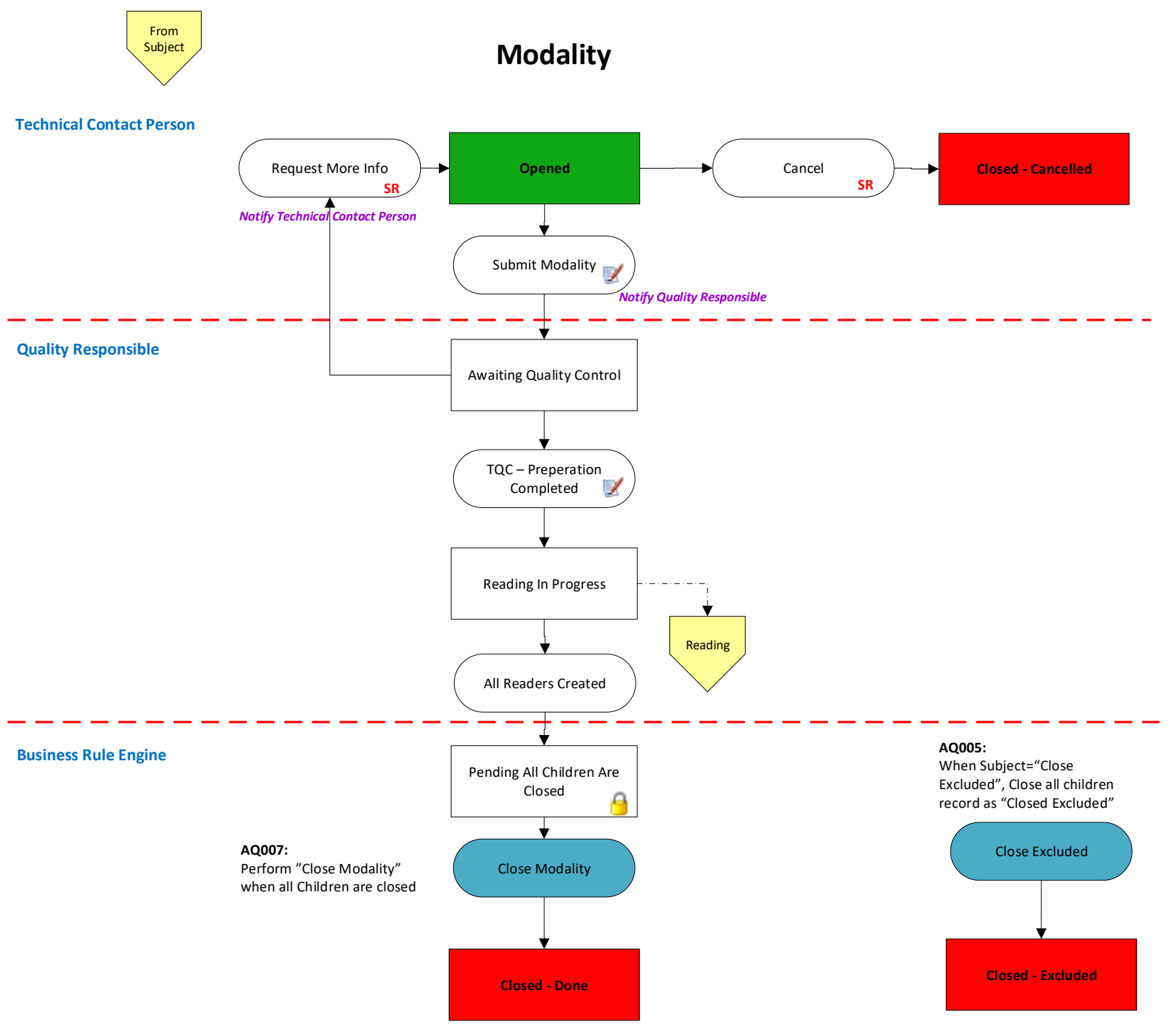


Monitoring Visit



Subject

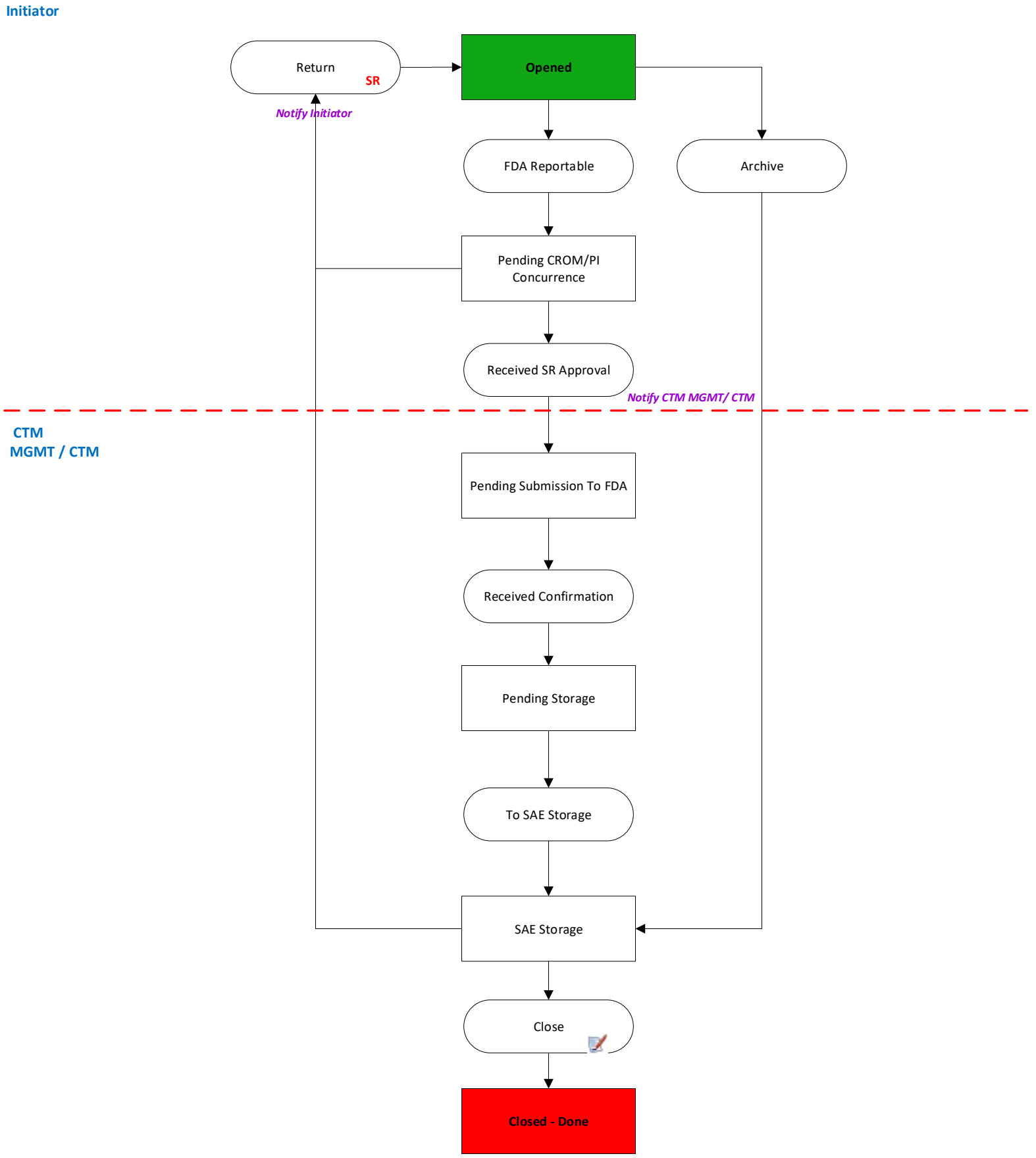

From Clinical Site
Initiator
Opened
Cancel
SR
Closed - Cancelled
Submit Subject
Notify CS / CTM
CS / CTM
Active
Violation
Subject Action Item
Close
Closed - Done



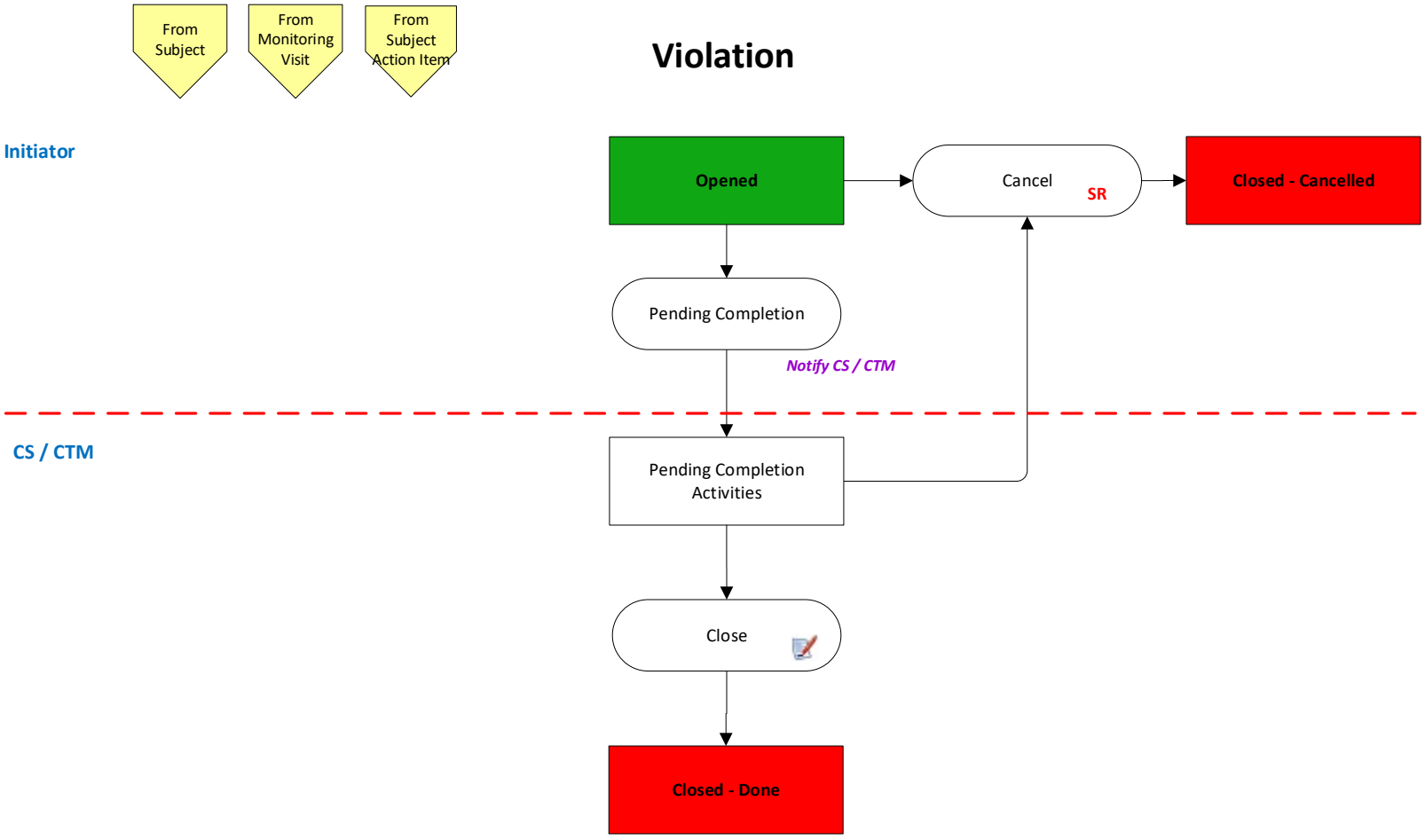
- Each time the ”Technical Contact Person” is changing, Sudy IRC Resposable will be notifyed
- Reports Ideas:
  - Randomization List Report: The list of all related ”Reader” processes to the ”Study” and thier ”randomization number”.
  - Create report that will display the Block and the list of readers processes related to him.
  - Create report that will display the Reader List and the amount of modalities they are dealing with)(all reader by reader name)
  - Create report that will display the Modality list and the amount of reader per modality.

From Subject Action Item

Serious Adverse Event

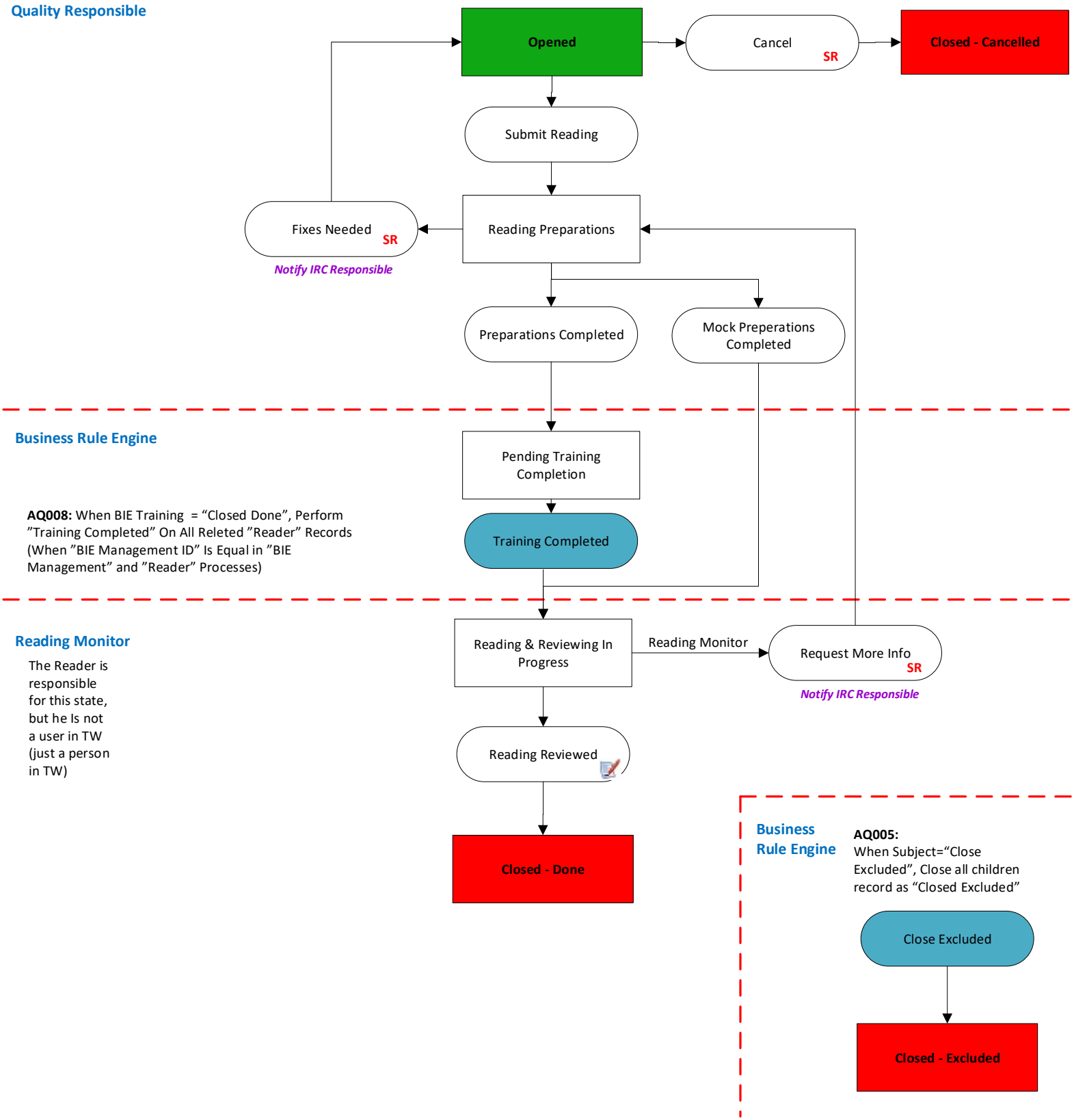


Violation


From Subject
From Monitoring Visit
From Subject Action Item
Initiator
Opened
Cancel
SR
Closed - Cancelled
Pending Completion
Notify CS / CTM
CS / CTM
Pending Completion Activities
Close
Closed - Done

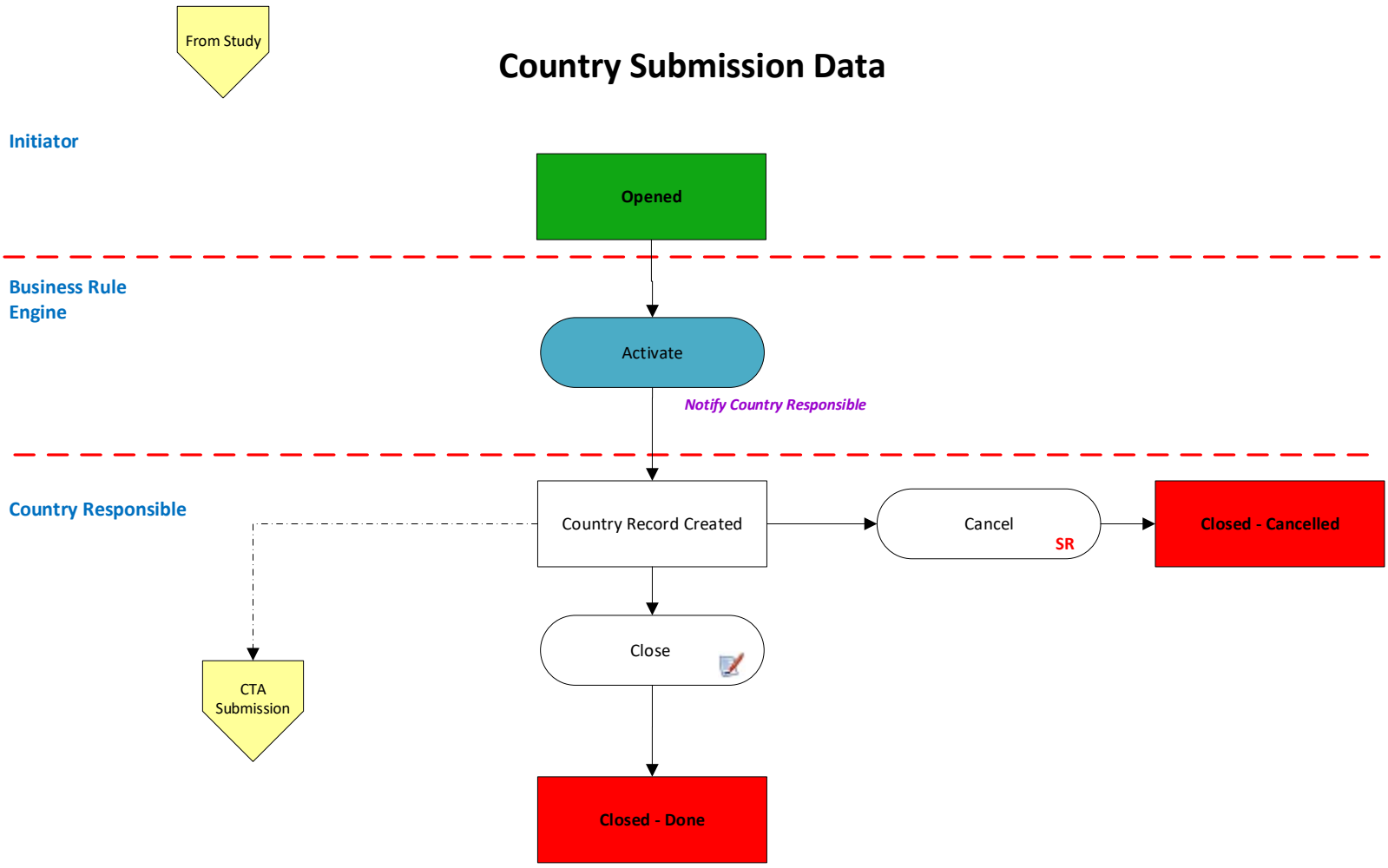
From Modality

Reading

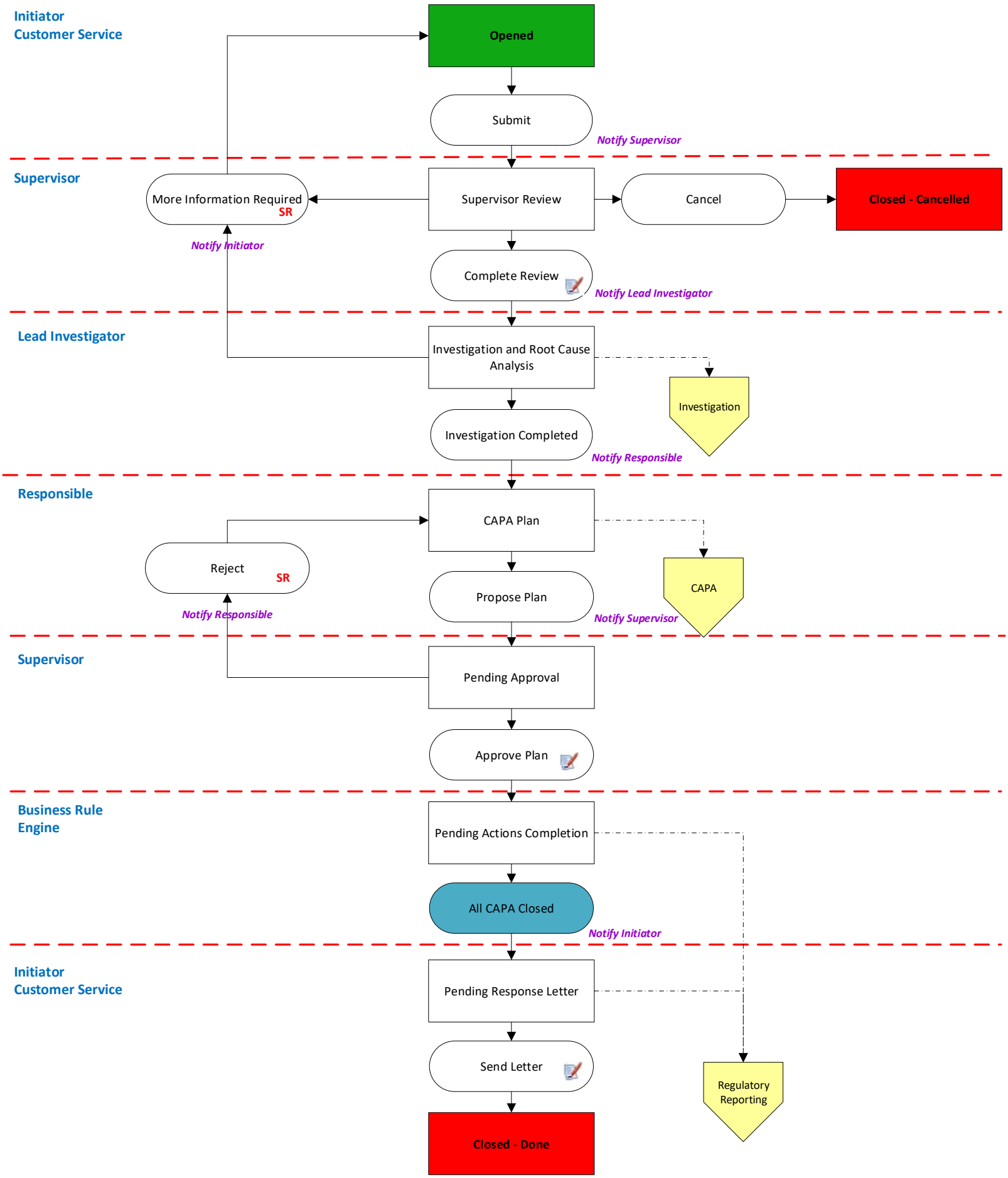


- The Study IRC Responsible will be able to reopen the Reader process

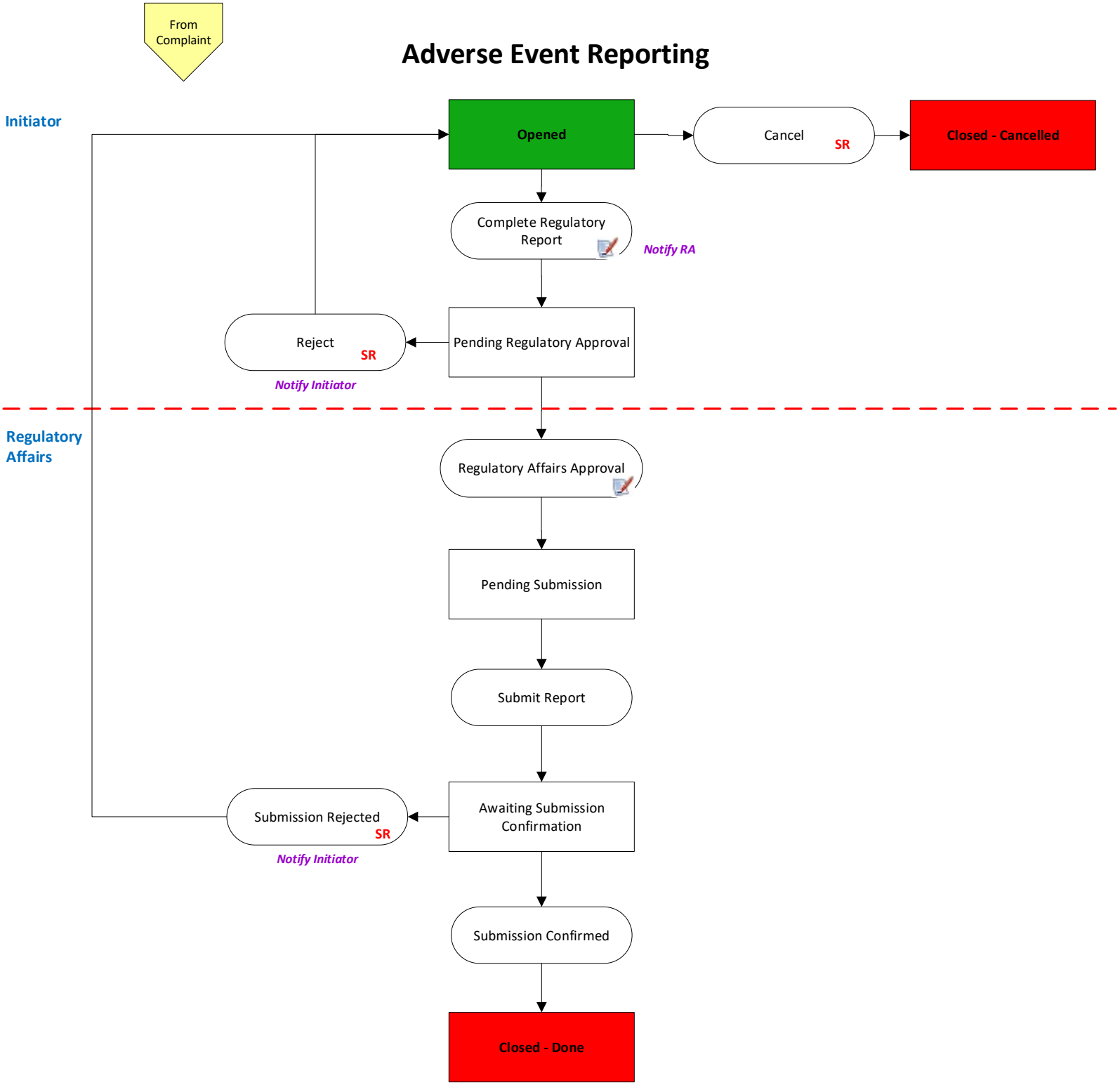
Country Submission Data



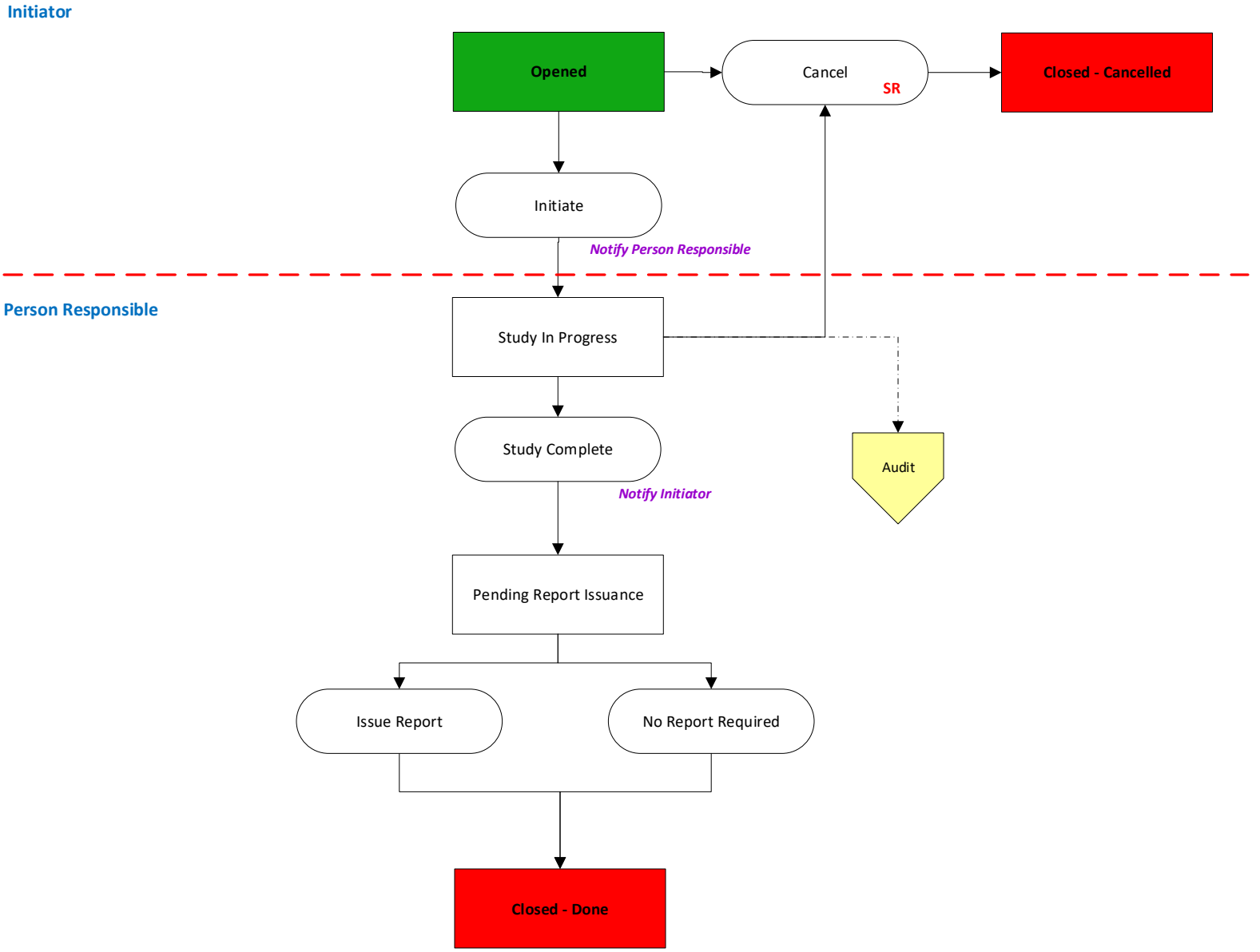
Complaint


Initiator
Customer Service
Opened
Submit
Notify Supervisor
Supervisor
More Information Required
SR
Notify Initiator
Supervisor Review
Cancel
Closed - Cancelled
Complete Review
Notify Lead Investigator
Lead Investigator
Investigation and Root Cause Analysis
Investigation
Investigation Completed
Notify Responsible
Responsible
CAPA Plan
Reject
SR
Notify Responsible
Propose Plan
CAPA
Notify Supervisor
Supervisor
Pending Approval
Approve Plan
Business Rule Engine
Pending Actions Completion
All CAPA Closed
Notify Initiator
Initiator
Customer Service
Pending Response Letter
Send Letter
Regulatory Reporting
Closed - Done

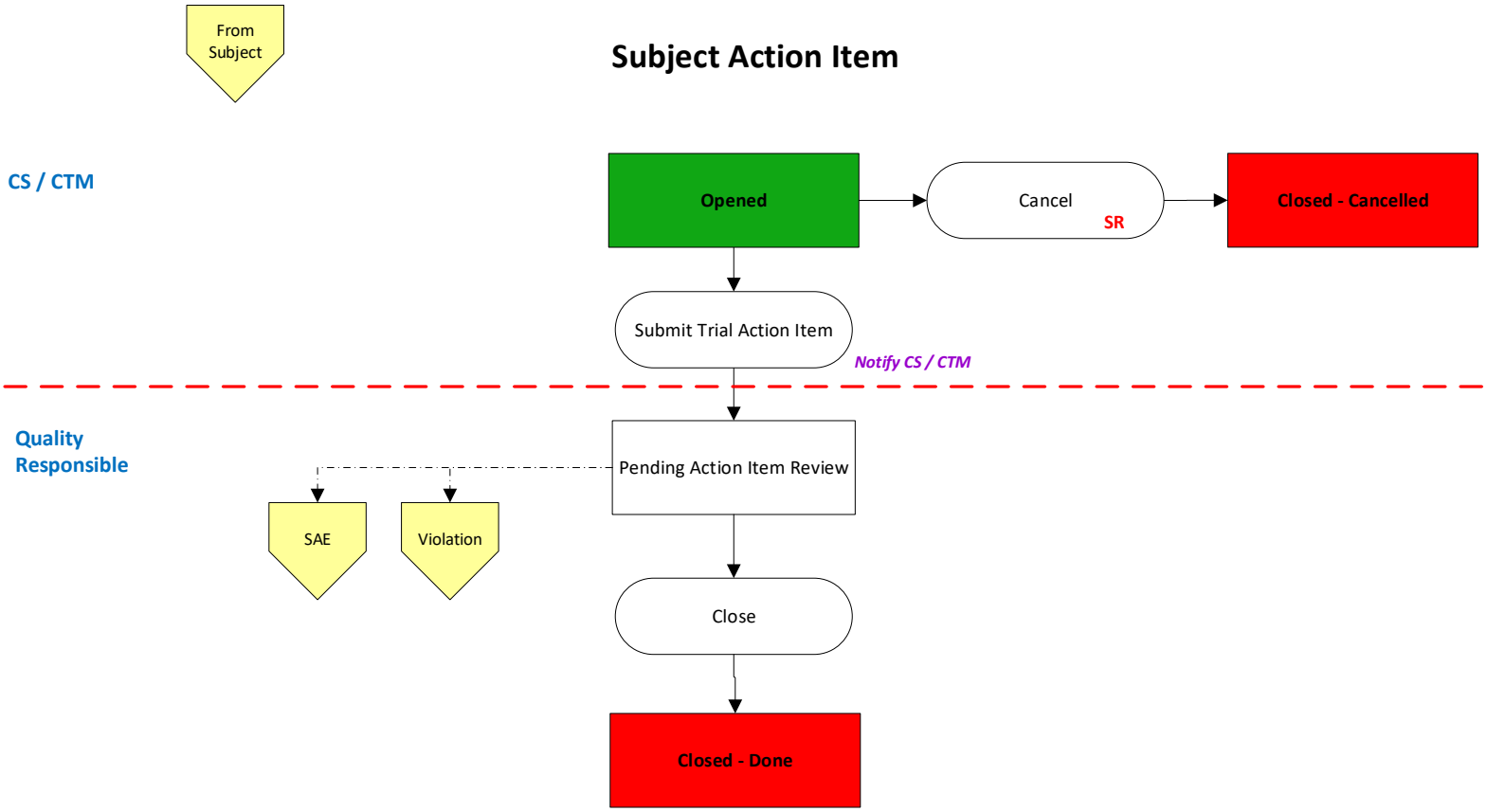
Adverse Event Reporting



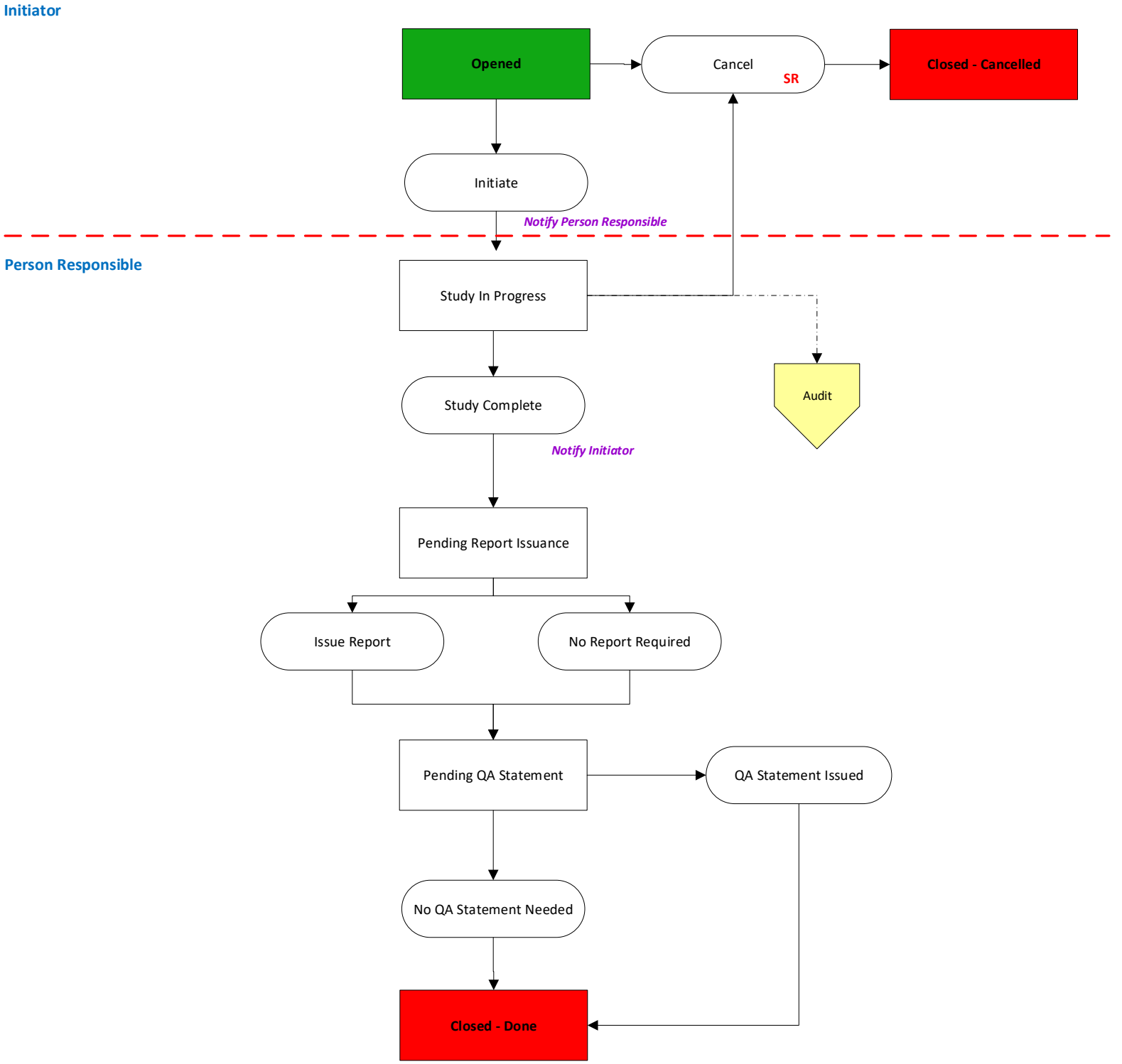
GCP Study


Initiator
Opened
Cancel
SR
Closed - Cancelled
Initiate
Notify Person Responsible
Person Responsible
Study In Progress
Study Complete
Audit
Notify Initiator
Pending Report Issuance
Issue Report
No Report Required
Closed - Done

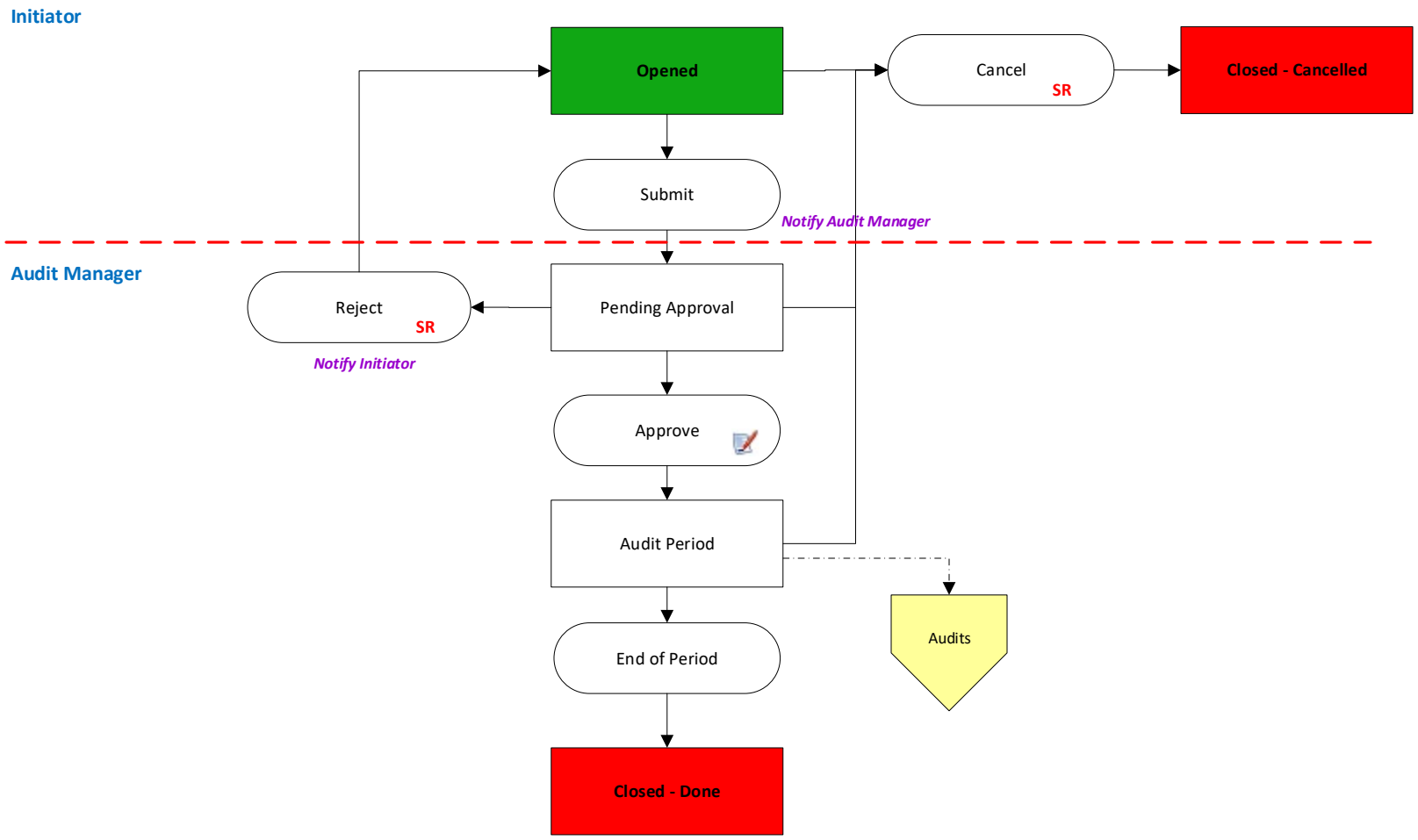
Subject Action Item



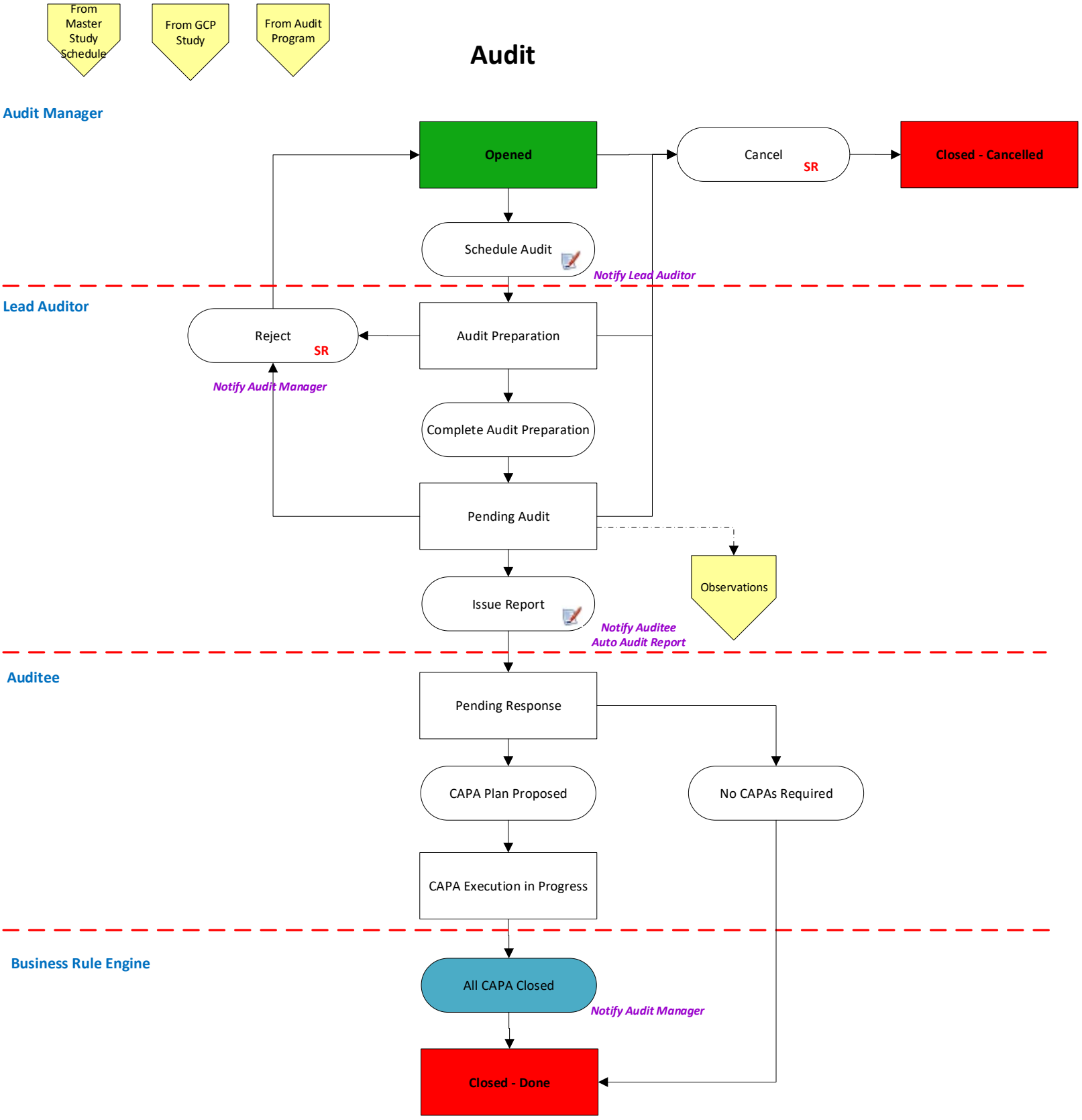
Master Study Schedule



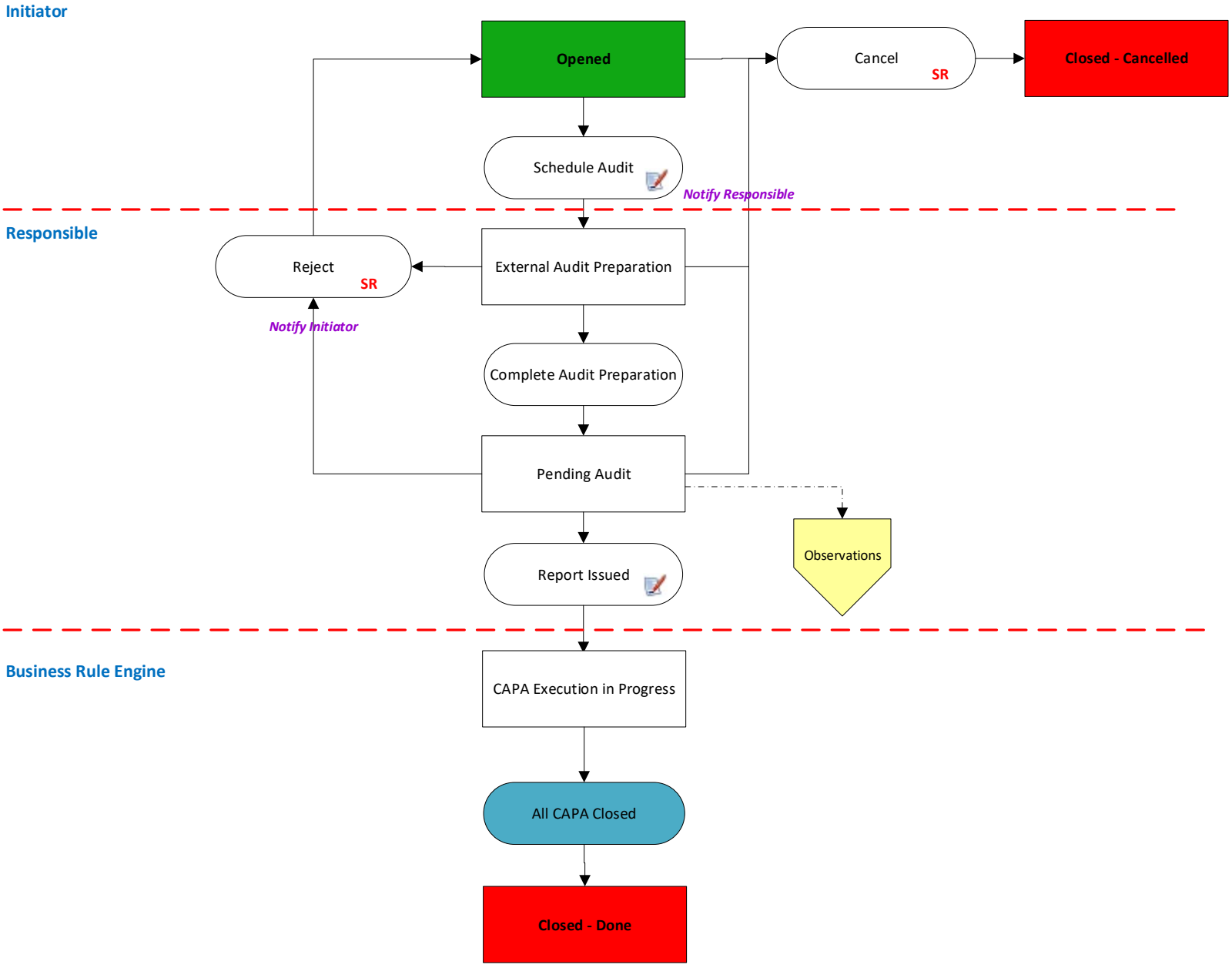
Audit Program



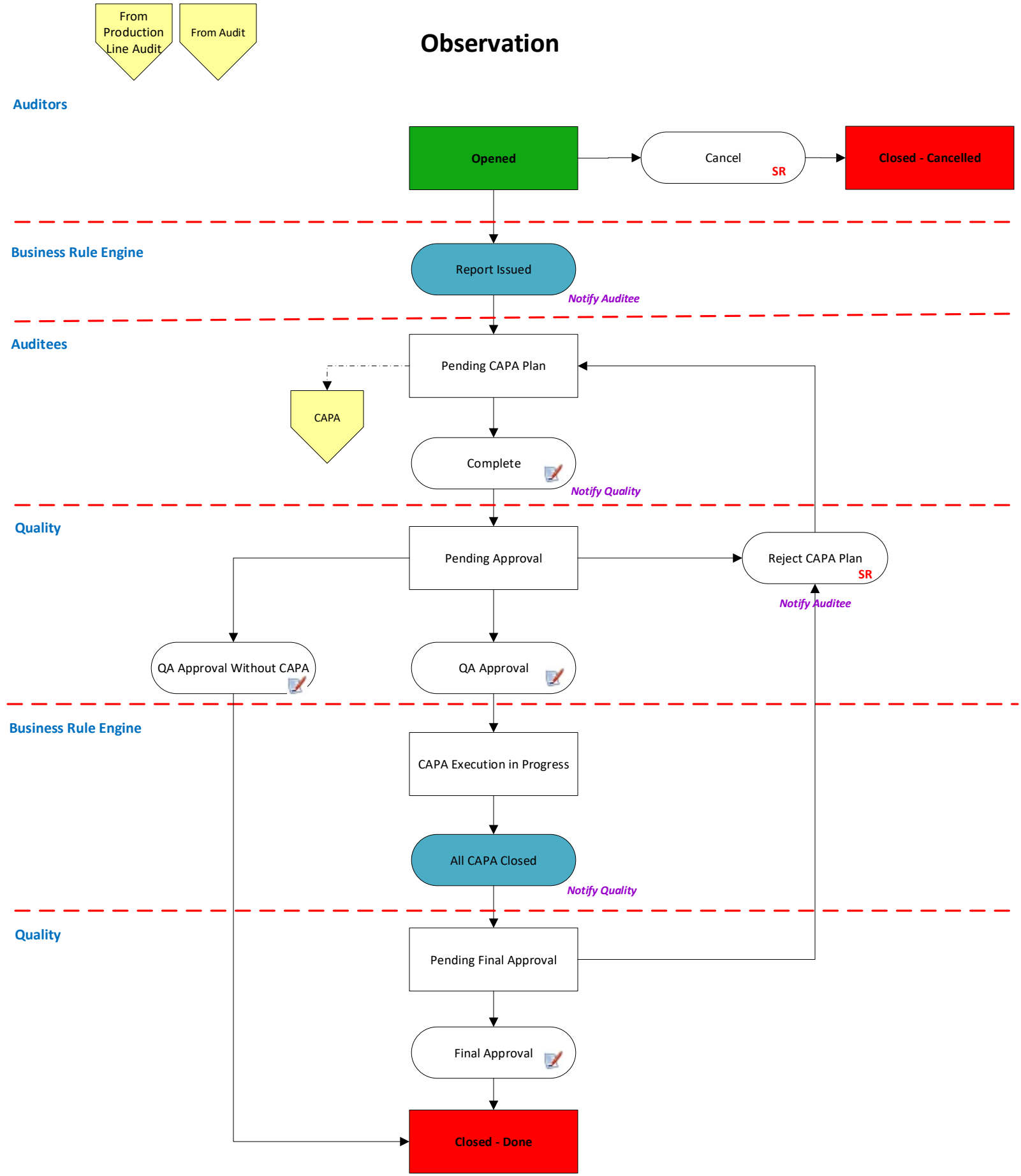
Audit


From Master Study Schedule
From GCP Study
From Audit Program
Audit Manager
Opened
Cancel
SR
Closed - Cancelled
Schedule Audit
Notify Lead Auditor
Lead Auditor
Reject
SR
Audit Preparation
Notify Audit Manager
Complete Audit Preparation
Pending Audit
Observations
Issue Report
Notify Auditee
Auto Audit Report
Auditee
Pending Response
CAPA Plan Proposed
No CAPAs Required
CAPA Execution in Progress
Business Rule Engine
All CAPA Closed
Notify Audit Manager
Closed - Done

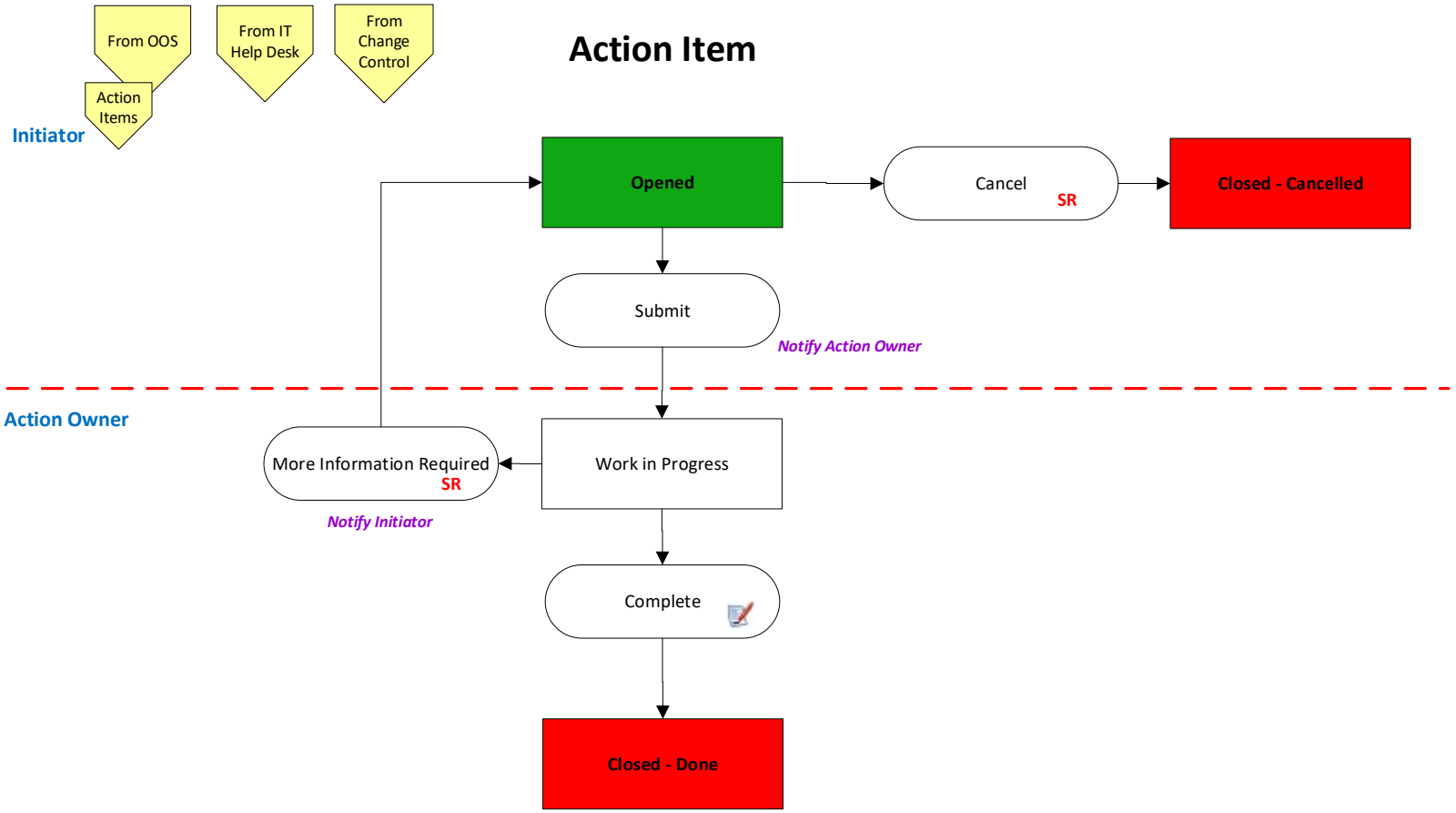
External Inspection



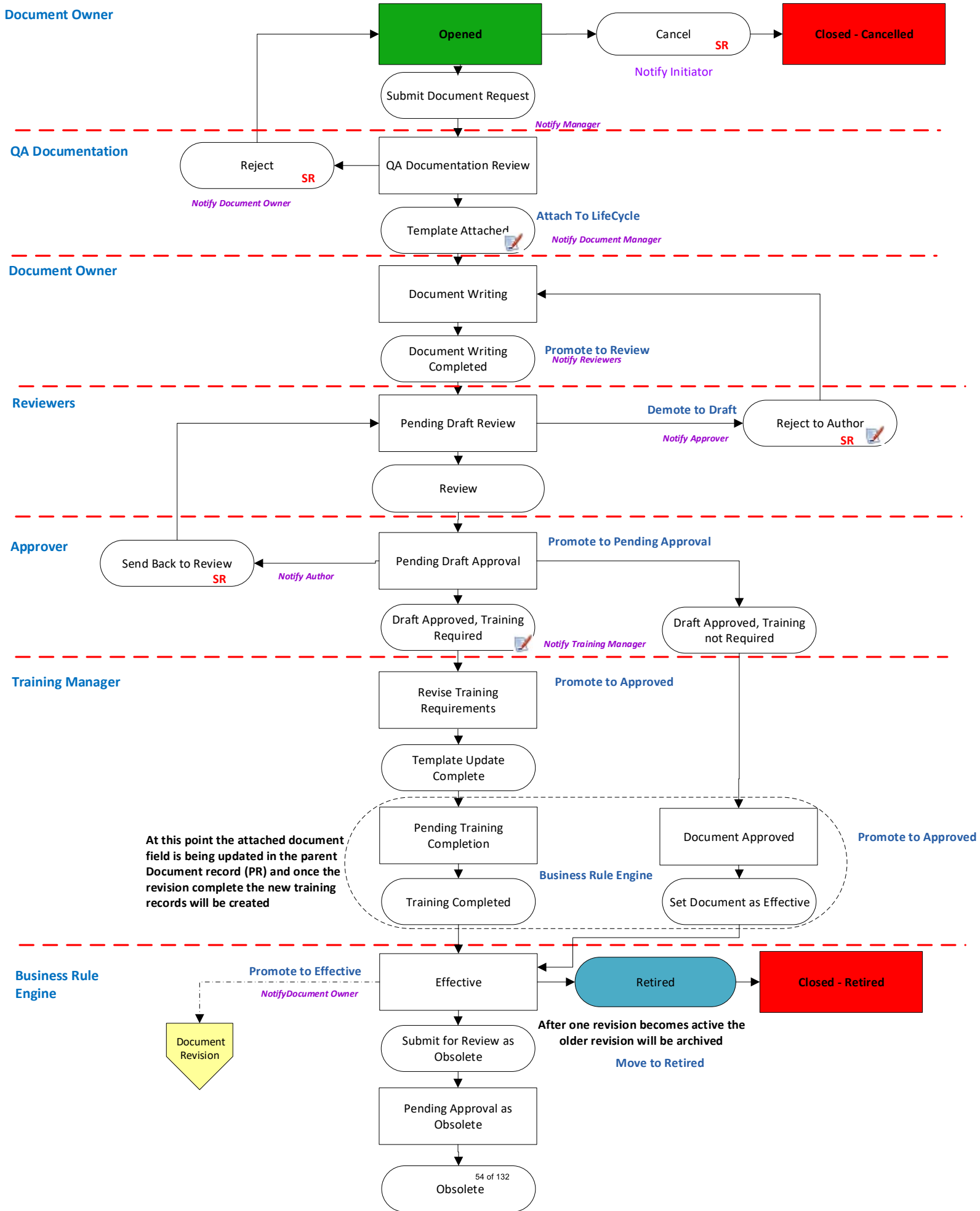
Observation

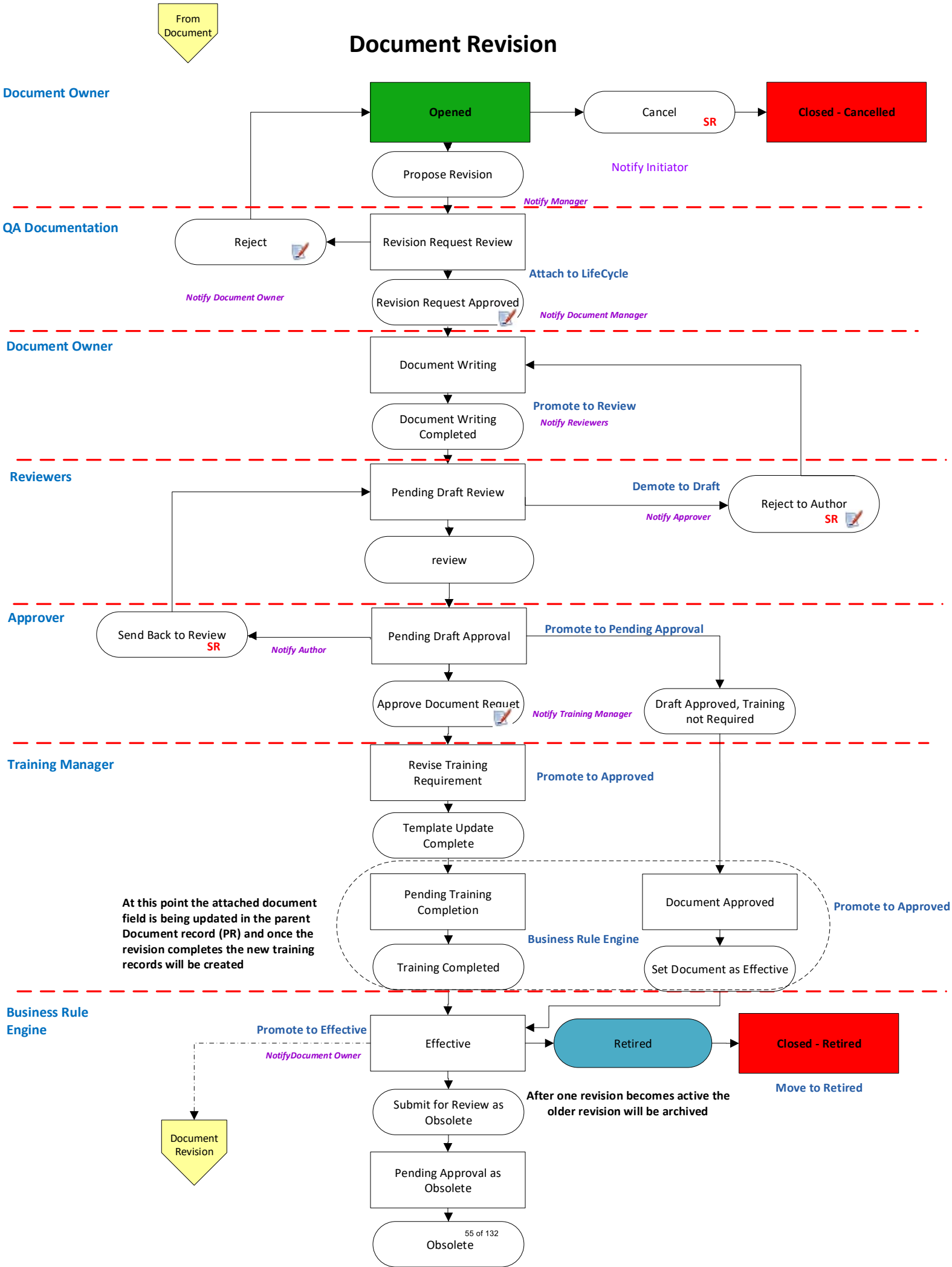


Action Item

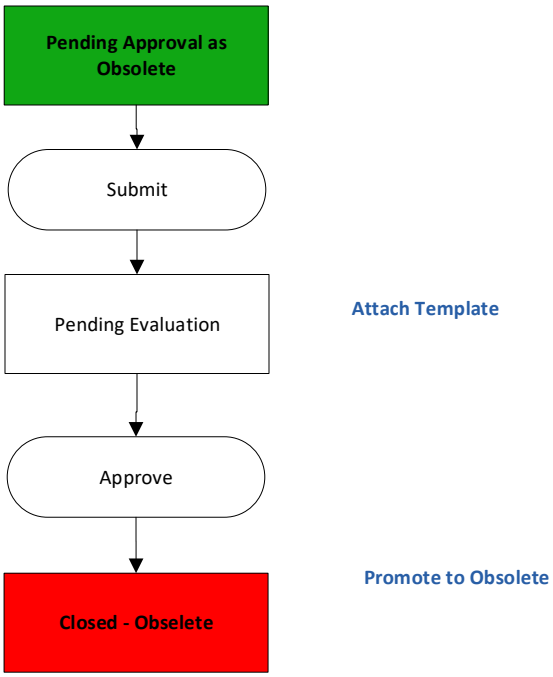

From OOS
From IT Help Desk
From Change Control
Action Items
Initiator
Opened
Cancel
SR
Closed - Cancelled
Submit
Notify Action Owner
Action Owner
More Information Required
SR
Notify Initiator
Work in Progress
Complete
Closed - Done

New Document



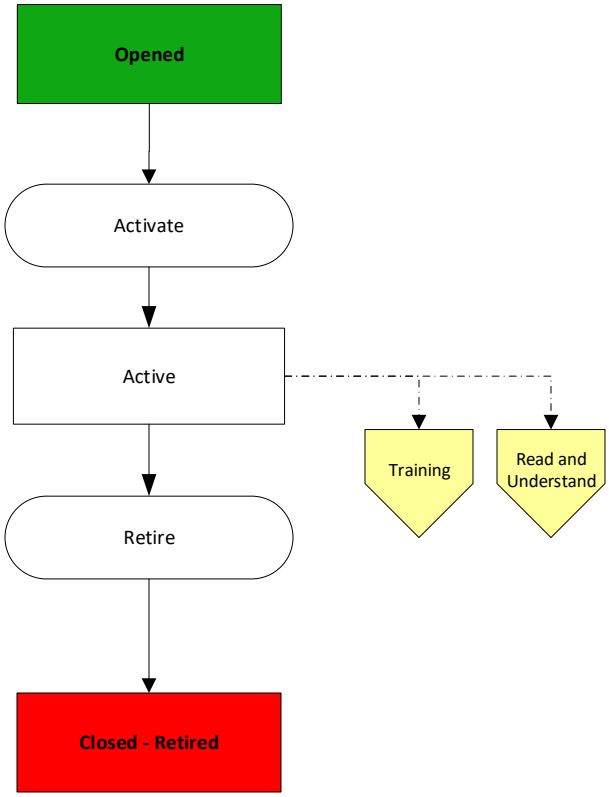

From Document
Document Revision
Document Owner
Opened
Cancel
SR
Closed - Cancelled
Propose Revision
Notify Initiator
Notify Manager
QA Documentation
Reject
Revision Request Review
Attach to LifeCycle
Notify Document Owner
Revision Request Approved
Notify Document Manager
Document Owner
Document Writing
Promote to Review
Document Writing Completed
Notify Reviewers
Reviewers
Pending Draft Review
Demote to Draft
Notify Approver
Reject to Author
SR
review
Approver
Send Back to Review
SR
Notify Author
Pending Draft Approval
Promote to Pending Approval
Approve Document Requet
Notify Training Manager
Draft Approved, Training not Required
Training Manager
Revise Training Requirement
Promote to Approved
Template Update Complete
Pending Training Completion
Document Approved
Promote to Approved
At this point the attached document field is being updated in the parent Document record (PR) and once the revision completes the new training records will be created
Business Rule Engine
Training Completed
Set Document as Effective
Business Rule Engine
Promote to Effective
NotifyDocument Owner
Effective
Retired
Closed - Retired
Move to Retired
Submit for Review as Obsolete
After one revision becomes active the older revision will be archived
Document Revision
Pending Approval as Obsolete
Obsolete
55 of 132

Obsolete


Pending Approval as Obsolete
Submit
Pending Evaluation
Attach Template
Approve
Promote to Obsolete
Closed - Obselete

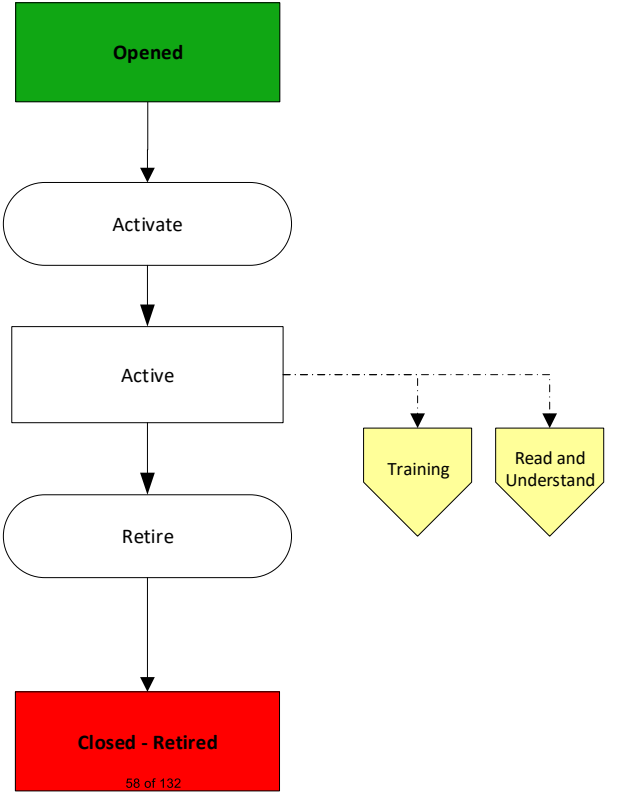
Employee

HR Manager



Employee

HR Manager



Pre-employment Medical Checkup

HR / P& Admin

Opened

name, DOB, Gender, department, payroll etc

Details of Employee Entered

HR

Active

upload external medical reports

upload external medical reports

Medical Officer

Pending Medical Check Up

Medical Check Up Completed

Nursing Staff

Pending Nursing Staff Update

history, BMI, Vision test, blood reports

Updated

Medical Officer

Pending Pre- Employment Check Up Examination

Satisfactory

Not Satisfactory

OHC Head

Under Review by OHC Head

Fit for Employment

Unfit for Employment

Hold the Recruitment

Medical Officer

Pending Follow Up by Medical officer

Send for OHC Head Approval

OHC Head

Pending OHC Head Review

Fit for Employment

Unfit for Employment

Hold the Recruitment

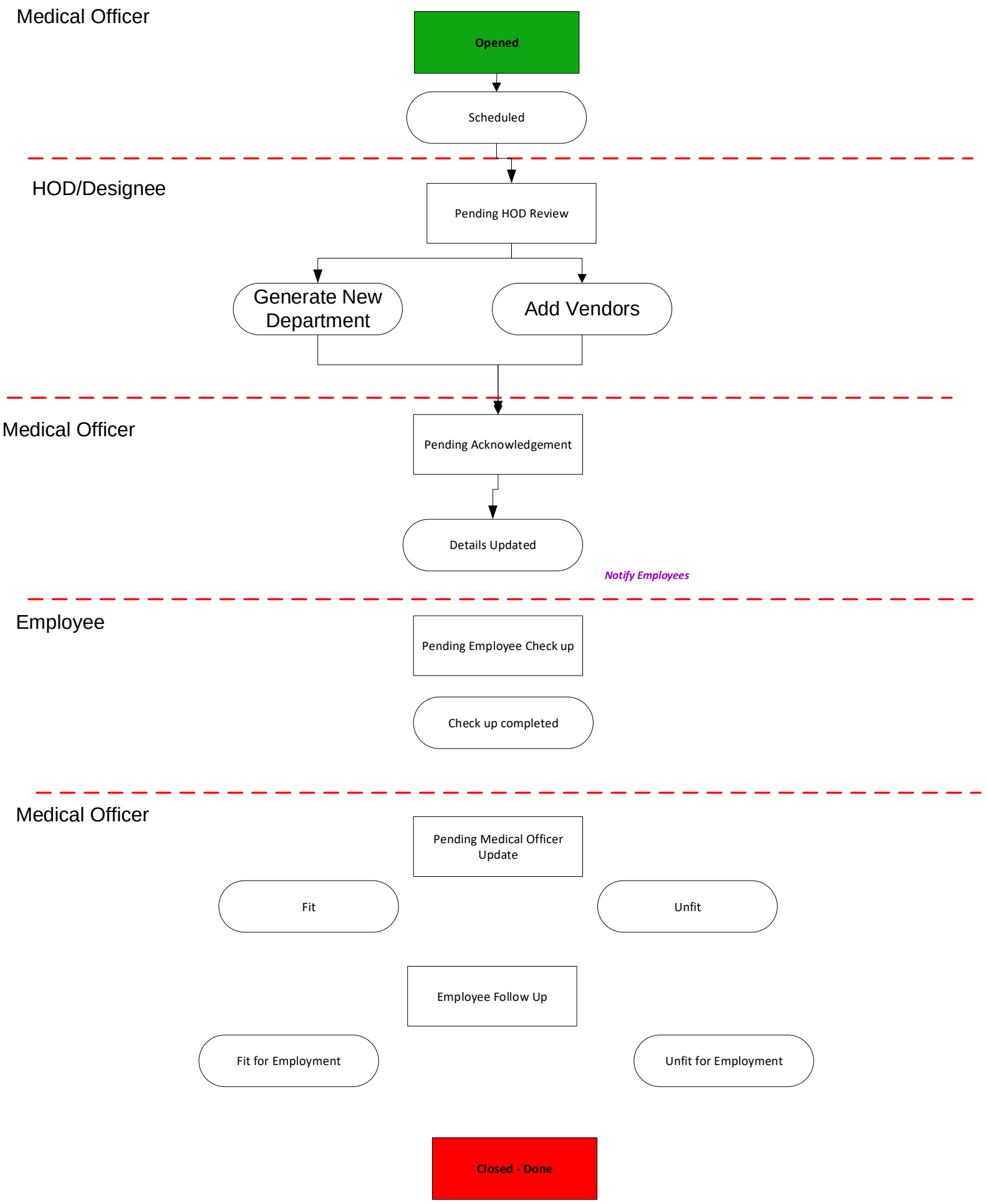
HR

Pending HR Review

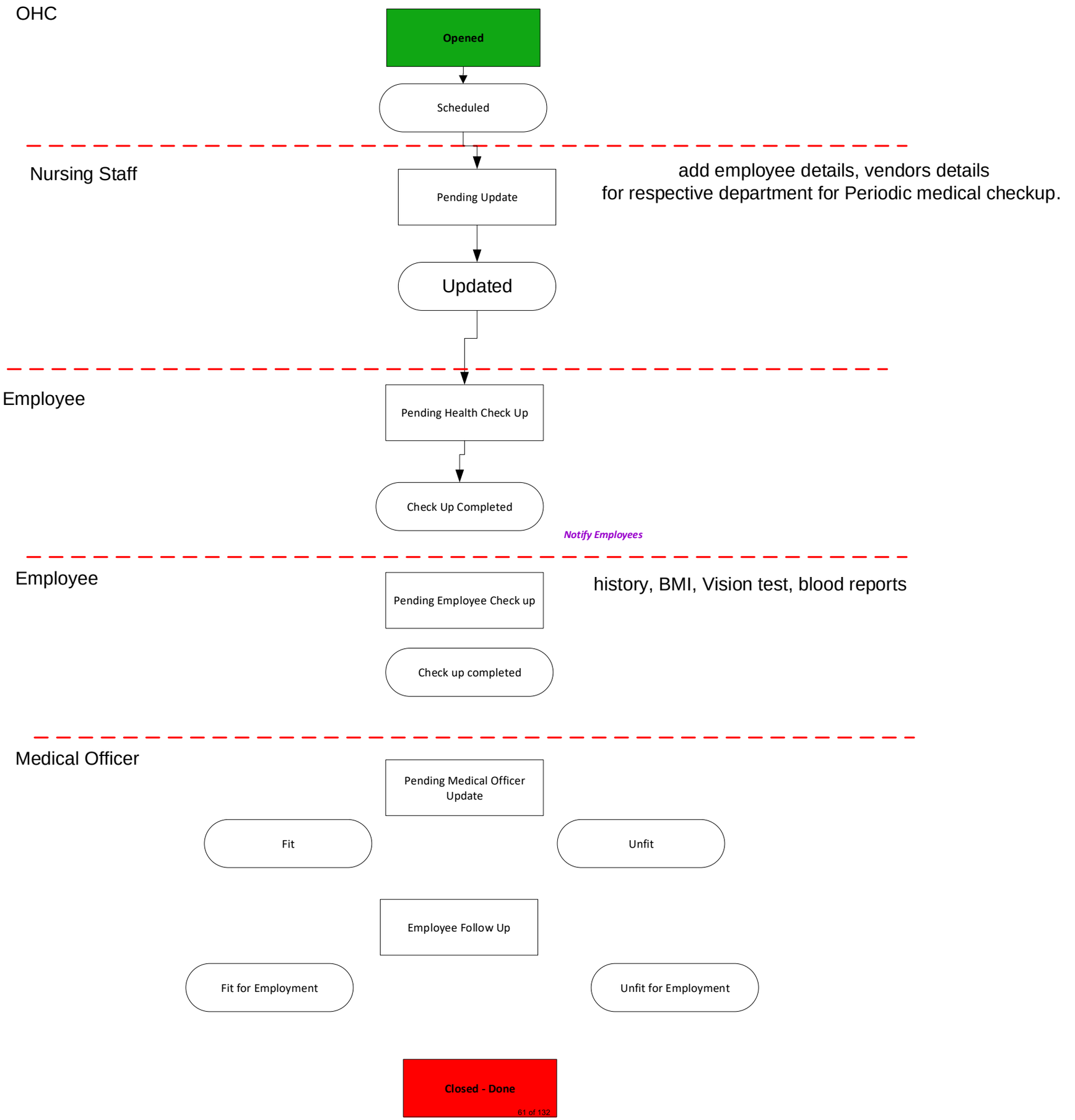
HR Review Completed

Closed - Done

Periodic Medical Checkup

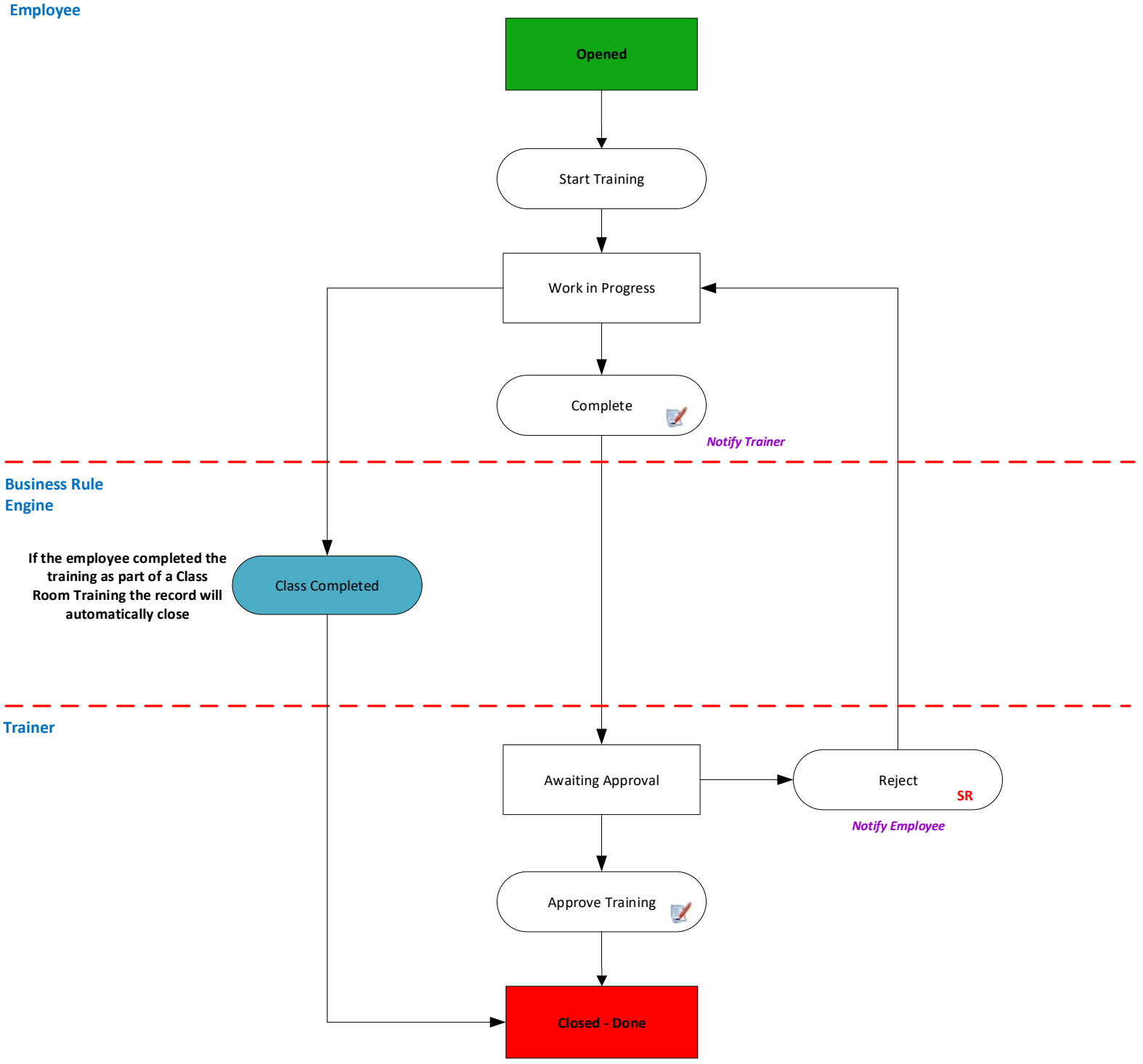


Annual Health Checkup



From Employee

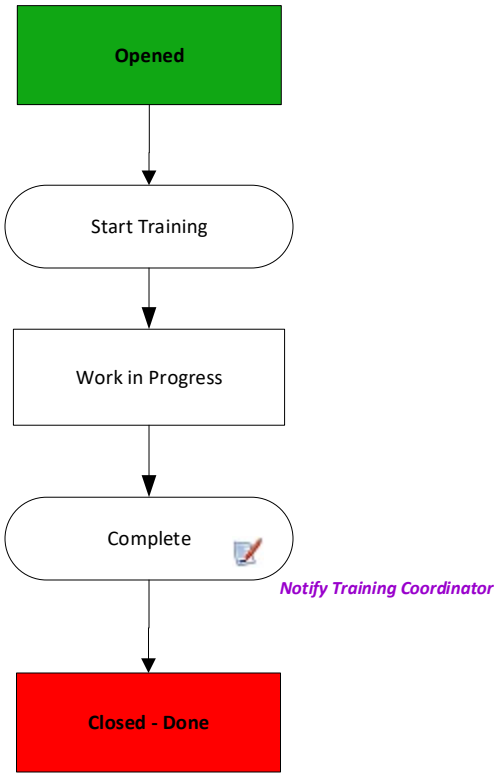
Training



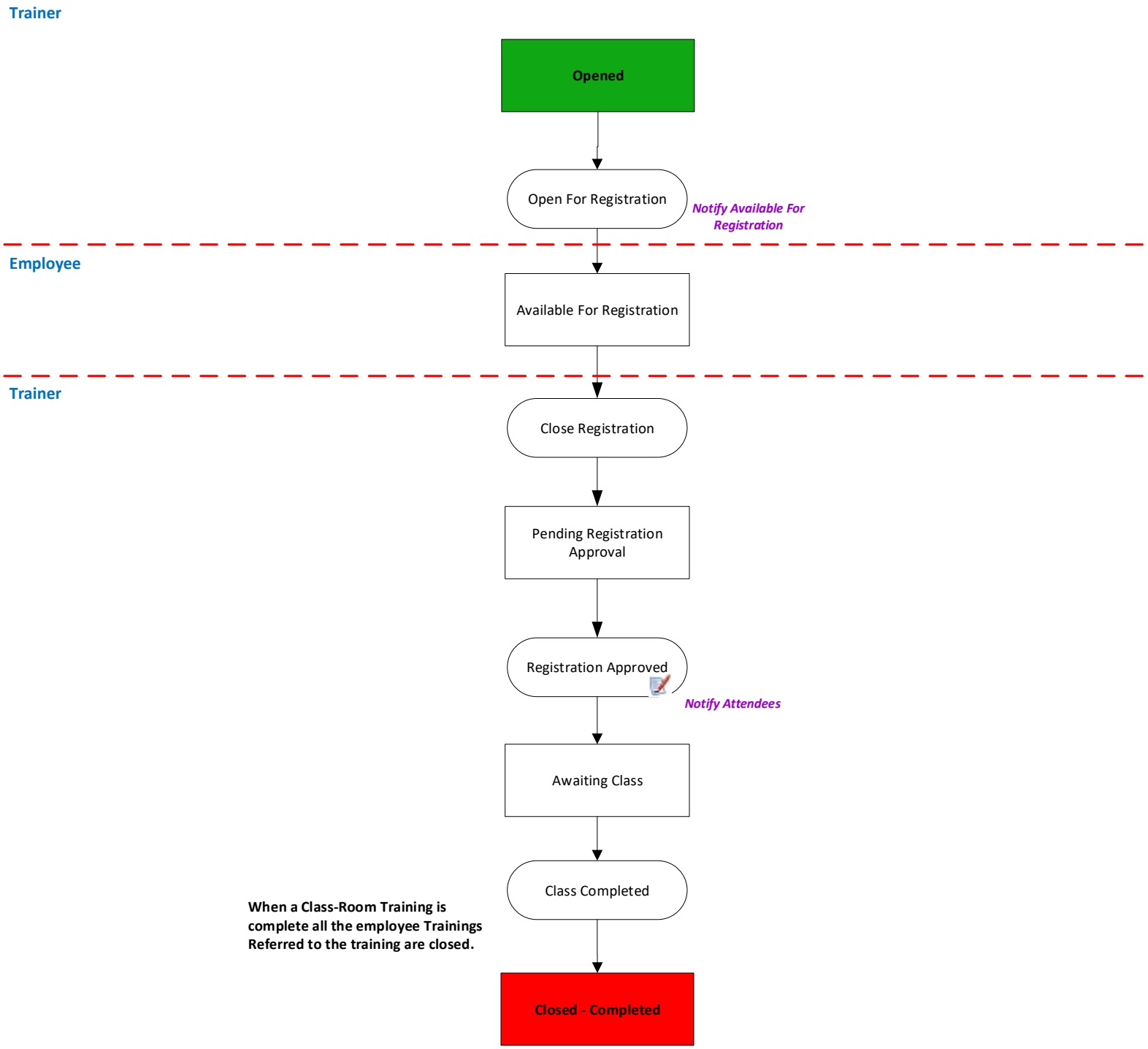
From Employee

Read and Understand

Employee



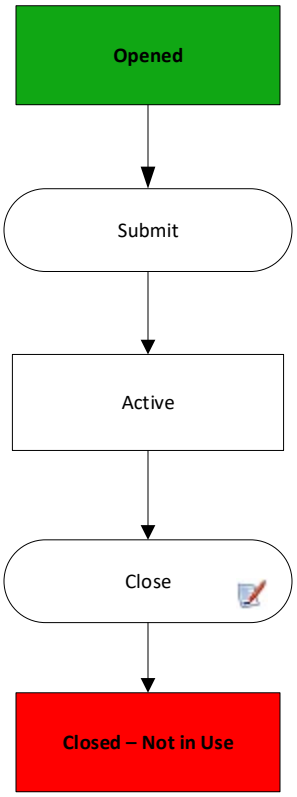
Class Room Training



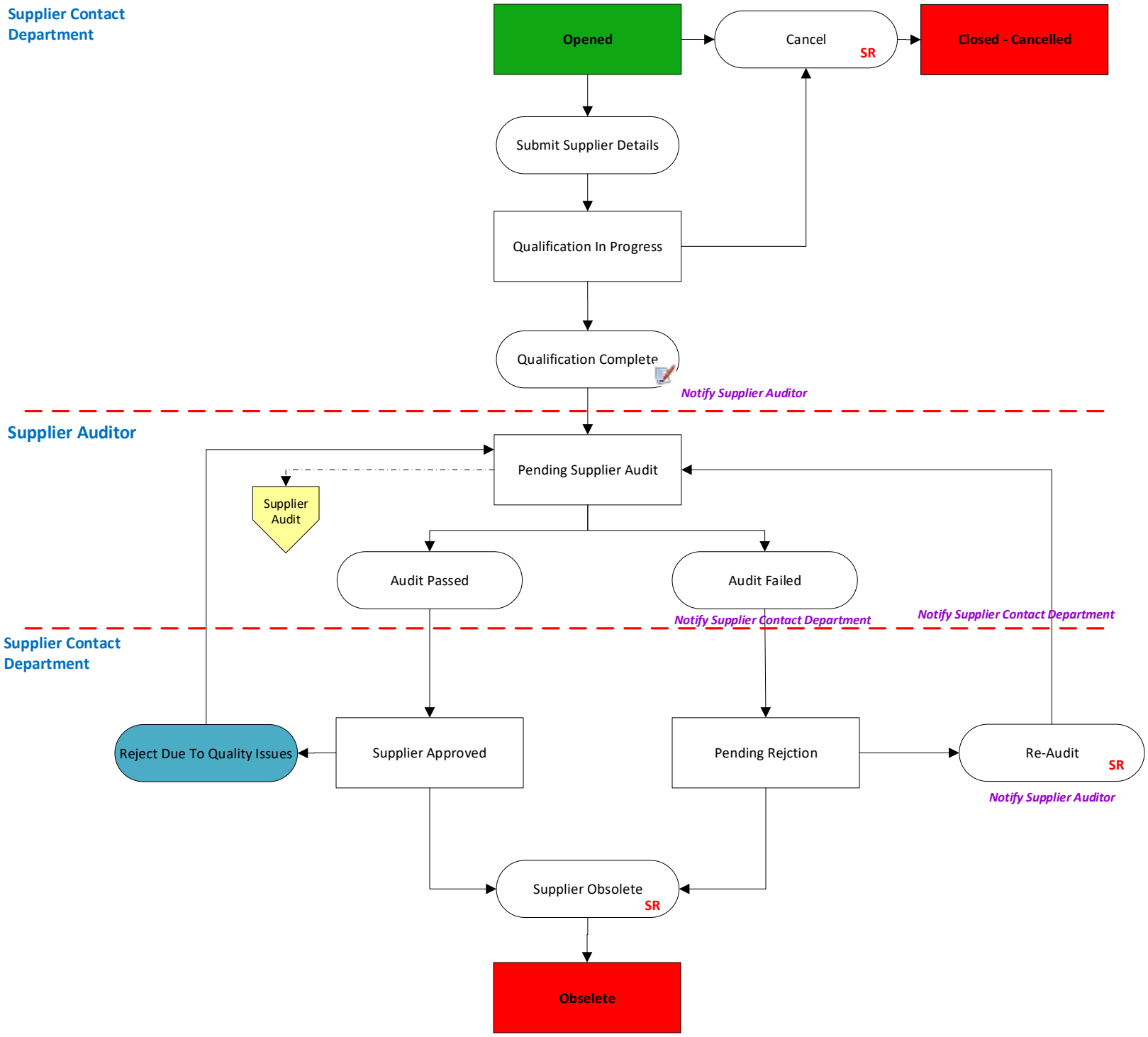
When a Class-Room Training is complete all the employee Trainings Referred to the training are closed.

Requirement Template

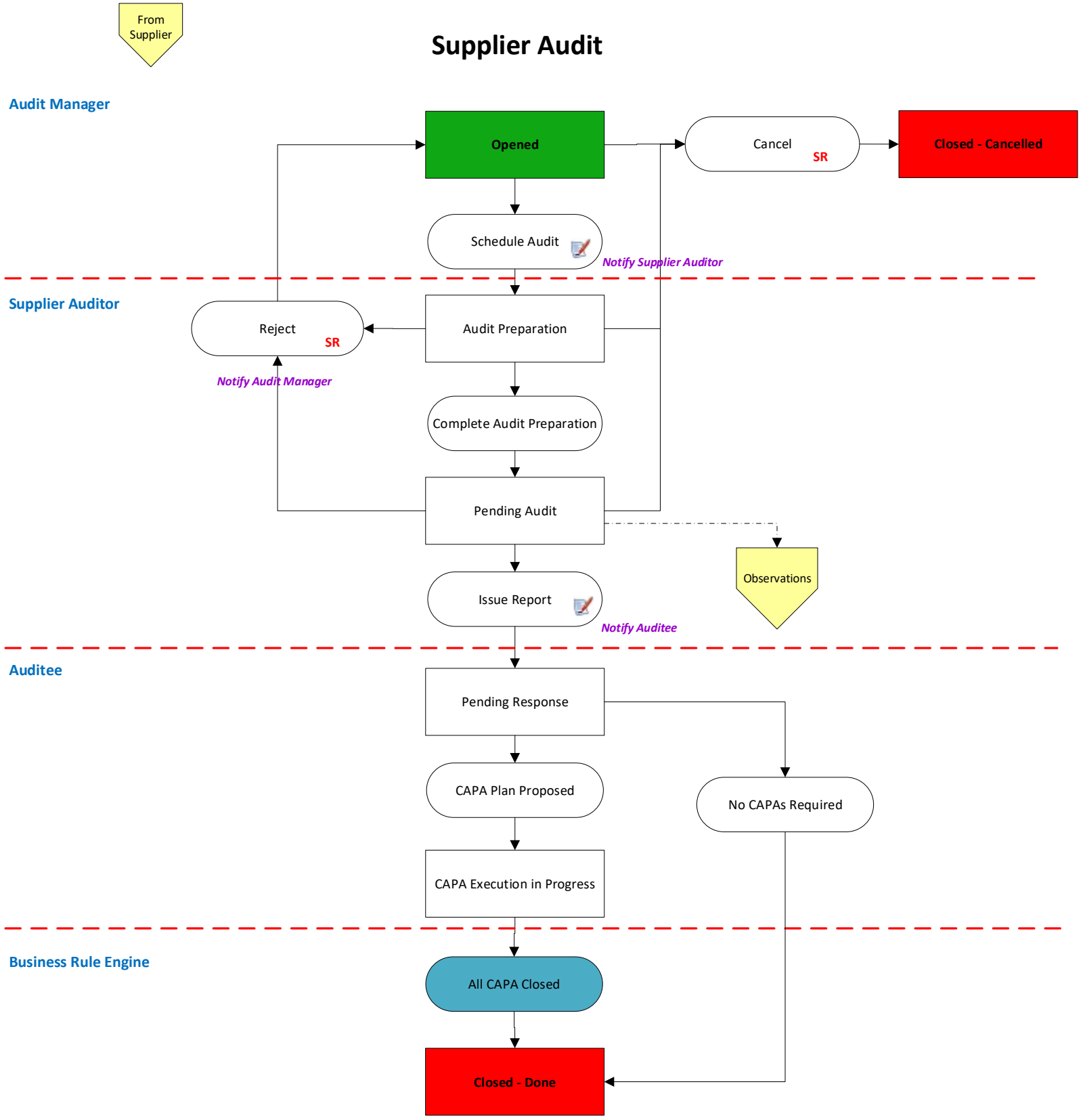
Training Coordinator

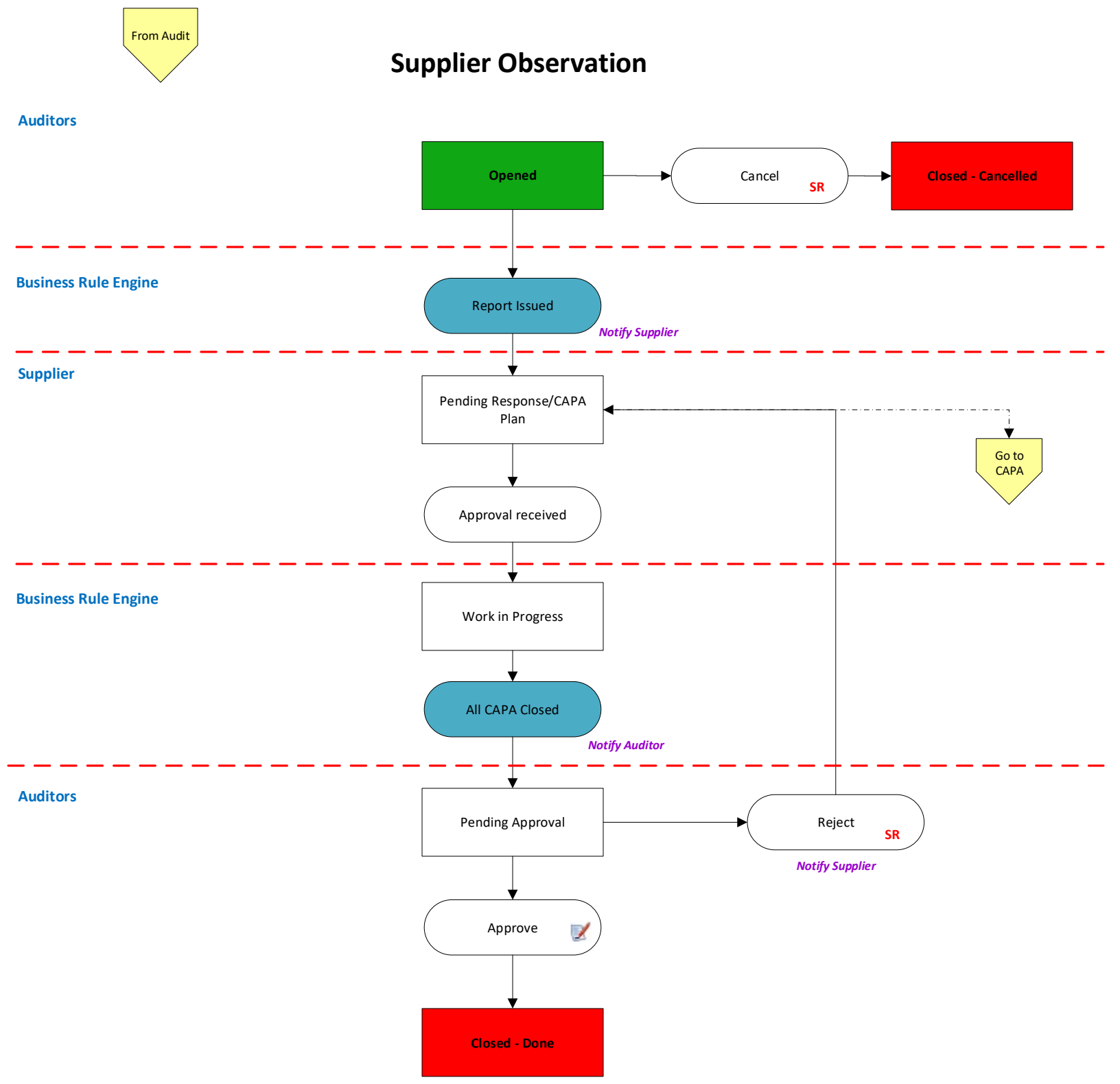


Supplier

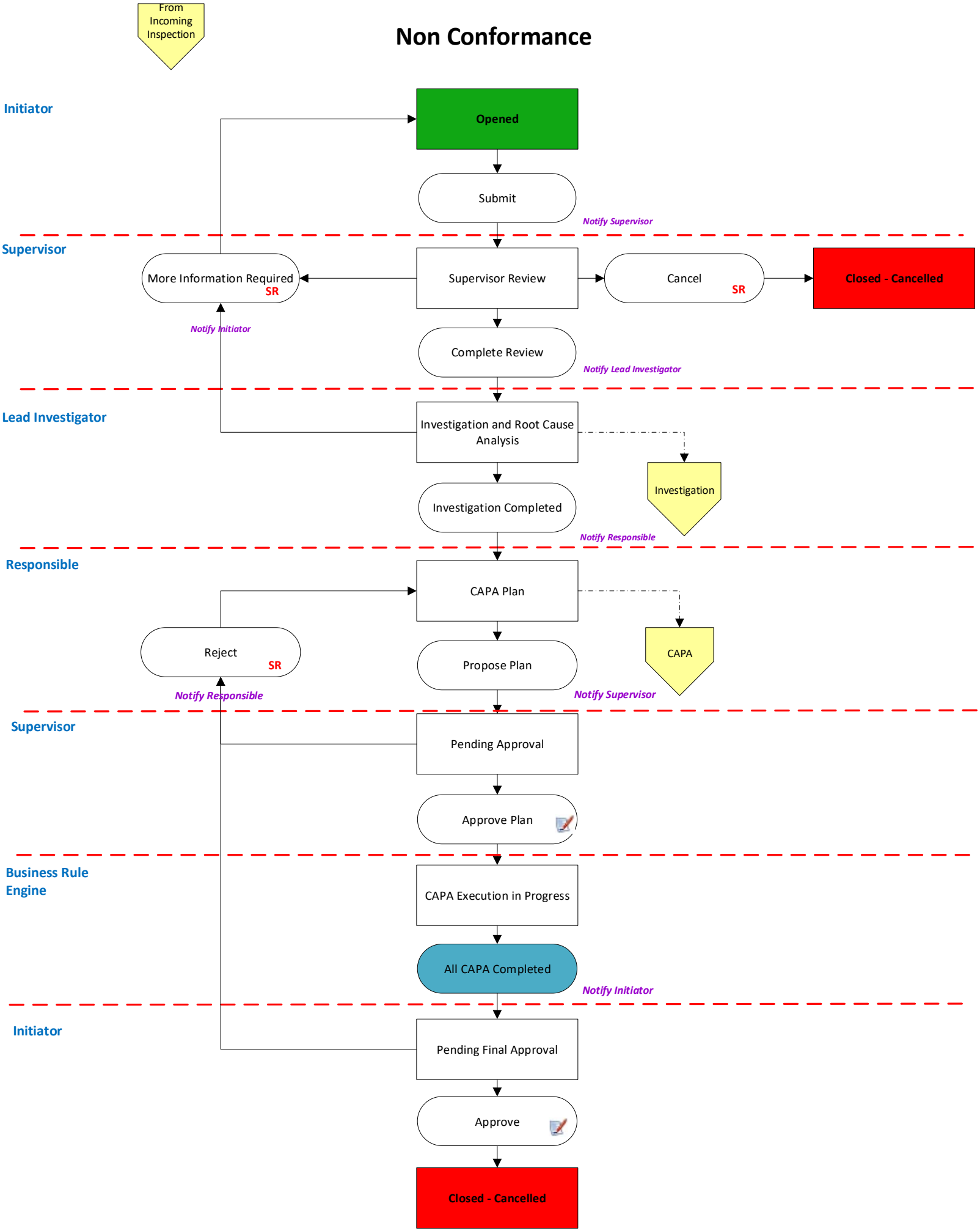

Supplier Contact Department
Opened
Cancel
SR
Closed - Cancelled
Submit Supplier Details
Qualification In Progress
Qualification Complete
Notify Supplier Auditor
Supplier Auditor
Pending Supplier Audit
Supplier Audit
Audit Passed
Audit Failed
Notify Supplier Contact Department
Notify Supplier Contact Department
Supplier Contact Department
Reject Due To Quality Issues
Supplier Approved
Pending Rejction
Re-Audit
SR
Notify Supplier Auditor
Supplier Obsolete
SR
Obselete

Supplier Audit

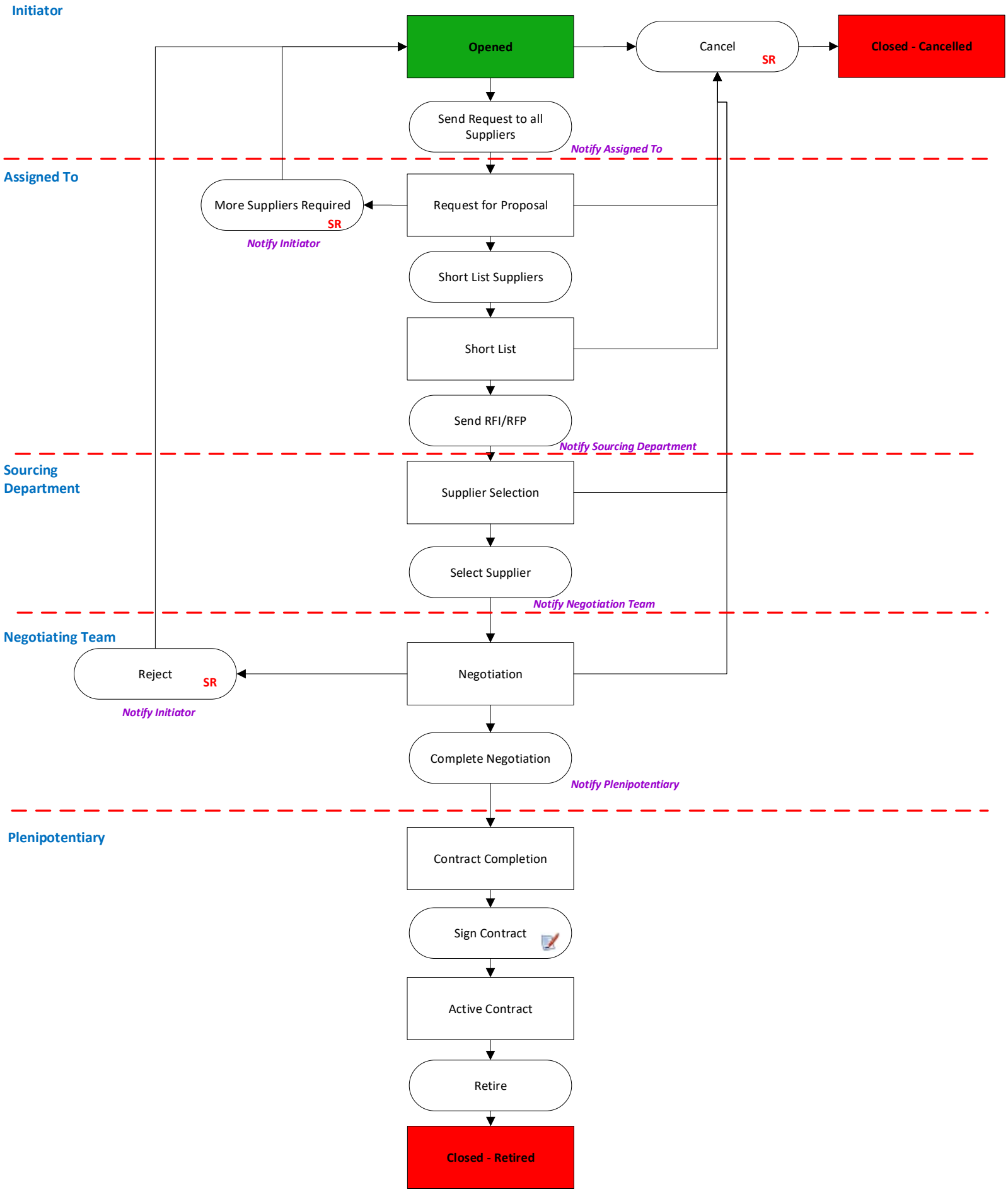



From Audit
Supplier Observation
Auditors
Opened
Cancel
SR
Closed - Cancelled
Business Rule Engine
Report Issued
Notify Supplier
Supplier
Pending Response/CAPA Plan
Go to CAPA
Approval received
Business Rule Engine
Work in Progress
All CAPA Closed
Notify Auditor
Auditors
Pending Approval
Reject
SR
Notify Supplier
Approve
Closed - Done

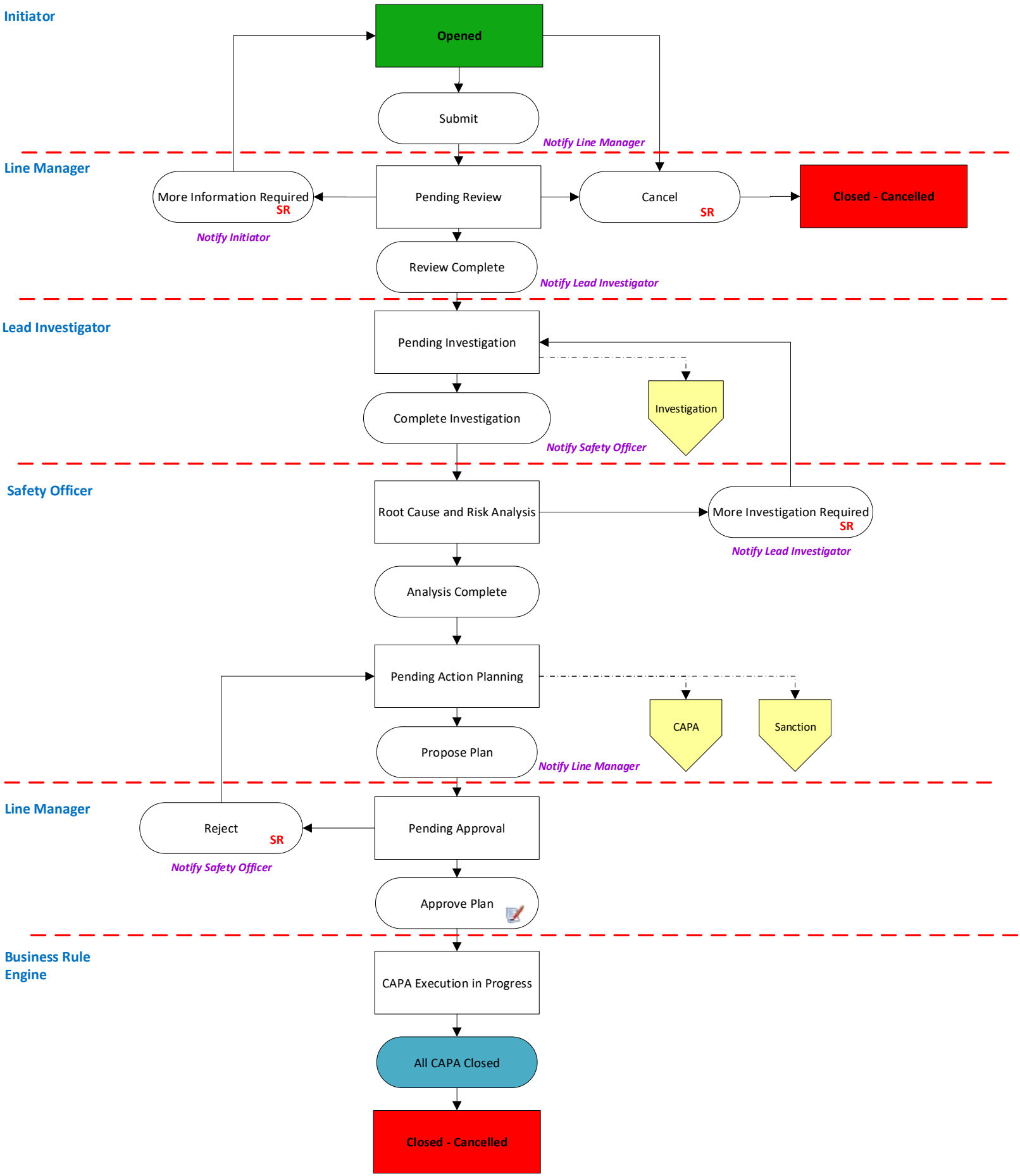
Non Conformance



Contract

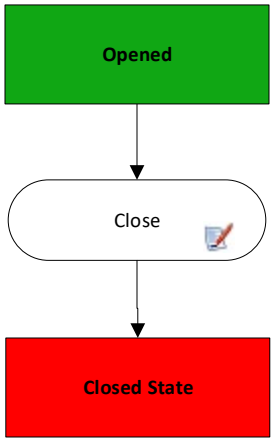

Initiator
Opened
Cancel
SR
Closed - Cancelled
Send Request to all Suppliers
Notify Assigned To
Assigned To
More Suppliers Required
SR
Notify Initiator
Request for Proposal
Short List Suppliers
Short List
Send RFI/RFP
Notify Sourcing Department
Sourcing Department
Supplier Selection
Select Supplier
Notify Negotiation Team
Negotiating Team
Reject
SR
Notify Initiator
Negotiation
Complete Negotiation
Notify Plenipotentiary
Plenipotentiary
Contract Completion
Sign Contract
Active Contract
Retire
Closed - Retired

EHS Event


Initiator
Opened
Submit
Notify Line Manager
Line Manager
More Information Required
SR
Notify Initiator
Pending Review
Cancel
SR
Closed - Cancelled
Review Complete
Notify Lead Investigator
Lead Investigator
Pending Investigation
Investigation
Complete Investigation
Notify Safety Officer
Safety Officer
Root Cause and Risk Analysis
More Investigation Required
SR
Notify Lead Investigator
Analysis Complete
Pending Action Planning
CAPA
Sanction
Propose Plan
Notify Line Manager
Line Manager
Reject
SR
Notify Safety Officer
Pending Approval
Approve Plan
Business Rule Engine
CAPA Execution in Progress
All CAPA Closed
Closed - Cancelled

Monthly Working Hours

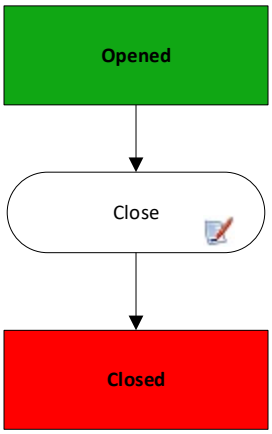
HR Manager



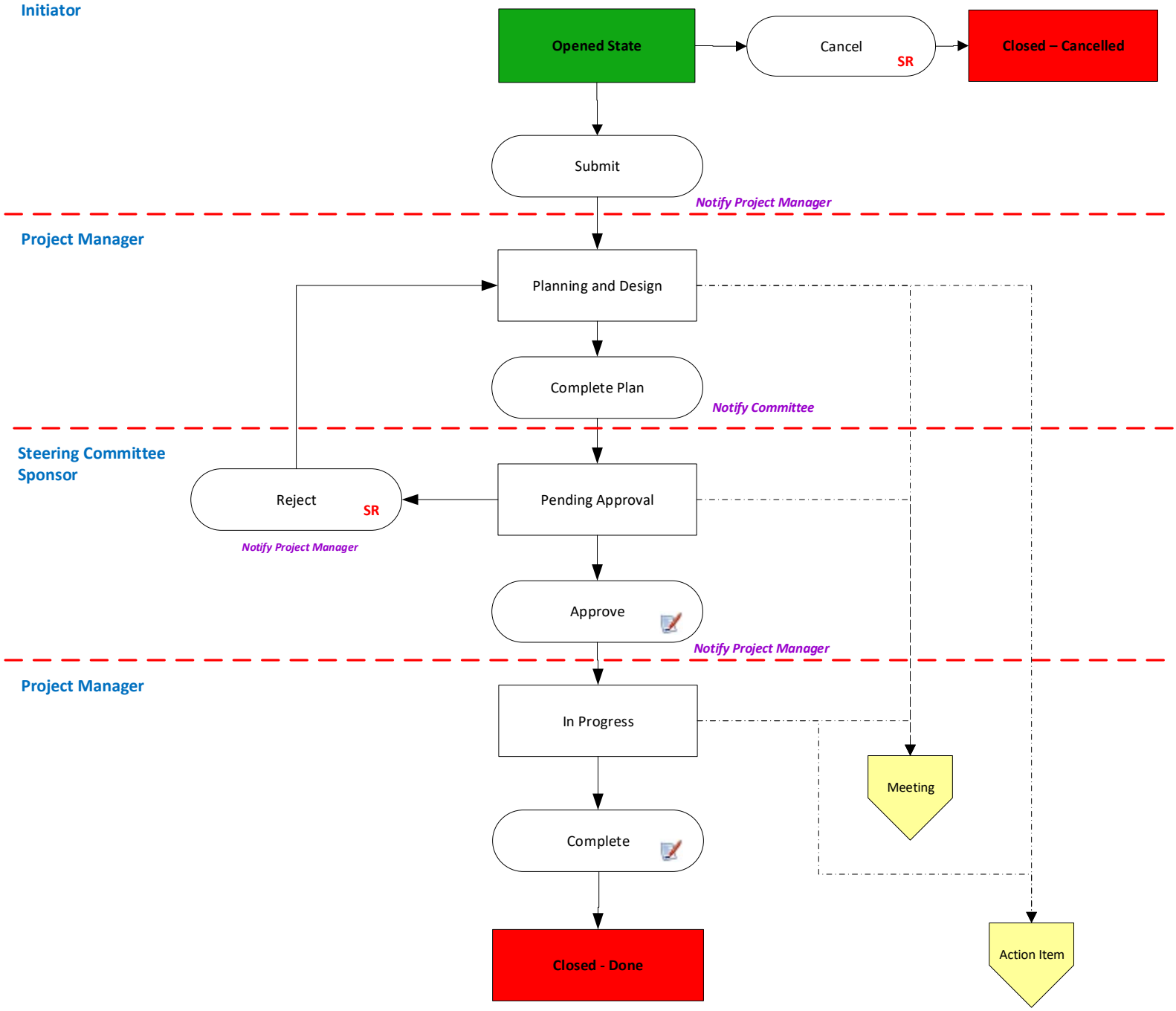
From EHS Event

Sanction

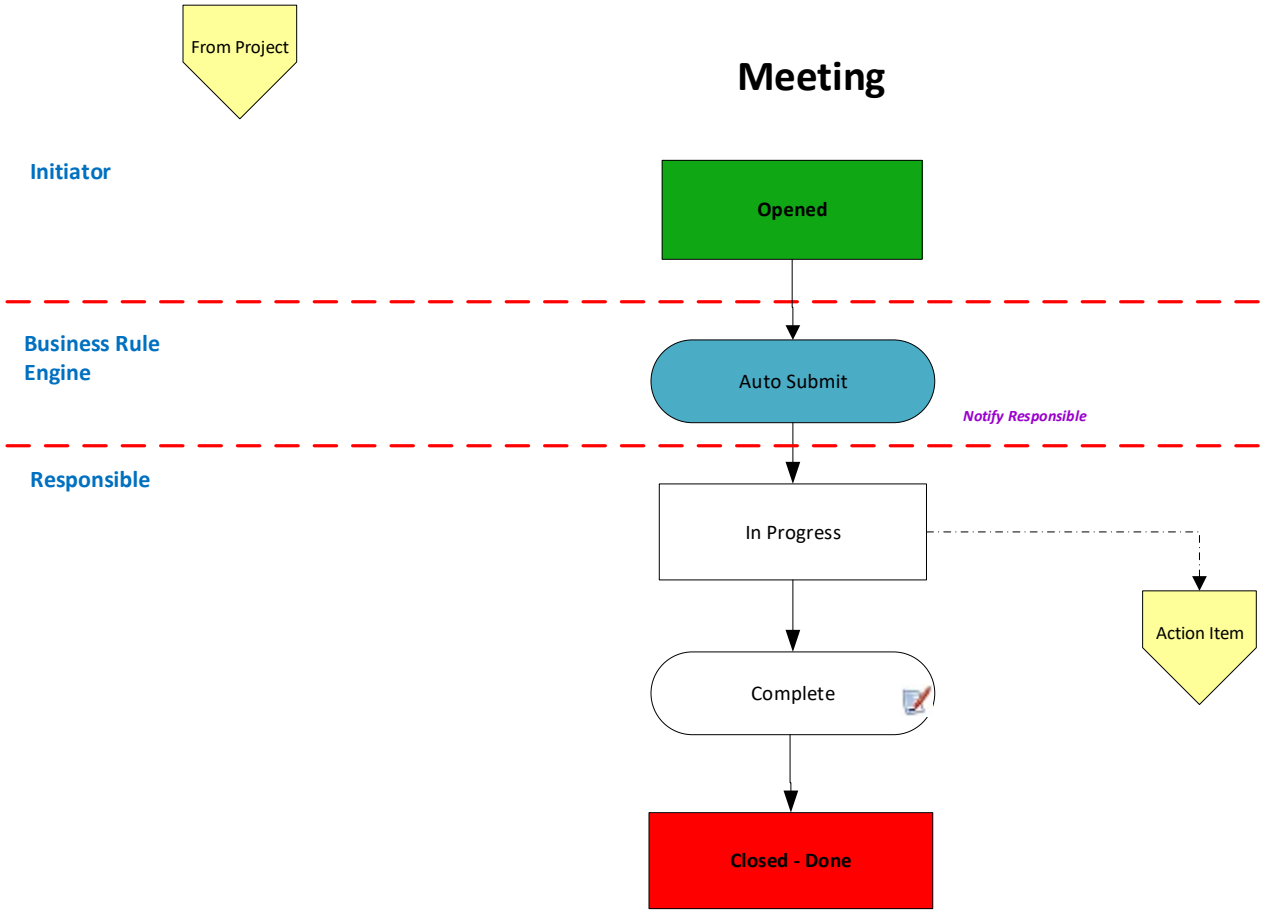
Safety Officer



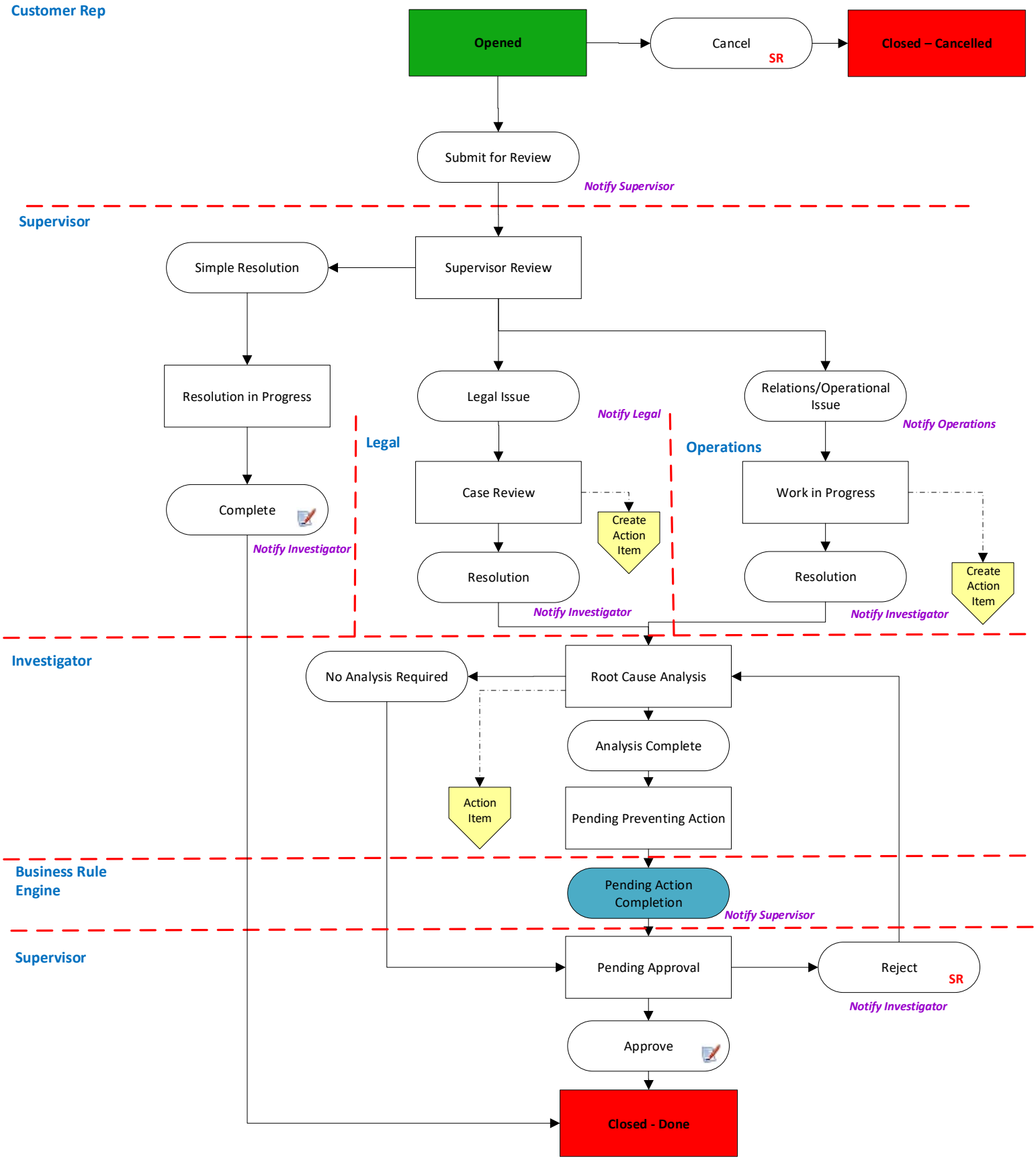
Project


Initiator
Opened State
Cancel
SR
Closed – Cancelled
Submit
Notify Project Manager
Project Manager
Planning and Design
Complete Plan
Notify Committee
Steering Committee
Sponsor
Reject
SR
Pending Approval
Notify Project Manager
Approve
Notify Project Manager
Project Manager
In Progress
Meeting
Complete
Closed - Done
Action Item

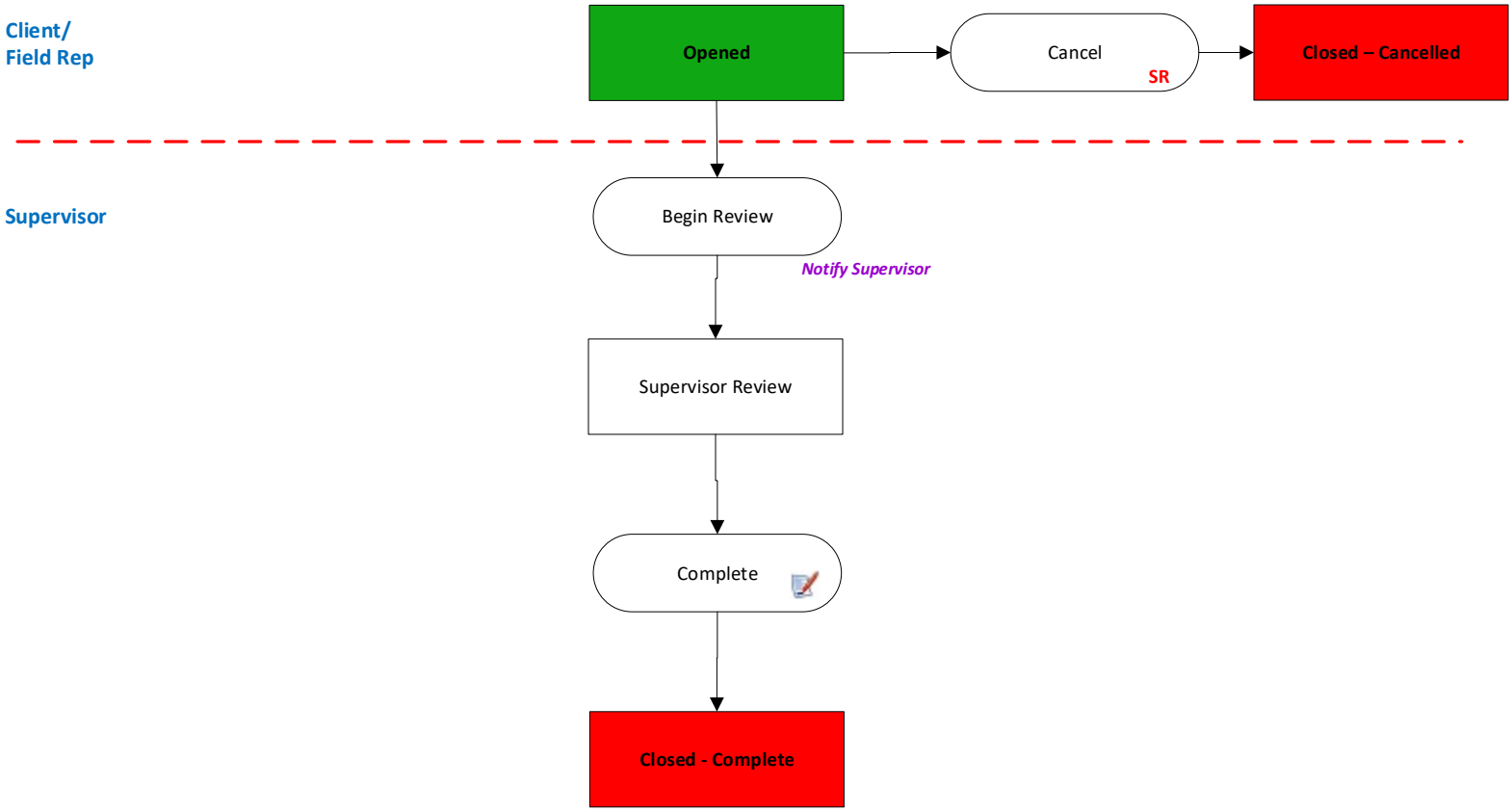
Meeting


From Project
Initiator
Opened
Business Rule Engine
Auto Submit
Notify Responsible
Responsible
In Progress
Action Item
Complete
Closed - Done

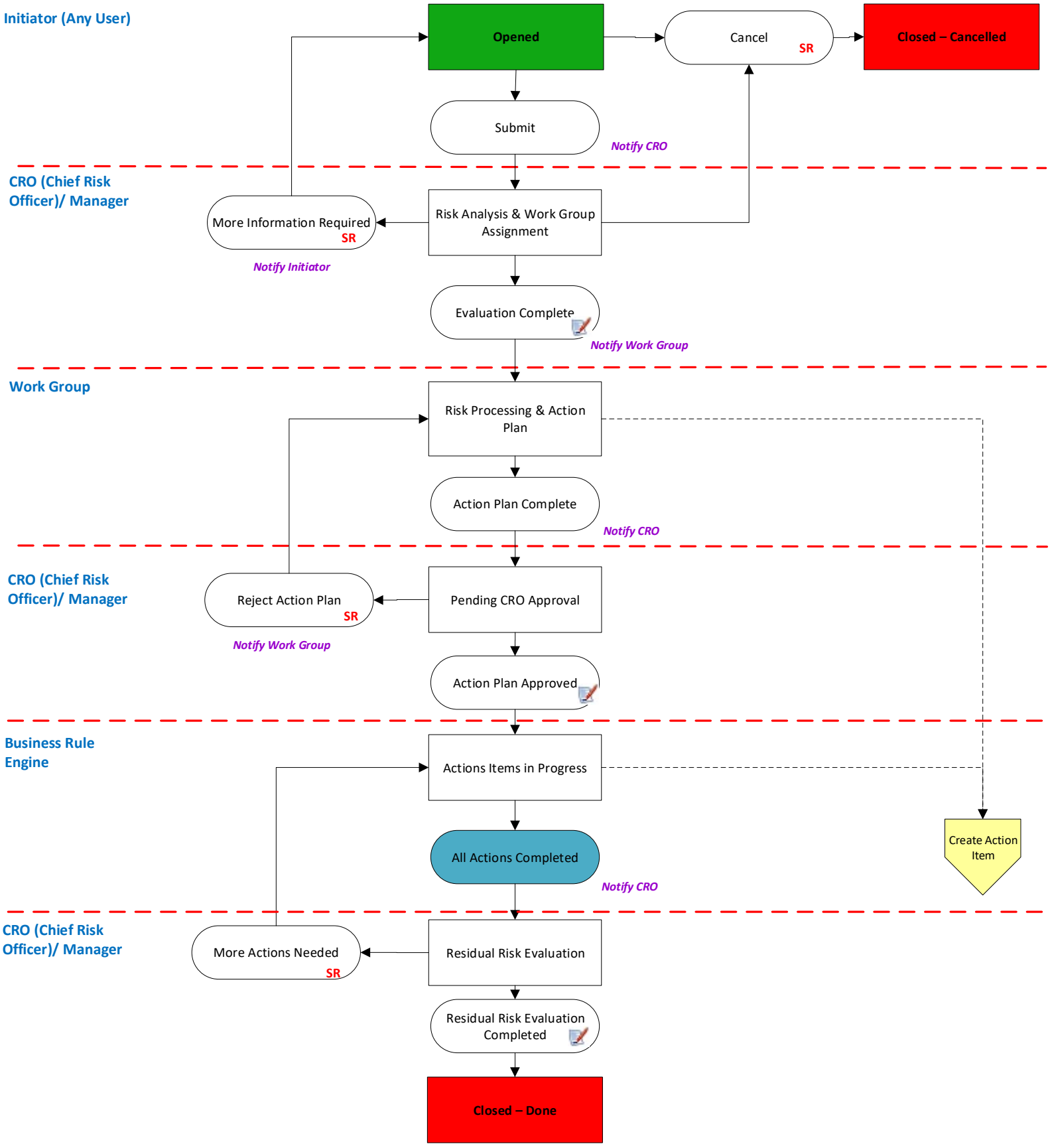
Client Inquiry



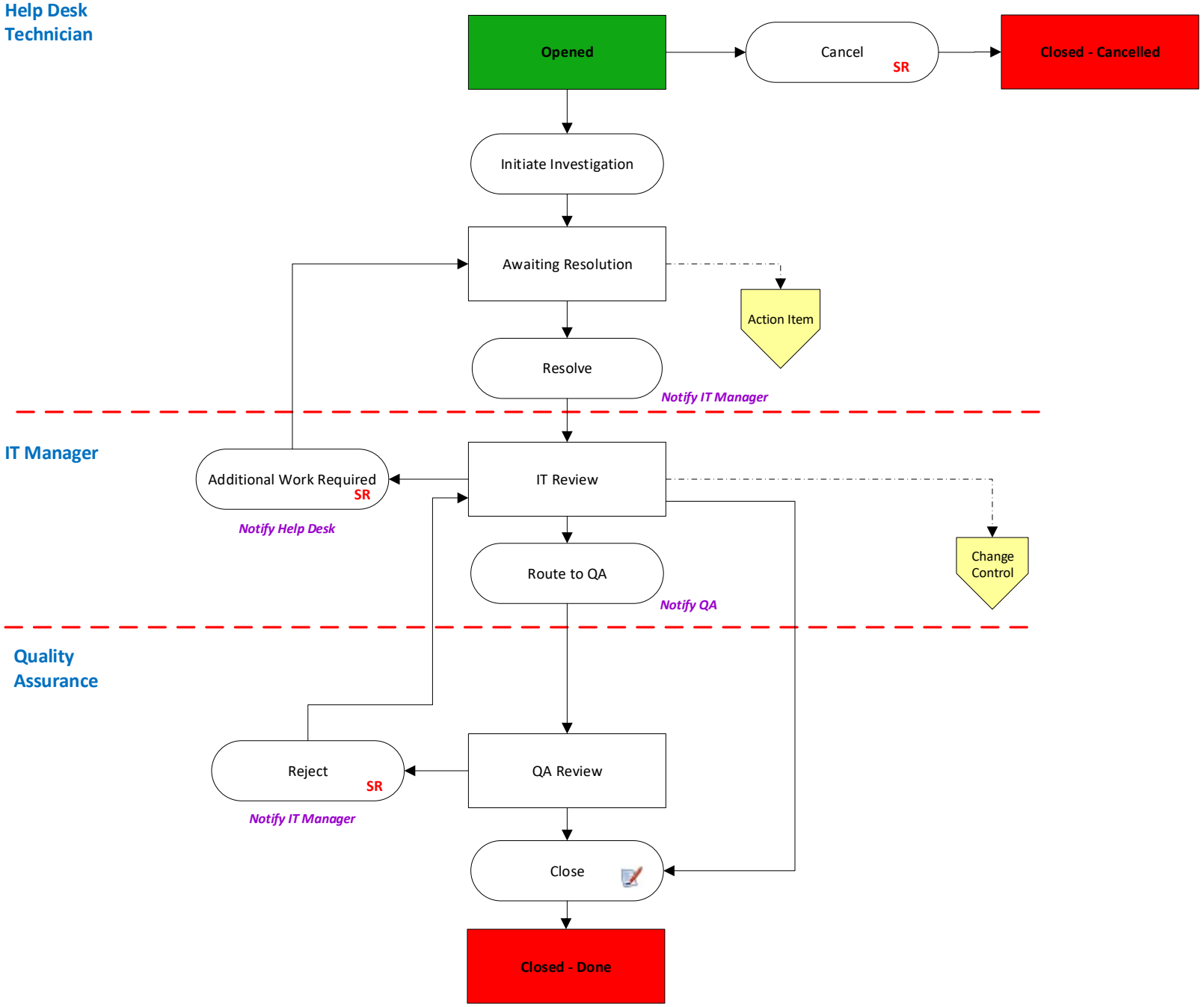
Field Inquiry

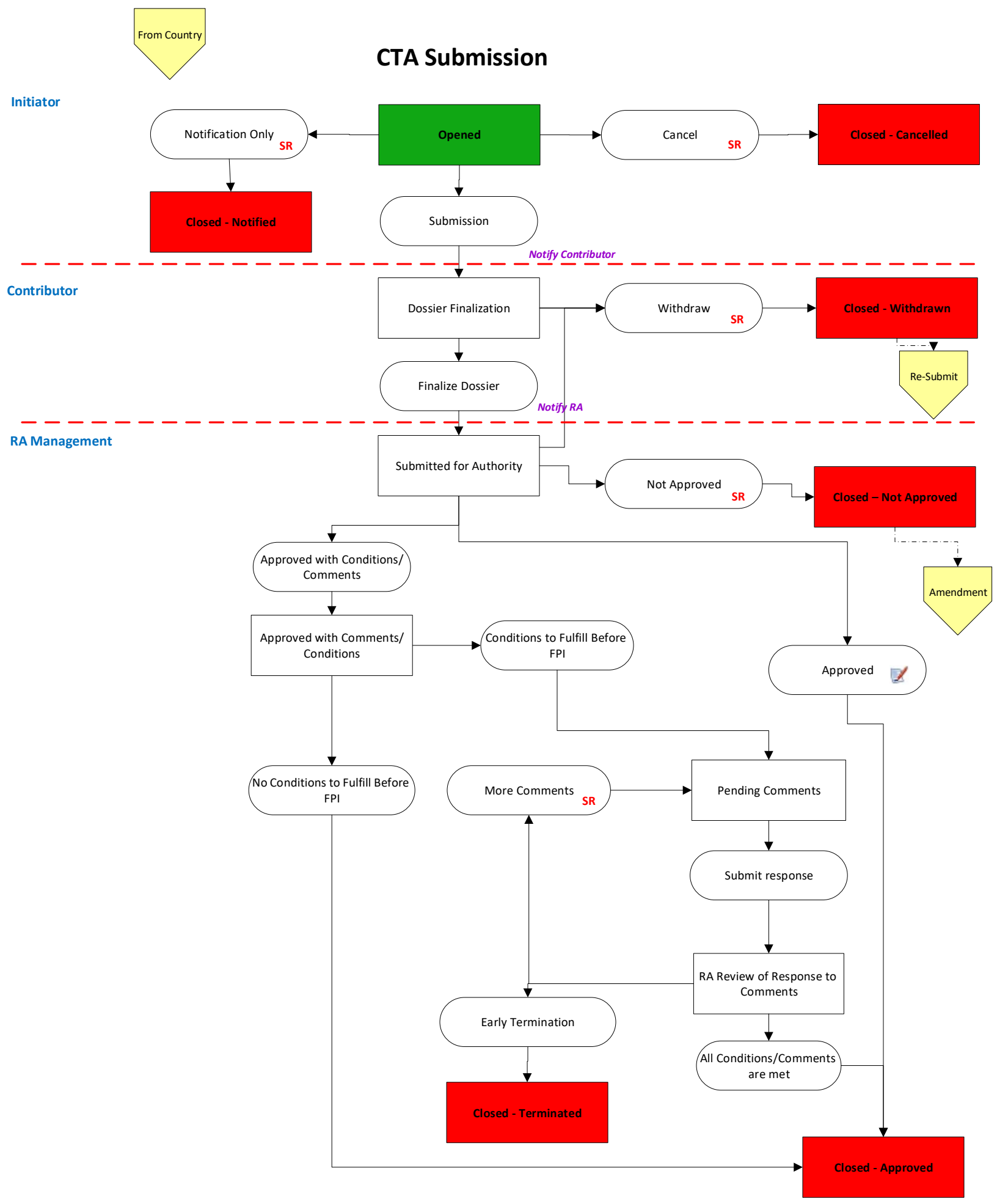


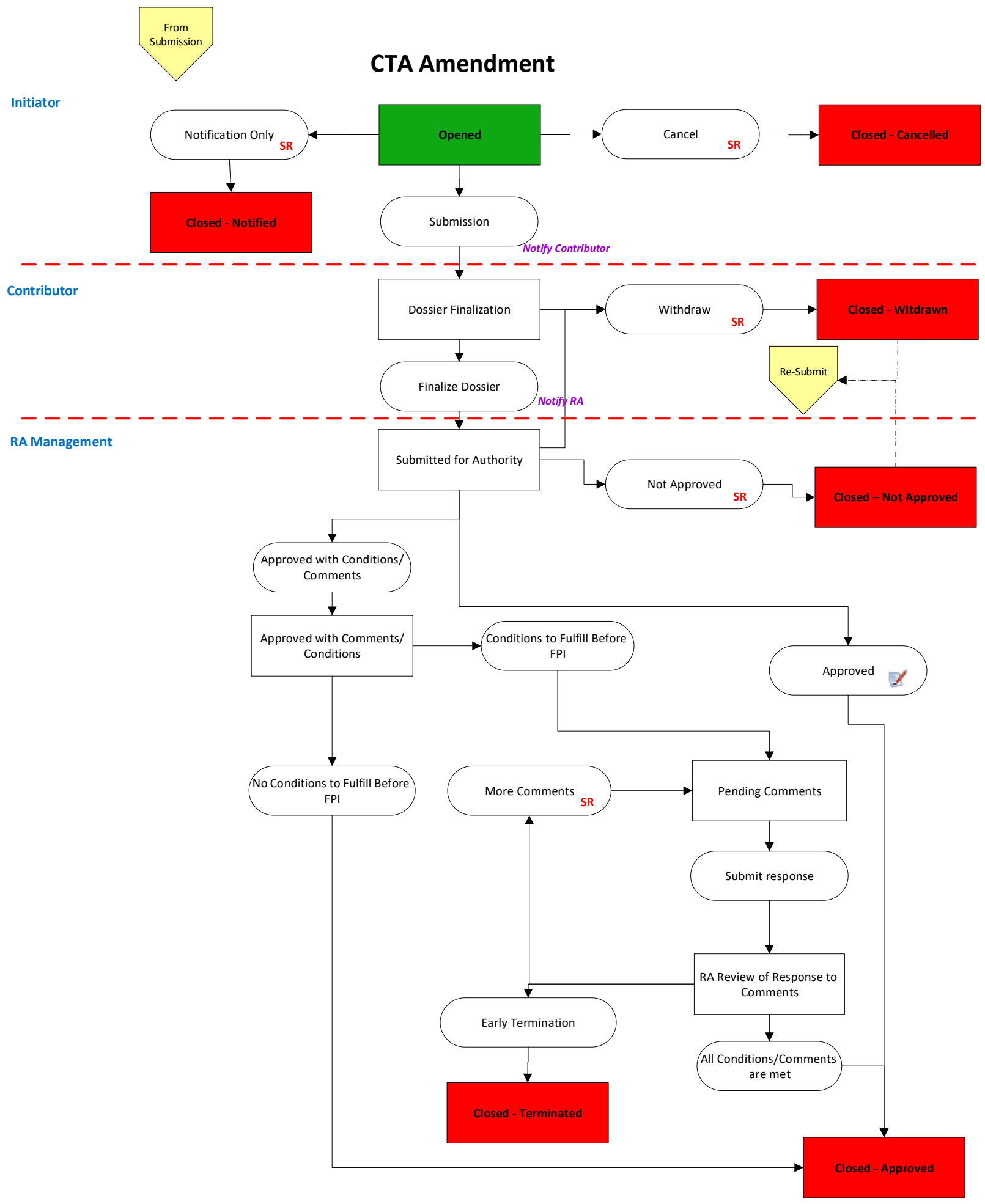
Risk Management



IT Help Desk/Incident

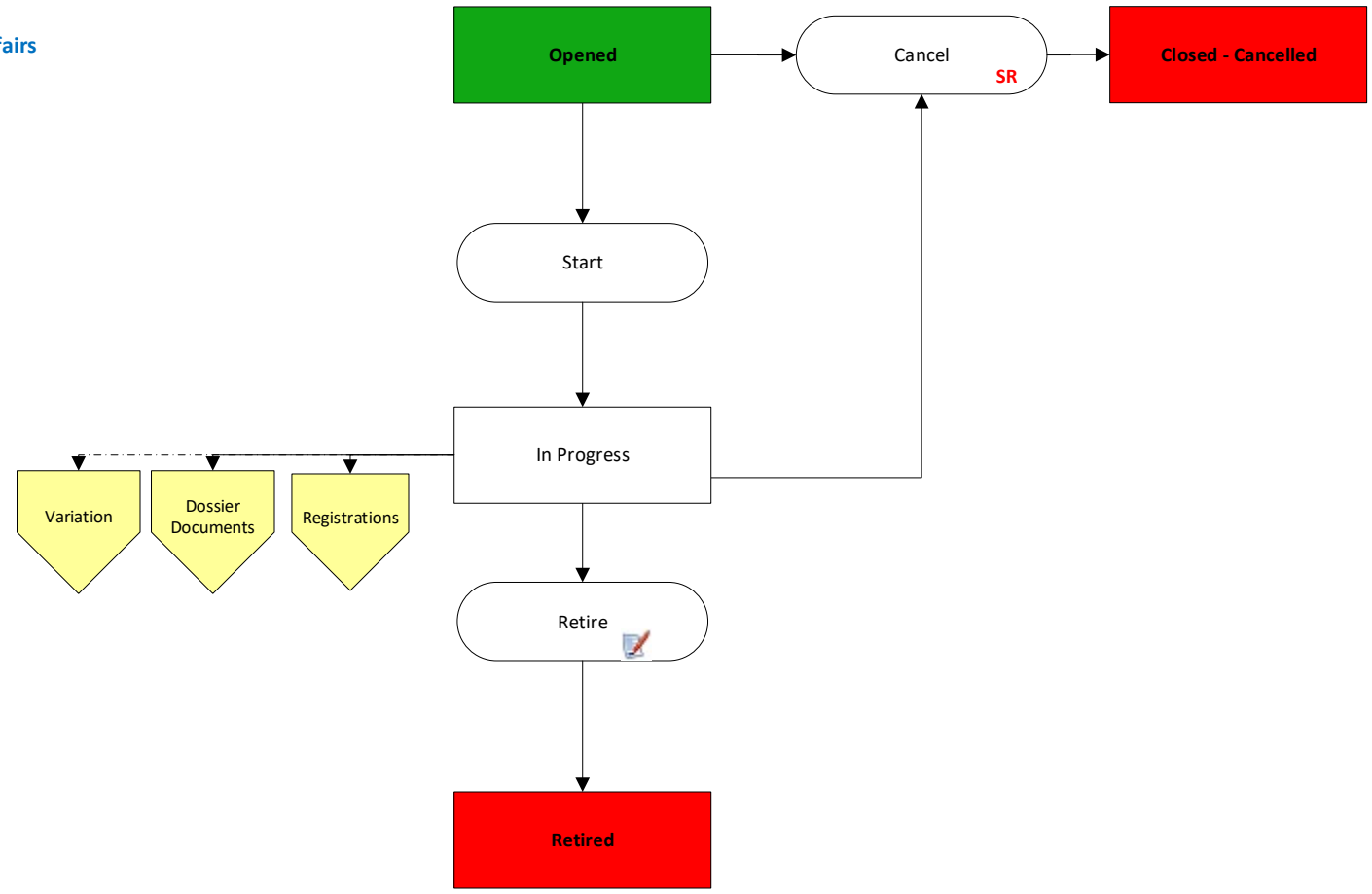



From Country
CTA Submission
Initiator
Notification Only
SR
Opened
Cancel
SR
Closed - Cancelled
Closed - Notified
Submission
Notify Contributor
Contributor
Dossier Finalization
Withdraw
SR
Closed - Withdrawn
Re-Submit
Finalize Dossier
Notify RA
RA Management
Submitted for Authority
Not Approved
SR
Closed – Not Approved
Amendment
Approved with Conditions/ Comments
Approved with Comments/ Conditions
Conditions to Fulfill Before FPI
Approved
No Conditions to Fulfill Before FPI
More Comments
SR
Pending Comments
Submit response
RA Review of Response to Comments
Early Termination
All Conditions/Comments are met
Closed - Terminated
Closed - Approved


From Submission
CTA Amendment
Initiator
Notification Only
SR
Opened
Cancel
SR
Closed - Cancelled
Closed - Notified
Submission
Notify Contributor
Contributor
Dossier Finalization
Withdraw
SR
Closed - Witdrawn
Re-Submit
Finalize Dossier
Notify RA
RA Management
Submitted for Authority
Not Approved
SR
Closed – Not Approved
Approved with Conditions/ Comments
Approved with Comments/ Conditions
Conditions to Fulfill Before FPI
Approved
No Conditions to Fulfill Before FPI
More Comments
SR
Pending Comments
Submit response
RA Review of Response to Comments
Early Termination
All Conditions/Comments are met
Closed - Terminated
Closed - Approved

Medicinal Product

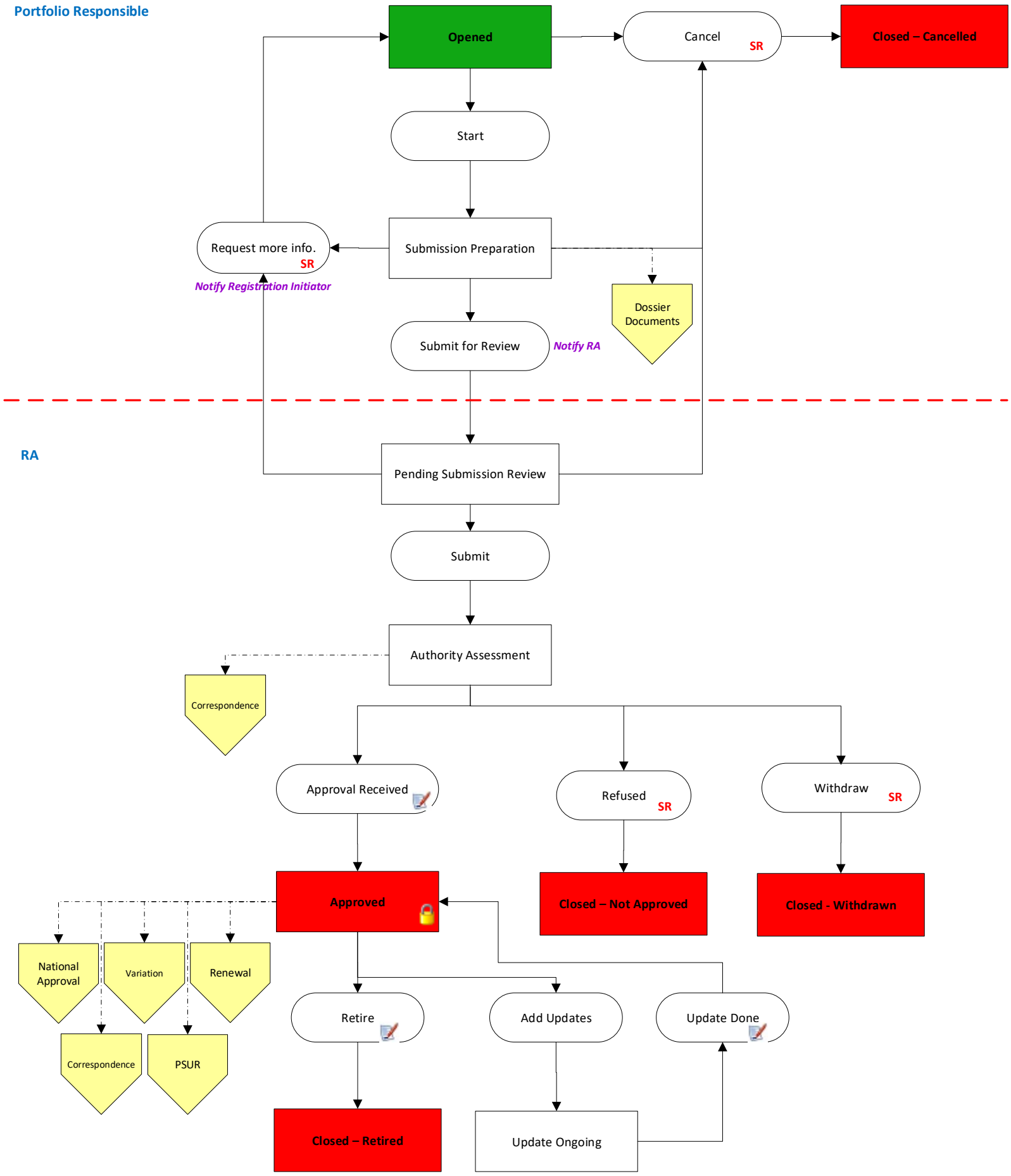
Regulatory Affairs

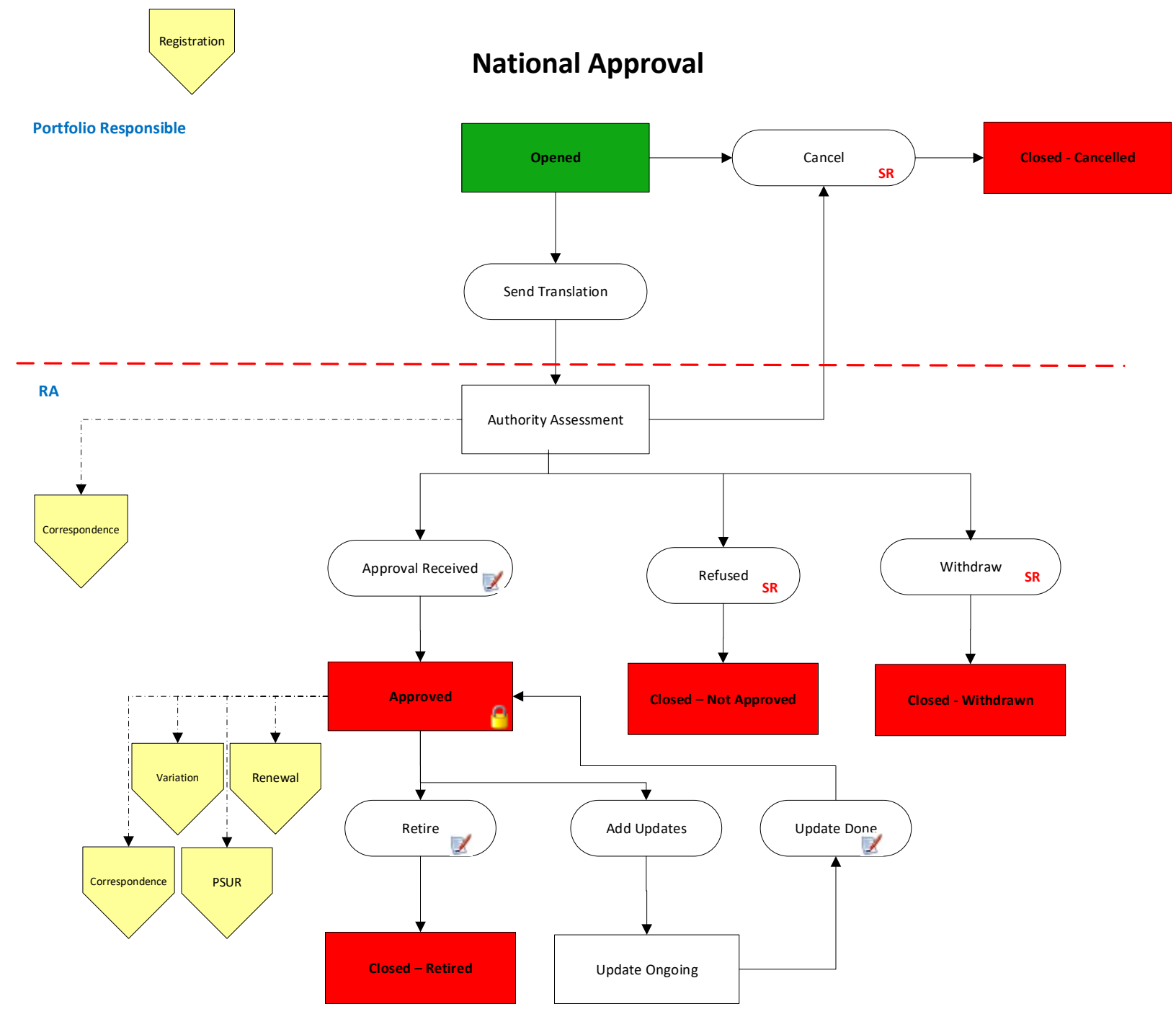


Medicinal Product

Submission Planning

CP Registration – DCP/MRP Registration - National Registration



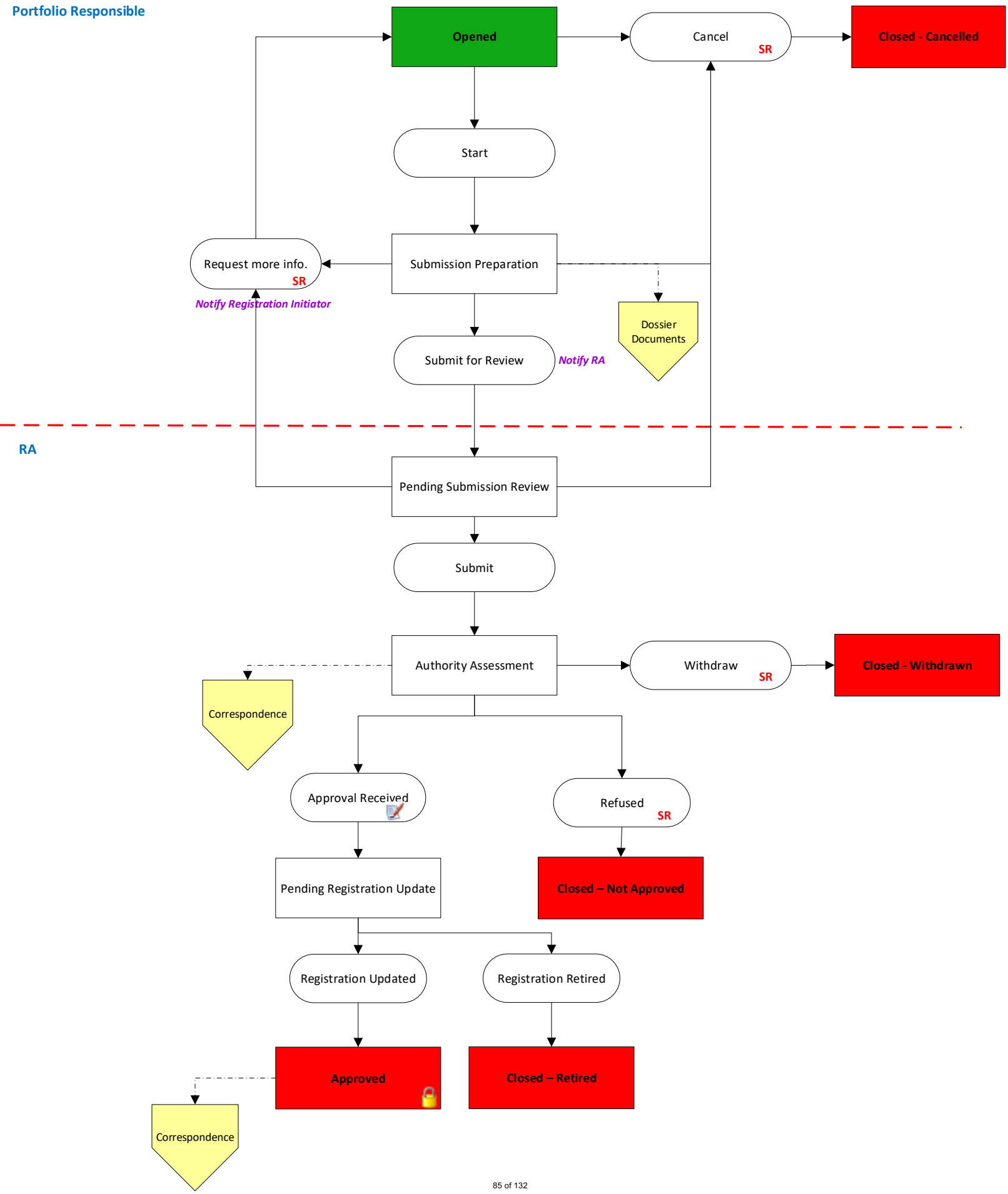

Registration
National Approval
Portfolio Responsible
Opened
Cancel
SR
Closed - Cancelled
Send Translation
RA
Authority Assessment
Correspondence
Approval Received
Refused
SR
Withdraw
SR
Approved
Closed – Not Approved
Closed - Withdrawn
Variation
Renewal
Retire
Add Updates
Update Done
Correspondence
PSUR
Closed – Retired
Update Ongoing

Medical Device Registration

National Approval

Registration

Renewal

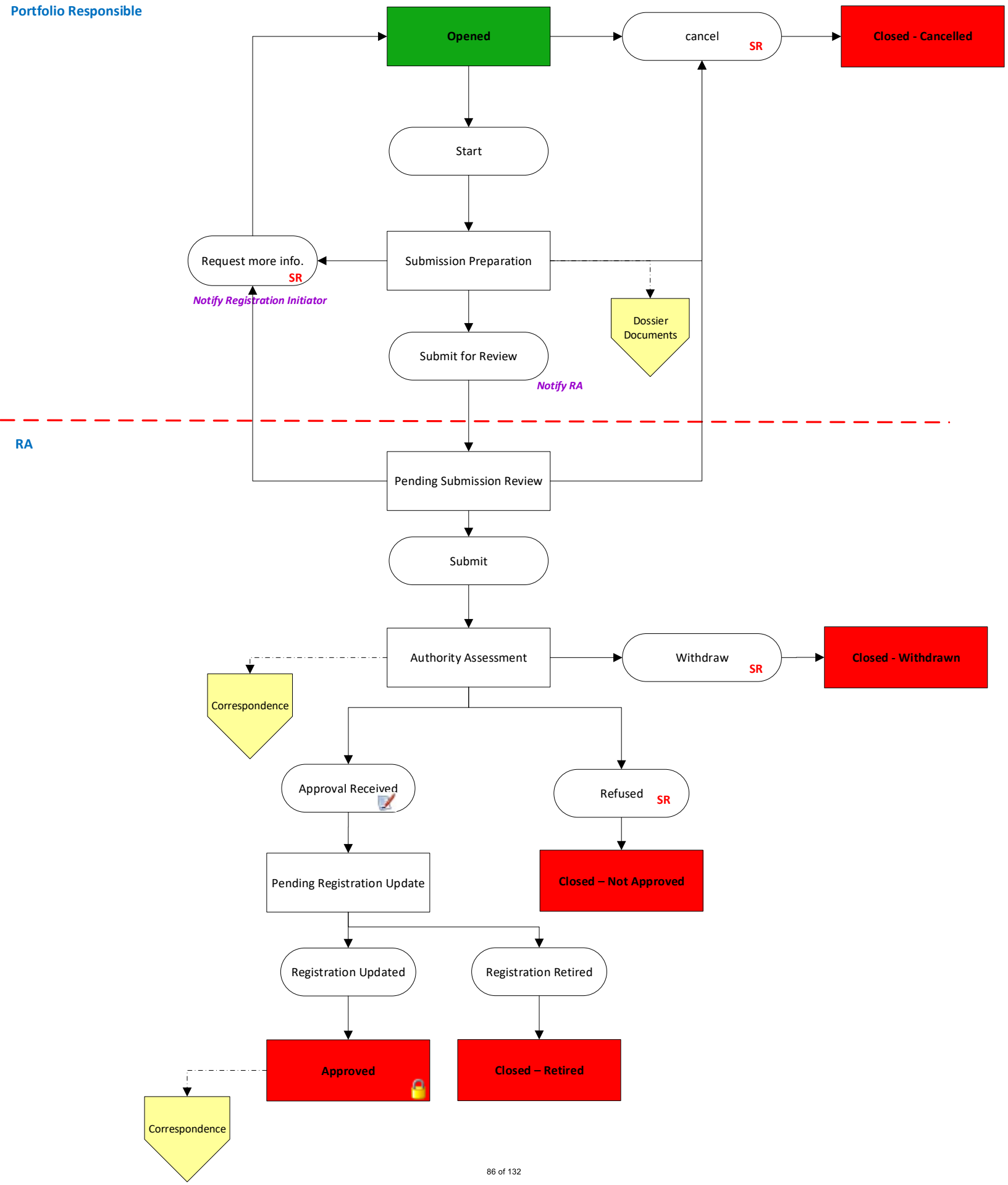


Medical Device Registration

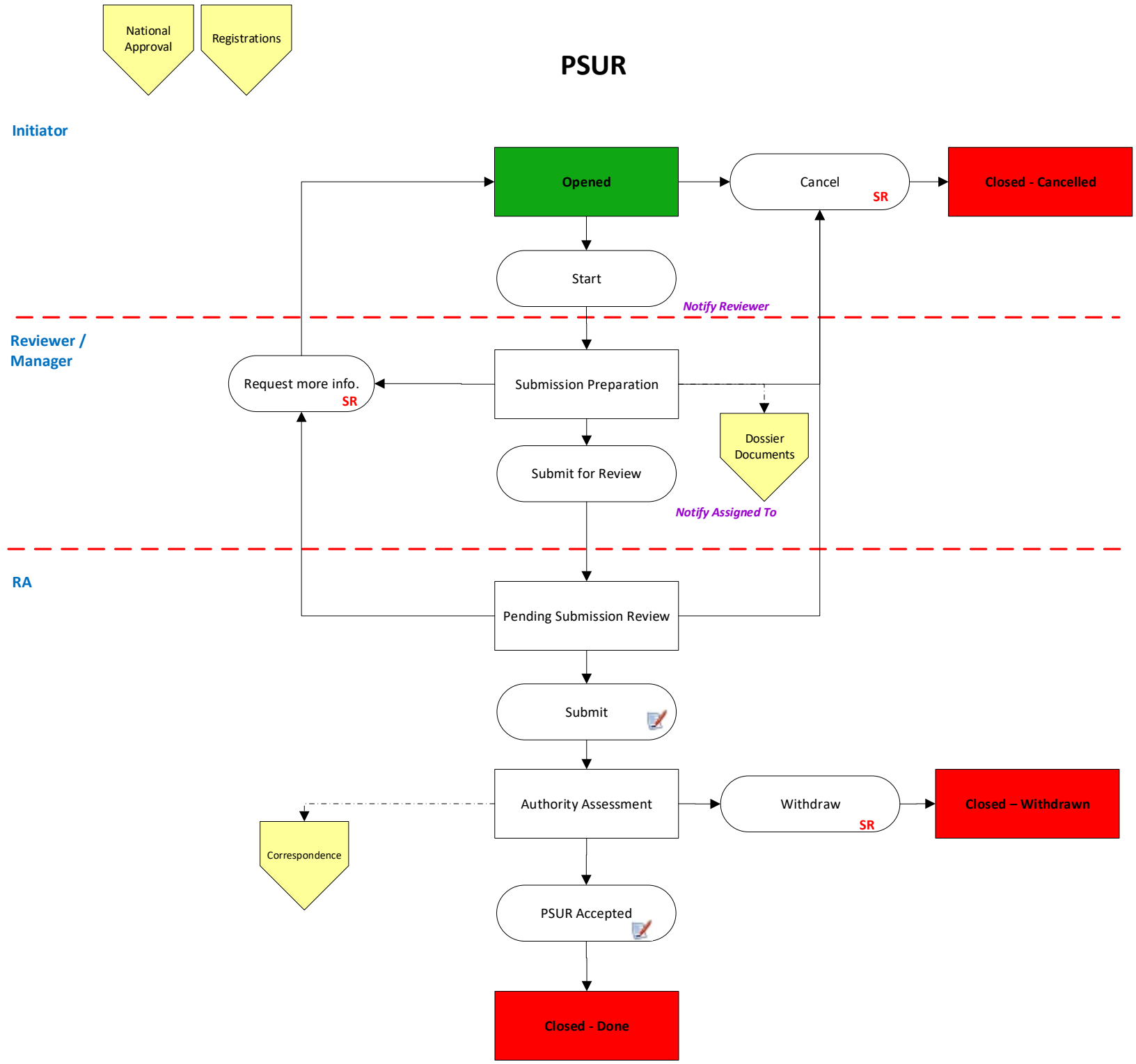
National Approval

Registration

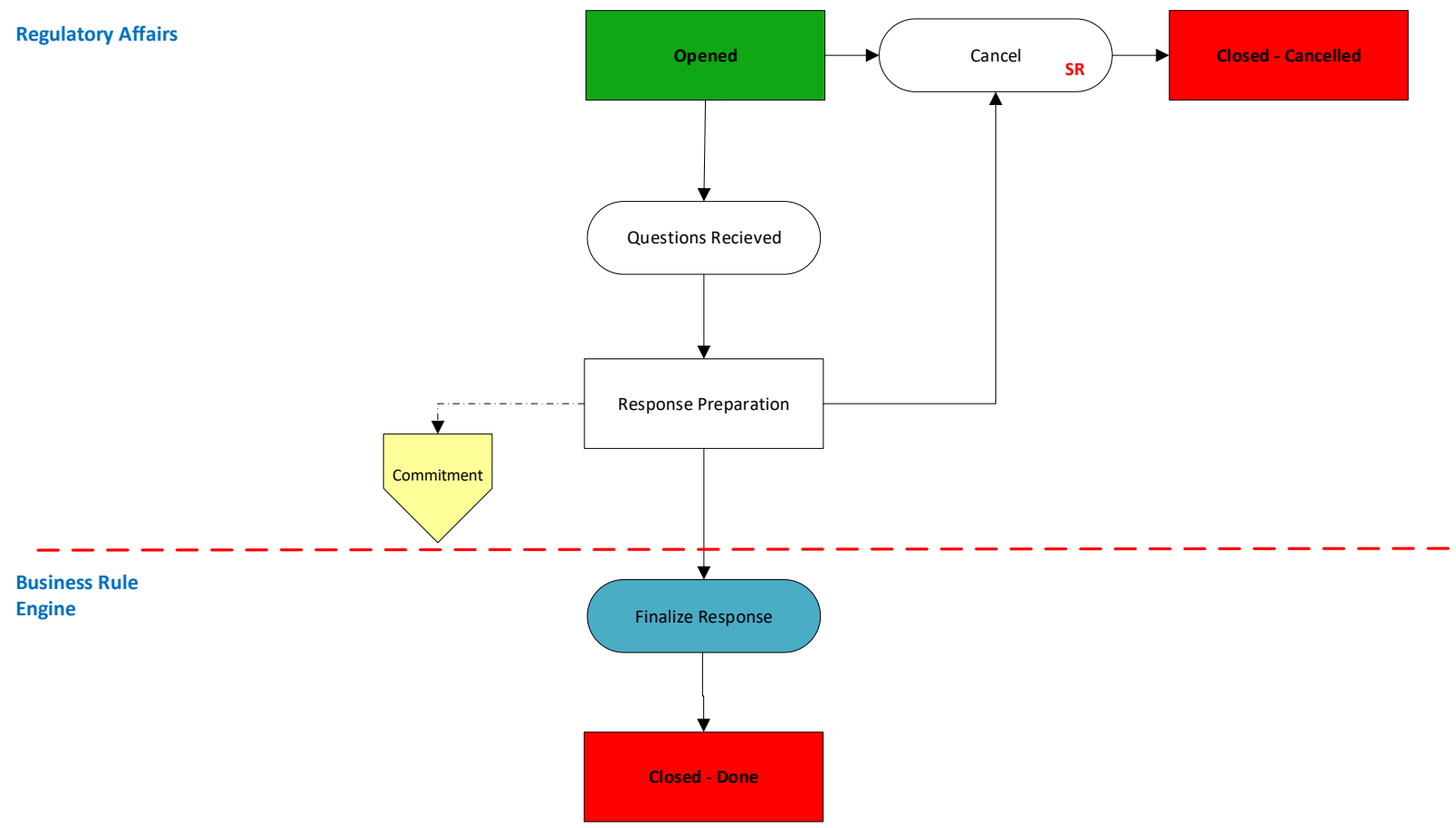
Variation



PSUR

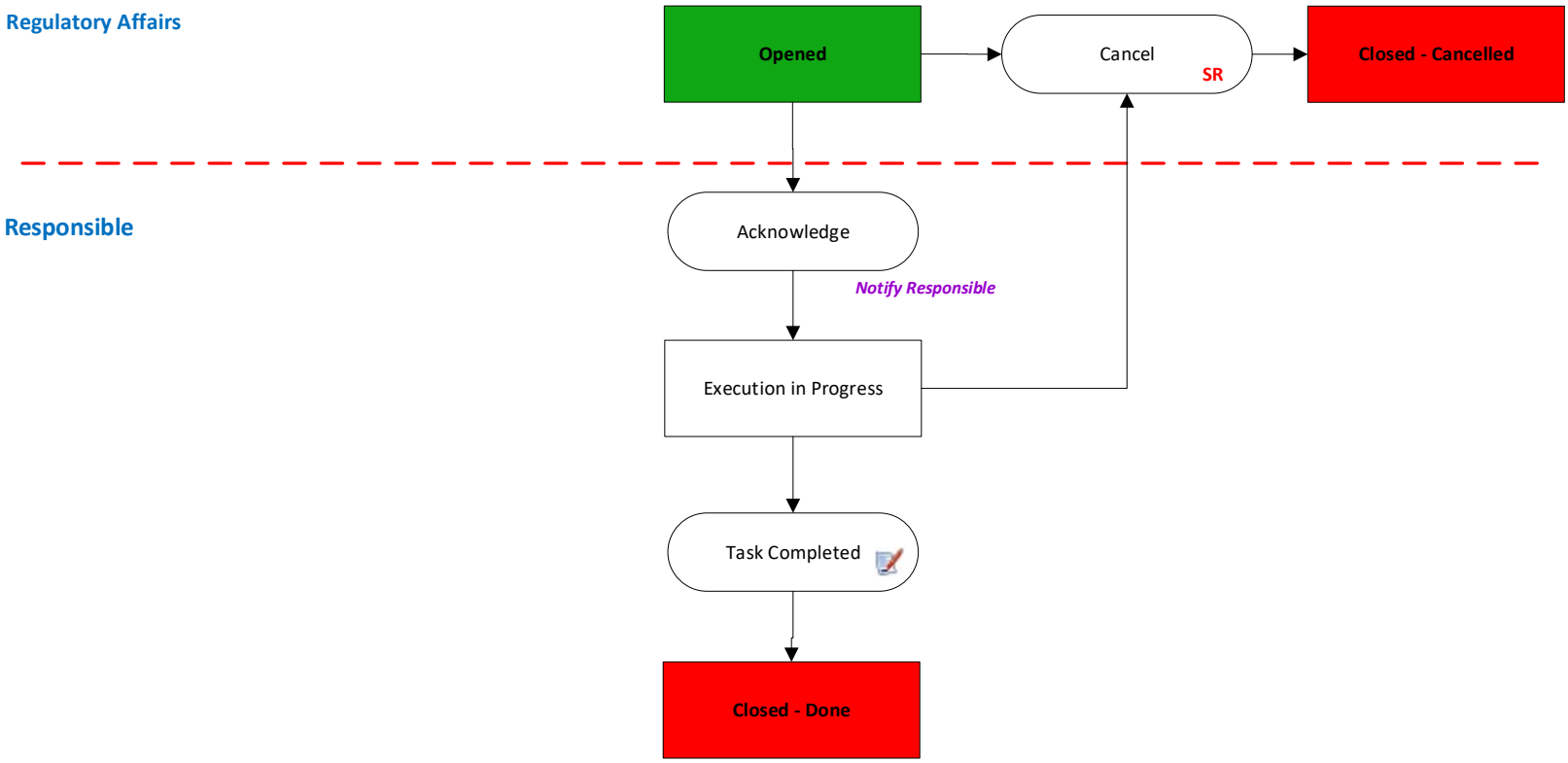

National Approval
Registrations
Initiator
Opened
Cancel
SR
Closed - Cancelled
Start
Notify Reviewer
Reviewer / Manager
Request more info.
SR
Submission Preparation
Dossier Documents
Submit for Review
Notify Assigned To
RA
Pending Submission Review
Submit
Authority Assessment
Withdraw
SR
Closed – Withdrawn
Correspondence
PSUR Accepted
Closed - Done

Correspondence



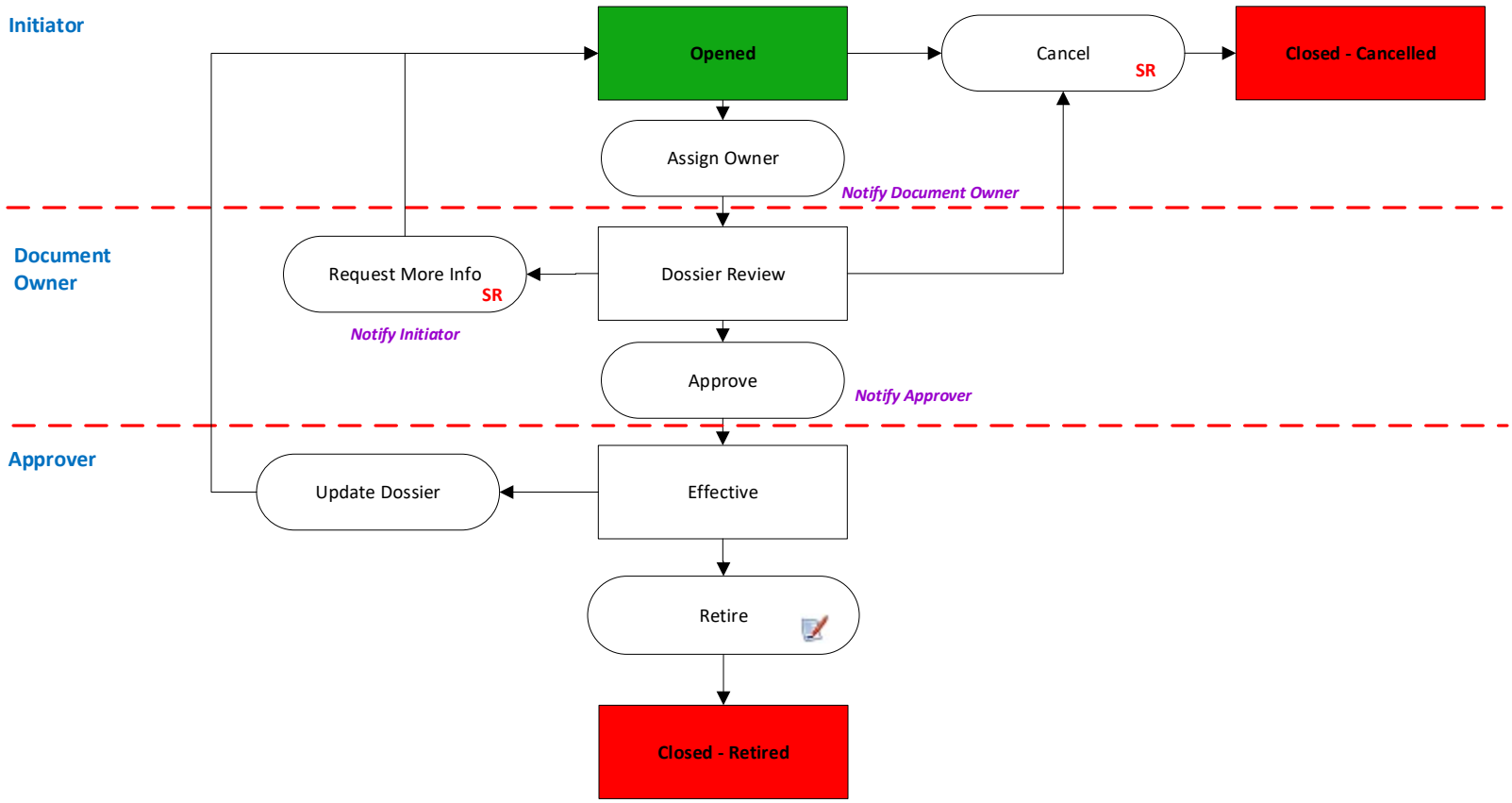
Correspondence

Commitment

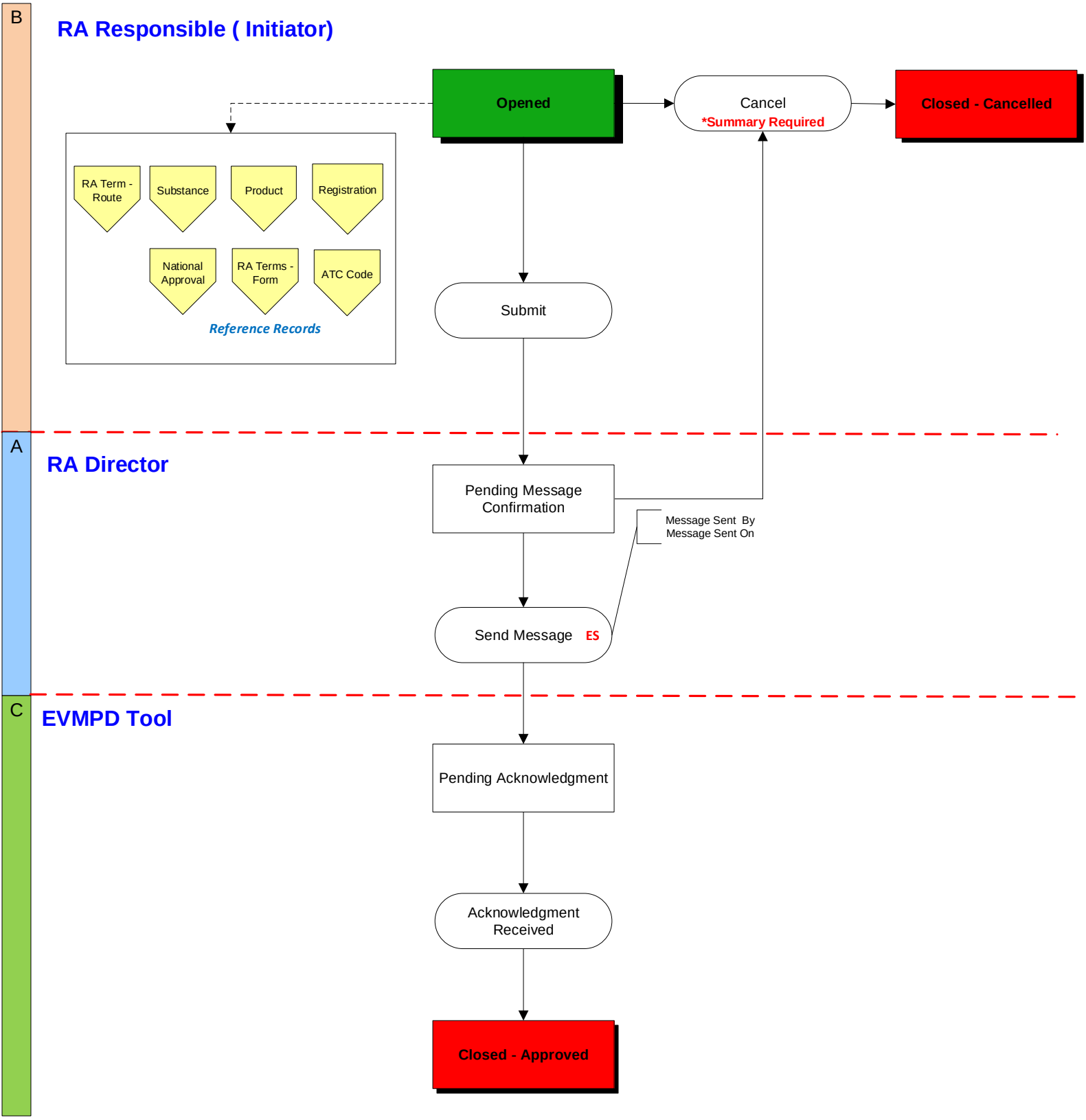


Submission Planning | Medicinal Product | From Medical Device | Renewal | Variation | PSUR

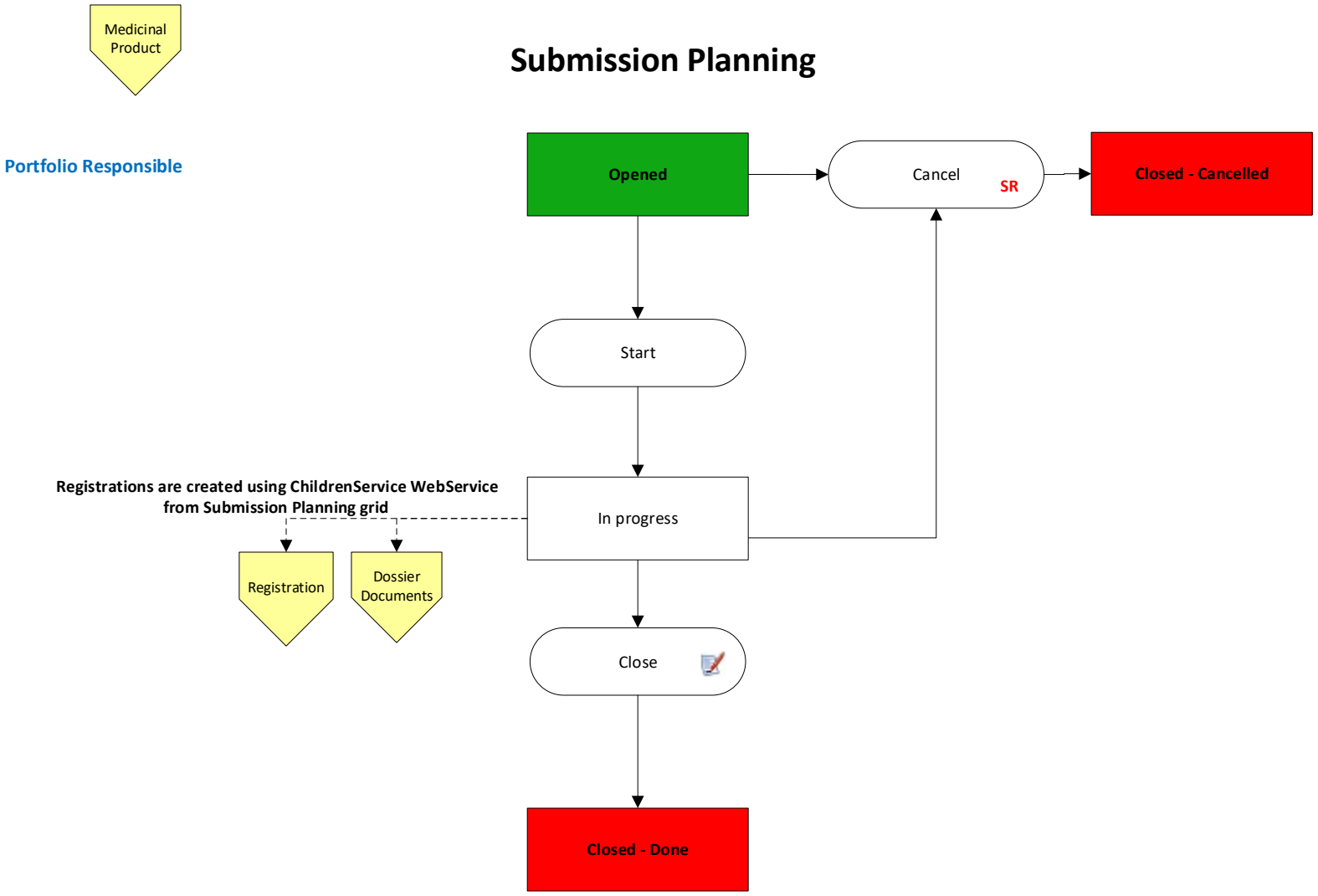
Dossier



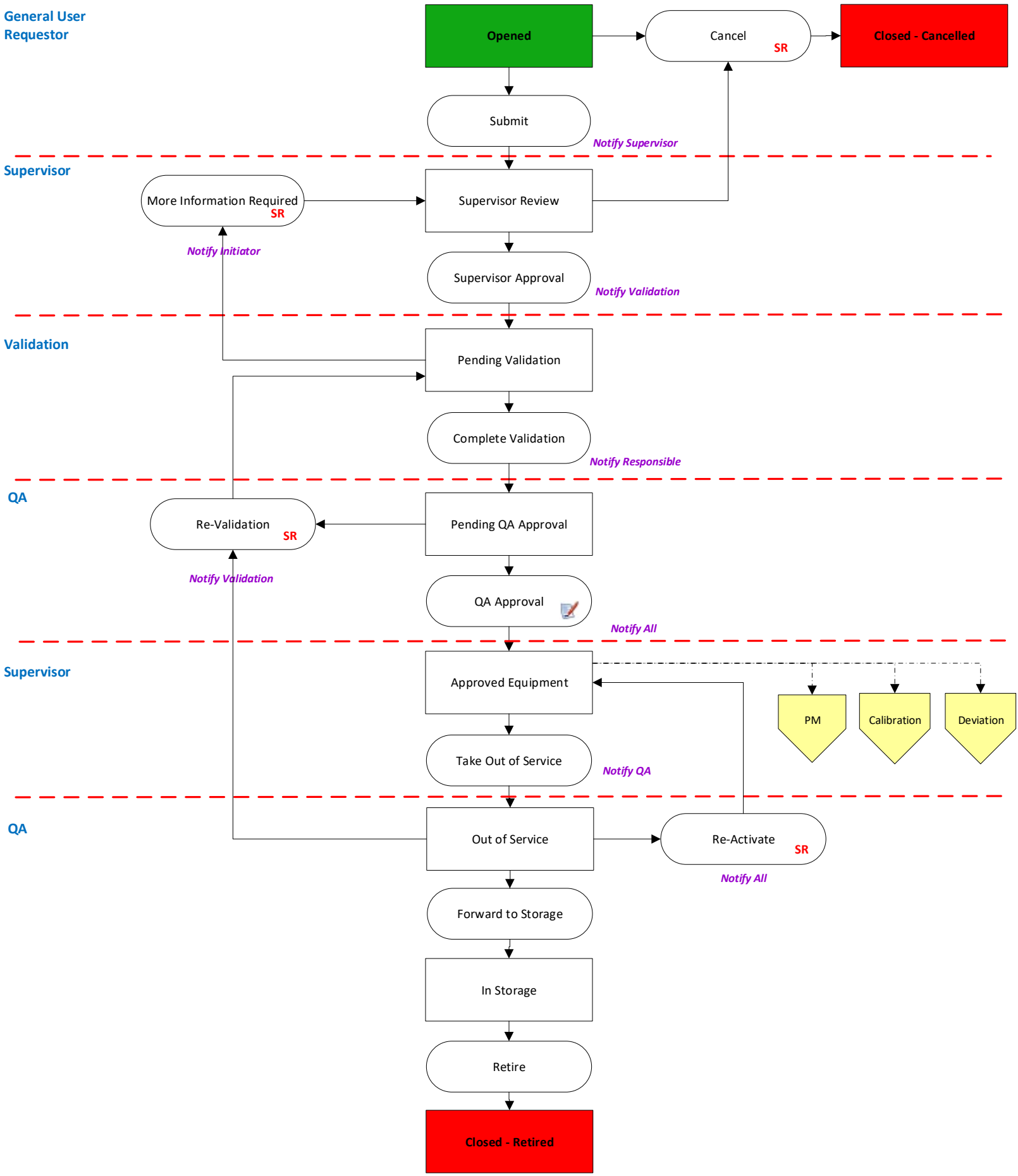
EVMPD Message



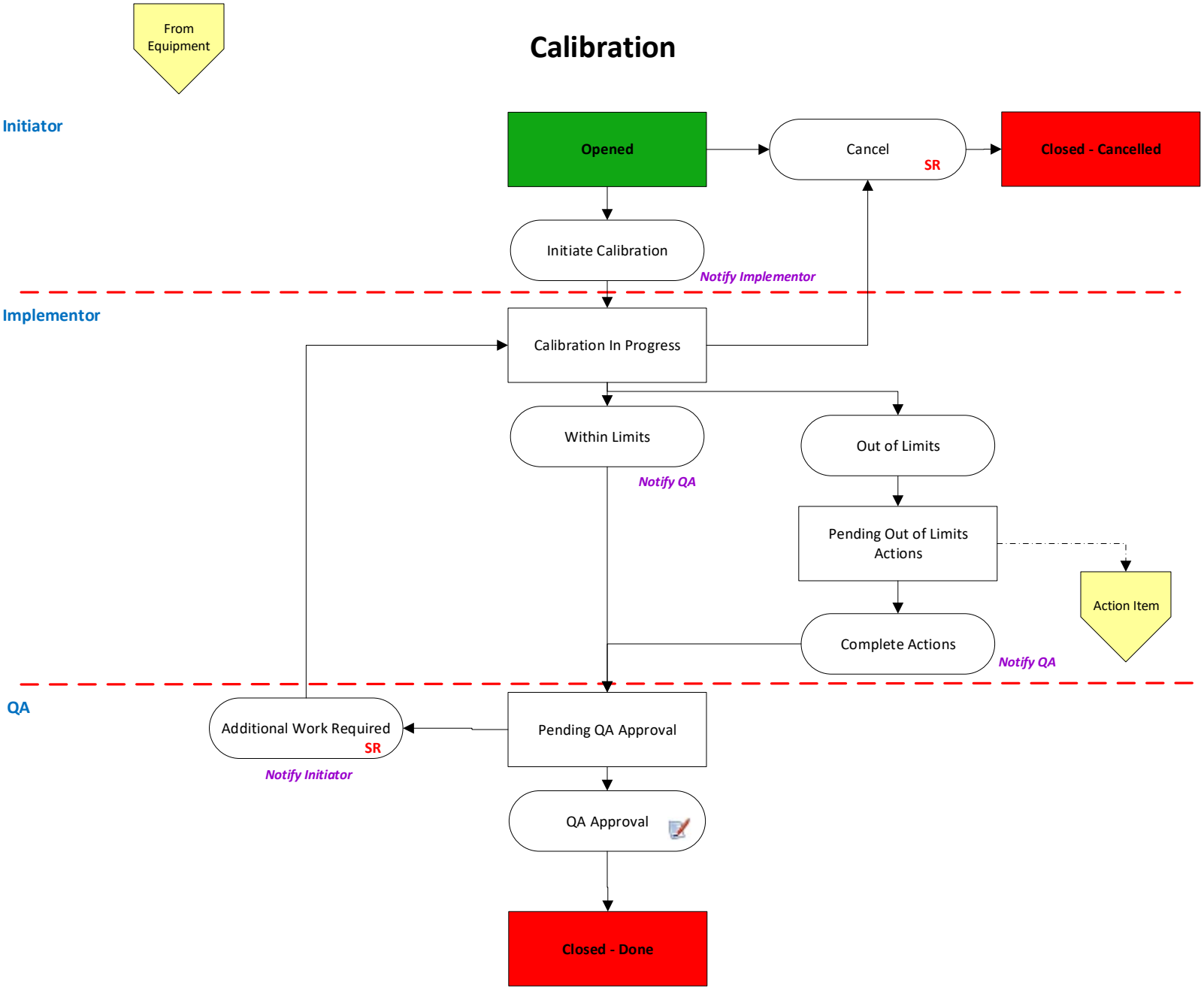
Submission Planning



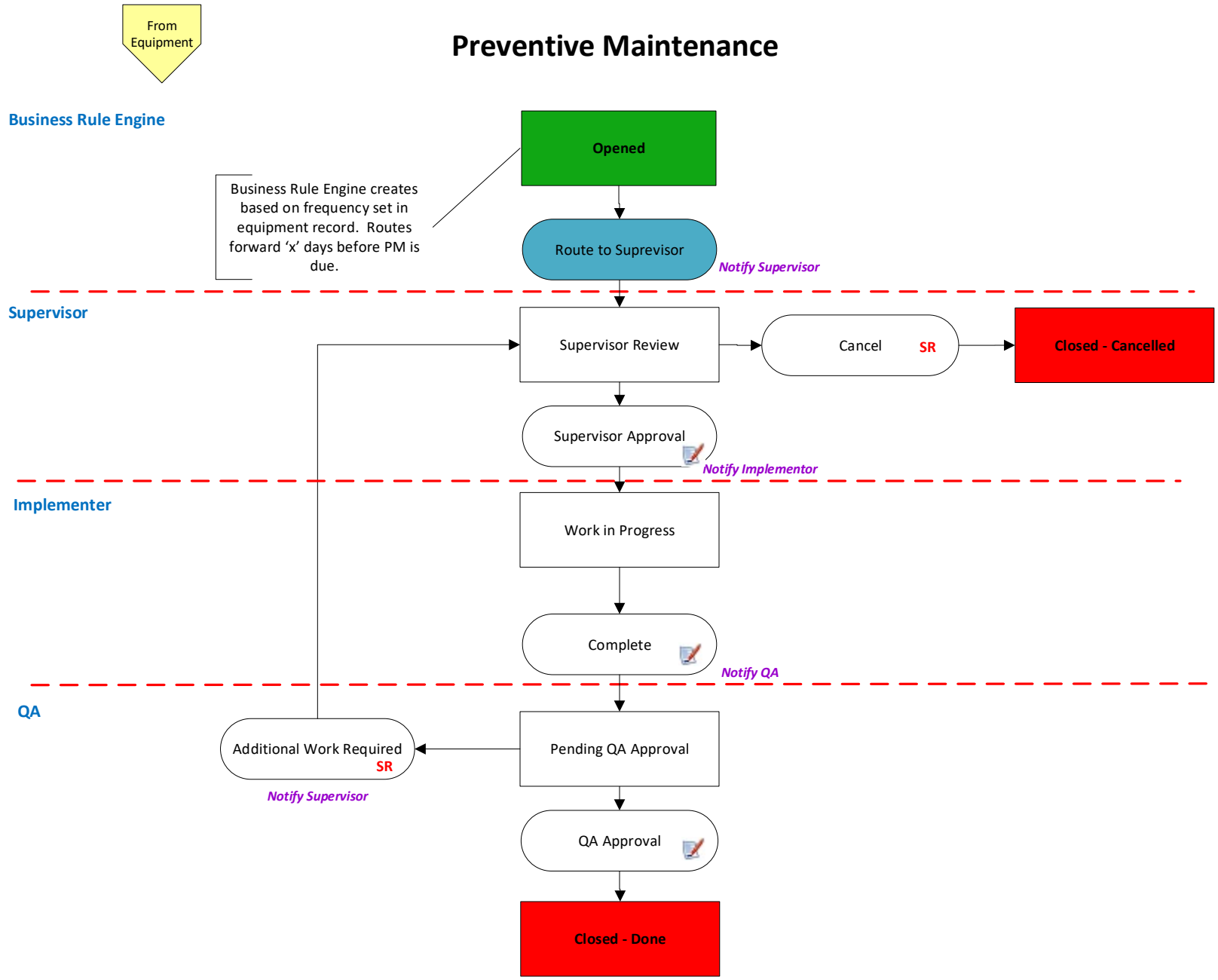
Equipment


General User
Requestor
Opened
Cancel
SR
Closed - Cancelled
Submit
Notify Supervisor
Supervisor
More Information Required
SR
Supervisor Review
Notify Initiator
Supervisor Approval
Notify Validation
Validation
Pending Validation
Complete Validation
Notify Responsible
QA
Re-Validation
SR
Pending QA Approval
Notify Validation
QA Approval
Notify All
Supervisor
Approved Equipment
PM
Calibration
Deviation
Take Out of Service
Notify QA
QA
Out of Service
Re-Activate
SR
Notify All
Forward to Storage
In Storage
Retire
Closed - Retired

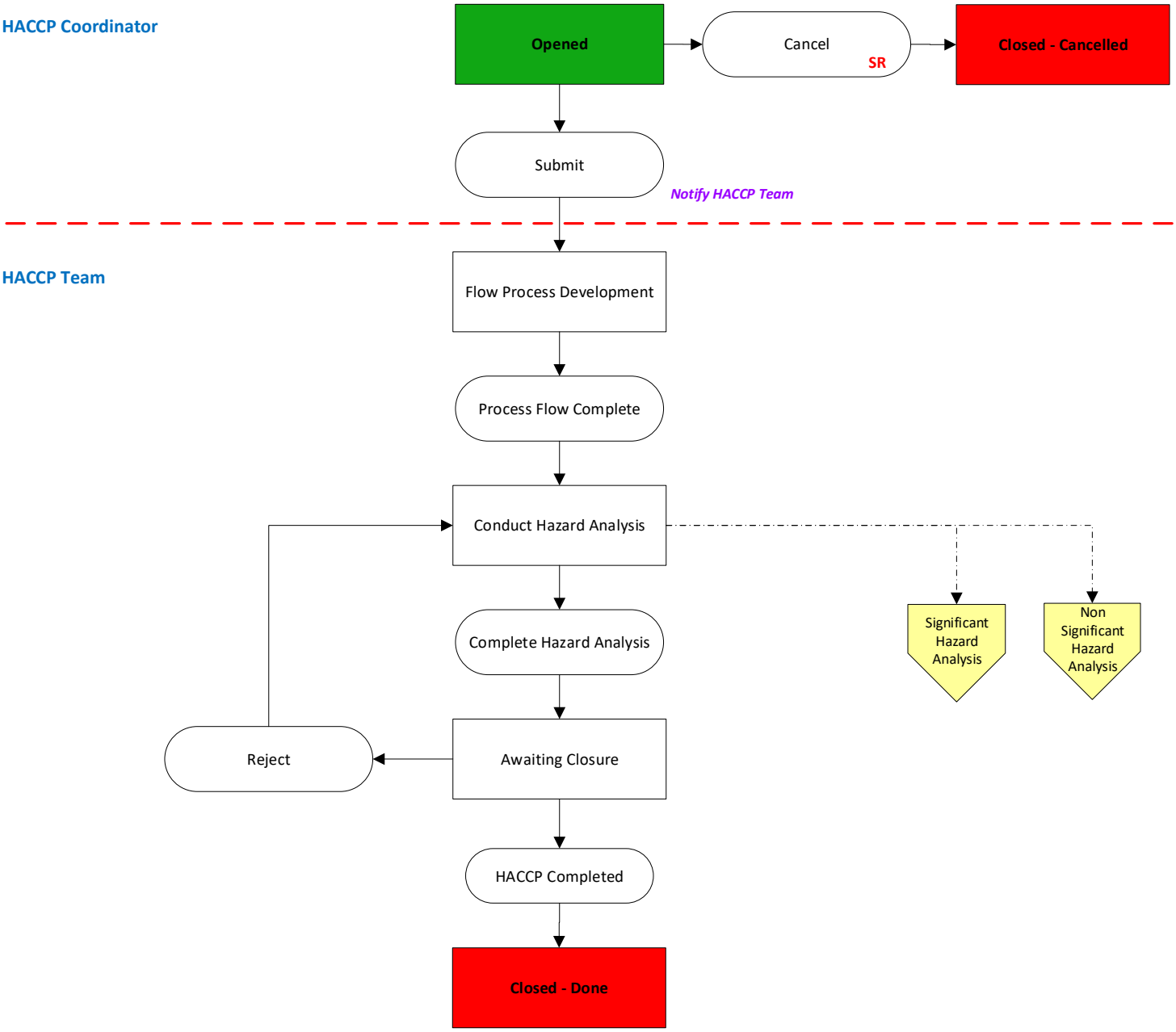
Calibration



Preventive Maintenance



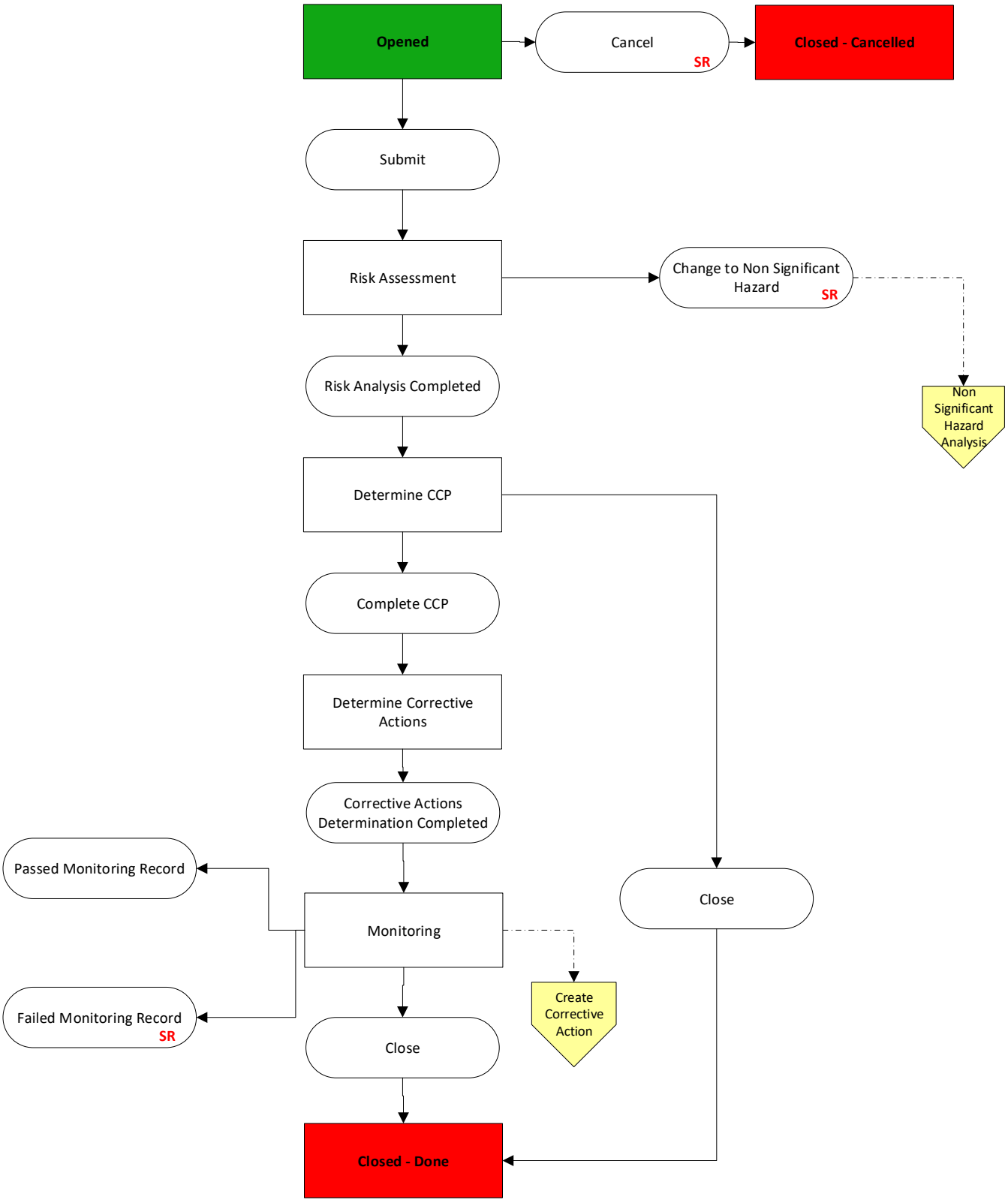
HACCP Plan


HACCP Coordinator
Opened
Cancel
SR
Closed - Cancelled
Submit
Notify HACCP Team
HACCP Team
Flow Process Development
Process Flow Complete
Conduct Hazard Analysis
Complete Hazard Analysis
Significant Hazard Analysis
Non Significant Hazard Analysis
Reject
Awaiting Closure
HACCP Completed
Closed - Done

From HACCP Plan

Significant Hazard Analysis

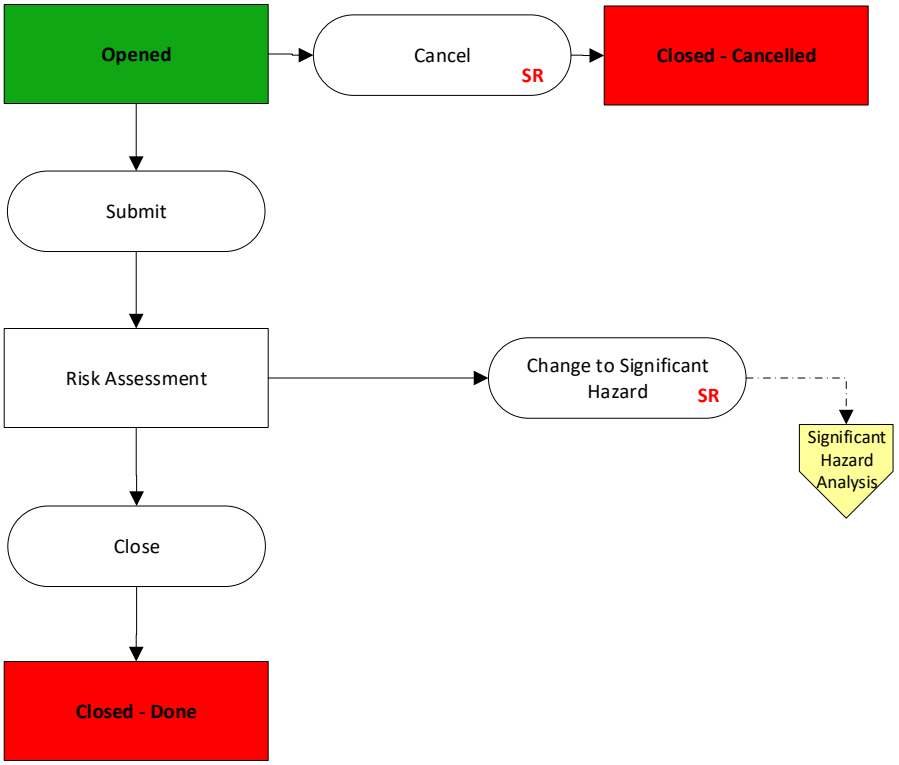
HACCP Team



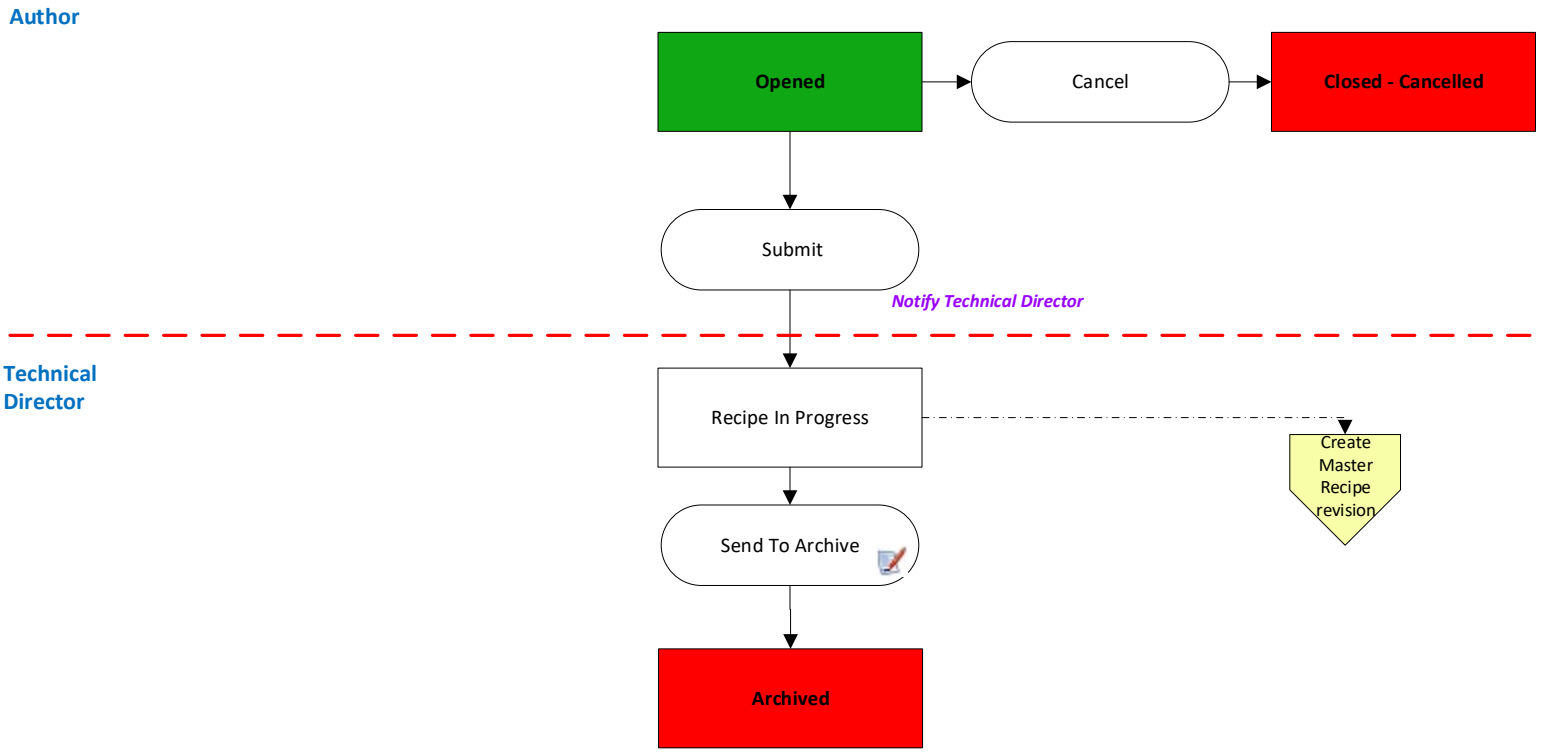
From HACCP Plan

Non Significant Hazard Analysis

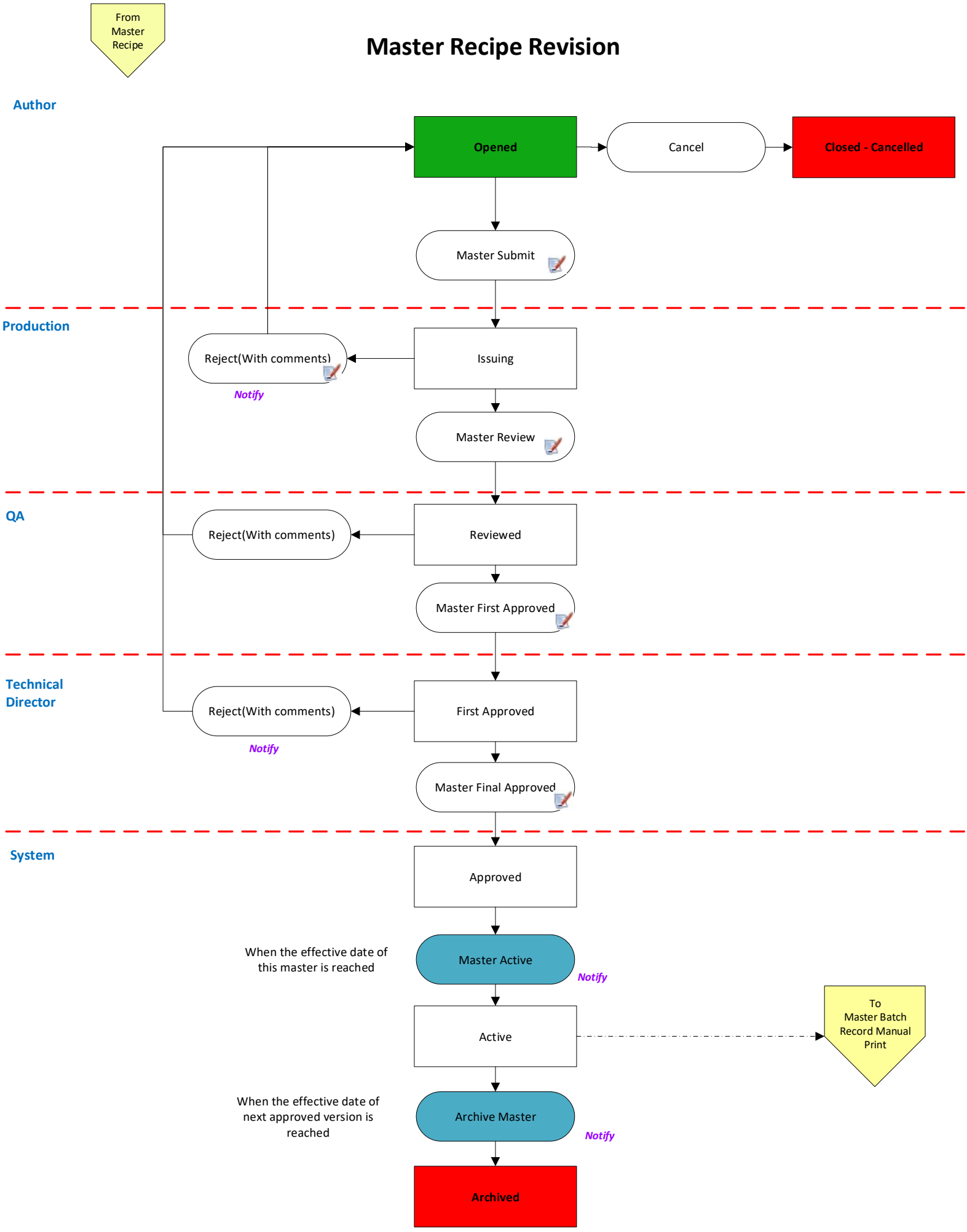
HACCP Team



Master Recipe



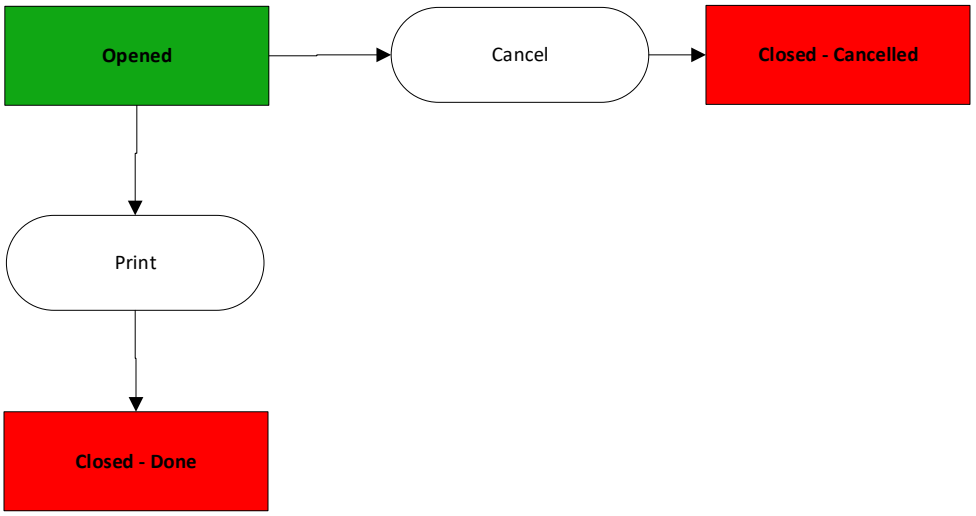
Master Recipe Revision



To
Master Recipe
Revision

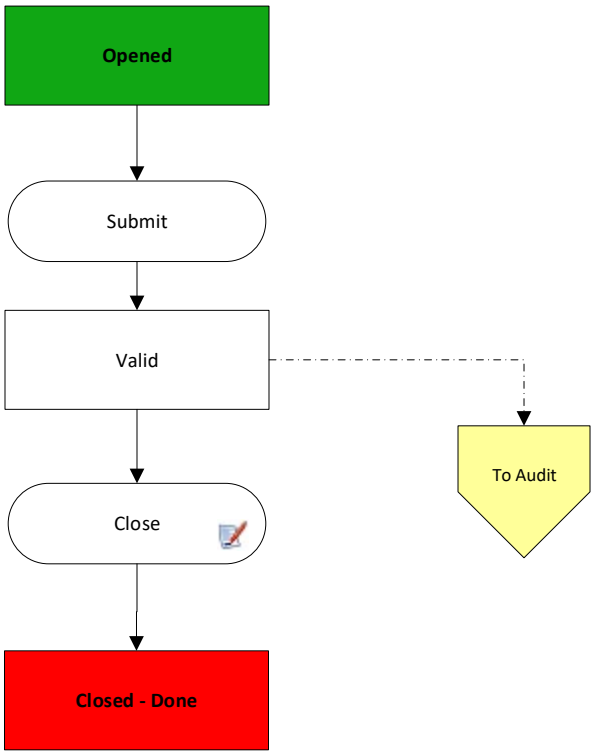
Master Batch Record Manual Print

Originator

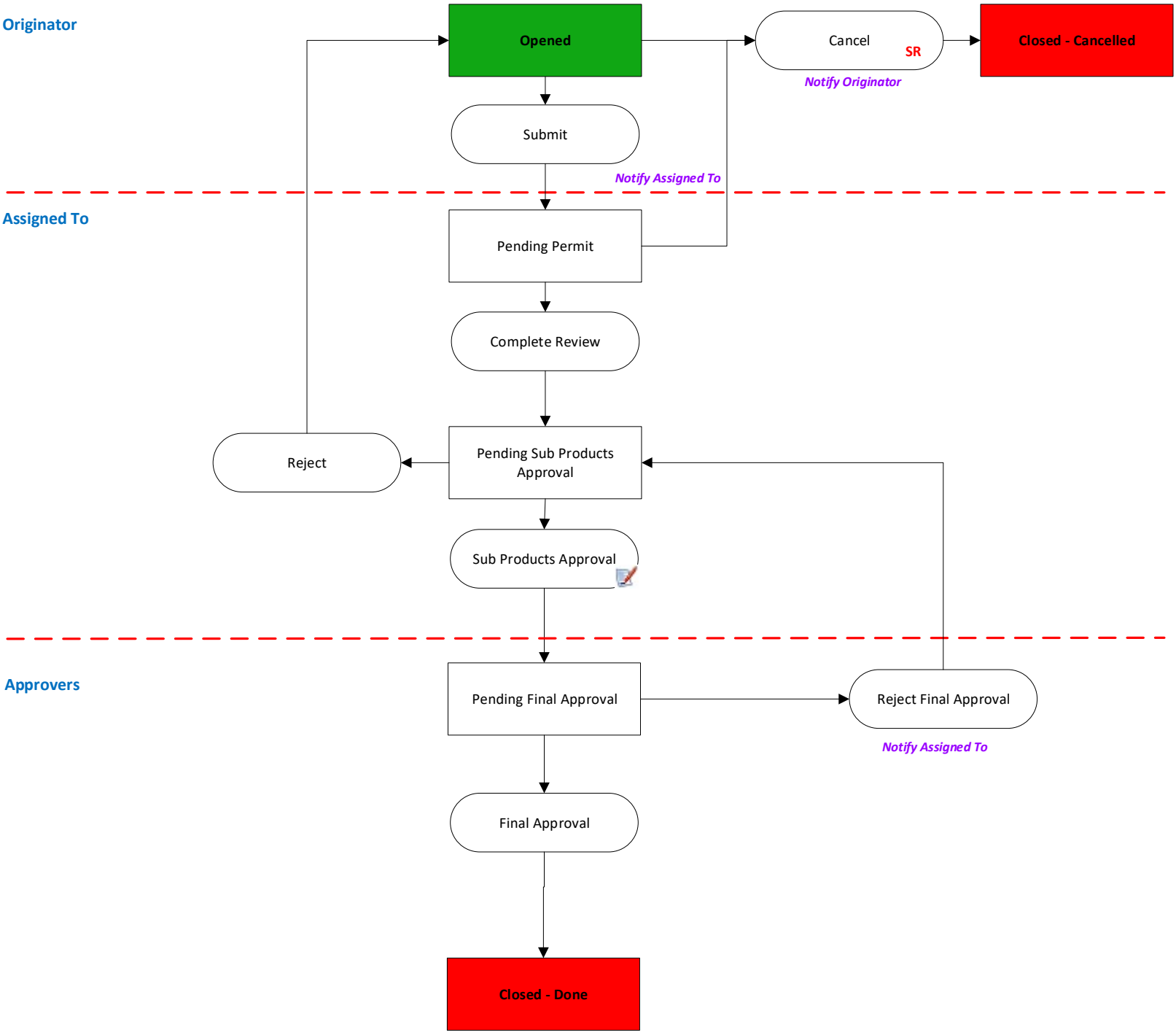


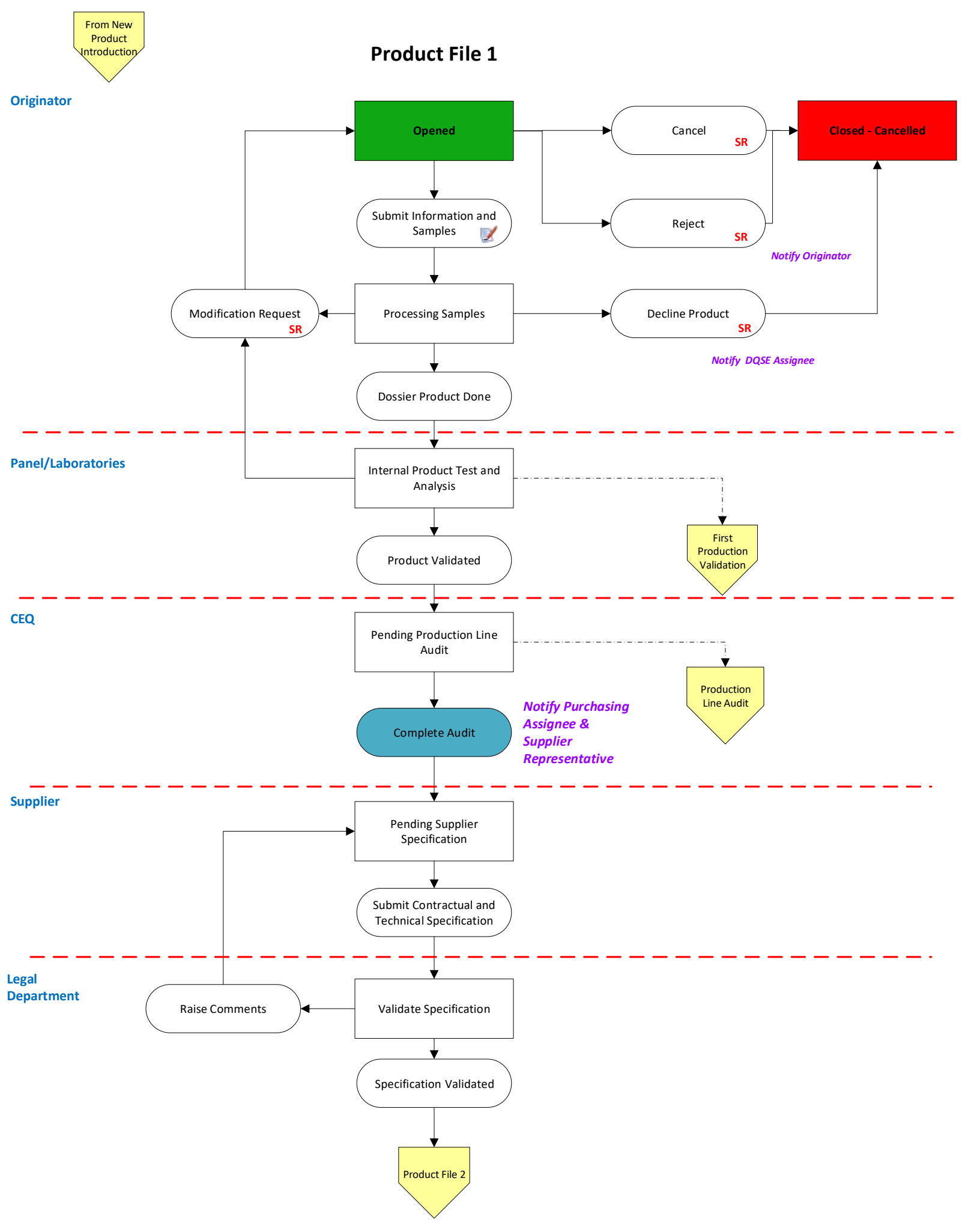
Auditee

Originator

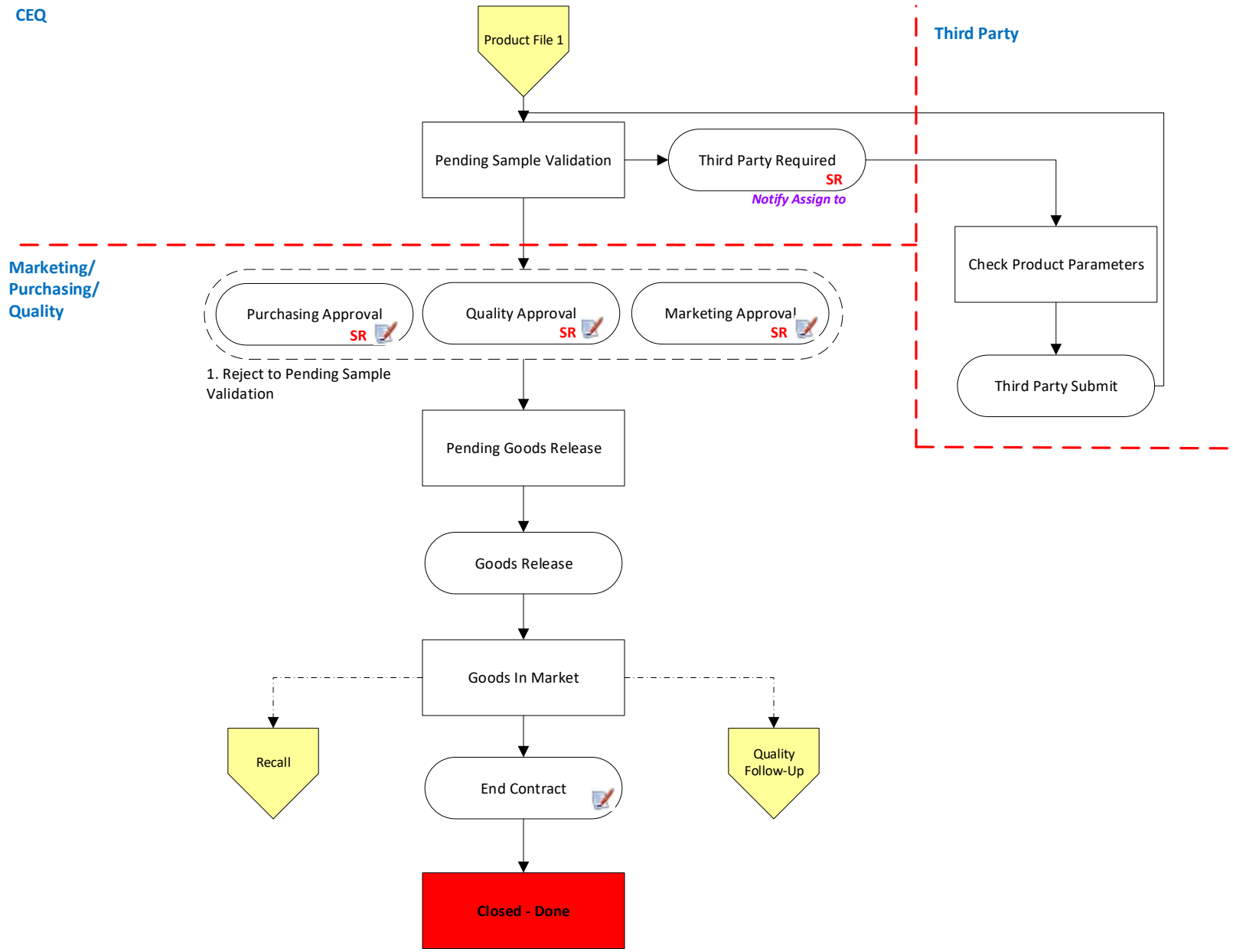


New Product Introduction

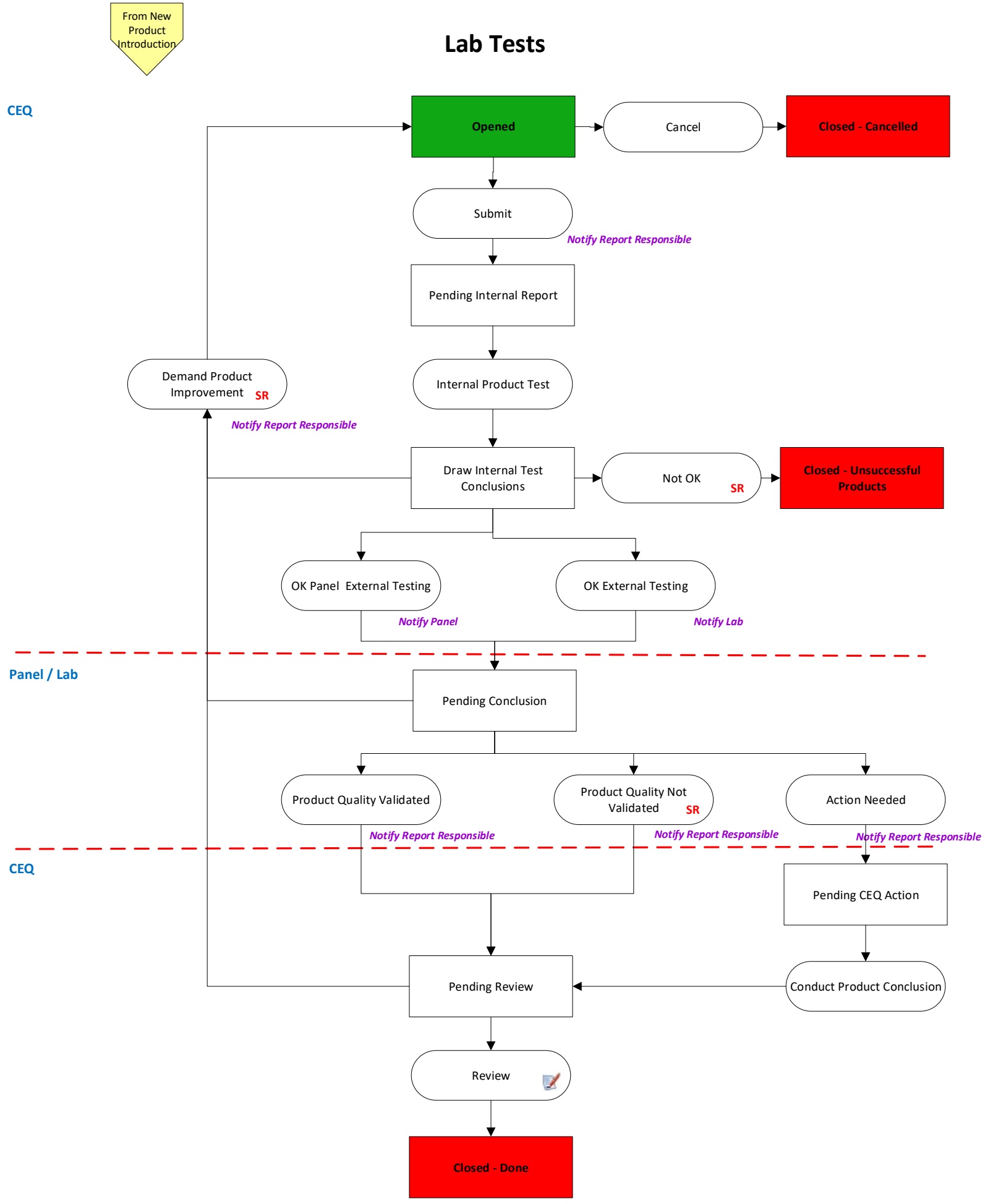


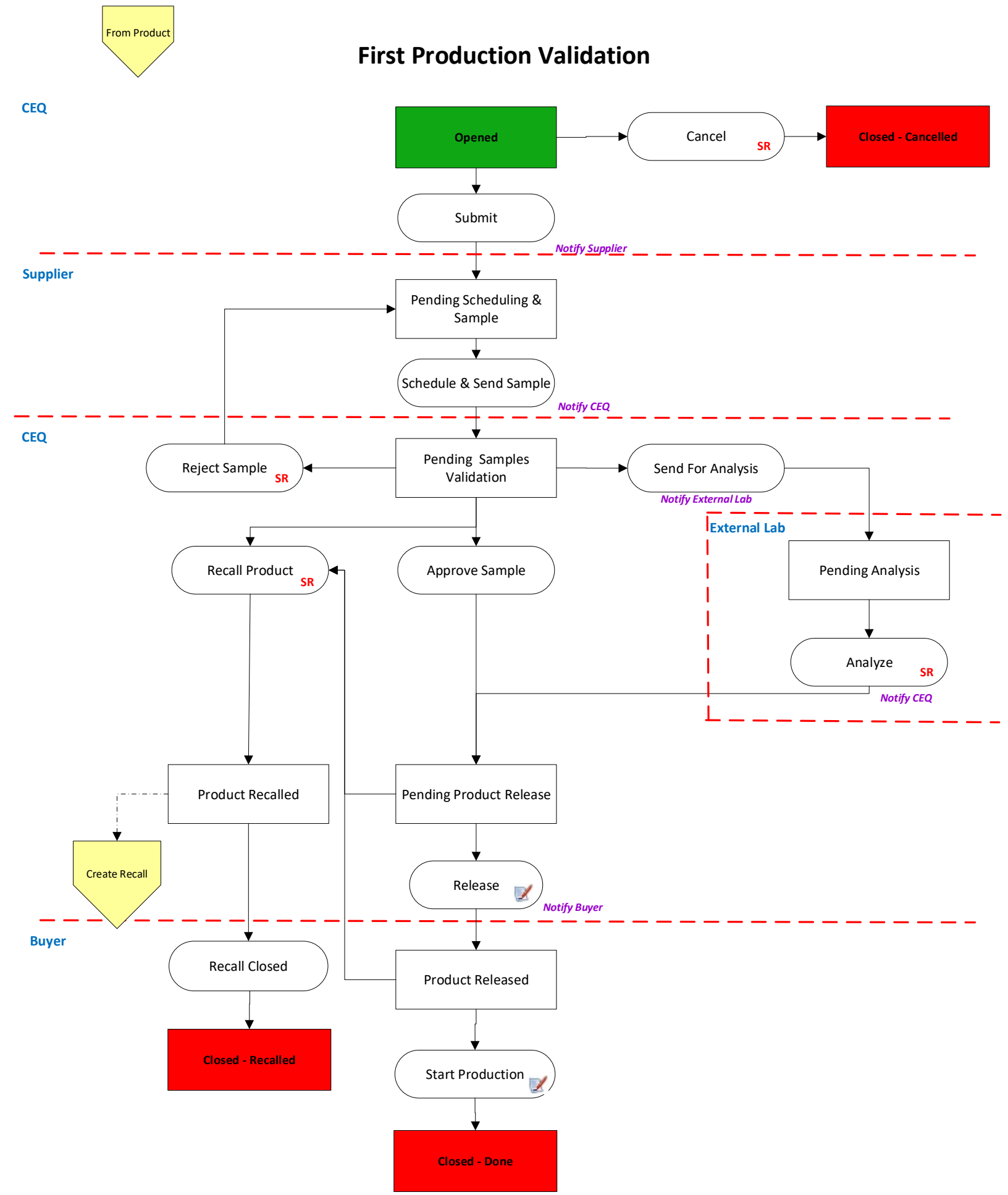

From New Product Introduction
Product File 1
Originator
Opened
Cancel
SR
Closed - Cancelled
Submit Information and Samples
Reject
SR
Notify Originator
Modification Request
SR
Processing Samples
Decline Product
SR
Notify DQSE Assignee
Dossier Product Done
Panel/Laboratories
Internal Product Test and Analysis
First Production Validation
Product Validated
CEQ
Pending Production Line Audit
Production Line Audit
Complete Audit
Notify Purchasing Assignee & Supplier Representative
Supplier
Pending Supplier Specification
Submit Contractual and Technical Specification
Legal Department
Raise Comments
Validate Specification
Specification Validated
Product File 2

Product File 2



Lab Tests

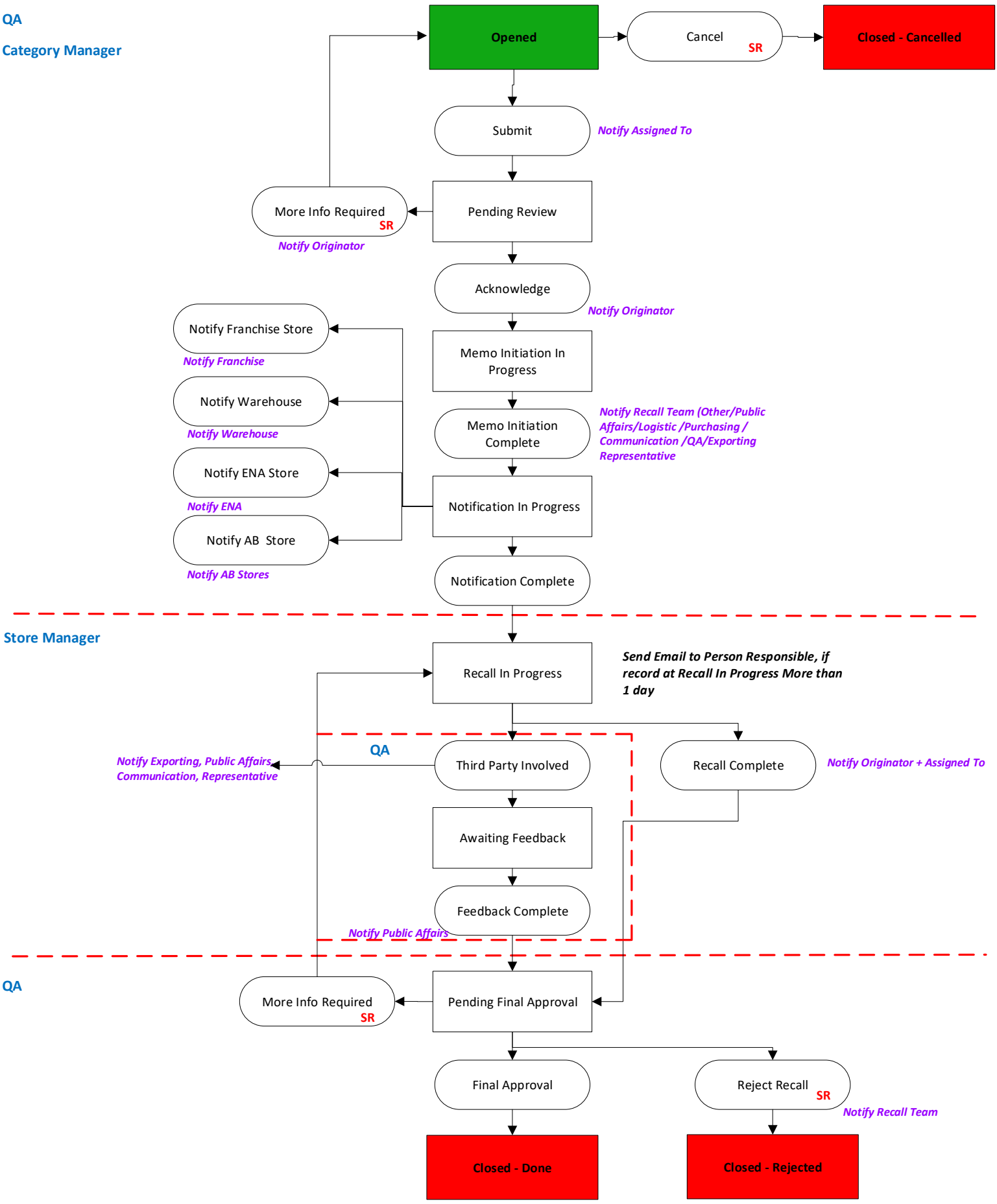

From New Product Introduction
CEQ
Opened
Cancel
Closed - Cancelled
Submit
Notify Report Responsible
Pending Internal Report
Demand Product Improvement SR
Internal Product Test
Notify Report Responsible
Draw Internal Test Conclusions
Not OK SR
Closed - Unsuccessful Products
OK Panel External Testing
OK External Testing
Notify Panel
Notify Lab
Panel / Lab
Pending Conclusion
Product Quality Validated
Product Quality Not Validated SR
Action Needed
Notify Report Responsible
Notify Report Responsible
Notify Report Responsible
CEQ
Pending CEQ Action
Pending Review
Conduct Product Conclusion
Review
Closed - Done


From Product
First Production Validation
CEQ
Opened
Cancel
SR
Closed - Cancelled
Submit
Notify Supplier
Supplier
Pending Scheduling & Sample
Schedule & Send Sample
Notify CEQ
CEQ
Reject Sample
SR
Pending Samples Validation
Send For Analysis
Notify External Lab
External Lab
Recall Product
SR
Approve Sample
Pending Analysis
Analyze
SR
Notify CEQ
Product Recalled
Pending Product Release
Create Recall
Release
Notify Buyer
Buyer
Recall Closed
Product Released
Closed - Recalled
Start Production
Closed - Done

From Product

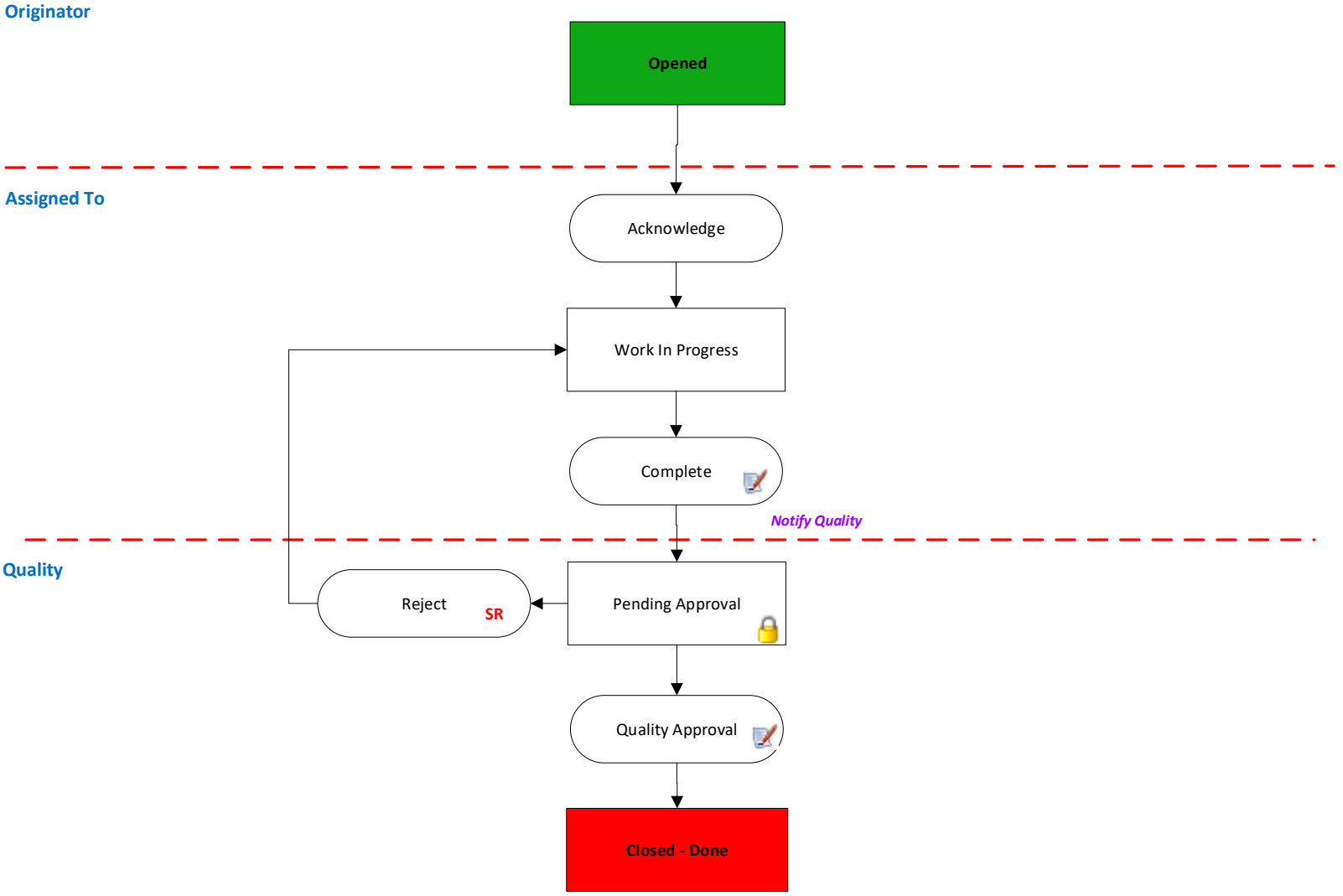
From First Production Valiation

Recall Workflow

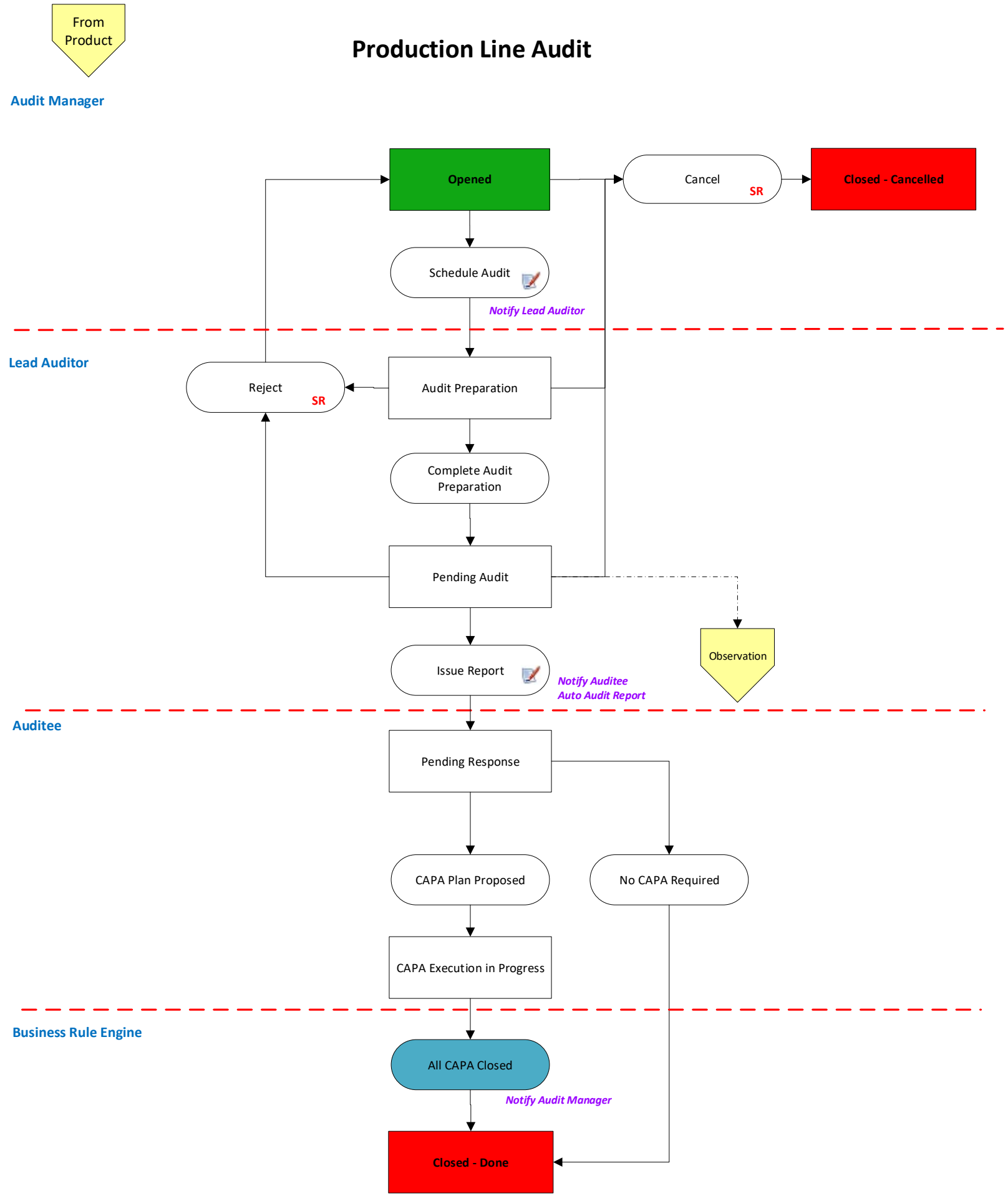


From Product

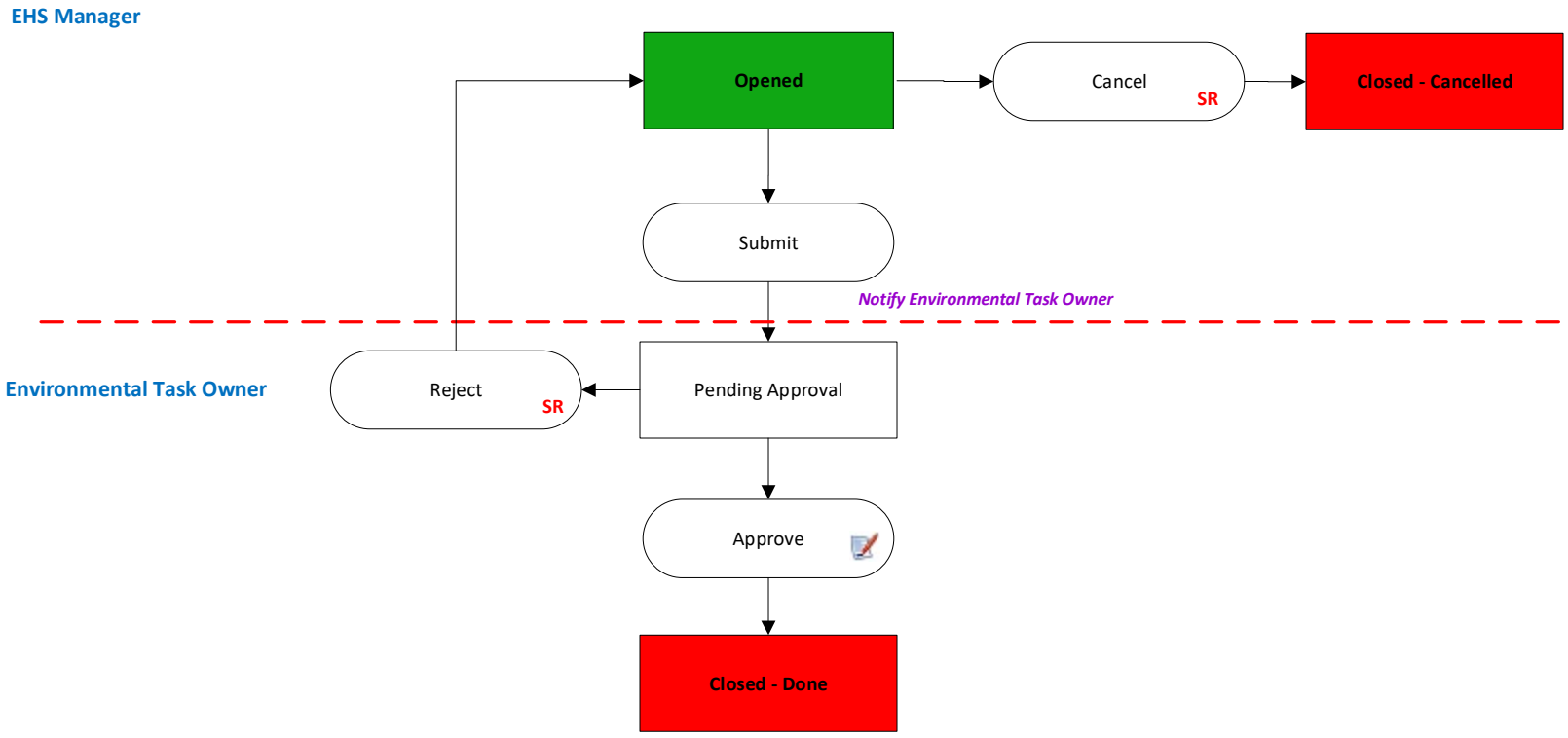
Quality Follow Up



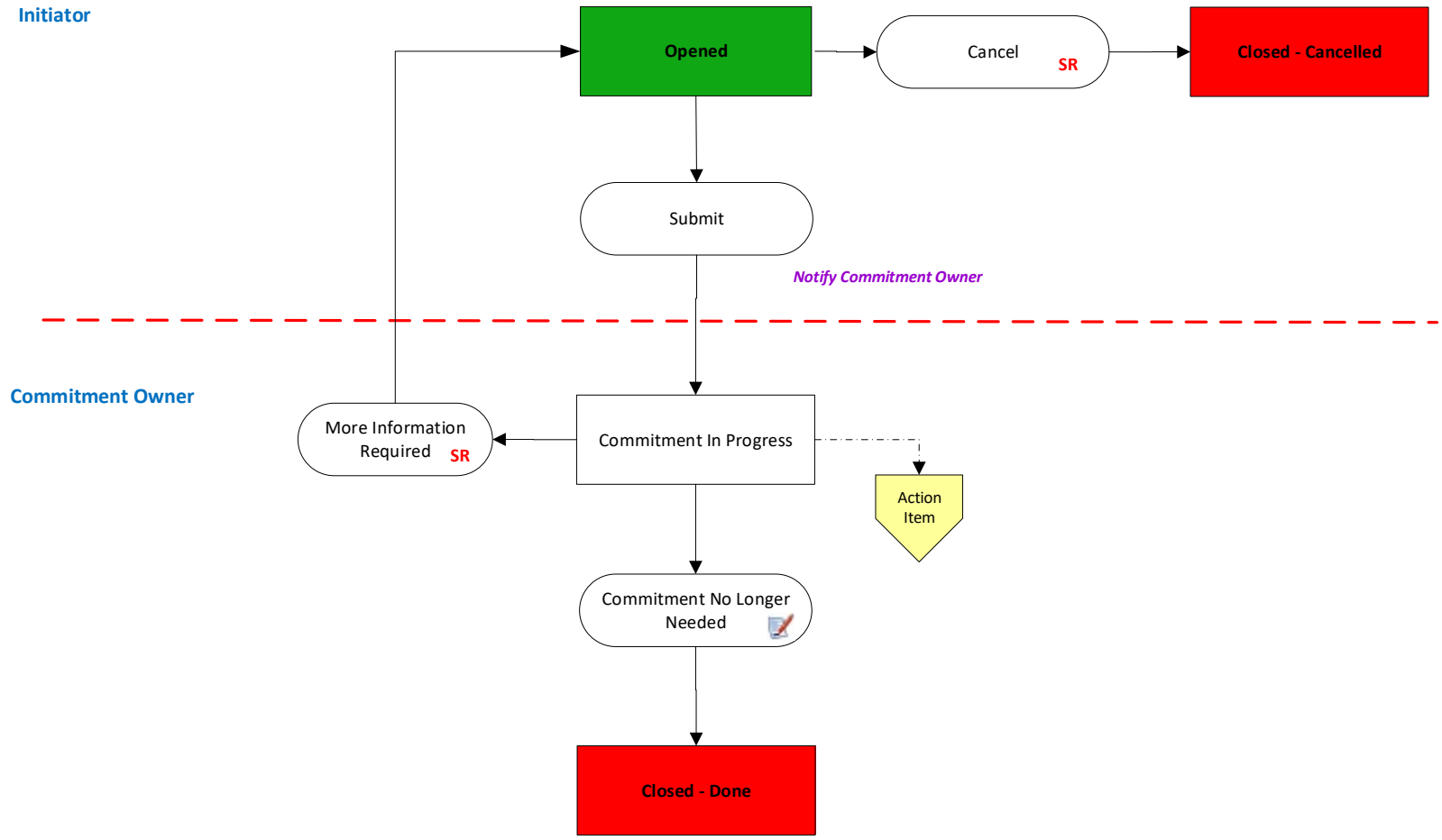
Production Line Audit



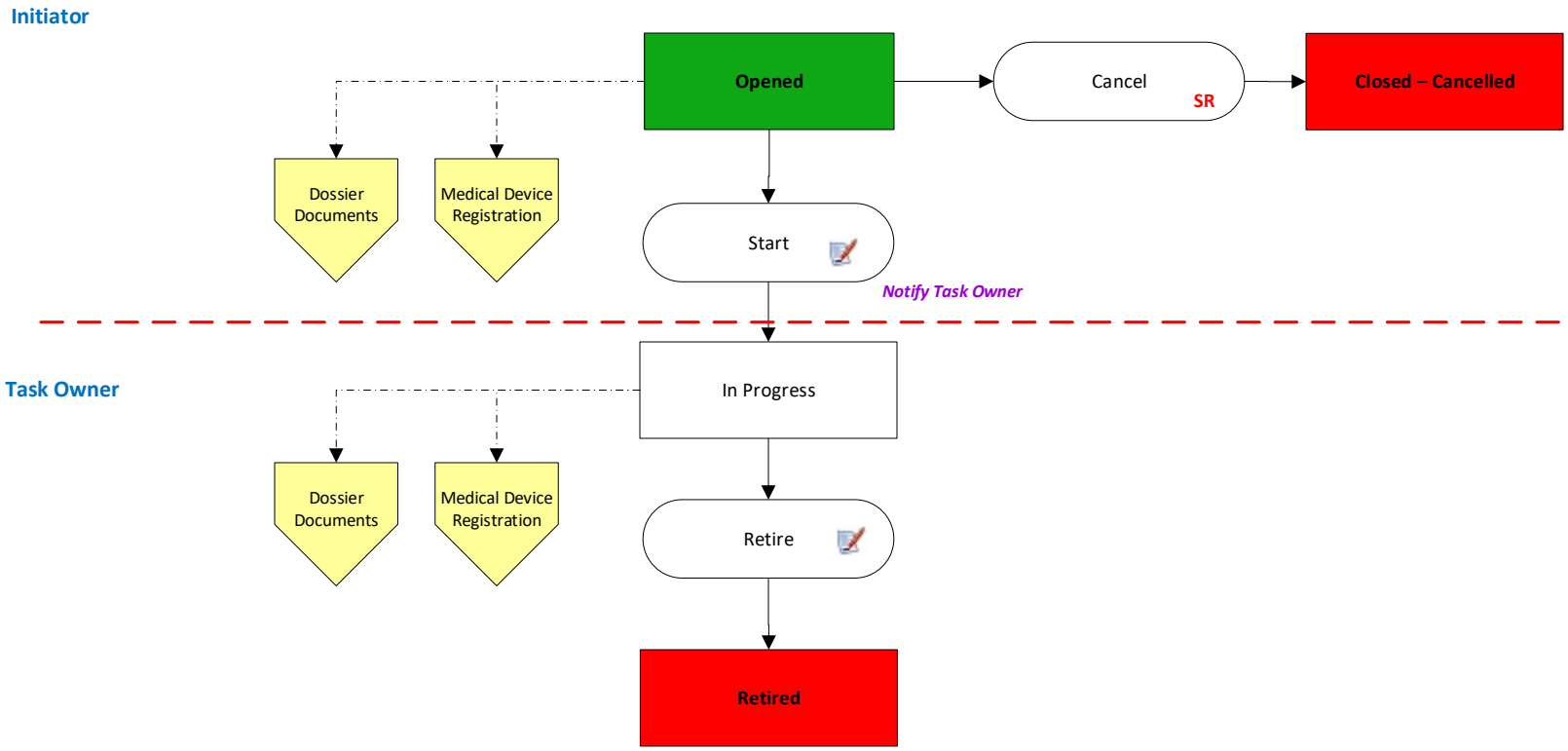
Environmental Task

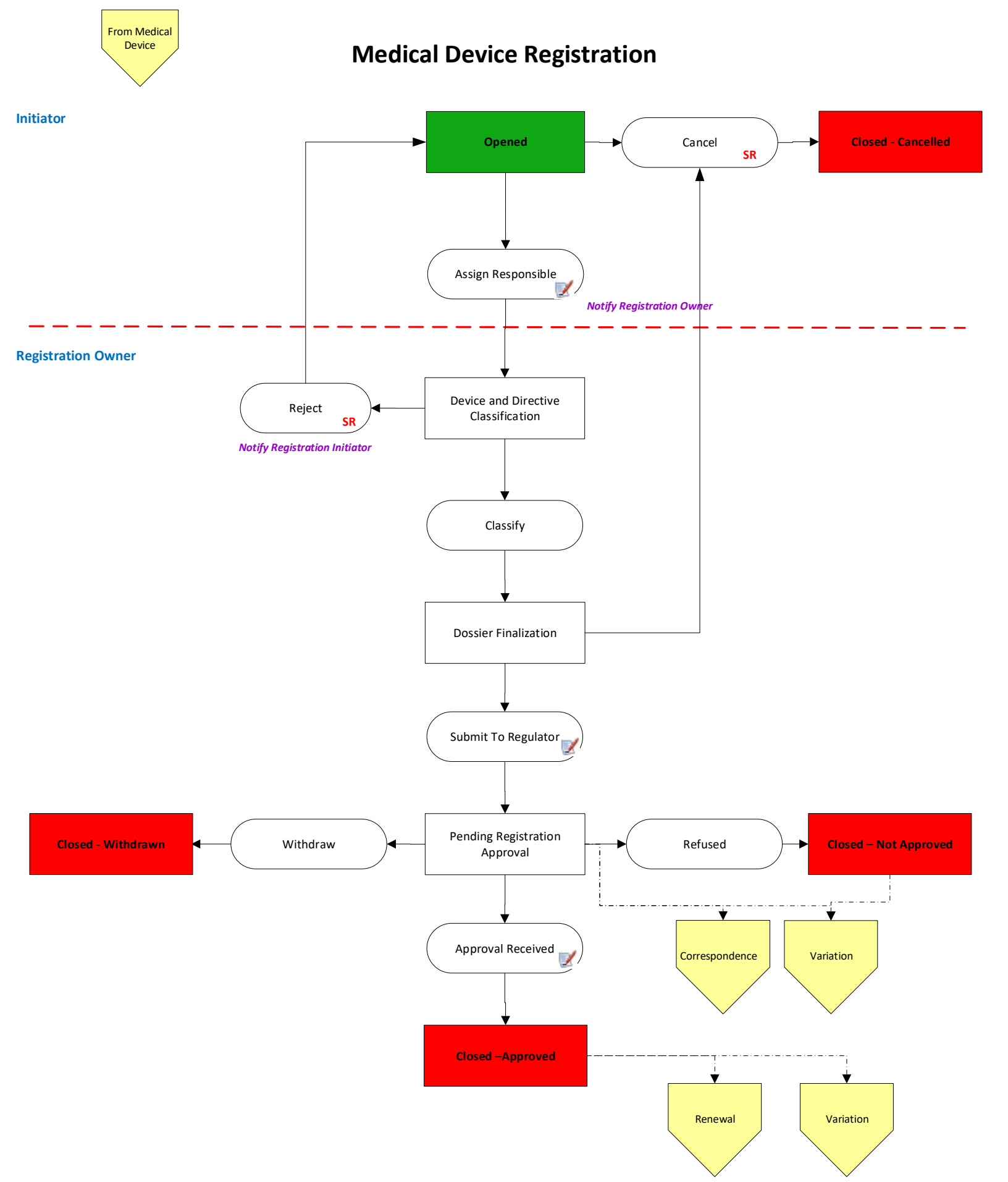


Recurring Commitment

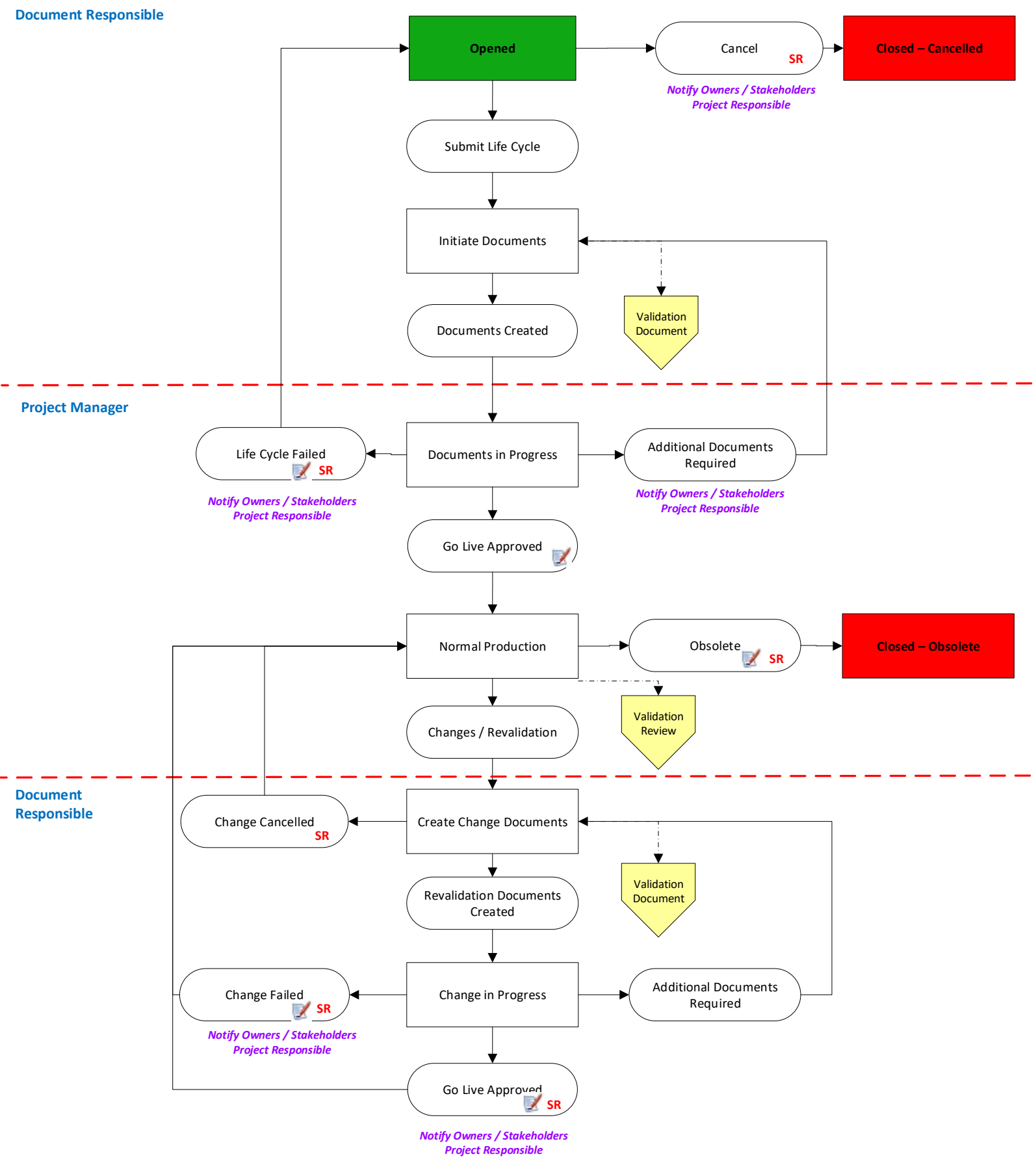


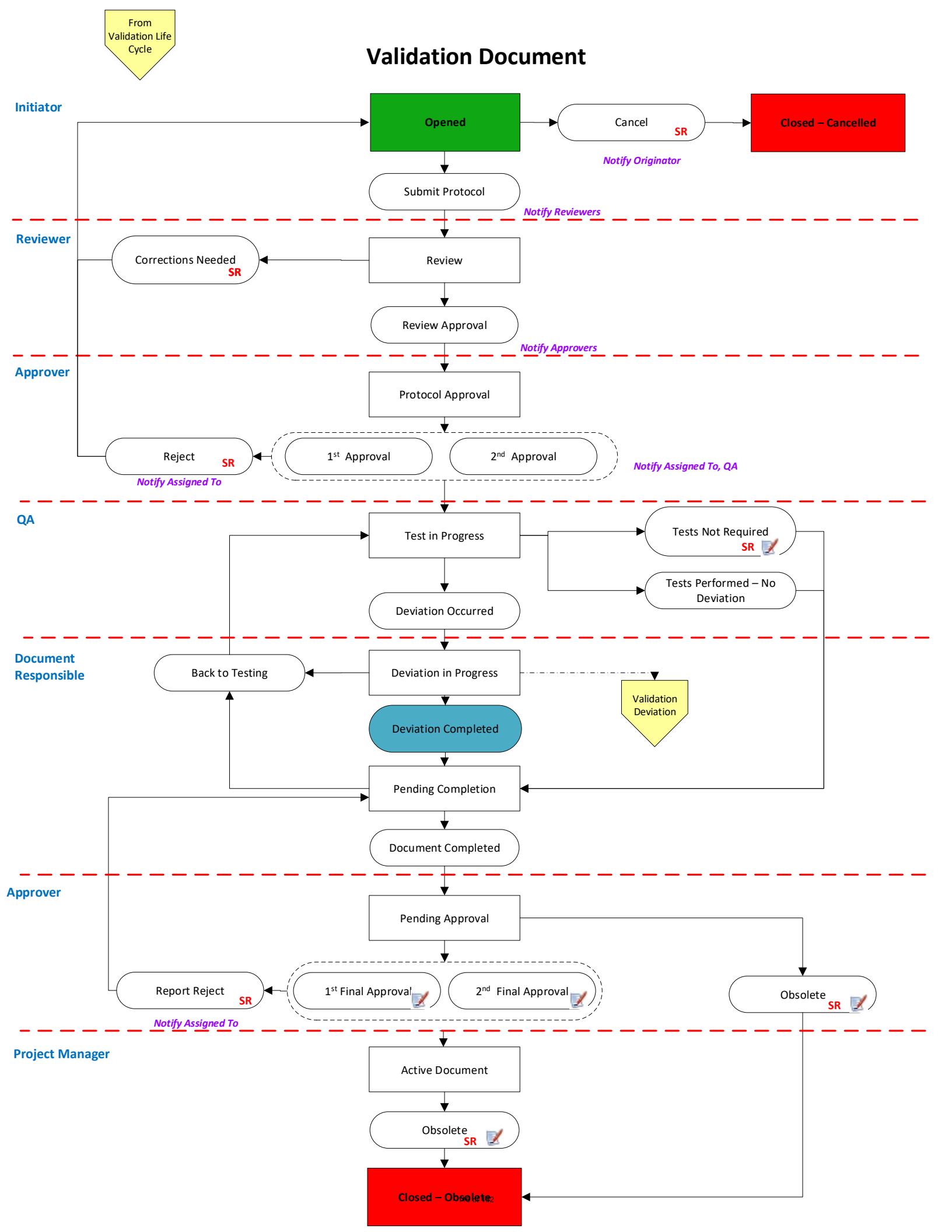
Medical Device




From Medical Device
Medical Device Registration
Initiator
Opened
Cancel
SR
Closed - Cancelled
Assign Responsible
Notify Registration Owner
Registration Owner
Reject
SR
Notify Registration Initiator
Device and Directive Classification
Classify
Dossier Finalization
Submit To Regulator
Closed - Withdrawn
Withdraw
Pending Registration Approval
Refused
Closed – Not Approved
Correspondence
Variation
Approval Received
Closed –Approved
Renewal
Variation

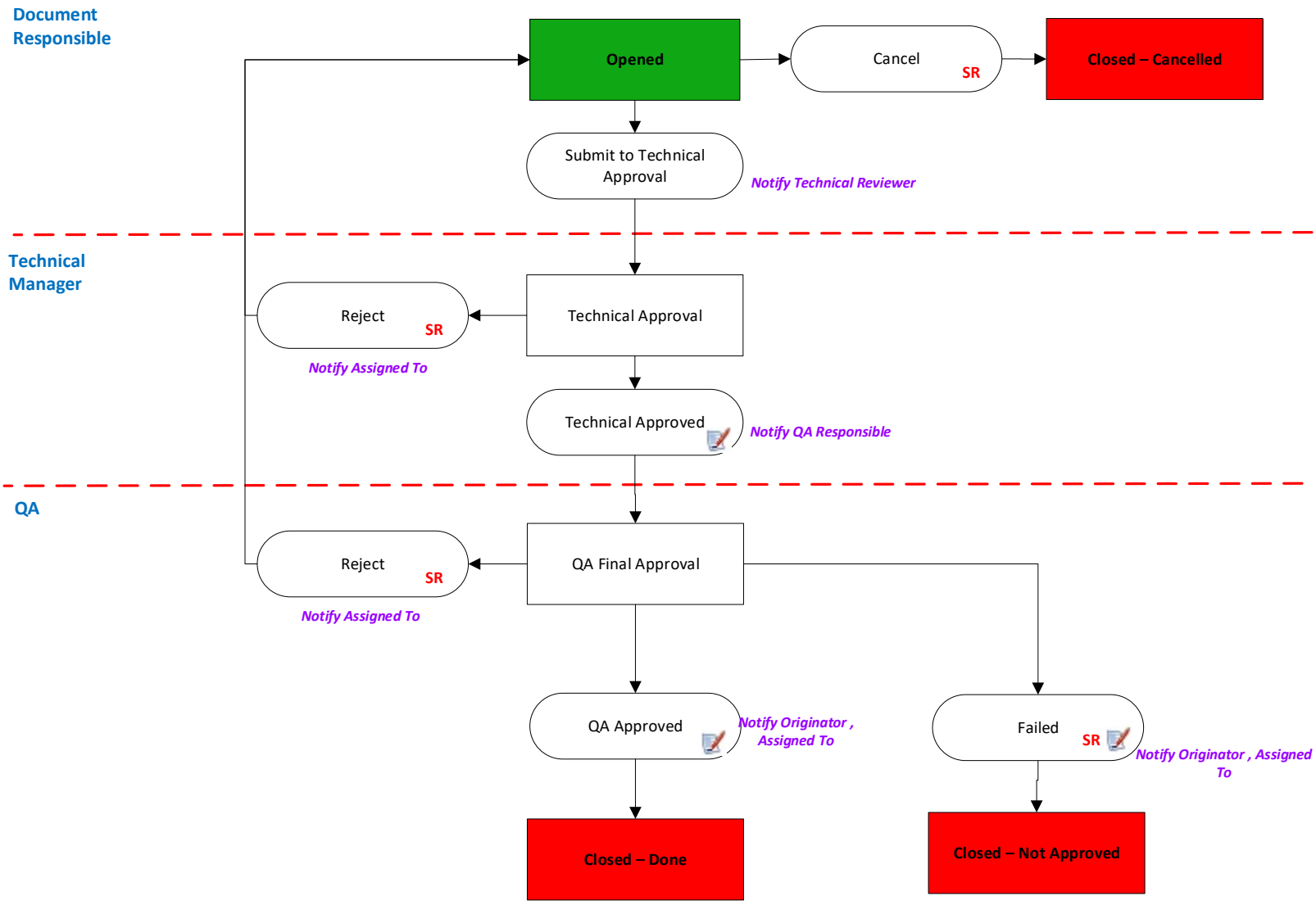
Validation Life Cycle




From Validation Life Cycle
Validation Document
Initiator
Opened
Cancel
SR
Closed – Cancelled
Notify Originator
Submit Protocol
Notify Reviewers
Reviewer
Corrections Needed
SR
Review
Review Approval
Notify Approvers
Approver
Protocol Approval
Reject
SR
1st Approval
2nd Approval
Notify Assigned To, QA
Notify Assigned To
QA
Test in Progress
Tests Not Required
SR
Tests Performed – No Deviation
Deviation Occurred
Document Responsible
Back to Testing
Deviation in Progress
Validation Deviation
Deviation Completed
Pending Completion
Document Completed
Approver
Pending Approval
Report Reject
SR
1st Final Approval
2nd Final Approval
Obsolete
SR
Notify Assigned To
Project Manager
Active Document
Obsolete
SR
Closed – Obsolete

From Validation Document

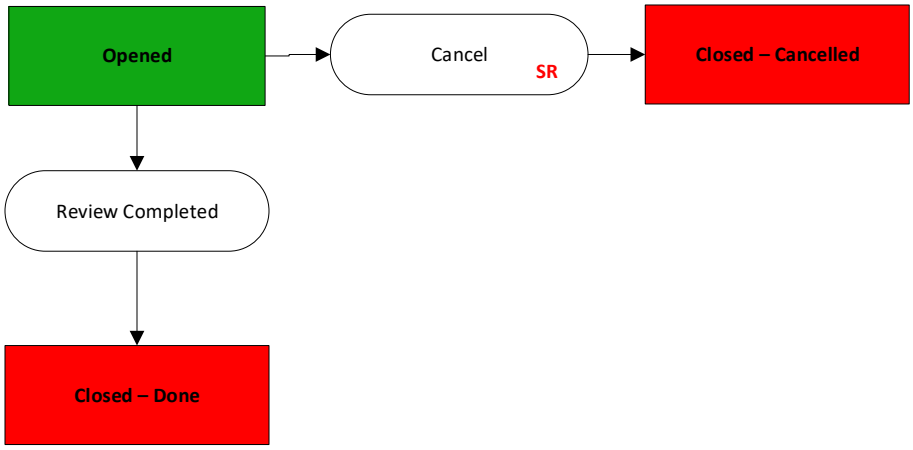
Validation Deviation



From Validation Life Cycle

Validation Review

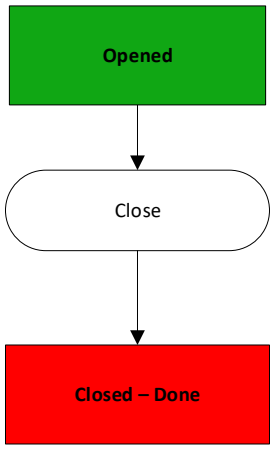
Project Manager



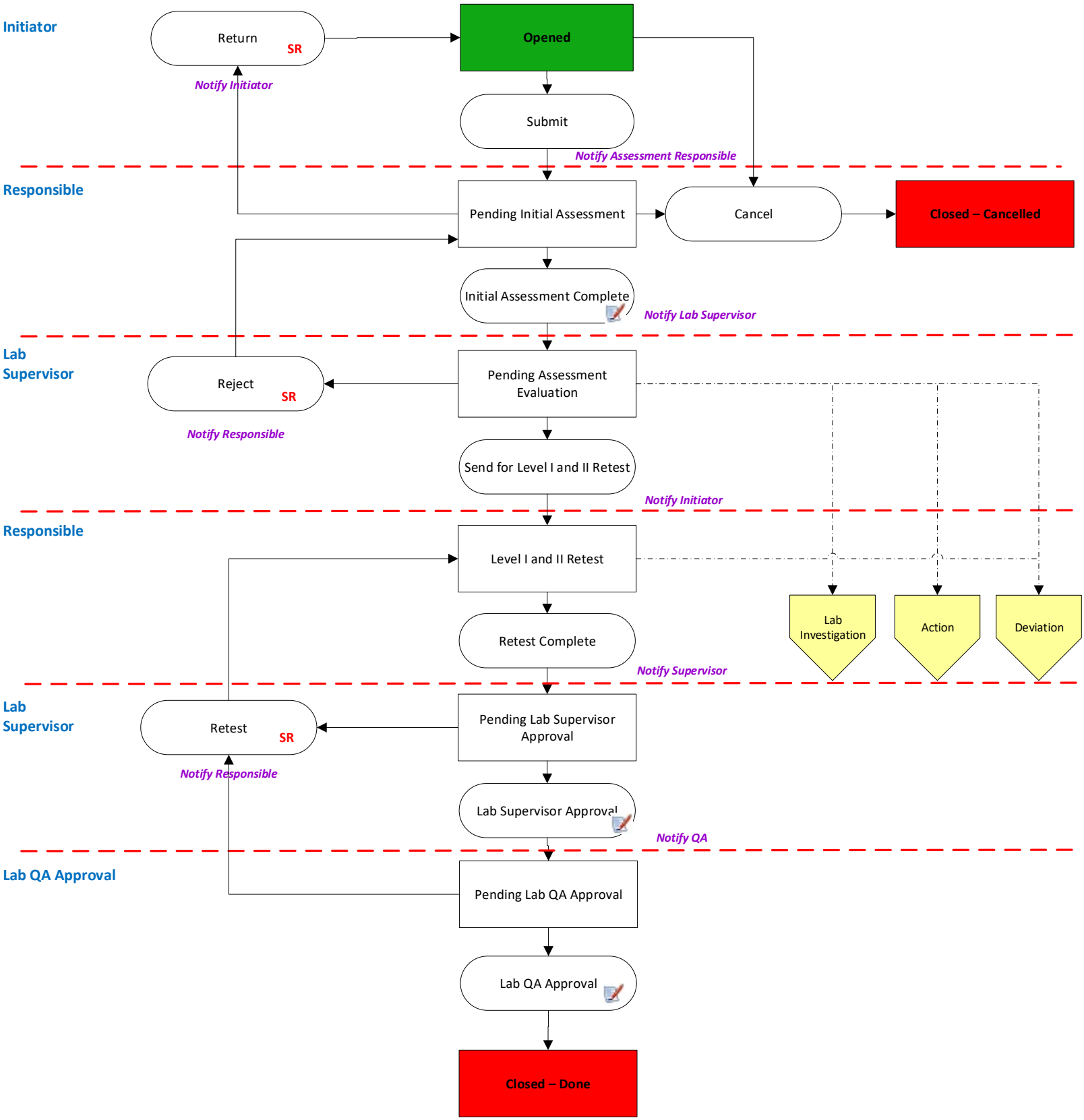
From Validation Deviation

Validation Template

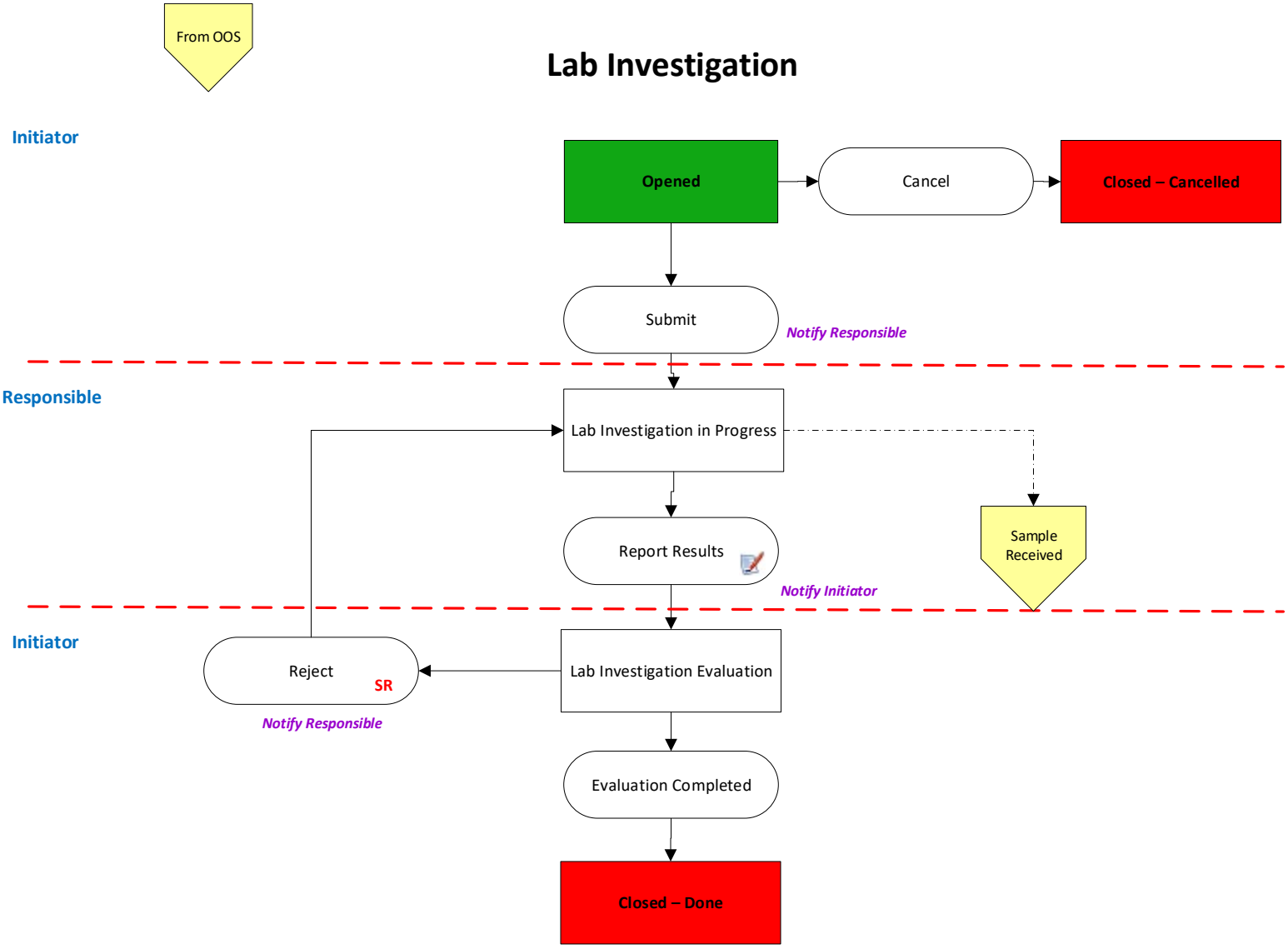
Administrator



OOS

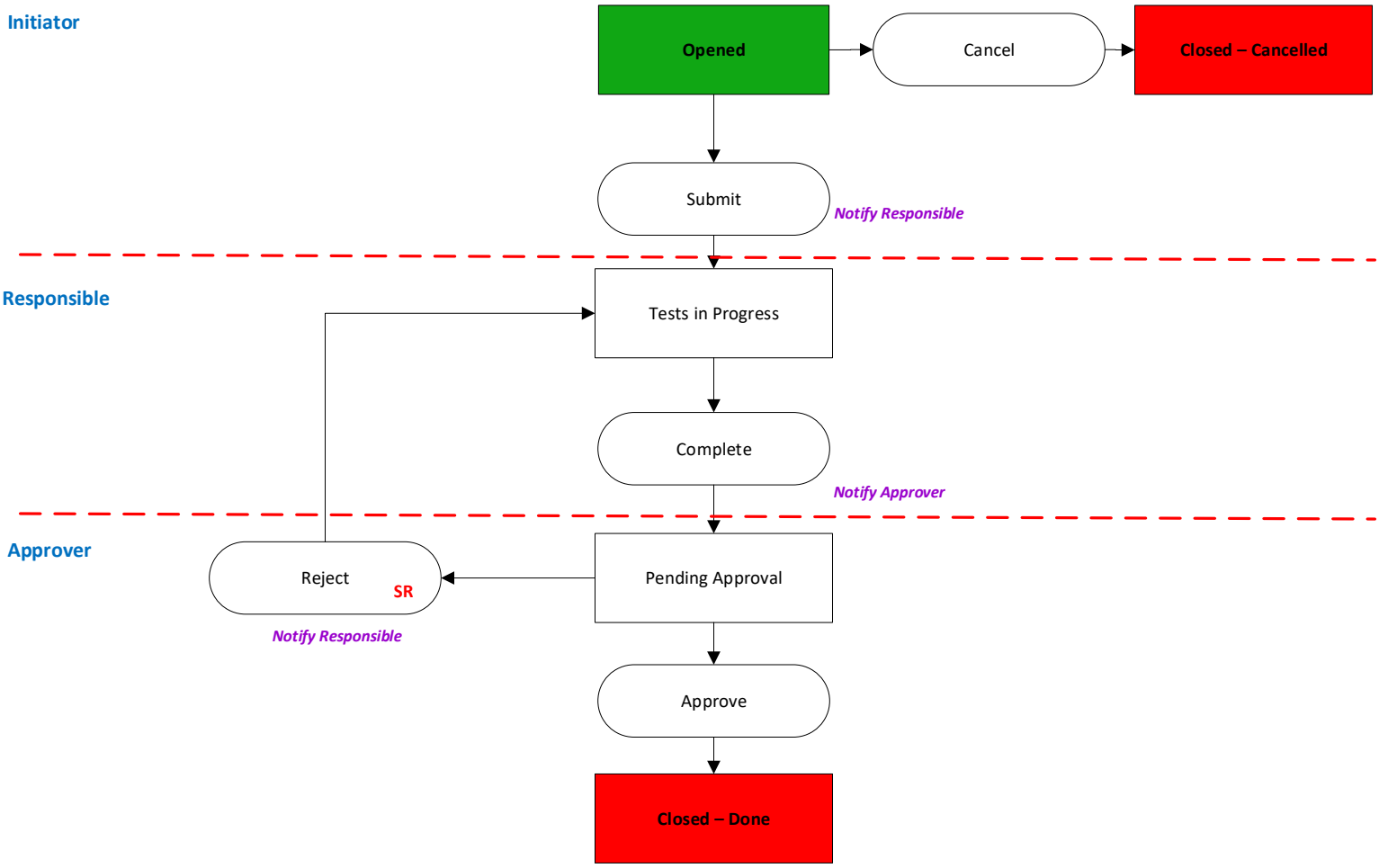

Initiator
Return
SR
Opened
Notify Initiator
Submit
Notify Assessment Responsible
Responsible
Pending Initial Assessment
Cancel
Closed – Cancelled
Initial Assessment Complete
Notify Lab Supervisor
Lab Supervisor
Reject
SR
Pending Assessment Evaluation
Notify Responsible
Send for Level I and II Retest
Notify Initiator
Responsible
Level I and II Retest
Lab Investigation
Action
Deviation
Retest Complete
Notify Supervisor
Lab Supervisor
Retest
SR
Pending Lab Supervisor Approval
Notify Responsible
Lab Supervisor Approval
Notify QA
Lab QA Approval
Pending Lab QA Approval
Lab QA Approval
Closed – Done

Lab Investigation

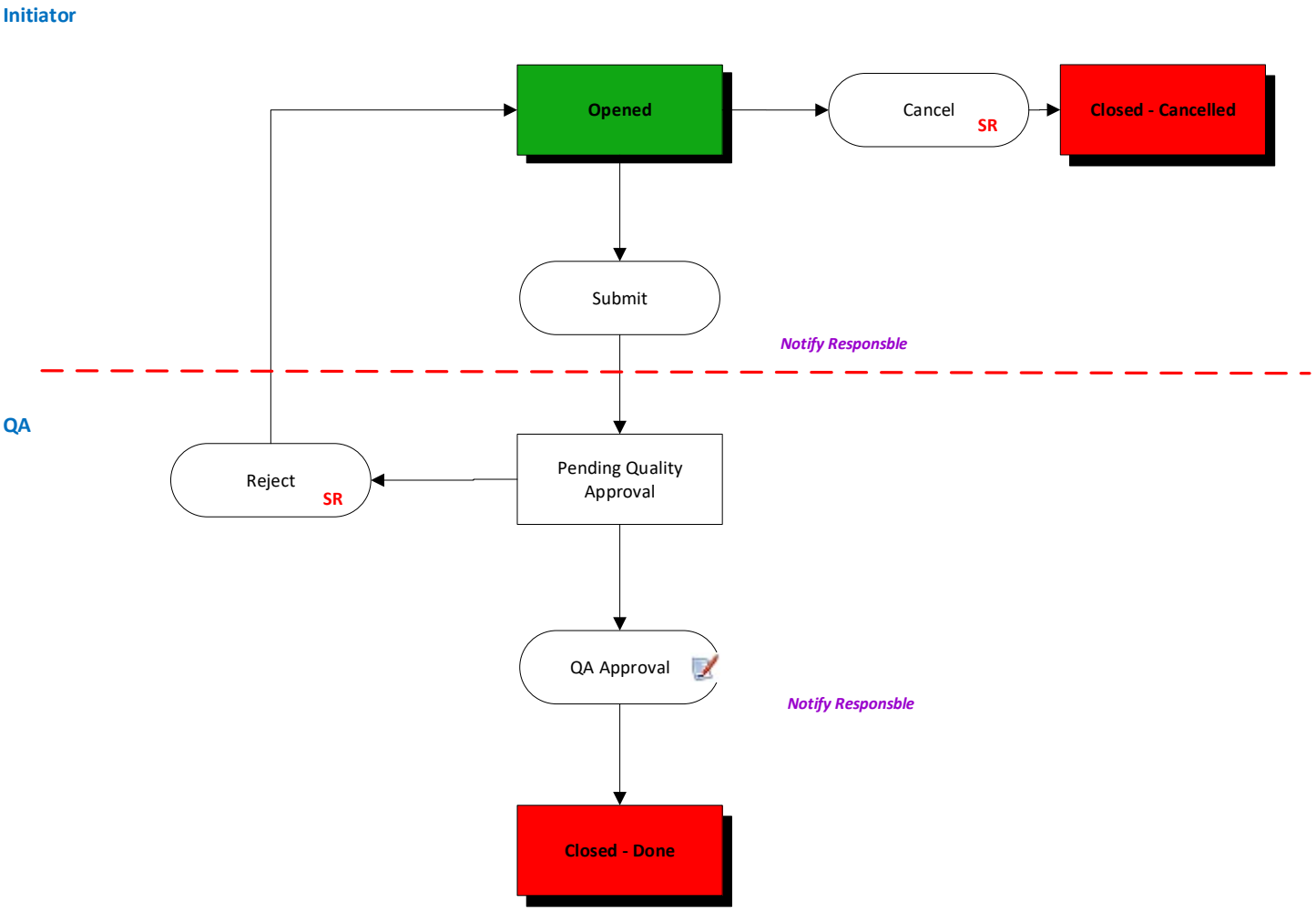


From Lab Investigation

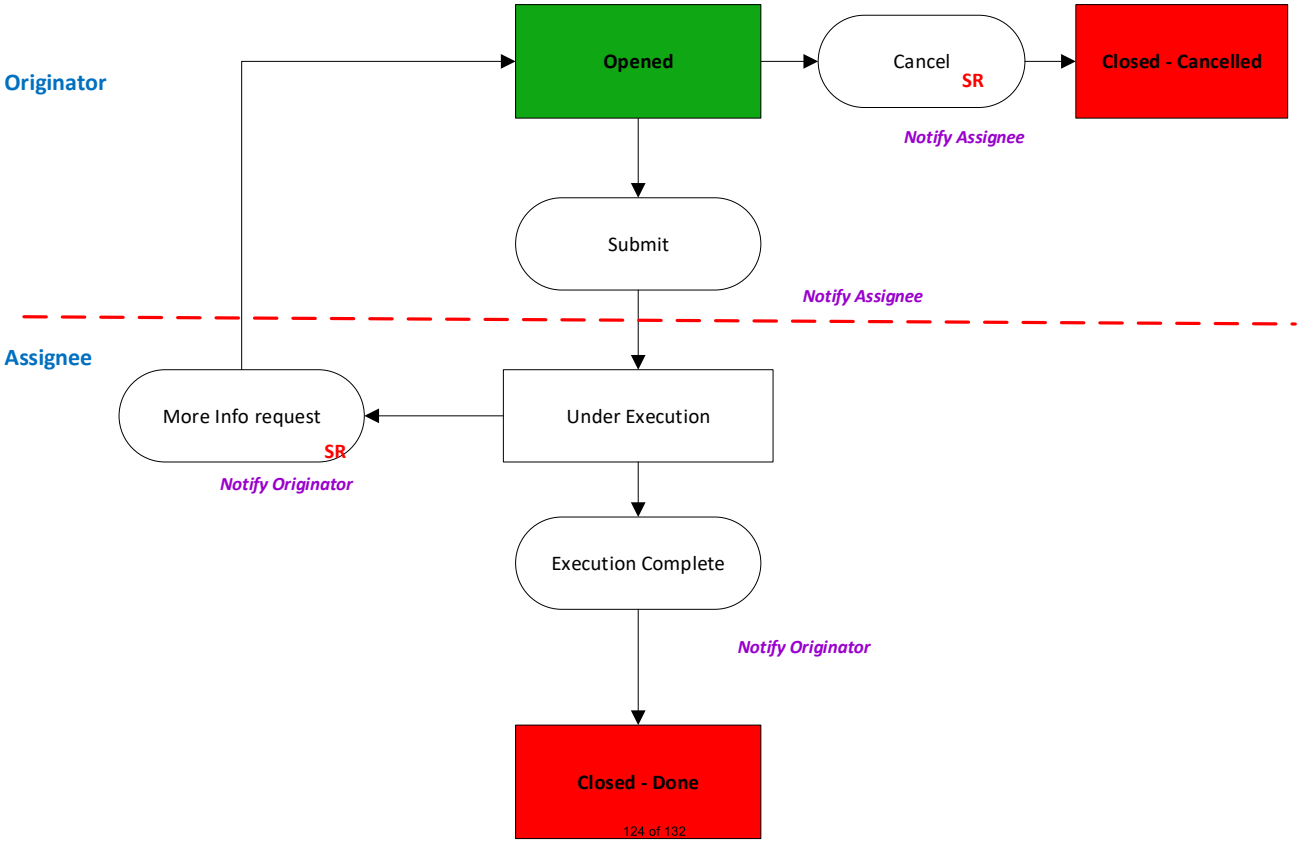
Sample Received



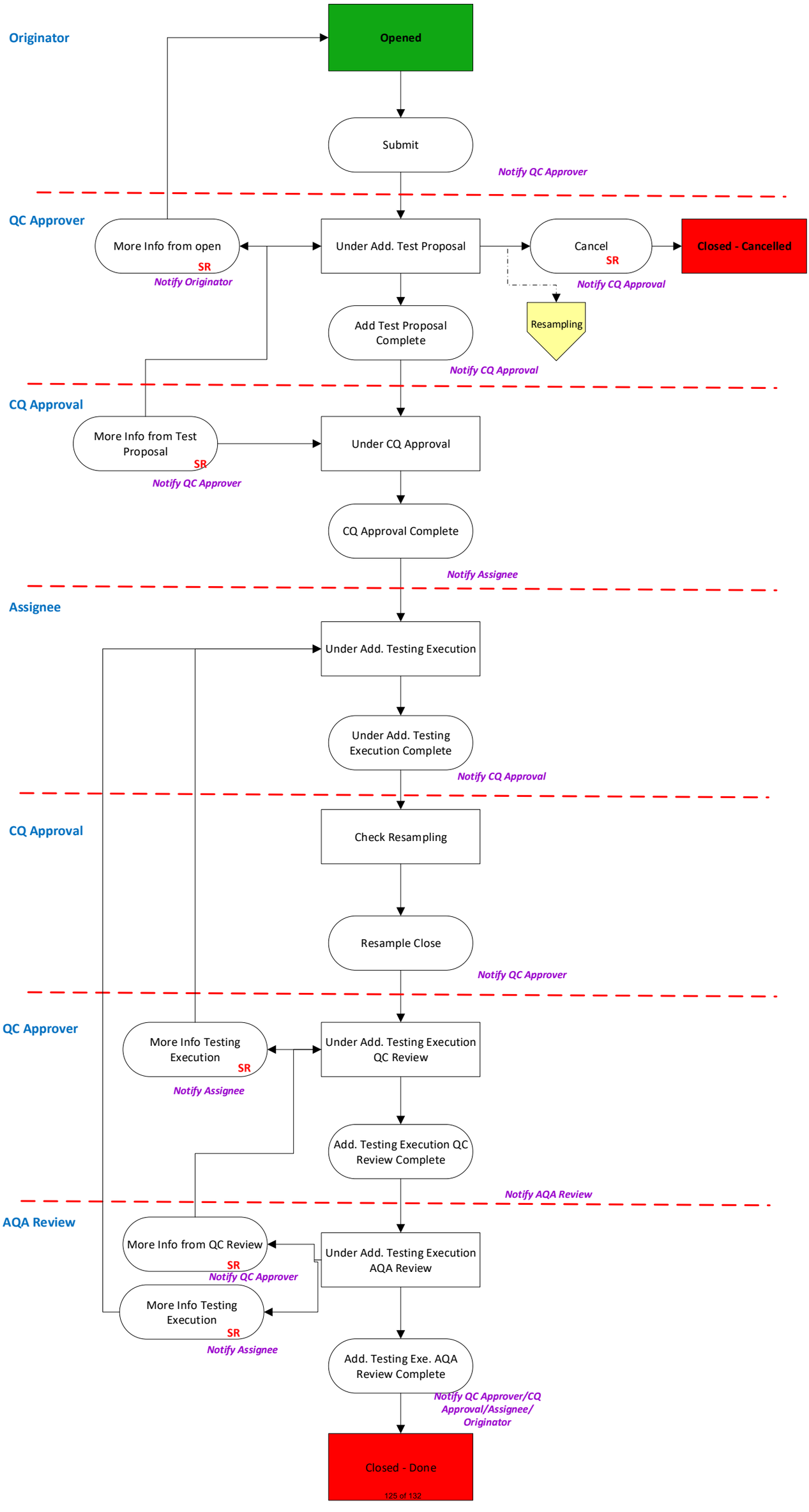
Addendum


Initiator
Opened
Cancel
SR
Closed - Cancelled
Submit
Notify Responsble
QA
Reject
SR
Pending Quality Approval
QA Approval
Notify Responsble
Closed - Done

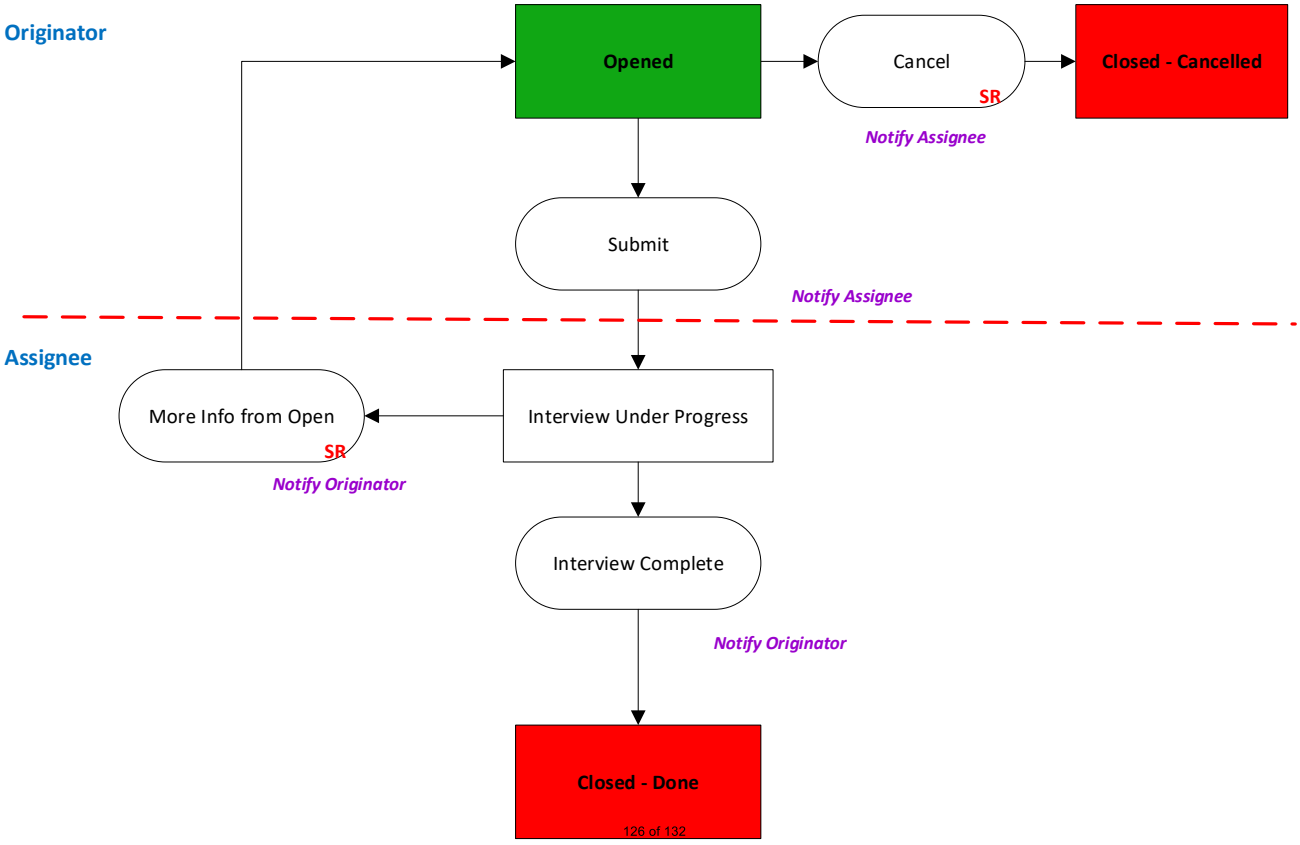
Additional Information



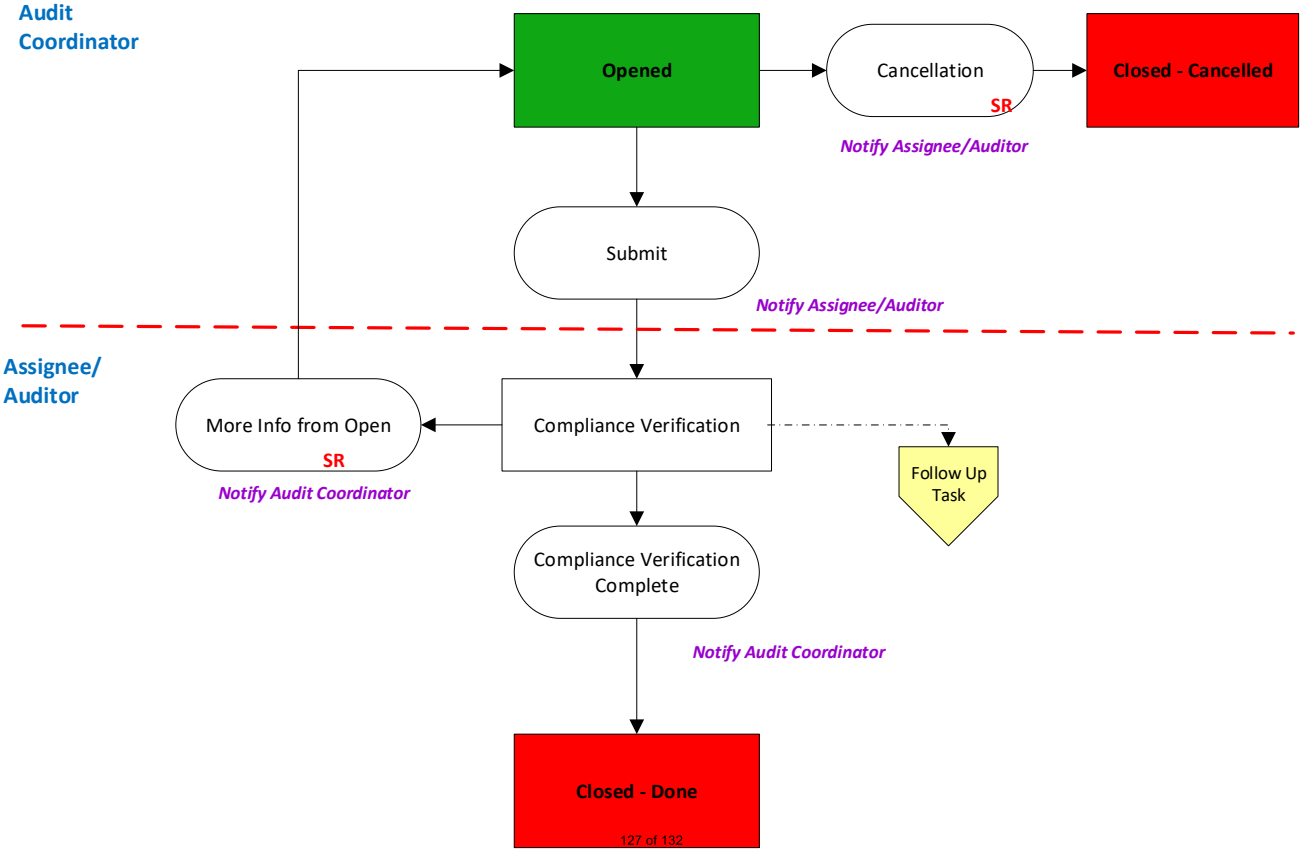
Additional Testing



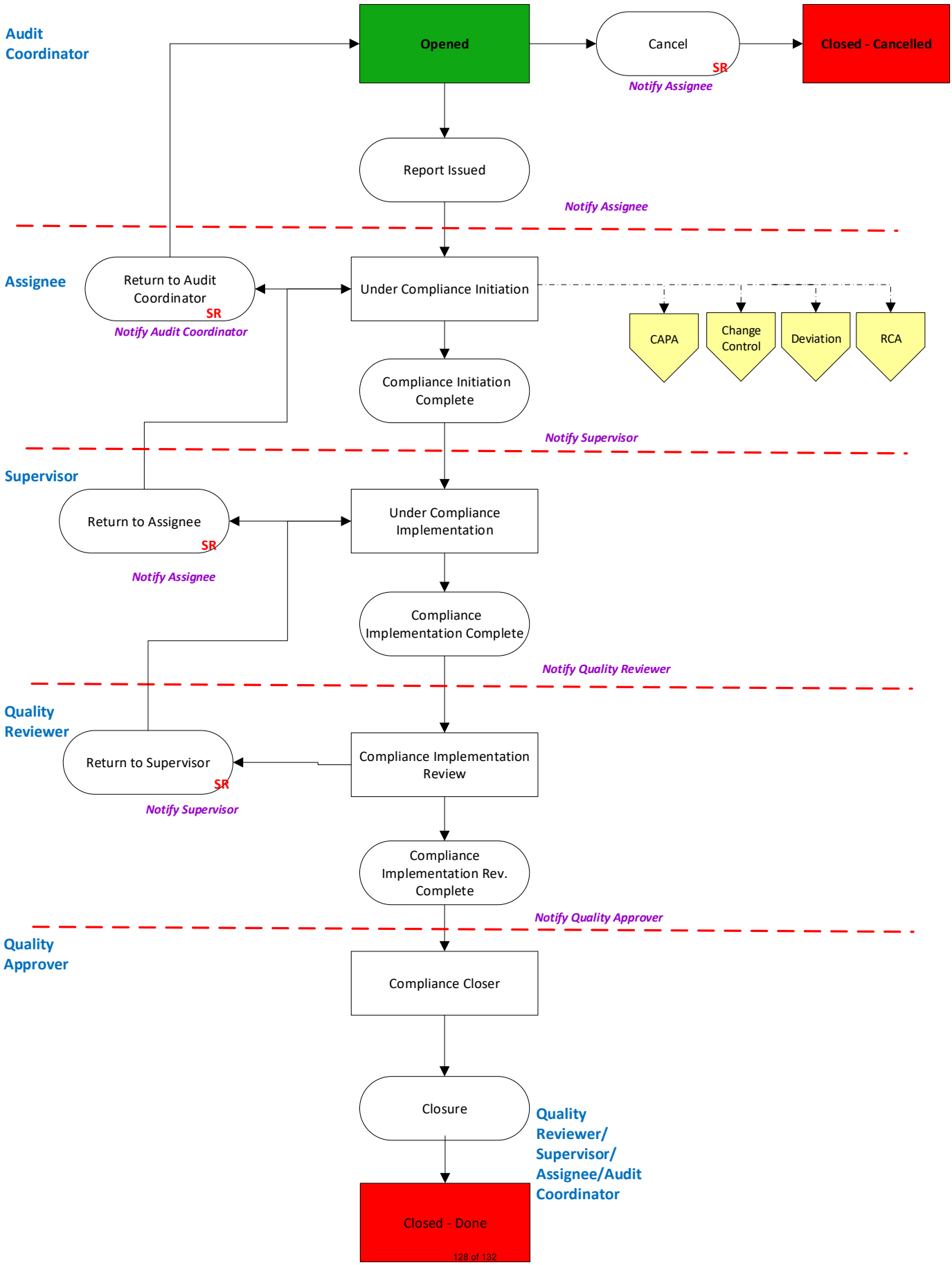
Analyst Interview



Audit Task

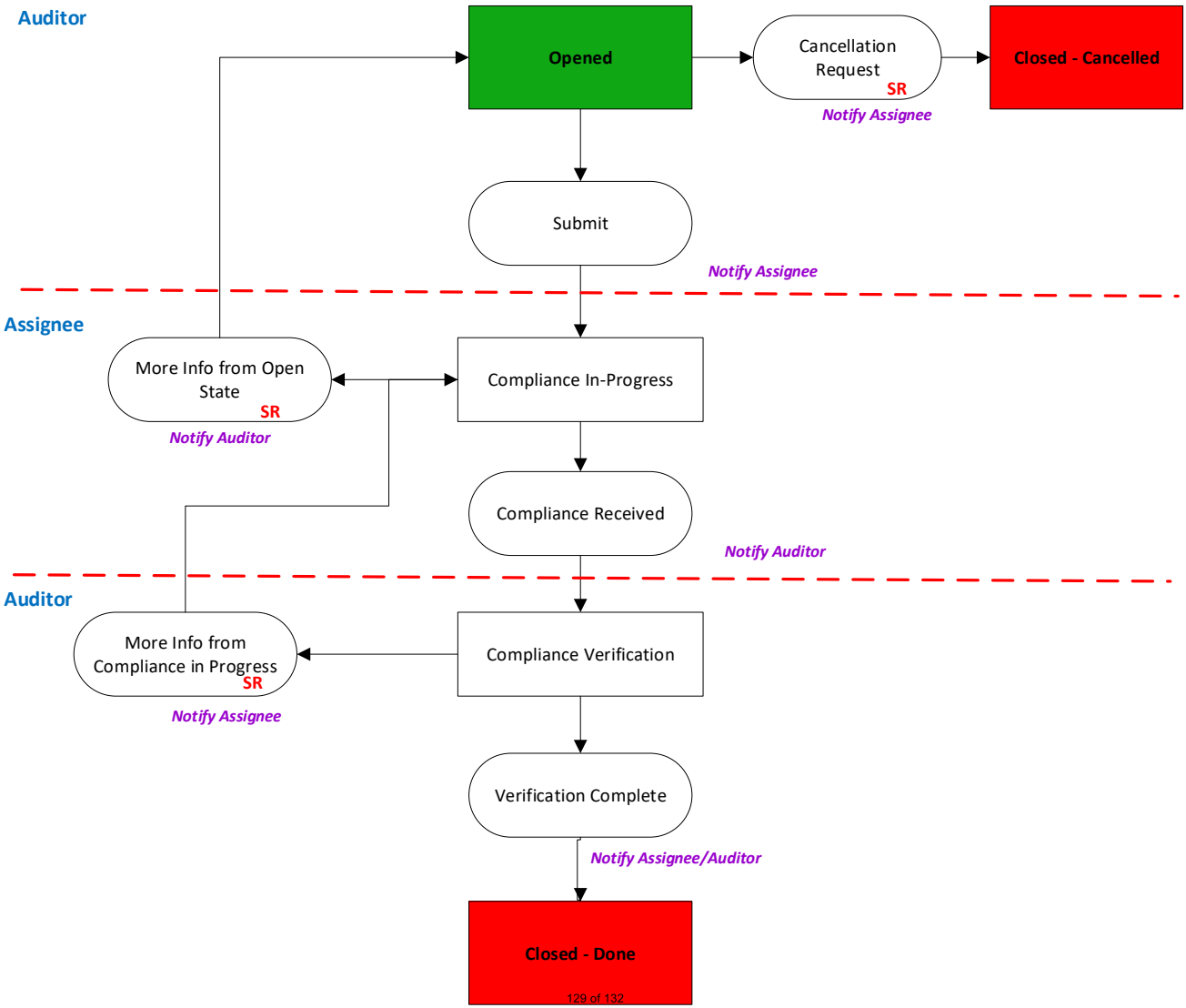

Audit Coordinator
Opened
Cancellation
SR
Closed - Cancelled
Notify Assignee/Auditor
Submit
Notify Assignee/Auditor
Assignee/ Auditor
More Info from Open
SR
Notify Audit Coordinator
Compliance Verification
Follow Up Task
Compliance Verification Complete
Notify Audit Coordinator
Closed - Done

Compliance Task

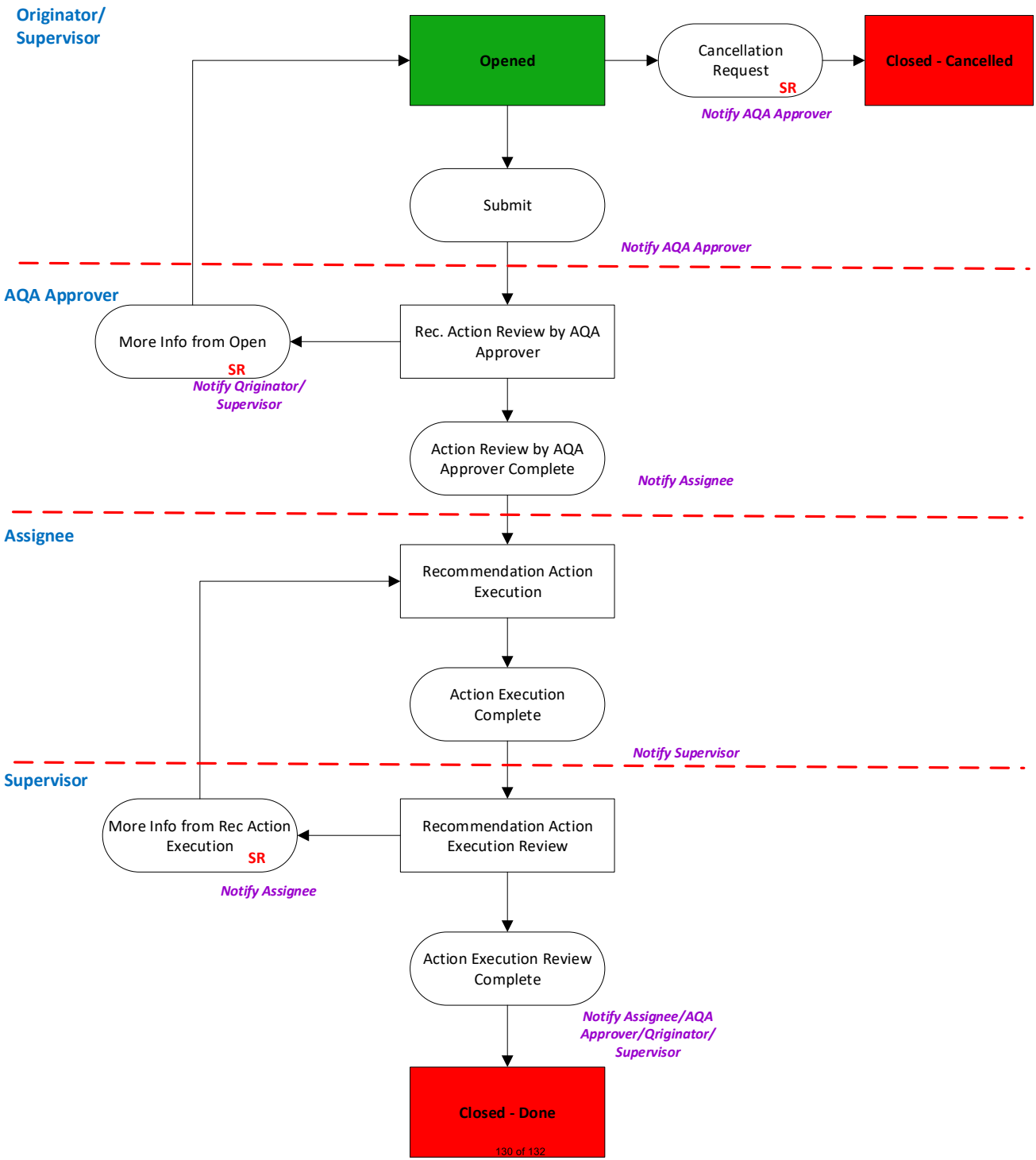


Audit Task

Follow Up Task

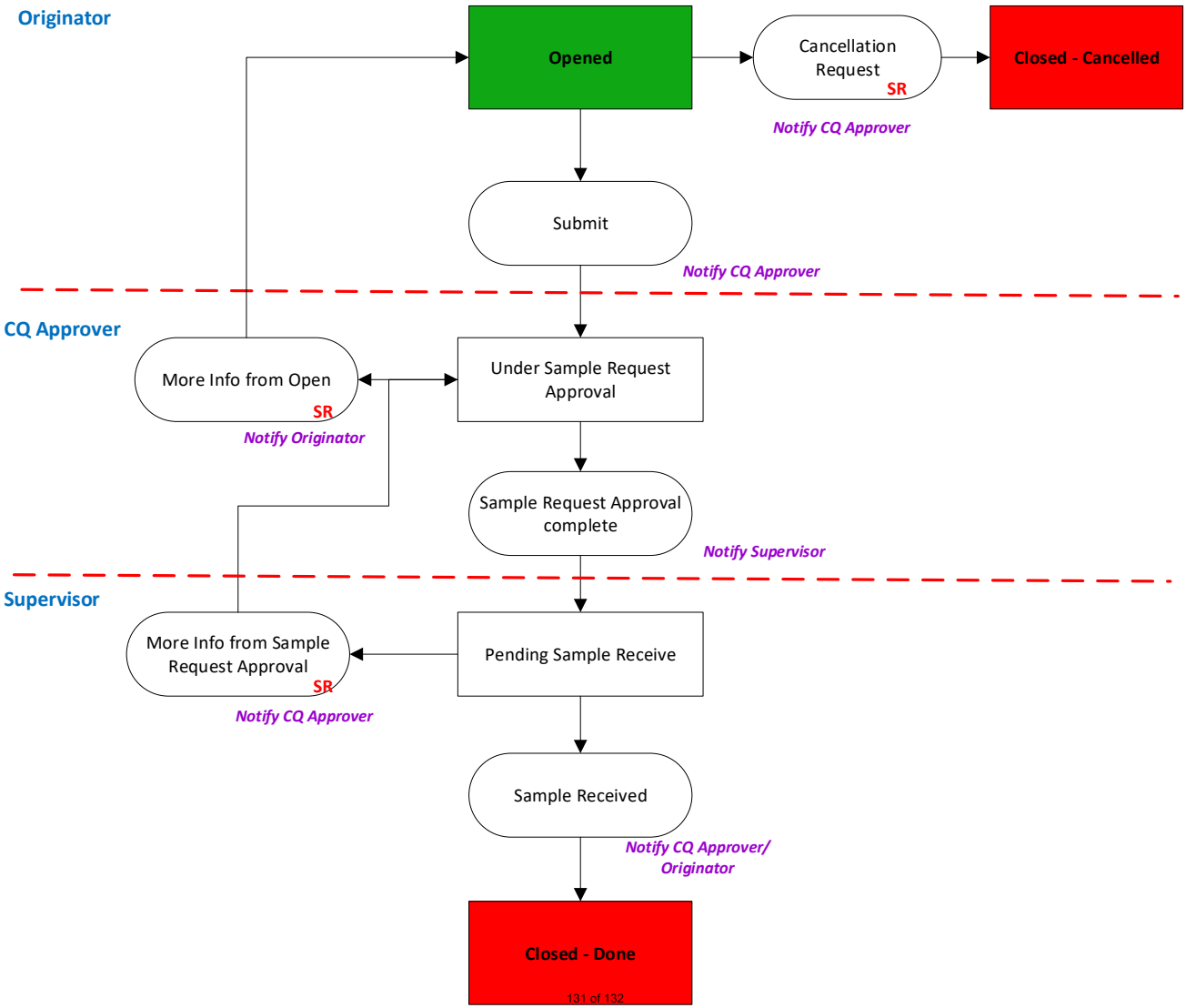
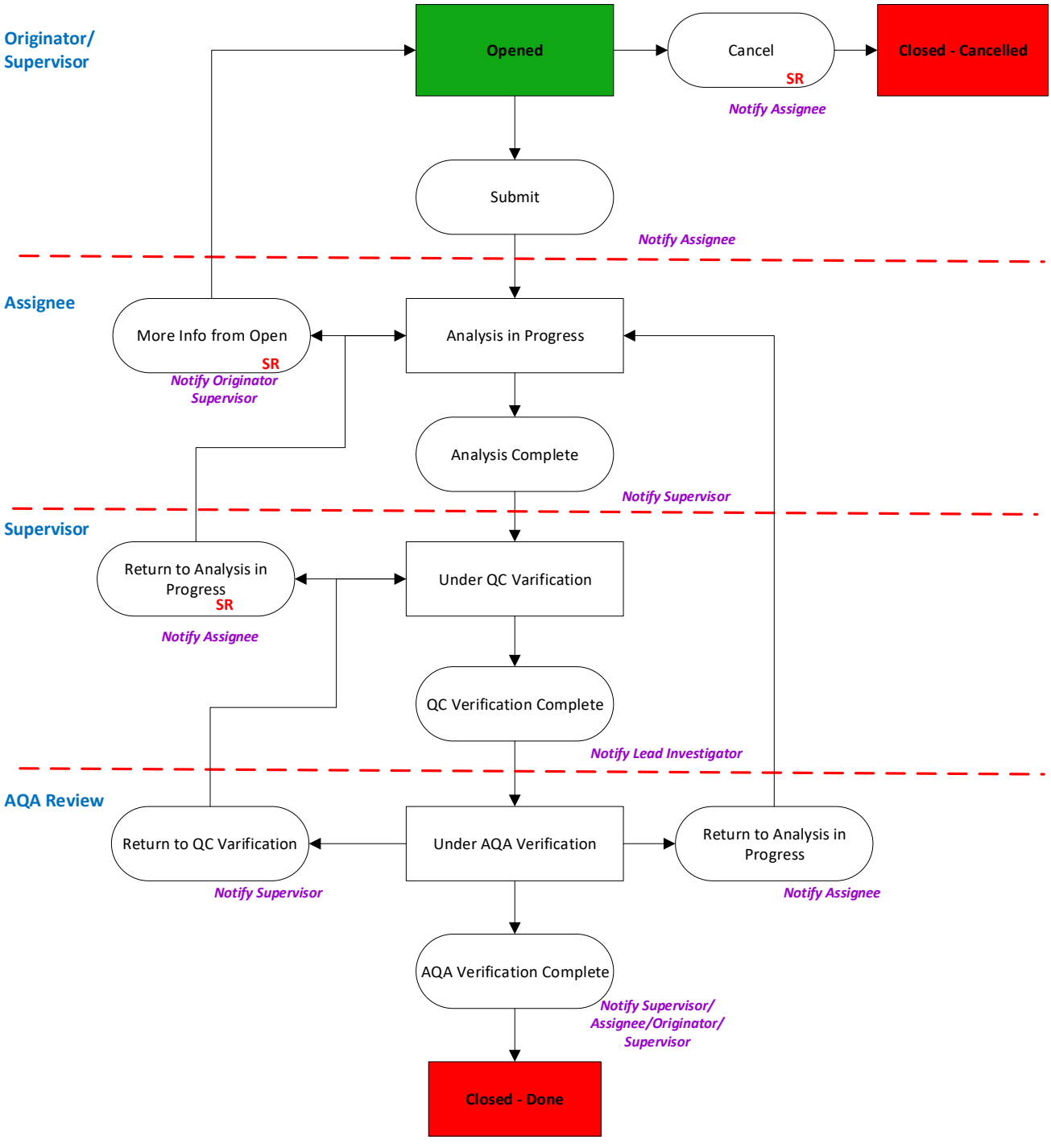


Recommended Action



Additional Testing

Resampling



Verification