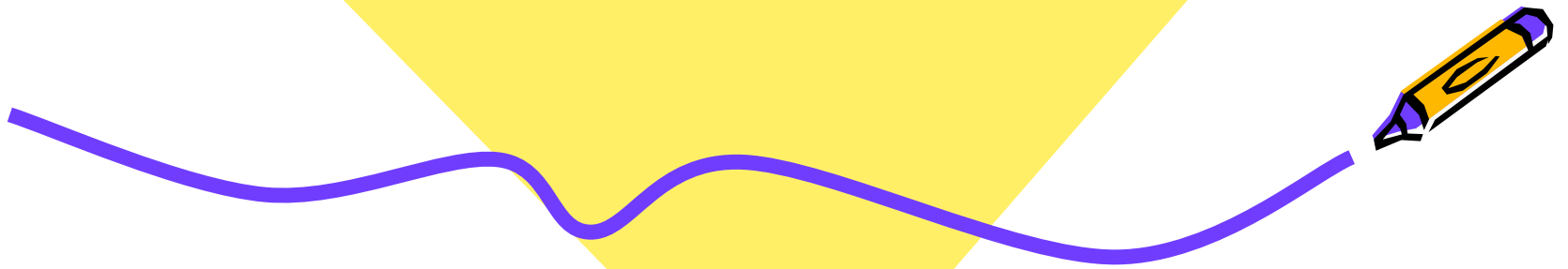


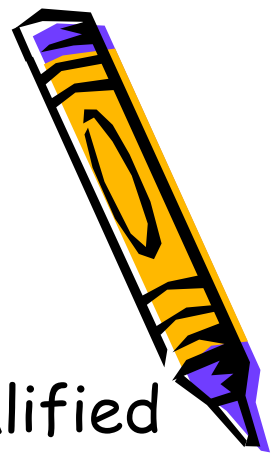


CHANGE CONTROL

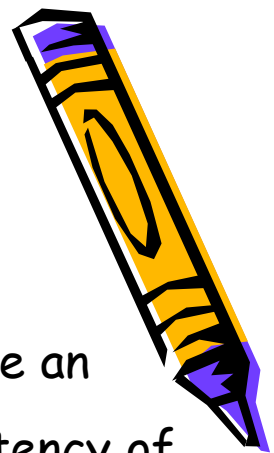


Definition

- **Change control** is a formal system by which a qualified representative of appropriate disciplines review proposed and actual changes that might affect the validated status.
- The intent is to determine the need for action that would ensure that the system is maintained in a validated state.



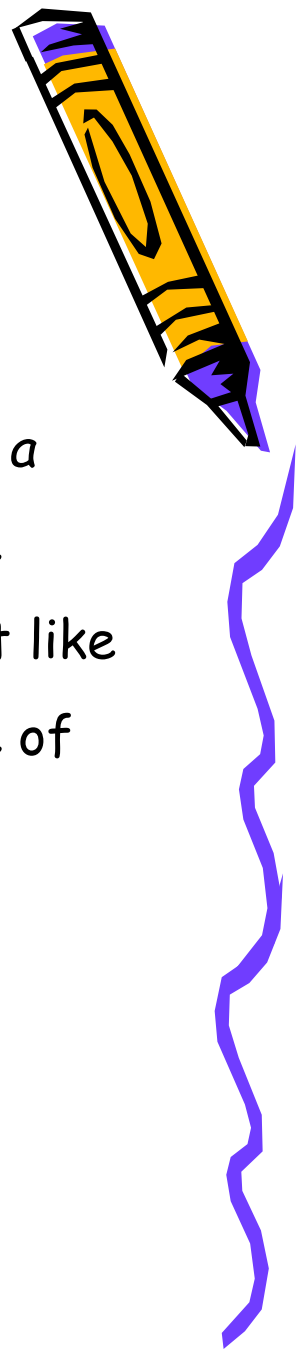
Types of Change control



- 1 - **Minor change** is a change that has minimal potential to have an adverse effect on identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product.
- 2 - **Major change** is a change that has a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product.
- 3- **Critical change** is a change that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of a product as they may relate to the safety or effectiveness of the product.



Levels of approval of Change control



- *"Level -1 signifies level of approval required to approve a change"* Initiator department and the quality assurance department only e.g. SOPs related to single department like operating procedure of equipment's, cleaning procedure of equipments, etc.



Levels of approval of Change control

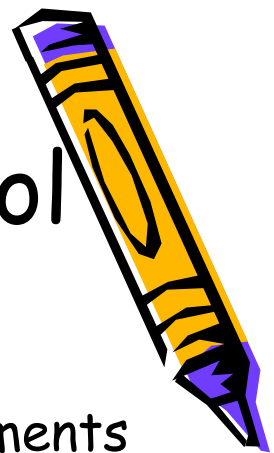


- *"Level -2 signifies level of approval required to approve a change"* Initiator department and all other interlinked departments within the plant e.g. Change in SOPs which are being followed at different departments at plant level.

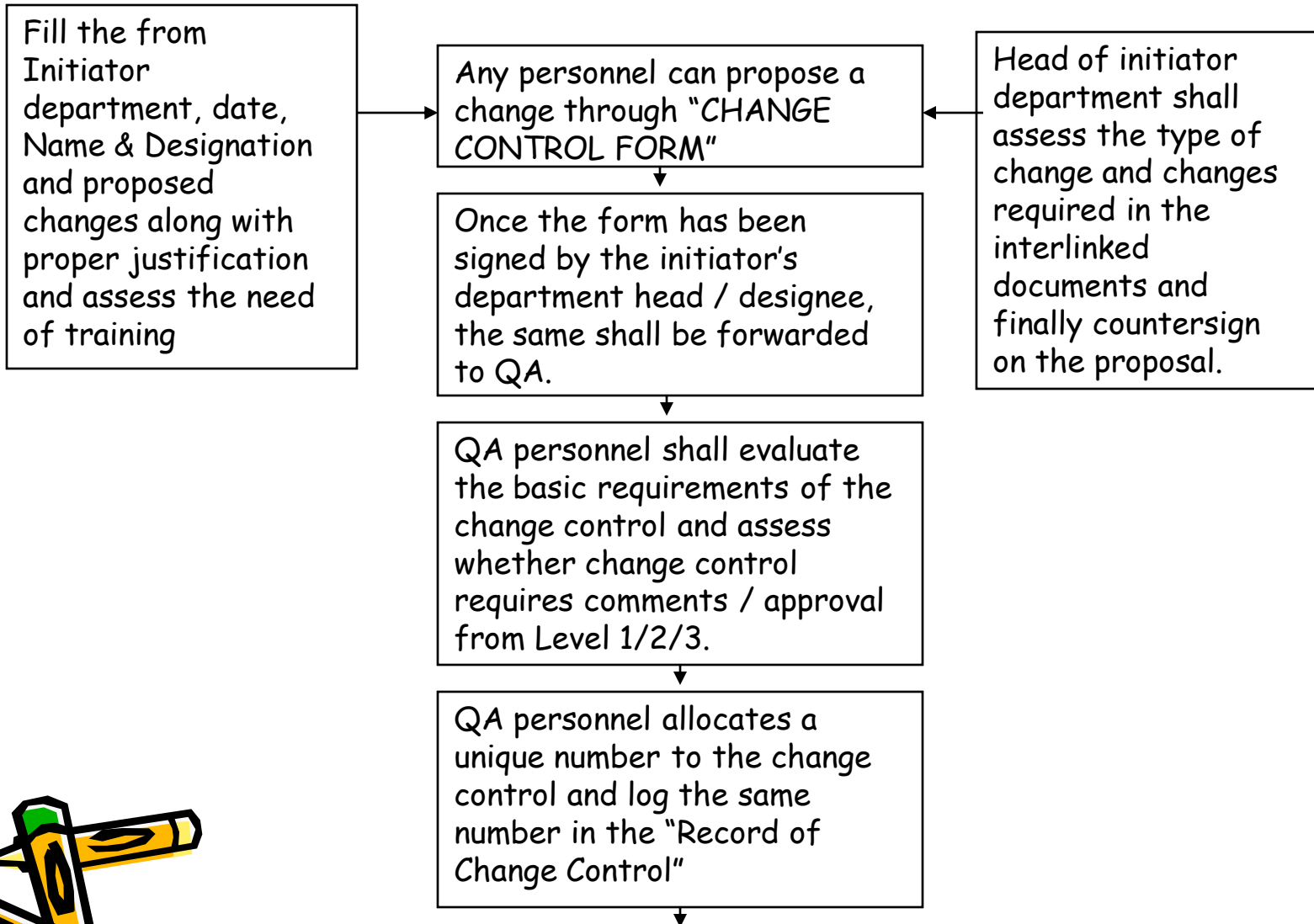
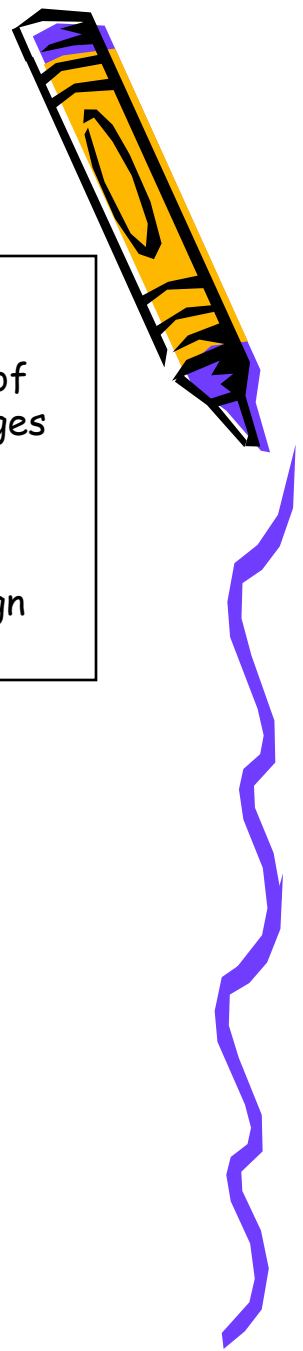


Levels of approval of Change control

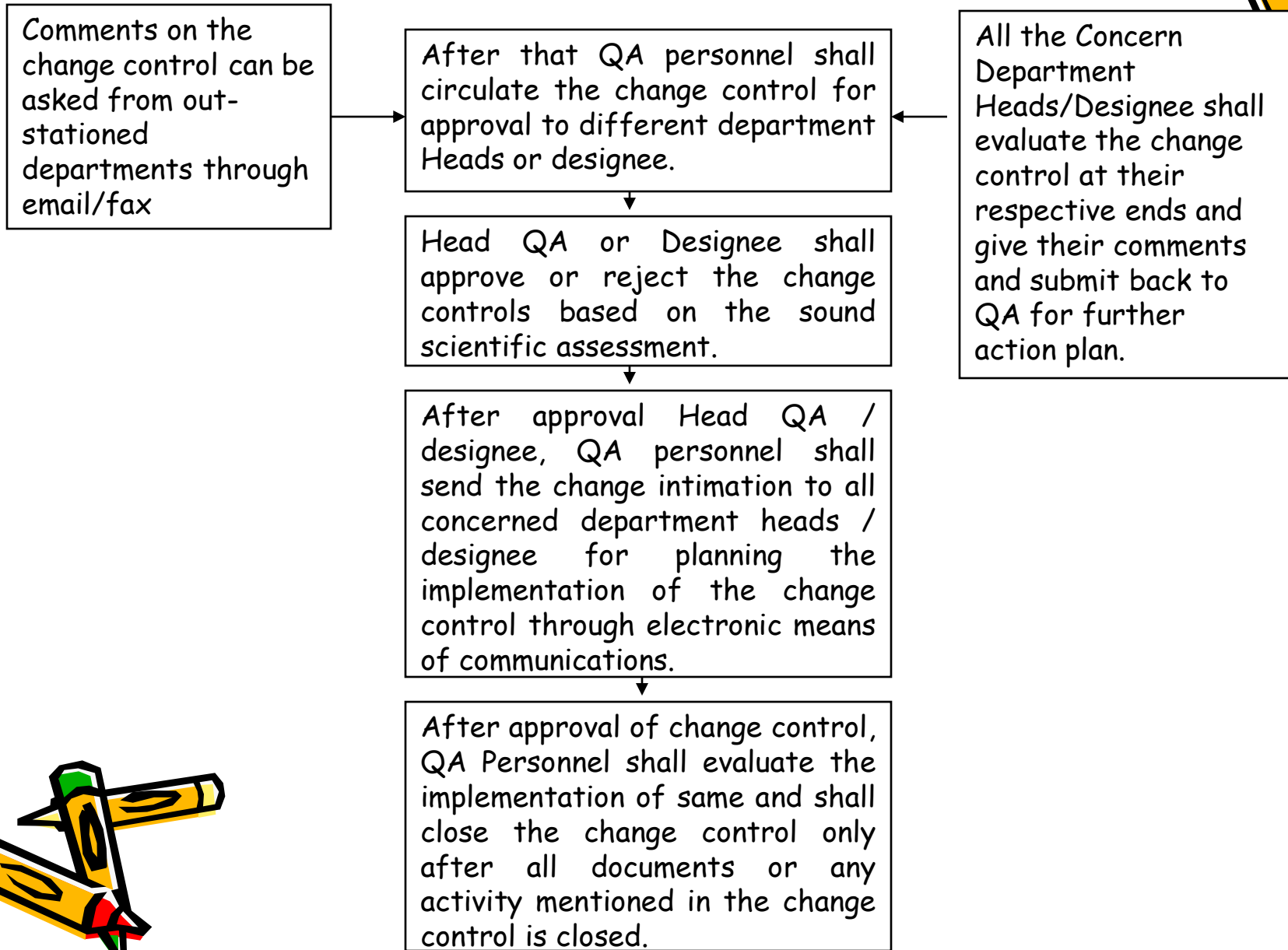
- "Level -3 signifies level of approval required to approve a change" Initiator department and all other relevant departments (within plant or outside the plant) including marketing, RA and Quality and Compliance, etc. e.g.
- Change Controls which include change in specifications /STPs / GTPs / Artworks / License related issues / BMR / process change / Vendor change, etc.
- These type of changes may require company's R.A. department to ask for approval of regulatory agency(ies) that have impact on regulatory dossiers submissions.



Procedure of Change Control

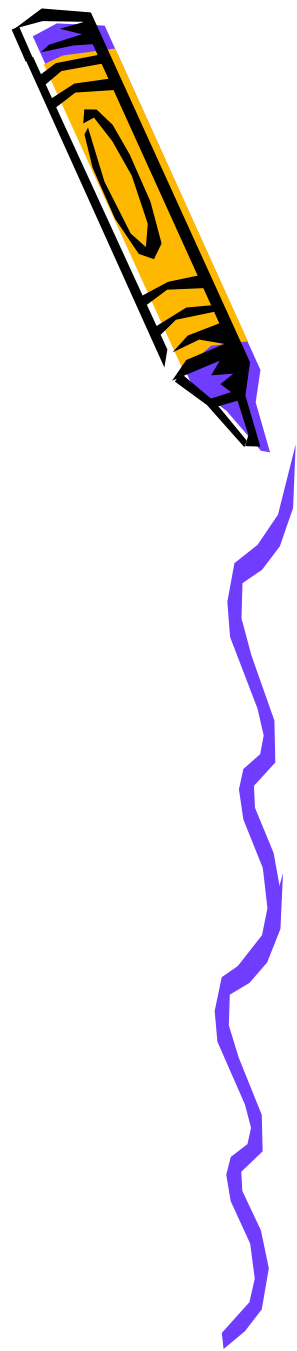


Procedure of Change Control



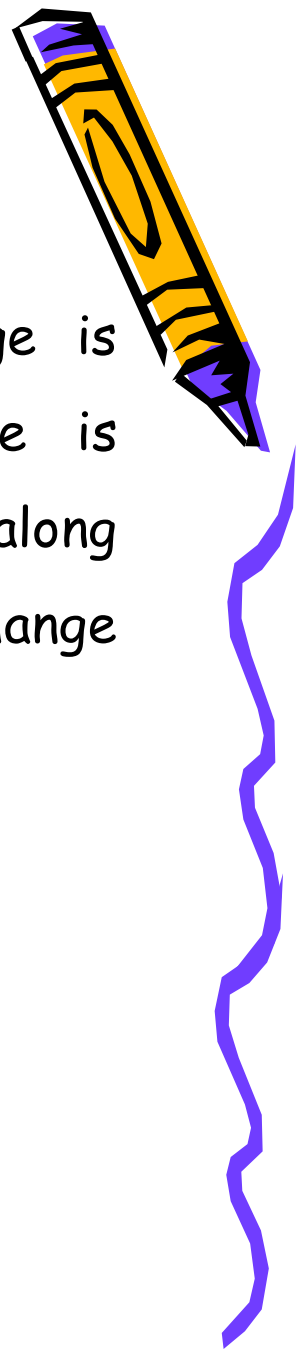
Steps of change control

- Documenting the change request
- Formal assessment of the change
- Proper Planning and timeline
- Final Impact assessment of the change
- Implementation of change
- Final assessment after implementation



Steps of change control

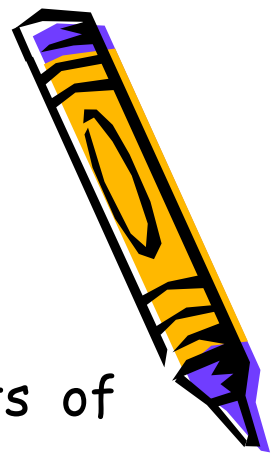
- **Documenting the change request:** When any change is proposed, the request form is filled and change is categorized in minor, major, critical and recorded, along with informal assessments of the importance of that change and the difficulty of implementing it.



Steps of change control

- **Formal assessment of the change**

The justification for the change and risks and benefits of making/not making the change are evaluated. If the change request is accepted, a change control review team will be assigned. If the change request is rejected, that fact is documented and communicated to the Initiator.



Steps of change control



- **Proper Planning and timeline:** The review team responsible for the change reviews approval or rejection, implementation and plans properly for its implementation within timeline.

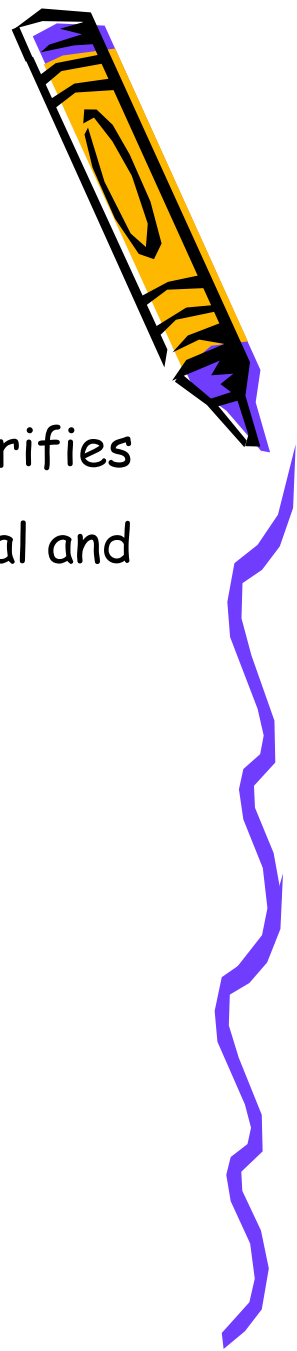


Steps of change control

- **Final Impact assessment of the change:** The review team does correct impact assessment of the change with respect to *GMP*. If the change is found to have no impact on *GMP* and it is improving for the system, then the review team requests approval and gives the timeline for implementation.



Steps of change control



- **Implementation of change:** The review team also verifies the implementation status of the change after approval and the timeline of the change implementation.

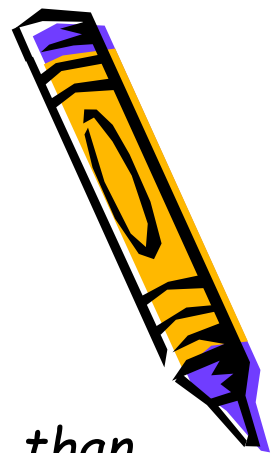


Steps of change control

- **Final assessment after implementation:** If the initiator, review team and QA are satisfied that the change was implemented satisfactorily, the change request is closed.



REMEMBER!



- *If a Change Control is pending for approval for more than 30 working days from the date of login, it is the discretion of Head QA or designee to approve or reject the change control.*
- *QA personnel shall take the re-evaluation of the change controls after every three months or need based.*



THANK YOU!

