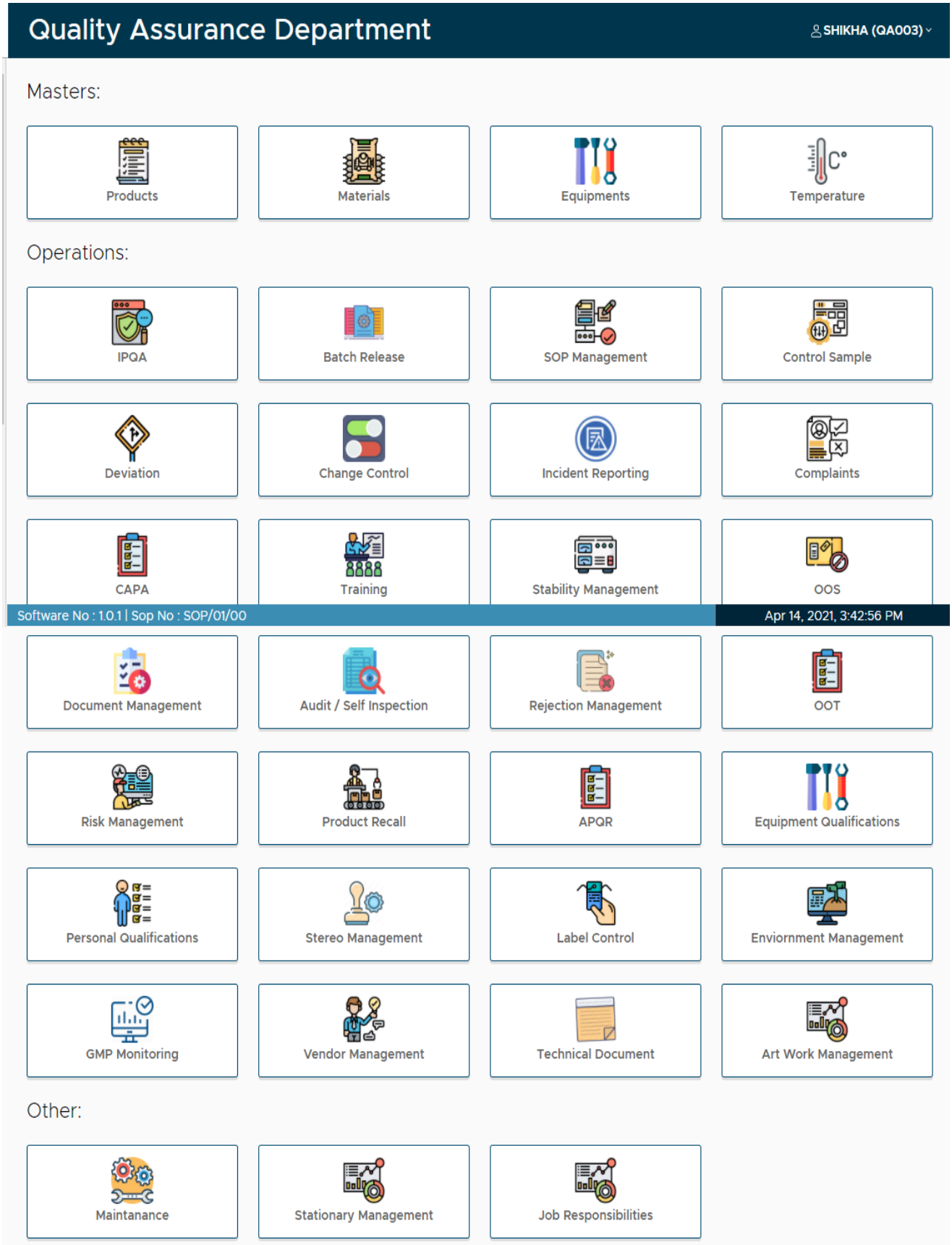
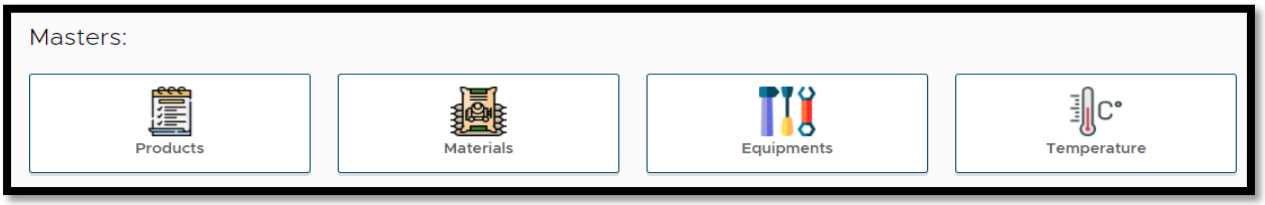
Quality Assurance

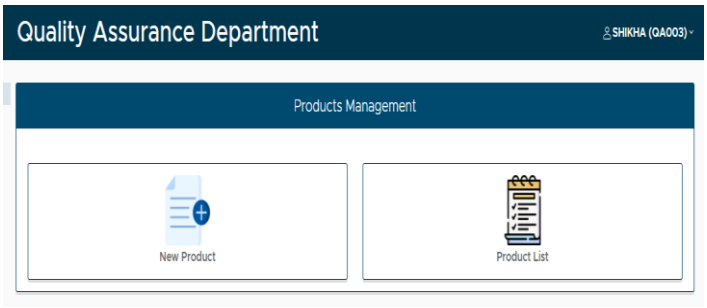


Quality Assurance

- **Masters**



1. Product Master

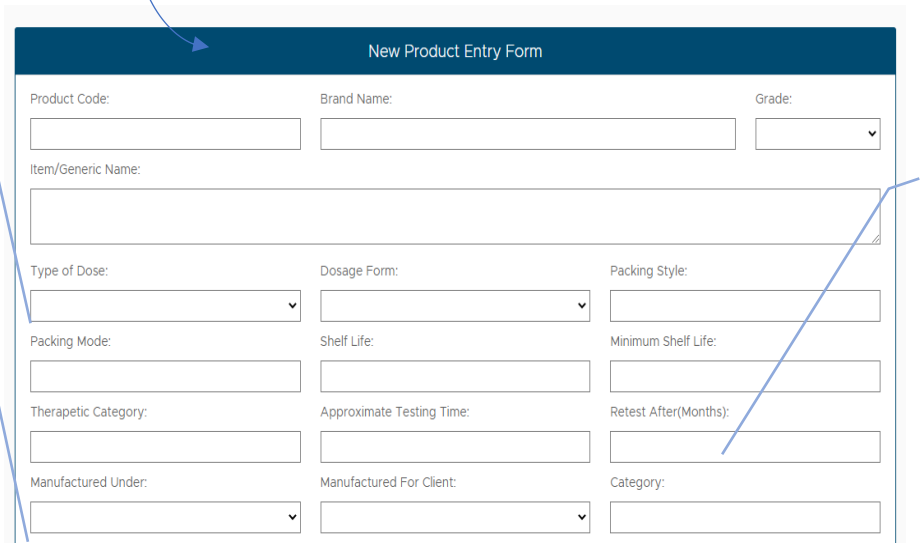


1.Solid
2.Semisolid
3.Liquid

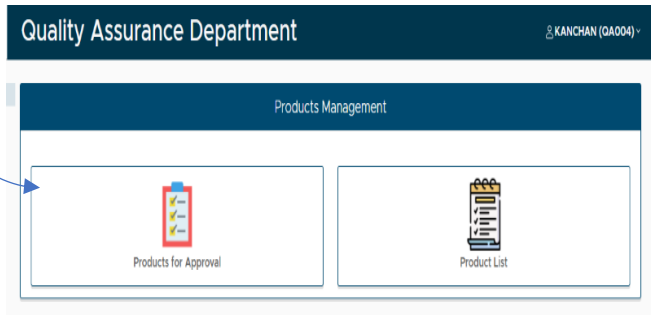
1.Self

2.LL

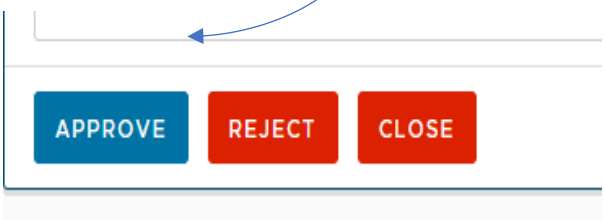
3.Contract Manufacturing



On the Basis of Retest Period PGMP will give you the reminder before 7days

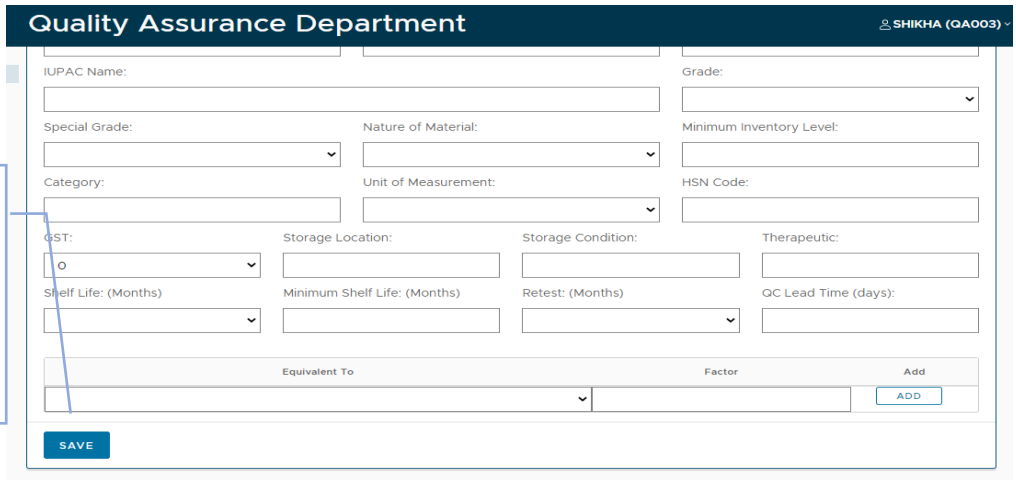


After Entry of New Product to Product; Take approval from Manager login as shown in fig. aside



Quality Assurance

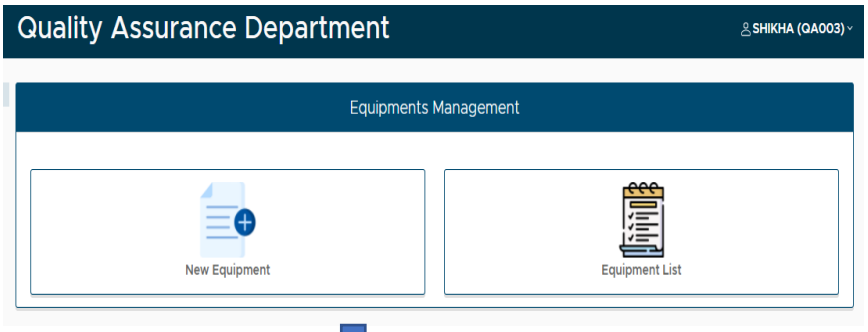
2. Material Master



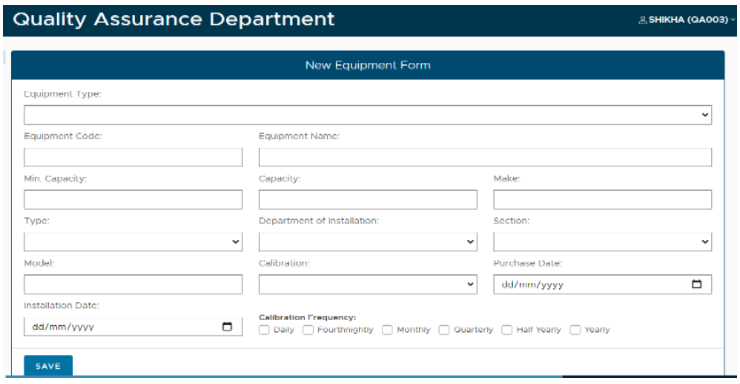
The Equivalent to factor will be appear when you will add it in Material Master.

[Take approval of New Material in Manager's Login]

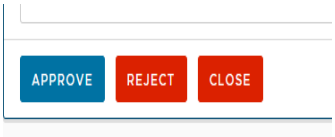
3. Equipment Master



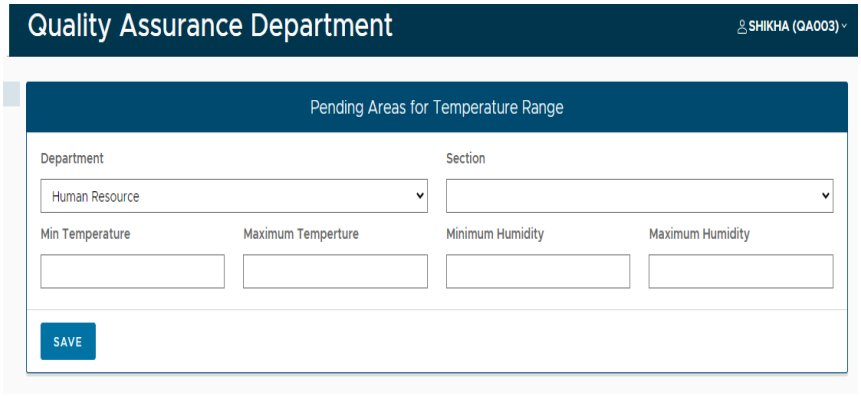
[Officer



[Manager Login]



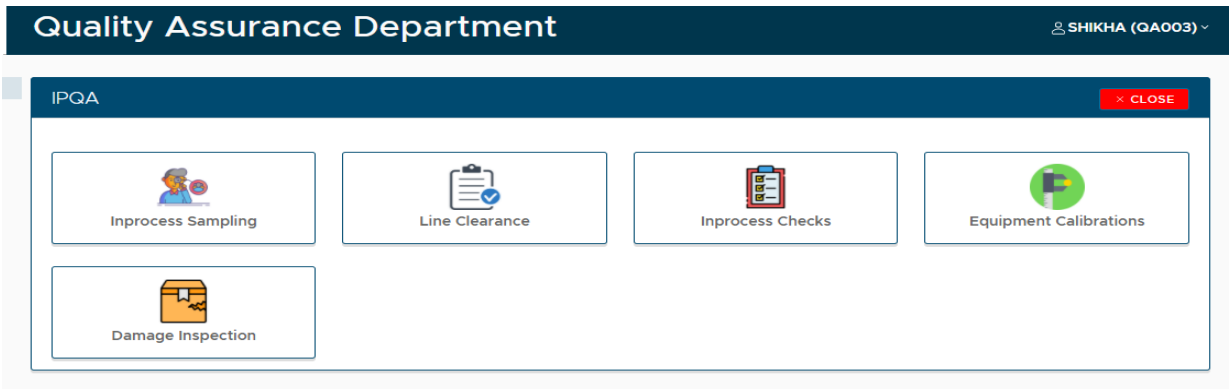
Quality Assurance



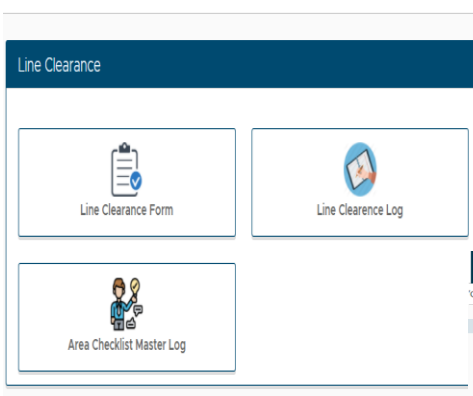
- The Department and section master is given in HR Department.

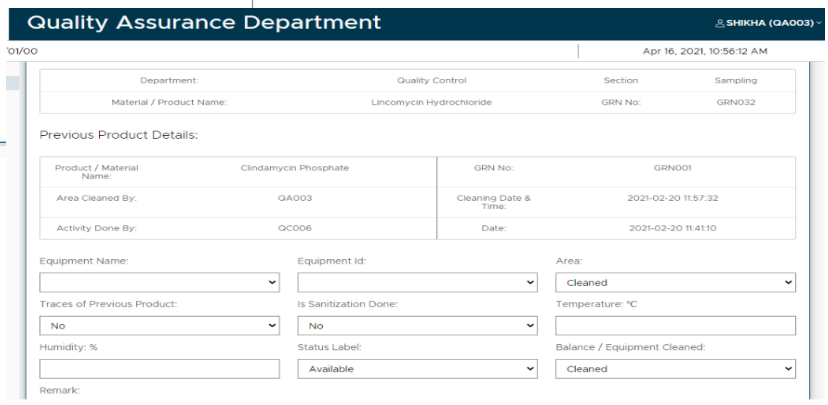
- After adding new Department and section through master from HR department it will come for area temp. and humidity record.

- **IPQA**

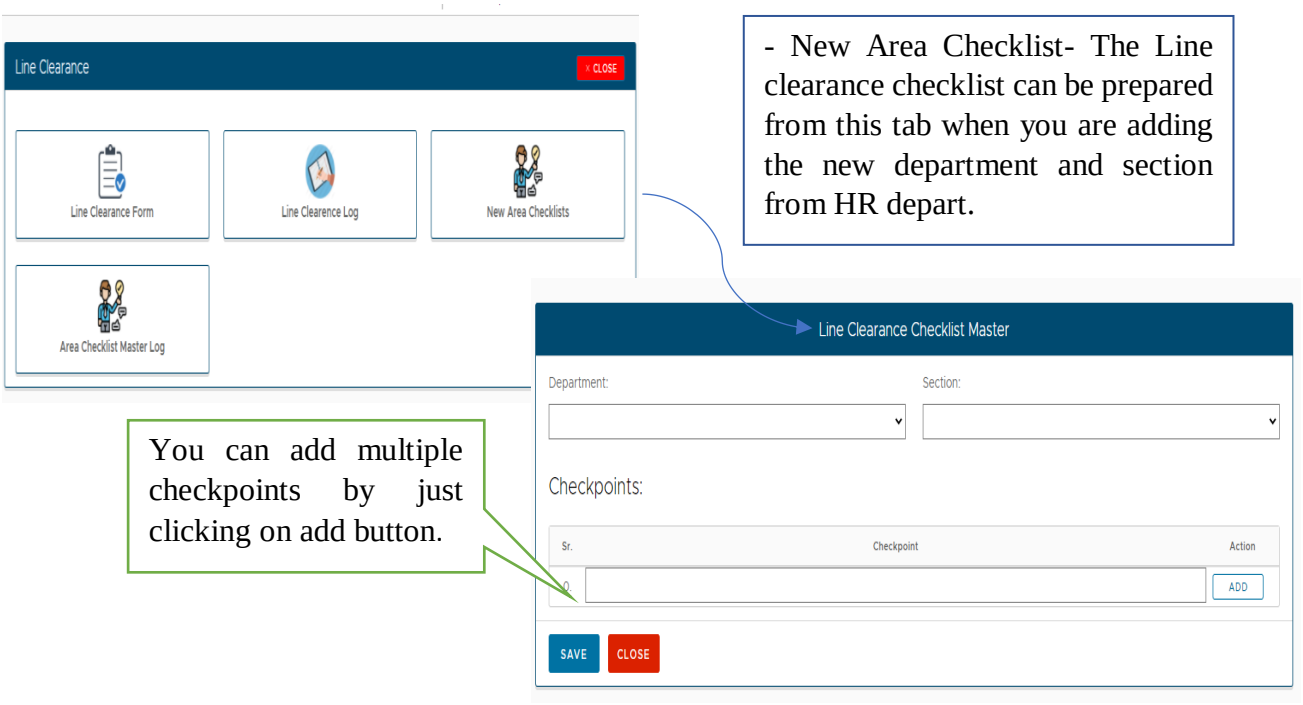


1. **In process sampling** – The In process sampling entries will come from Production department.
2. **Line Clearance** – All kind of Line Clearance request from Stores, Production, Packing and QC department will come to QA.





Quality Assurance

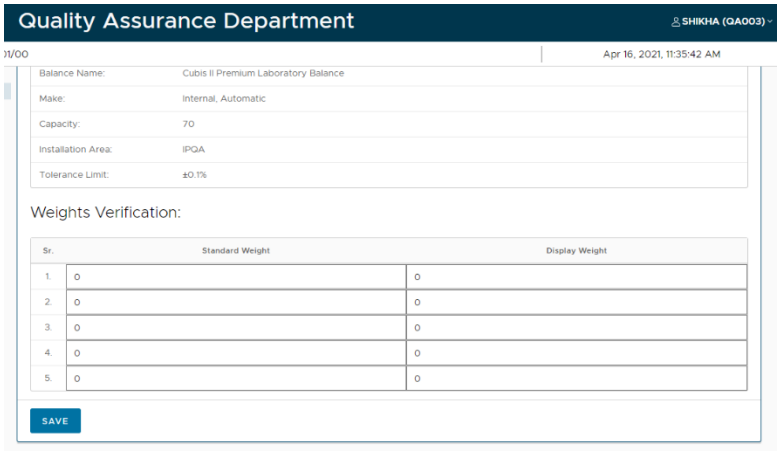


- New Area Checklist- The Line clearance checklist can be prepared from this tab when you are adding the new department and section from HR depart.

You can add multiple checkpoints by just clicking on add button.

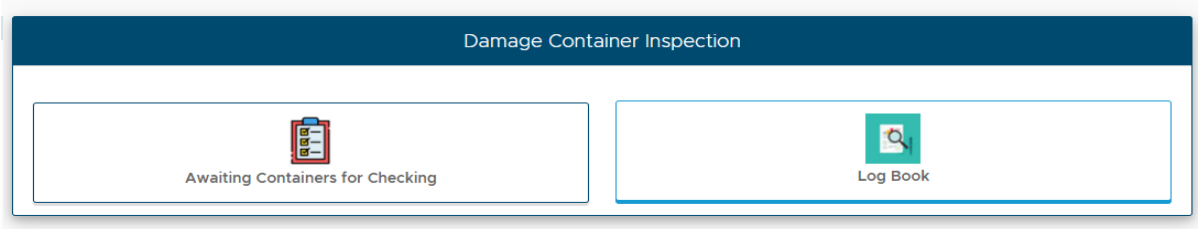
3. **In process Checks** – It will also come from production department.

4. **Daily Verification-**



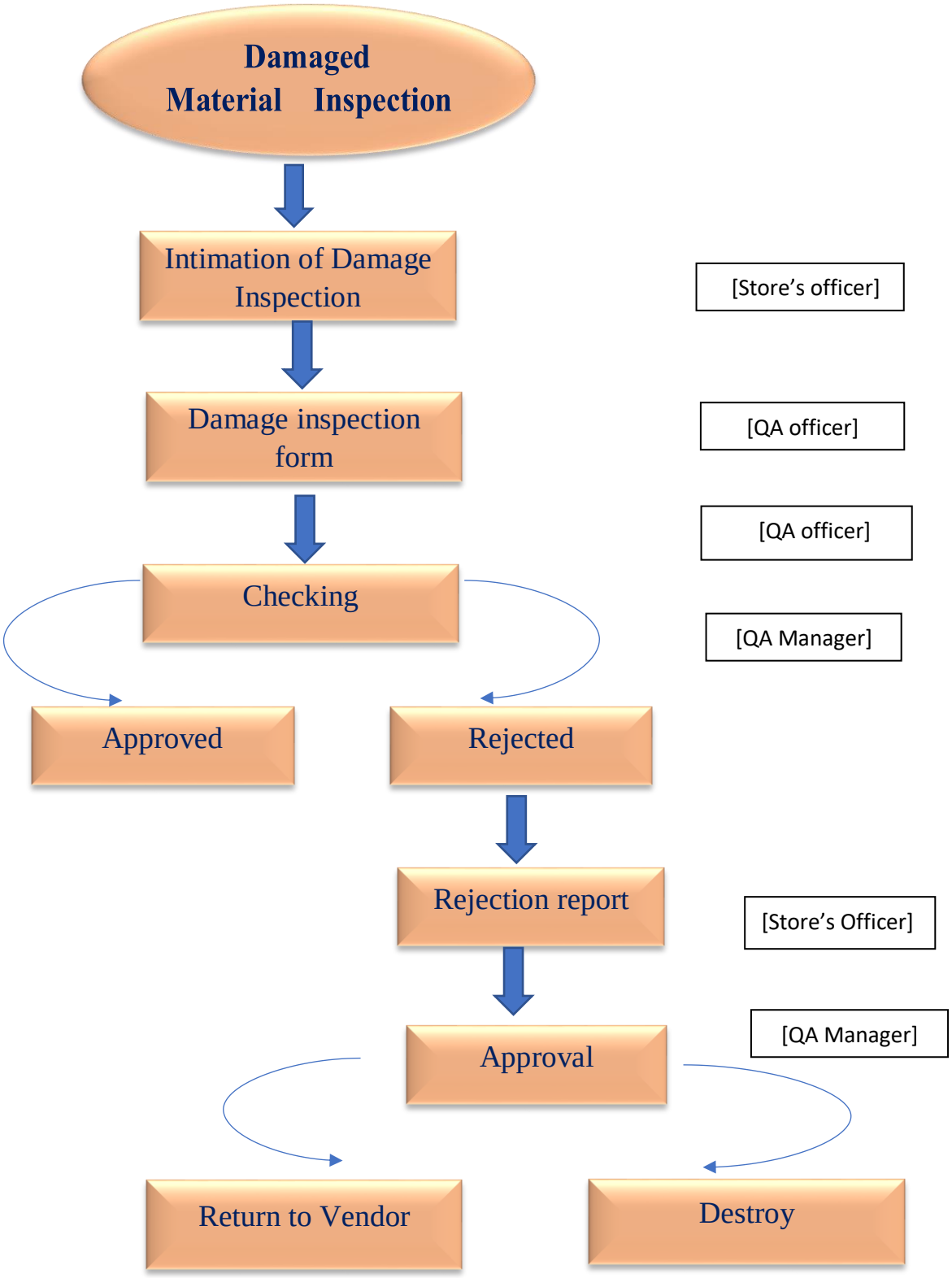
- The Daily Verification of balance can be done from the given tab, Here the standard weights and tare weights you have to enter.
- If the calibration has not been done as per the frequency that equipment will not be accepted by software for performing operation.

5. **Damage Container Inspection:**



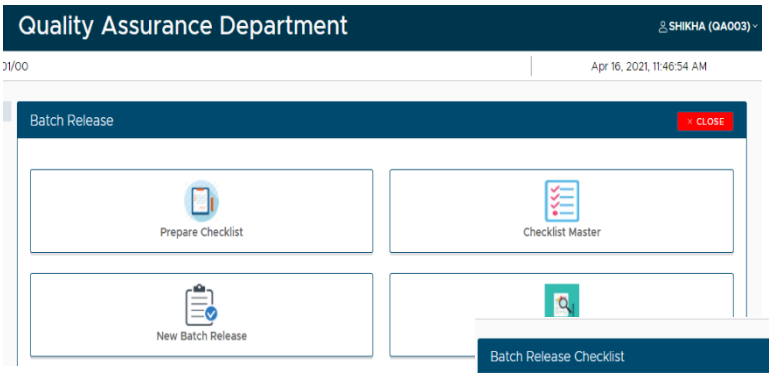
Quality Assurance

- Flow of Damage Container Inspection:

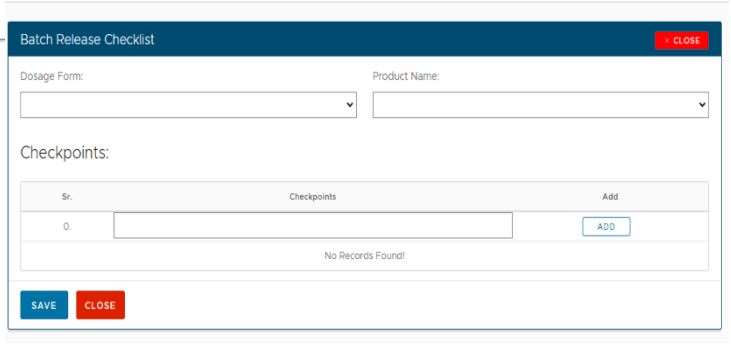


Quality Assurance

- **BATCH RELEASE**

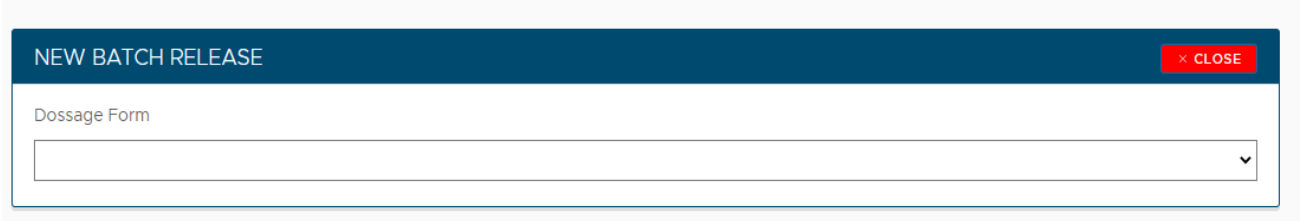


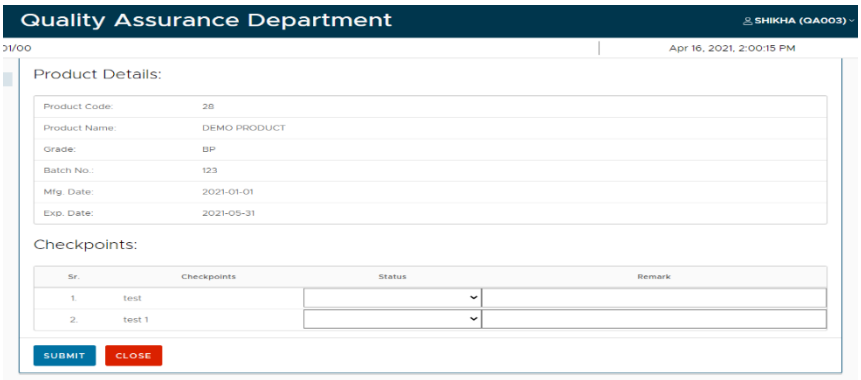
1. Prepare Checklist
- for preparation of new batch release checklist: Prepare checklist » fill the form for Batch release checklist
- Add Checkpoints; Save



- The revision of Checklist only can be done after approval of manager.
- The executive or manager only can revise the checklist.

2. New Batch Release



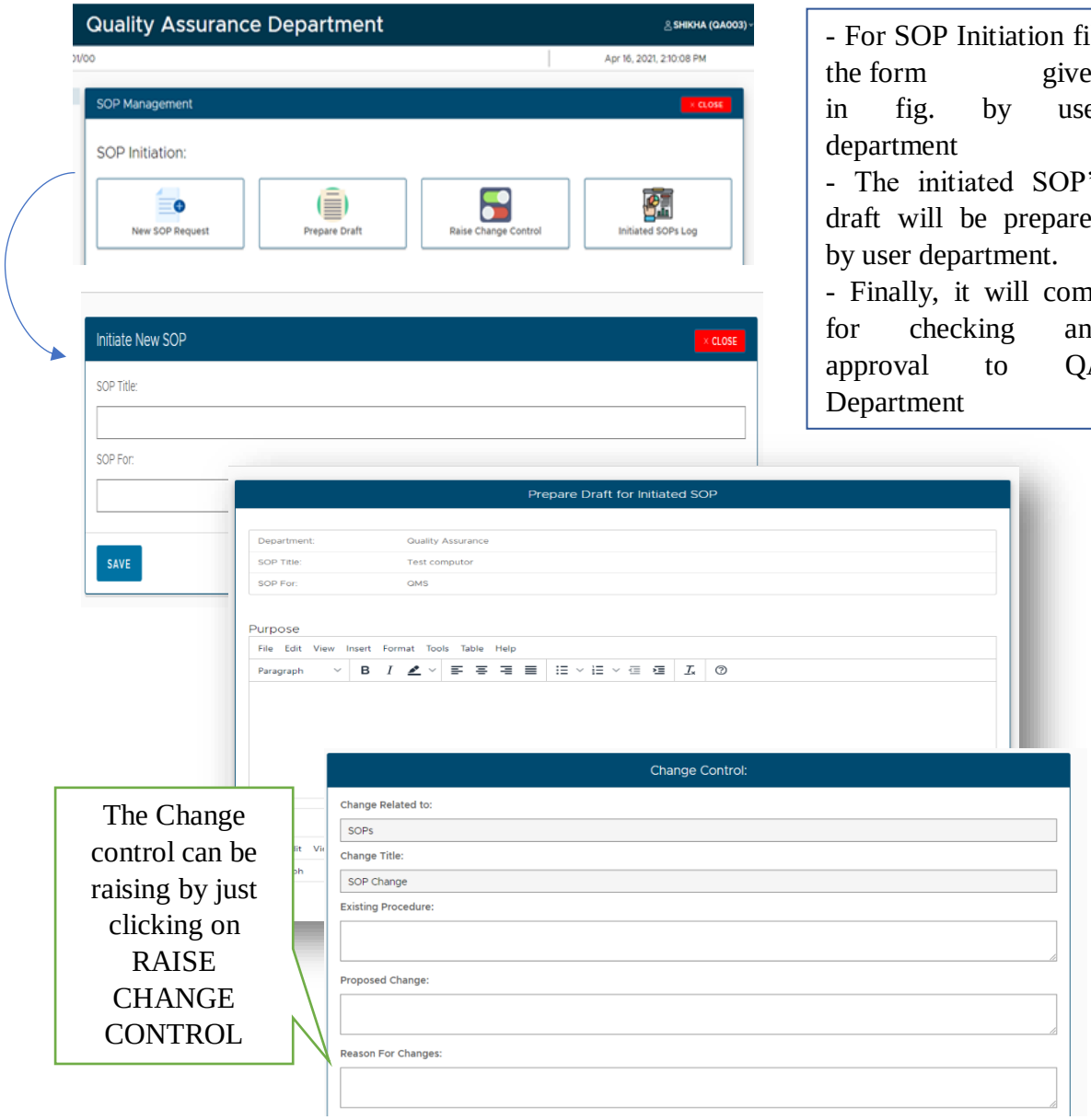


- The new batch release record can be maintained here.
- Select Dosage Form
- Add checkpoints, Remark, Save and approve it from QA manager.

Quality Assurance

- **SOP MANAGEMENT**

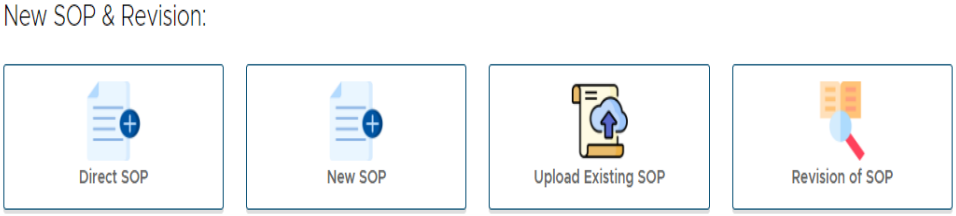
1. SOP initiation



- For SOP Initiation fill the form given in fig. by user department
- The initiated SOP's draft will be prepared by user department.
- Finally, it will come for checking and approval to QA Department

The Change control can be raising by just clicking on RAISE CHANGE CONTROL

2.



- Through DIRECT SOP tab you can prepare the SOP directly.
- The drafted SOP will come for finalization in NEW SOP tab through which the New final SOP will get prepare.

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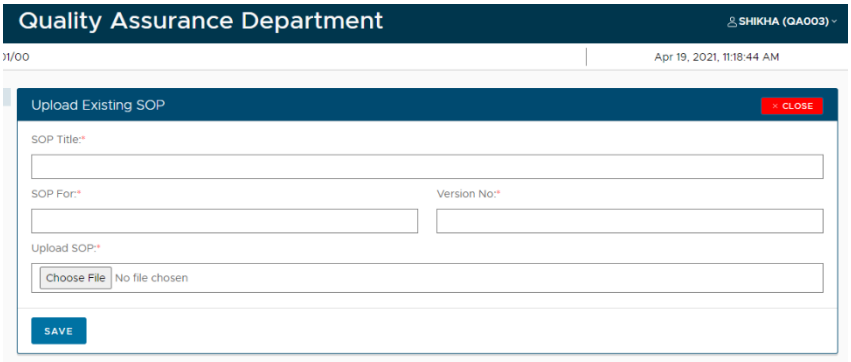
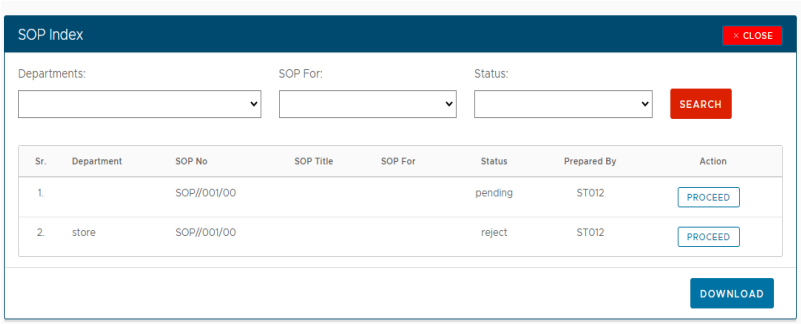
- The Existing SOP can be upload through UPLOAD EXISTING SOP tab; there you can find the option for upload sop.



3. SOP Index



- By clicking on the showing dropdowns for view of SOP index can be done from here.

✓ Receive Hard Copies

- To get to know about the distribution of SOP in the form of Hard copies will be visible and to maintain the record of it in this tab we have given provision with the same.

✓ Obsolete SOP

- The original SOP's which are get revised into new SOP's; it will be listed in obsolete SOP's.

4.

Training & Implementation:

- At the time of New SOP preparation, we have given the field about in which departments the given SOP training required, according to that the SOPs with pending training will come in the tab of PENDING SOP'S FOR TRAINING.

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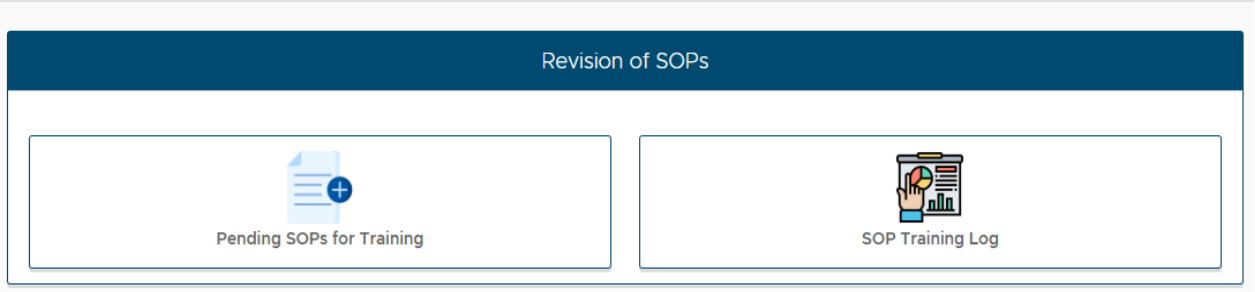
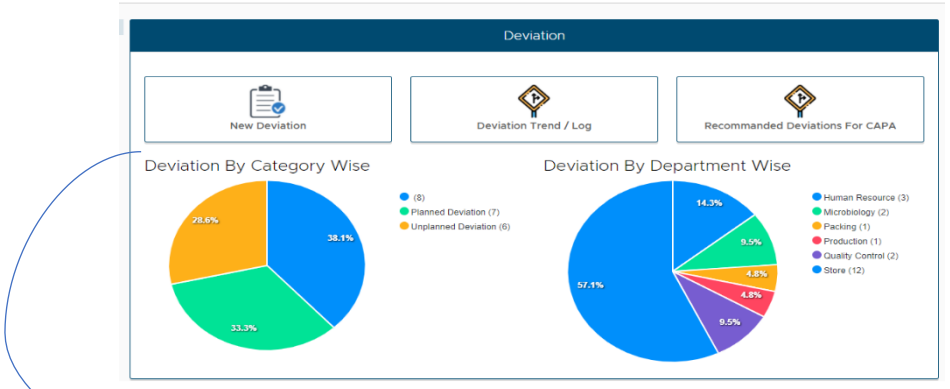


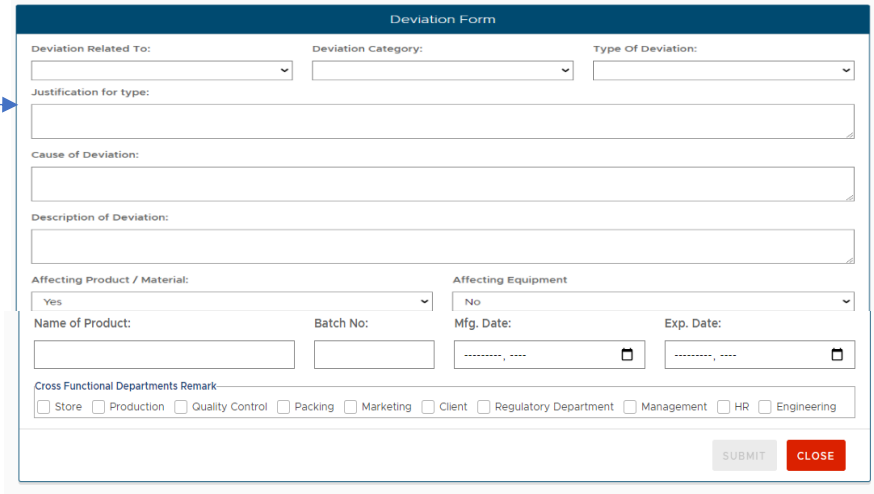
✓ Pending SOPs for Implementation

- The SOPs for which the training has been done but the implementation is yet pending will come to this tab for the selection of Effective Date.

✓ SOP Distribution record will be maintained in SOP DISTRIBUTION RECORD tab.

- **DEVIATION**





Flow chart for deviation**:**

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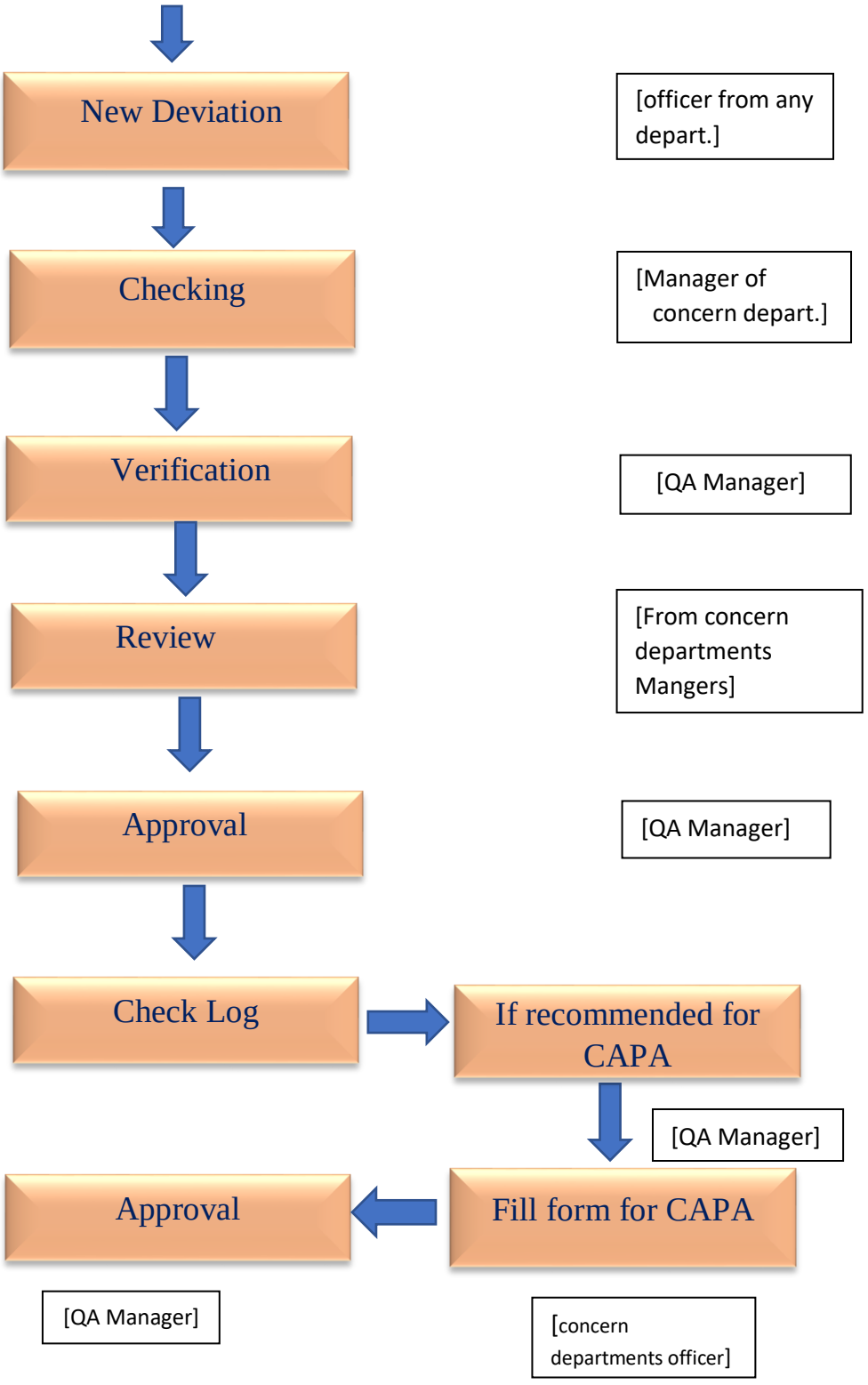

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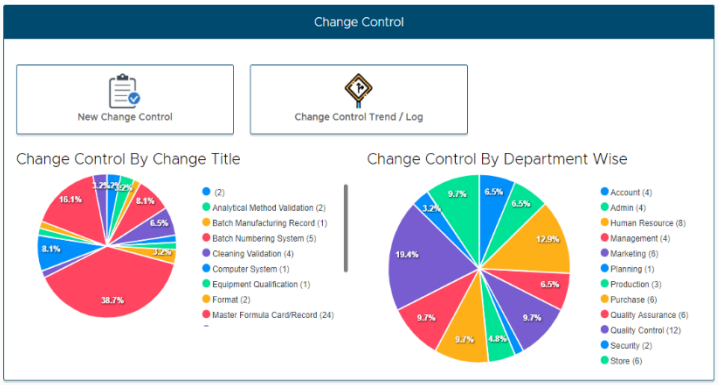
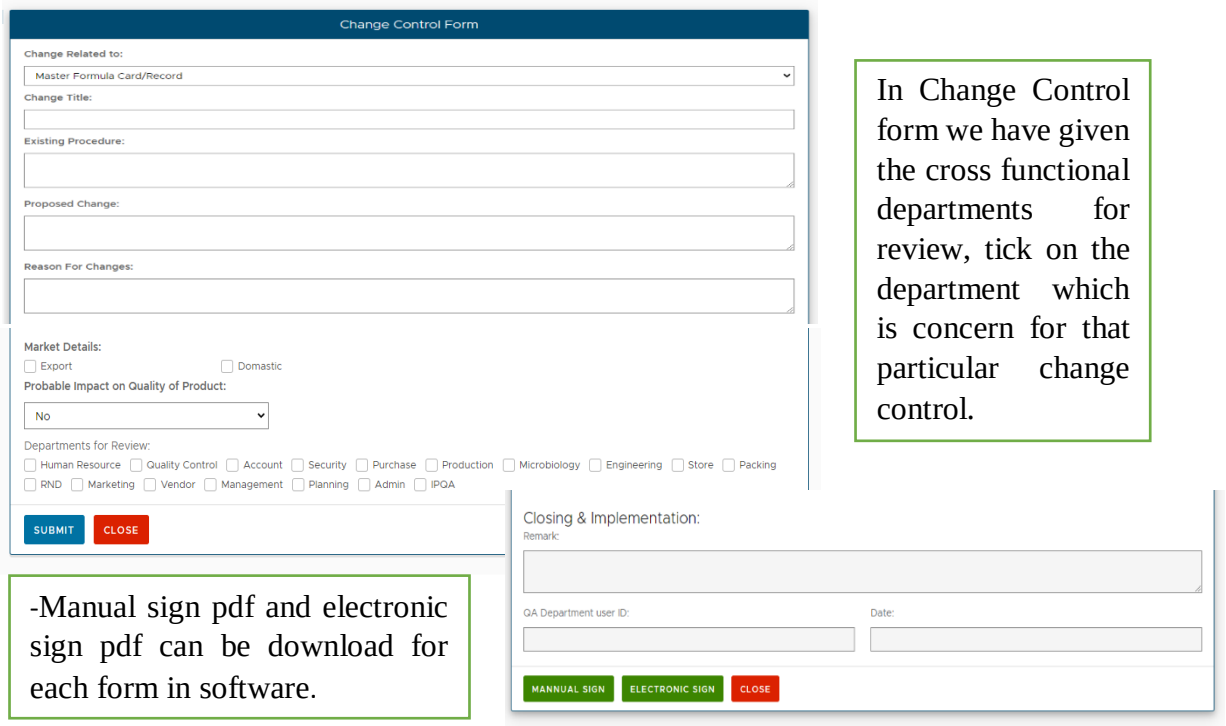
- **CHANGE CONTROL**

- In Change Control you will find the New Change Control form we have and its trend or log.

-additionally, the graphical representation has been given which gives us up to date.





In Change Control form we have given the cross functional departments for review, tick on the department which is concern for that particular change control.

-Manual sign pdf and electronic sign pdf can be download for each form in software.

- Flow Chart for Change Control:

[officer from any depart]

Quality Assurance

[Manager of concern depart.]

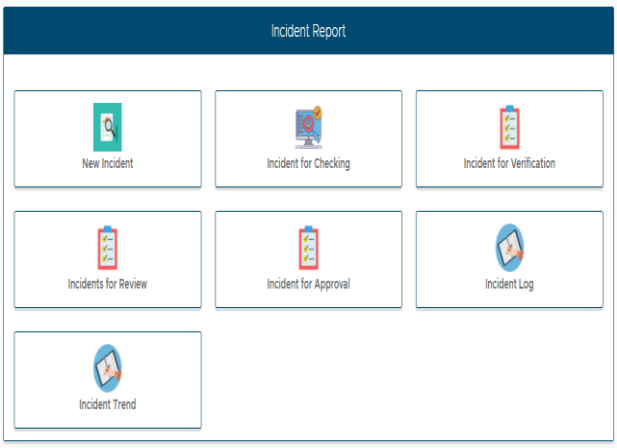
[QA Manager]

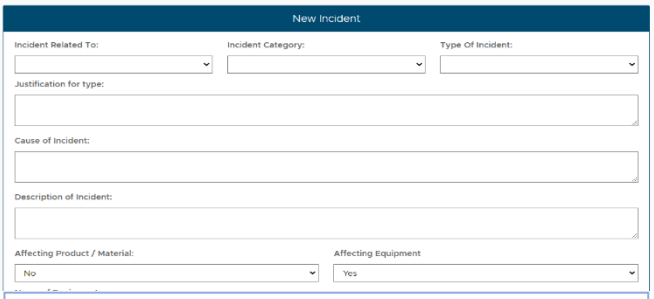
[From cross functional department's Mangers]

[QA Manager]

[from raised department]

- **Incident Report**





- In New incident reporting form if there is any product or equipment is getting affected then according to that the fields get appear for mentioning the details

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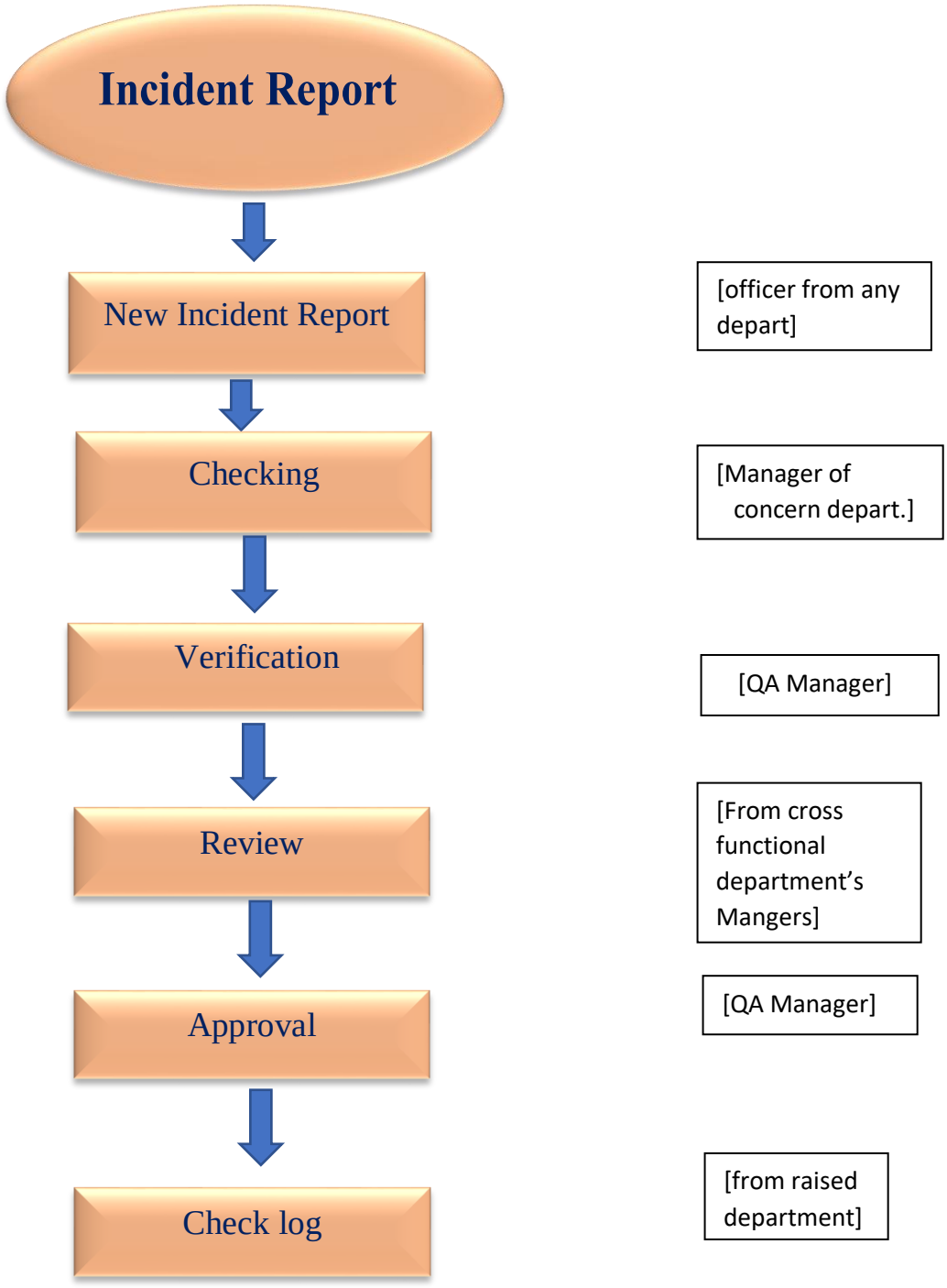
- **Flow Chart for Incident Report:**



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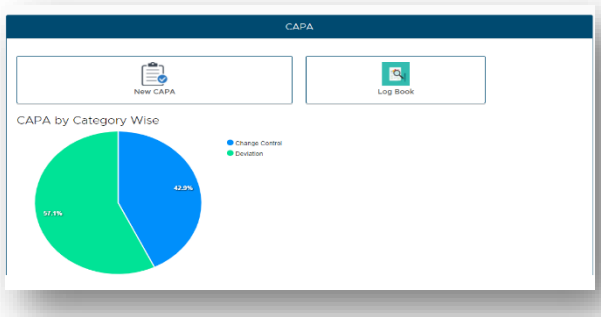
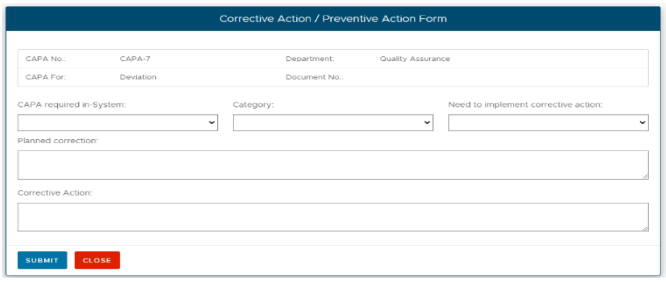
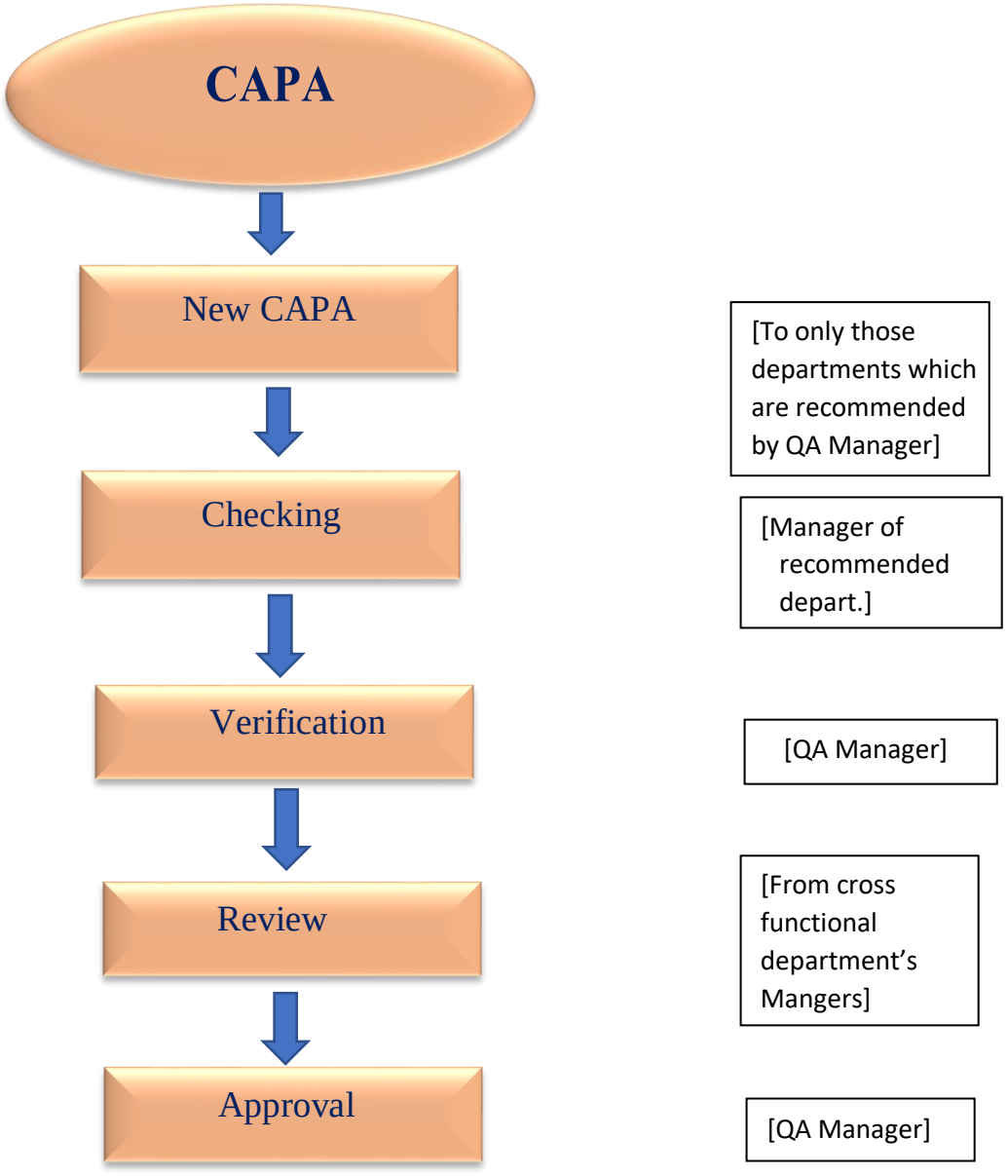
- **CAPA**





- Flow Chart for CAPA:



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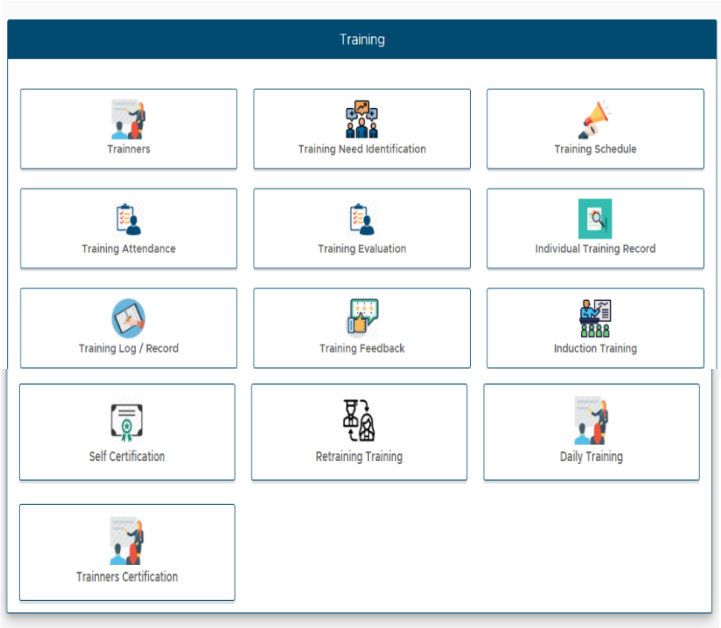
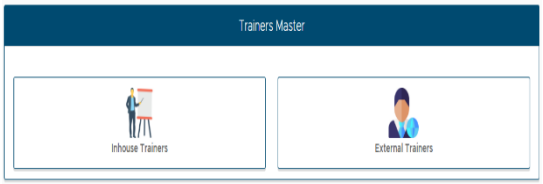
Check log

[from raised department]

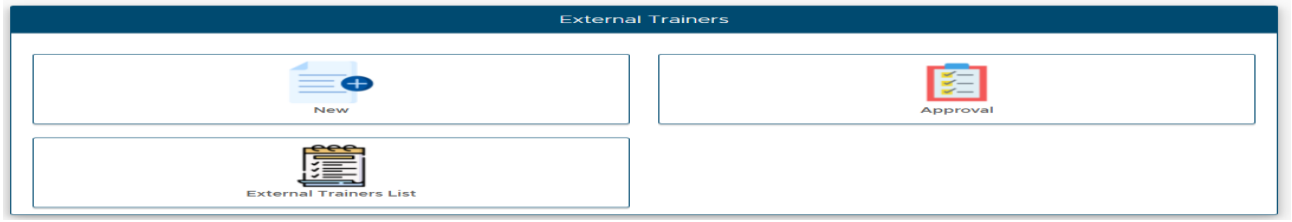
- **Training**



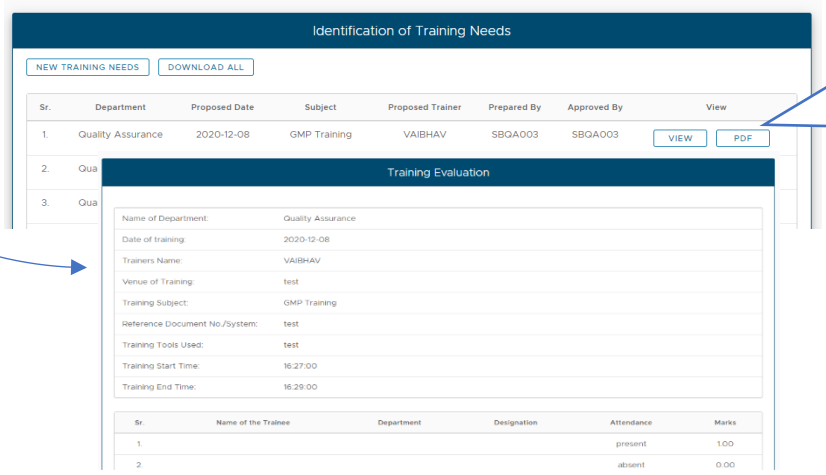
- On the left we have shown the dashboard of Training Module.



- In Trainers tab; Inhouse Trainers Name will come from where you have filled the form for Employee and assigned him the job as trainer.
- External trainers can be added by filling the form for new trainer and get the Approval.



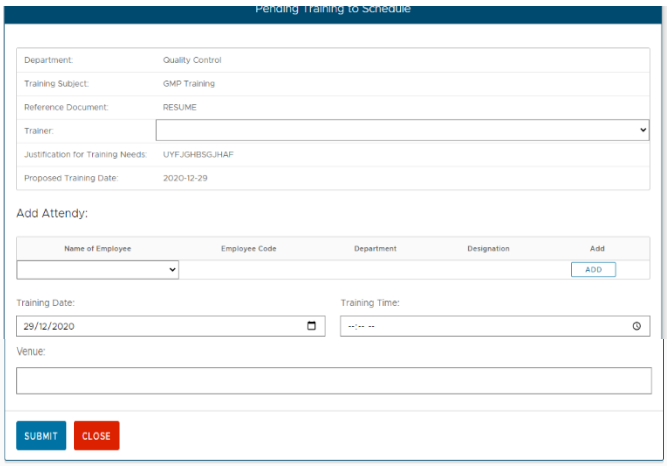
✓ Training Need Identification

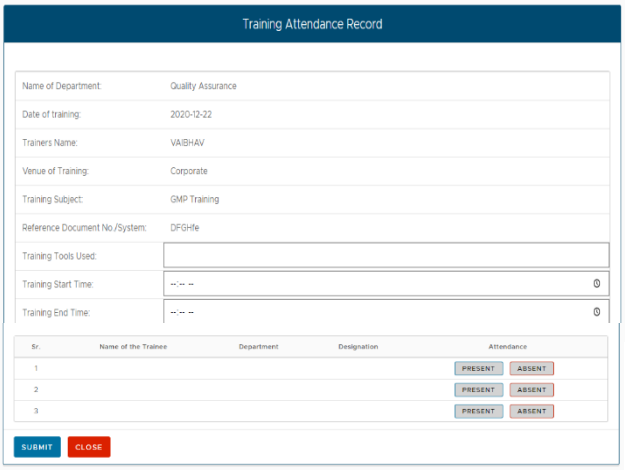


-The Training Need Identification form can be view or can be download as pdf also.

- Choose training sub. From dropdown.
- Multiple Employee can be select by just click on ADD button

Quality Assurance

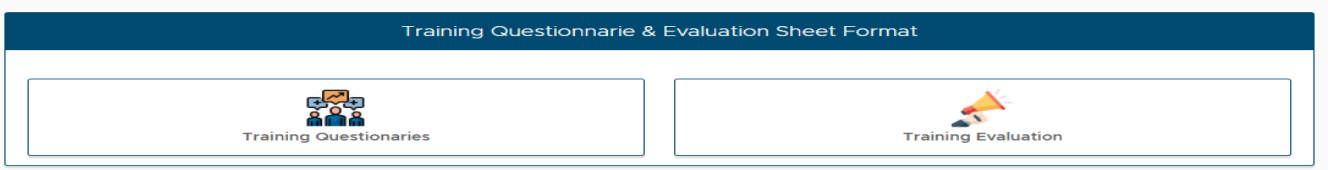


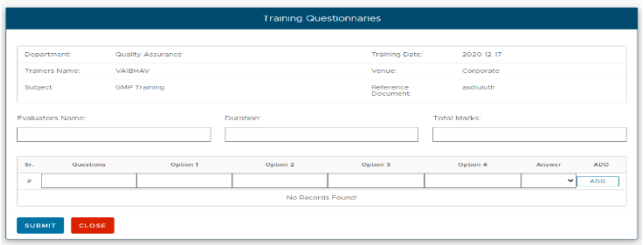


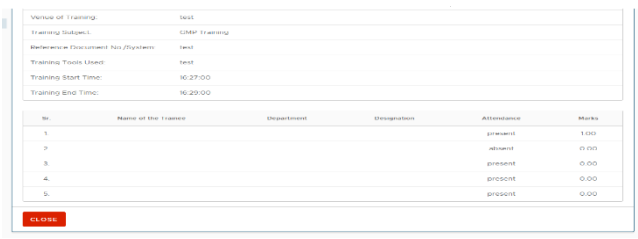
-The additional employees can be added at the time of scheduling of Training.

- The attendance record of Employees can be maintained here by click on present or absent.

✓ Training Evaluation

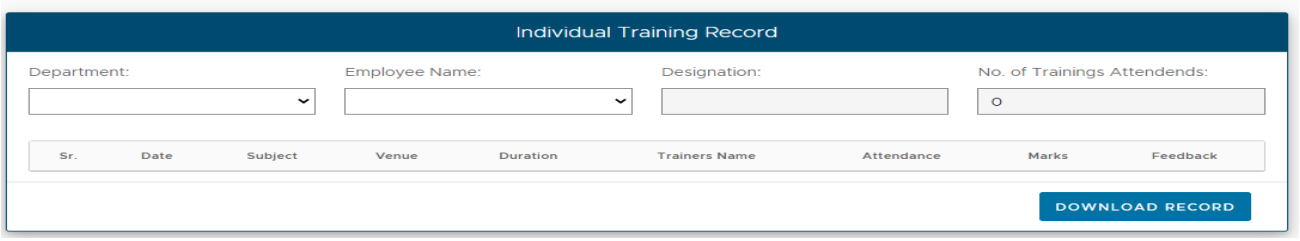






- Training Questionnaire can be prepared which will go to Attendees for the evaluation and Evaluation of training will be done on the basis of marks they obtained in the questionnaire.

✓ Individual Training Record



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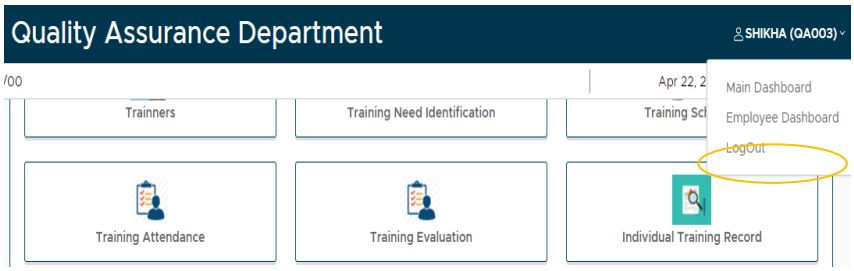
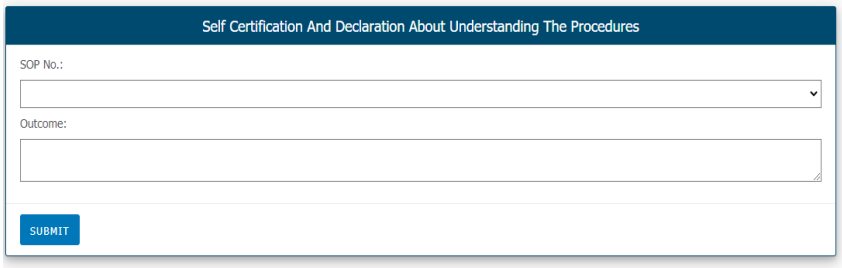
✓ Self-Certification



- for self-certification go to employee dashboard first

- Open SELF CERTIFICATE fill the form.

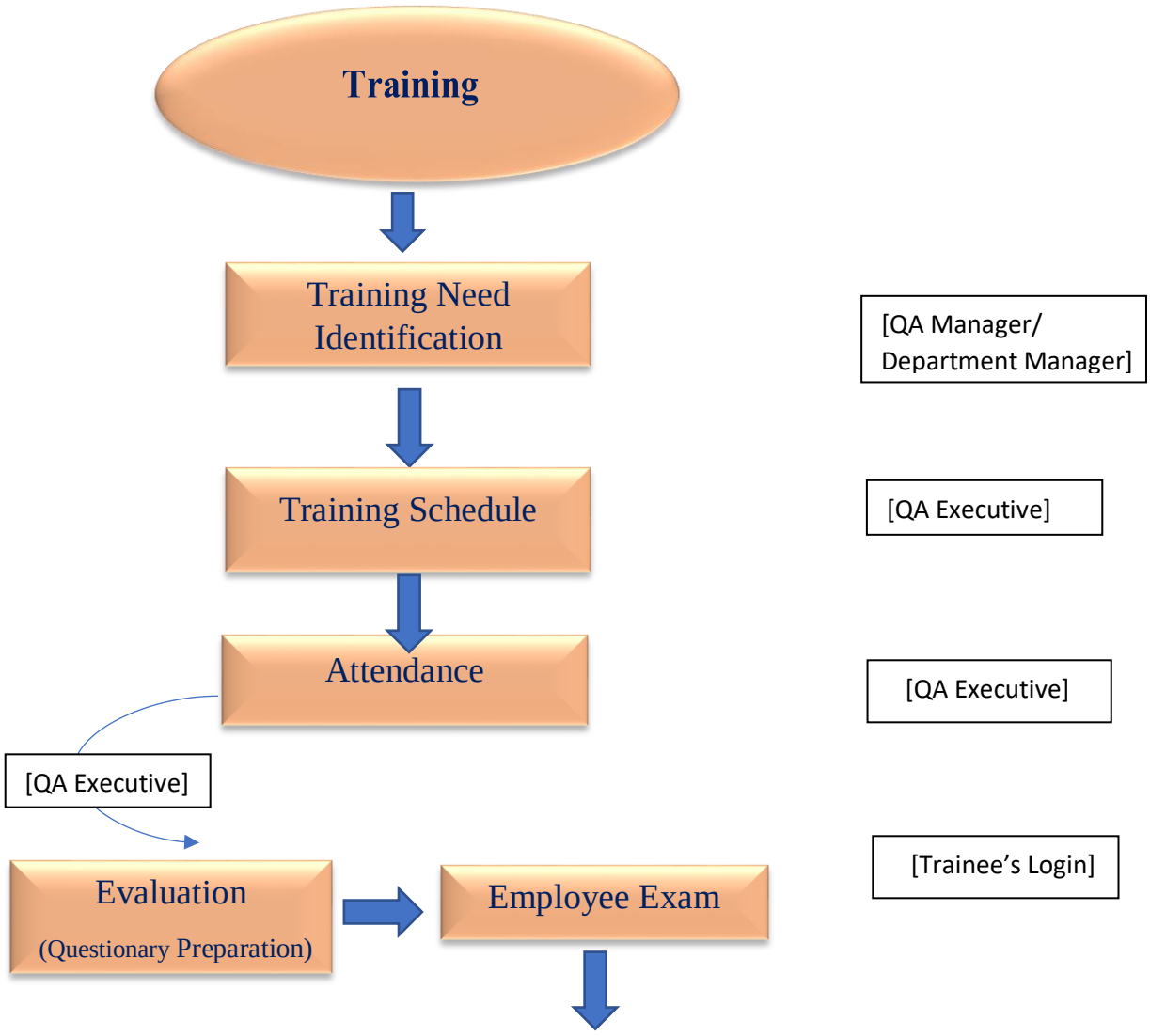
- Submit



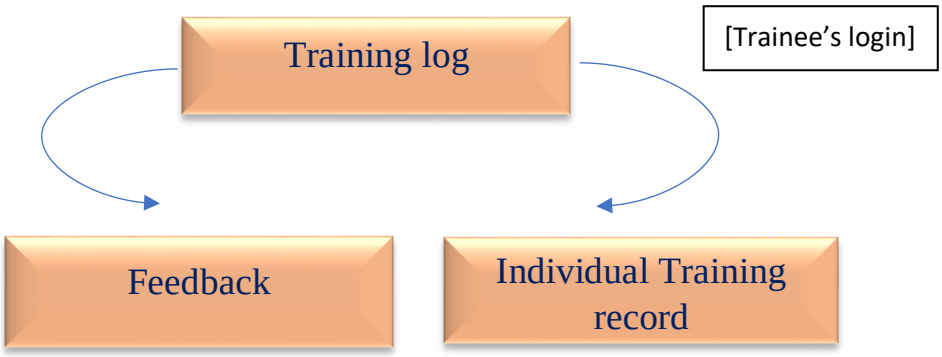
-Get Approval from QA Manager.

- Record will be maintained at Self Certificate log.

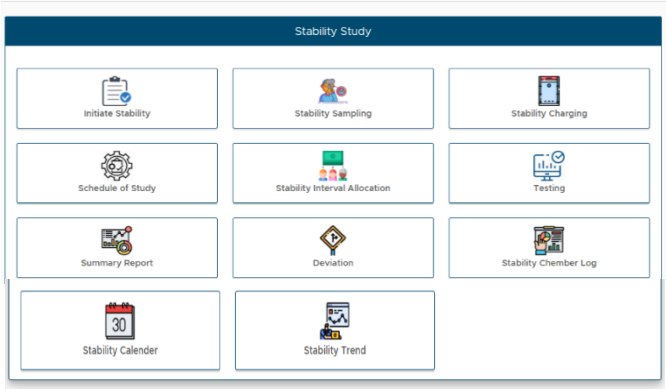
Flow Chart of Training:

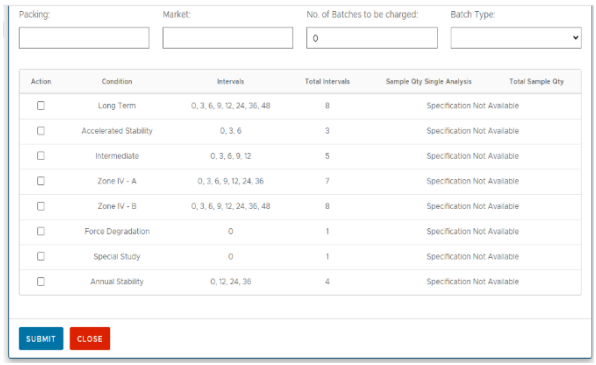


Quality Assurance

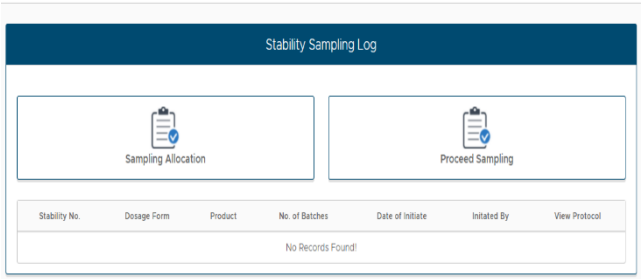


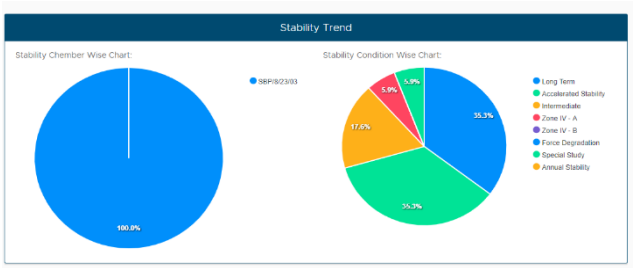
- **Stability Management**



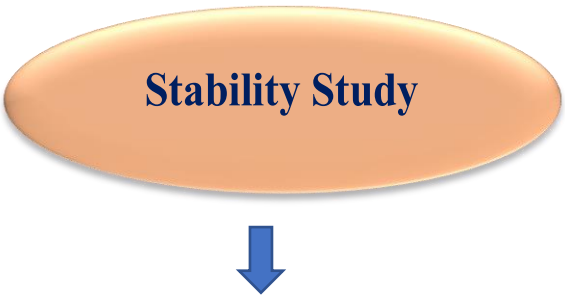


- Initiate new stability form is having provision that just have to click on which stability study you want to initiate and automatically interval calculation will be done for the

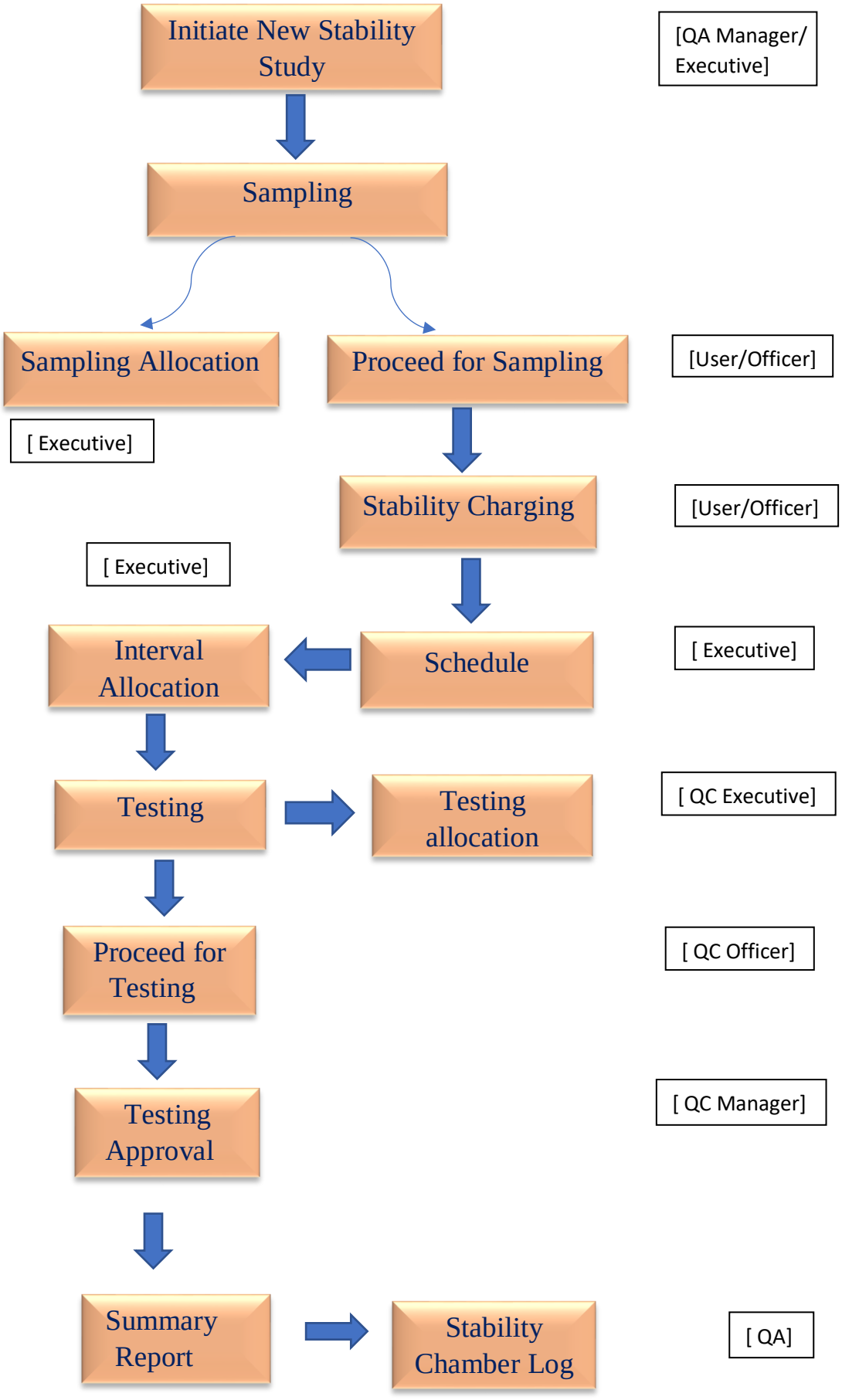




Flow Chart of Stability Study:



Quality Assurance



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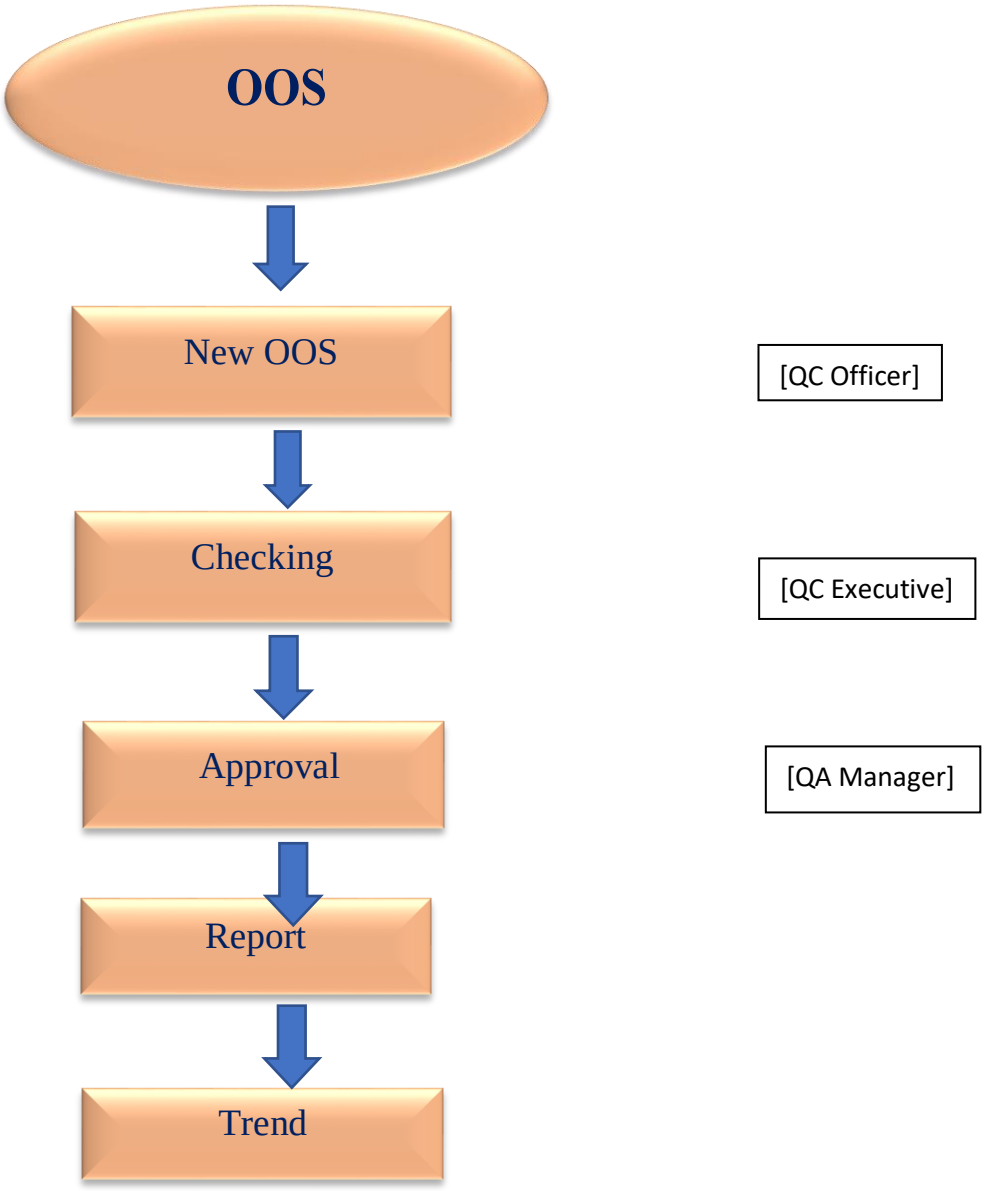
- **OOS:**



- **Risk Management:**

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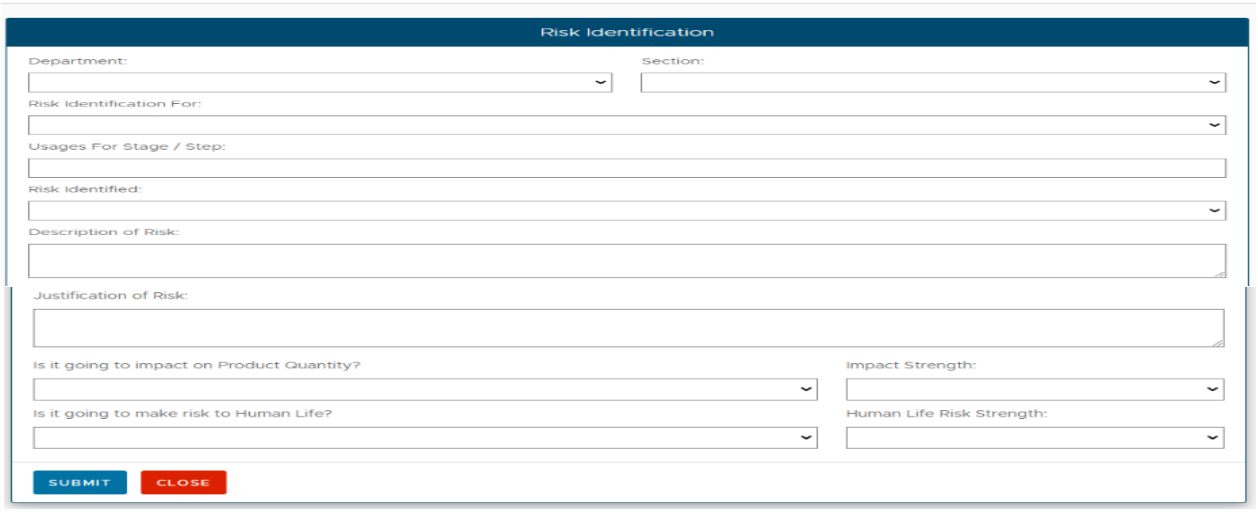

- The Risk Identification, Assessment, Analysis, Evaluation, Control, Review, Risk CAPA, Risk Log. Can be done with the Risk Management tab.
- Risk probability and severity will be determined.

- After Each stage of Risk Management, it will come to Manager for approval

Flow Chart of Risk Management:

Quality Assurance