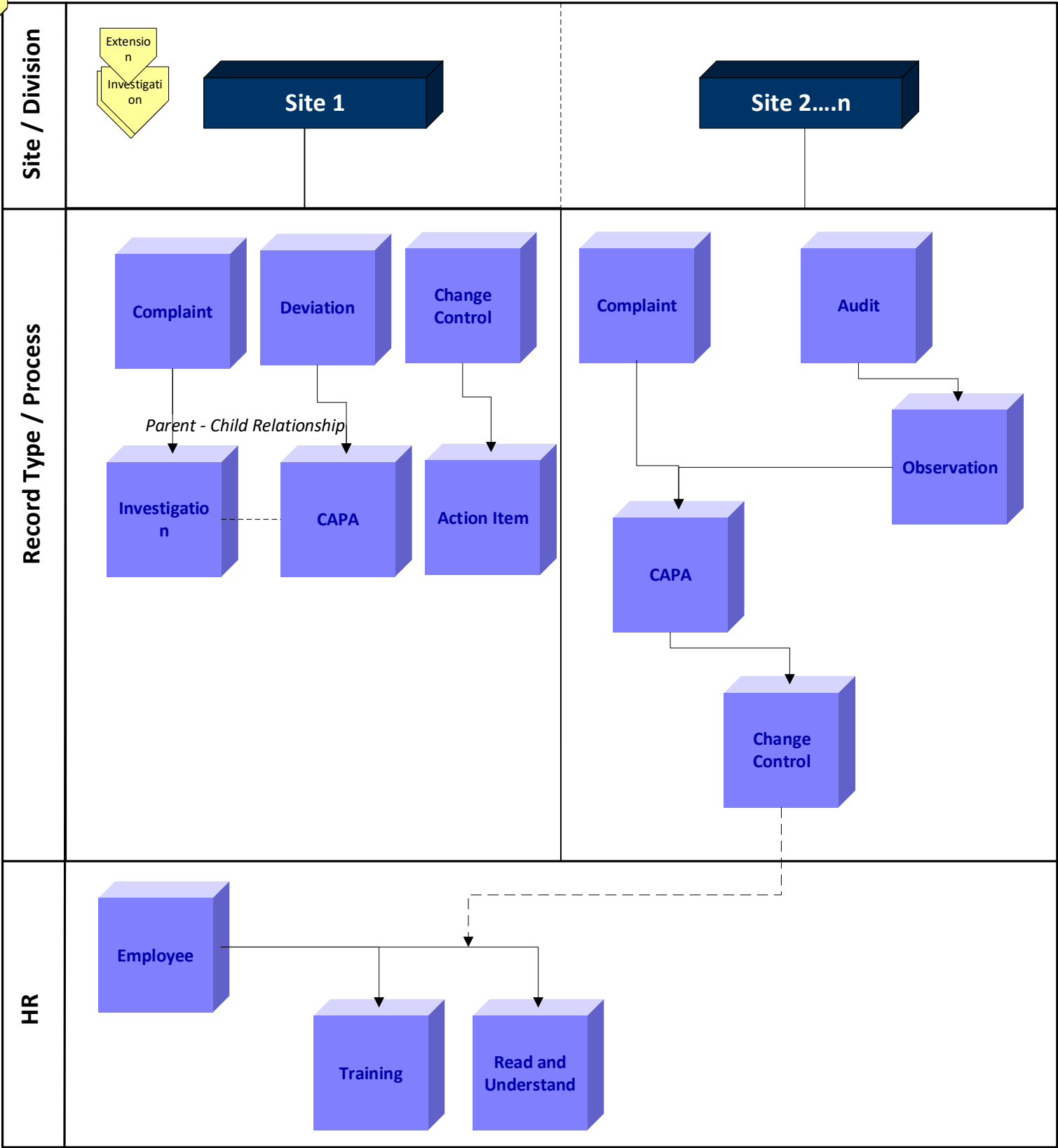
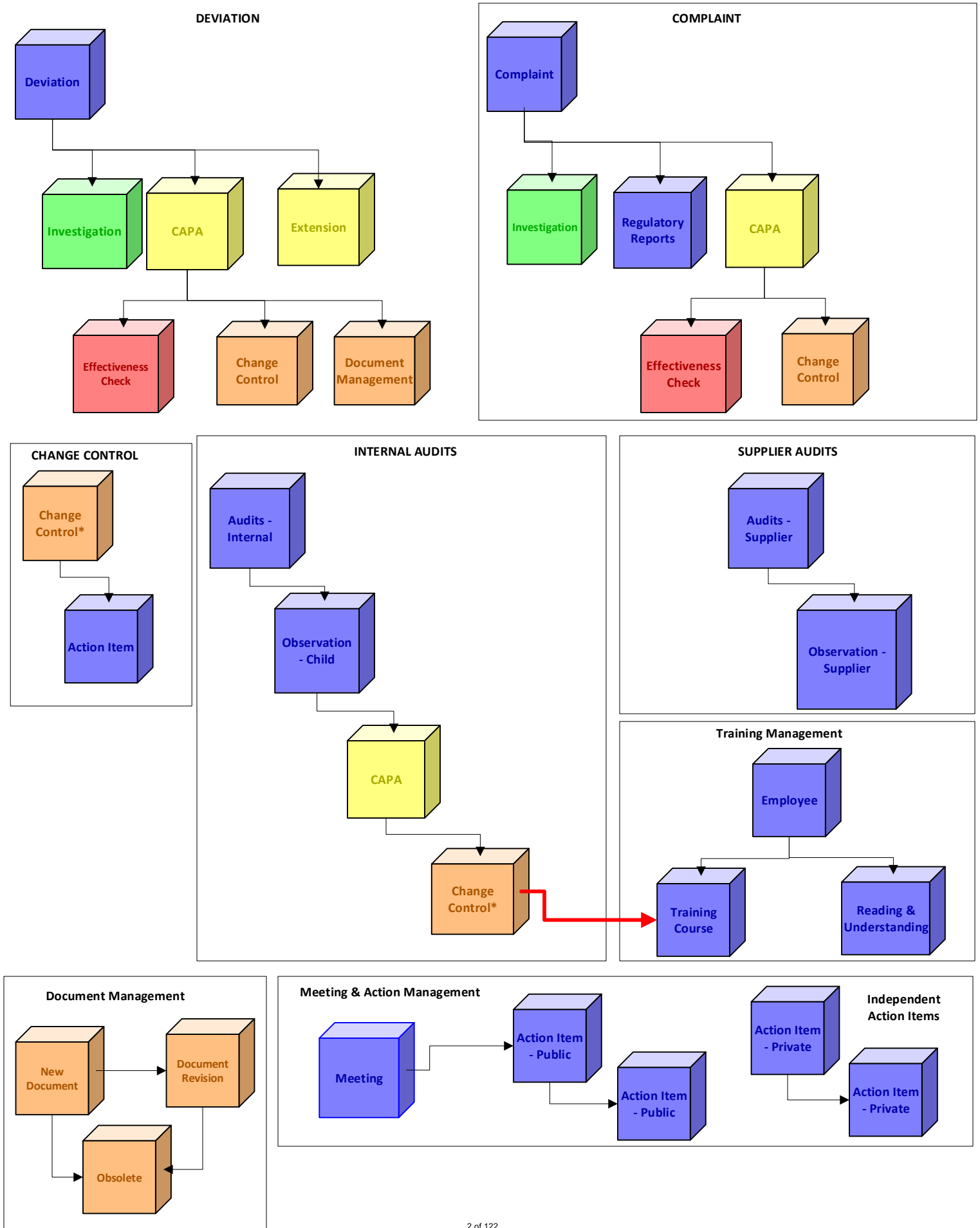


Configuration Overview



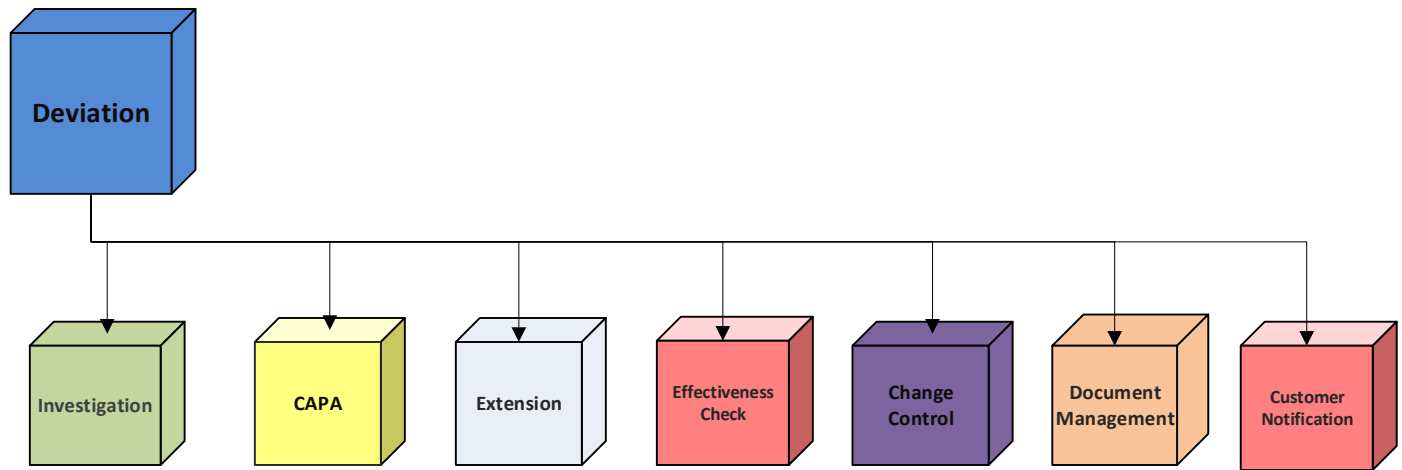
- NOTES
- Unlimited Sites can be created
 - Unlimited Projects can be created within each Site
 - Each Site can share workflows, forms, notification rules, escalations, etc. OR can have individual / separate rules for its Projects
 - User membership and permissions are assigned based on Project. For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

Parent Child Relationships

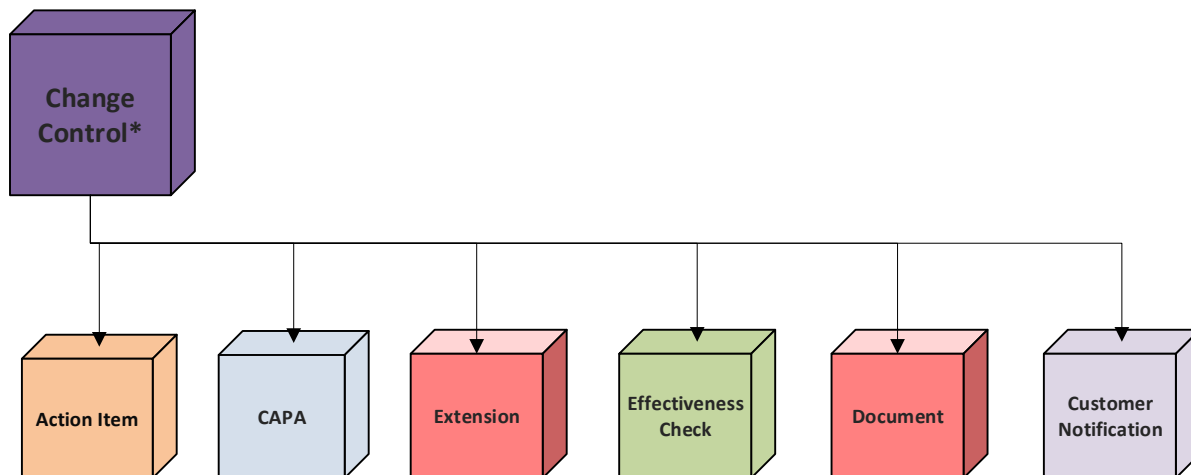


Parent Child Relationships

DEVIATION FAMILY

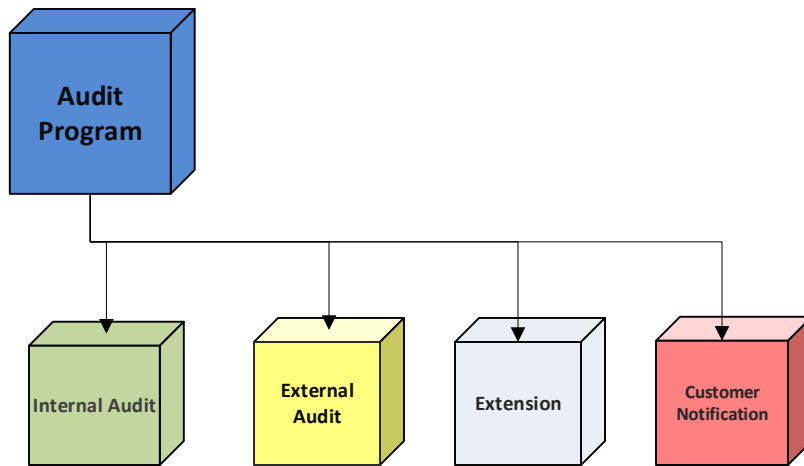


Change Control

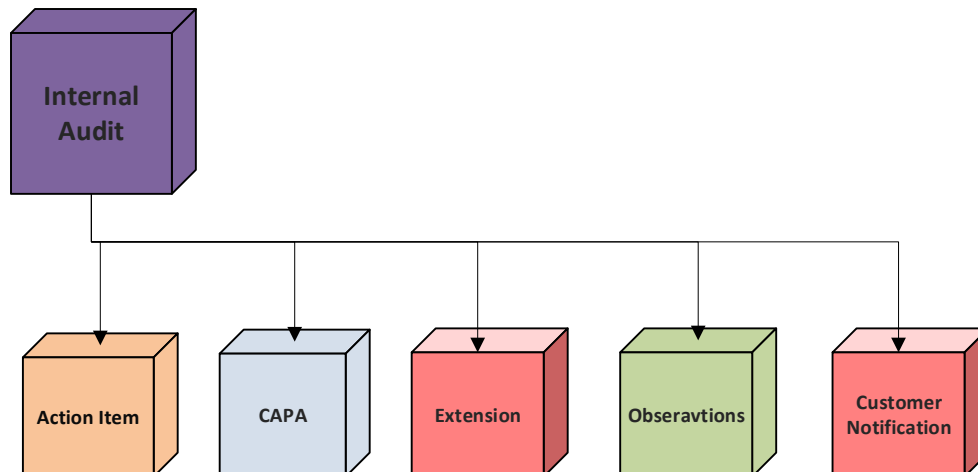


Parent Child Relationships

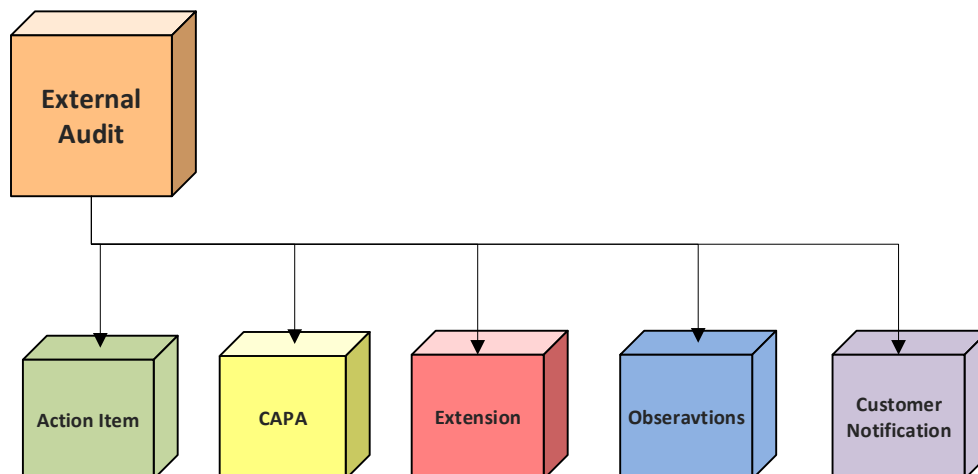
Audit Program



Internal Audit

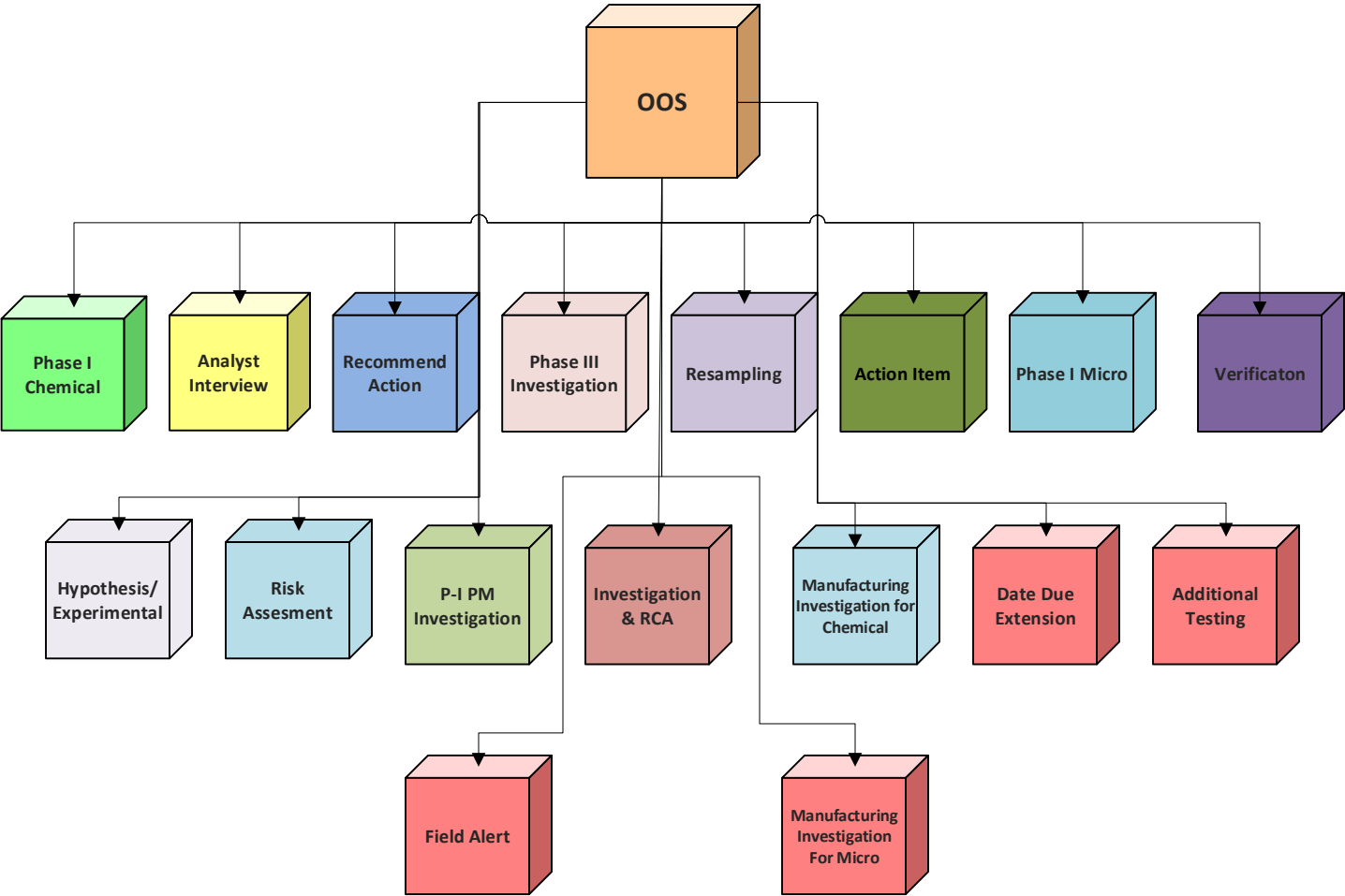


External Audit

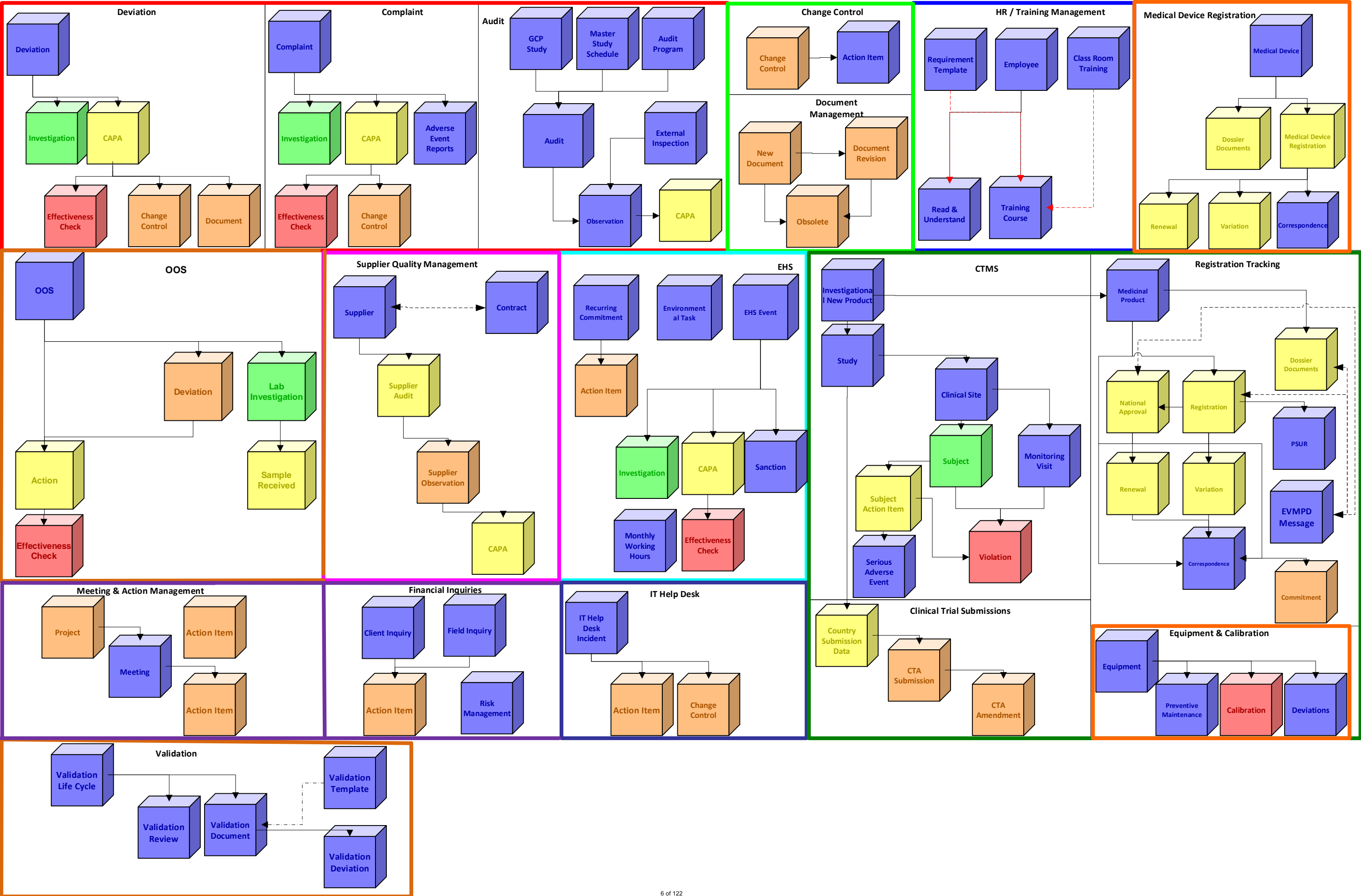


Parent Child Relationships

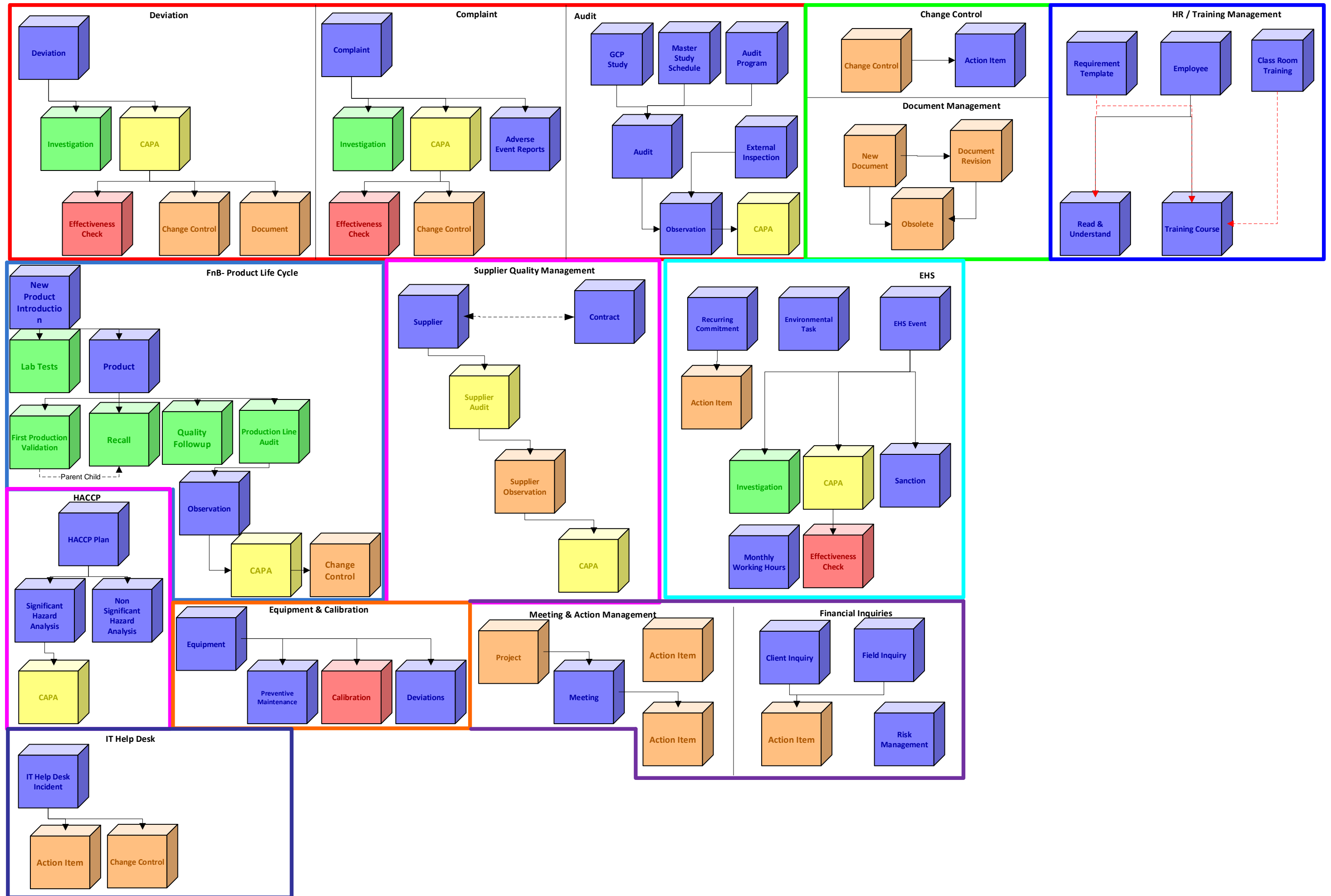
OOS



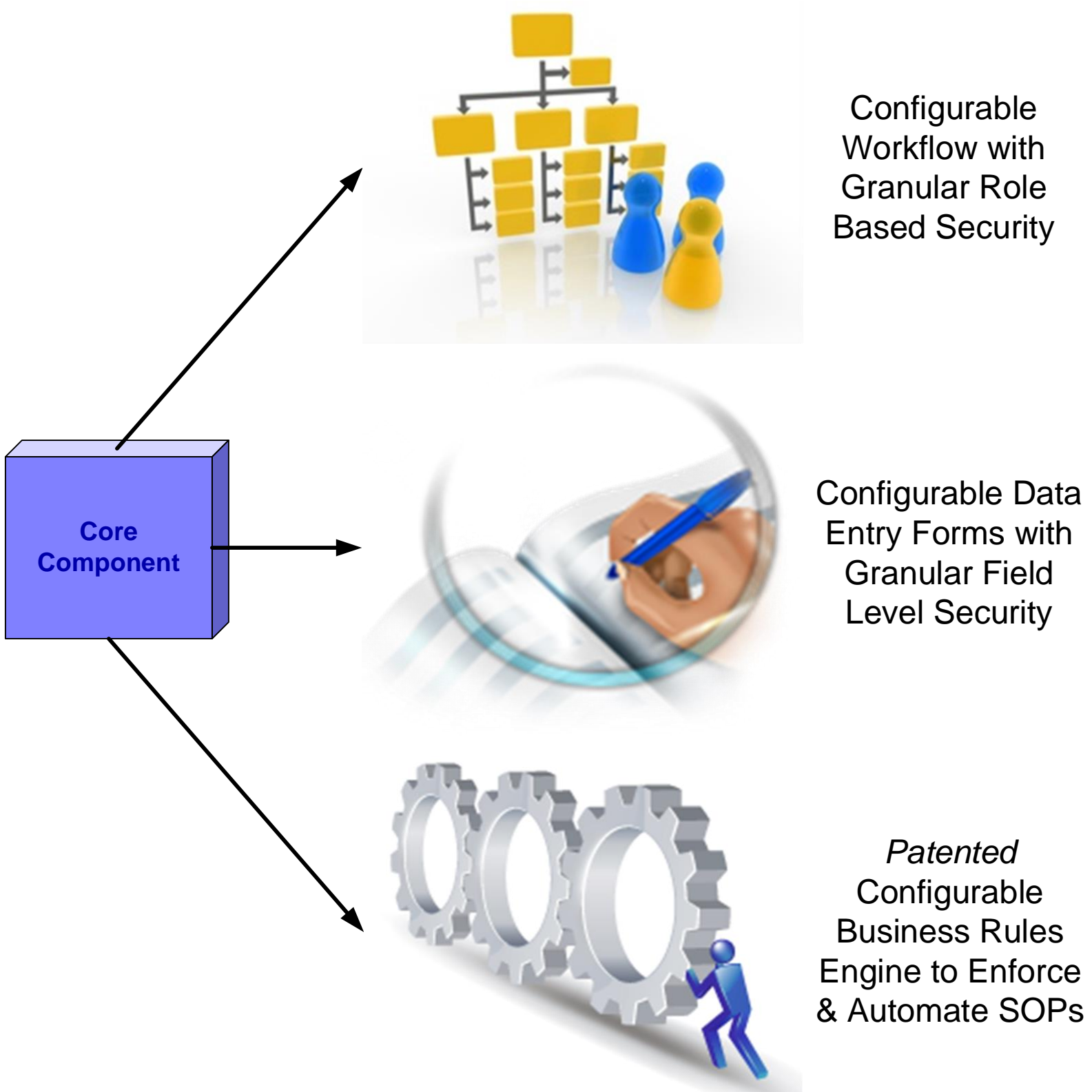
Life science-Preconfigured Solution



None Life science Preconfigured Solution

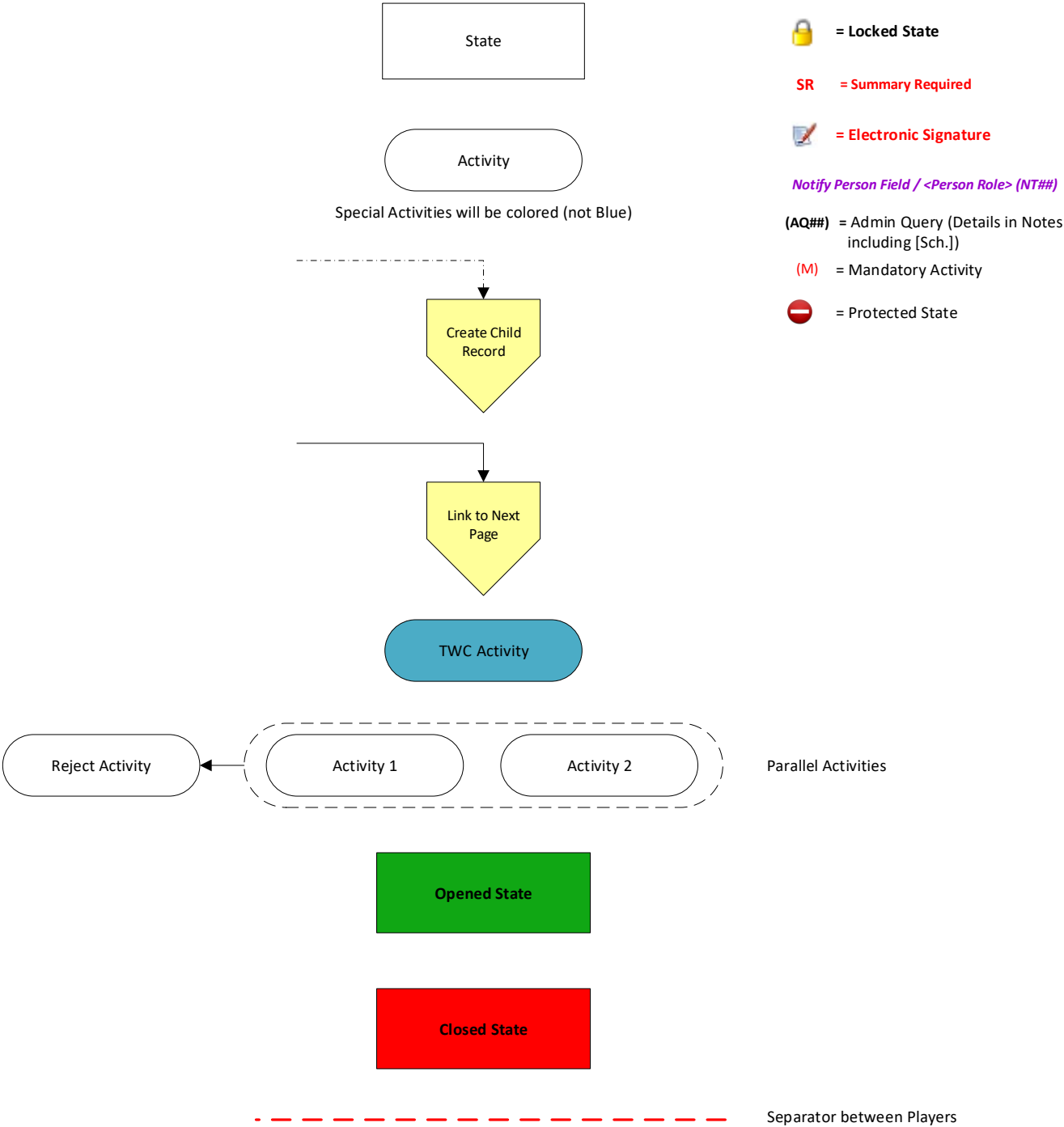


The TrackWise Core



Legend

Player



From OOS

Deviation

Initiator

Supervisor

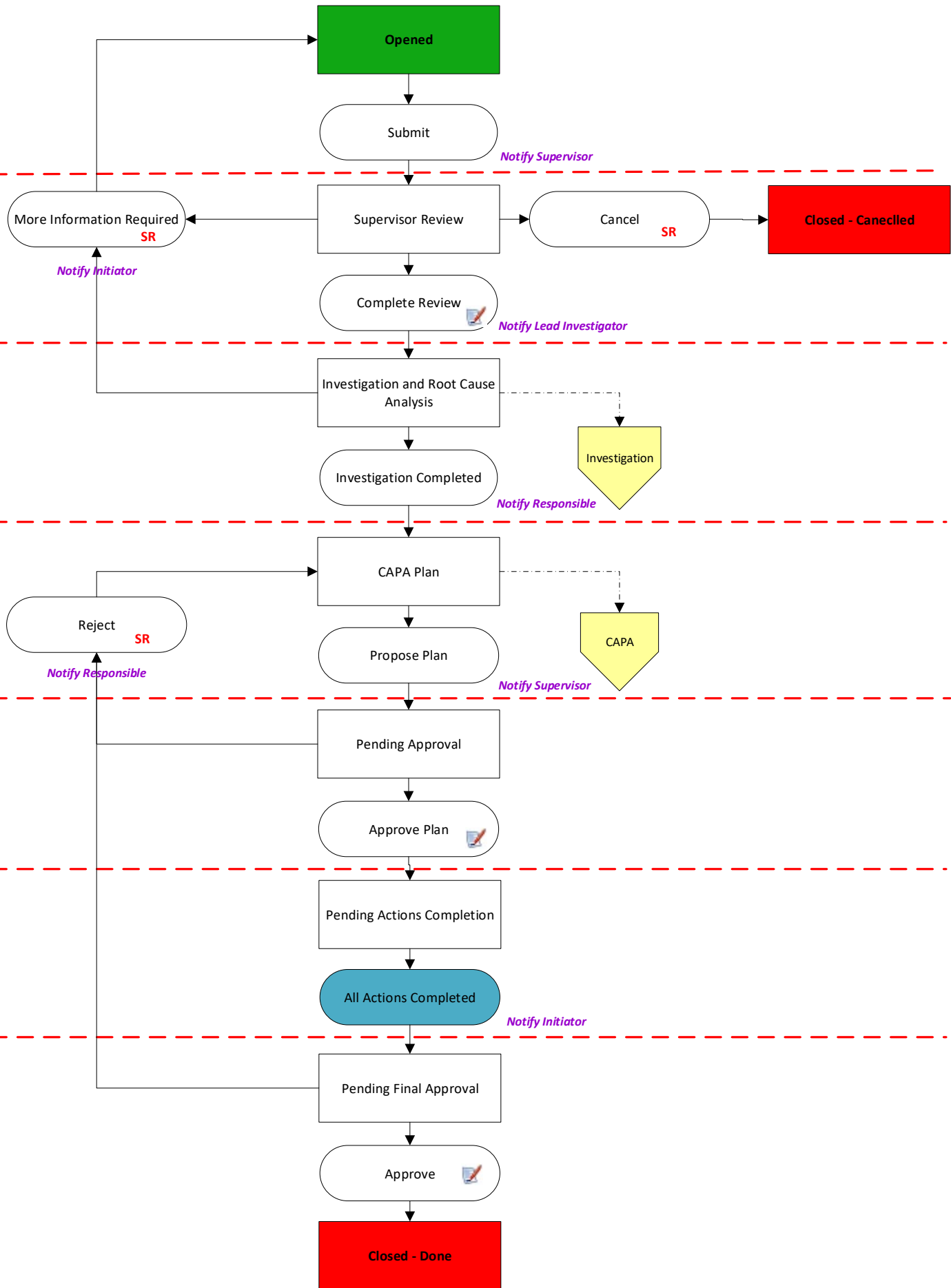
Lead Investigator

Responsible

Supervisor

Business Rule
Engine

Supervisor



From OOS

Deviation (Page1)

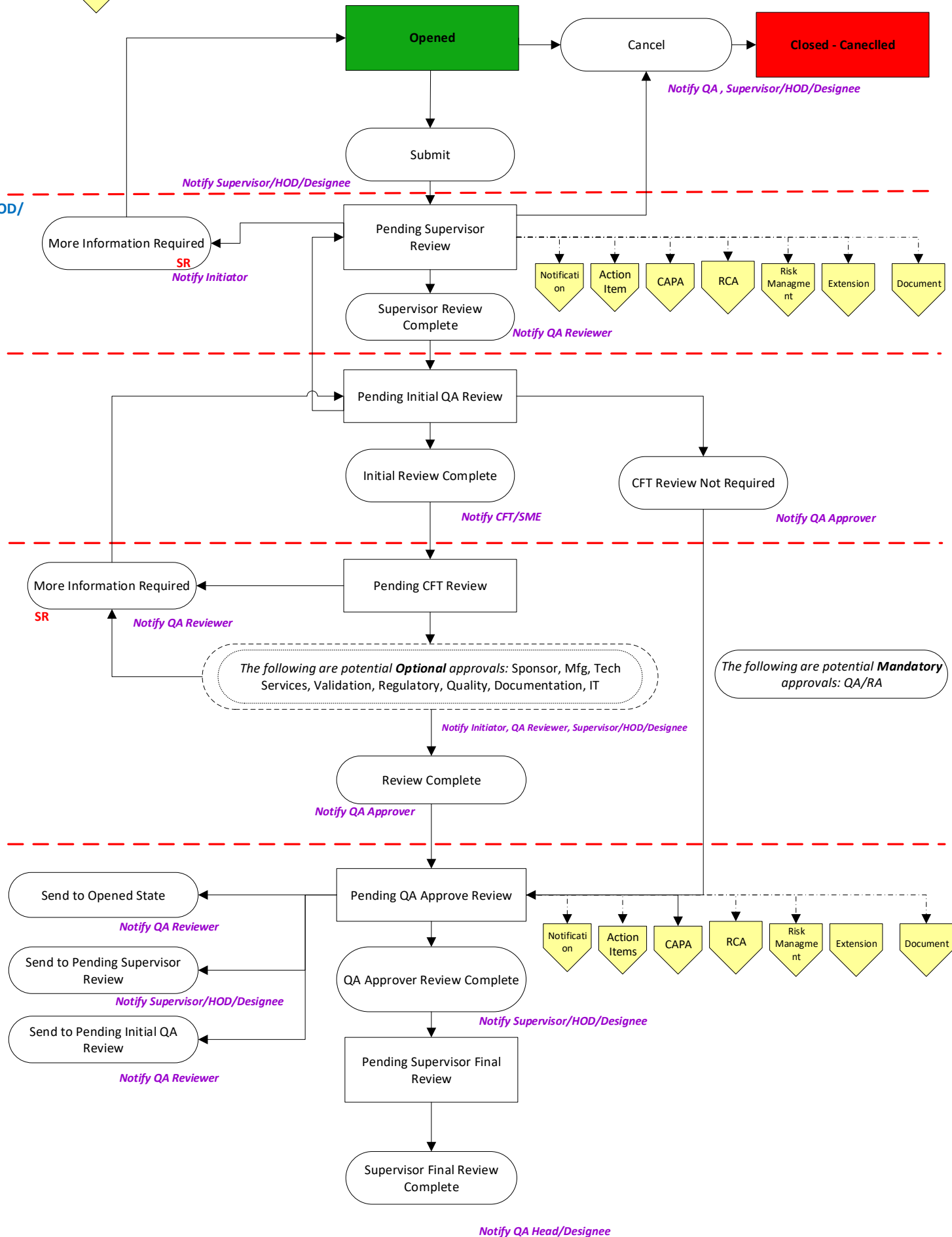
Initiator

Supervisor / HOD/
Designee

QA Reviewer

CFT/SME

QA Approver



Incident (Page1)

From OOS

Initiator

Supervisor / HOD/
Designee

QA Reviewer

CFT/SME

QA Approver



Non-Conformance (Page1)

From OOS

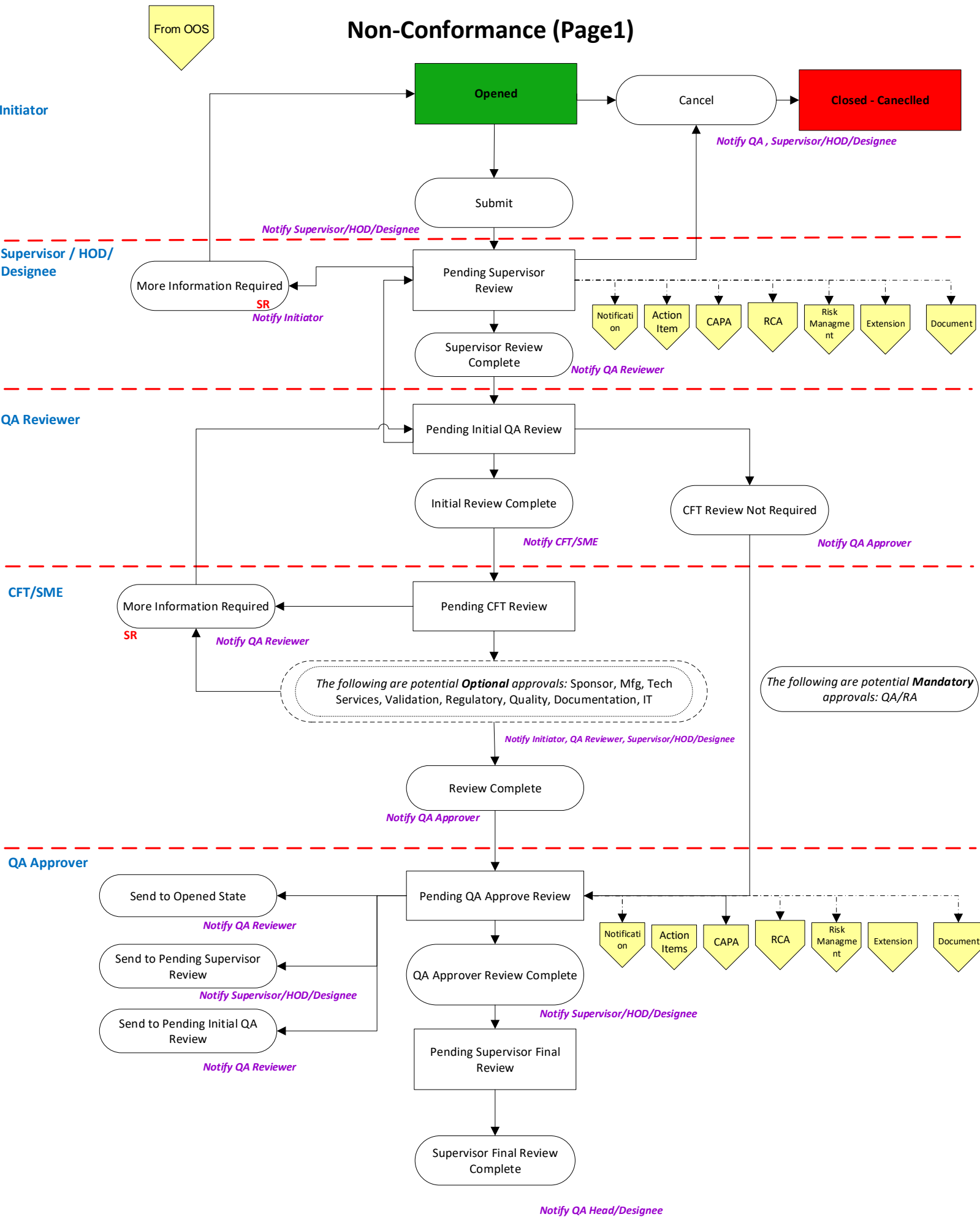
Initiator

Supervisor / HOD/ Designee

QA Reviewer

CFT/SME

QA Approver



Failure Investigation (Page1)

From OOS

Initiator

Supervisor / HOD/
Designee

QA Reviewer

CFT/SME

QA Approver



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

Effectiveness
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

Notify QA Approver

Addendum Execution Complete

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

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

Effectiveness
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

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

Effectiveness
Checking

QA Approver

Re-open

Notify Initiator, QA Reviewer, Supervisor/HOD/Designee ,
QA Approver, QA Head/DesigneePending for Re-open
AddendumRe-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
onAction
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

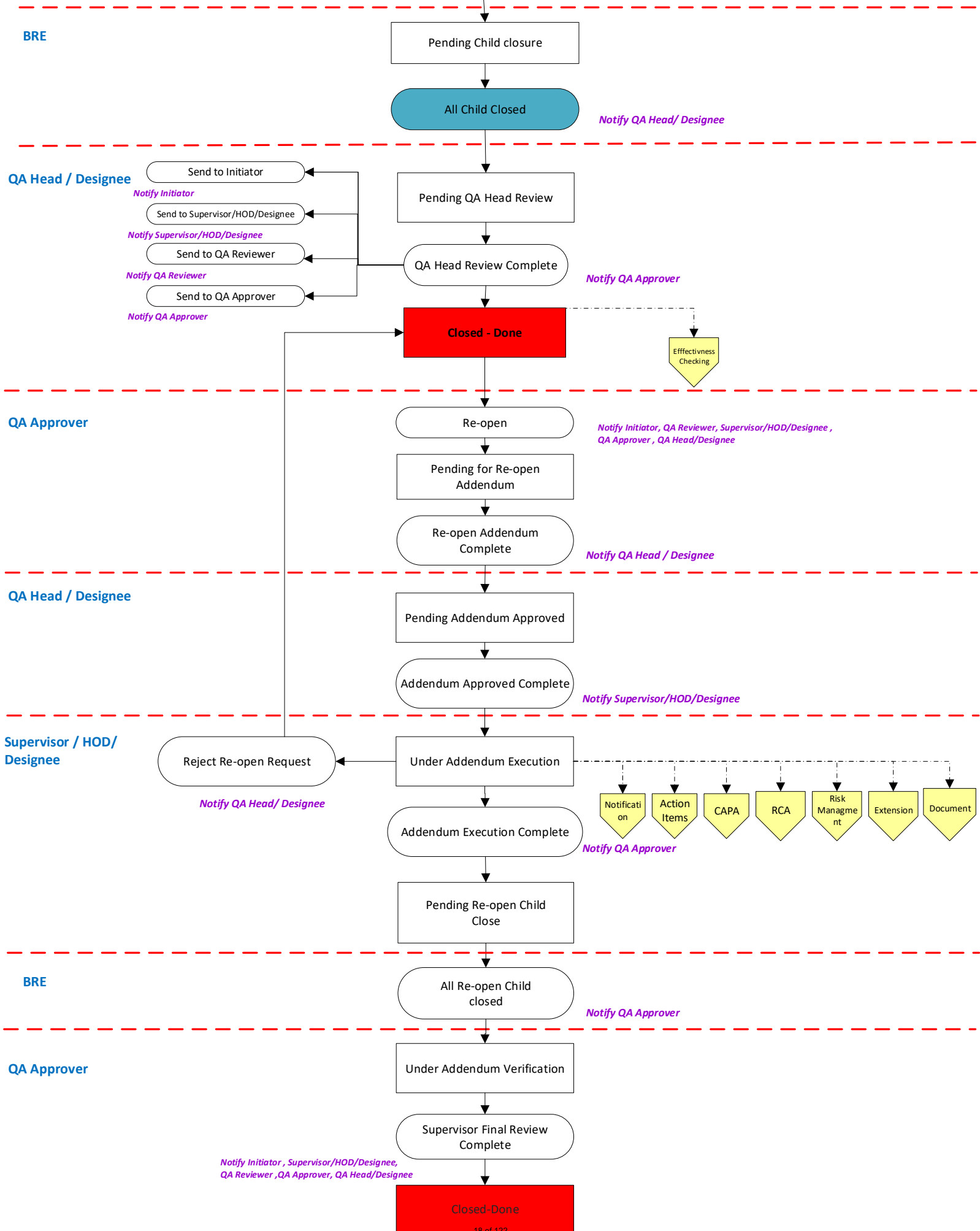
Notify QA Approver

QA Approver

Under Addendum Verification

Supervisor Final Review
CompleteNotify Initiator , Supervisor/HOD/Designee,
QA Reviewer ,QA Approver, QA Head/Designee

Closed-Done



Change Control (Page1)

From OOS

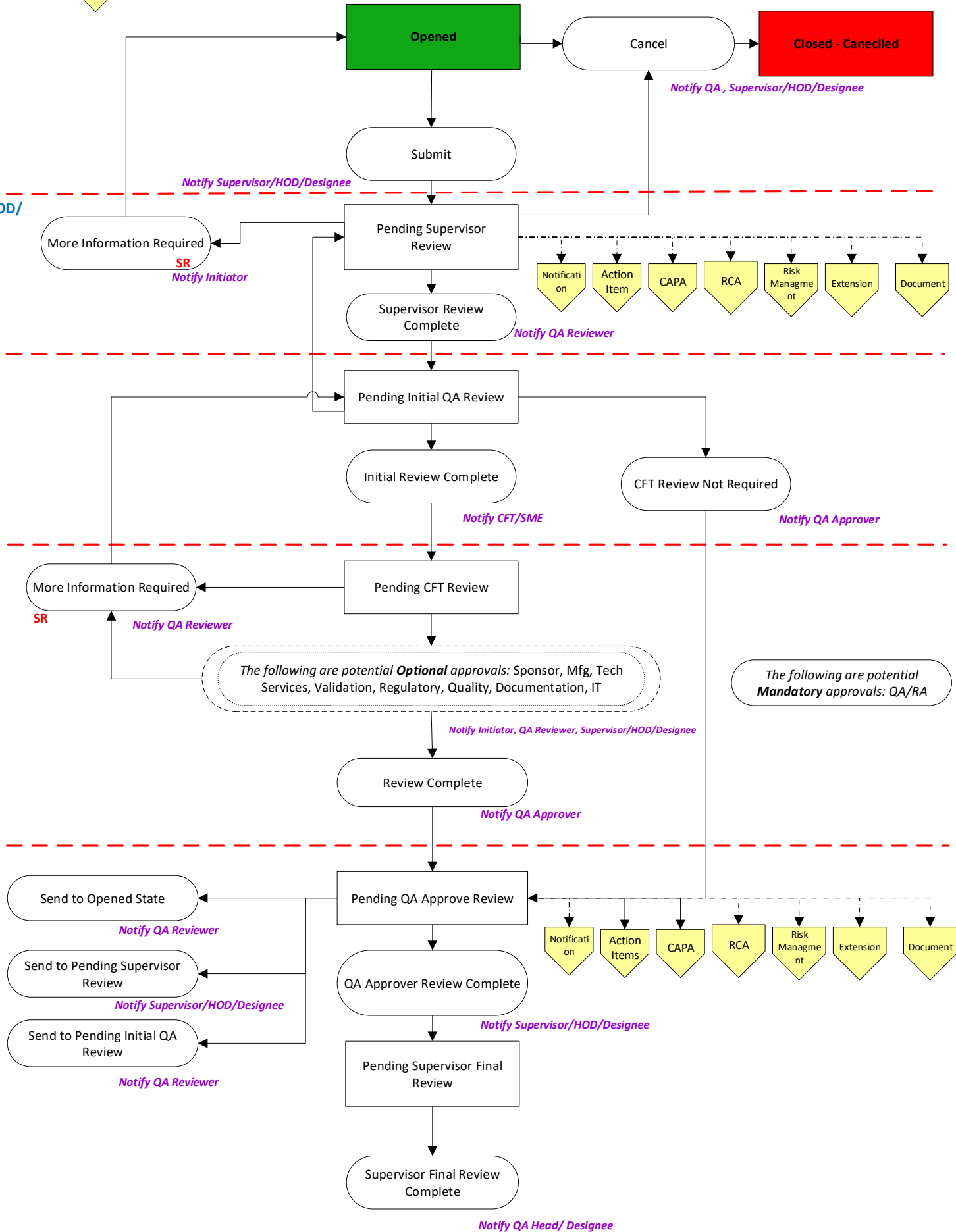
Initiator

Supervisor / HOD/
Designee

QA Reviewer

CFT/SME

QA Approver



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

Effectiveness
Checking

QA Approver

Re-open

Notify Initiator, QA Reviewer, Supervisor/HOD/Designee ,
QA Approver, QA Head/DesigneePending for Re-open
AddendumRe-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
onAction
Items

CAPA

RCA

Risk
Managme
nt

Extension

Document

Notify QA Approver

Addendum Execution Complete

Pending Re-open Child
Close

BRE

All Re-open Child
closed

Notify QA Approver

QA Approver

Under Addendum Verification

Supervisor Final Review
CompleteNotify Initiator , Supervisor/HOD/Designee,
QA Reviewer ,QA Approver, QA Head/Designee

Closed-Done

Lab Incident (Page1)

From OOS

Opened

Cancel

Closed - Canecled

Submit

Notify Supervisor/HOD/Designee

Notify QA , Supervisor/HOD/Designee

More Information Required

SR

Notify Initiator

Pending Supervisor Review

Notification

Action Item

CAPA

RCA

Risk Managme nt

Extension

Document

Supervisor Review Complete

Notify QA Reviewer

Pending Initial QA Review

Initial Review Complete

Notify CFT/SME

CFT Review Not Required

Notify QA Approver

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

Notify Initiator, QA Reviewer, Supervisor/HOD/Designee

Review Complete

Notify QA Approver

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

Pending QA Approve Review

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

QA Approver Review Complete

Notify Supervisor/HOD/Designee

Pending Supervisor Final Review

Supervisor Final Review Complete

Notify QA Head/Designee

CAPA(Page1)

From OOS

Opened

Cancel

Closed - Canelled

Submit

Notify Supervisor/HOD/Designee

Notify QA, Supervisor/HOD/Designee

More Information Required

Notify Initiator

SR

Pending Supervisor Review

Supervisor Review Complete

Notify Responsible Person

More Information Required

Notify Supervisor / HOD / Designee

Pending Responsible Person Update

Responsible Person Update Complete

Notify QA Reviewer

Pending Initial QA Review

Initial Review Complete

Notify CFT/SME

CFT Review Not Required

Notify QA Approver

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

Notify Initiator, QA Reviewer, Supervisor/HOD/Designee

Review Complete

Notify 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

QA Approver Review Complete

Notify Supervisor/HOD/Designee

Pending Supervisor Final Review

Supervisor Final Review Complete

22 of 122

Notify QA Head/Designee

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

Notification

Action Item

Document

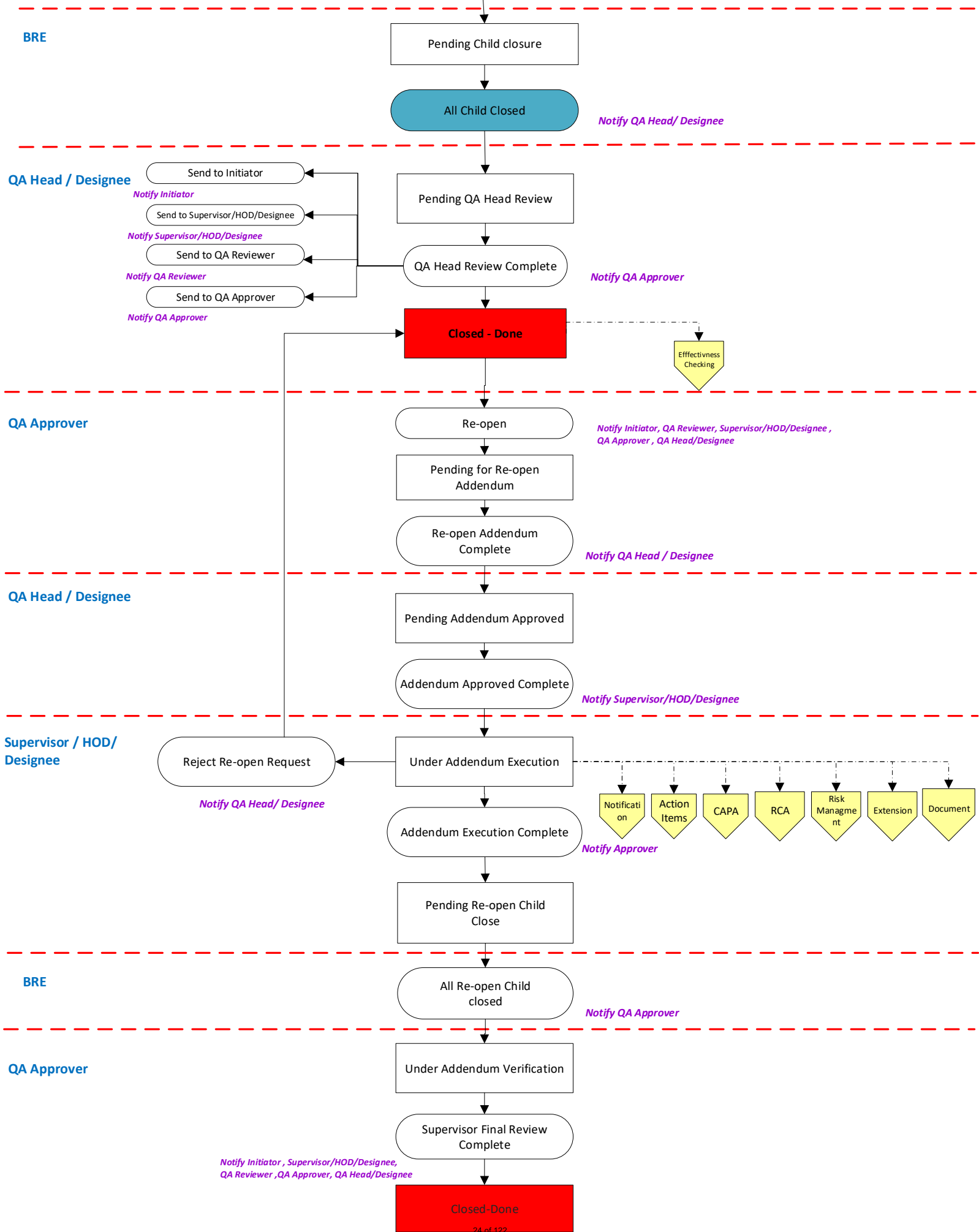
RCA

Risk Management

Extension

From OOS





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

Effectiveness
Checking

QA Approver

Re-open

Notify Initiator, QA Reviewer, Supervisor/HOD/Designee ,
QA Approver , QA Head/DesigneePending for Re-open
AddendumRe-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
onAction
Items

Document

RCA

Risk
Managme
nt

Extension

Notify Approver

Addendum Execution Complete

Pending Re-open Child
Close

BRE

All Re-open Child
closed

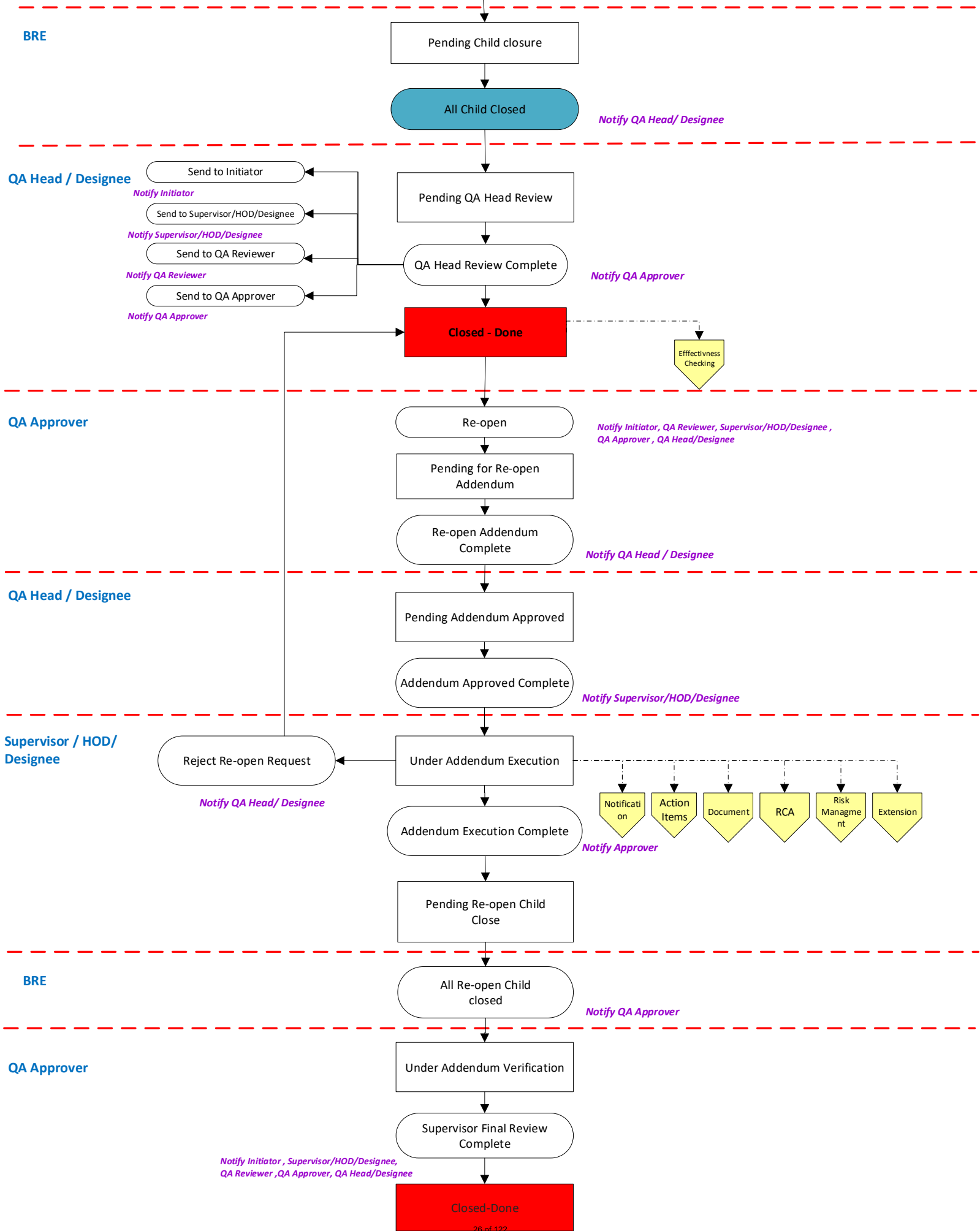
Notify QA Approver

QA Approver

Under Addendum Verification

Supervisor Final Review
CompleteNotify Initiator , Supervisor/HOD/Designee,
QA Reviewer ,QA Approver, QA Head/Designee

Closed-Done



From OOS

Complaint(Page1)

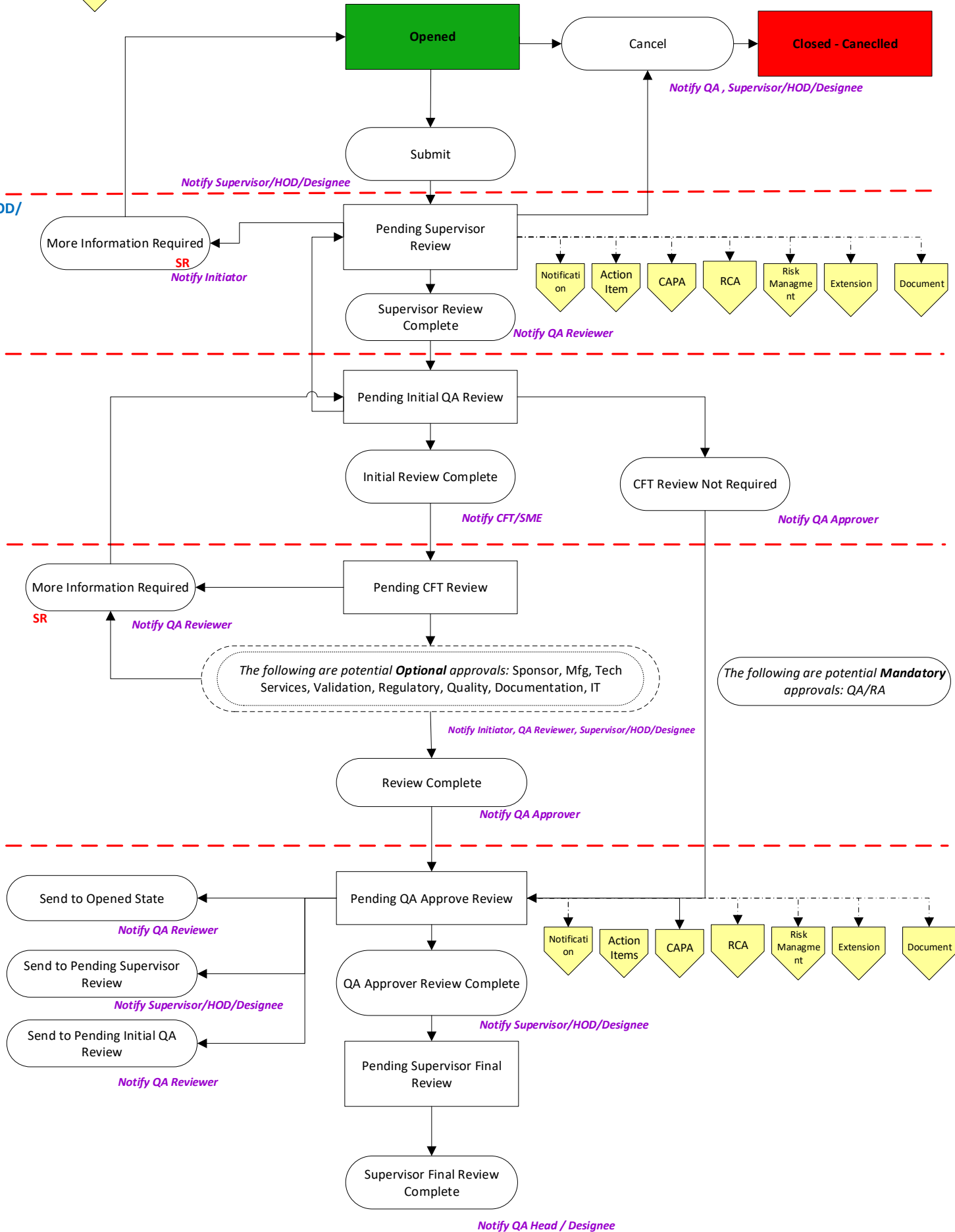
Initiator

Supervisor / HOD/
Designee

QA Reviewer

CFT/SME

QA Approver



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

Effectiveness
Checking

QA Approver

Re-open

Notify Initiator, QA Reviewer, Supervisor/HOD/Designee ,
QA Approver, QA Head/DesigneePending for Re-open
AddendumRe-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

Notification
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
CompleteNotify Initiator , Supervisor/HOD/Designee,
QA Reviewer ,QA Approver, QA Head/Designee

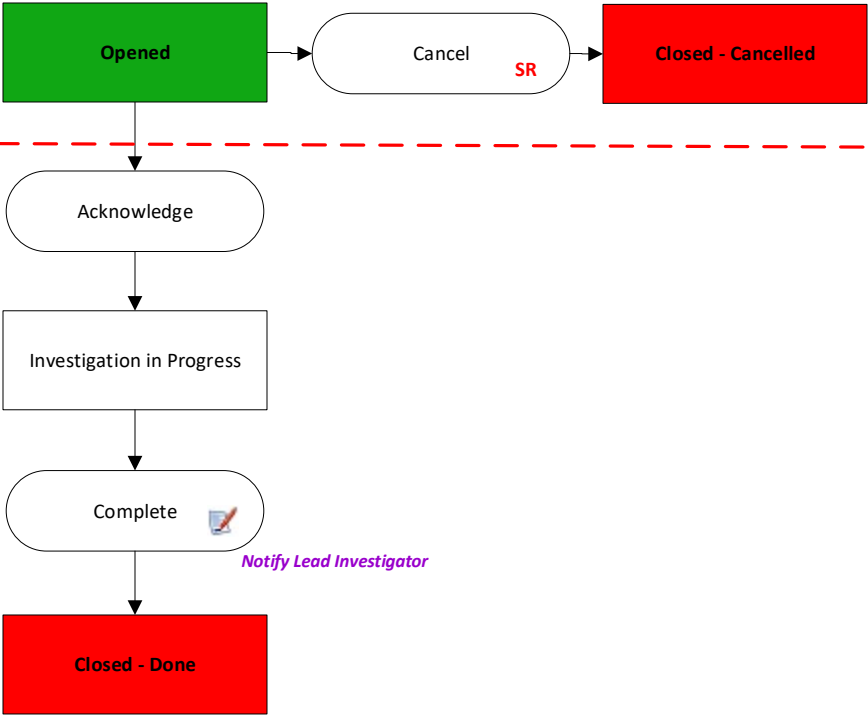
Closed-Done



Investigation

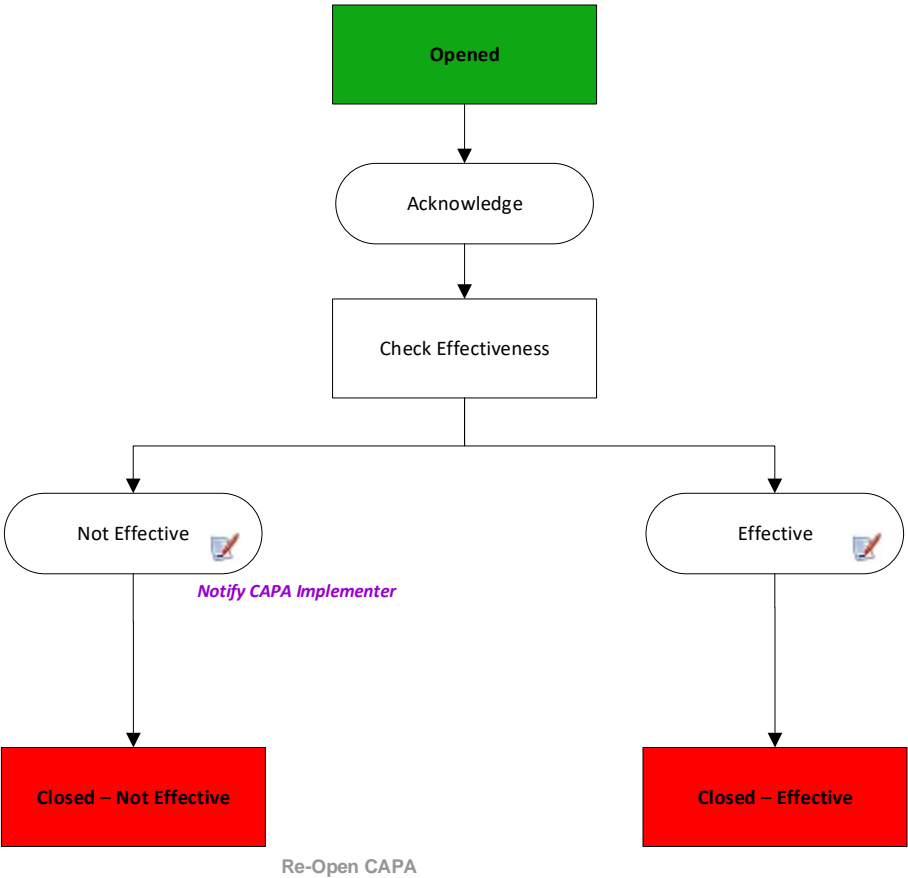
Lead Investigator

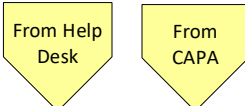
Responsible



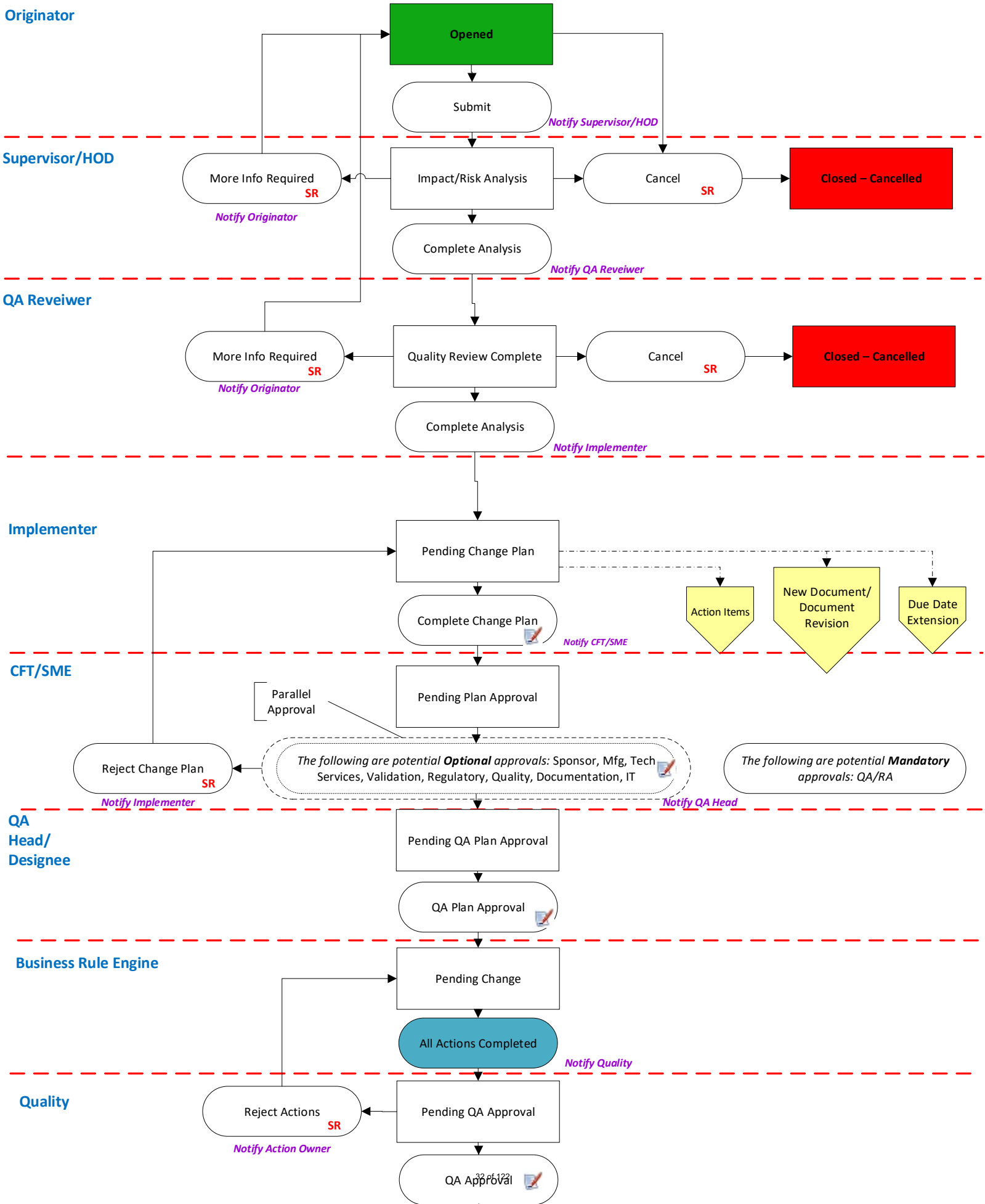
Effectiveness Check

Responsible





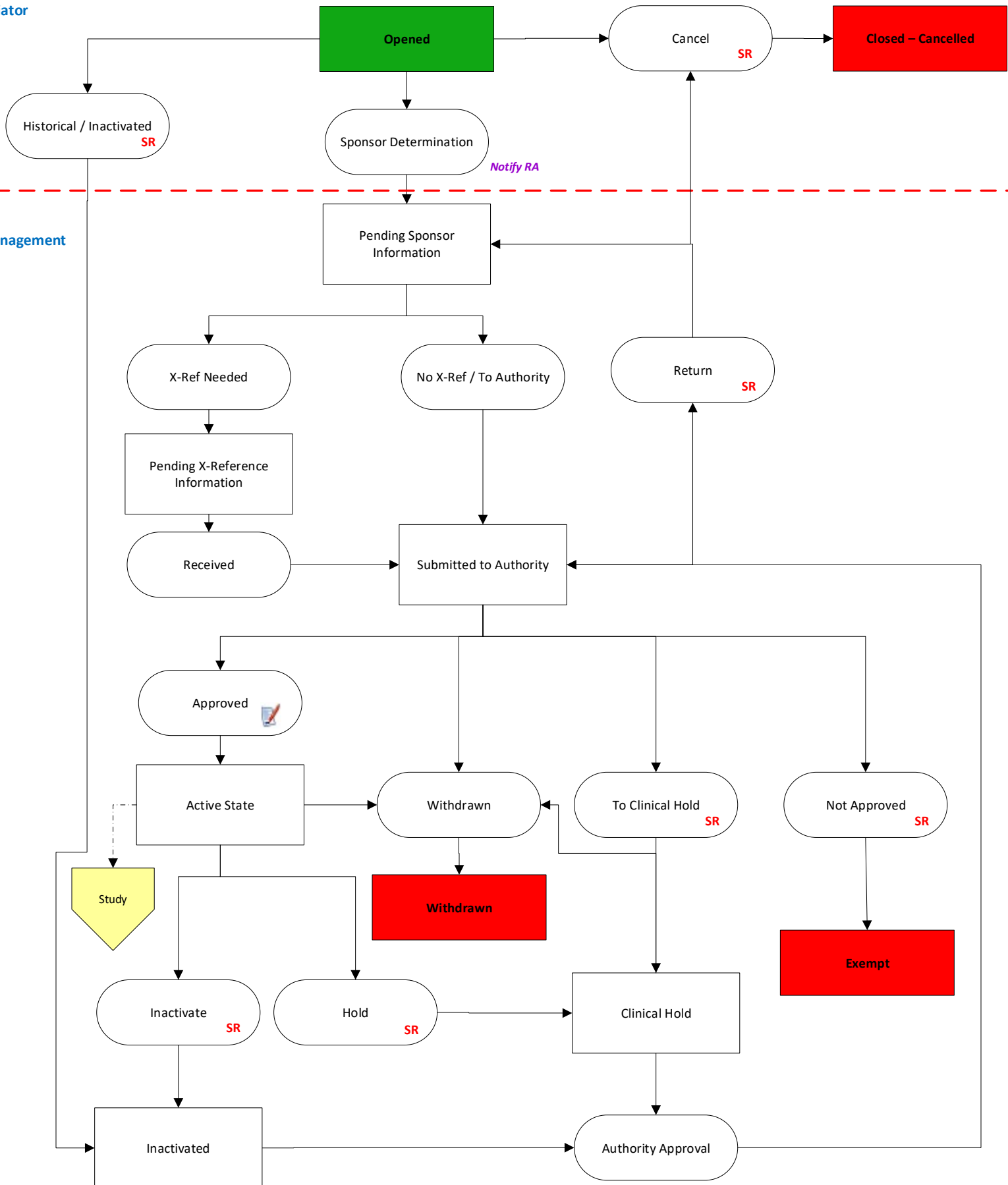
Change Control



Investigational Product

Initiator

RA
Management

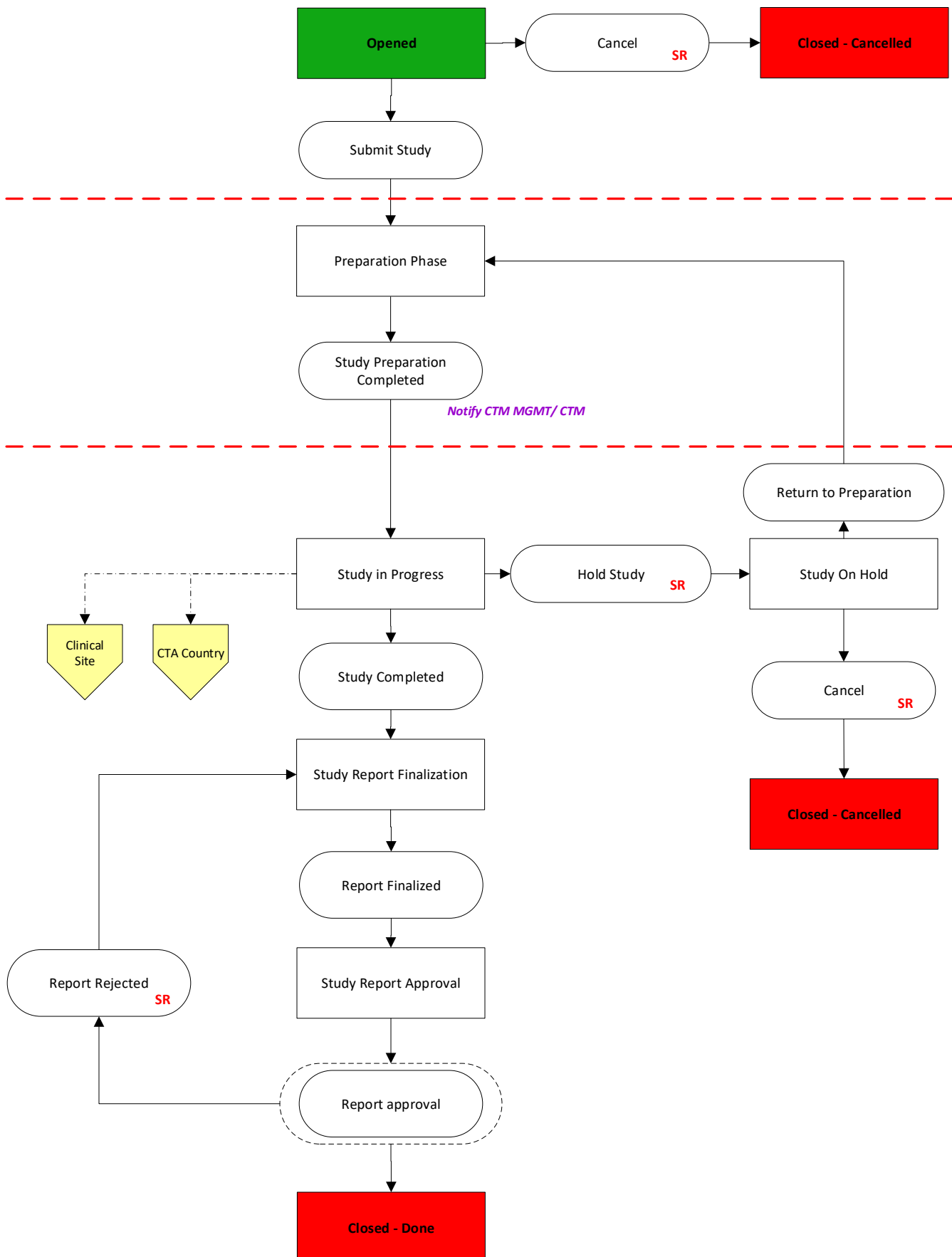


Study

Initiator

Quality
Responsible

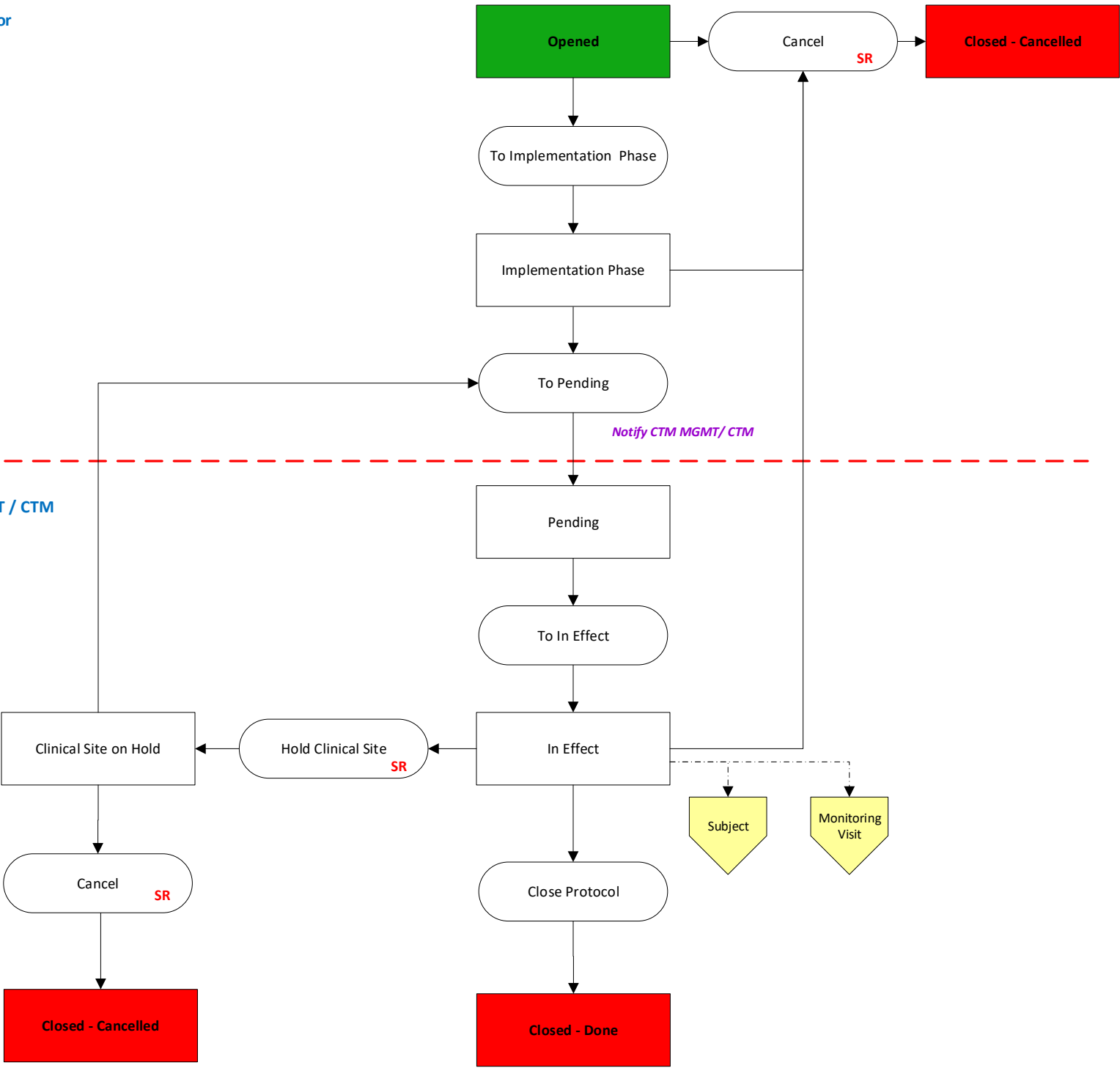
CTM
MGMT / CTM



Clinical Site

Initiator

CTM
MGMT / CTM

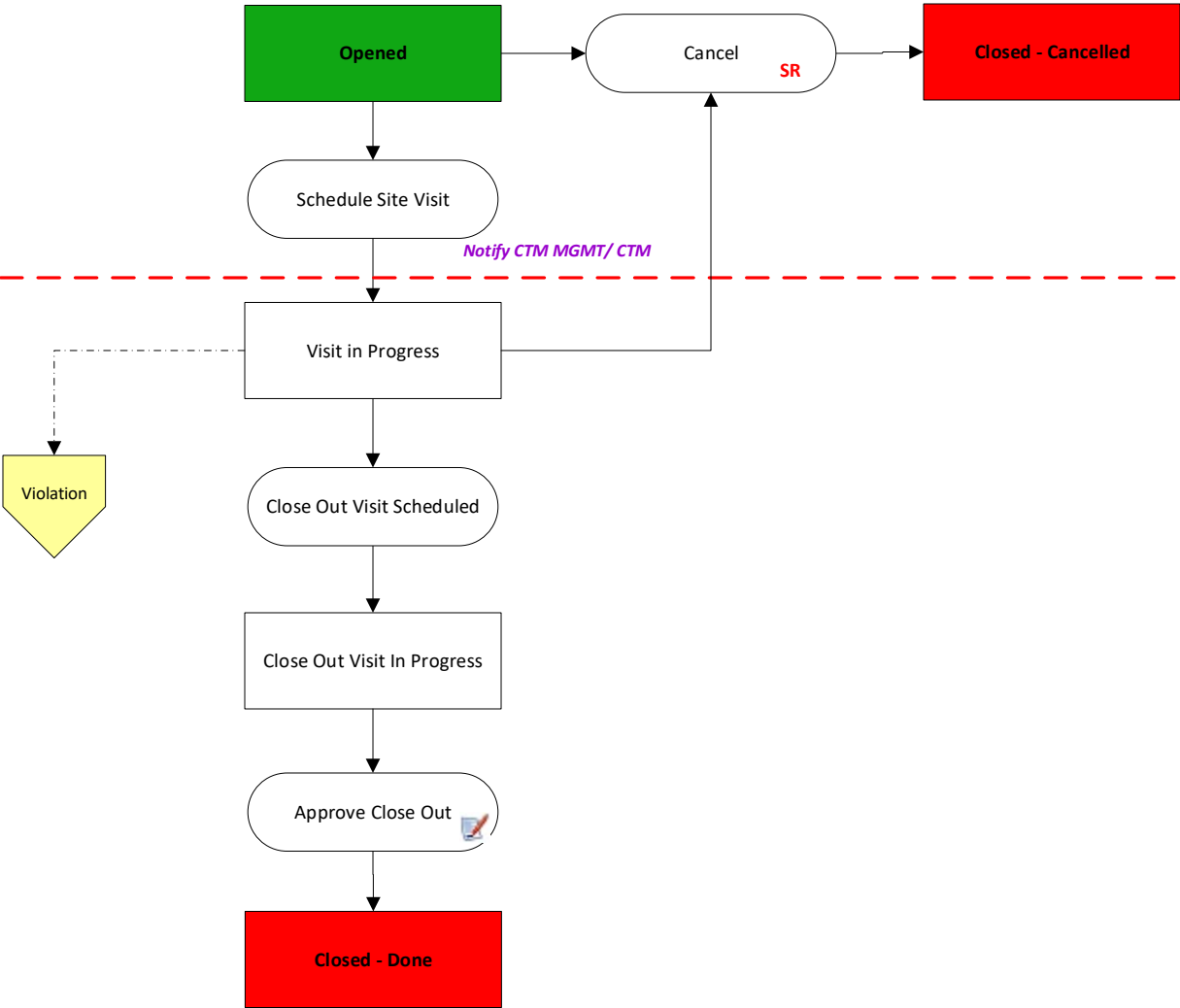




Monitoring Visit

Initiator

CTM
MGMT / CTM

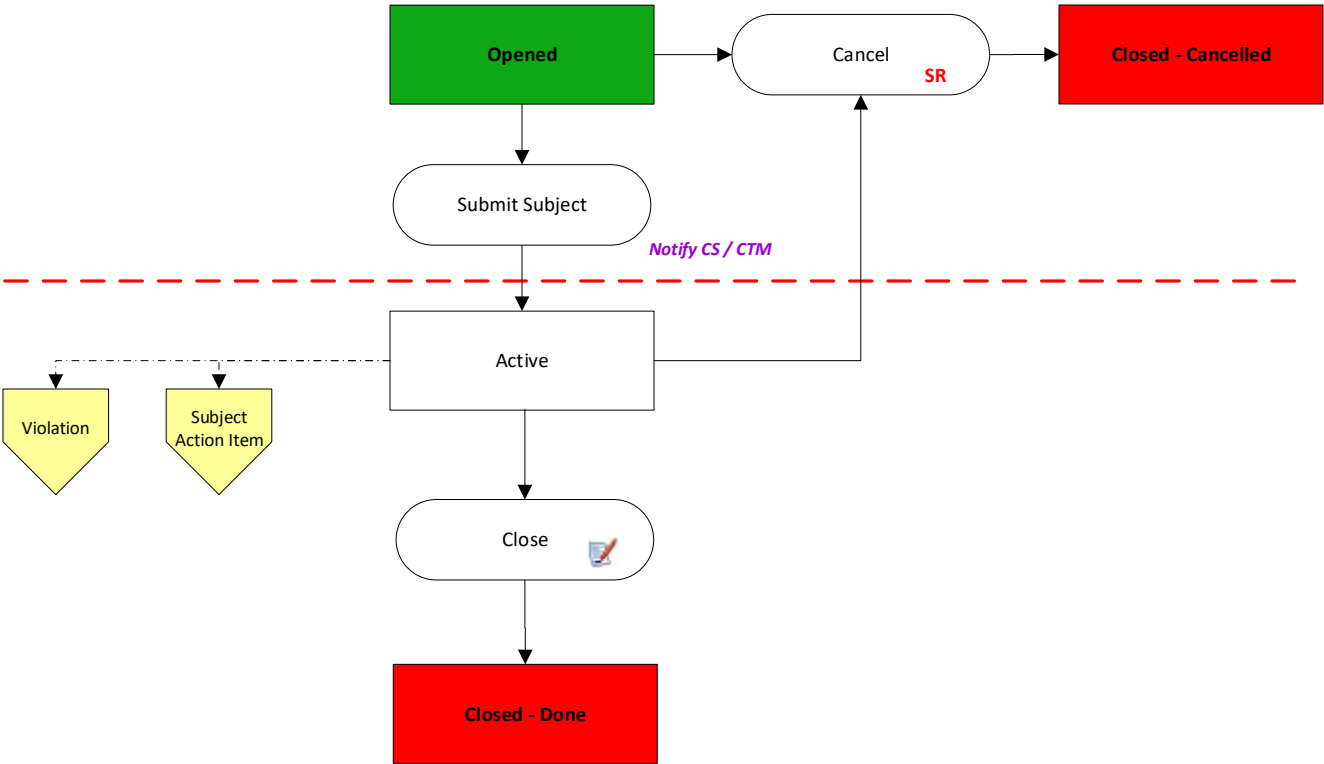




Subject

Initiator

CS / CTM

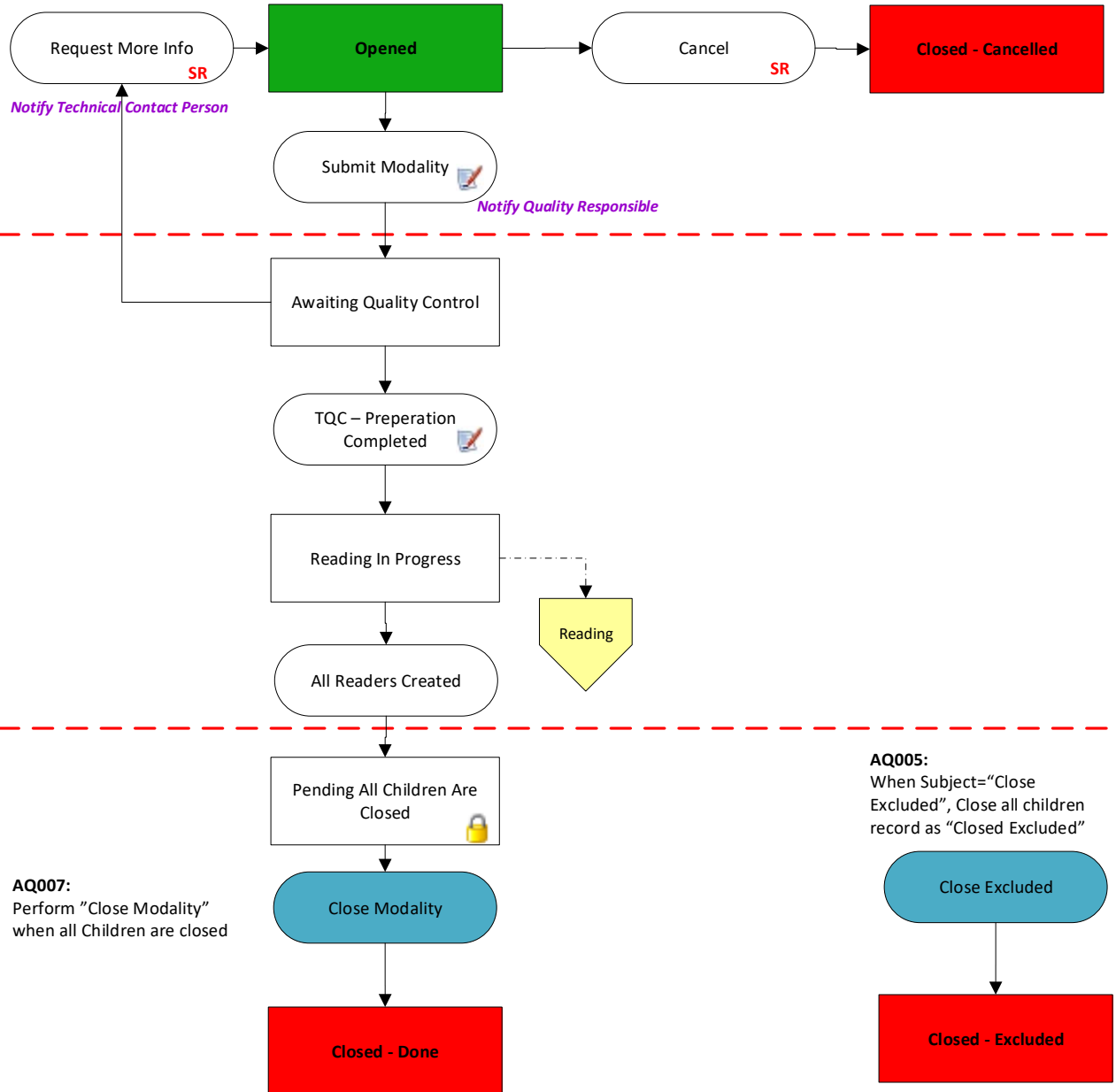


Modality

Technical Contact Person

Quality Responsible

Business Rule Engine

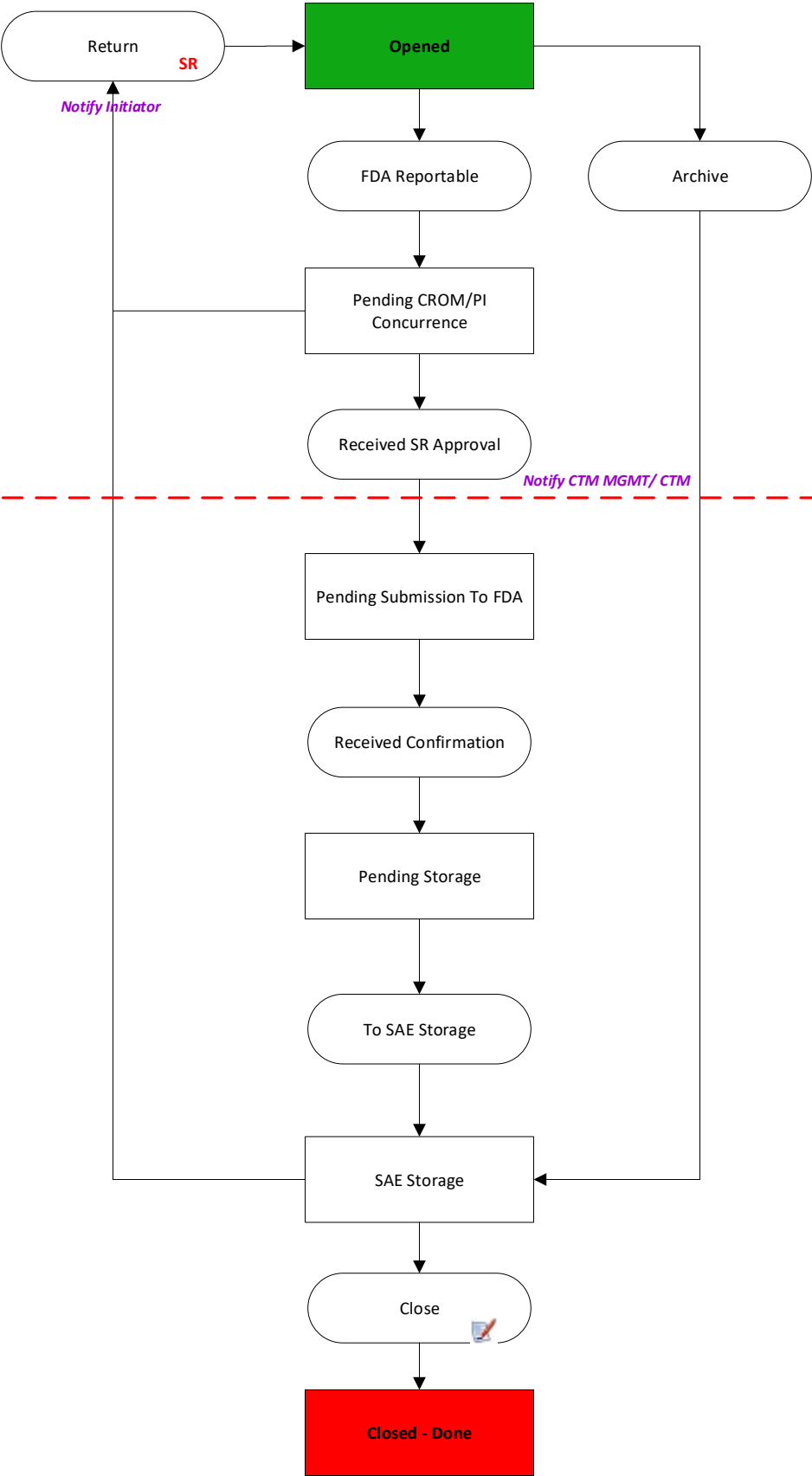


- Each time the "Technical Contact Person" is changing, Sudy IRC Resposable will be notified
- Reports Ideas:
 - Randomization List Report: The list of all related "Reader" processes to the "Study" and thier "randomization number".
 - Create report that will display the Block and the list of readers 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.

Serious Adverse Event

Initiator

CTM
MGMT / CTM

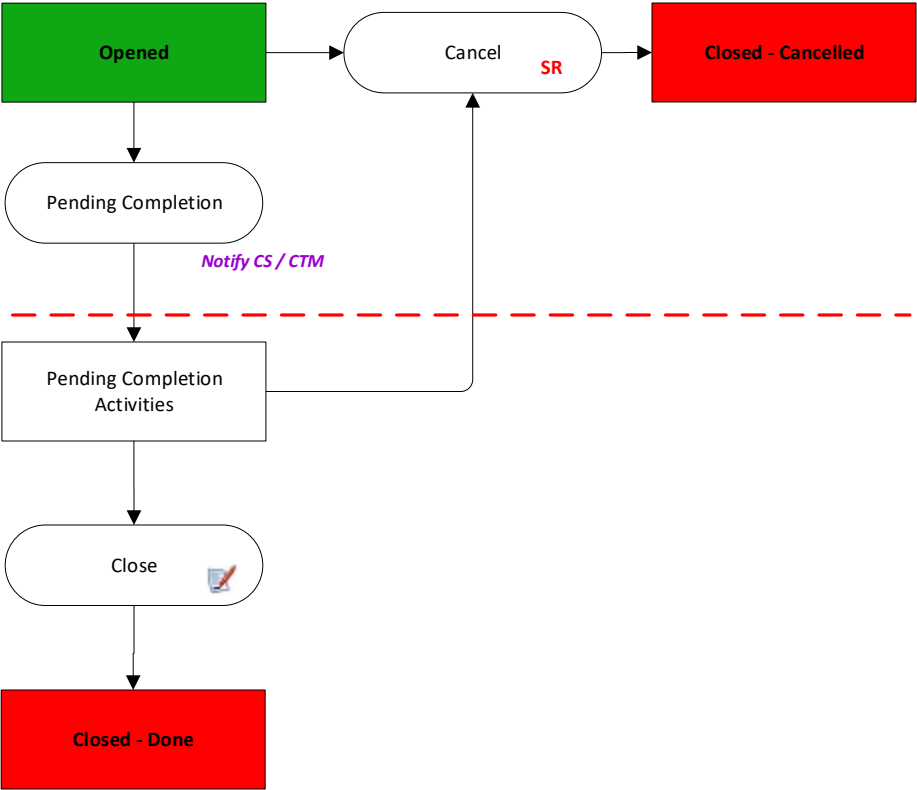




Violation

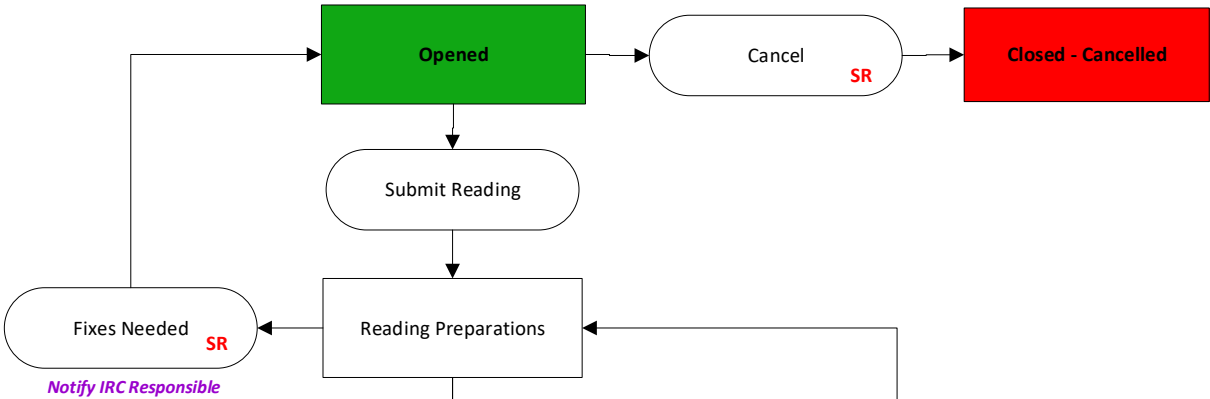
Initiator

CS / CTM



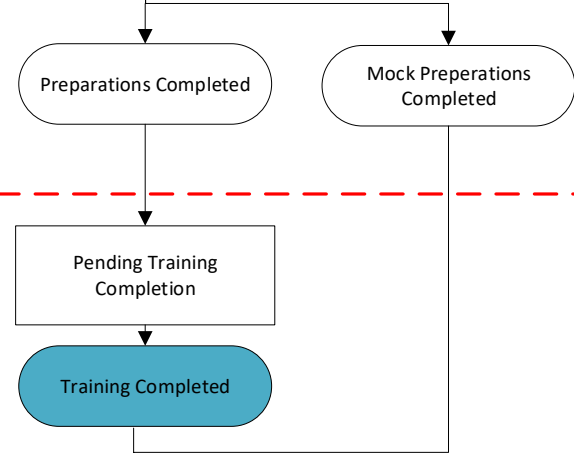
Reading

Quality Responsible



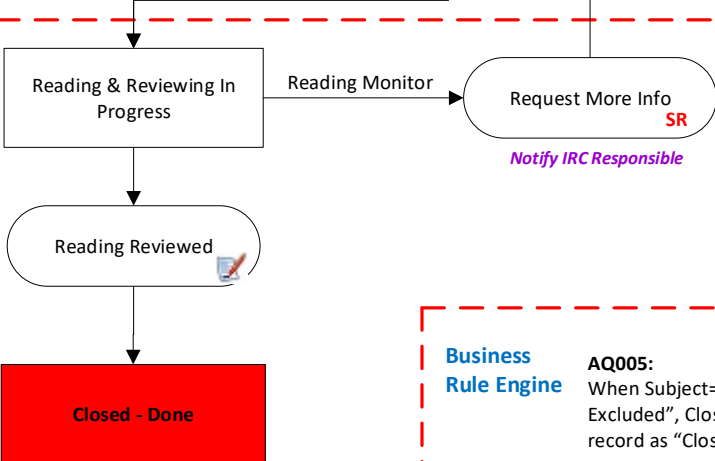
Business Rule Engine

AQ008: When BIE Training = “Closed Done”, Perform “Training Completed” On All Releted “Reader” Records (When “BIE Management ID” Is Equal in “BIE Management” and “Reader” Processes)



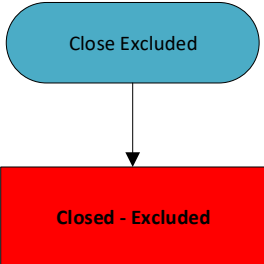
Reading Monitor

The Reader is responsible for this state, but he is not a user in TW (just a person in TW)



Business Rule Engine

AQ005: When Subject=“Close Excluded”, Close all children record as “Closed Excluded”



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

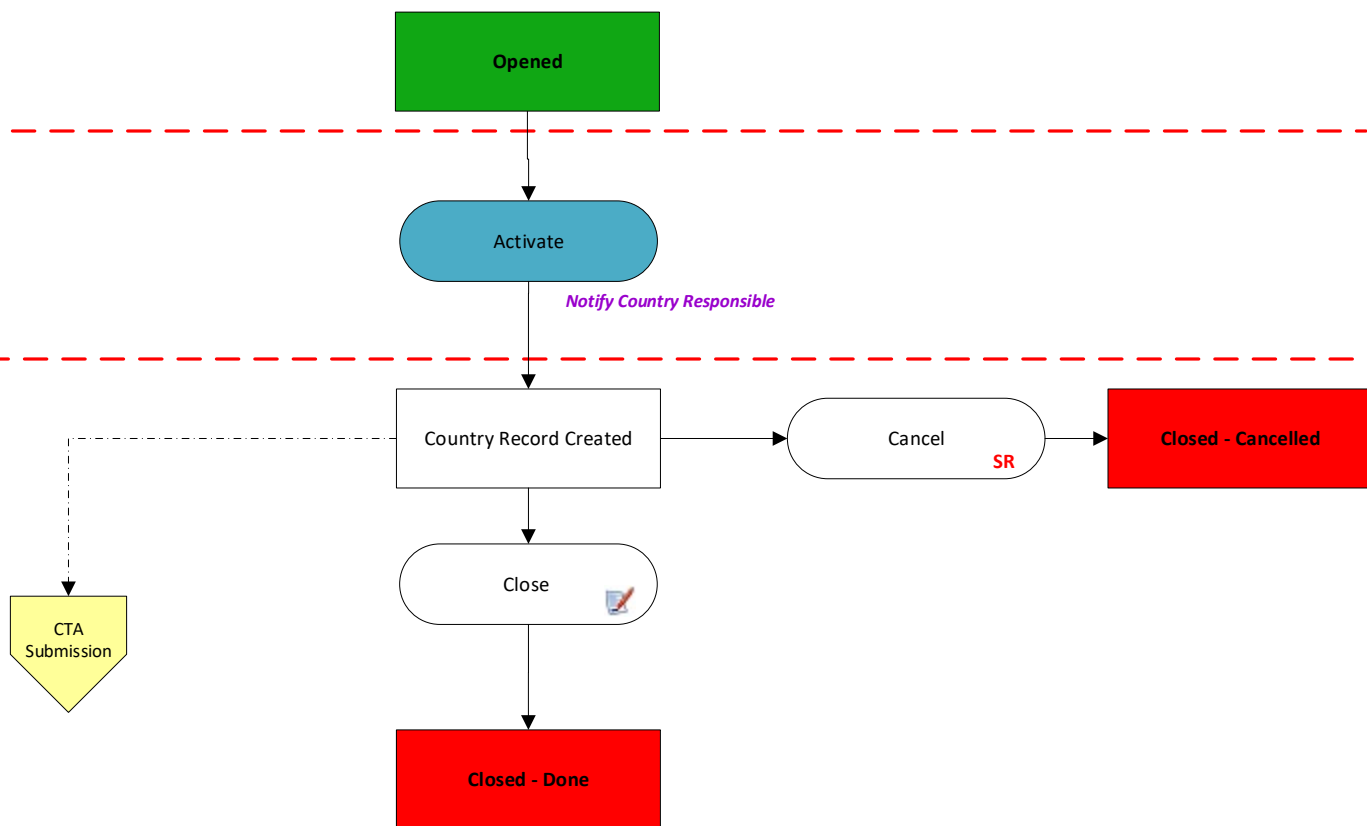
From Study

Country Submission Data

Initiator

Business Rule
Engine

Country Responsible



Complaint

Initiator
Customer Service

Supervisor

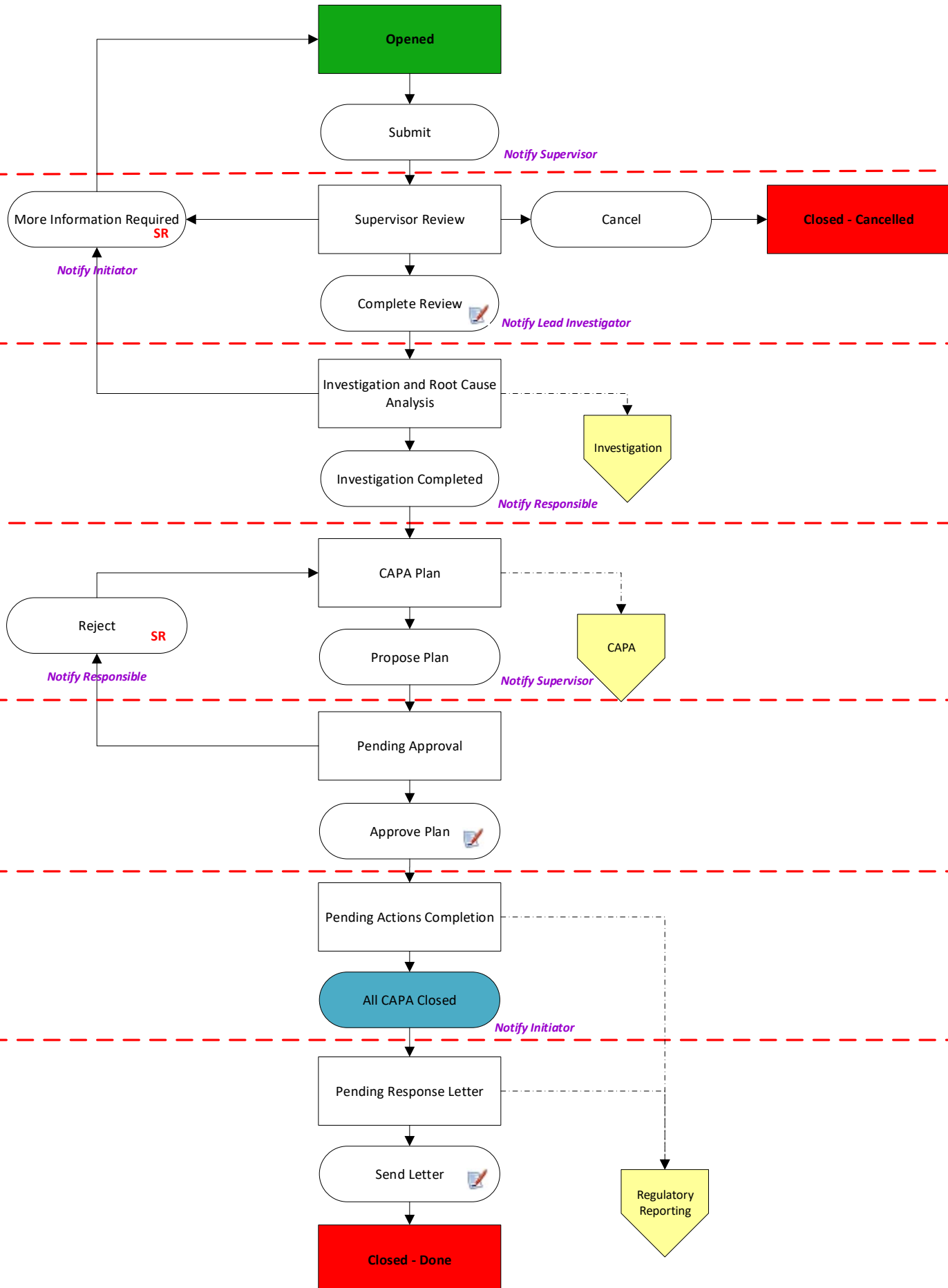
Lead Investigator

Responsible

Supervisor

Business Rule Engine

Initiator
Customer Service

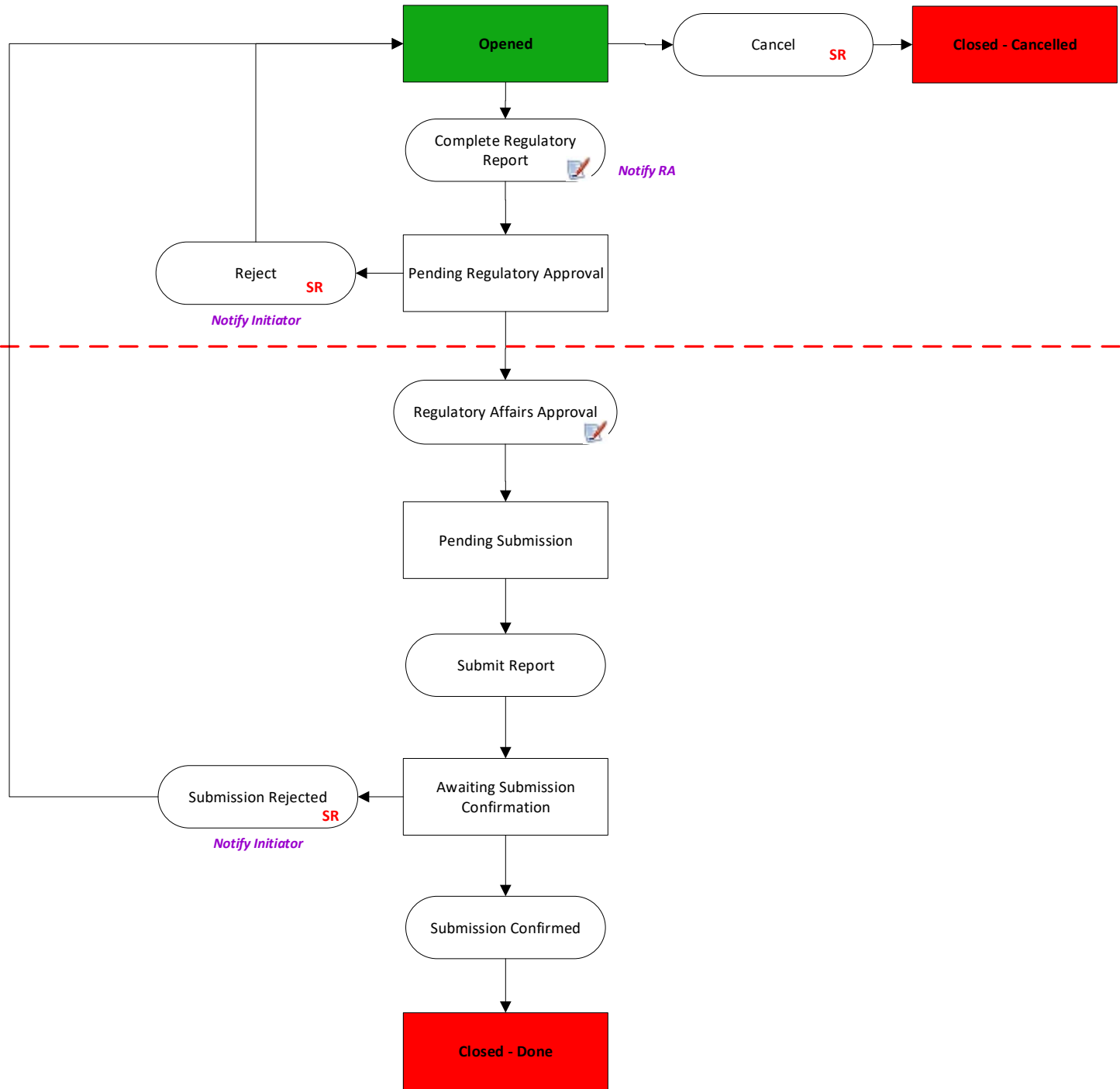


From
Complaint

Adverse Event Reporting

Initiator

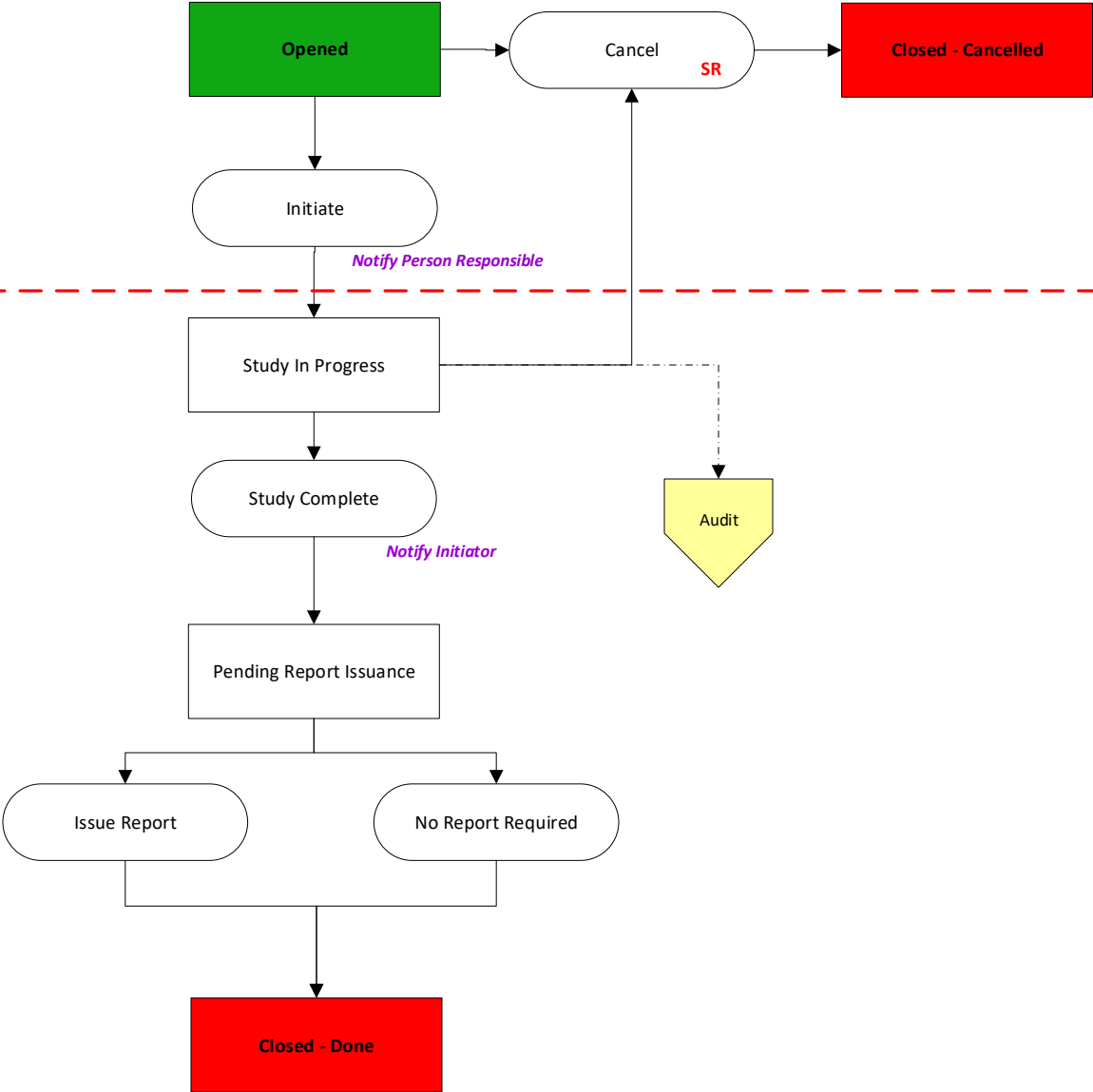
Regulatory
Affairs

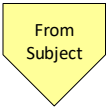


GCP Study

Initiator

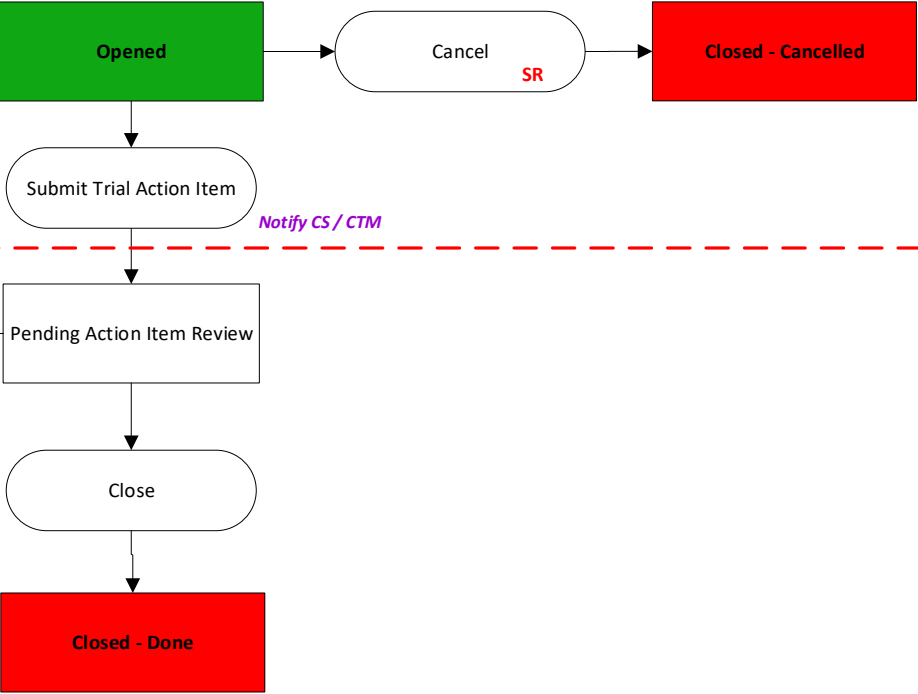
Person Responsible





Subject Action Item

CS / CTM

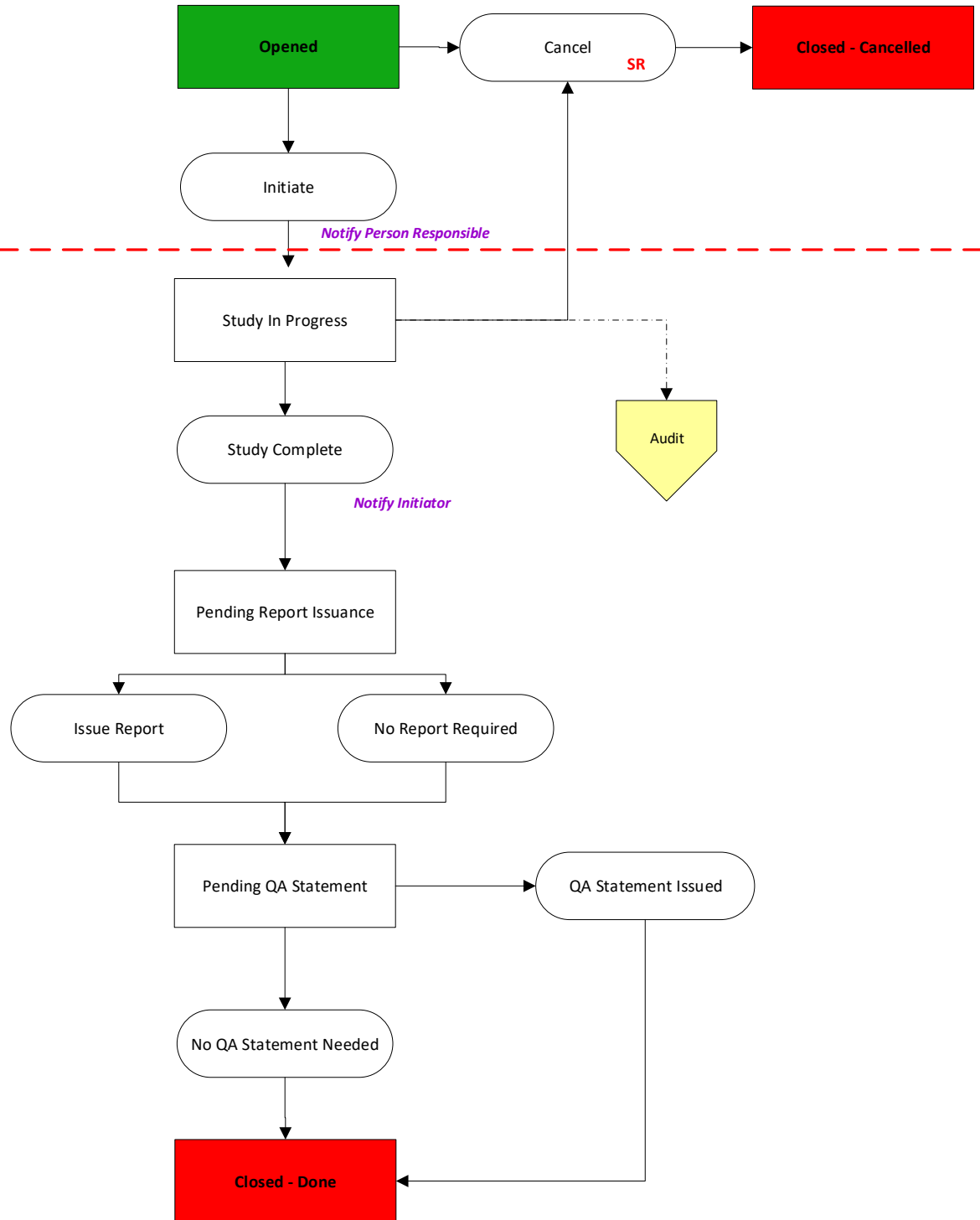


Quality
Responsible

Master Study Schedule

Initiator

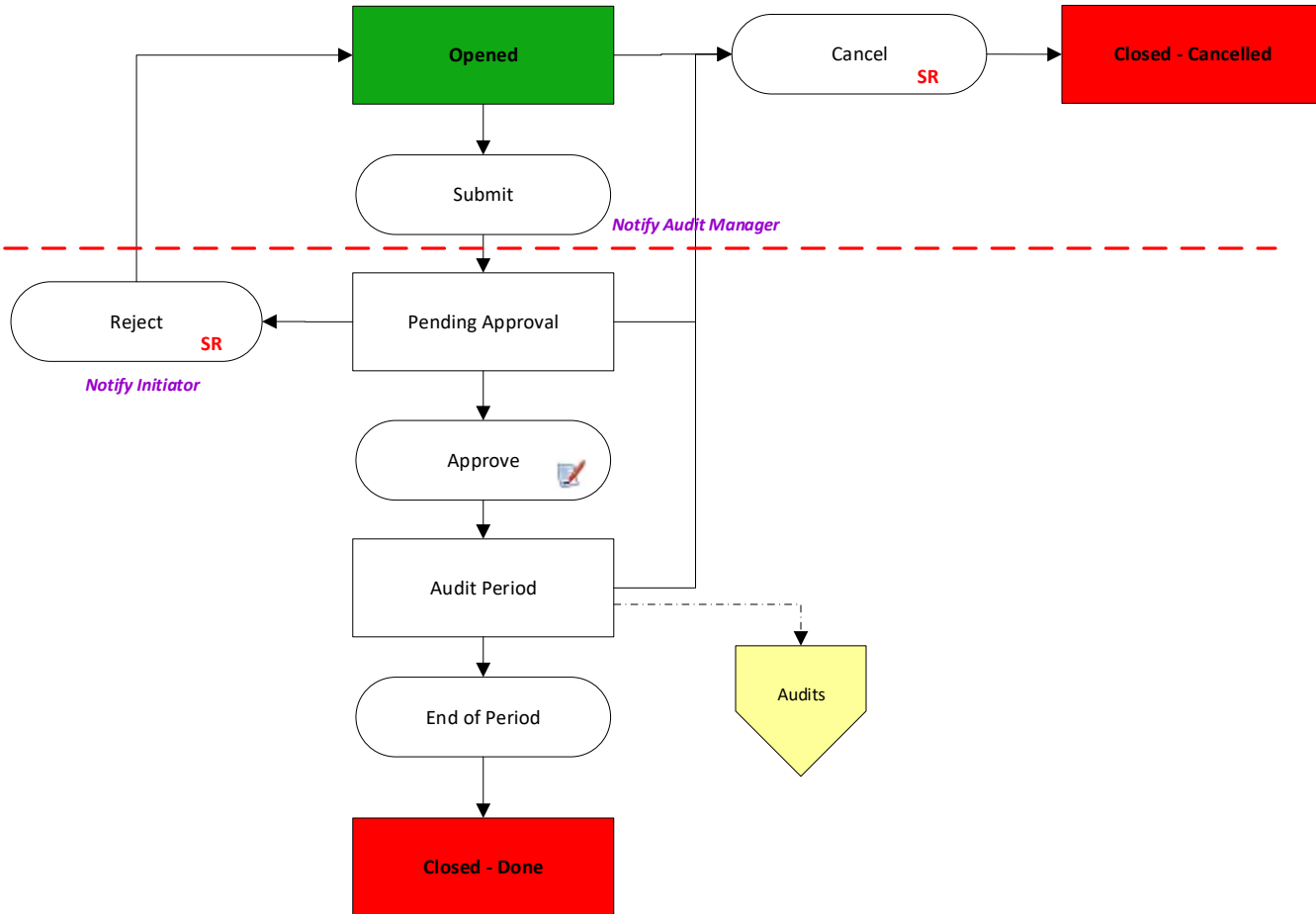
Person Responsible



Audit Program

Initiator

Audit Manager



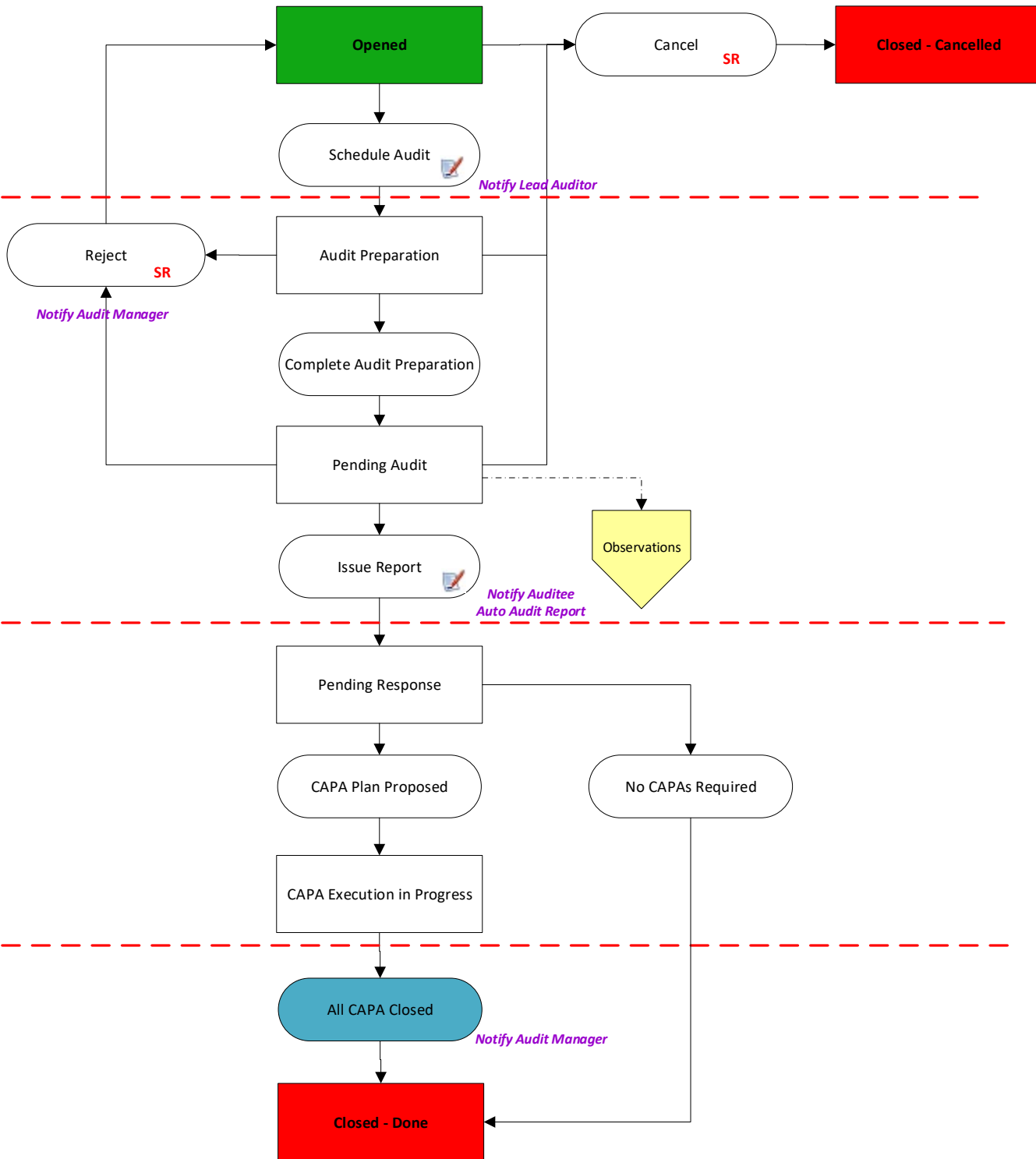
Audit

Audit Manager

Lead Auditor

Auditee

Business Rule Engine

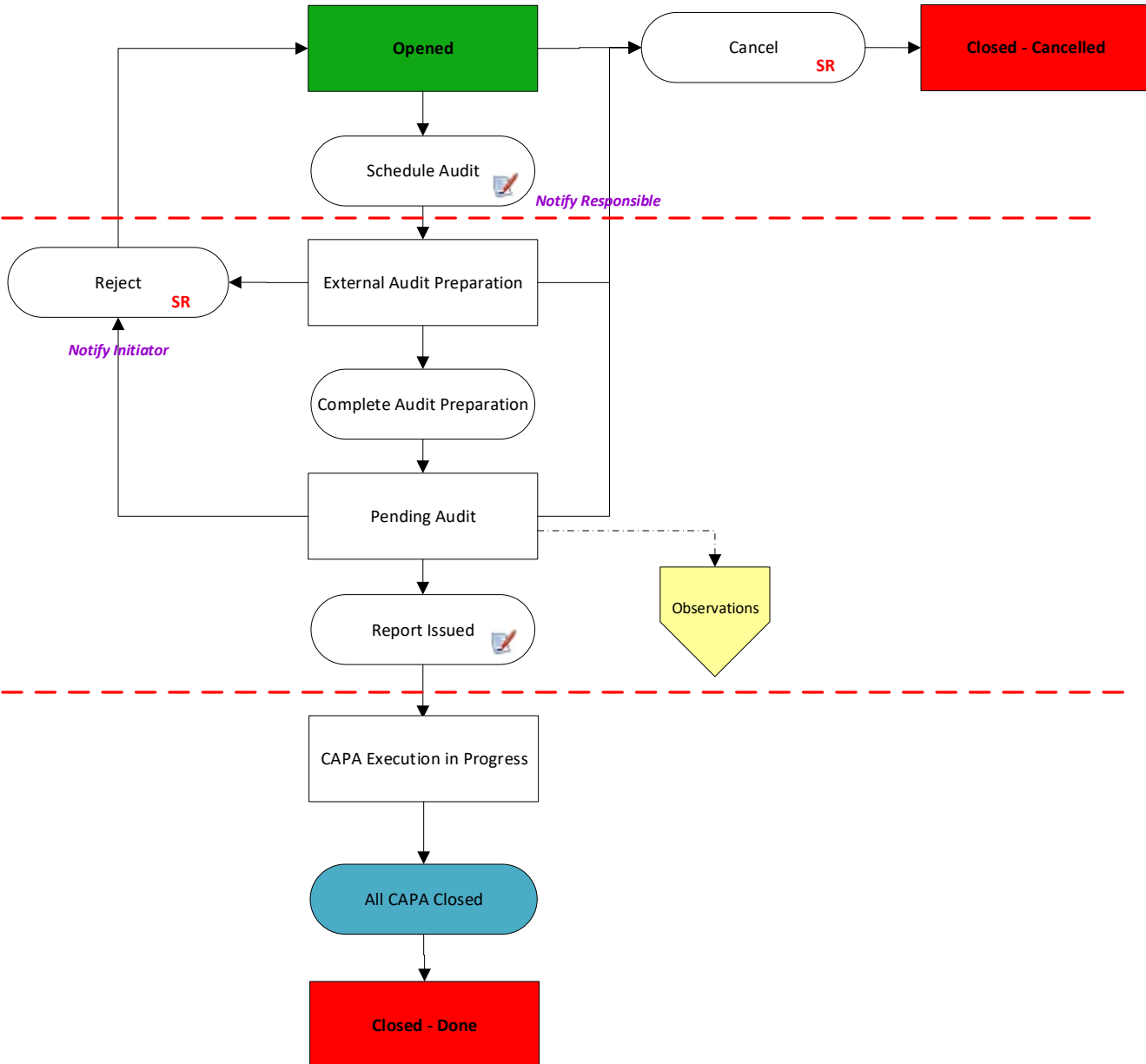


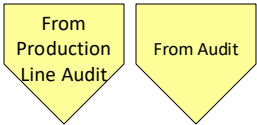
External Inspection

Initiator

Responsible

Business Rule Engine





Observation

Auditors

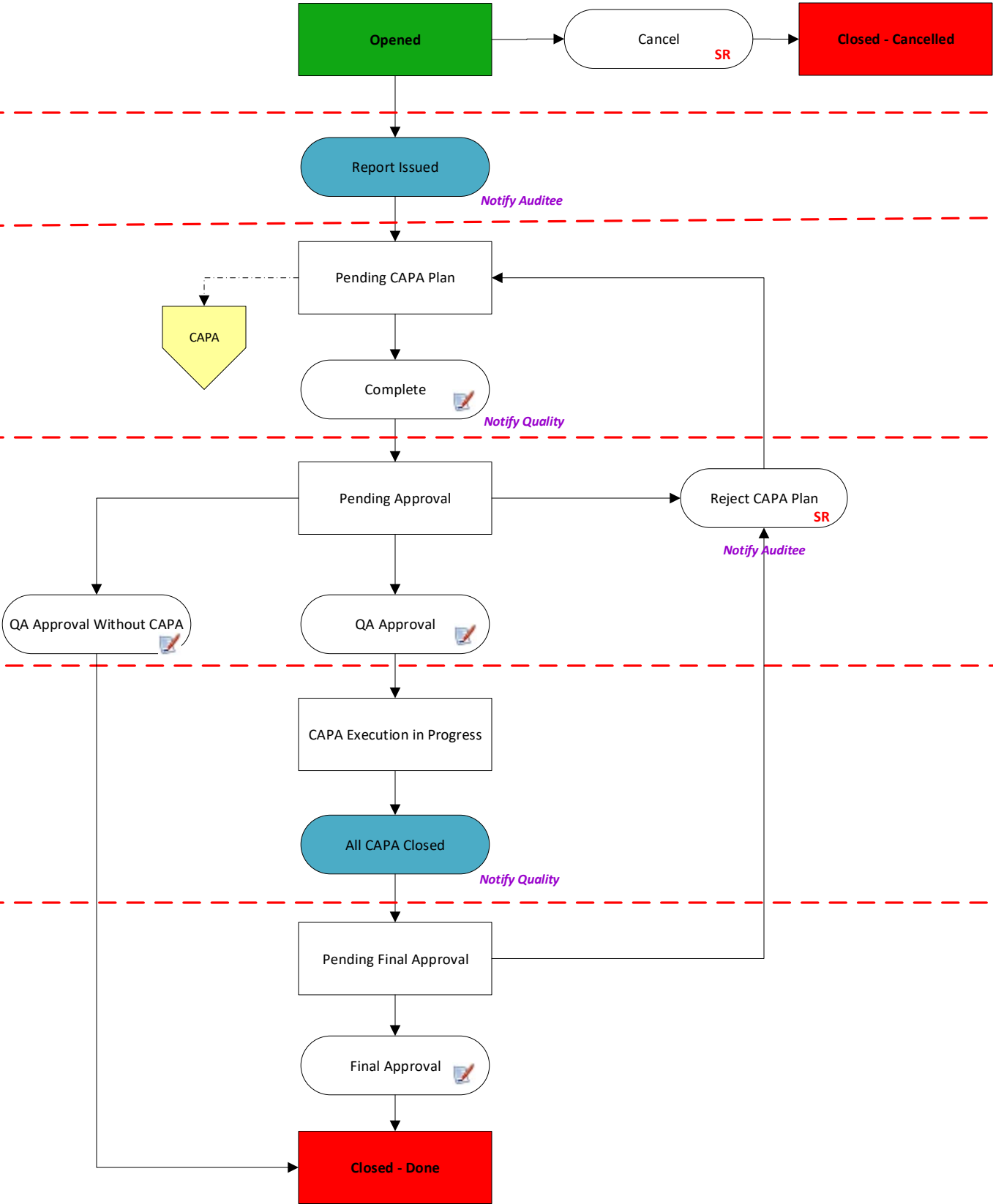
Business Rule Engine

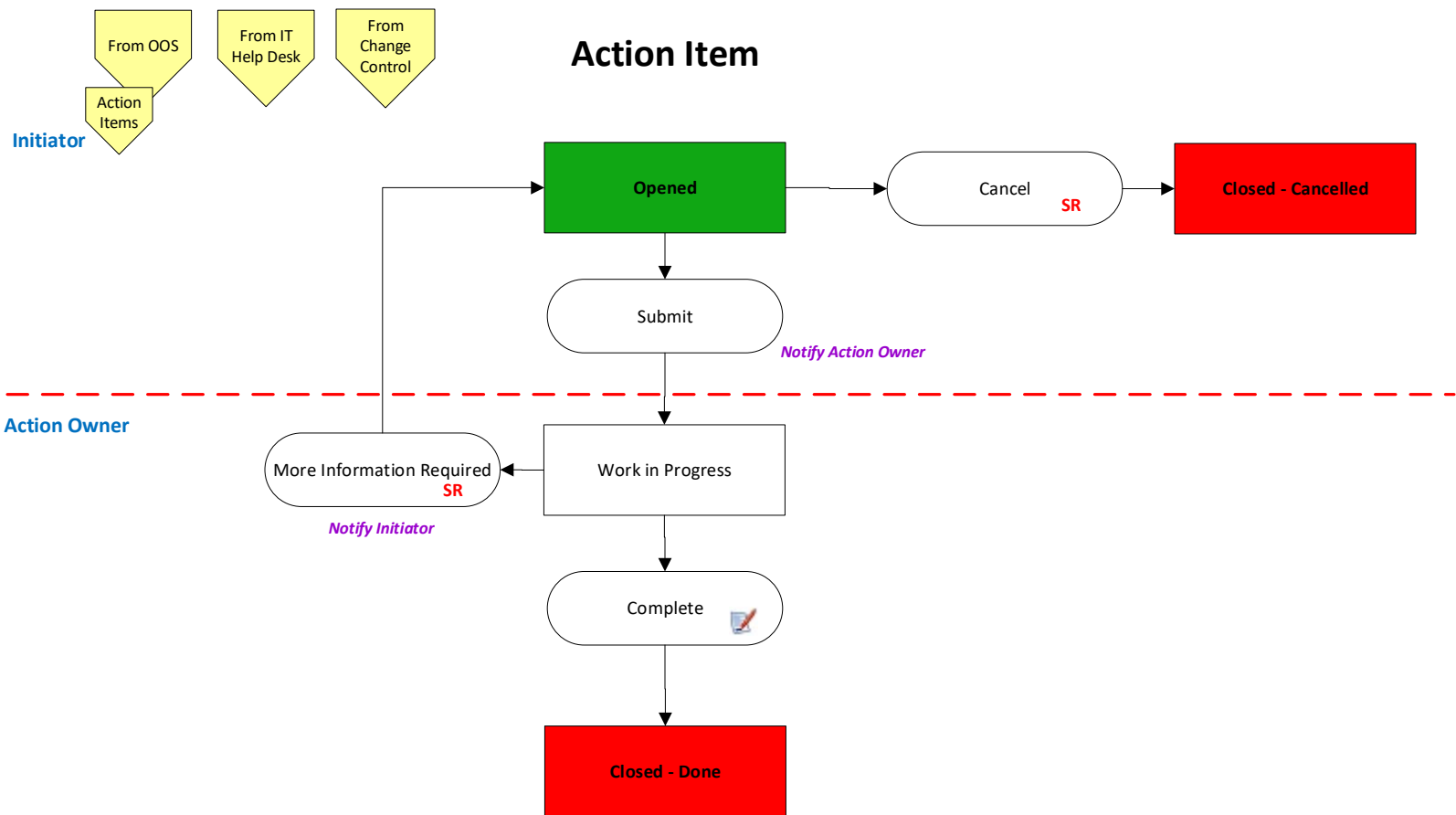
Auditees

Quality

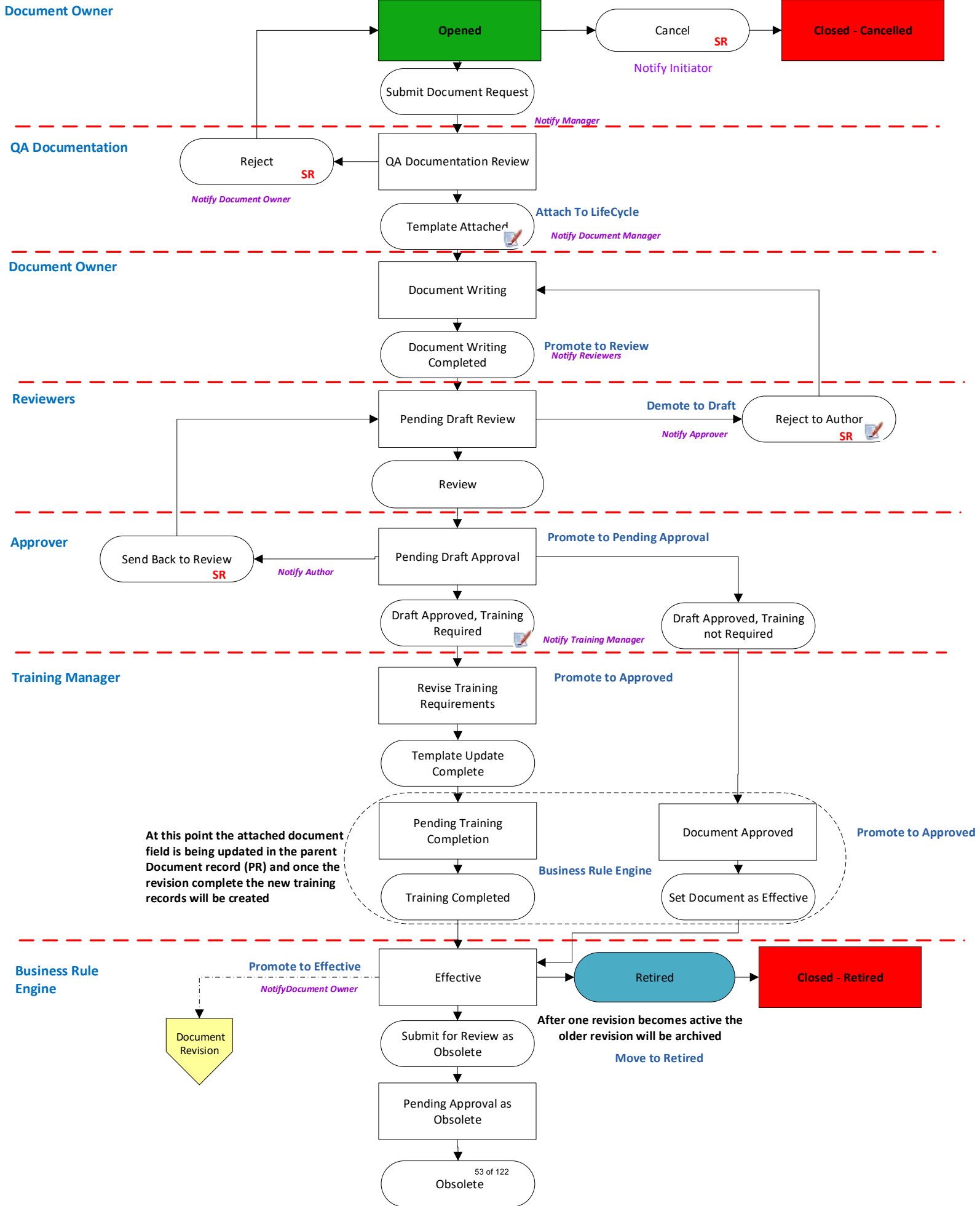
Business Rule Engine

Quality





New Document





Document Revision

Document Owner

QA Documentation

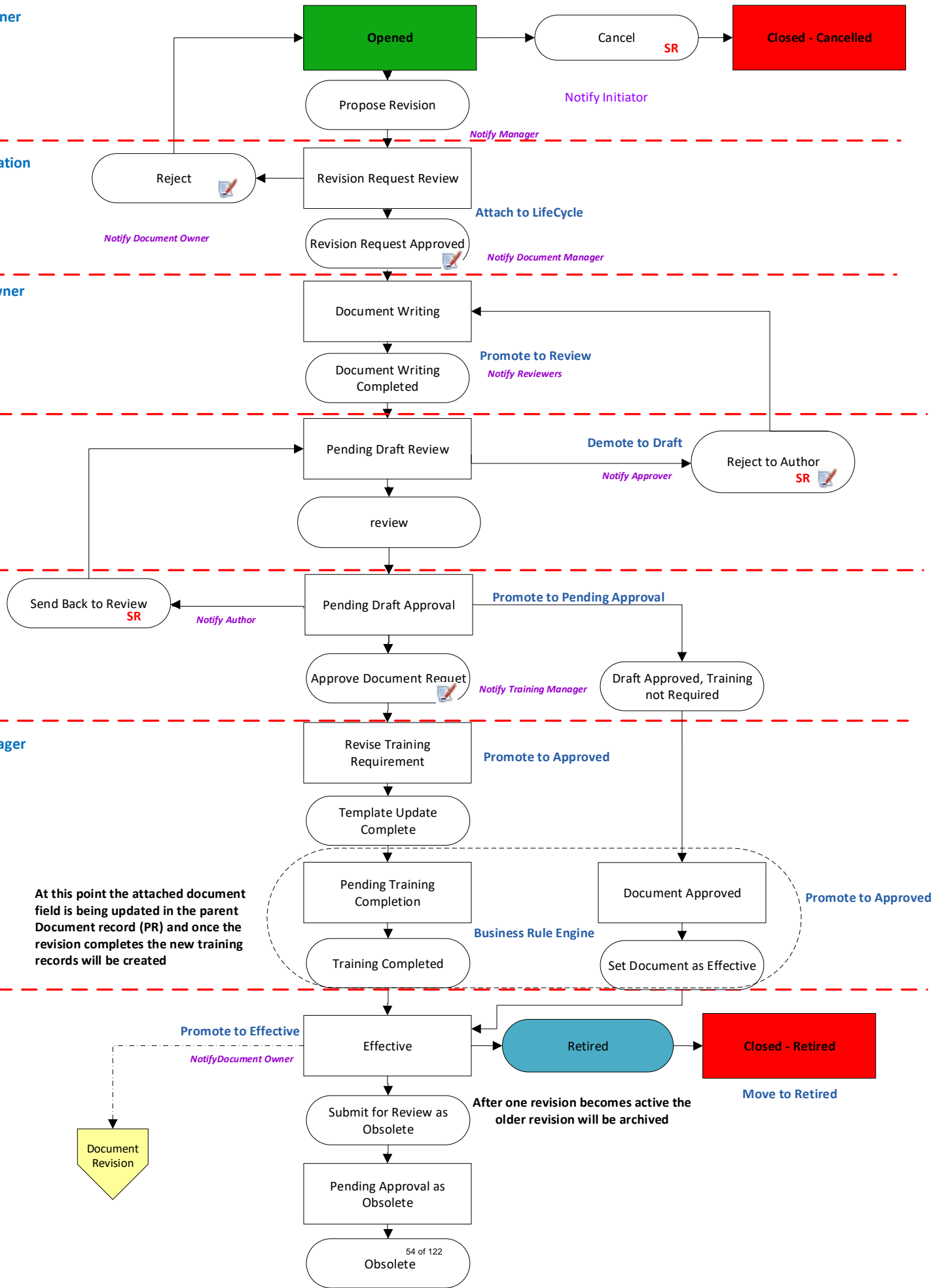
Document Owner

Reviewers

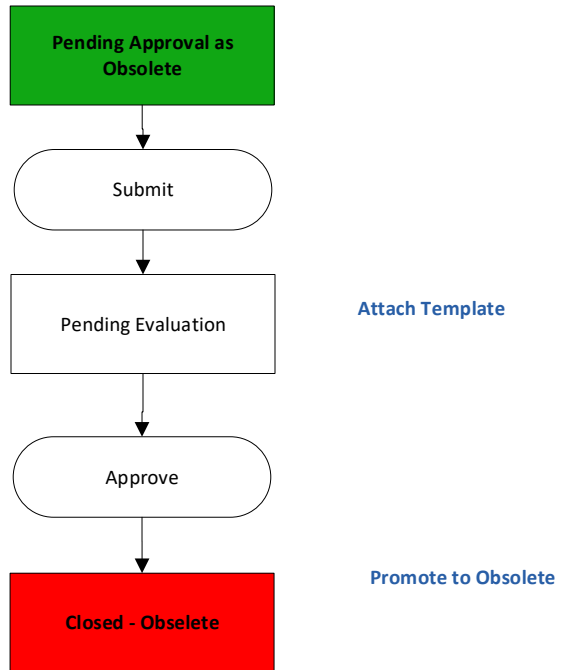
Approver

Training Manager

Business Rule Engine

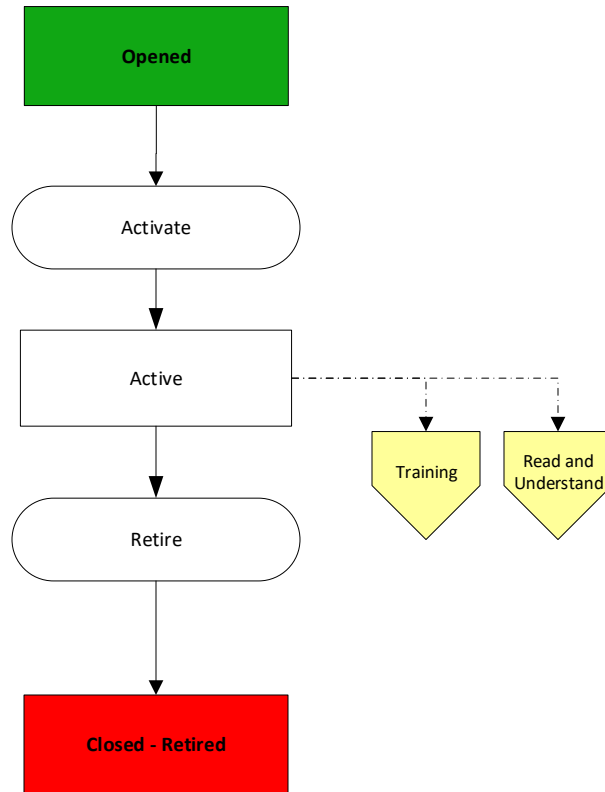


Obsolete



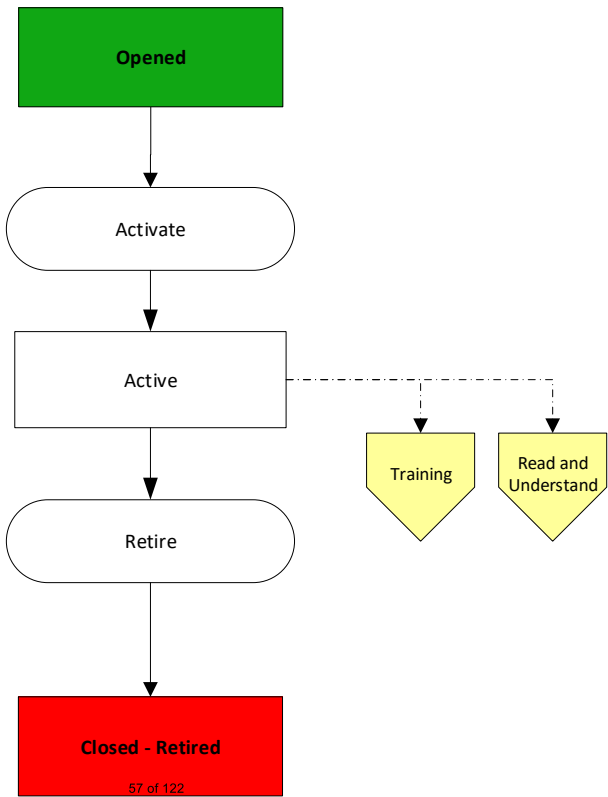
Employee

HR Manager

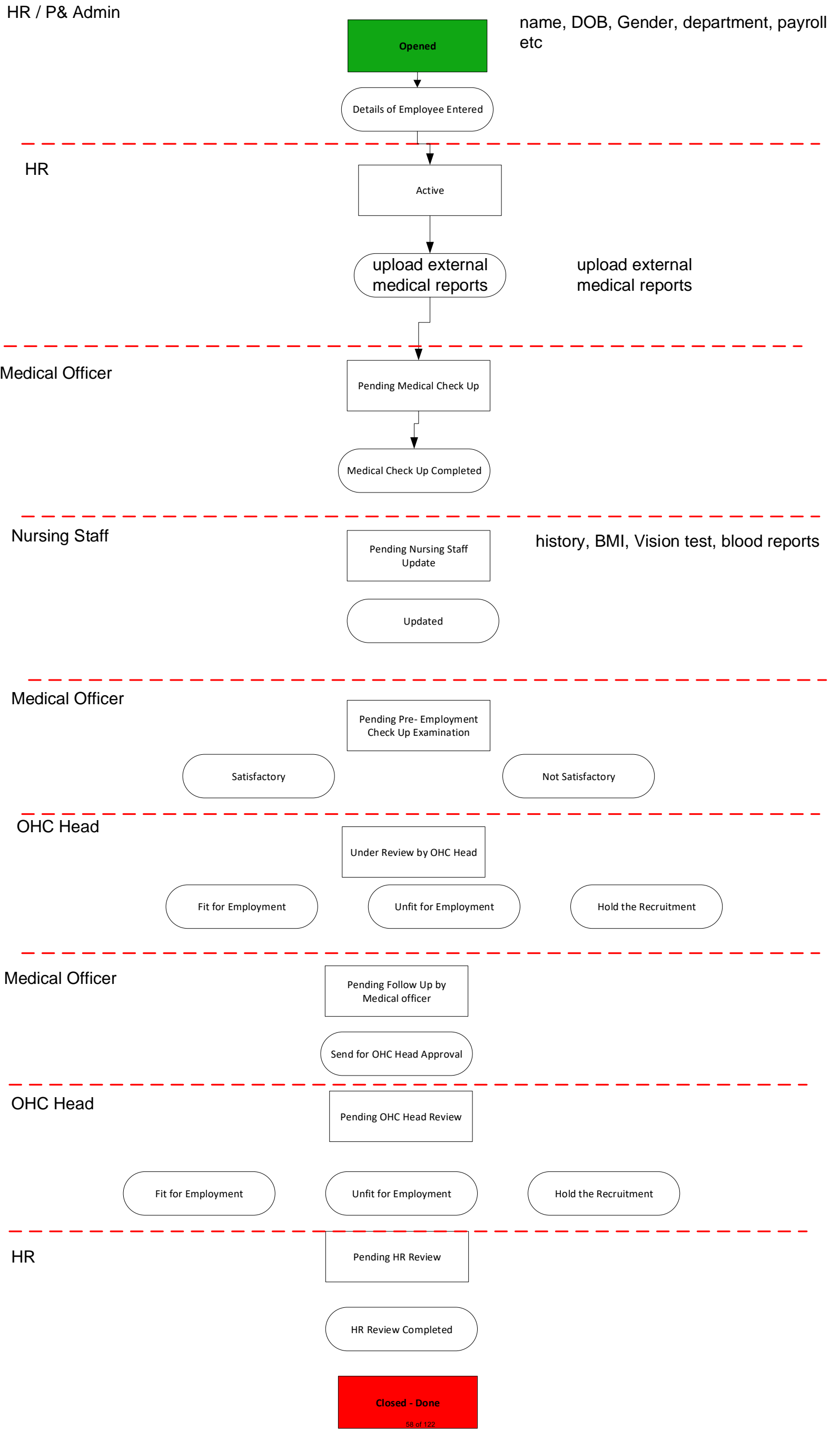


Employee

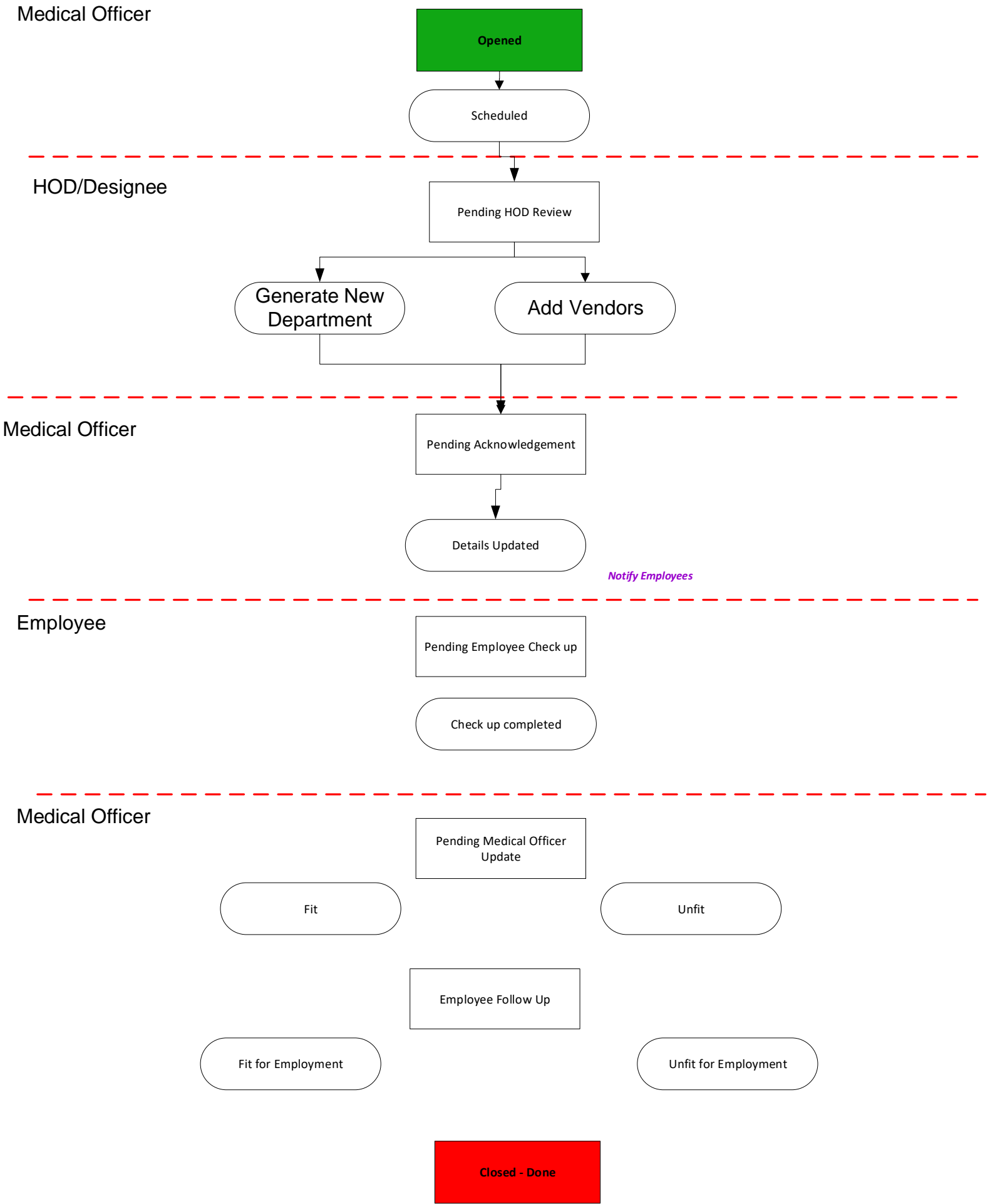
HR Manager



Pre-employment Medical Checkup

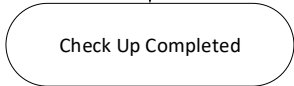
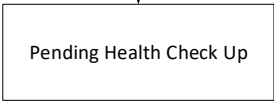
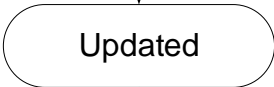
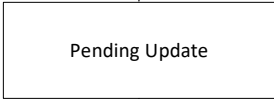
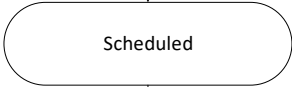
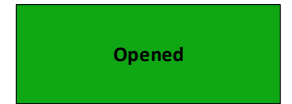


Periodic Medical Checkup



Annual Health Checkup

OHC



Notify Employees

Nursing Staff

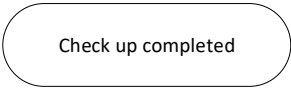
add employee details, vendors details
for respective department for Periodic medical checkup.

Employee

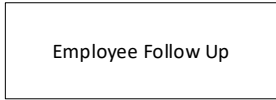
Employee



history, BMI, Vision test, blood reports



Medical Officer



From Employee

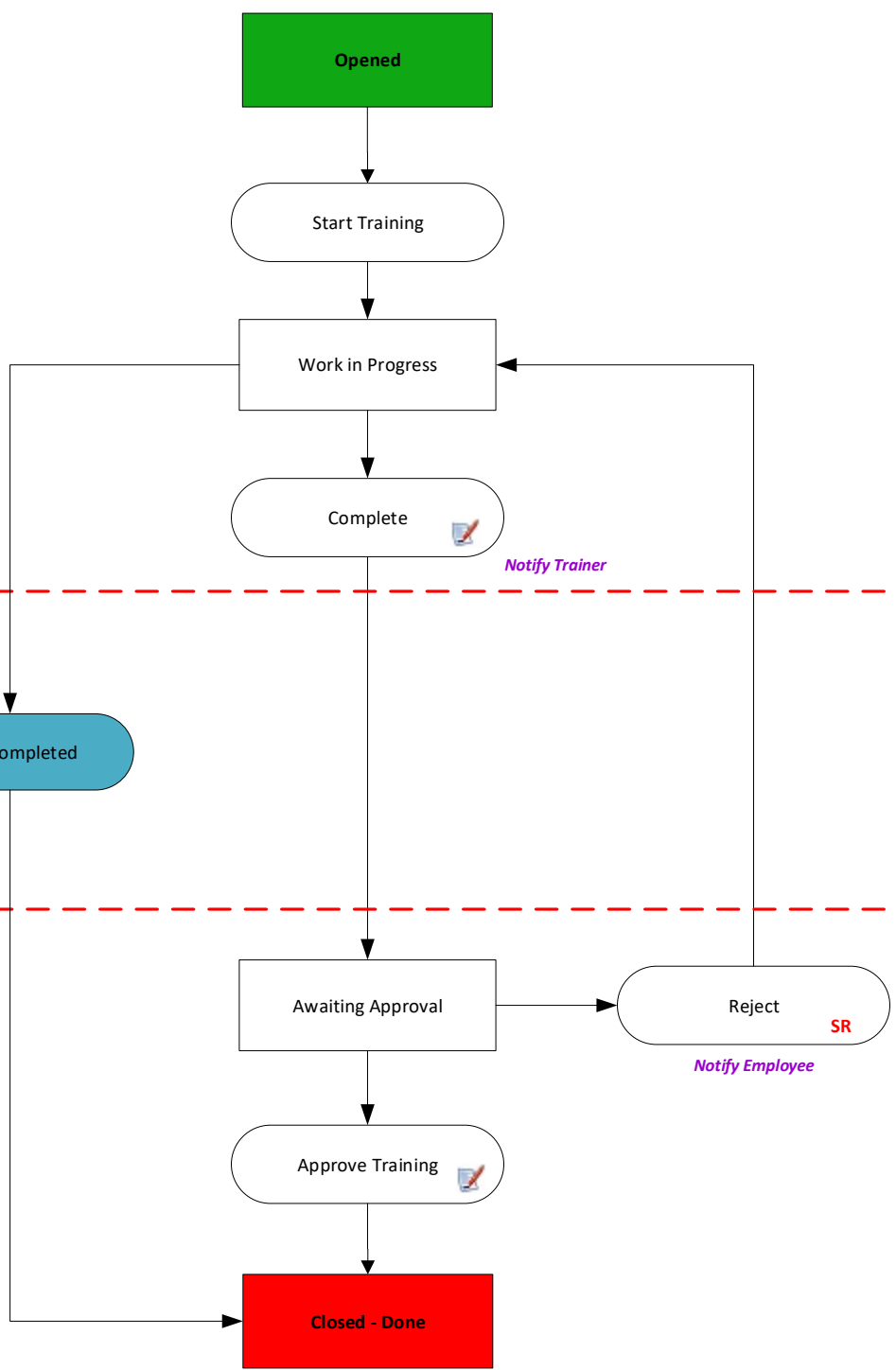
Training

Employee

Business Rule Engine

Trainer

If the employee completed the training as part of a Class Room Training the record will automatically close

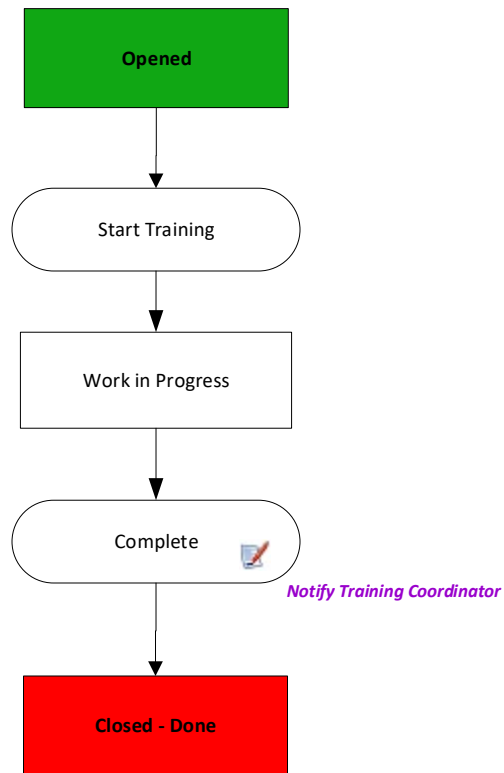


Notify Trainer

Notify Employee

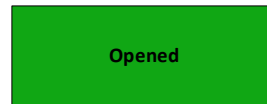
Read and Understand

Employee



Class Room Training

Trainer



Opened

Open For Registration

Notify Available For Registration

Employee

Available For Registration

Trainer

Close Registration

Pending Registration Approval

Registration Approved

Notify Attendees

Awaiting Class

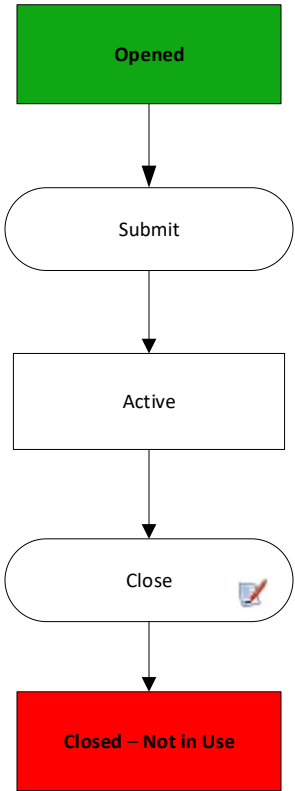
Class Completed

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

Closed - Completed

Requirement Template

Training Coordinator

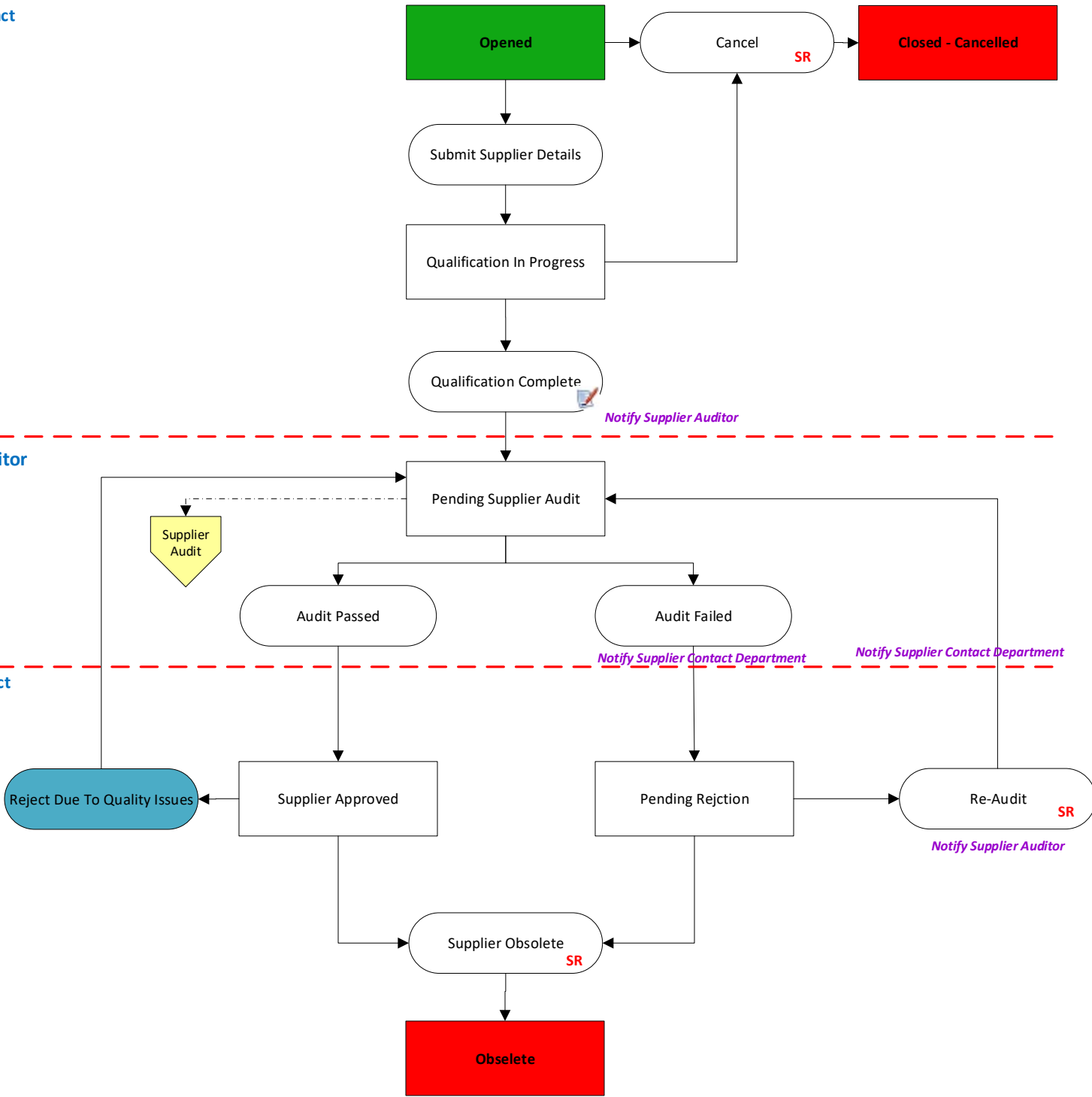


Supplier

Supplier Contact
Department

Supplier Auditor

Supplier Contact
Department



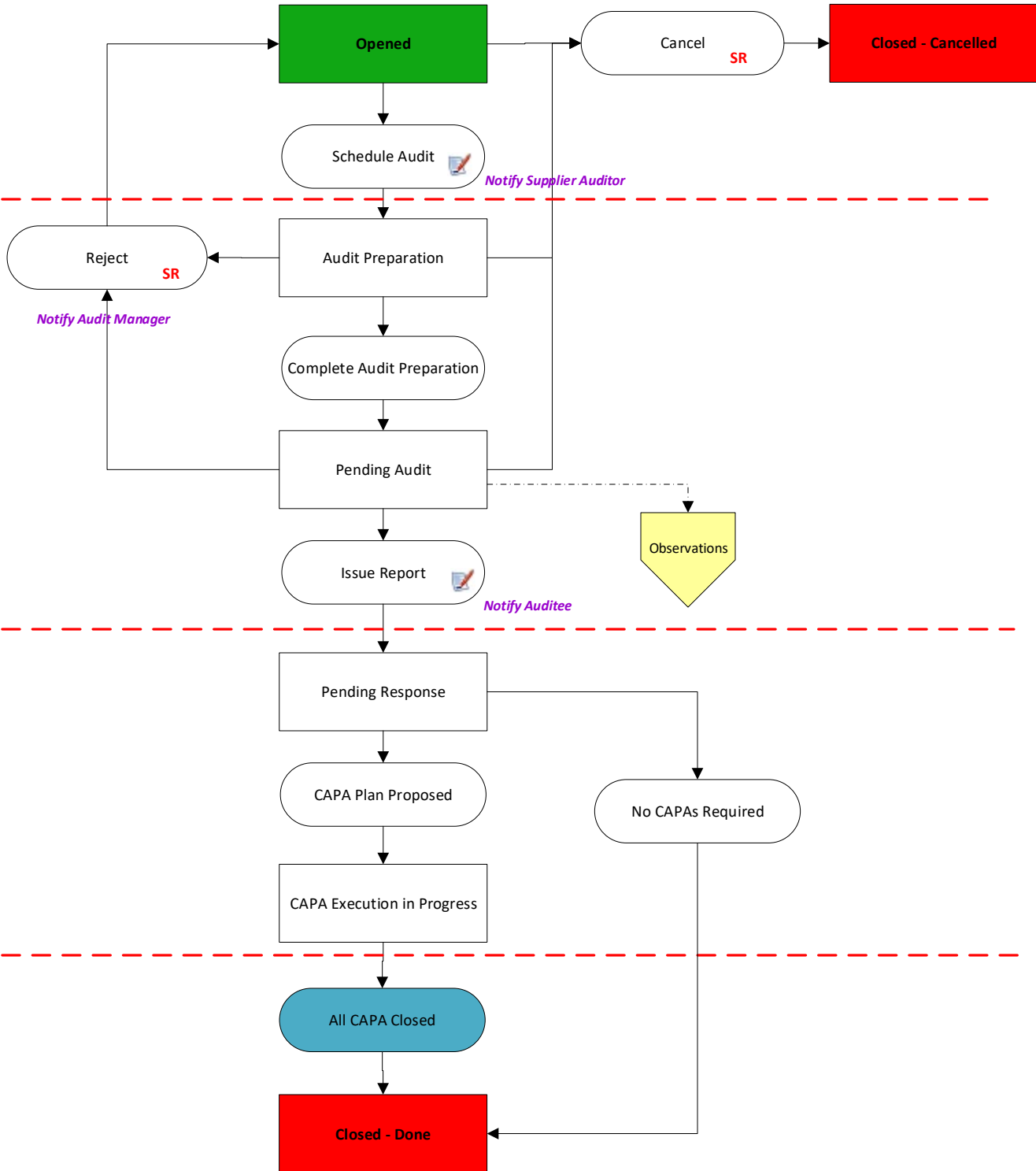
Supplier Audit

Audit Manager

Supplier Auditor

Auditee

Business Rule Engine



Supplier Observation

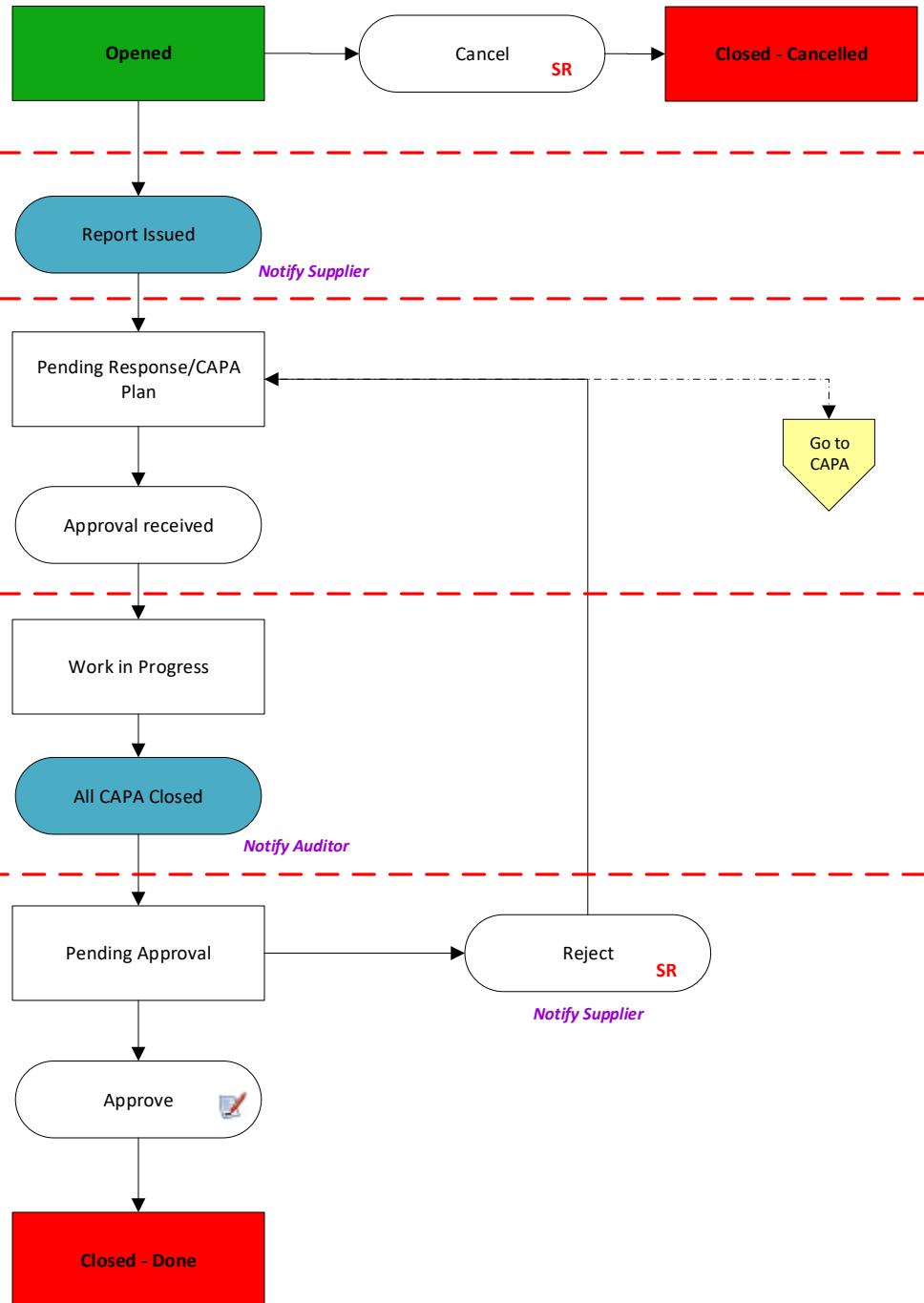
Auditors

Business Rule Engine

Supplier

Business Rule Engine

Auditors



From Incoming Inspection

Non Conformance

Initiator

Supervisor

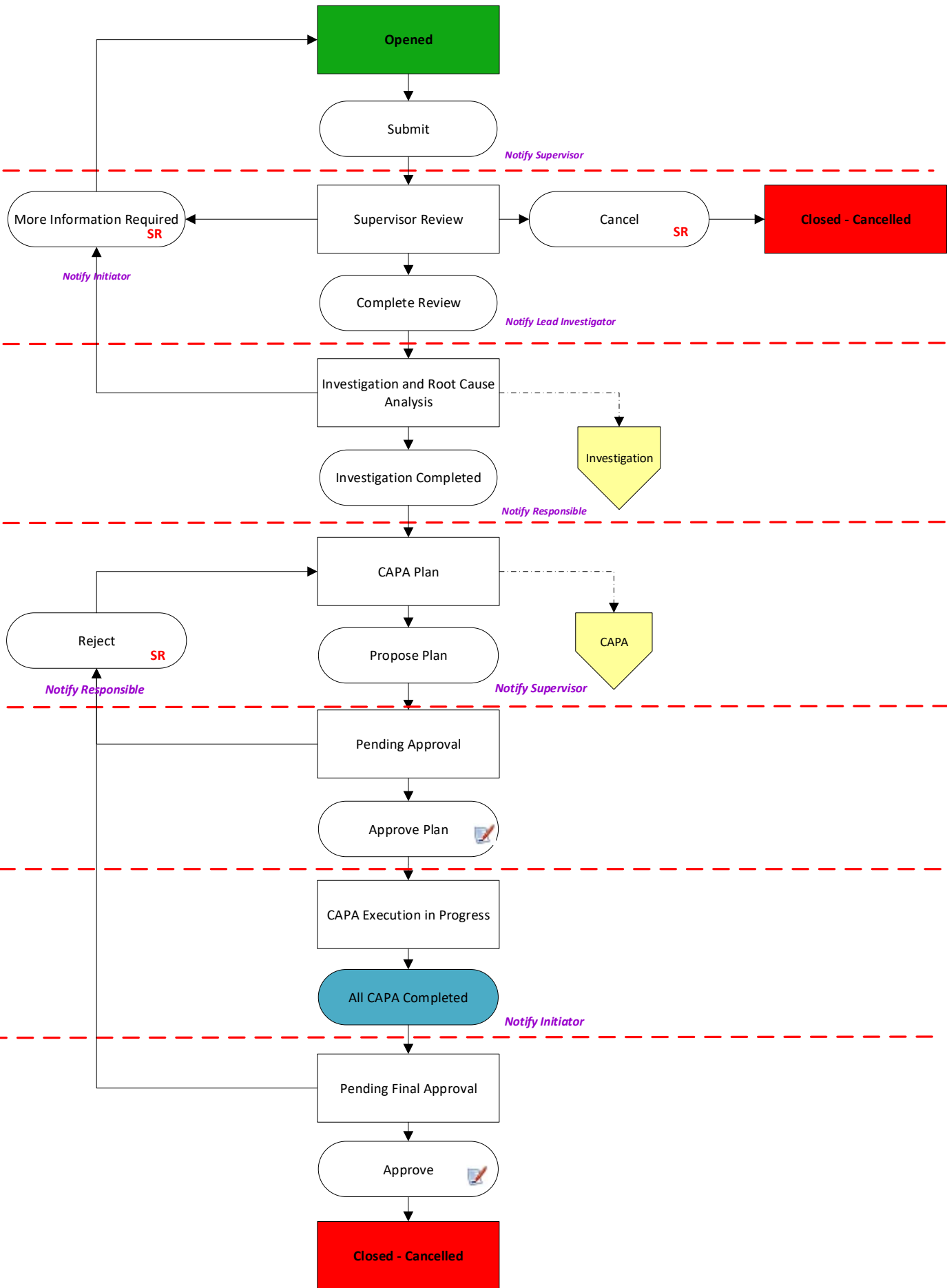
Lead Investigator

Responsible

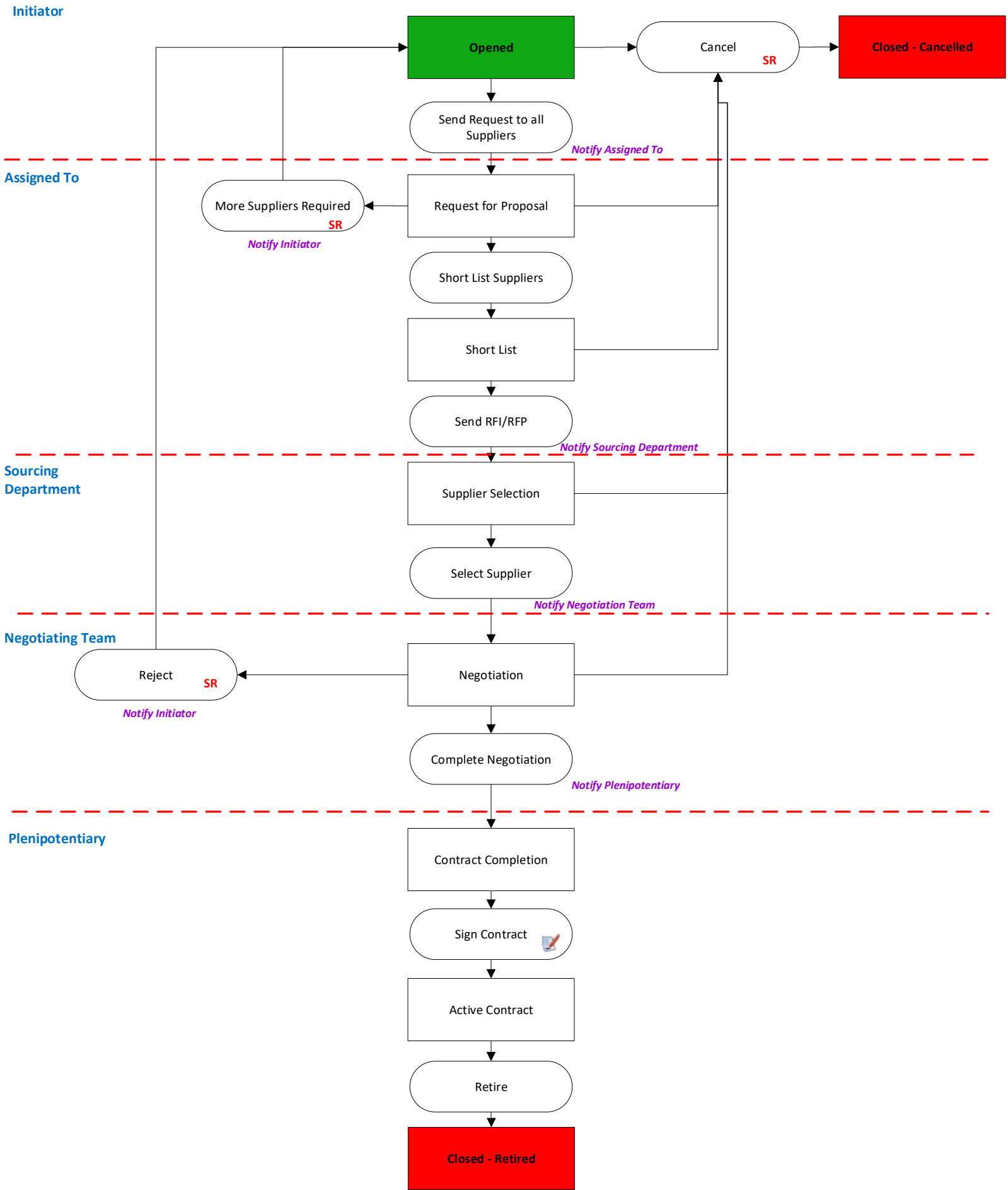
Supervisor

Business Rule Engine

Initiator



Contract



EHS Event

Initiator

Line Manager

Lead Investigator

Safety Officer

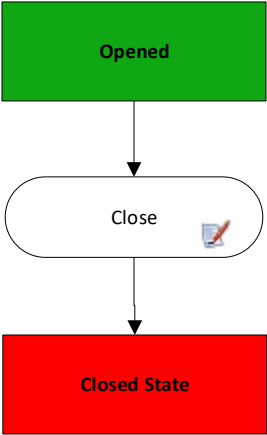
Line Manager

Business Rule
Engine



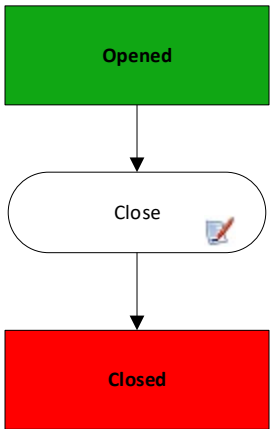
Monthly Working Hours

HR Manager



Sanction

Safety Officer

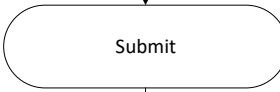


Project

Initiator

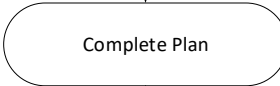
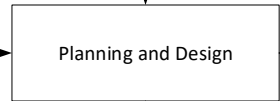


Project Manager

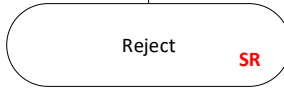


Notify Project Manager

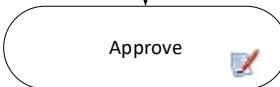
Steering Committee
Sponsor



Notify Committee

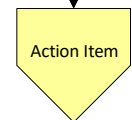
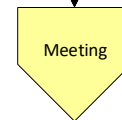
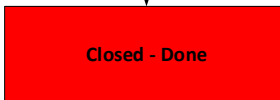
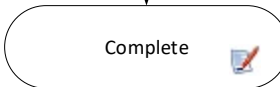
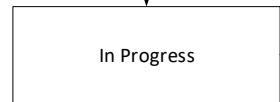


Notify Project Manager



Notify Project Manager

Project Manager



From Project

Meeting

Initiator

Opened

Business Rule
Engine

Auto Submit

Notify Responsible

Responsible

In Progress

Action Item

Complete

Closed - Done

Client Inquiry

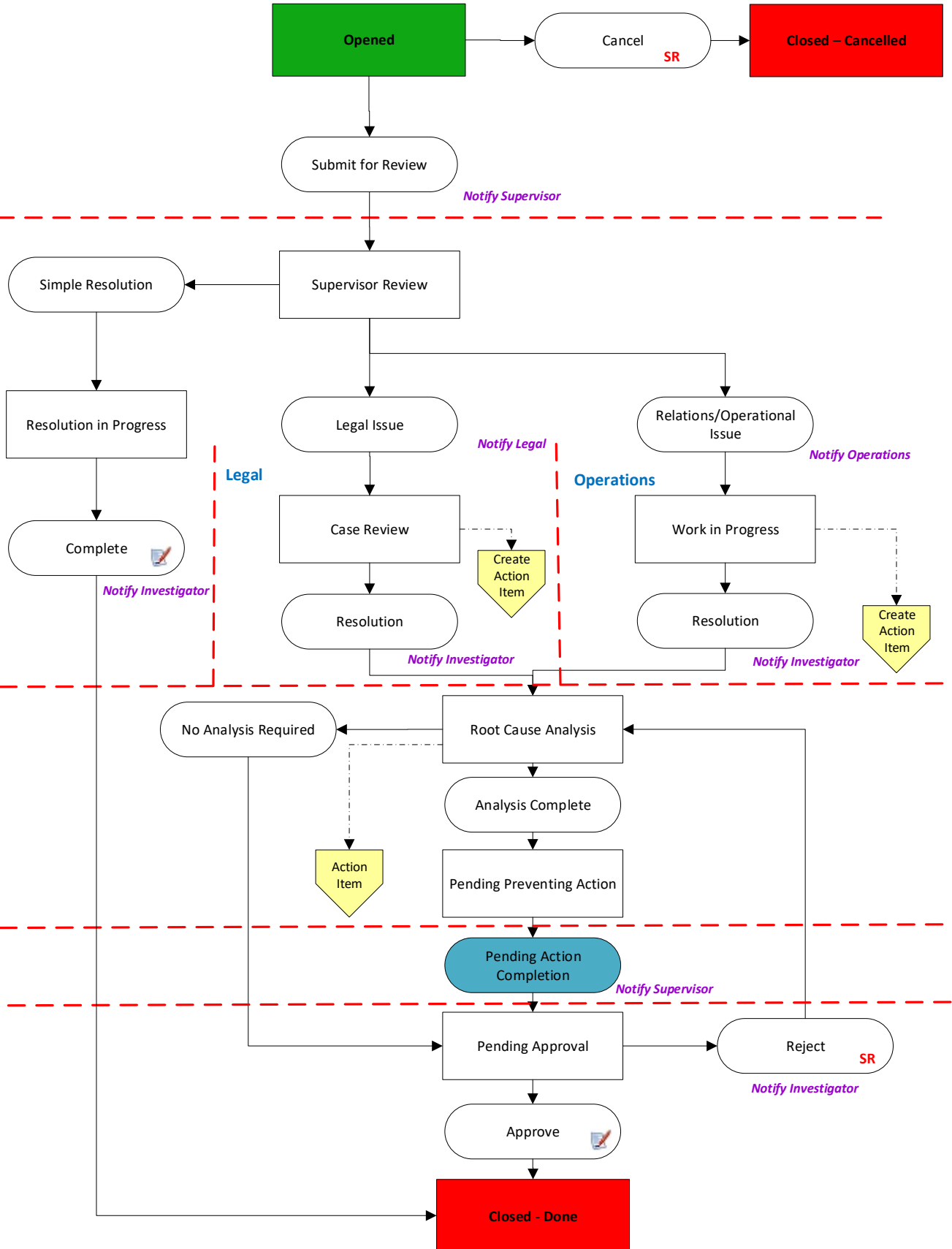
Customer Rep

Supervisor

Investigator

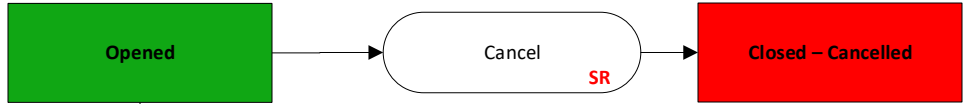
Business Rule Engine

Supervisor

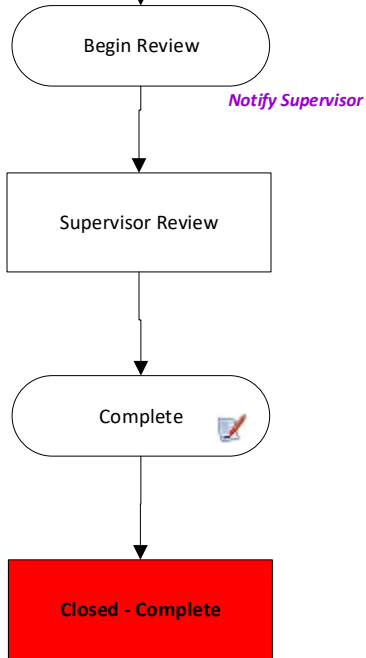


Field Inquiry

Client/
Field Rep



Supervisor



Risk Management

Initiator (Any User)

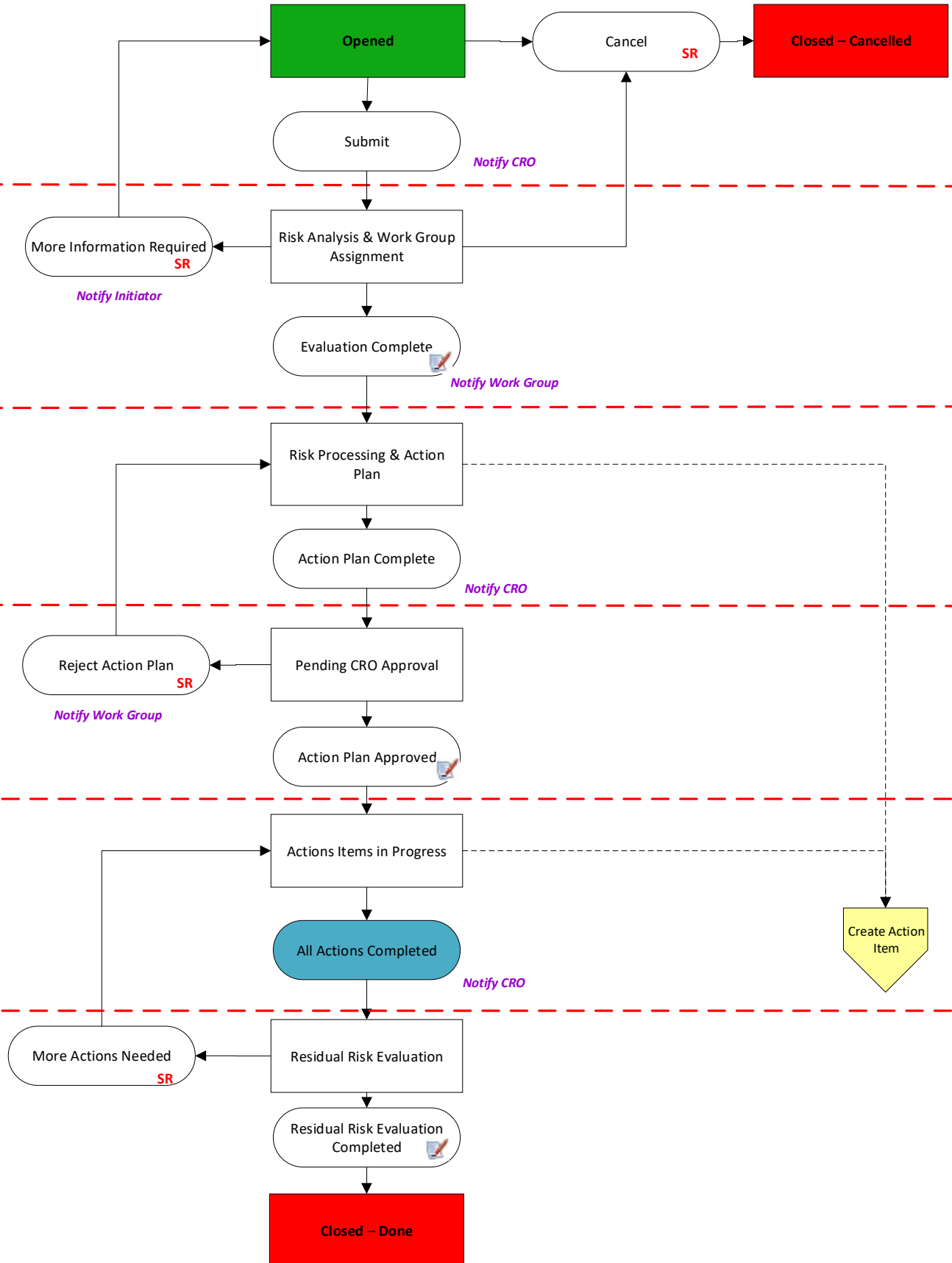
CRO (Chief Risk Officer)/ Manager

Work Group

CRO (Chief Risk Officer)/ Manager

Business Rule Engine

CRO (Chief Risk Officer)/ Manager

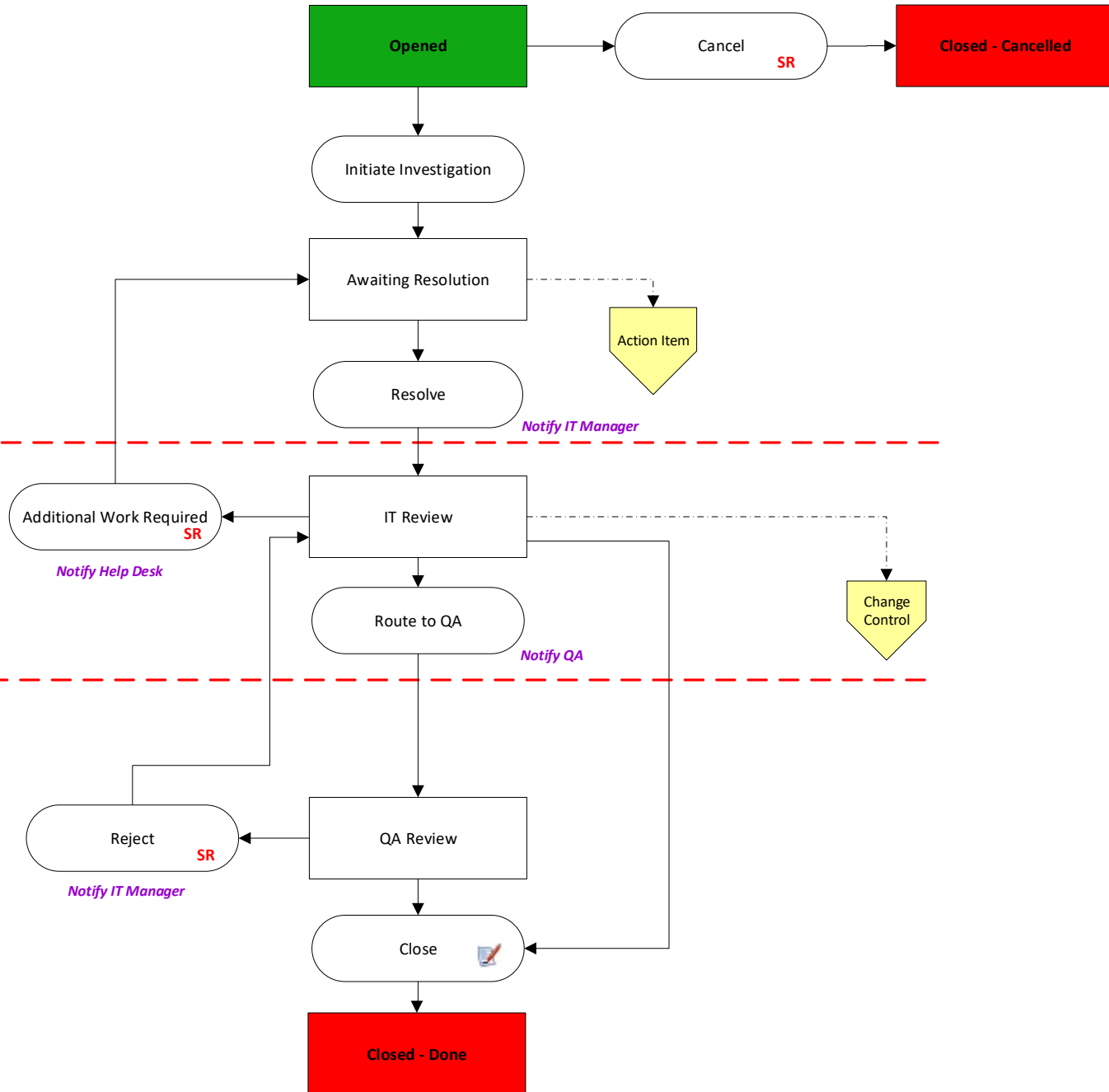


IT Help Desk/Incident

Help Desk
Technician

IT Manager

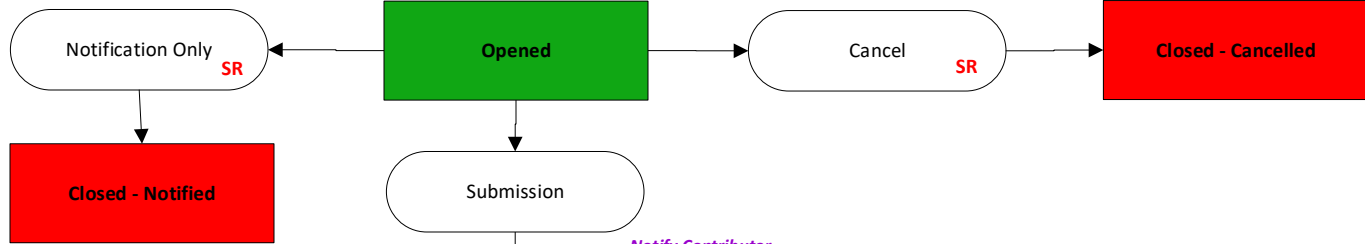
Quality
Assurance



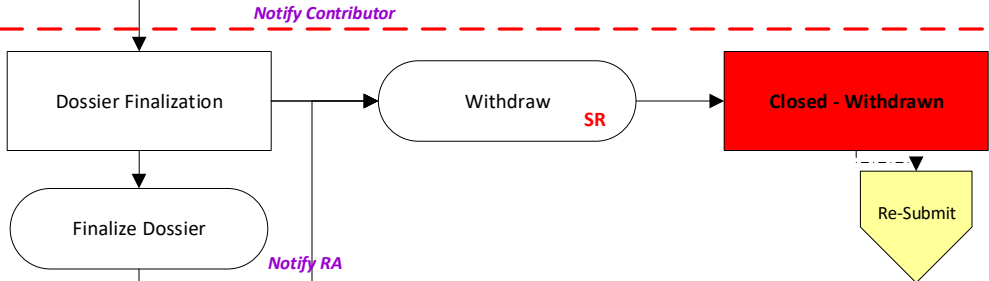
From Country

CTA Submission

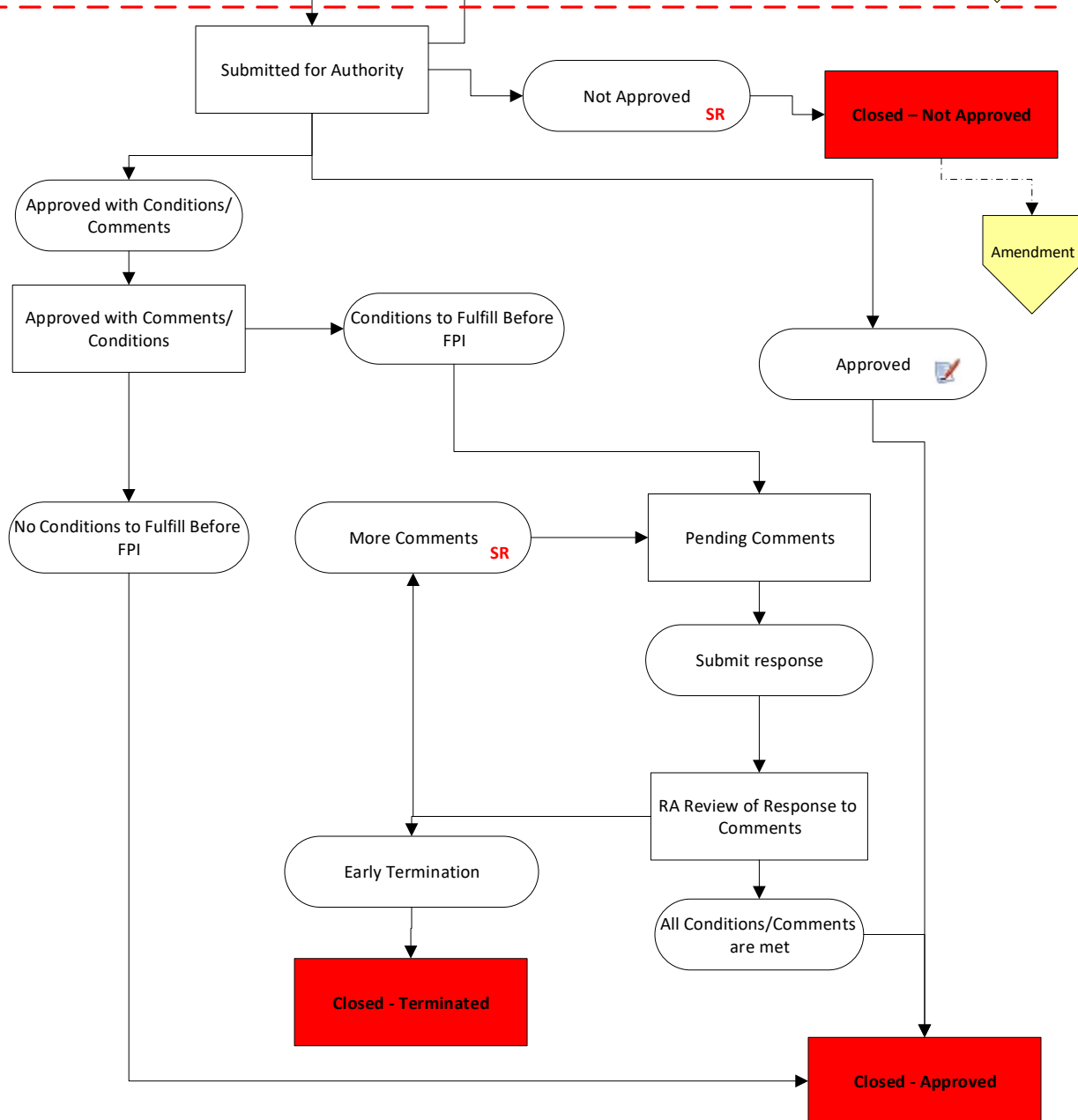
Initiator



Contributor



RA Management



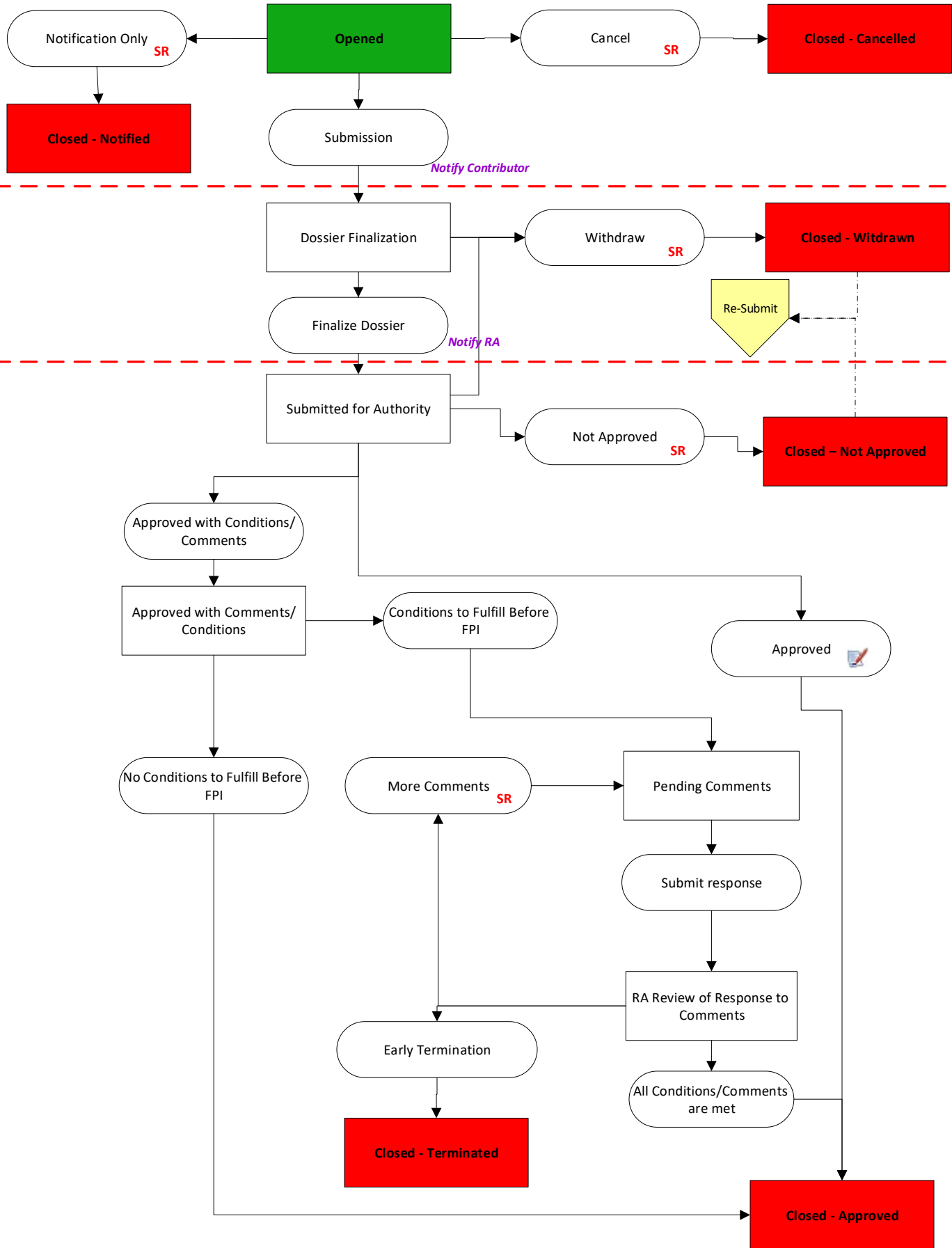
From Submission

CTA Amendment

Initiator

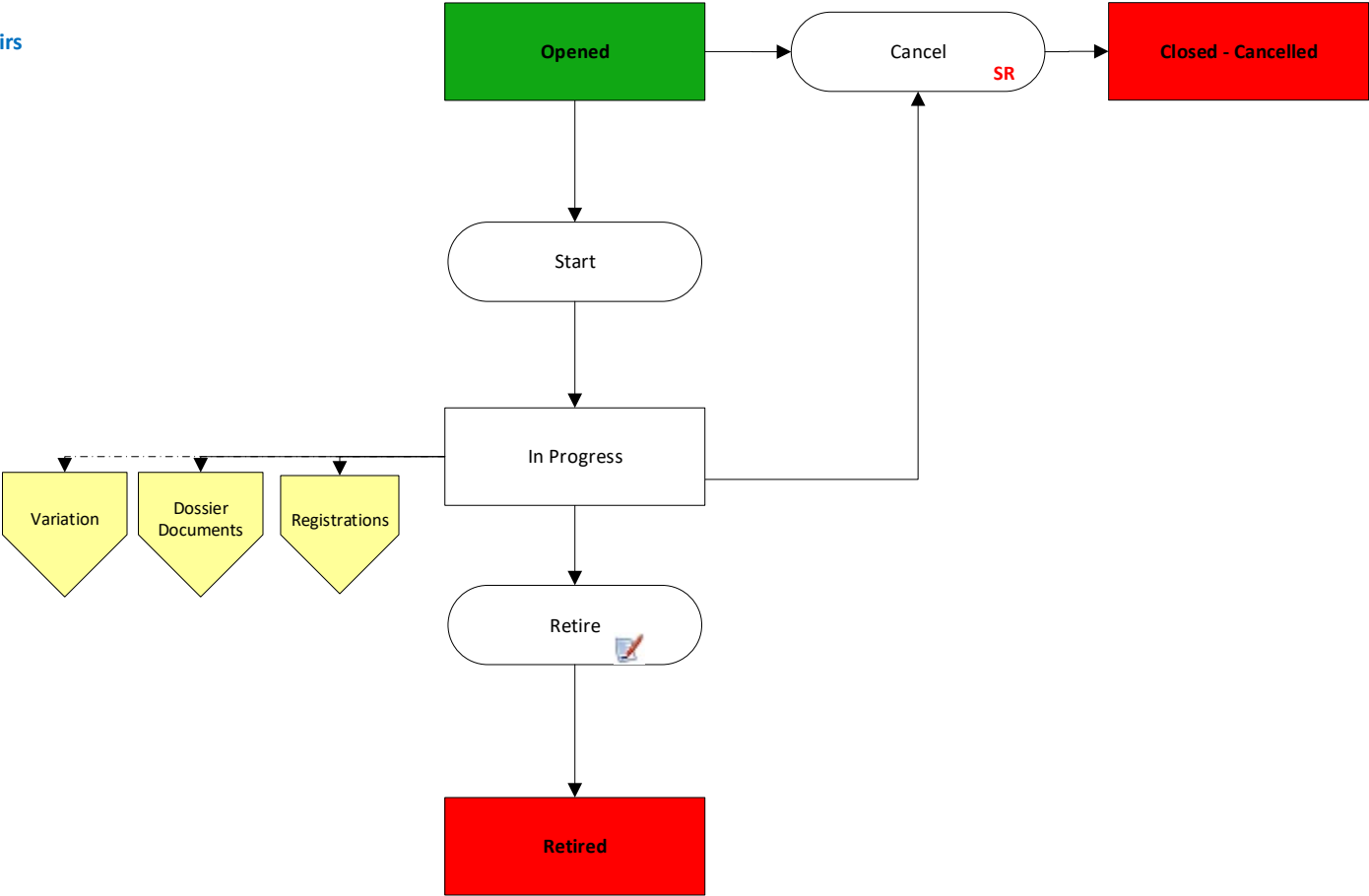
Contributor

RA Management



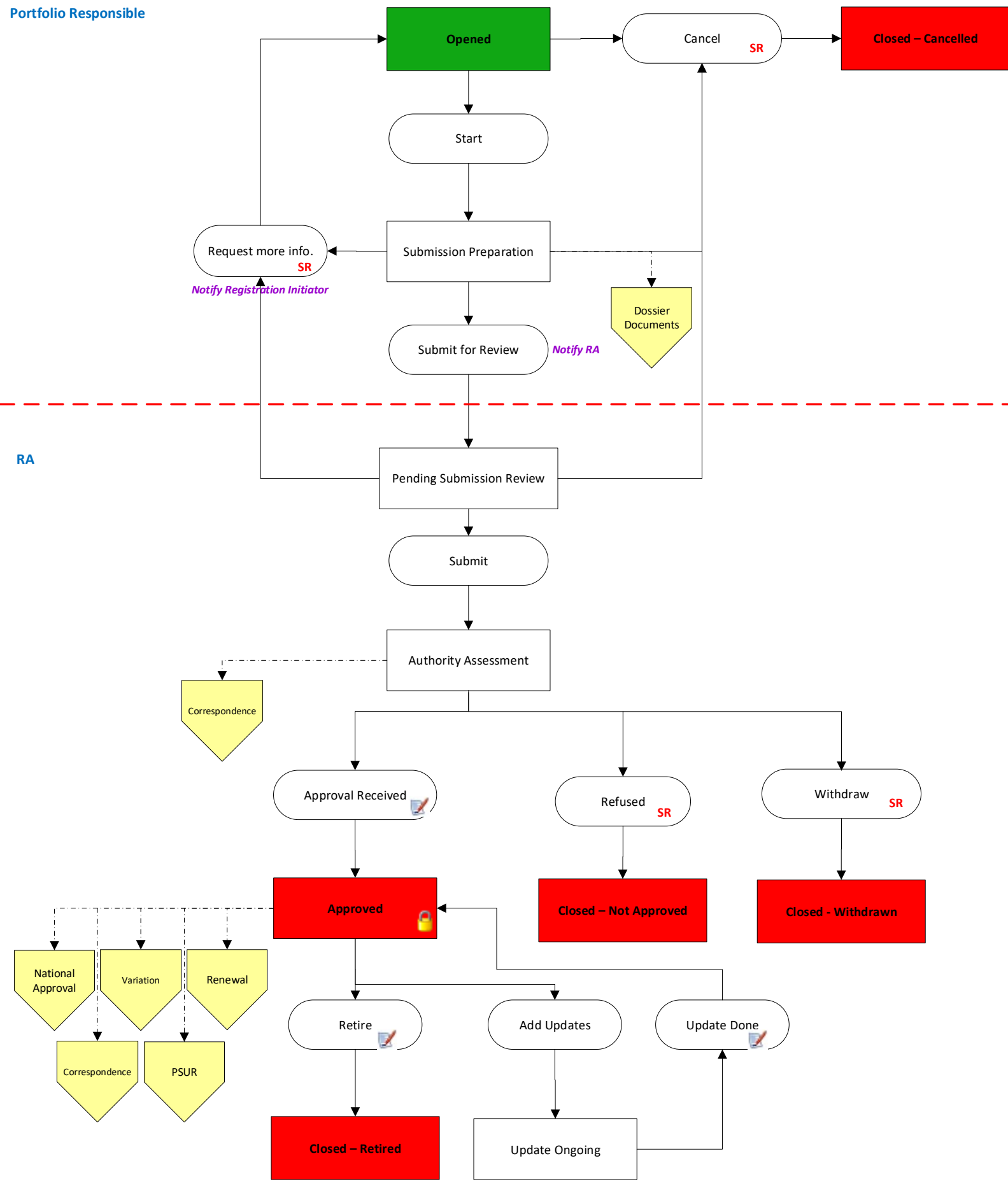
Medicinal Product

Regulatory Affairs



CP Registration – DCP/MRP Registration - National Registration

Portfolio Responsible

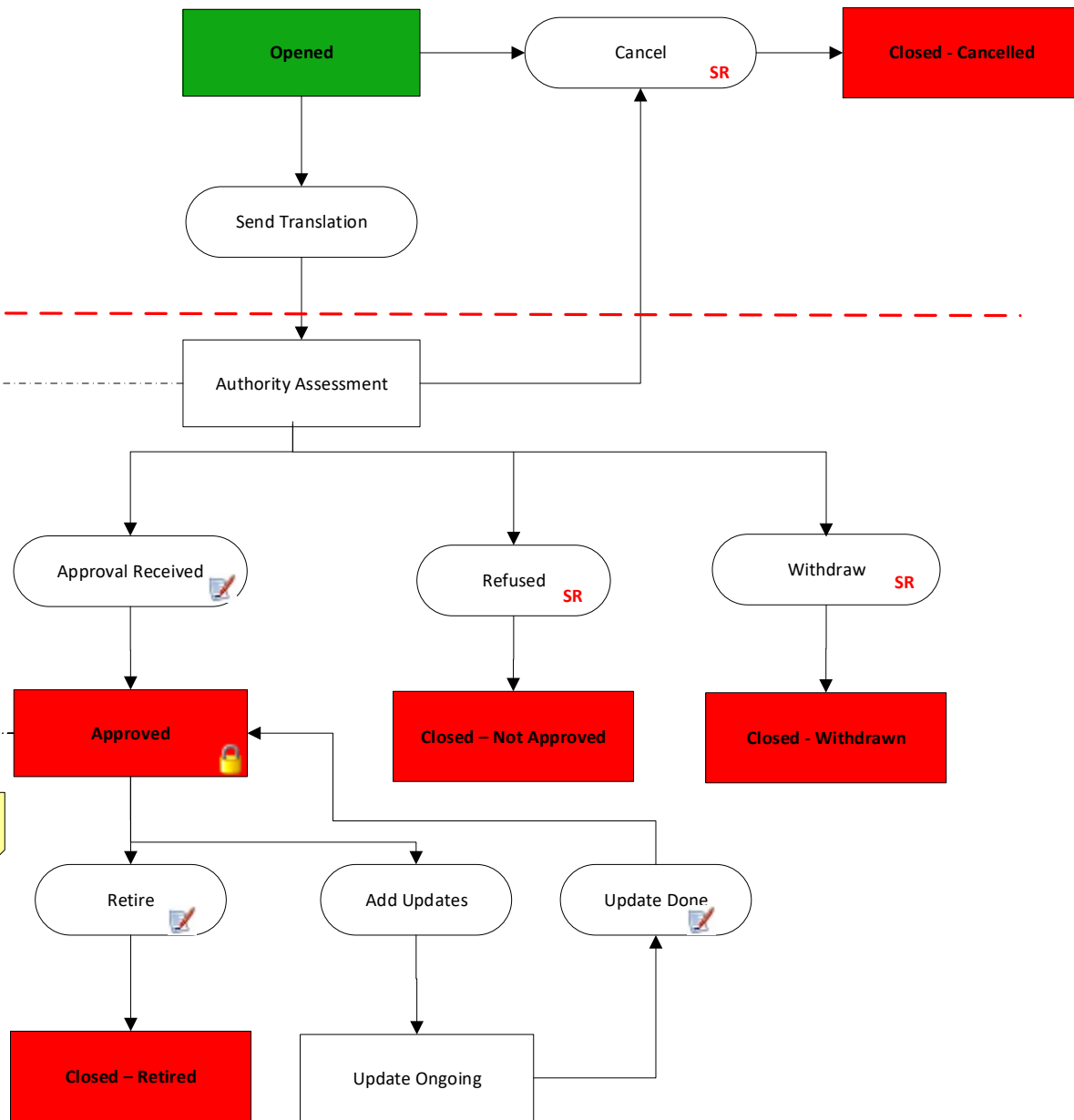
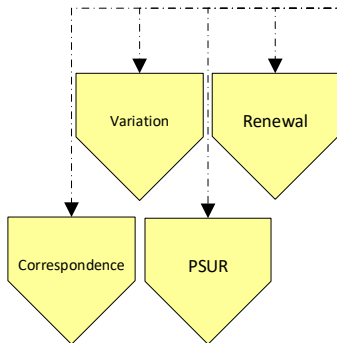
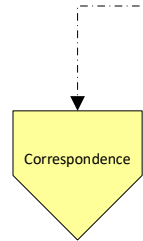




National Approval

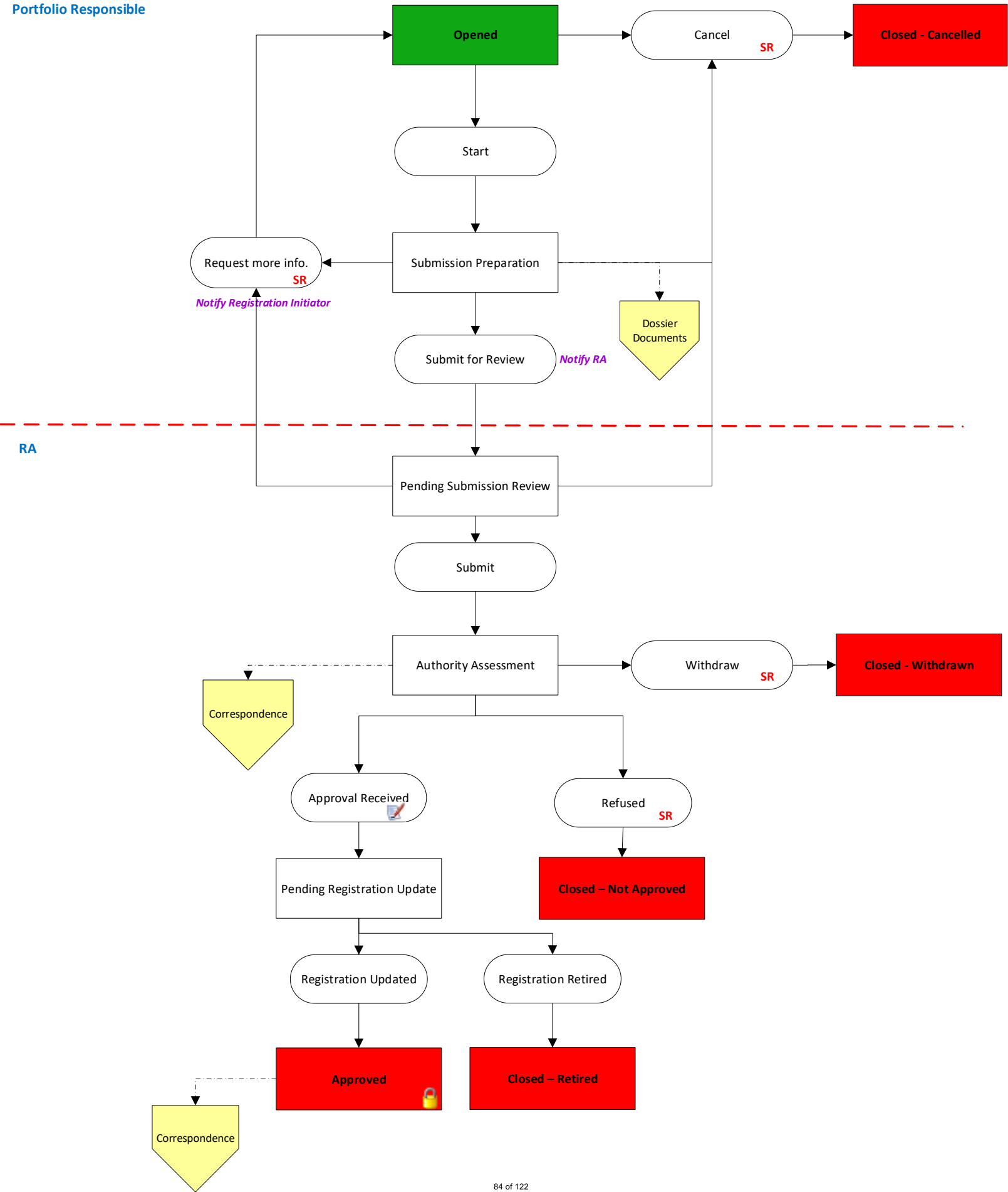
Portfolio Responsible

RA



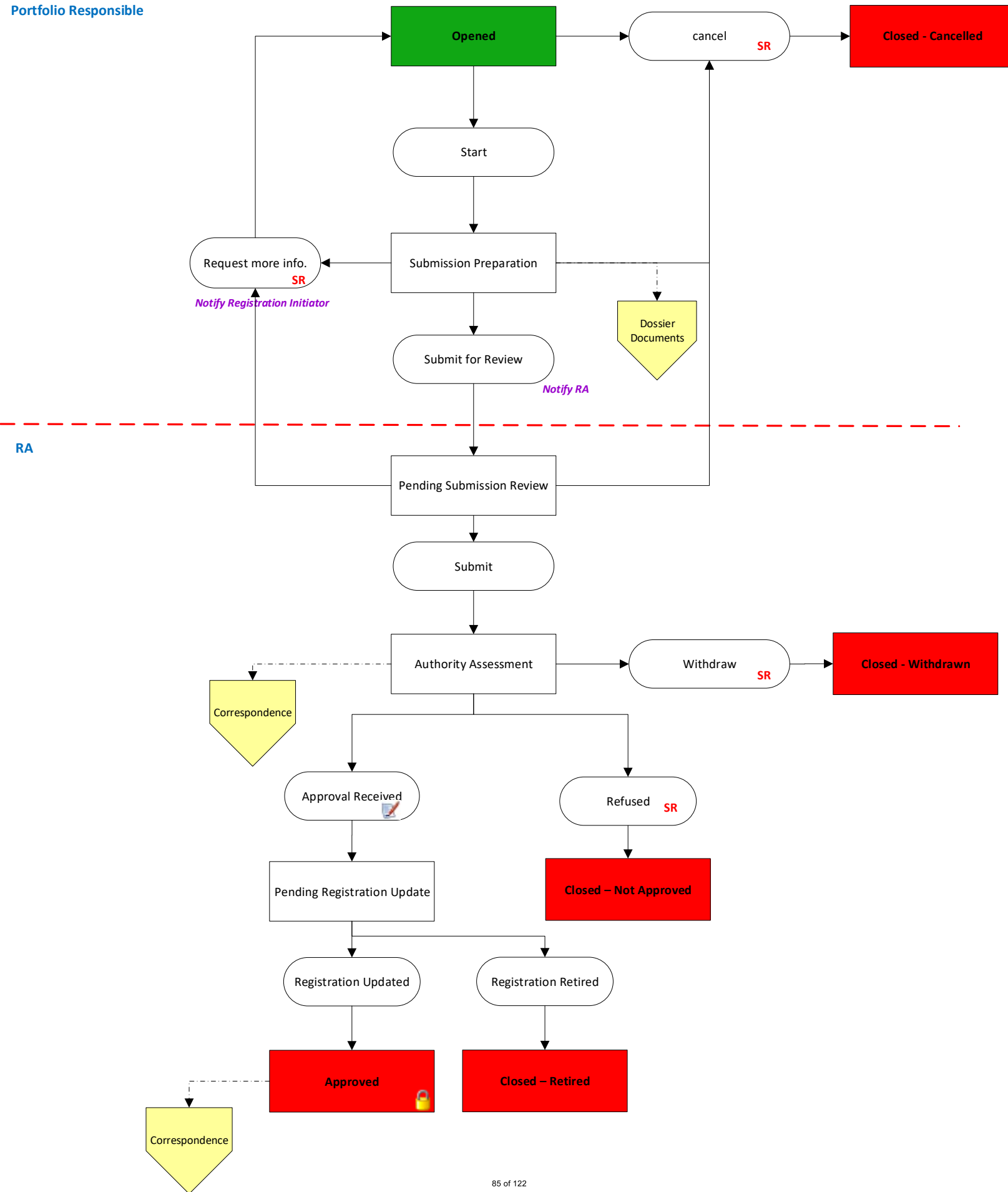
Renewal

Portfolio Responsible



Variation

Portfolio Responsible

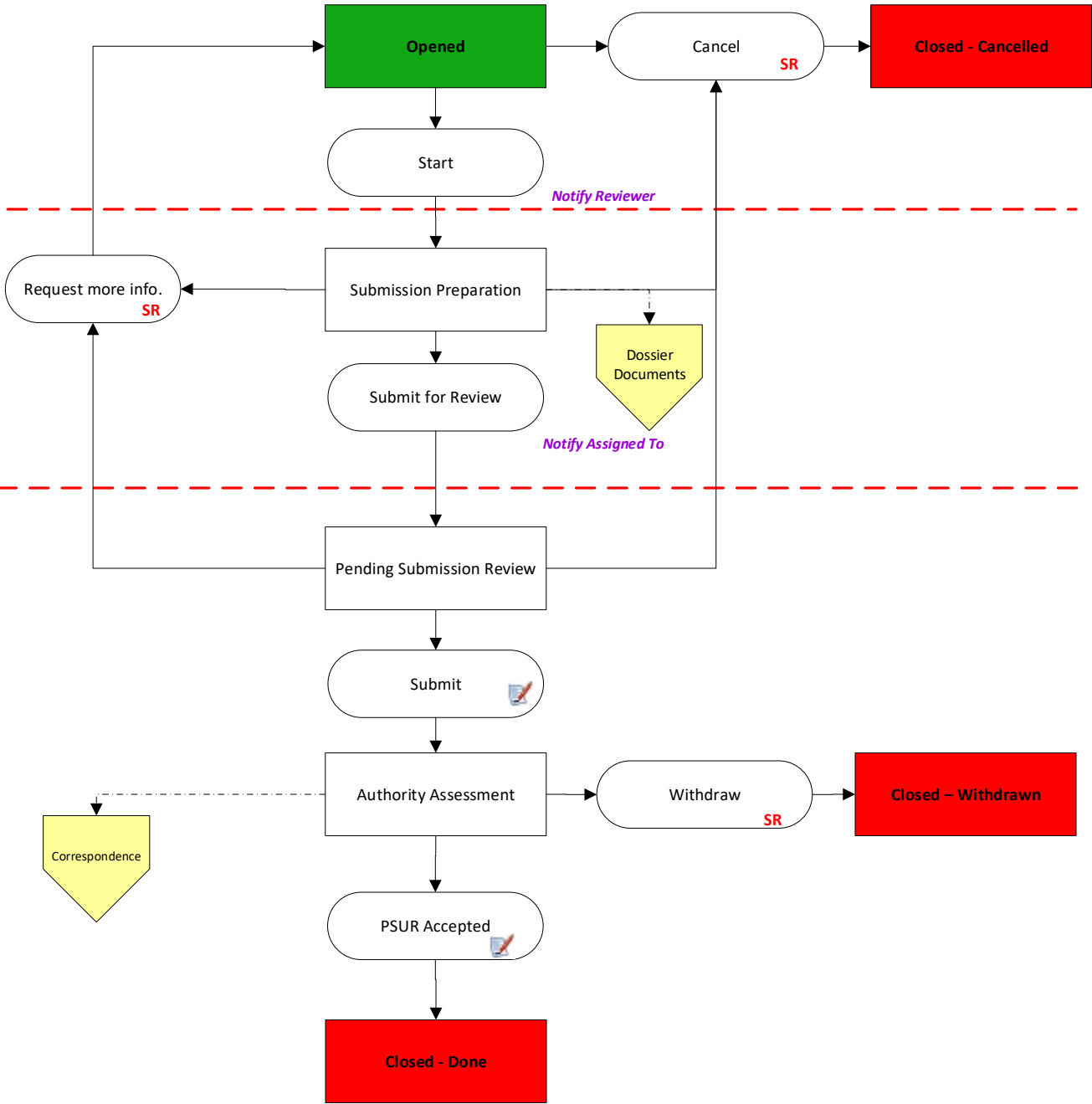


PSUR

Initiator

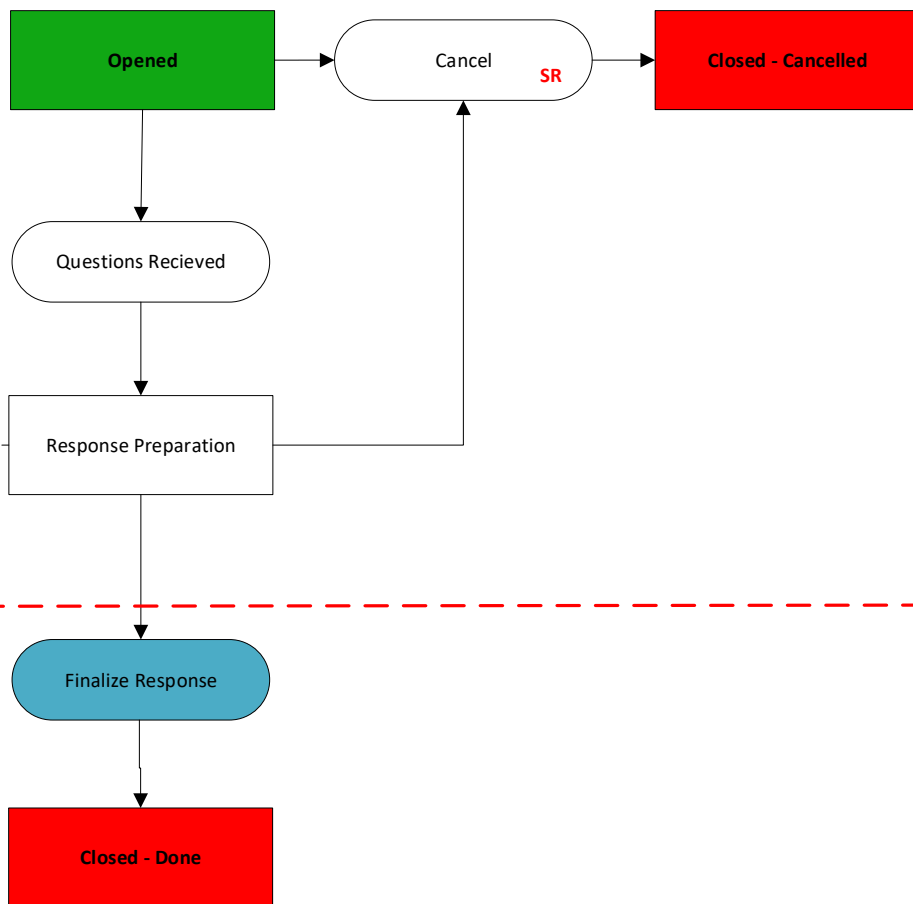
Reviewer / Manager

RA



Correspondence

Regulatory Affairs

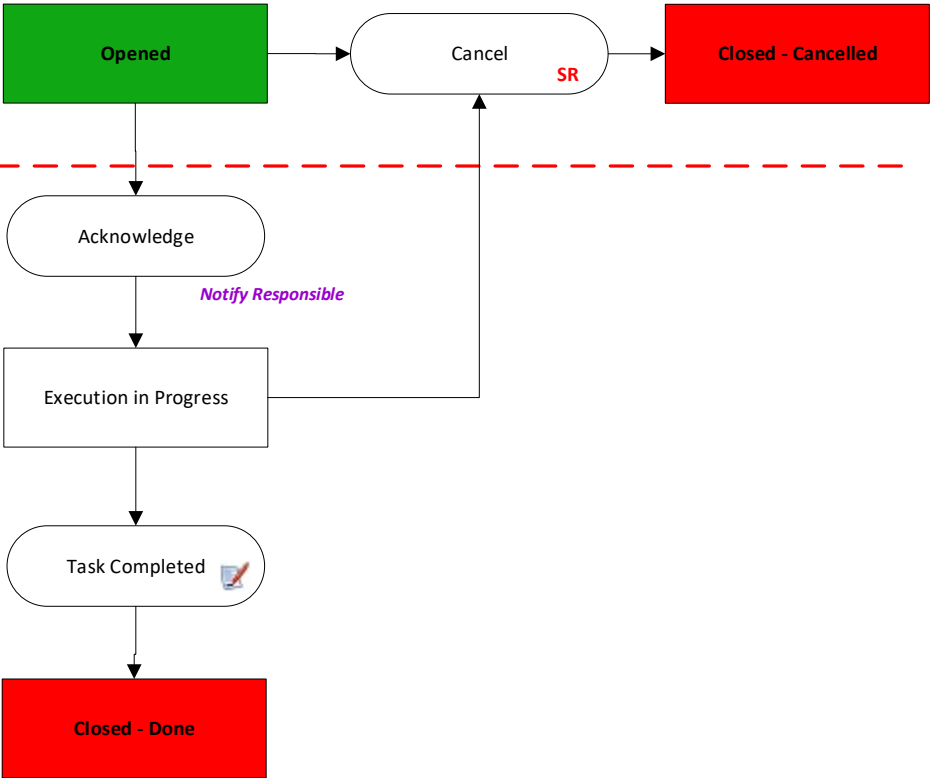


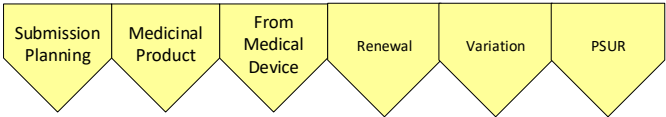
Business Rule
Engine

Commitment

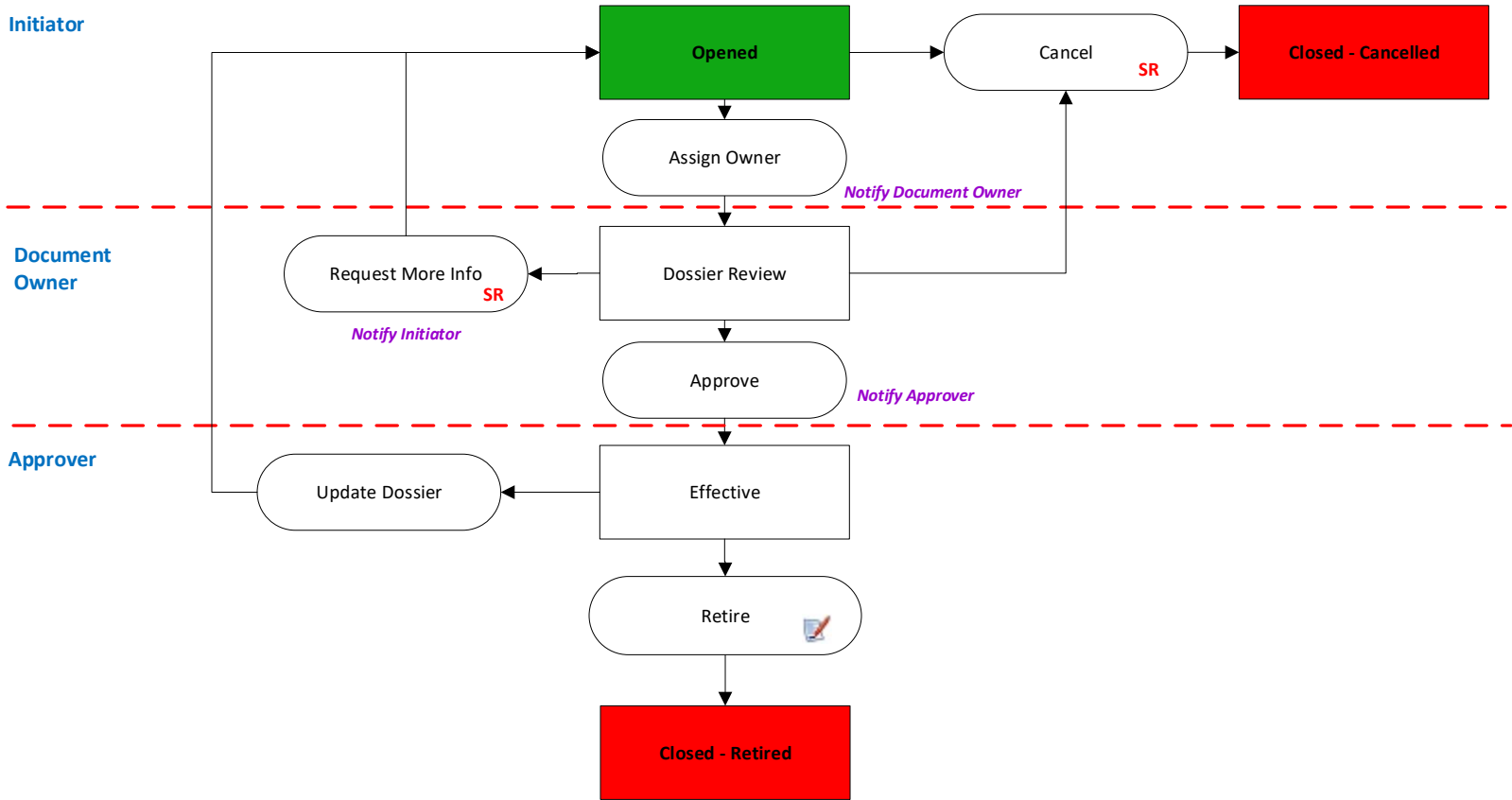
Regulatory Affairs

Responsible

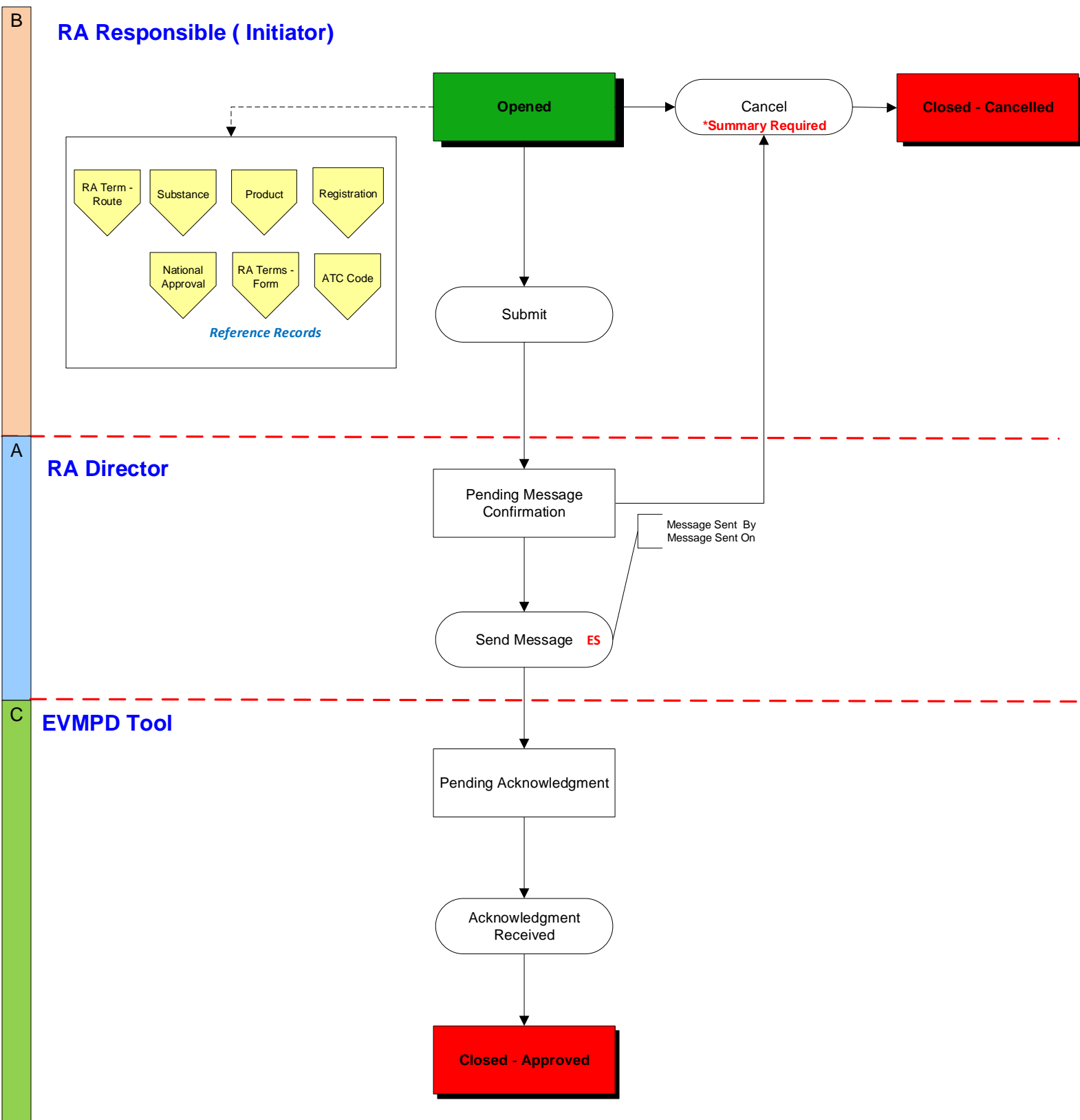




Dossier

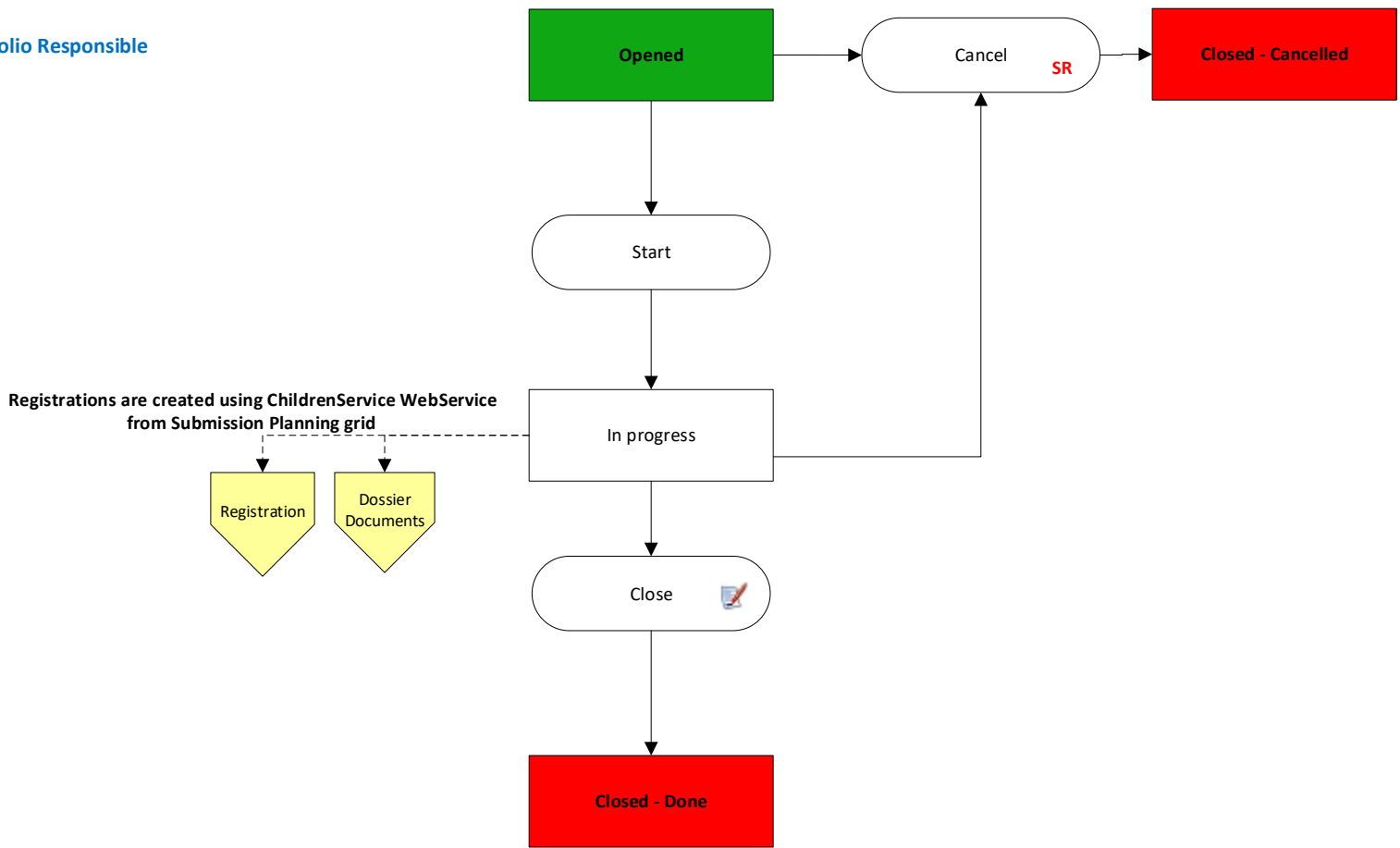


EVMPD Message

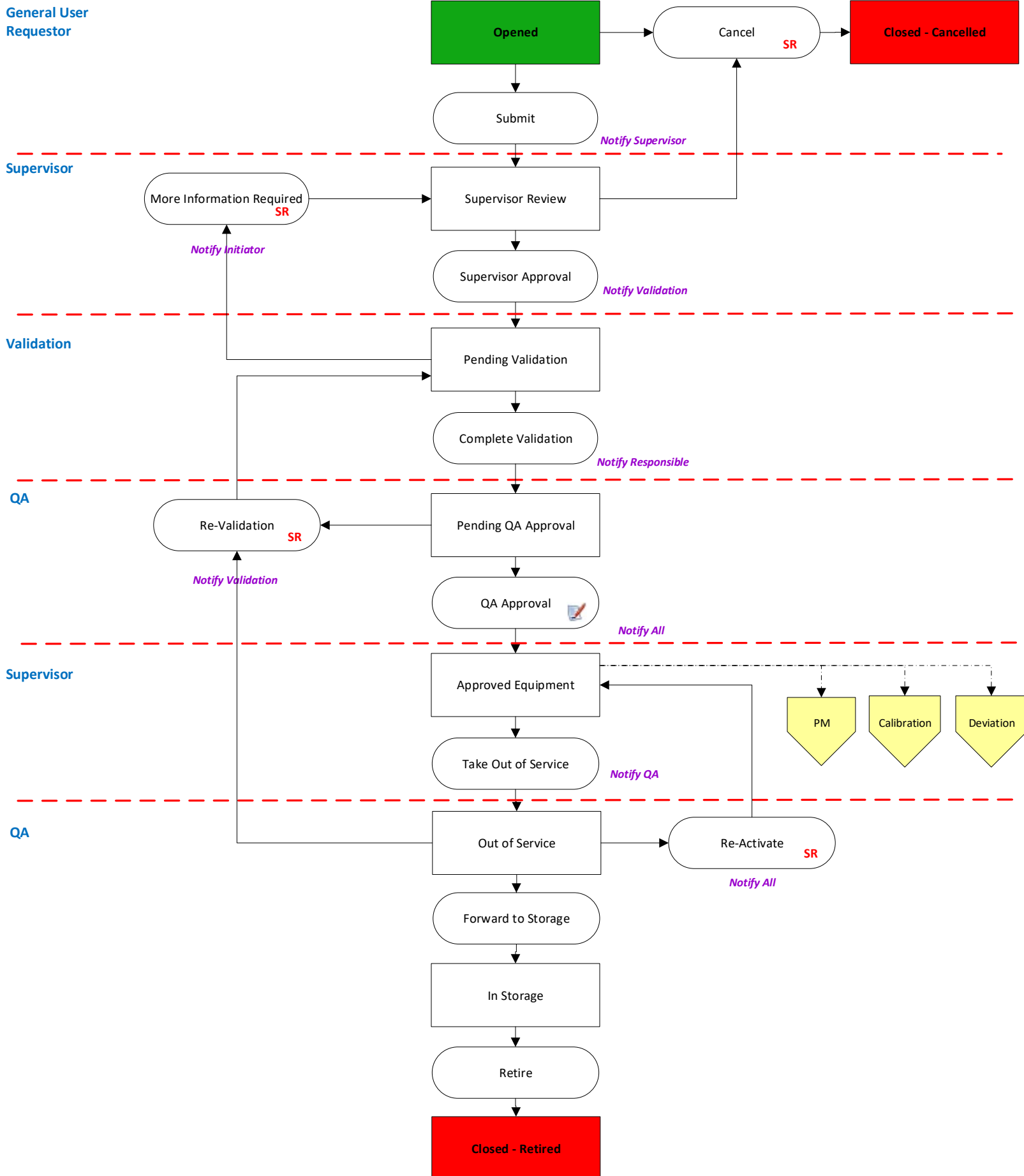


Submission Planning

Portfolio Responsible



Equipment



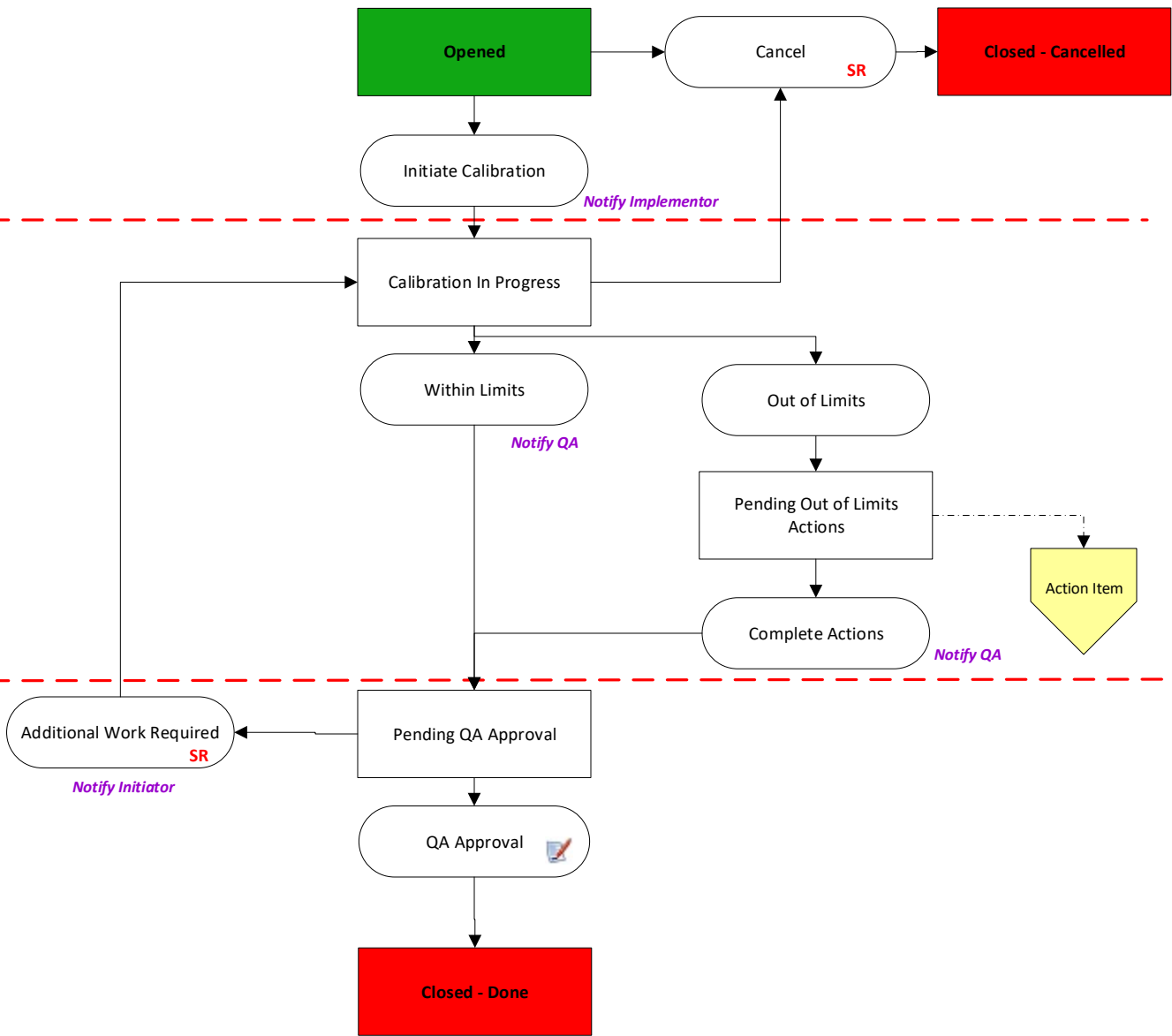


Calibration

Initiator

Implementor

QA





Preventive Maintenance

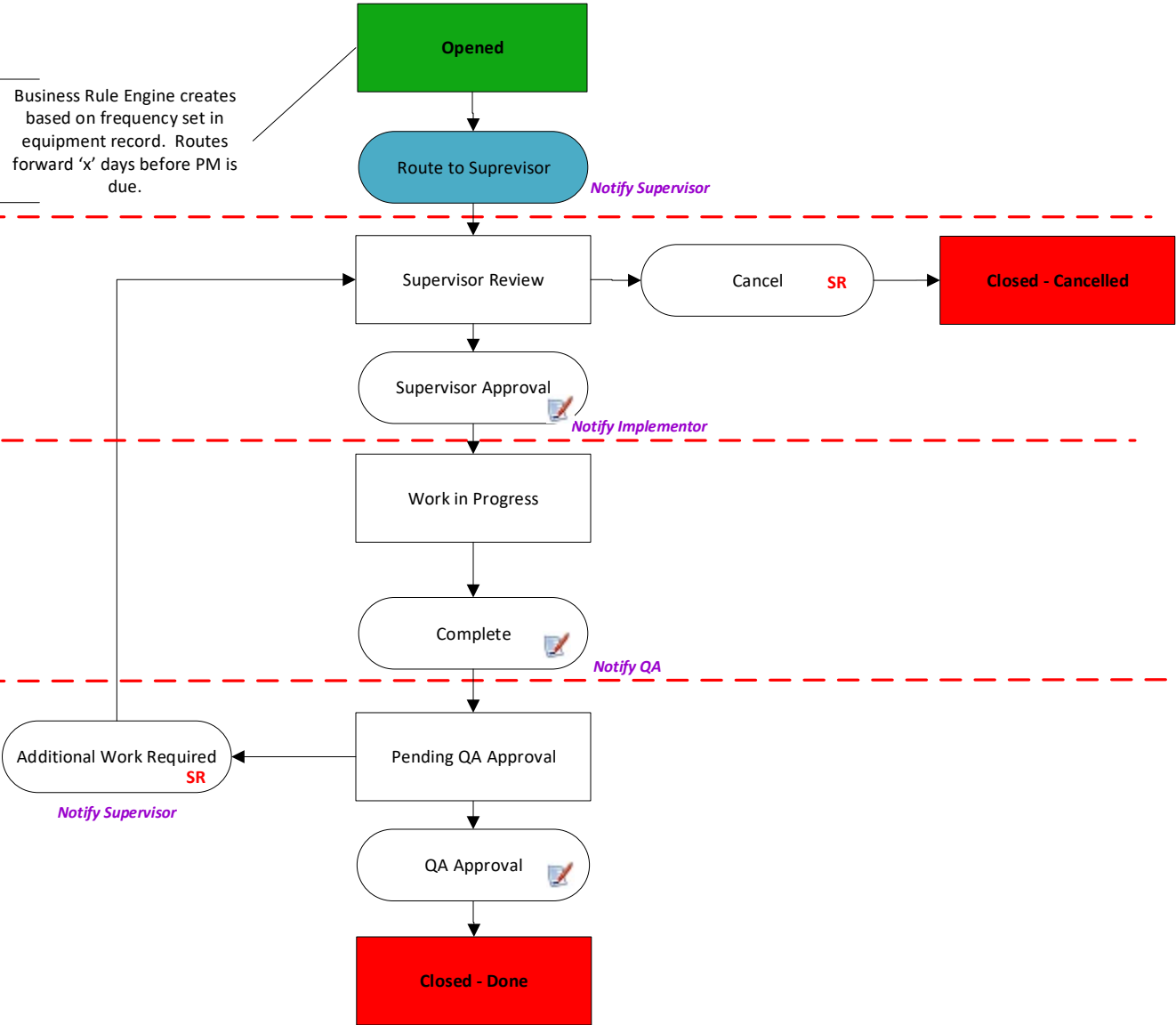
Business Rule Engine

Business Rule Engine creates based on frequency set in equipment record. Routes forward 'x' days before PM is due.

Supervisor

Implementer

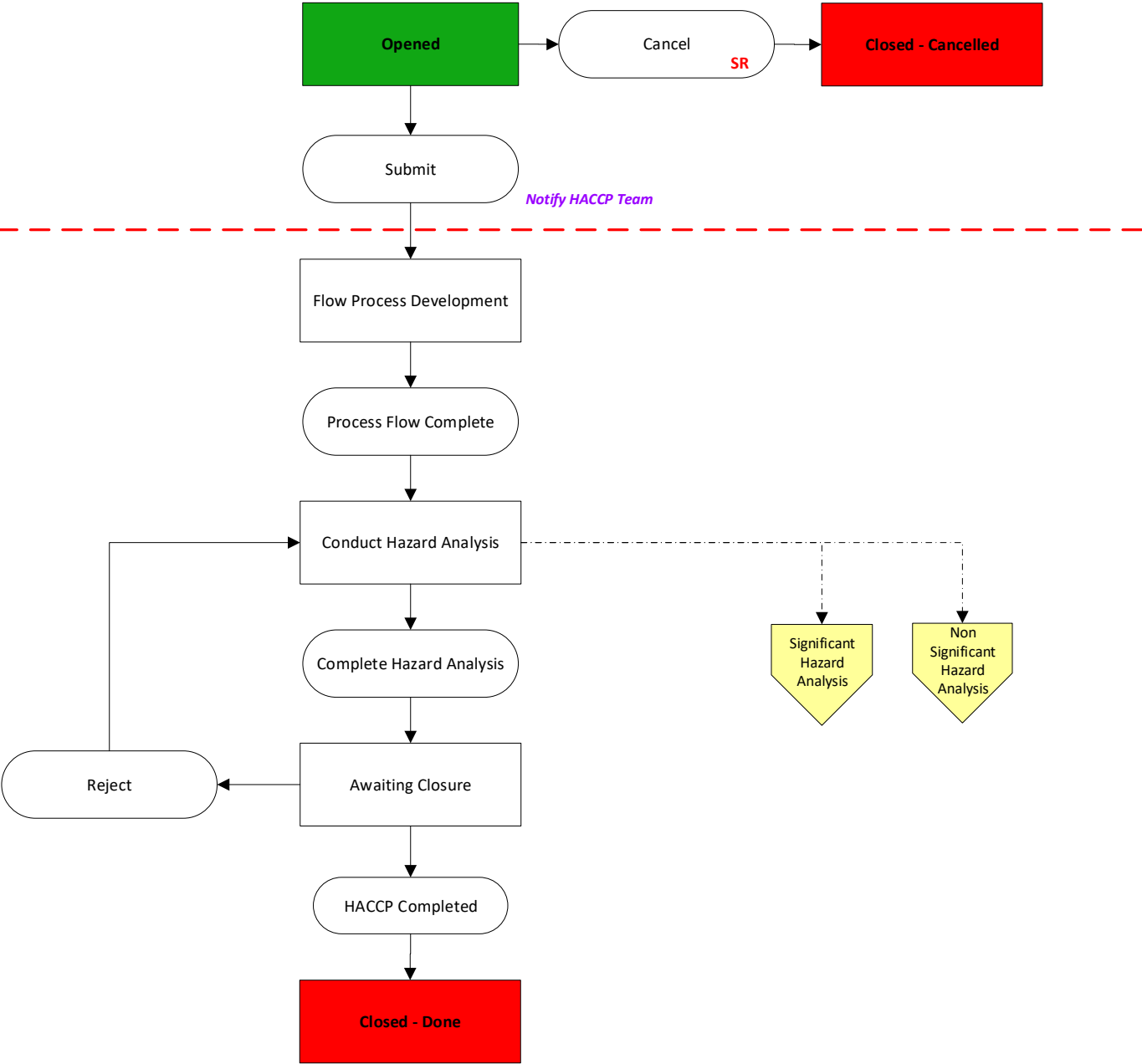
QA



HACCP Plan

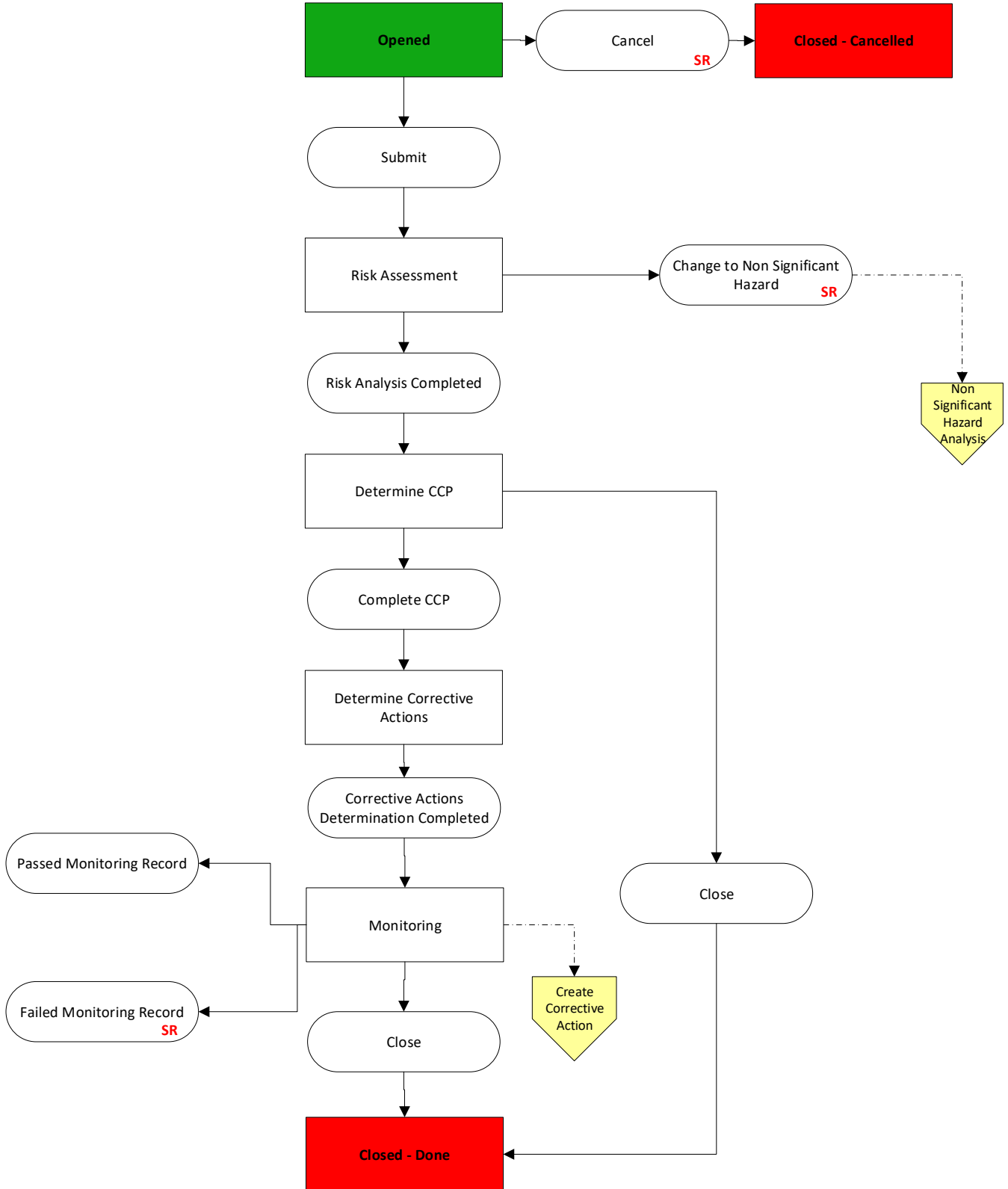
HACCP Coordinator

HACCP Team



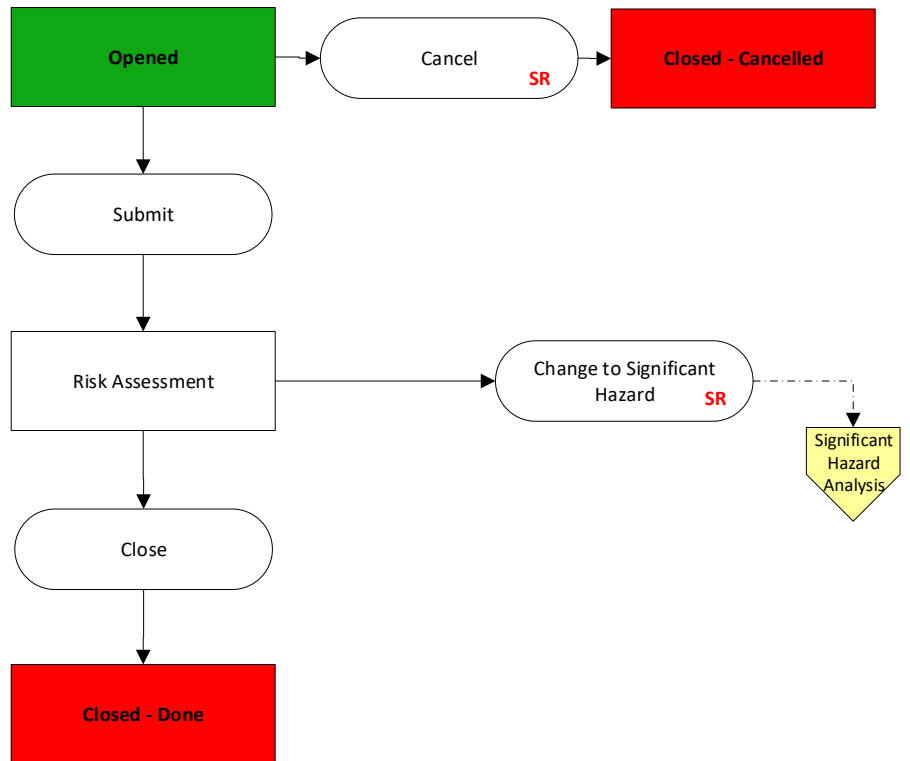
Significant Hazard Analysis

HACCP Team



Non Significant Hazard Analysis

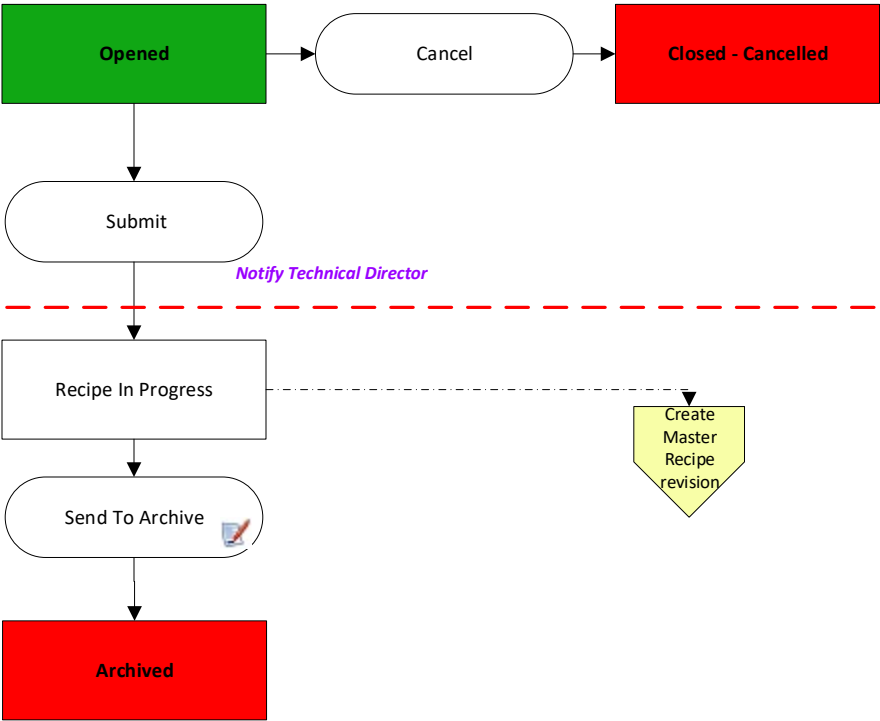
HACCP Team



Master Recipe

Author

Technical
Director





Master Recipe Revision

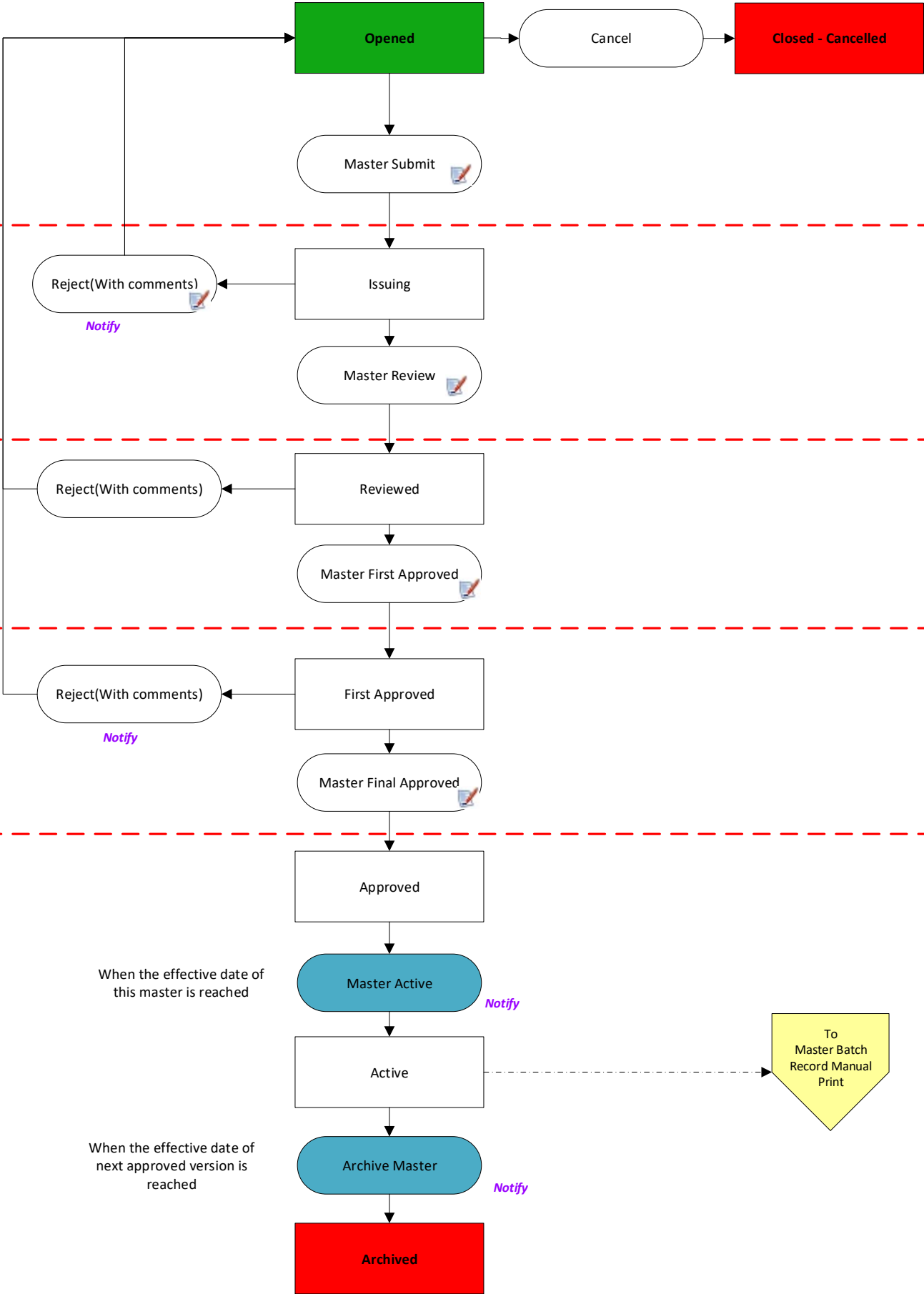
Author

Production

QA

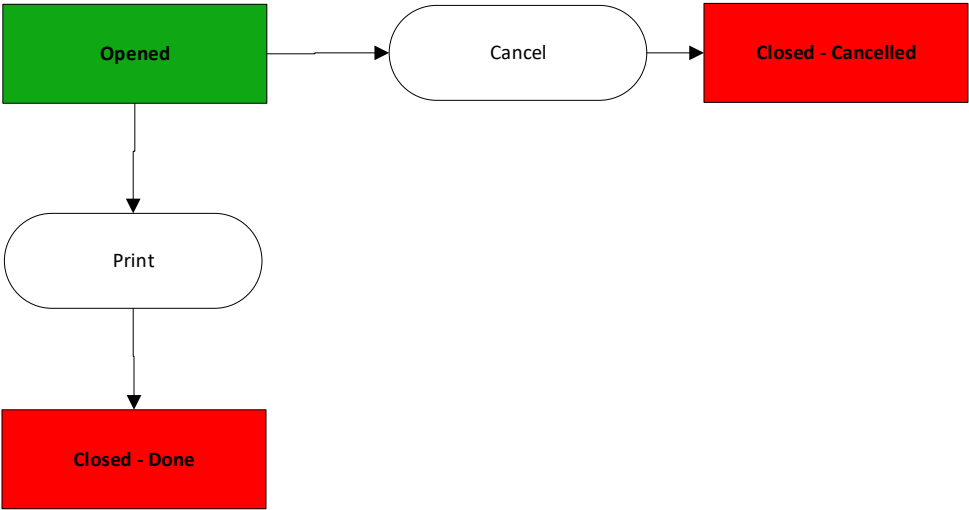
Technical Director

System



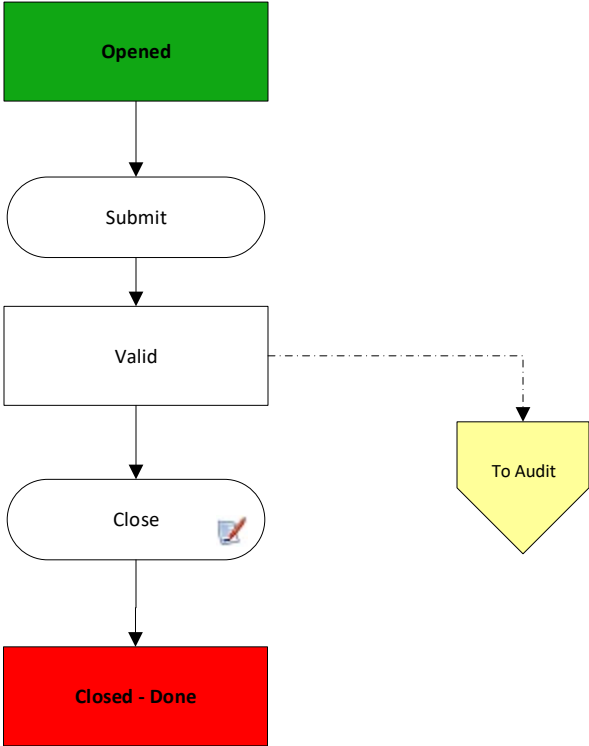
Master Batch Record Manual Print

Originator



Auditee

Originator

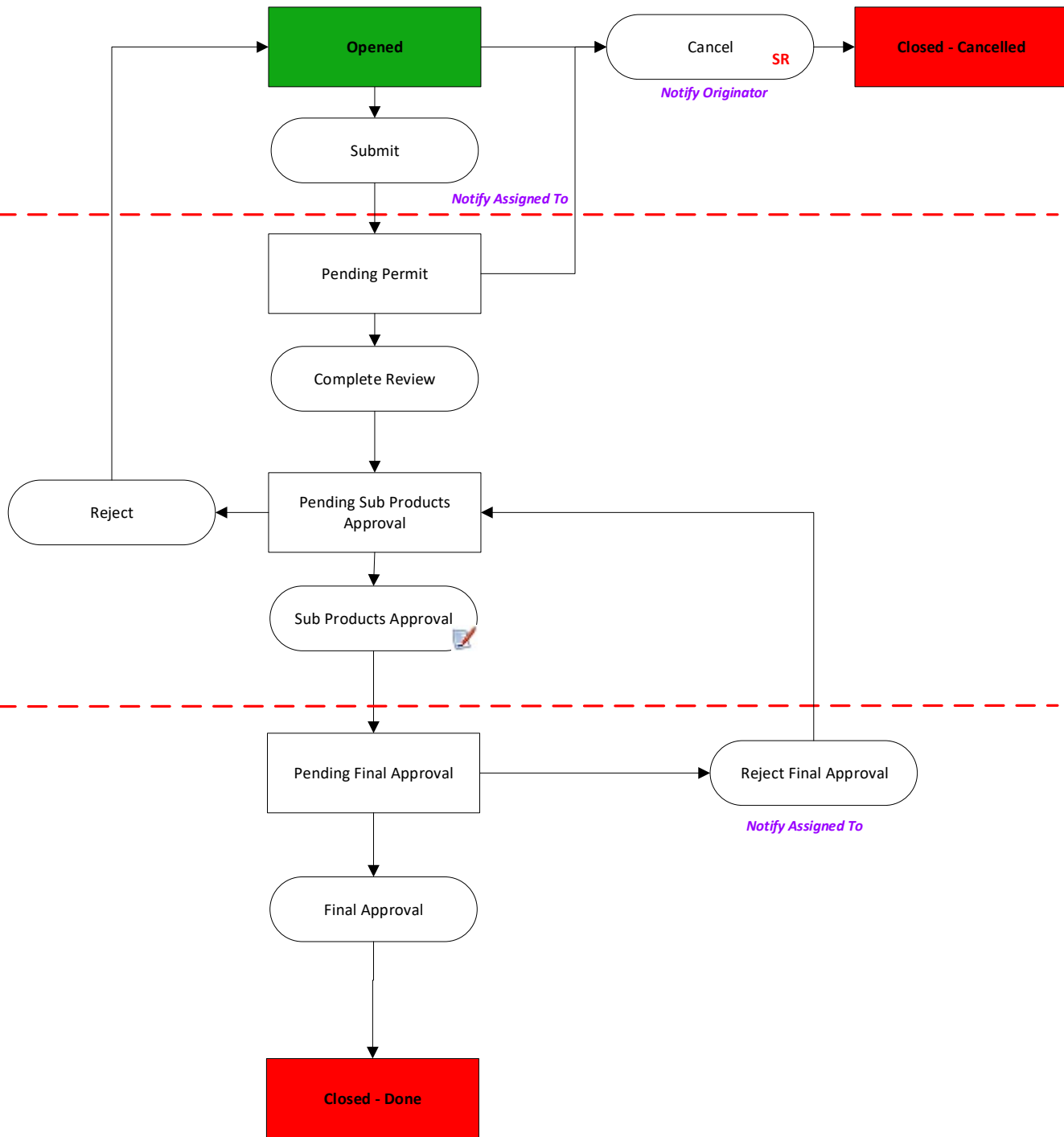


New Product Introduction

Originator

Assigned To

Approvers



From New
Product
Introduction

Product File 1

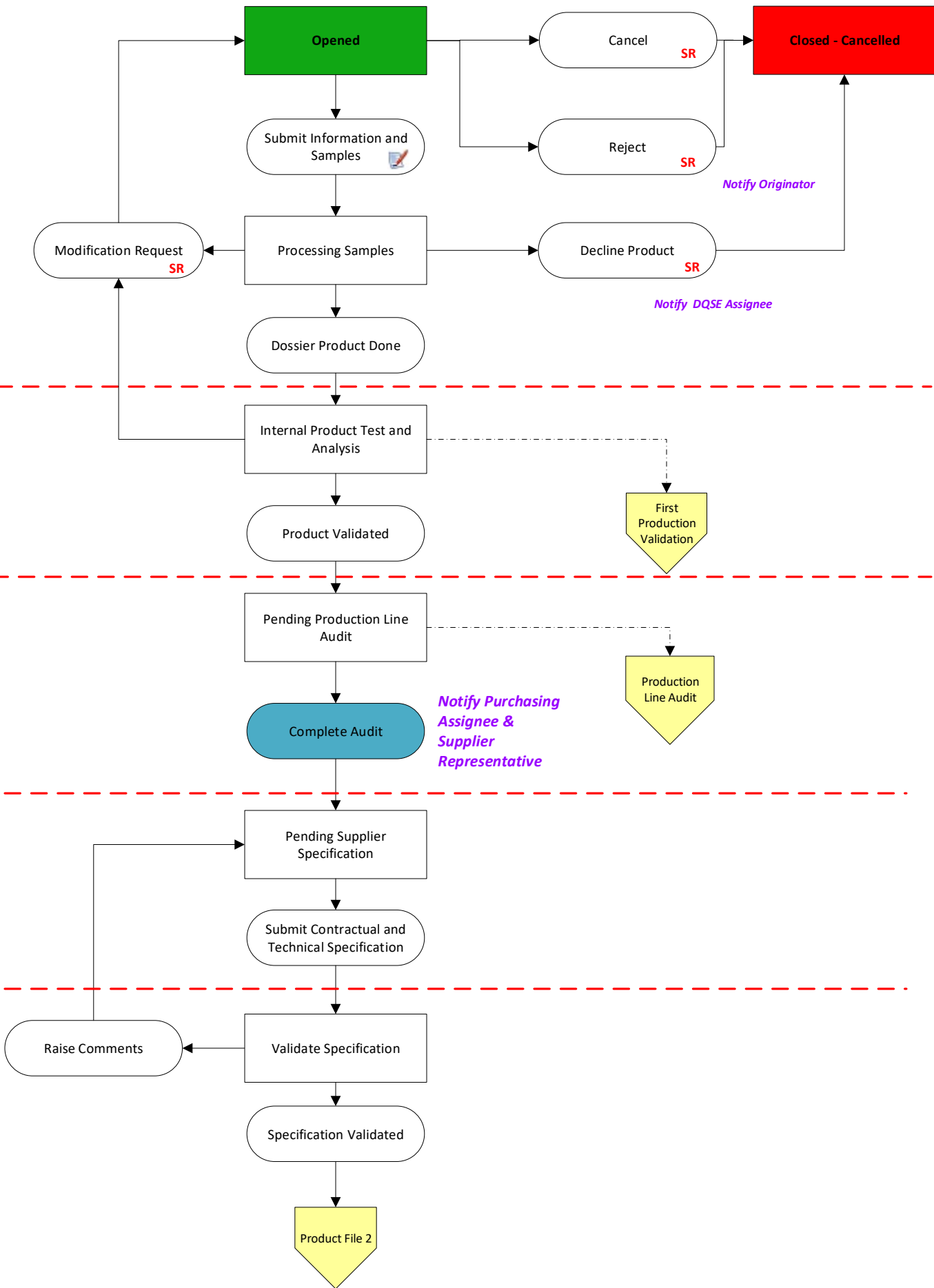
Originator

Panel/Laboratories

CEQ

Supplier

Legal
Department

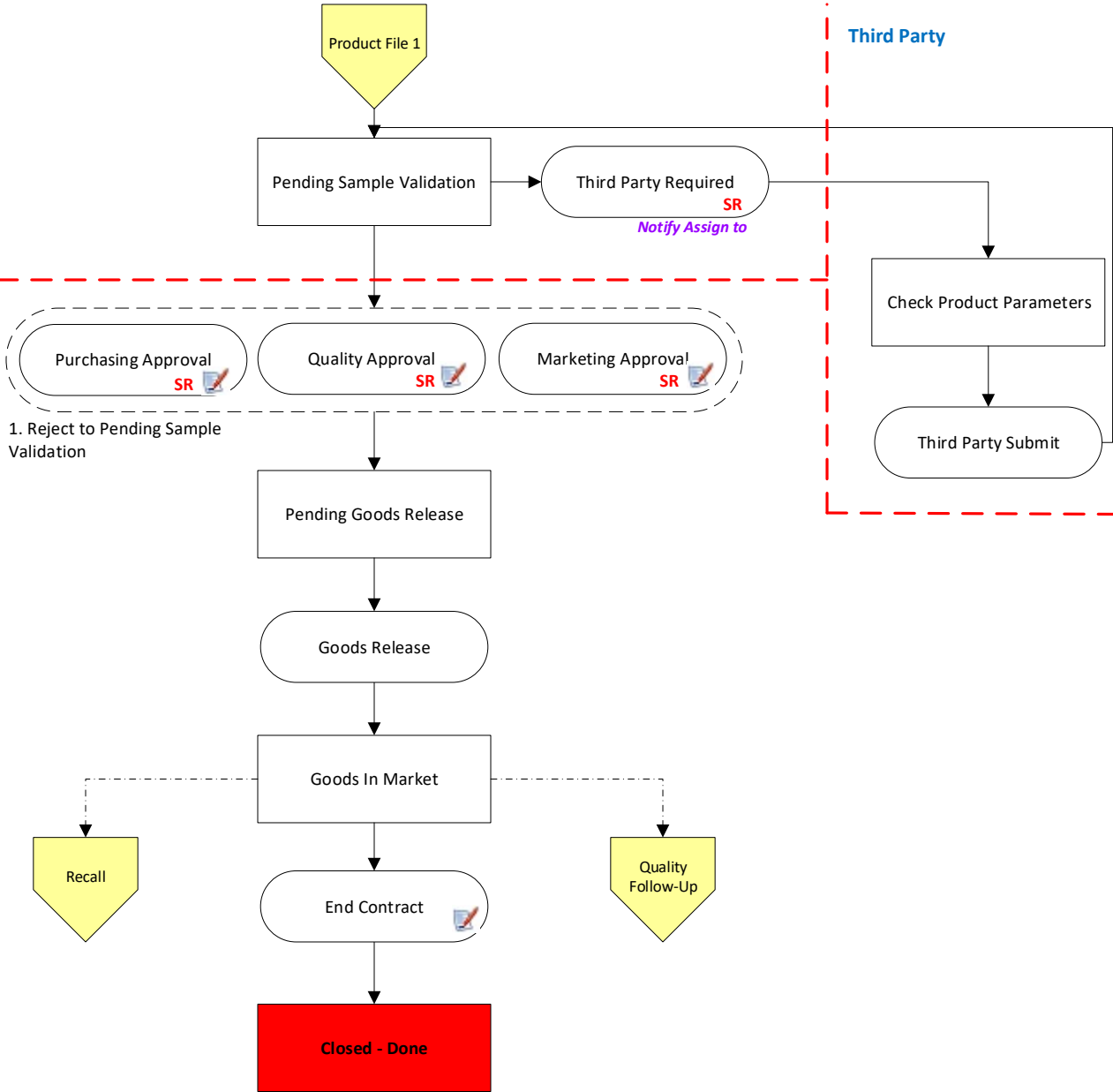


Product File 2

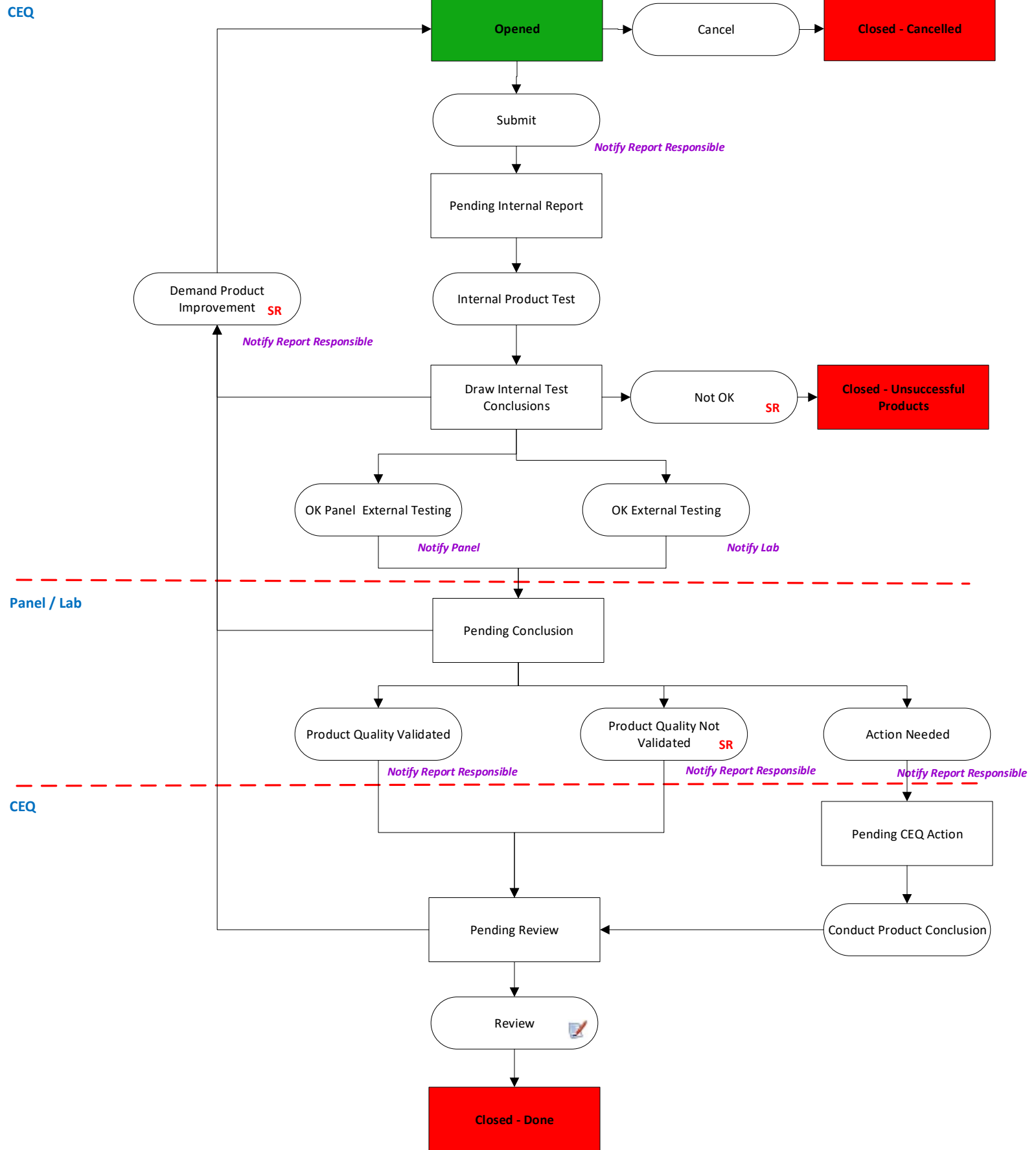
CEQ

Marketing/
Purchasing/
Quality

Third Party



Lab Tests



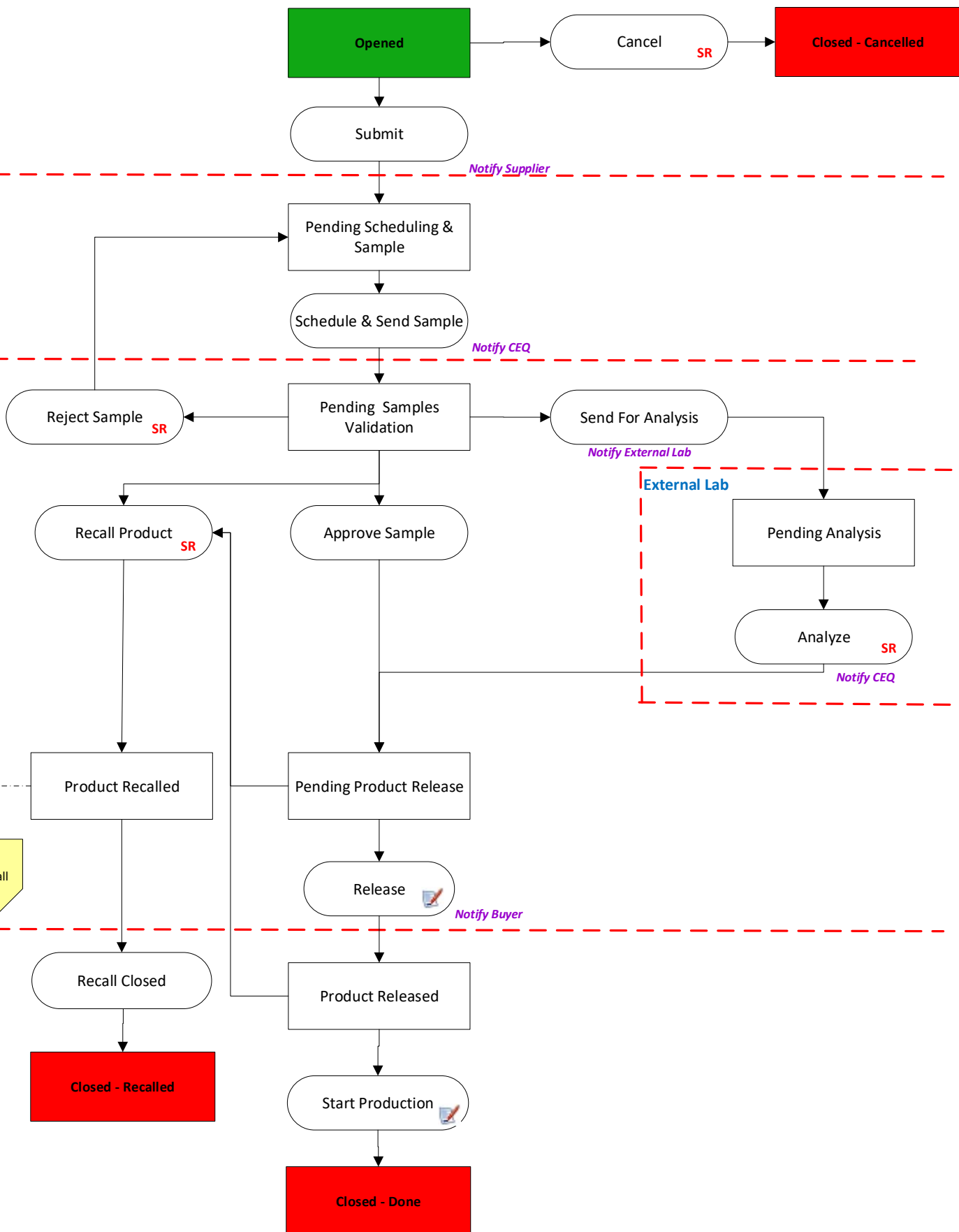
First Production Validation

CEQ

Supplier

CEQ

Buyer



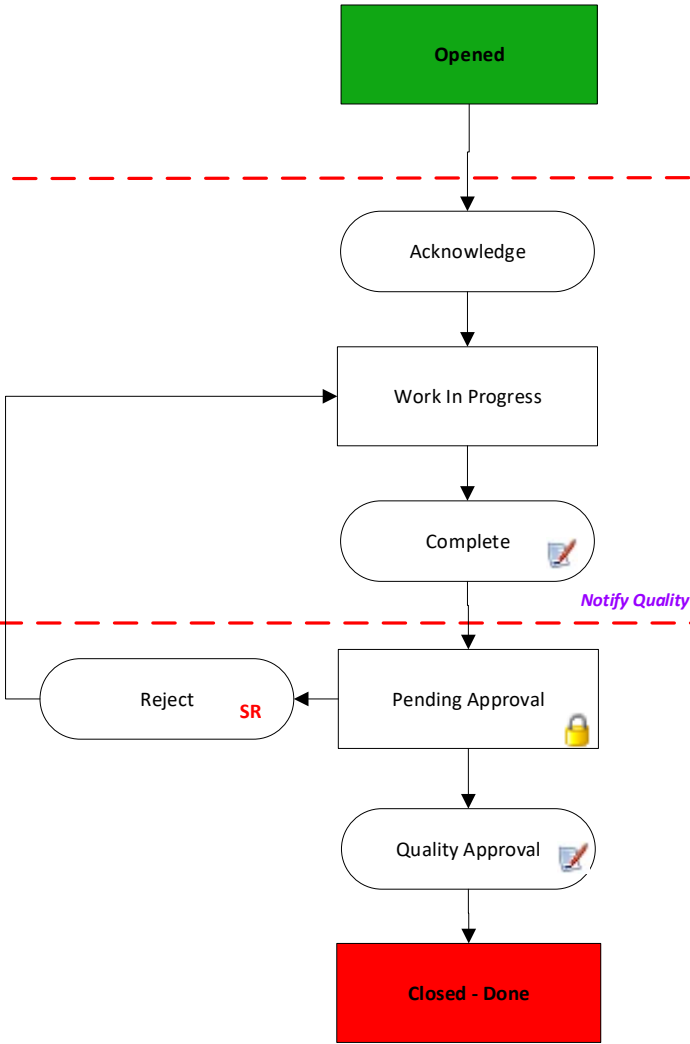


Quality Follow Up

Originator

Assigned To

Quality





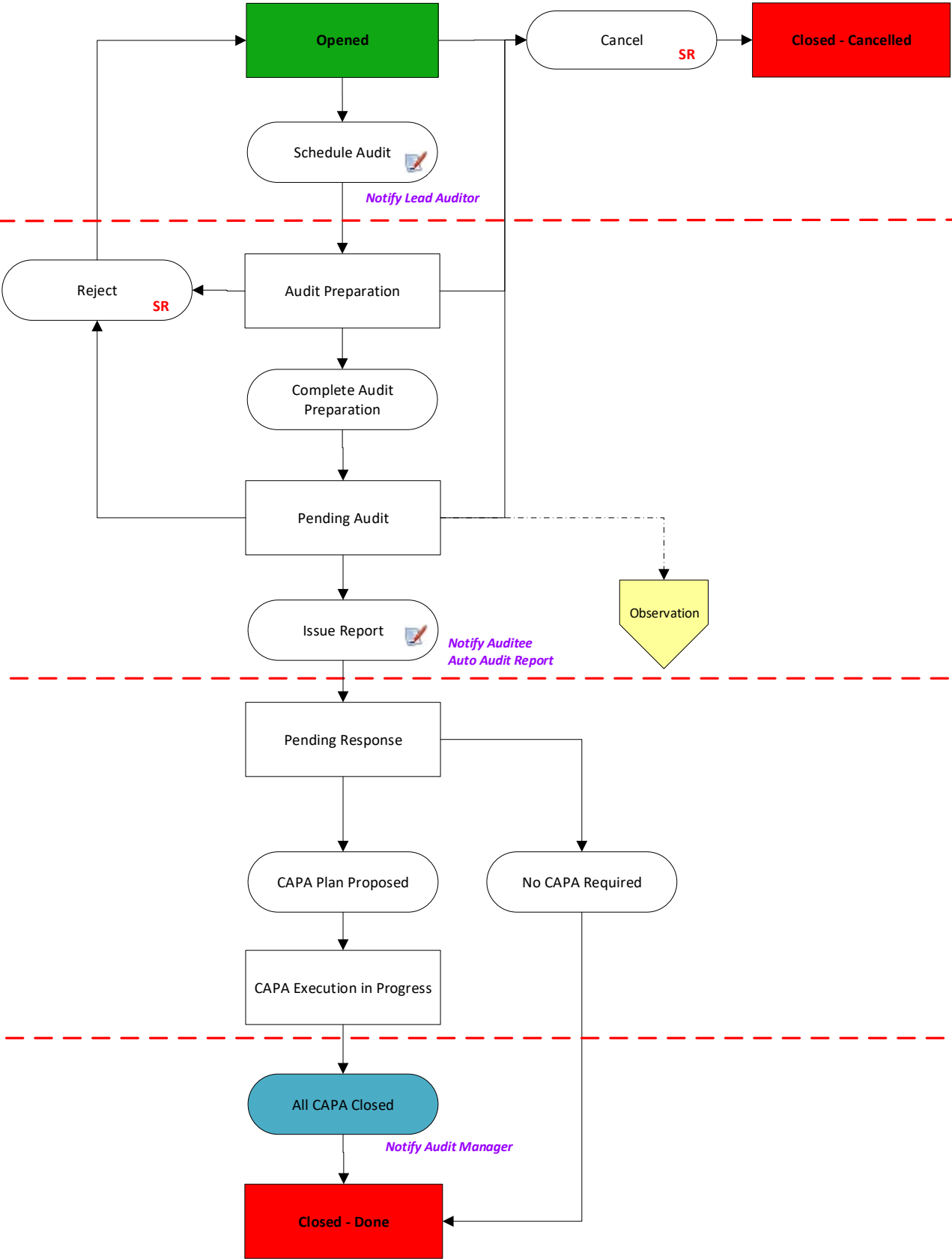
Production Line Audit

Audit Manager

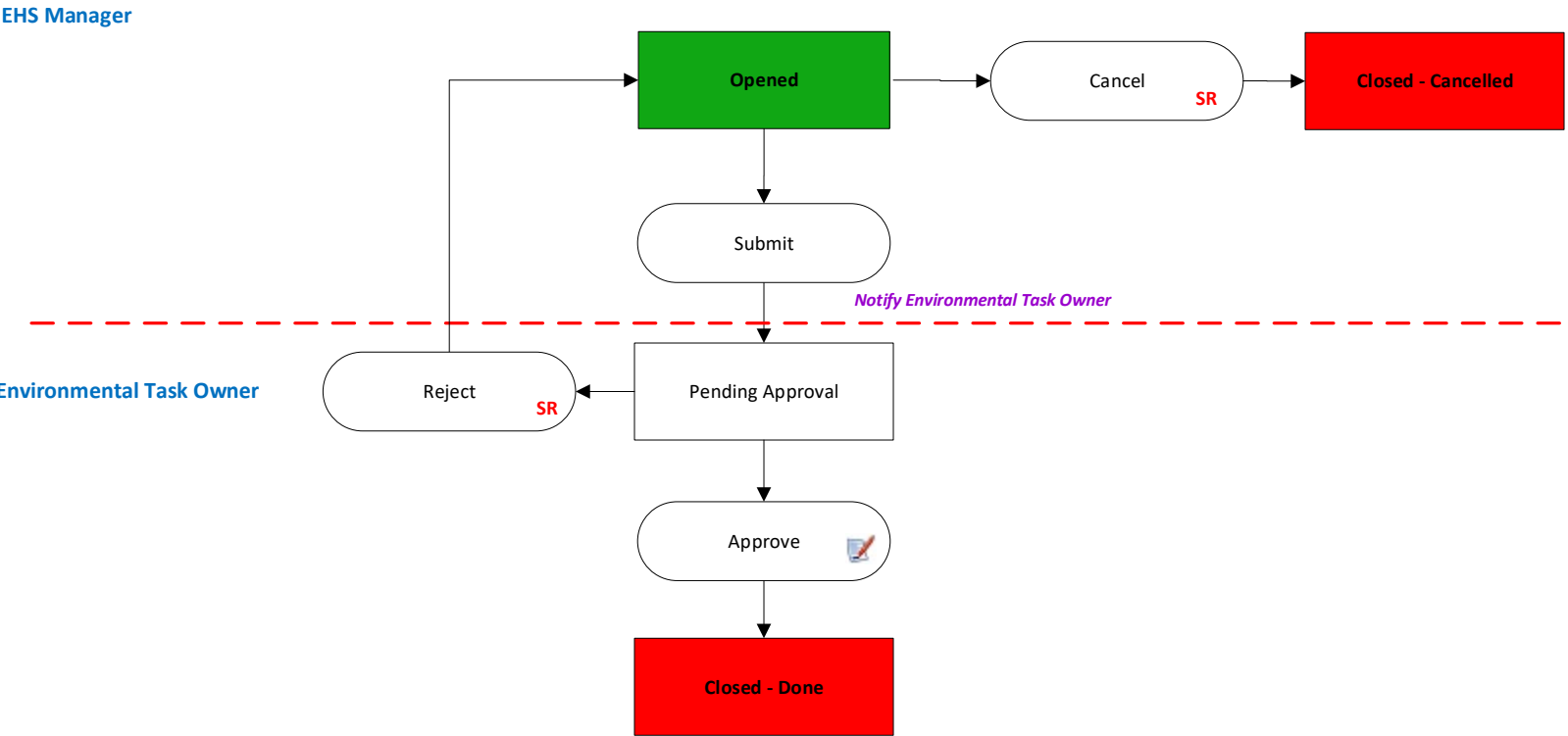
Lead Auditor

Auditee

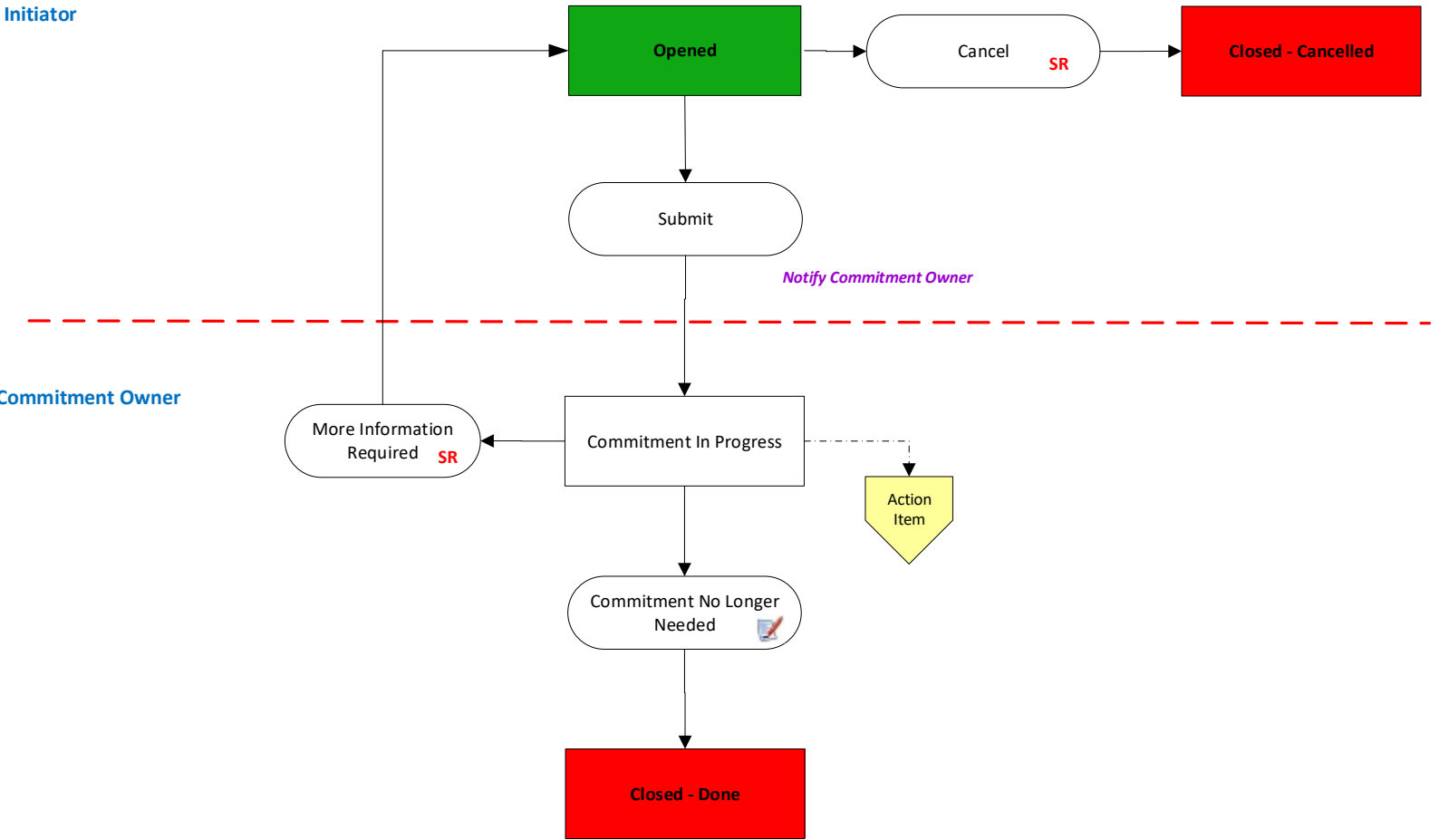
Business Rule Engine



Environmental Task

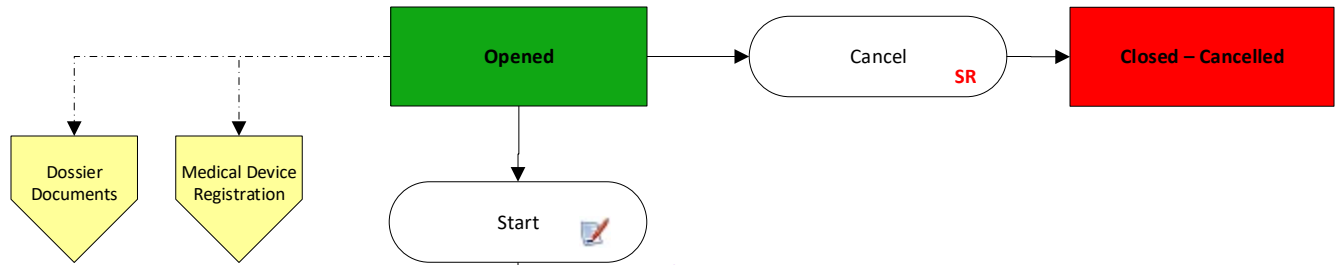


Recurring Commitment



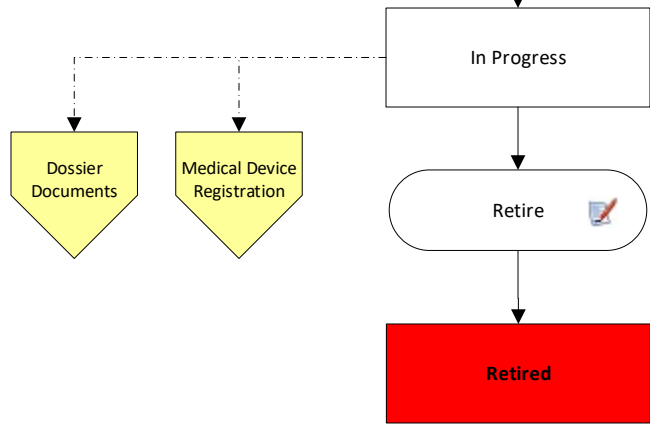
Medical Device

Initiator



Notify Task Owner

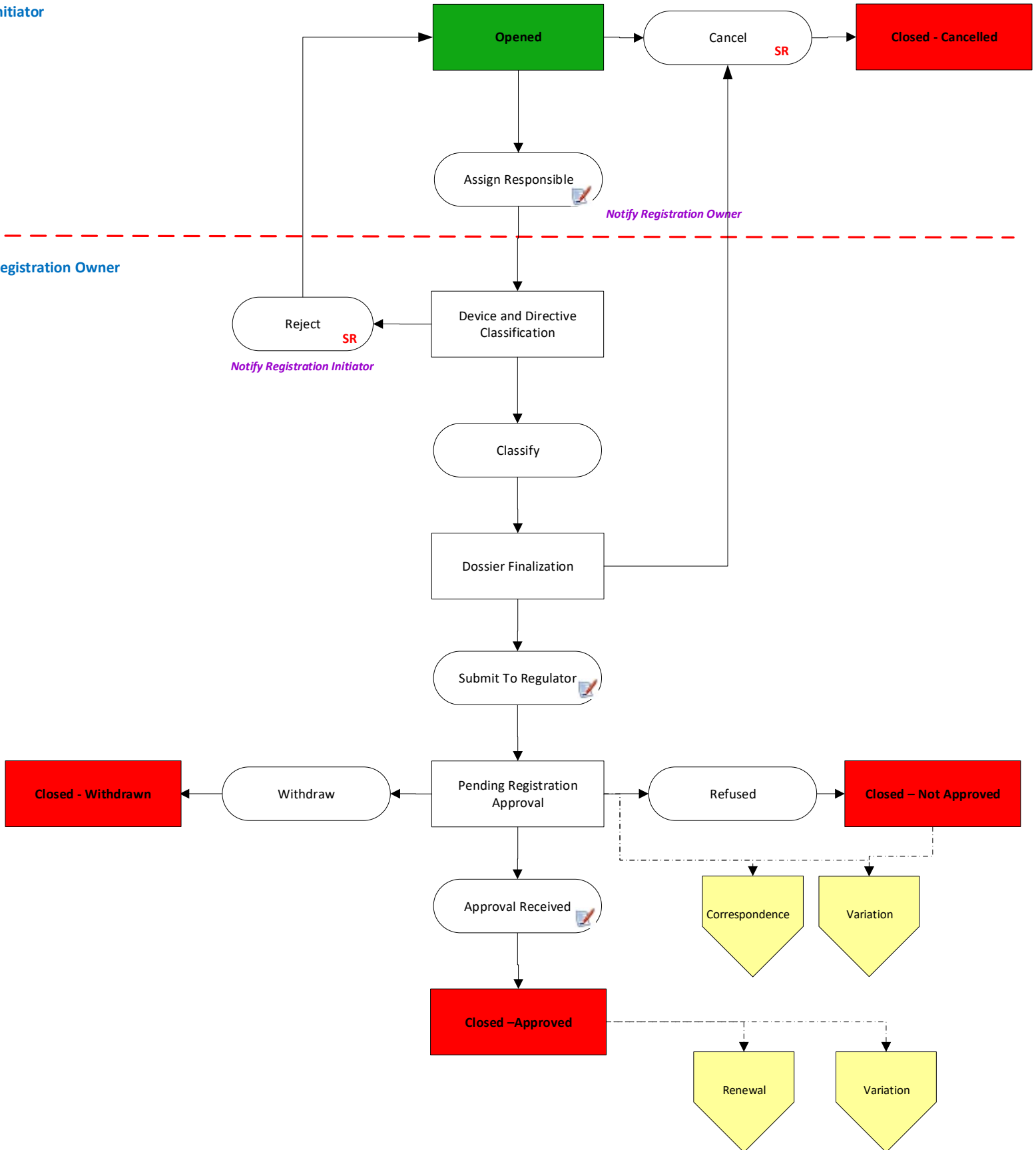
Task Owner



Medical Device Registration

Initiator

Registration Owner



Validation Life Cycle

Document Responsible

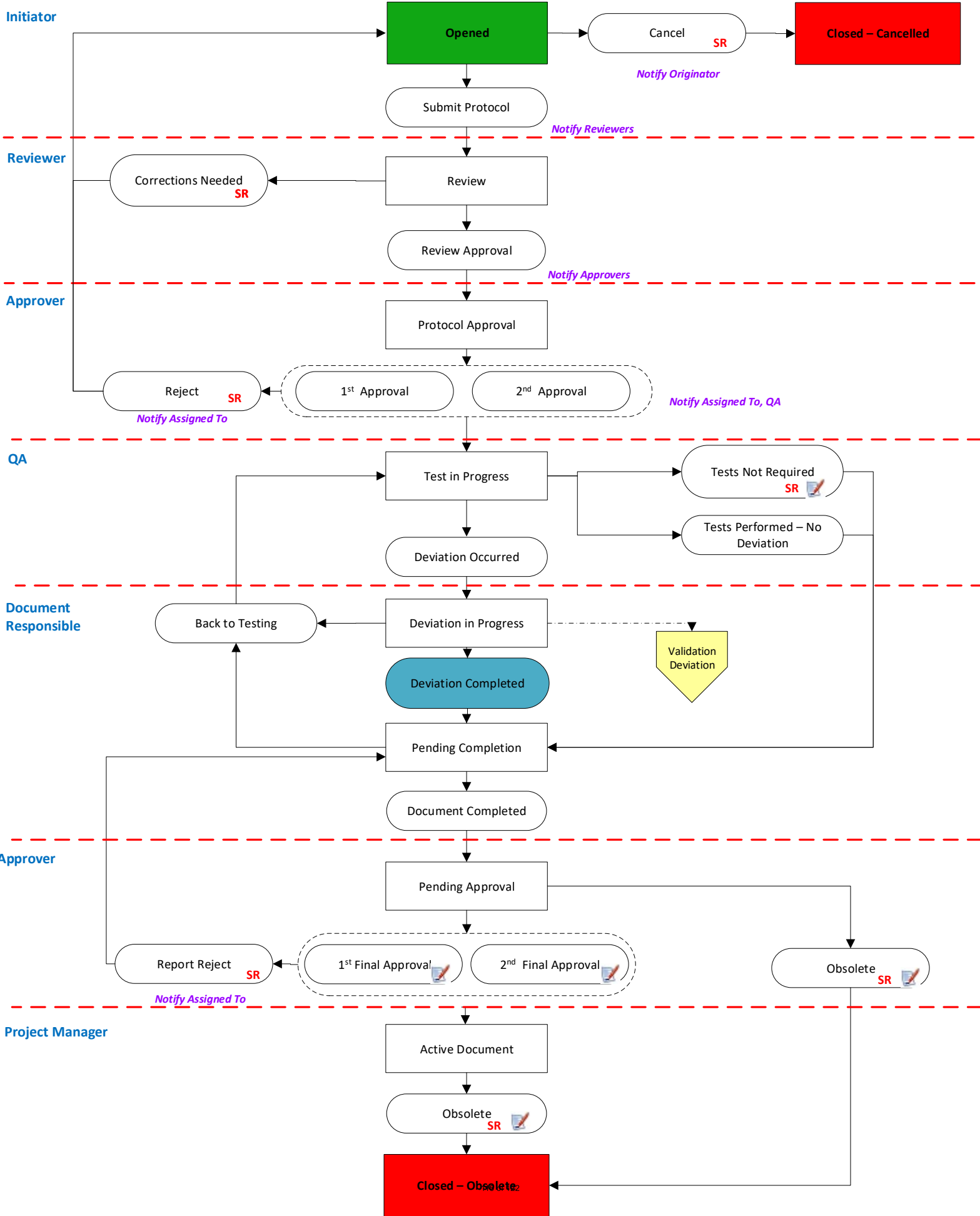
Project Manager

Document Responsible

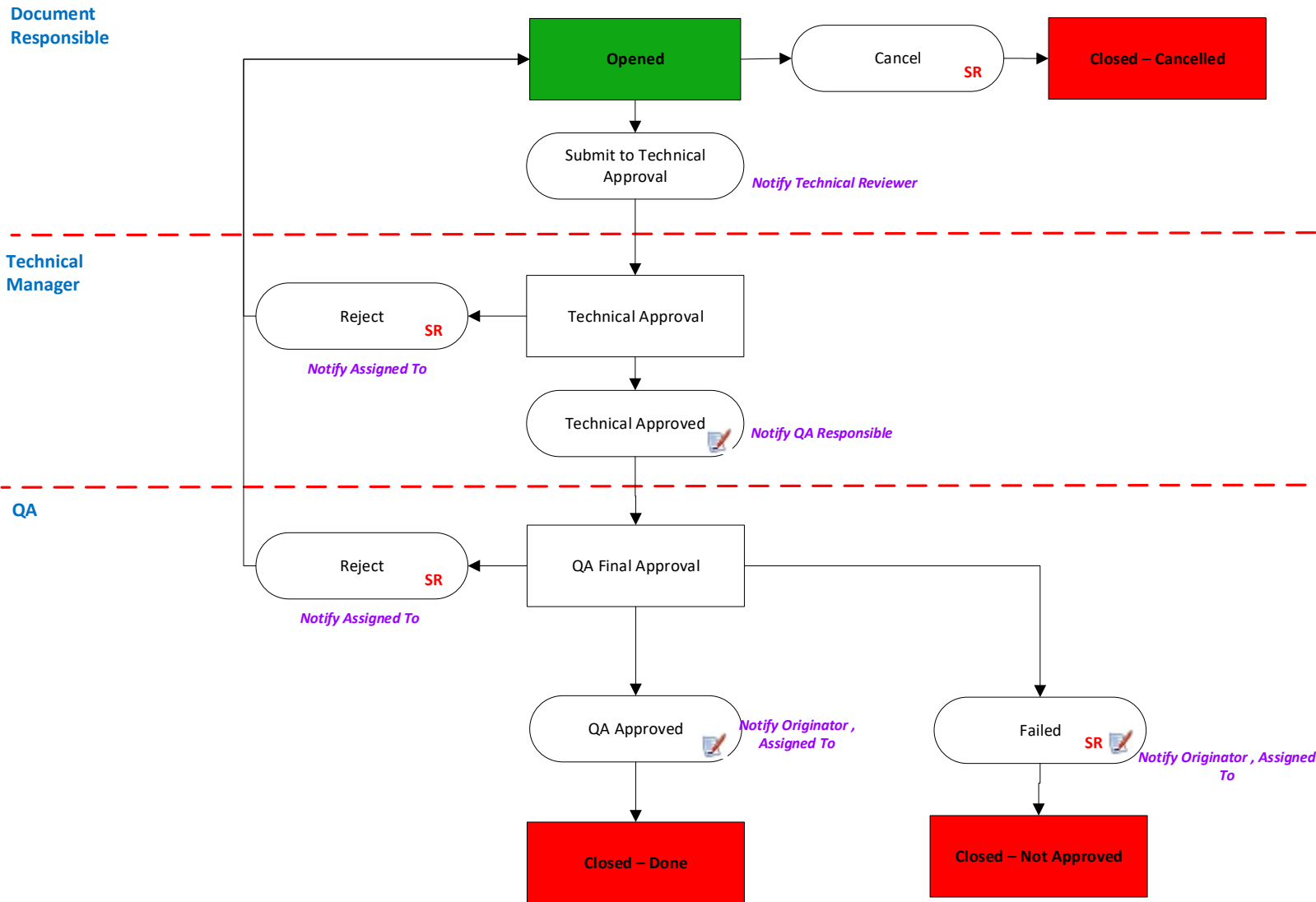


From
Validation Life
Cycle

Validation Document

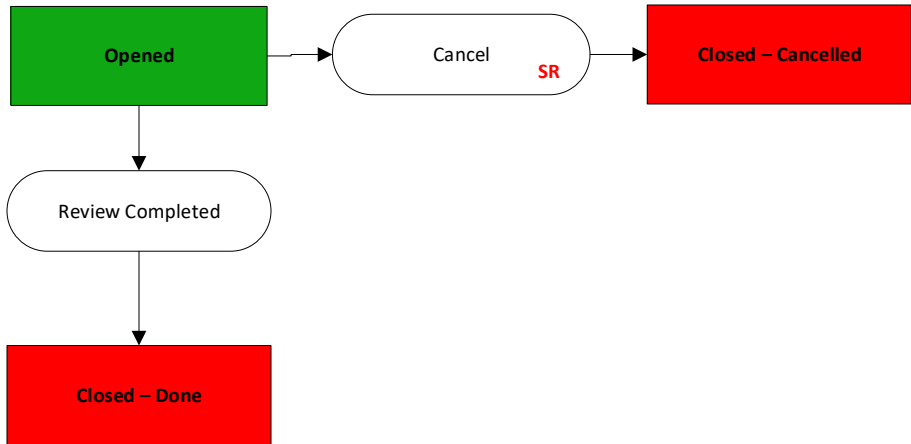


Validation Deviation

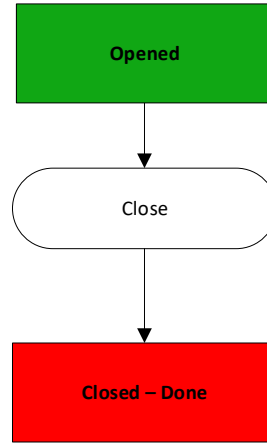


Validation Review

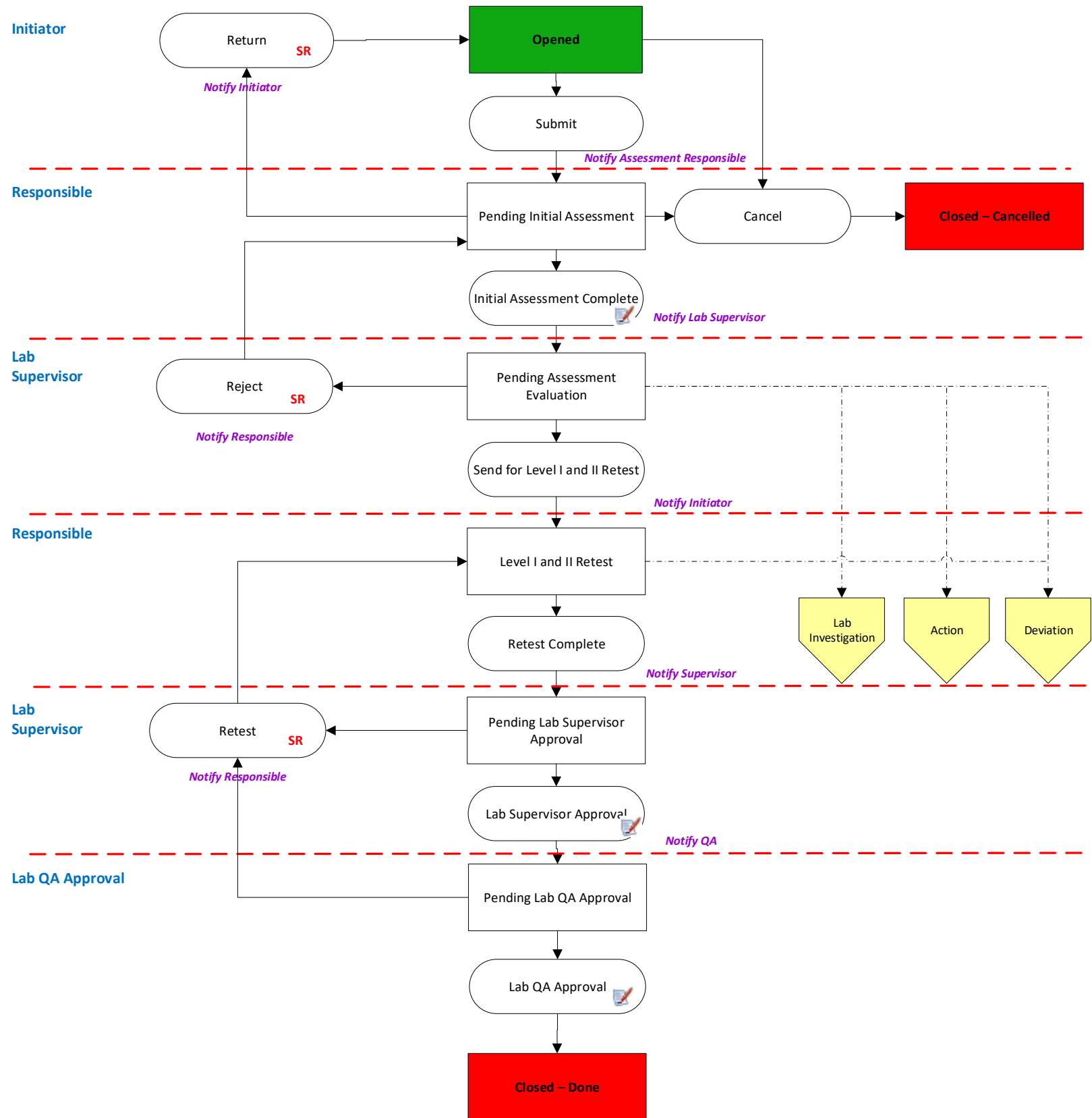
Project Manager



Validation Template



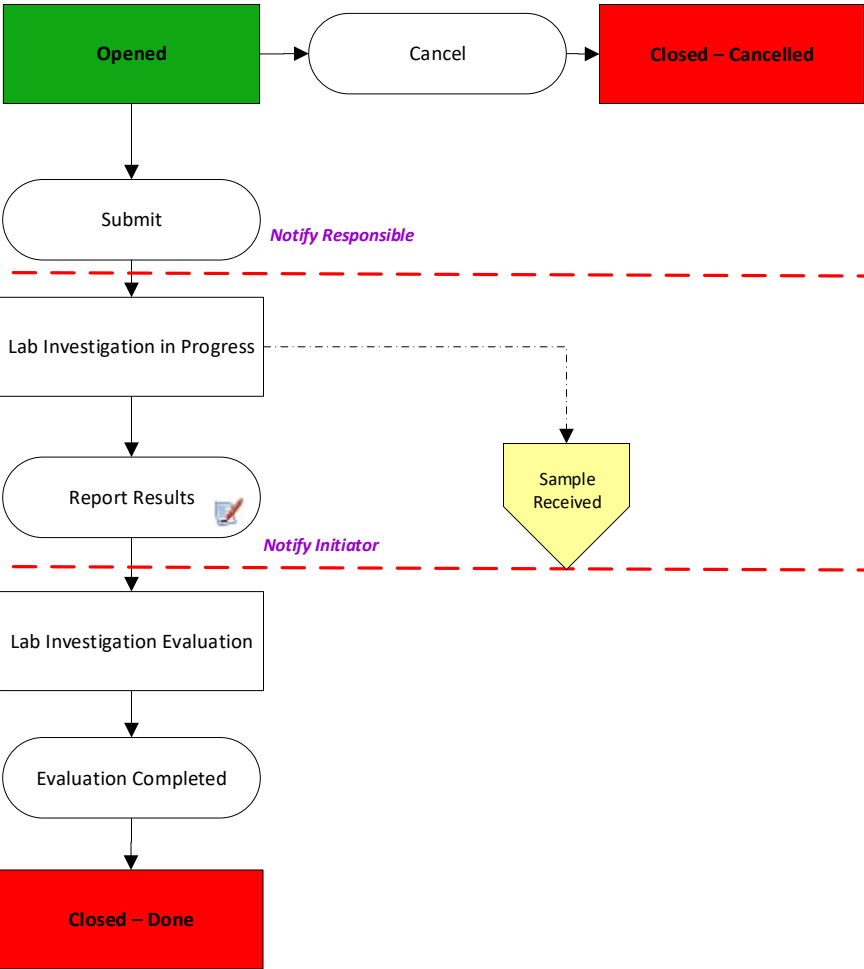
OOS





Lab Investigation

Initiator



Responsible

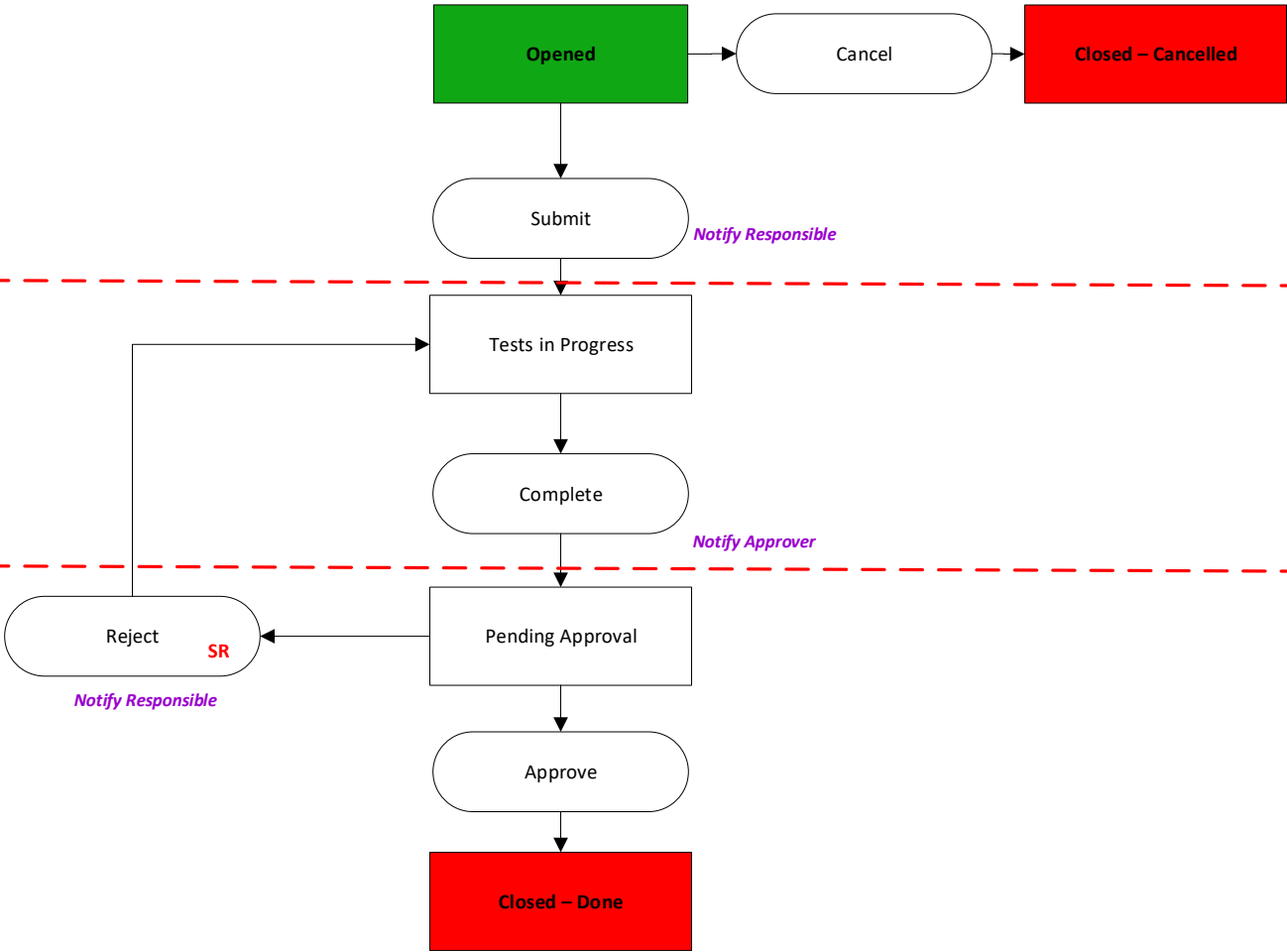
Initiator

Sample Received

Initiator

Responsible

Approver



Addendum

Initiator

QA

