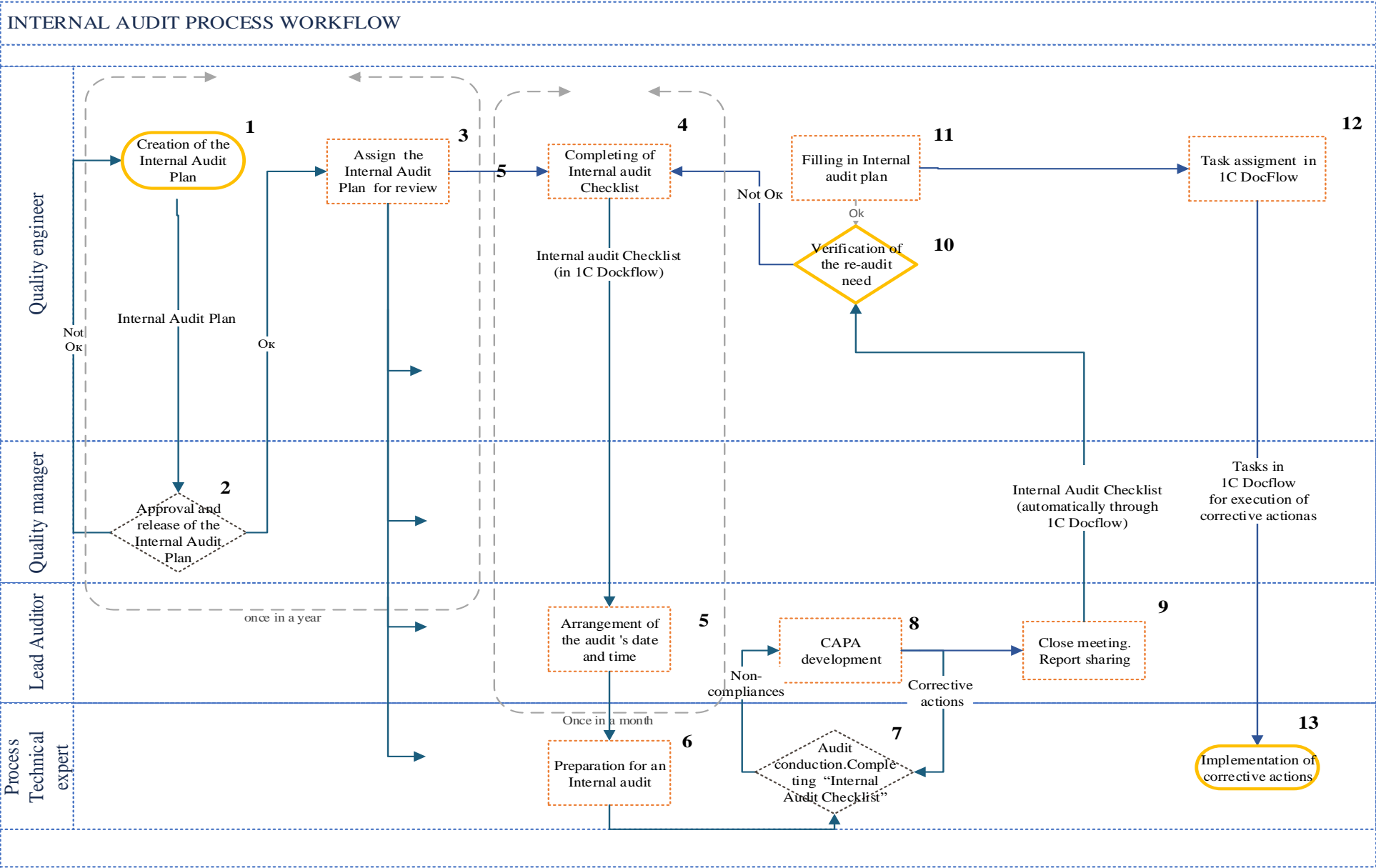


INTERNAL AUDIT PROCEDURE



INTERNAL AUDIT PROCEDURE

1. Creation of the Internal audit plan

Quality Engineer creates an Annual **Internal audit plan** once in a year. The annual audit plan requires information about all processes, auditors details and preliminary date of the audit.

2. Approval and release of Internal audit plan

Quality Manager approves **Internal audit plan** in the 1C Docflow. If there are any comments, the **Internal audit plan** is returned for revision.

3. Assign Internal Audit Plan for review

After approval in the 1C Docflow of the **Internal audit plan** , it is automatically sent to internal auditors , technical experts for review.

4. Complete Internal Audit Checklist

At the beginning of the month Quality engineer arranges of date and time of the audit ,process. Data is entered in the appropriate columns of **Internal audit plan**.

After Quality Engineer enters all necessary information and sends **Internal Audit Checklist** to the Lead auditor and Technical expert of the process being checked to the through 1C Docflow.

The appropriate template) is listed in the 1C Docflow.

5. Arrangement of the audit' s date and time

After Lead auditor have received an **Internal Audit Checklist** for execution in 1C Docflow, he/she starts planning the audit .

Ten days before the appointed date, the Lead auditor must agree with the Technical expert of the audited unit the date and time of the audit (as noted in **Internal Audit Checklist**).

6. Preparation for the internal audit

At the preparation stage (prior to the on-site audit), auditors should analyze the regulatory documentation (quality procedures, regulations on divisions, role descriptions, Also inspected object should be compliant with the requirements of ISO 9001:2015. In addition, they discover all documents related to the audited unit and results of previous audits.

If necessary, the auditors specify all employees with the Technical expert of the audited unit , that will participate in the audit. However , the auditor has the right to check any employees process of the audited unit.

The Lead auditor and auditor prepares a list of questions in **Internal Audit Checklist**.

7. Audit conduction. Completing the Internal Audit Checklist

Entry part of the internal audit is a meeting of auditors), where the lead auditor explains the objectives, essence and procedure of the internal audit (introductory meeting).

INTERNAL AUDIT PROCEDURE

Auditors conduct direct inspections at the workplaces of the unit's employees. At the same time, they use : methodologies, work instructions and other guidance documents. Auditors collect information and provide evidence of it by interviewing employees, analyzing documents used in the unit, inspecting and monitoring activities and conditions at work sites.

The survey is conducted in the form of interviews with individual employees. Contradictions and ambiguities must be discussed and analyzed. Responses, if possible, should be documented.

8. CAPA development .

Based on the results of the audit, the Lead auditor fills out **Internal Audit Checklist** with the description of the nonconformities. The person responsible for the process organizes the identification of the causes that led to the non-compliance, discusses them with the auditor and proposes corrective actions with the determination of the time frame and responsible persons for their implementation.

9. Close meeting. Report sharing

At the end of the audit the lead auditor reports on the main results of the audit, conclusions and decisions of the auditors, lists of identified nonconformities, gives them a brief assessment, informs about the corrective actions assigned.

Lead auditor fills out **Internal Audit Checklist** and sends it for approval in 1C Docflow to the Technical expert.

10.Verification of the re-audit need

Quality engineer checks the checkbox of the re-audit need in **Internal Audit Checklist**. If the Lead Auditor notes the need for a second audit, the Quality Engineer makes appropriate notes in **Internal audit plan** and steps mentions 5-9 should be repeated.

11.Filling in the Internal audit plan

The Quality engineer filling in all the necessary information based on the results of the audit to the **Internal audit plan**.

12.Task assignment in 1C Docflow

The quality engineer assigns the corrective actions listed in **Internal Audit Checklist** as tasks in 1C Docflow.

13.Implementation of corrective actions

Responsible for the process receives the task organizes corrective actions in the specified time.