NC&T NILE
النيل للإستشارات والتدريب وخدمات المعامل
Committed to Quality...Committed to You

by
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4. Management Requirements

4-11 Corrective Actions

4.11.1 Procedure :
The laboratory shall establish policy and procedures for take timely corrective action to eliminate the cause of nonconformity. This procedure will determine the following

Reviewing nonconformities

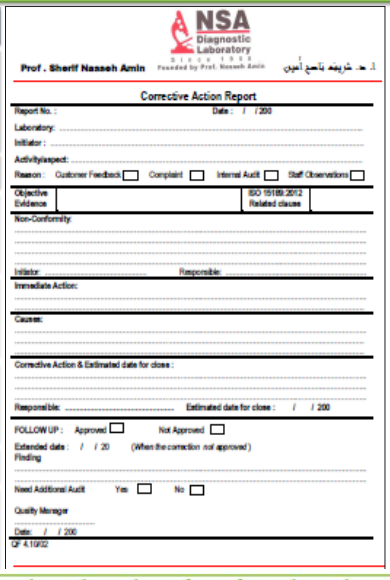
2- Cause analysis:
Investigate to determine the root causes of the problem to ensure that the corrective actions is appropriate to the nonconformities.

3- Selection and implementation
Select the corrective action to eliminate the problem and prevent recurrence, the required changes shall be documented

4- Monitoring of corrective action
Reviewing the effectiveness of the corrective action taken to ensure its suitability for the nonconformity and nonconformity do not recur;

Recording the results of corrective action taken

5- Additional audits,
When the nonconformity affect on the management system procedures and process.


NSA Diagnostic Laboratory
Prof . Sherif Nasseh Amin
Corrective Action Report
Report No. : Date : / / 200
Laboratory:
Initiator :
Activity/aspect:
Reason : Customer Feedback ☐ Complaint ☐ Internal Audit ☐ Staff Observations ☐
Objective Evidence
ISO 15189:2012 Related clause
Non-Conformity:
Initiator: Responsible:
Immediate Action:
Causes:
Corrective Action & Estimated date for close :
Responsible: Estimated date for close : / / 200
FOLLOW UP : Approved ☐ Not Approved ☐
Extended date : / / 20 (When the correction not approved)
Finding
Need Additional Audit Yes ☐ No ☐
Quality Manager
Date : / / 200
QF 4.10/02

4. Management Requirements

4-12 Preventive Actions

The laboratory shall ***determine action to eliminate the causes of potential nonconformities*** in order to prevent their occurrence.

Preventive actions shall be ***appropriate to the effects of*** the potential problems.

The laboratory shall have ***a documented procedure*** for:

a) ***Reviewing laboratory data*** and information to ***determine where potential nonconformities exist***

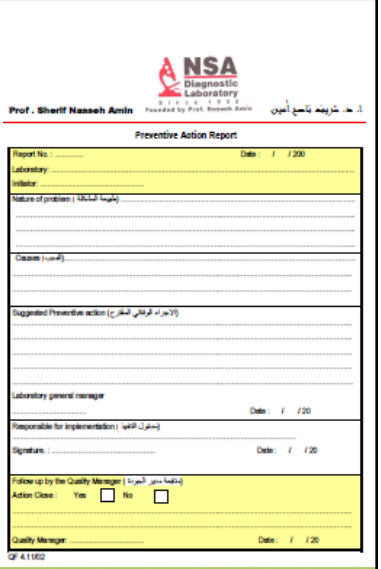
b) determining ***the root cause(s)*** of potential nonconformities

c) ***Evaluating the need for preventive action*** to prevent the occurrence of nonconformities

d) Determining and implementing preventive action needed;

e) Recording the results of preventive action taken

f) reviewing the effectiveness of the preventive action taken



4. Management Requirements

4-12 Preventive Actions

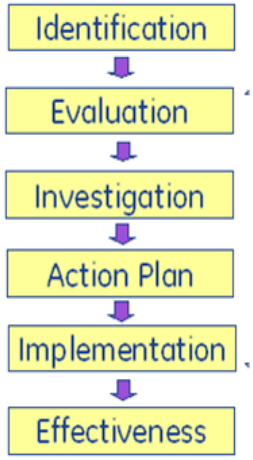
Preventive action is a *proactive process for identifying opportunities for improvement* rather than a reaction to the identification of problems or complaints

In addition to review of the operational procedures, preventive action might involve *analysis of data including trend and risk analyses and external quality assessment (proficiency testing)*

- When preventive actions is required Action plan shall be Develop , implement and monitor to reduce nonconformance and to improve the performance

Management System Plans

- Internal audits plan
- Document evaluation plan
- System backup Plan
- Proficiency testing plan
- Continuous training Plan
- Methods verification plan
- Annually Calibrations plan
- Maintenances plan
- Intermediate checks plan



4. Management Requirements

4.13 .2 Technical records

- The laboratory shall retain records of ***original observations, derived data and information*** to establish an audit trail,
- Test records, staff records and a copy of each test report or calibration certificate issued, **shall retain for a defined period** , ***Retention time shall be defined*** according to the nature of the examination
- The ***date and, the time of amendments to records shall be captured*** along with the identity of personnel making the amendments
- The records for each test shall **contain sufficient information**
- The records shall include identity of **personnel responsible for performance** of the test and checking of results
- Observations, data and calculations shall be recorded **at the time they are made and shall be identifiable to the specific task**
- When mistakes occur in records, **each mistake shall be crossed out, not erased**
- All such alterations to records shall be **signed or initialed** by the person making the correction

4. Management Requirements

4.14 Internal Audits

Systematic and independent examination of the quality management system (QMS) What are you doing? Does it comply with the standard?

Can be by someone within the organisation or from someone outside

To Check that the QMS implemented exactly as intended ?

Identify opportunities to improve

To see if the QMS meets the requirements of standards ?

To investigate a problem
- why did it occur ?
- how can it be resolved ?
- how can it be prevented in future ?

4. Management Requirements

4.14 Internal Audits

The laboratory shall conduct internal audits at ***planned intervals*** to determine whether ***all activities*** in the quality management system ***are complied*** to :

17025 Standard	Laboratory requirements	customers requirements	ACC. Bodies requirements

2- Audits shall be:

- Formally planned and organized,
- Carried out by the quality manager.
- Implemented by qualified personnel.
- Personnel shall not audit their activities.

Defined and documented procedure include

a) The types of audit,
b) Frequencies,
c) Methodologies,
d) Required documentation.

4. Management Requirements

4.14 Internal Audits

1- Internal audit to quality system

- Conducted periodically (6 Month, Yearly)
- Carried out by independent , trained and qualified personnel,
- According to procedure and plan
- Under authority and planned by of the quality manager
- Address all elements of the system, including the testing activities

2- Lab. Shall take:

- Timely corrective action
- Notify customers in written if defects show that the lab results may have been affected.

3- Record the audited area , the activity, the audit findings and corrective actions

4- Follow up to ensure the effectiveness of implementation of corrective actions

The positive and negative findings shall be recorded and summered to the top management and discussed in the management review.

- Vertical Audit : Audit all Activities (All clauses) for one sample at the same time
- Horizontal Audit : Audit one Activities for the laboratory in details at the same time

4. Management Requirements

4.15 Management reviews

4.15.1 General

1-The top management ***periodically review the quality system to ensure*** their ***suitability and effectiveness and to introduce necessary improvements,***

- ❑ A typical period for conducting a management review is ***once every 12 months***
- ❑ Results should ***feed the laboratory planning system*** and should include the ***goals, objectives and action plans for the coming year.***

2- Management reviews findings and actions taken shall be **recorded and ensure that they carried out in time**

4. Management Requirements

4.15 Management reviews

4.15.2 Management review inputs

- ❑Suitability of procedures
- ❑ Assessment of user feedback
- ❑ Staff suggestions
- ❑ Internal audits
- ❑ Risk management;
- ❑ Use of quality indicators;
- ❑ Reviews by external organizations
- ❑ Quality Objectives

- ❑ Performance of suppliers
- ❑ Results of participation in inter-laboratory comparison programs
- ❑ Monitoring and resolution of complaints

4. Management Requirements

4.15 Management reviews

4.15.2 Management review inputs

- ❑ Identification and control of nonconformities
- ❑ Current status of corrective actions and preventive actions
- ❑ Follow-up actions from previous management reviews
- ❑ Changes in the personnel that could affect the quality management system;
- ❑ Changes in premises that could affect the quality management system;
- ❑ Recommendations for improvement, including technical requirements
- ❑ Training and awareness plan and records
- ❑ Internal Quality Control
- ❑Supervisor reports

5. Technical Requirements

5.2.1 Personnel Qualifications

Laboratory staff shall ***be qualified*** **and competent, for perform test, operate equipment and evaluate results** . The records should reflect the appropriate ***education, training, experience and demonstrated skills needed***, and be appropriate to the tasks performed.

5.2.2 Procedure

The laboratory shall ***have a documented procedure*** for **formulate the goal w.r.to Education, training, and skills of lab staff.** and ***maintain records*** for all personnel ***to indicate compliance with requirements.***

5.2.3 New and unemployed personnel

The laboratory shall have a ***program to introduce new staff to the laboratory*** , the department or area in which the person will work, the terms and conditions of employment, staff facilities.

ISO 17025 Awareness	**On job training**	**Management system Procedure**
Emergency and Fire	**Risk Awareness**	**Safety requirement awareness**

When laboratory uses unemployed personnel; it shall ensure that they are supervised and competent

5. Technical Requirements

5.2.4 Job descriptions

The laboratory shall have and ***Maintain current job descriptions for managerial, technical, and key support personnel*** that describe ***responsibilities, authorities and tasks for them.***

5.2.5 Personnel Authorization and Training

- ❑ Personnel who performing particular types of sampling,, issuing test reports, give opinion and interpretation and operate equipment shall be authorized and maintain its records of qualification.
- ❑ The laboratory shall provide ***training for the personnel*** in the following areas
- ❑ The quality management system;
- ❑ Confidentiality of customers data and information
- ❑ Assigned work processes and procedures
- ❑ Ethics
- ❑ Health and safety

The ***effectiveness of the training*** programs shall be ***periodically reviewed***.

5. Technical Requirements

5.2 Personnel

5.2.6 Competency Assessment

the laboratory ***shall assess the competence*** of each person to perform ***assigned managerial or technical tasks according to established criteria***

Direct Observation
- ❑ Procedure observations
- ❑ Calculation of z Score
- ❑ Calculation of precision factor
- ❑ Equipment maintenance

Indirect Observations
- ❑ monitoring records
- ❑ re-testing
- ❑ case studies

- **Planed and timely according to experiences**
- **Use standard forms**
- **Date and keep confidential**

Name :		**Title :**		
Procedure for Evaluation	**Evaluation Date**			**Evaluator**
Procedure item	Accept	Partial	No	Comment
Read procedure manual				
Equipment set up appropriately				
Work area neat				
Reagent preparation				
Perform task accurately				
Perform task timely				
Other: Specify				

Reassessment shall take place ***at regular intervals***. ***Retraining*** shall occur ***when necessary***.

5. Technical Requirements

Personnel records

Records of the ***relevant educational and professional qualifications, training and experience, and assessments of competence*** of all personnel shall be ***maintained***

- Educational and professional qualifications
- Previous work experience
- Introduction of new staff to the works
- Records of continuing education and achievements
- Copy of certification
- Job descriptions
- Training in current job tasks
- Competency and performance assessments

The records may be ***stored in the laboratory*** or in ***other specified locations***, providing they ***remain accessible as needed***

5. Technical Requirements

5.3 Accommodation and environmental conditions

Laboratory facilities shall be in such as correct performance of the tests

The laboratory shall have ***space allocated*** for the **performance of its work that is designed** to ensure the ***quality, safety and efficacy of the service*** provided to the users and the health and safety of laboratory personnel, patients and visitors

1-Technical requirements for accommodation and env. conditions affect results shall be documented.

2- Environmental conditions as sterility , dust , electromagnetic disturbances , humidity, electrical supply, temperature, sound and vibration levels shall be ***monitored, controlled and recorded***.

4- ***Control the accessing*** to and using of areas affecting quality.

3- Effective separation between neighboring areas to prevent cross contamination.

5- ***Measuring of house keeping performance***.

5. Technical Requirements

5.3 Accommodation and environmental conditions

Laboratory premises shall be maintained in a functional and reliable condition. Work areas shall be clean and well maintained.

The laboratory shall monitor, control and record environmental conditions, as relevant specifications required or where they may influence the quality of the sample, results

There shall be effective separation between laboratory sections in which there are incompatible activities

The laboratory shall provide a *quiet and uninterrupted work environment*

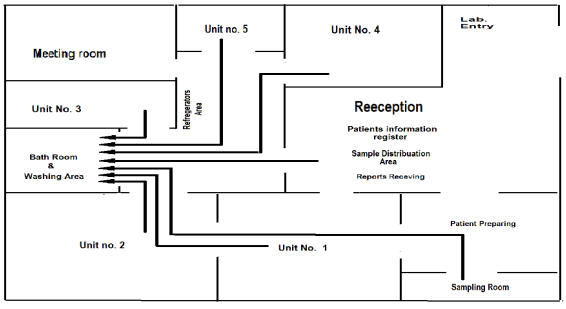
- ***Daily***
  - bench tops
  - floors
- ***Weekly***
  - ceiling and walls
- ***Other***
  - refrigerators
  - freezers
  - storage areas
- ***Record date and cleaning staff***

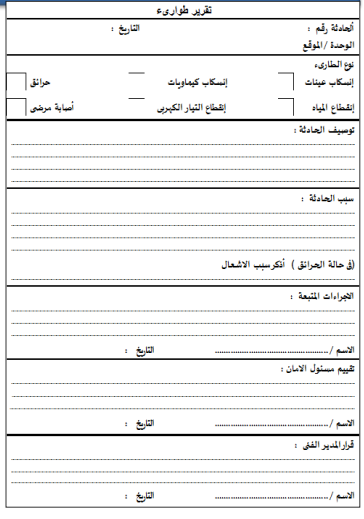
5. Technical Requirements

Contingency plans

Preparing Contingency plan to cover the following points

1- مواجهة مخاطر الحرائق	2- مواجهة مخاطر أعطال نظام الحاسبات
3- مواجهة مخاطر أنقطاع المياه عن المعمل	4- أنسكاب العينات و الكيماويات .
5- مواجهة مخاطر الطقس السيء	6- مواجهة مخاطر أنقطاع التيارالكهربى .
7- مواجهة مخاطر عدم تواجد العمالة و الافراد	8- مواجهة مخاطر تغييرات نظام الادارة .





5. Technical Requirements

5.4 Test methods validation

5-4-1 GENERAL:
The laboratory shall use ***appropriate methods and procedures for all tests within its scope*** , These include ***sampling, handling, transport, storage and preparation of items to be tested***.

The lab. shall have instructions on the ***use and operation of all relevant equipment, and on the handling and preparation*** of items for testing

All instructions, standards and manuals relevant to the work shall be ***kept up to date and shall be made readily available to personnel***

Deviation from the methods shall be ***documented and accepted by the customers***

5-4-2 SELECTION OF METHODS:
The Laboratory shall use test methods (published in National/international standards or others) that is appropriate, and meet client needs.

Types Of Test Methods

Standard Methods	Modified/Developed Methods	Non Standard Methods
وهى الطرق التى تصدر عن جهات منوط بها أصدار و تقي الطرق سواء كانت هذه الجهات دولية أو وطنية	وهى الطرق القياسية التى تم تعديل جميع بنودها او جزء منها بواسطة المعمل لتناسب طبيعة عمله	وهى الطرق التى يتم وضعها بمعرفة المعمل وغير منشورة باى نشرات أو معترف بها خارج المعمل .

5-4-3 LAB. DEVELOPED METHODS :
When the laboratory used developed methods shall be ***validated , planned , agreed by the client before use, assigned to qualified personnel and documented***

5-4-4 NON-STANDARD METHODS:
Non Standard methods shall be ***validated , agreed by the client before use, assigned to qualified personnel and documented***

5. Technical Requirements

5.4 Test methods validation

5-4-5 VALIDATION OF METHODS:
Validate non-standard methods and lab developed methods and the standard methods used outside their intended scope.

The lab. Should record the validation results

The range and accuracy of validated methods shall be relevant to clients needs.

5-4-6 ESTIMATION OF UNCERTAINTY OF MEASUREMENTS:
The laboratory shall have procedure to estimate the uncertainty of all tests. Consider all uncertainty components using appropriate methods of analysis..

5-4-7 CONTROL OF DATA:
Calculations and data transfers shall checks in a systematic manner

2- When computers or automated equipment are used
a) Computer software shall documented in detail and is suitably *validated as being adequate for use*
b) Procedures are established a*nd implemented for protecting the data;*
c) Maintenance plan for computer to ensure proper functioning and are provided with the environmental and operating condition

Maintenance Plan	Computer Password
Software Validation	Staff Authorization

Work Shop No. 2