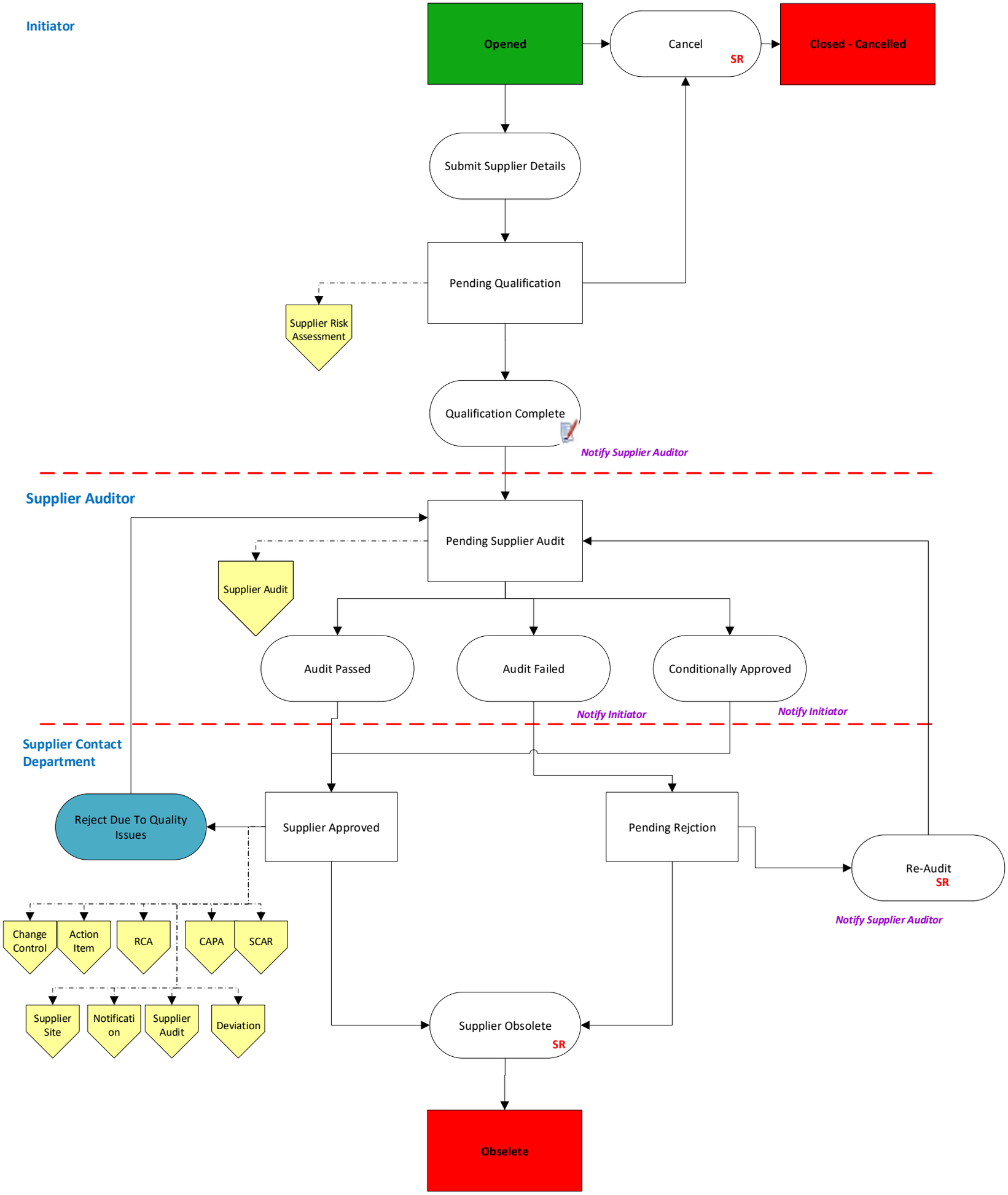
Configuration Overview

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.**

Supplier Quality Management

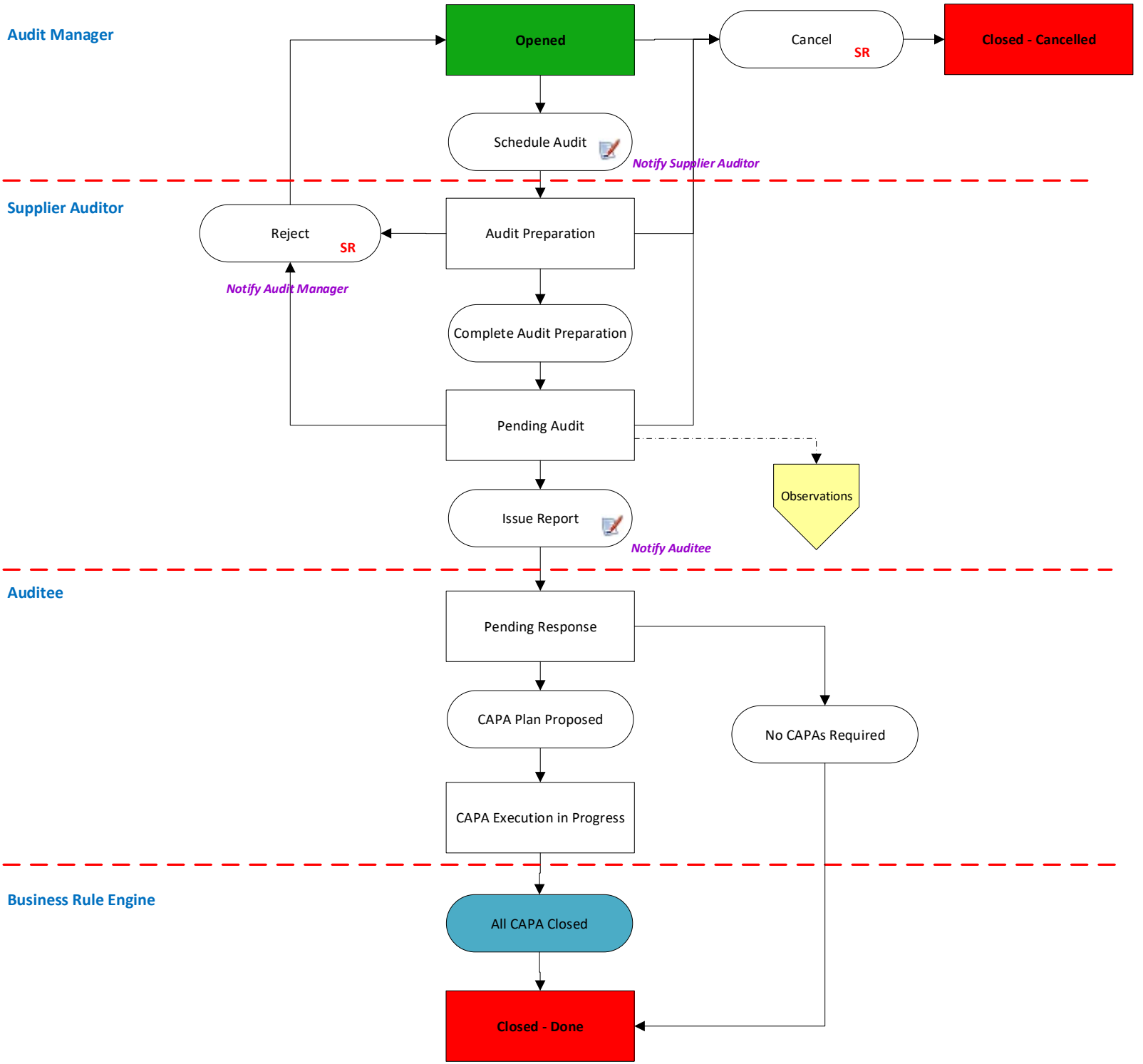


SQM

From Supplier

Supplier Audit

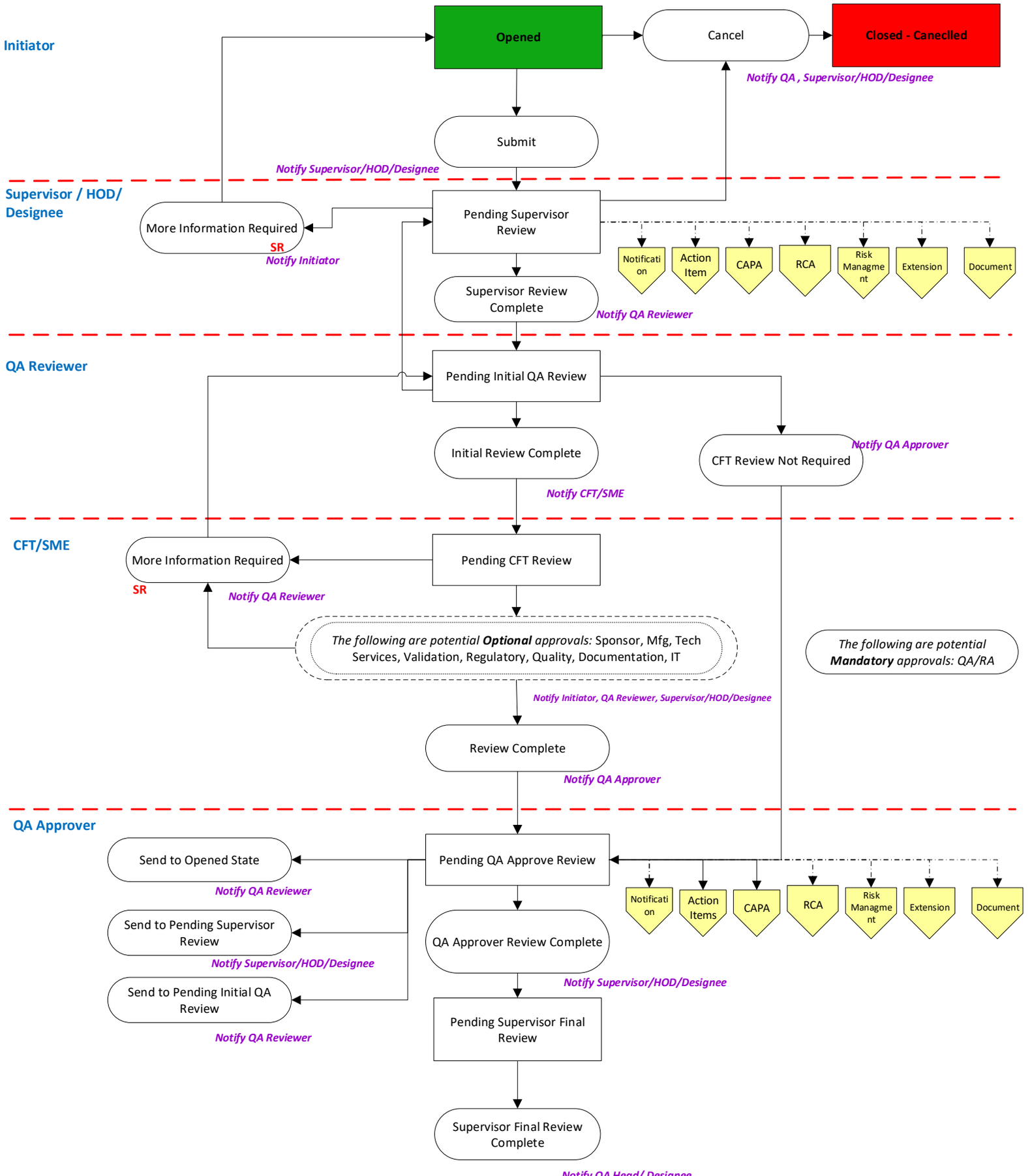
VidyaGxP
Data informs, wisdom discerns.



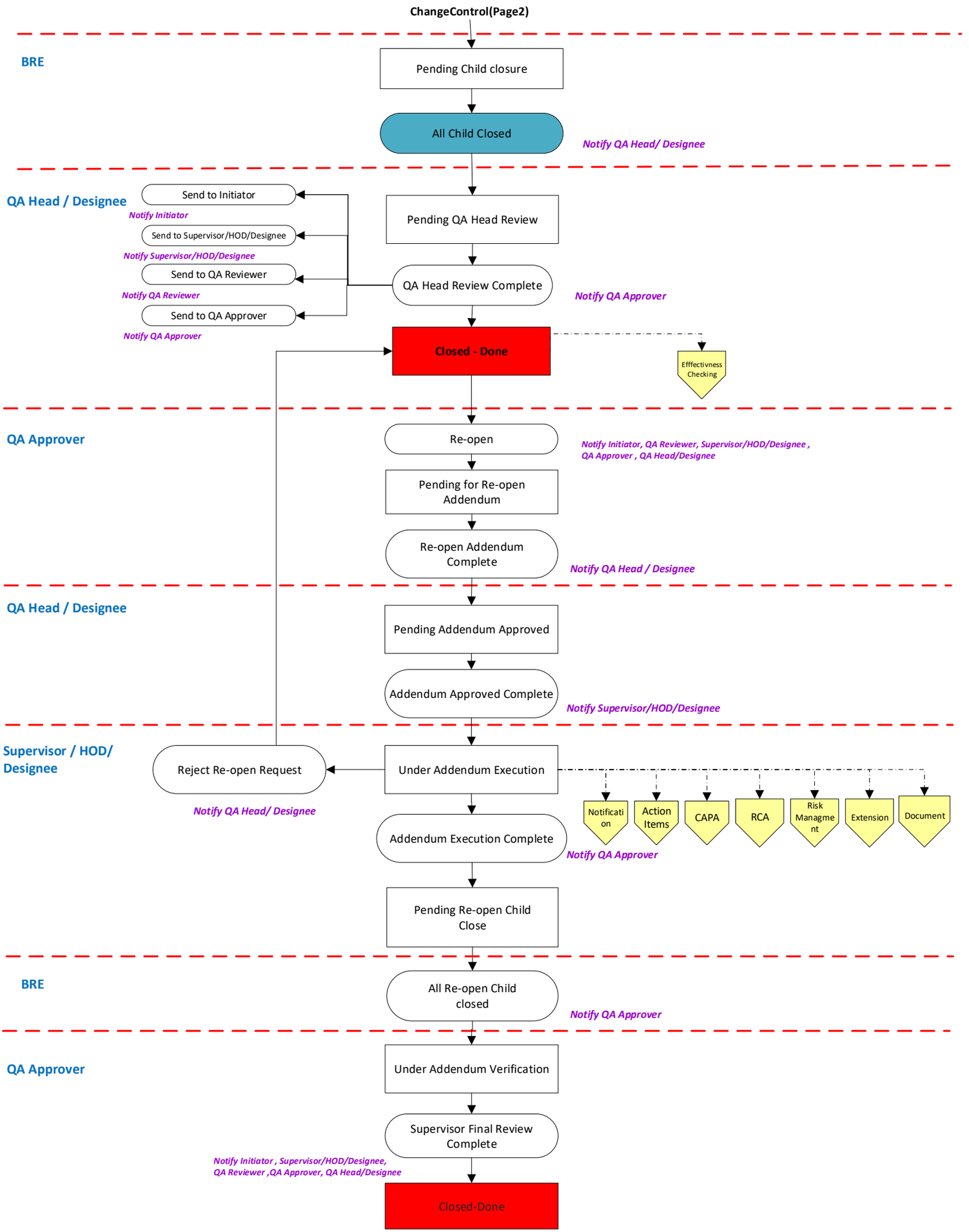
SQM From OOS

Change Control (Page1)

VidyaGxP
Data informs. wisdom discerns.

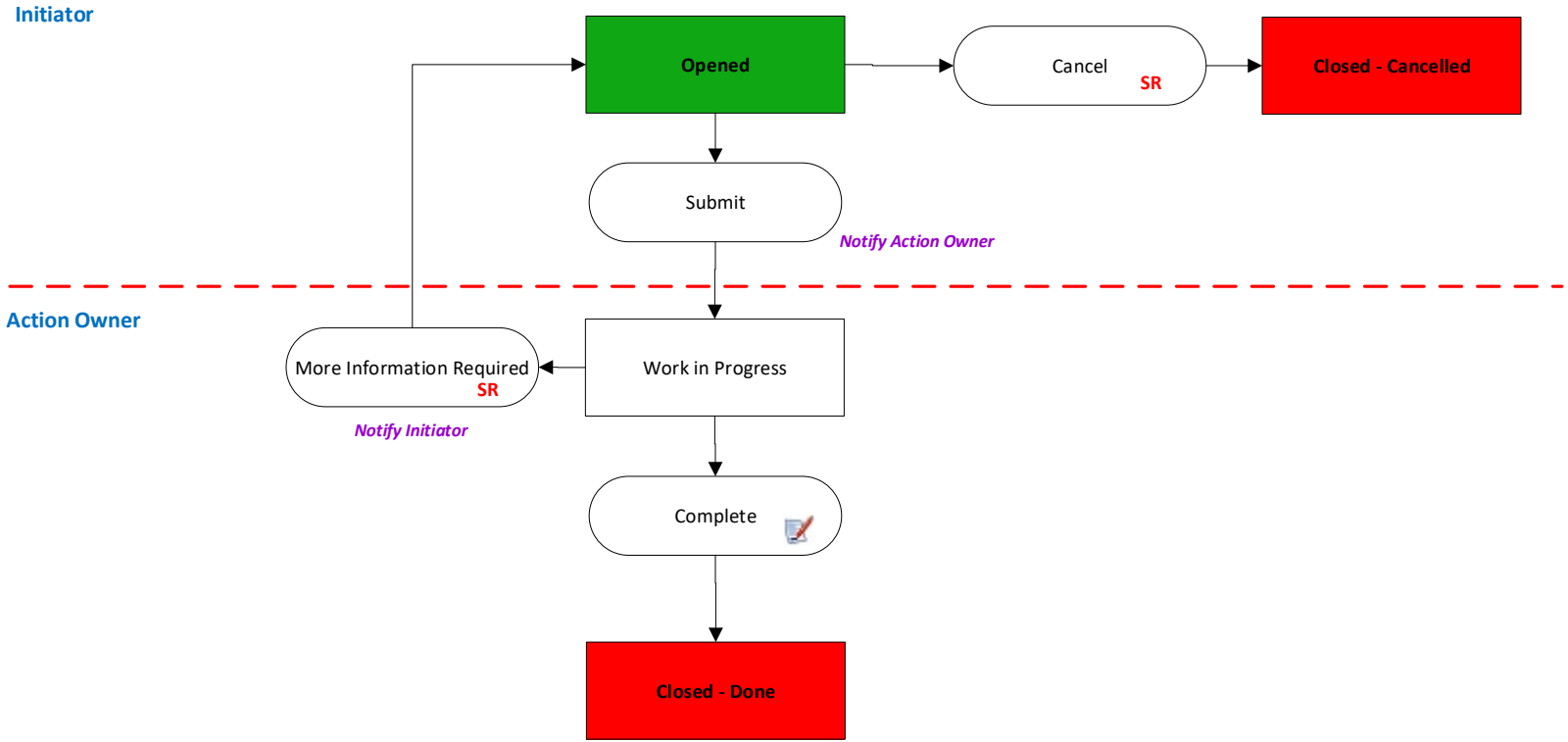


Change Control



SQM | From OOS | From IT Help Desk | From Change Control

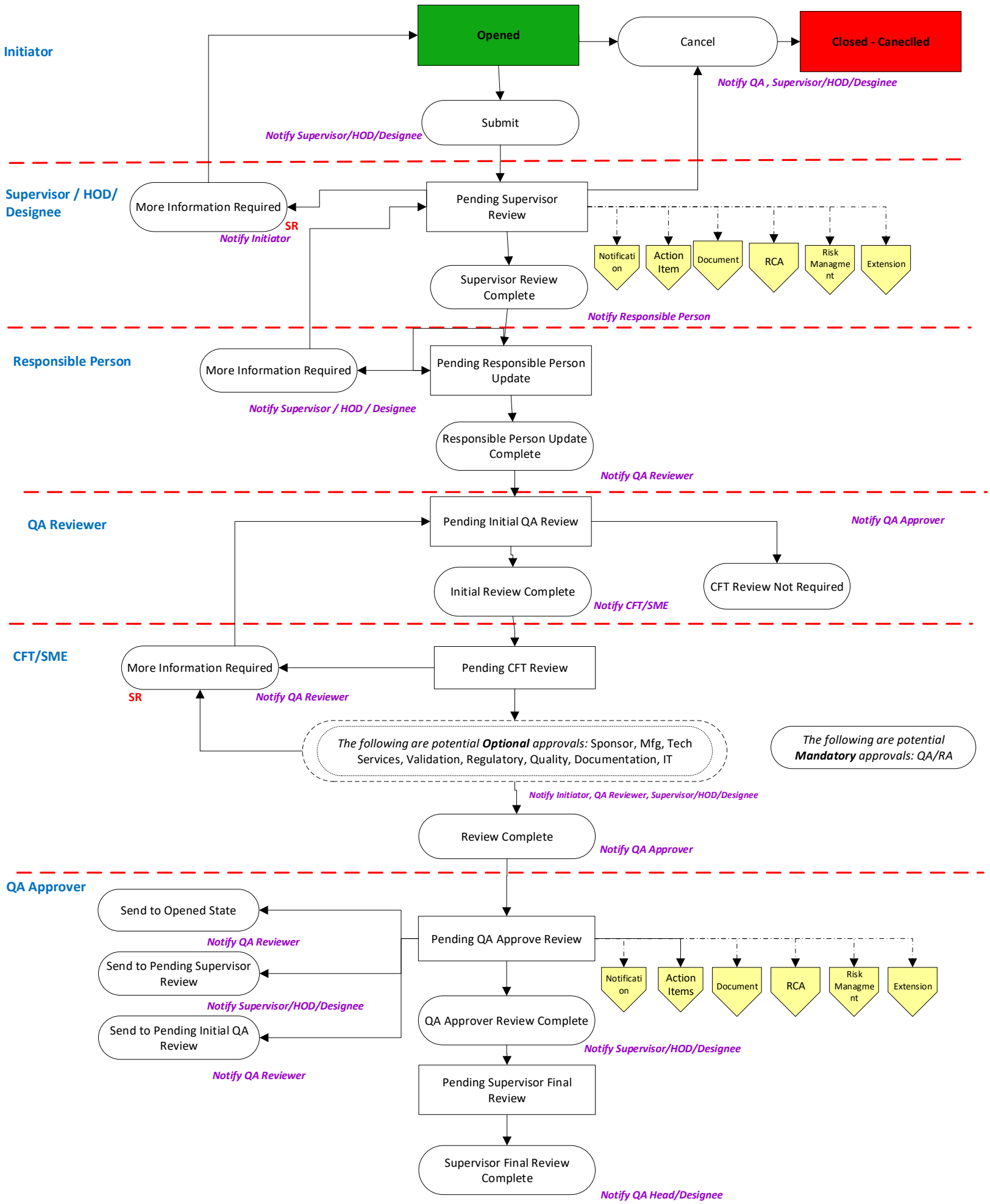
Action Item

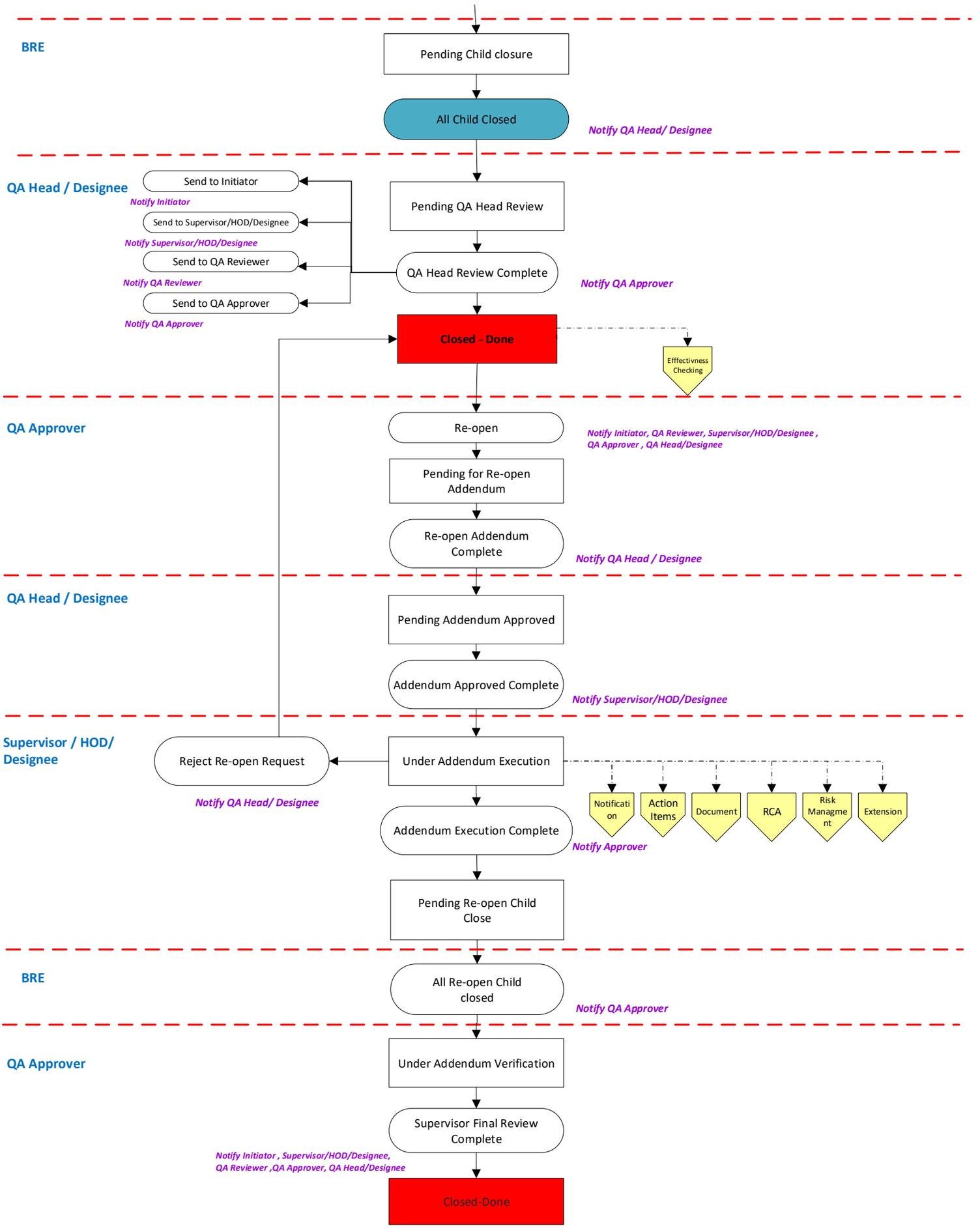


Compliance Task | From OOS | SQM

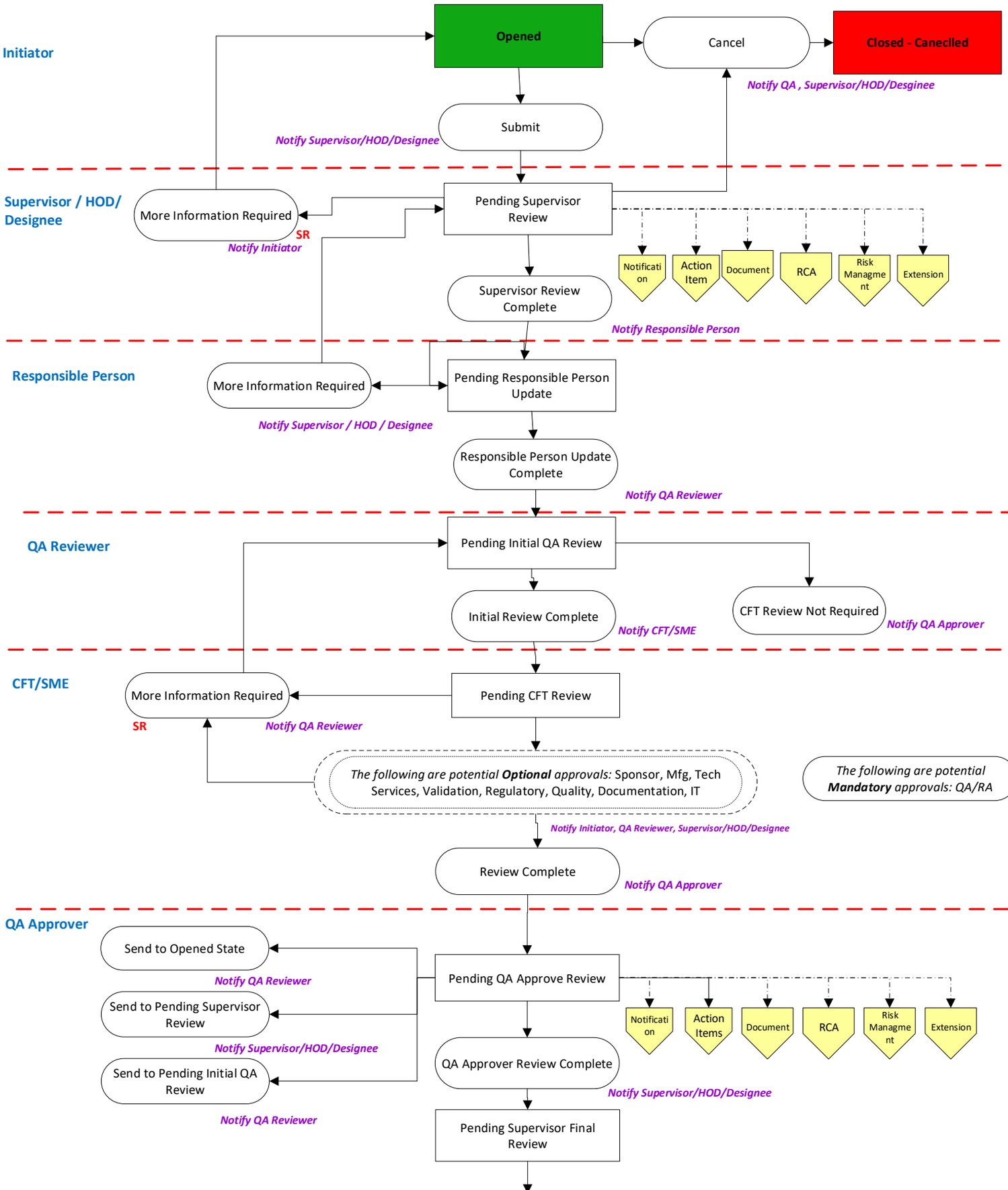
Root Cause Analysis(Page1)

VidyaGxP
Data informs, wisdom discerns.

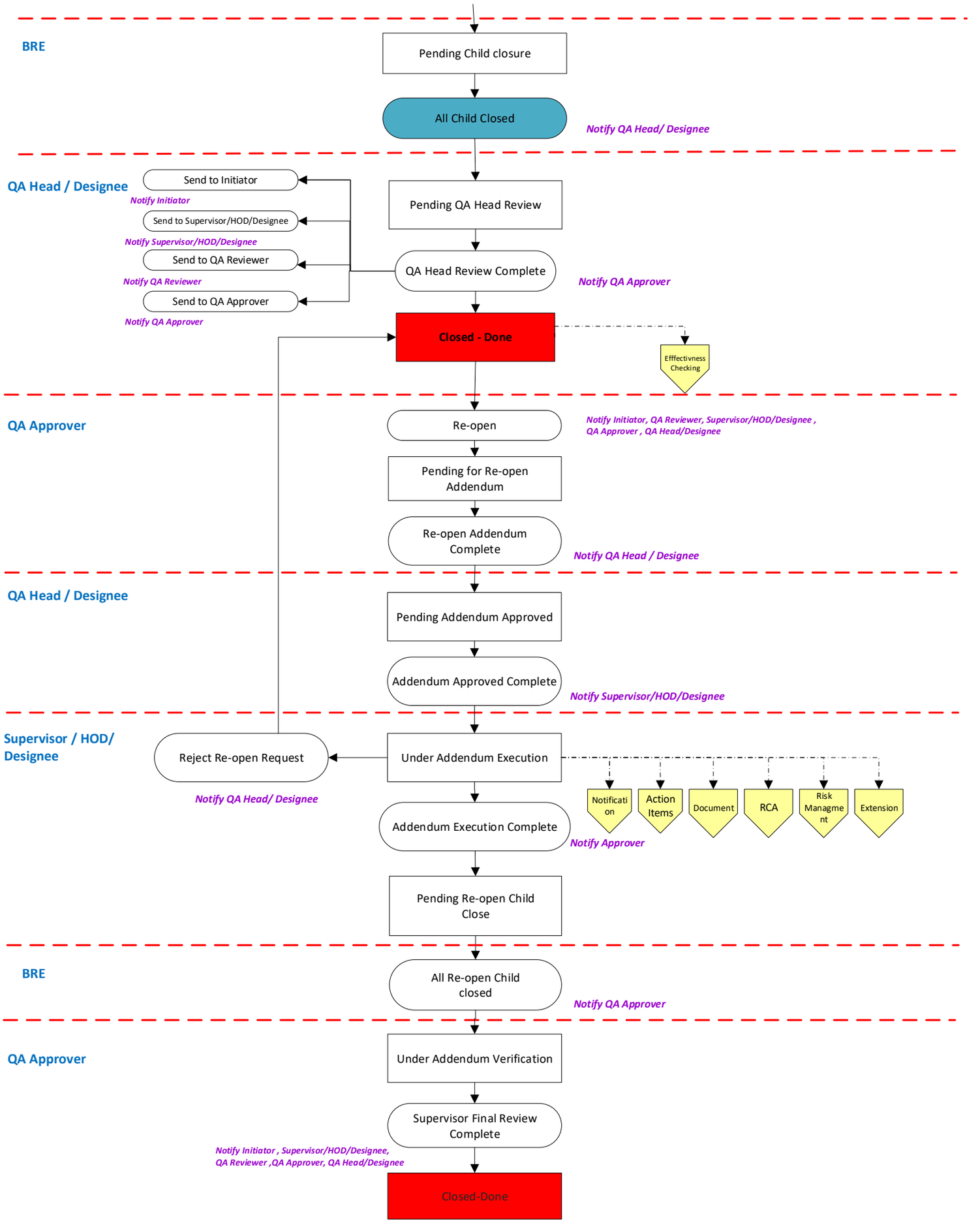



BRE
Pending Child closure
All Child Closed
Notify QA Head/ Designee
QA Head / Designee
Send to Initiator
Notify Initiator
Send to Supervisor/HOD/Designee
Notify Supervisor/HOD/Designee
Send to QA Reviewer
Notify QA Reviewer
Send to QA Approver
Notify QA Approver
Pending QA Head Review
QA Head Review 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

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

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

SQM

Deviation (Page1)

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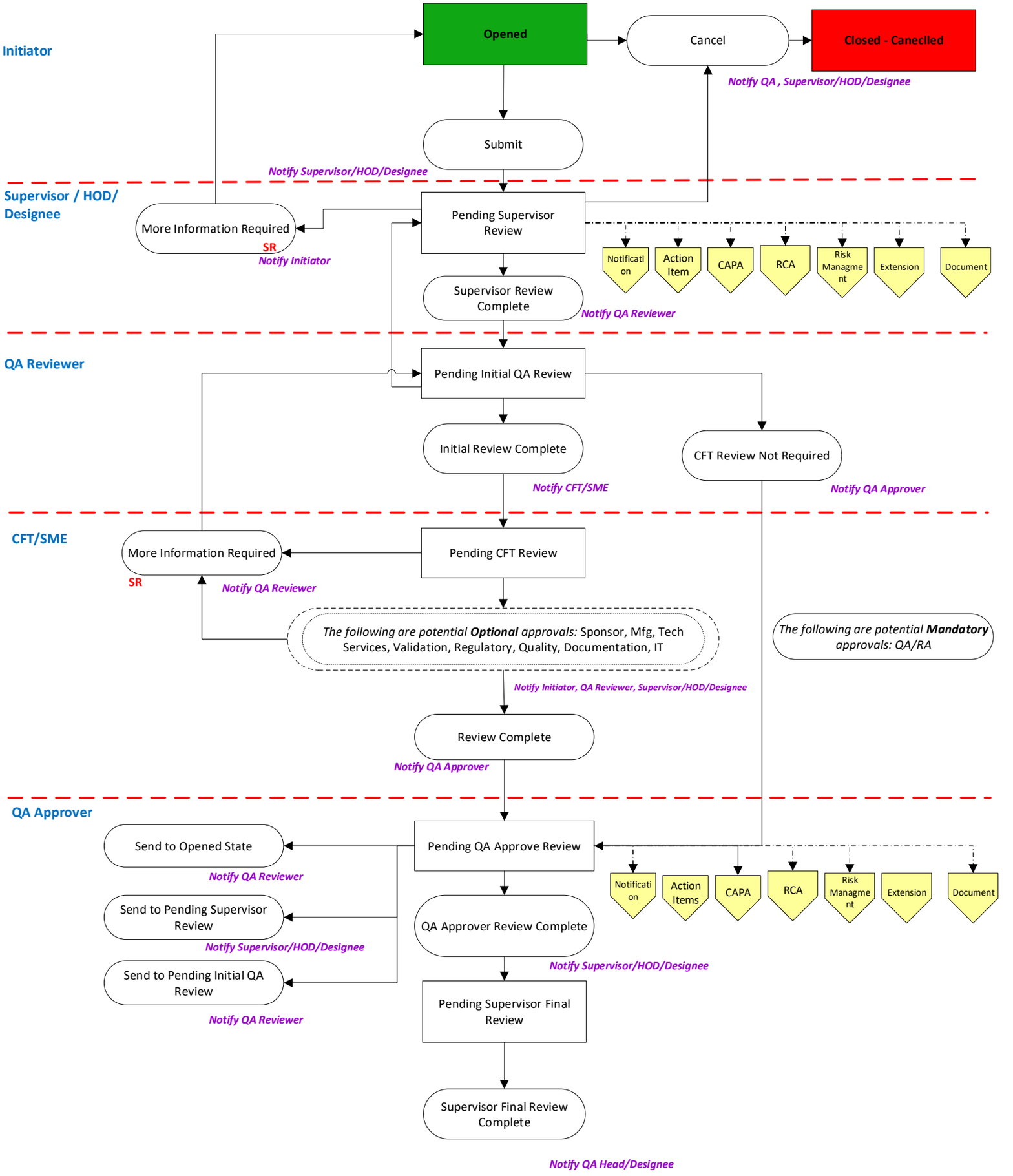
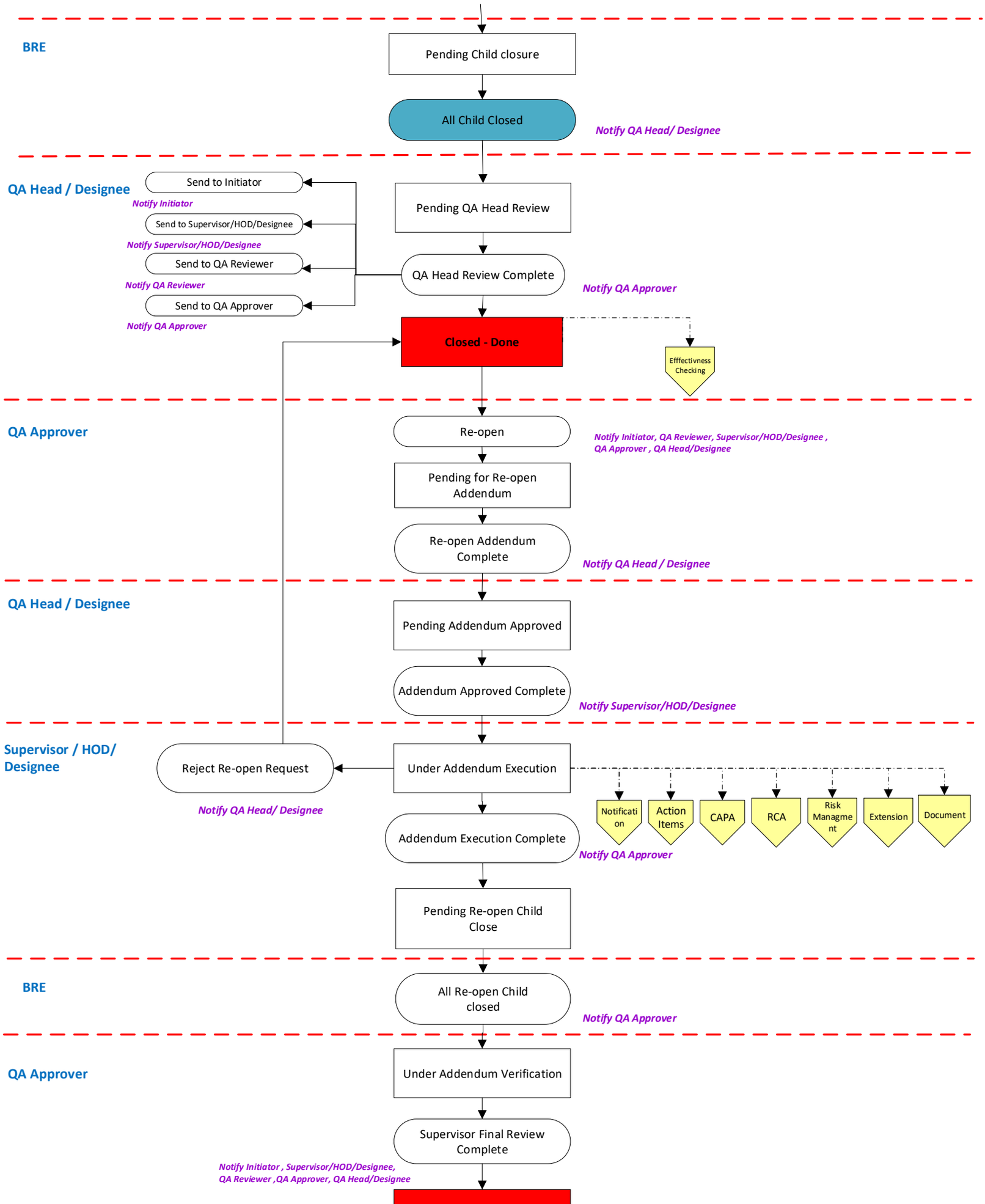
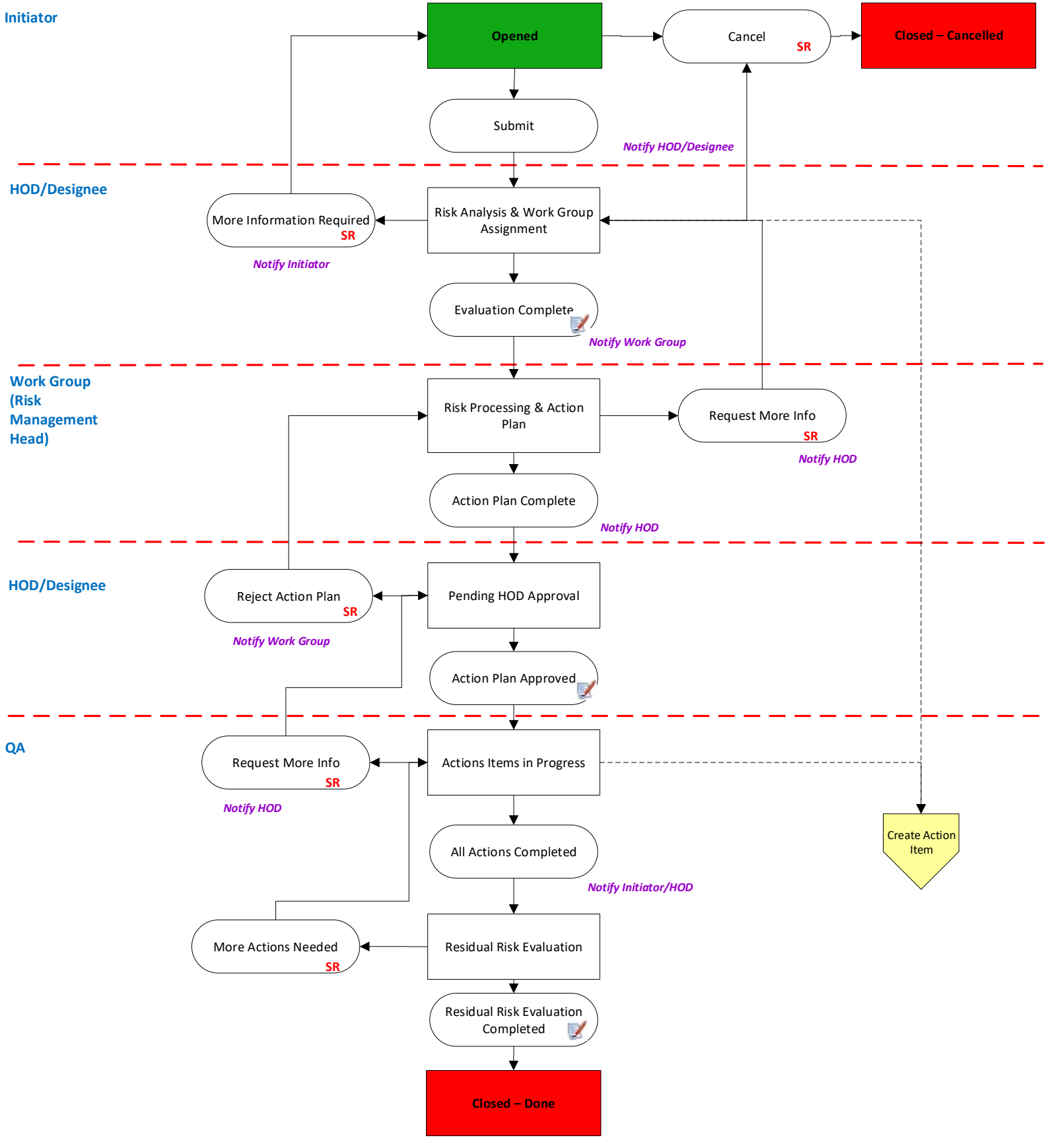


Deviation (Page2)



Risk Assessment