# Tool 1: Selecting Improvement Projects

Listed below are Improvement Projects (IP) by workshop that you can select from. Once selected, a detailed plan of implementation must be developed using Worksheet: Quality Improvement Project Plan. Four examples of IP assignments are provided in this tool: Workstation Set-up, Safety Audit, SOP Development, and Internal Audit.

| Activity | Improvement Project | What is to be measured |
|---|---|---|
| **Workshop #1** | | |
| Balanced Scorecard | Monitor one of the Quality Indicators presented in this activity | Chosen Quality Indicator |
| Floor Plan Activities | Re-design your laboratory layout | Show before and after layout (or pictures). List the number of changes made to the layout or measure by way of improved TAT before and after. |
| Competency Assessment | Design a competency assessment program for the laboratory and conduct some assessments | Number of staff competent on each procedure |
| Workstation Set-up See example | Improve workstation set-up | Availability of required items and documentation of each workstation. See example |
| **Workshop #2** | | |
| Safety Audit See example | Conduct a safety audit using the Safety section of the Checklist | Improvement of score for the Safety section of the Checklist |
| Inventory Management | Introduce an inventory management system:<br>monitor consumption, calculate minimum stock / reorder levels, stock counts, reagent inventory list, review of suppliers and list of preferred suppliers | Stock outs, number of supplies with stock cards, number of stock with documented minimum stock or re-order level, consumption rate and stock counts, number of orders tracked and inspected on receipt, number of supplier reviews and preferred supplier list created |
| Equipment | Equipment maintenance and service | Number of days and times (weekly, bi-weekly, monthly, etc.) equipment maintained by user as per manufacturers requirements, measure of equipment down time, number of equipment serviced on time, number of records of after service checks |

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| Activity | Improvement Project | What is to be measured |
|---|---|---|
| Documentation See example | Improve documentation (Policies, SOPs, quality logs and checklists) in the laboratory | Number of policies available vs. required by WHO AFRO SLIPTA checklist question 1.3. Number of SOPs available vs. required by the laboratory plus listed on question 1.3 of the WHO SLIPTA checklist. See example |
| **Workshop #3** | | |
| Quality Control | Monitor running of IQC | Number of days IQC run and reviewed by tester. Number of L-J charts plotted as the IQC is done. Number of corrective actions done for failed IQC. Number of IQC logs and L-J charts reviewed by supervisor. |
| External Quality Assurance | Monitor performance and documentation of EQA | Number of tests enrolled on EQA vs tests done in the lab, EQA pass rate (analytes done vs. passed), EQA submitted on time. Documentation of (i) receipt of EQA material (who received, when and in what condition) (ii) date tested and results submitted and by whom (ii) review of results, corrective action and review of corrective actions by supervisor |
| Specimen Management | Monitor specimen rejection | Specimen rejection rates, number of specimens rejected by sample type, test, source e.g. which ward, reason for rejection |
| Referral Specimens | Monitor results of referral specimens | Number of tests referred, tracking of referral results and TAT, reviews of referral logbook. |
| Customer Service | Customer satisfaction survey | Customer Satisfaction Survey results, follow up actions |
| Internal Audit See example | Conduct an internal audit using the WHO AFRO SLIPTA checklist sections 1-11 | Improve of the checklist score. Document action plans with timelines and tasks assigned to personnel. Track number of non conformities (YES, Partial and NOs) from baseline to final |

# Tool 1: Selecting Improvement Projects

## Compulsory Activities

These are projects that are not extensive enough to be considered a SLMTA IP. These will be assigned as "compulsory activities" i.e. all participants must implement these in addition to the selected IP.

- Laboratory Organization - "Sort / Straighten / Shine / Standardize / Sustain" an area of the laboratory:
  - The storeroom
  - One workstation (e.g., the phlebotomy area)
  - The office
  - The records
  - Remove non-functioning equipment from the laboratory
- Duty Roster
- Management Calendar
- Equipment Master list/Inventory

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# IP: Workstation Set-up

**Workstation Set-up**: Improving workstation set up

1. Discuss and explain the IP in a team meeting. Document the minutes
2. Create an initial listing of every analytical workstation in your laboratory as follows, for example FBC workstation, CD4 workstation, sample reception workstation, sample referral workstation, TB microscopy screening, TB staining station…..Fill these in column 1 of the data collection tool below
3. List all the equipments associated with each work station e.g. CD4 workstation: FACS Count. Also include ancillary equipments within that workstation e.g. for CD4 workstation: blood mixer, printer, 2-8°C Fridge. Fill these in column 2 of the data collection tool below
4. Assign specific individuals specific workstations to work on for the IP.
5. For baseline data, complete columns 3. If the item is in place e.g. maintenance log indicate by marking column under Y (YES). If the item does not apply e.g. QC log in the sample collection area indicate N/A in any of the columns Y or N.
6. Count the number of Y (YES) and N (NO) for each item e.g. SOPs: Yes = 12, NO = 28
7. Add up the number of Y and N for all items e.g. if Service Stocker = 15 Yes, small parts = 0 YES, book of life = 2 YES……total YES = 15 + 0 + 2 + …. …. = 17 YES (baseline)

### Data Collection Tool

| Work-station | Equipment + Ancillary Equipment | Uniquely Identified | | Service Sticker | | SOP | | QC Log | | Maintenance Log | | Backup Plan | | Small parts | | Competency Assessment checklist | | Book of Life | | User Manual | | Quality Docs Reviewed | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Y | N | Y | N | Y | N | Y | N | Y | N | Y | N | Y | N | Y | N | Y | N | Y | N | Y | N |
| Automated FBC | Sysmex K21 | | | | | | | | | | | | | | | | | | | | | | |
| | Coulter Act 5 | | | | | | | | | | | | | | | | | | | | | | |
| | Blood Rotator | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | |
| Totals (Y or N) | | | | | | | | | | | | | | | | | | | | | | | |

8. Report baseline data at the next team meeting
9. Assign tasks to be completed to specific individuals within certain workstations with timelines for completion. See example below

| Deficiency Identified | Cause or Reason for the Deficiency | Proposed Corrective Action | Action Plan | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | Task to be completed | Who is responsible | By When | Review 1 | Review 2 | Review 3 |
| | | | 1) | | | | | |
| | | | 2) | | | | | |
| | | | 3) | | | | | |
| | | | 1) | | | | | |

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| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | 2) | | | | | |

10. Review the progress of the IP monthly. Indicate progress of the assigned tasks under review 1 to 3.
11. At the end of the IP (1-2 weeks before next workshop), collect final data using the same data collection tool
12. Add up the total Y and N for each item and for all items as given in steps ?//
13. Compare baseline and final data
14. For areas still not improved, discuss how these will be improved.
15. Complete another action item for the incomplete tasks as in the above action plan
16. Prepare report to present at the workshop

**This improvement project supports the following accreditation checklist items:**

1.3 Are policies and standard operating procedures (SOPs) for laboratory functions current and available and approved by an authorized person?

1.4 Are policies and SOPs easily accessible / available to all staff?

1.5 Is there documentation that all staff have read and understood the policies and SOPs that relate to their responsibilities in the laboratory?

2.2 Does the laboratory supervisor routinely perform a documented review of all quality records?

2.3 Does the laboratory identify and undertake quality improvement project?

2.4 Does the laboratory communicate with upper management regularly regarding personnel, facility, and operational needs?

3.5 Are personnel files present? *: Periodic Performance Review- including observation, competency assessment, coaching/feedback, on-the job training.*

5.3 Is current equipment inventory data available on all equipment in the laboratory?

5.4 Is relevant equipment service information readily available in the laboratory?

5.6 Is routine calibration of laboratory equipment – including pipettes, centrifuges, balances, and thermometers – scheduled, indicated on the equipment, and verified?

5.7 Is routine preventative maintenance performed on all equipment and recorded according to SOPs?

5.9 Is stock of expendable parts present on site?

5.12 Are there back-up procedures for equipment failure?

5.13 Are the equipment manufacturer's operator manuals readily available to testing staff?

9.2 Have acceptable ranges been defined for all temperature dependent equipment with procedures that detail what to do when temperatures are out of range?

9.10 Are SOPs for specific testing present and easily accessible at the workbench?

9.11 Is internal quality control (IQC) performed, documented, and reviewed prior to release of patient results?

9.12 Is the laboratory result report(s) in a standard form determined to be acceptable in consultation with clients?

9.18 Does the laboratory participate in a Proficiency Testing (PT) scheme or inter-laboratory comparison?

10.2 Are out-of-control runs reviewed and submitted to troubleshooting and cause analysis?

# IP: Safety Audit

**Safety Audit:** Implementing, conducting and improving performance on safety audit

*The **ISO 15190:2003(E) states that** "Safety is the primary consideration; cost is of secondary importance"*

## Steps

1. Discuss the IP in the team meeting. Document the minutes
2. Using Section 12 of the WHO Accreditation checklist or any other safety audit checklist approved by the Lab, perform a Safety Audit.
3. List all areas identified as deficient or noncompliant from the safety audit findings. Specify if the deficiency applies to all areas of the laboratory or only to specific sections of the laboratory. E.g. "the Lab does not have suitable chairs" instead of " Hematology and bleeding room have chairs that are absorbent to fluids, hence not suitable for lab use"
4. Present the audit findings to the laboratory staff and upper management. Document the minutes for these meetings.
5. Propose corrective actions for all identified areas that include an action plan developed with clear timelines. The proposed corrective action should be based upon the cause or reason for the deficiency. See table below

| Deficiency Identified | Cause or Reason for the Deficiency | Proposed Corrective Action | Action Plan | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | Task to be completed | Who is responsible | By When | Review 1 | Review 2 | Review 3 |
| | | | 1) | | | | | |
| | | | 2) | | | | | |
| | | | 3) | | | | | |
| | | | 1) | | | | | |
| | | | 2) | | | | | |

1) Document all corrective and follow-up actions taken.
2) Review the action plans at after each due date and document progress or proposed new dates.
3) Perform the final safety audit at the end of the IP
4) List the audit findings and action items as done at baseline
5) Review the findings
   - Which areas were able to be sustained?
   - Is there need to train the rest of the staff in the newly introduced and sustained areas?
   - Which areas persisted as non conformities and why? What is the plan for the Lab to resolve these?
6) Compile a report to report at the next SLMTA workshop

**This improvement project supports the following accreditation checklist items:**

A ll Questions under Section 12 of the checklist

# IP: Documentation

## Documentation: Improving documentation in the Laboratory

The clause below refers to documentation and document control from ISO 15189
**Clause: 4.3.1.** *The laboratory shall define, document and maintain procedures to control all documents and information (from internal and external sources) that form its quality documentation. A copy of each of these controlled documents shall be archived for later reference and the laboratory director shall define the retention period. These controlled documents may be maintained on any appropriate medium – including, or not, paper.*
*National, regional and local regulations concerning document retention could apply.*

## Data Collection Tool

| # | Document (SOP/Policy/Works station Tasks/Log/checklist etc) | In Place (Yes/No) | | | |
|---|---|---|---|---|---|
| | | Baseline Yes/No | Comment (Draft, authorized, expired, read by all staff) | Final Yes/No | Comment (Draft, authorized, expired, read by all staff) |
| | | | | | |
| | | | | | |
| | | | | | |

## Steps

1. Discuss the IP in the team meeting
2. Assign all sections to:
    - Make a list of all activities and tests conducted in their section

SOPs
- Using the data collection tool above, list the SOPs needed for each of the procedures and activity listed
    - E.g. In Chemistry, activities include: Chemistry testing using Selectra junior Analyzer: ***SOP for chemistry analysis using Selectra Junior***
    - Maintenance of Selectra Junior: ***SOP for Maintenance of Selectra Junior***
    - Training Plan

Training Plans
- Training plan for each test or workstation listed above

Logs
- Maintenance logs for Selectra Junior, centrifuge
- Temperature logs for fridge, freezer and room
- Cleaning of room and bench surfaces logs
- Quality Indicator monitoring logs

Checklists
- Competency Assessment checklists for chemistry testing using Selectra Junior

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NOTE: Do this for all sections of the laboratory, including sample reception, sample referral, cross check areas, store room, phlebotomy.

3. Include all SOPs and Policies from **Question 1.3** on the WHO AFRO SLIPTA checklist.
4. For each document, indicate under comments section whether it is:
   - In place or not?
   - In draft form?
   - Authorized?
   - Expired?
5. After listing all the documents count how many:
   - Are supposed to be in place?
   - Are in place?
6. For those in place how many are:
   - In draft?
   - Expired? or
   - Read by all staff?
7. After collecting baseline data, present to lab team. Document minutes.
8. List improvements that need to be put in place. Formulate an Action Item table

| Deficiency Identified | Cause or Reason for the Deficiency | Proposed Corrective Action | Action Plan | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | Task to be completed | Who is responsible | By When | Review 1 | Review 2 | Review 3 |
| | | | 1) | | | | | |
| | | | 2) | | | | | |
| | | | 3) | | | | | |
| | | | 1) | | | | | |
| | | | 2) | | | | | |

9. Continue monitoring the progress of the project by reviewing monthly
10. At the end of the project timeline, collect final data using the same data collection tool 1-2 weeks before next workshop
11. Compare baseline and final data results. If there are still some outstanding action items or new ones, list the action items as done at baseline
12. Compile a report to report at the next SLMTA workshop

All documents produced must follow the laboratory document control system. i.e. the document must have:

- Document control number
- Version number
- Author
- Authorizer
- Effective date
- Date of retrieval
- Laboratory name/ministry of health
- Page numbers

All documents must be listed on the document Master list

# Tool 1: Selecting Improvement Projects

**This improvement project supports the following accreditation checklist items:**

1.1 Is there a system or procedure for document & record control and retention?
1.2 Are documents & records properly maintained, easily accessible and indicated on an up-to-date Master List?
1.3 Are policies and standard operating procedures (SOPs) for laboratory functions current, available, and approved by an authorized person?
- ✓ *Each testing procedure performed including QC guidelines, acceptability, what to do if QC is out of range*
- ✓ *Equipment Maintenance*
- ✓ *Specimen Collection & Processing*
- ✓ *Specimen pre- and post-test storage*

1.4 Is there documentation that all staff have read and understood the policies and SOPs that relate to their responsibilities in the laboratory?
1.5 Is there a system for competency assessment of staff (both new hires and existing staff) and does it include planning and documentation of retraining and reassessment, when indicated?
1.9 Are invalid or discontinued policies and procedures removed from use and retained according to schedule?
3.6 Does the laboratory have adequate training policies, procedures, and/or training plan, including cross training within the laboratory team, one-on-one mentoring, and/or off-site external training
4.2 Is there a laboratory handbook for clinicians' use that includes information on services offered, quality assurance, laboratory operations, sample collection and transport, and agreed turnaround times, etc.?
5.7 Is routine preventative maintenance performed on all equipment and recorded according to the SOPs?
5.12 Are there back-up procedures for equipment failure?
9.10 Are SOPs for specific testing present and easily accessible at the workbench?
- ✓ *Does the SOP include procedures that ensure specimen integrity and prevent mixing of samples?*
- ✓ *Is intermixing of test kit contents from different lot numbers prohibited, unless otherwise specified?*
- ✓ *Where appropriate, it there a procedure for performing grading and reporting microscopic examinations?*

## Tool 1: Selecting Improvement Projects

# IP: Internal Audit

**Internal Audit:** Implementing, conducting and improving performance on internal audits

**Quoted below is the ISO 15189 Clause on internal audit**
*"**4.14.1** In order to verify that operations continue to comply with the requirements of the quality management system, internal audits of all elements of the system, both managerial and technical, shall be conducted at intervals defined by the system itself. The internal audit shall progressively address these elements and emphasize areas critically important to patient care."*

## Data Collection Tool

| **Section 1: Documentation** | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **Baseline** | | | **Final** | | | **Comment** |
| | **Y** | **P** | **N** | **Y** | **P** | **N** | |
| Is there a SOP on how to conduct Internal Audit? | | | | | | | |
| Is there a person trained in conducting internal audits (Manager, Quality Manager or someone else)? | | | | | | | |
| Is there an internal audit checklist | | | | | | | |
| **Section 1: Total Marks** | | | | | | | |
| | | | | | | | |
| **Section 2: The Audit** | | | | | | | |
| | **Baseline** | | | **Final** | | | |
| Total Internal Audit Marks | | | | | | | |
| Total number of conformities (YES) | | | | | | | |
| Total number of Partials (P) | | | | | | | |
| Total number of non conformities (NO) | | | | | | | |

## Steps

1. Discuss the IP in the team meeting.
2. Set action items relate to the IP. Some of the action items will have specific activities to be dome to achieve the action item e.g. if there is no internal audit SOP
    - Action Item: Quality Officer to write SOP
    - Activities:
        - QA Officer draft SOP
        - Supervisor review SOP
        - QA Officer train staff on SOP
3. Using the internal audit checklist perform an internal audit.
4. List all areas identified as deficient or noncompliant from the internal audit findings. Specify if the deficiency applies to all areas of the laboratory or only to specific sections

of the laboratory. E.g. instead of saying "Lab not performing IQC consistently but say CD4 section not performing IQC on the FACS Count"

5. Present the audit findings to the laboratory staff and upper management. Document the minutes for these meetings.
6. Propose corrective actions for all identified areas that include an action plan developed with clear timelines. The proposed corrective action should be based upon the cause or reason for the deficiency

| Deficiency Identified | Cause or Reason for the Deficiency | Proposed Corrective Action | Action Plan | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | Task to be completed | Who is responsible | By When | Review 1 | Review 2 | Review 3 |
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| | | | 2) | | | | | |
| | | | 3) | | | | | |
| | | | 1) | | | | | |
| | | | 2) | | | | | |

1) Document all corrective and follow-up actions taken.
2) Review the action plans at after each due date and document progress or proposed new dates.
3) Perform the final internal audit at the end of the IP
4) List the audit findings and action items as done at baseline
5) Review the findings
   - Which areas were able to be sustained?
   - Is there need to train the rest of the staff in the newly introduced and sustained areas?
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