QUALITY MANUAL

National Drug Control Laboratory
(NDCL)

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Quality Manual

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17 May 2024	08	1. Updated to align with the Drug and Cosmetics Acts -2023. 2. 'Government Analyst' changed to 'Drug Analyst'. 3. 'National Control Laboratory (NCL)' changed to 'National Drug Control Laboratory (NDCL)'. 4. Medical Device, Traditional and Cosmetics Laboratory included.

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All Revisions to this Edition of the Quality Manual are Listed Below:

Sl. No.	Content of 8th (Current) Version
1	National Control Laboratory (NCL) changed to National Drug Control Laboratory (NDCL)
2	Government Analyst (GA) changed to Drug Analyst (DA)
3	The Drug and Cosmetics Act added in relevant places
4	Annexure 01C:- Functional Organogram of LT and Annexure 01D:- Functional Organogram of LR added
5	Definition of Validation, Change Control, KPI, Trend Analysis added
6	Clauses 7.8.1.3, 7.8.3.13, 7.8.4.1, 7.8.5.10, 7.8.11, 7.8.15.3-4, 7.8.17.2, 7.8.17.7, 7.8.17.10–12, 7.8.19.10. 8.2.11.2–5, 8.3.7–10, 8.4.2.4, 9.2, 10.5, 10.16, 12.9–11 added.

Revision History of Current Version; Version 08

Extensive revision has been made to comply with ISO:IEC 17025:2017 standard, ANAB, BAB and WHO guidelines. In this revision, revised part of the Quality Manual has been marked by yellow background in the revised area reflecting the requirements of WHO standards. QMS which adequately describes the scope of the laboratory's activities, laboratory management's commitments, references to specific procedures for each test have been specified in compliance with the WHO Prequalification and Maturity Level–3 requirements.

List of Abbreviations

ANAB	ANSI-ASQ National Accreditation Board
ANSI	American National Standards Institute
ASQ	American Society for Quality
ATCC	American Type Culture Collection
BAB	Bangladesh Accreditation Board
BP	British Pharmacopoeia
B. Pharm	Bachelor of Pharmacy
BSc	Bachelor of Science
BSR	Bangladesh Service Rule
BVSc	Bachelor of Veterinary Science
CAPA	Corrective Action and Preventive Action
CMSD	Central Medical Storage Depot
CFU	Colony Forming Units
CRI	Contract Research Institute
DC	Deputy Chief
DD	Deputy Director
DG	Director General
DGDA	Directorate General of Drug Administration
DGHS	Directorate General of Health Services
DNA	Deoxyribonucleic Acid
DQ	Design Qualification
DTL	Drug Testing Laboratory
EPI	Expanded Programme on Immunization
EQA	External Quality Assessment
EQAAS	External Quality Assurance Assessment Scheme
DA	Government Analyst
GLP	Good Laboratory Practices
GNL	General
HEPA	High Efficiency Particulate Air
ICH	International Committee on Harmonization
IEC	International Electrotechnical Commission
ILC	Inter-Laboratory Comparison
IPH	Institute of Public Health
IQ	Installation Qualification
IQA	Internal Quality Assessment
ISO	International Organization for Standardization
KPI	Key Performance Indicator
LIMS	Laboratory Information Management System
m^3	Cubic Meter

MBBS	Bachelor of Medicine, Bachelor of Surgery
µm	Micro-meter
mm	Millimeter
MOH&FW	Ministry of Health & Family Welfare
M.Sc	Master of Science
MU	Measurement of Uncertainty
NCL	National Control Laboratory
NDCL	National Control Laboratory
NIST	National Institute of Standards and Technology
NRA	National Regulatory Authority
NQCL	National Quality Control Laboratory
OIC	Officer in Charge
OQ	Operational Qualification
PAHO	Pan American Health Organization
PCR	Polymerized Chain Reaction
PMP	Project Management Plan
PQ	Performance Qualification
PQM	Promoting the Quality of Medicine
PT	Proficiency Test
QA	Quality Assurance
QAM	Quality Assurance Manager
QC	Quality Control
QM	Quality Manual
RAB	Rapid Action Battalion
Ref.	Reference
RT-PCR	Real Time Polymerase Chain Reaction
SI	System International
SOP	Standard Operating Procedure
STP	Standard Testing Procedure
TM	Technical Manager
UH	Unit Head
UNICEF	United Nations International Children's Emergency Fund
US	United States
USP	United States Pharmacopoeia
VMP	Validation Master Plan
WHO	World Health Organization

NC: Abbreviation of NC as National Control Laboratory is used only for numbering format.*

1. Introduction

In 2003, Ministry of Health and Family Welfare (MOH&FW) declared Drug Testing Laboratory (DTL), Dhaka as National Control Laboratory (NCL) for Vaccines and Drug Administration (DGDA) as National Regulatory Authority (NRA) for Vaccines. Since then, the activities of vaccines were performed by newly established vaccine lab of NCL and the testing of drugs were performed by Drug Testing Laboratory of NCL. On 18 September 2023, new Drug and Cosmetics Act was gazzeted from Ministry of Health and Family Welfare and NCL name was changed to National Drug Control Laboratory (NDCL). NDCL has taken its responsibility as a primary duty as per Section 18(1) of the National Constitution, to ensure the potency, safety and efficacy of these types of products to meet the national requirement set by the NRA. Directorate General of Drug Administration (DGDA) is given the following responsibilities for this purpose:

1.1. The functions of both NRA and NDCL are required to be backed by appropriate laws.

1.2. NDCL is given the authority by law to review available clinical, safety, potency and efficacy data and use other relevant information from the manufacturer in any relevant country.

1.3. Network of NDCLs of different countries may be encouraged that will result in technological maturity of the NDCLs/NQCLs of importer country.

1.4. To help the post marketing surveillance, NDCL may analyze the complaint sample and send the report to DGDA & the concerned authority.

1.5. NDCL has develop a written procedure for efficient lot release of vaccines, both locally produced and procured from abroad. (Ref. SOP No: NC-QA-GNL-13 & NC-QA-GNL-20)

2. Purpose

The main aim of NDCL is to have safe, potent and efficacious Drugs, Vaccines & Biologicals, Medical Devices, Cosmetics, Food Supplement and Nutraceuticals in the country. According to Act To achieve this goal, NDCL performs tests & assays to ensure that a particular product complies with the requirements and specifications established and approved by NRA during registration and licensing process. It is most important to have reliable, reproducible results and all the agencies should have confidence in the laboratory results of NDCL. For this, accreditation of the laboratory at each step of its performance is warranted and Laboratory Quality Manual (QM) is important component of this process. This QM contains all the requirements that our laboratory uses to demonstrate our quality management system (QMS), technical competence, and valid results.

3. Scope

This QM describes the quality systems applicable to Physico-chemical, Chemical, Microbiological including Virological, and Pharmacological testing laboratories of Drug, Vaccine & Biologics, Medical Device, Cosmetics, Food Supplement & Nutraceuticals of NDCL located beside the DGDA Head Office (Aushad Bhavan) and 7th and 8th floors of Aushad Bhavan, DGDA, Mohakhali, Dhaka, Bangladesh. The QM defines the assessment procedure of quality, efficacy, potency and toxicity of any Drug, Vaccine &

Biologics, Medical Device, Cosmetics, Food Supplement & Nutraceuticals products etc. produced in the country or imported from any country with a view to ensure a safe and effective use by the consumer following ISO/IEC 17025:2017 and WHO standard. This QM facilitates the areas as under:

3.1. The laboratory shall do the following areas of activities within the management scopes:

- 3.1.1 Organization Chart
- 3.1.2 Responsibilities
- 3.1.3 Management System Documentation
- 3.1.4 Control of Management System Documents
- 3.1.5 Control of Records
- 3.1.6 Control of Digital Records through Laboratory Information Management System
- 3.1.7 Actions to address Risks and Opportunities
- 3.1.8 Improvement
- 3.1.9 Subcontracting of Test & Calibration
- 3.1.10 Purchasing services and supplies
- 3.1.11 Services to customers
- 3.1.12 Corrective Actions
- 3.1.13 Deviations Mitigation
- 3.1.14 Change Control
- 3.1.15 Preventive or Risk Mitigation Actions
- 3.1.16 Internal Audits
- 3.1.17 External Audits
- 3.1.18 Trainings
- 3.1.19 Management Reviews
- 3.1.20 Calibration/Qualification/Validation/Verification/Vendor Assessment
- 3.1.21 Measurement of Uncertainty
- 3.1.22 Trend Analysis
- 3.1.23 Key Performance Indicator (KPI)
- 3.1.24 Documents Archive
- 3.1.25 Proficiency Testing/Inter-Laboratory Testing/Intra-Laboratory Testing/EQAAS
- 3.1.26 Complaints / Suggestions
- 3.1.27 Customer Satisfaction Survey
- 3.1.28 Laboratory Safety

3.2. General requirements for the competence to carry out tests and/or calibrations using standard methods, non-standard methods, and laboratory-developed methods.

3.3. Developing their management system for quality, administrative and technical operations.

3.4. Internal and external audits, audits by accreditation bodies

3.5. Meeting the requirements of ISO 17025:2017, ISO 9001, ISO 19011, ISO 13485 standard, WHO guidelines and TRSs and any other national and international standards related to laboratory activities.

3.6. Client/Customer satisfaction/survey

4. Normative References

4.1. This manual is developed based on the guidelines given in ISO/IEC 17025:2017, ISO 9001, ISO 19011, ISO 13485 standard and WHO which is applicable to NDCL as International Standards.

4.2. Vocabularies used in the international metrology are also used in this manual.

5. Terms and Definitions

This QM uses terms and definitions which are referred to in the ISO/IEC 17025:2017 International Standard. Following are some of the most frequently used terms mentioned below; however, additional terms related to technical issues are described in the respective methods, procedures and protocols.

5.1. Accreditation - a formal recognition of a laboratory by an independent science-based organization that the laboratory is competent to perform specific test (ISO Council Committee on Conformity Assessment, CASCO).

5.2. Calibration - a set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by material measure, and the corresponding known values of a measured standard. Also, comparison of a measurement standard or instrument with another standard or instrument to detect, correlate, report, or eliminate by adjustment any inaccuracy of the compared.

5.3. Complaint - expression of dissatisfaction by any person or Organization to a laboratory, relating to the activities or results of that laboratory, where a response is expected.

5.4. Corrective Action - An action taken to eliminate the cause of an existing deficiency or other undesirable situation in order to prevent recurrence.

5.5. Decision Rule - rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

5.6. Deficiency - The non-fulfillment of WHO/ISO 17025/BP/USP/ICH and other international and national requirements and/or criteria for accreditation.

5.7. External Audit - Appraisal of a testing laboratory by an outside body, using specified criteria and checklists to evaluate compliance for accreditation.

5.8. External Quality Assessment (EQA) - EQA is a system of assessing the laboratory performance with a defined objective by an outside agency. Both Internal Quality Assessment (IQA) and EQA are complementary in ensuring the reliability of procedures, their results and finally the quality of the product.

5.9. Good Laboratory Practices (GLPs) - An acceptable way to perform some basic operations or activities in a laboratory that is known or believed to influence the quality of its outputs. GLPs ordinarily are essentially independent of the measurement techniques used.

5.10. Inter-laboratory Comparisons - Organization, performance, and evaluation of tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions.

5.11. Internal Audit - the process of self-appraisal of a testing laboratory using specified criteria and checklists to evaluate compliance for accreditation; may be used as a quality management review as well.

5.12. Internal Quality Assessment (IQA) - IQA is the set of procedures undertaken by the competent personnel of a laboratory for continuously and concurrently assessing laboratory works and the emergent results to decide whether they are reliable enough to be released. It is a part of in-house quality assessment. Samples are prepared, distributed, evaluated and results are assessed internally.

5.13. Intra laboratory comparison - Organization, performance and evaluation of measurements or tests on the same or similar items within the same laboratory in accordance with predetermined conditions.

5.14. Laboratory - body that performs one or more of the following activities: testing; calibration; sampling, associated with subsequent testing or calibration.

5.15. On-Site Assessment - A formal examination or official inspection of a calibration or testing laboratory to evaluate its compliance with specific laboratory accreditation criteria.

5.16. Proficiency Testing - The determination of laboratory performance by means of comparing and evaluating tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions.

5.17. Standard, Reference / Primary - A standard, generally of the highest quality available at a given location, from which estimatons made at that location are derived.

5.18. Standard, Secondary - A standard whose value is assigned by comparison with a primary standard of the same quantity.

5.19. Standard, Working - A standard, usually calibrated aDAinst a secondary standard, which is used routinely to calibrate or check material measures or measuring instruments.

5.20. Standard Operating Procedure (SOP) - "Detailed, written instructions to achieve uniformity of the performance of a specific function" (ICH-GCP 1.55)

5.21. Verification - provision of objective evidence that a given item fulfils specified requirements.

5.22. Validation- "establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes." (US-FDA, 23 Nov 2023)

5.23. Deviation- A deviation is any departure from approved processes, procedures, instructions, specifications, or established standards.

5.24. Change Control- Change control is a systematic approach to managing product, process, or system changes.

5.25. KPI- Key Performance Indicators (KPIs) are measures of the performance of the laboratory and its activities, such as projects, processes, products, or services.

5.26. Trend Analysis- Trend analysis in quality management system is to identify, evaluate, and eliminate any issue that is having a negative effect on product quality.

6. General Requirements

6.1. Impartiality

6.1.1. NDCL management is committed to maintain impartiality in all of its activities as Impartiality Policy (Annexure-03).

6.1.2. All activities of NDCL are structured and managed in such a way that impartiality is properly safeguarded.

6.1.3. NDCL shoulders responsibility of its laboratory activities and does not allow any commercial, financial and other pressure to compromise impartiality (SOP No.: NC-QA-GNL-021).

6.1.4. NDCL will continually strive to identify risks to impartiality including possible risks from NDCL's activities, NDCL's or from its personnel relationships with clients.

6.1.5. Such risks, if identified, should be capably handled by NDCL to eliminate or minimize it.

6.2. Confidentiality

The laboratory maintains the confidentiality and proprietary rights of all information including type of work performed and results of tests to the extent allowable by law. It functions under the Drugs Acts 1940 and Bengal Drugs Rules 1946. The laboratory ensures confidentiality of the testing and its subsequent results to the other customers. All officials working in NDCL are governed by Bangladesh Services Rules (BSRs). All officials are bound by the oath they took at the time of induction into service and all employees sign Statement of Confidentiality of Information. (Ref.: SOP No. - NC-QA-GNL-021)

6.2.1. No people in the laboratory can advise / act as consultant to any manufacturer. The decision of Drug Analyst (DA) / Deputy Chief (DC) will be final on the quality of the product under consideration.

6.2.2. The DA and DC are responsible for ensuring that testing is carried out by only the competent and trained personnel. Every test method is authenticated by DA and / or DC of Drugs and Vaccines Wings of NDCL. They are also responsible for ensuring that the resources are made available for high quality of laboratory operations.

6.2.3. If any information is needed to put in the public domain, NDCL will inform the customer in advance about such information and obtain agreement from the customer about it. Otherwise, all information will be regarded as proprietary and confidential.

6.2.4. However, when required by law or by contractual agreement with the customer, potential information could be released and the customer or individual concerned will notified of information provided unless it is prohibited by law to do so.

6.2.5. Unless agreed by the source, information obtained from the sources other than the customer (Complainant, regulators etc.) will be confidential between the customer and NDCL. Sources/ Provider of the information also will be confidential and shall not be shared with the customer unless agreed by the source.

6.2.6. Any personnel involved in laboratory activities (e.g., Committee members, contractors, Vendors personnel of external bodies or any other individual) will keep confidential all information obtained or created during the laboratory activity, except as required by law.

7. Structural Requirements

7.1. Legal status

DTL acts as NDCL for Drugs, Vaccines & Biologicals in Bangladesh declared in 2003 by Ministry of Health & Family Welfare (MOH&FW), Bangladesh. This laboratory is established under the Drugs Acts 1940 and Rules thereunder. NDCL had been functioning independently under the supervision of DGDA since 07.06.2010. NDCL along with its staff were moved to the organogram of DGDA in August 2017. So, NDCL is now a government organization incorporated in the DGDA Organogram. It functions for testing and issuing certificate of all Drugs, Vaccines & Biologicals which are marketed in Bangladesh (produced & procured). It also provides support to NRA during registration and licensing process as its technical body.

7.2. Testing is of International Competence

The laboratory is committed to ensure the release of only safe and efficacious Drugs, Vaccines & Biologicals. The laboratory carries out the testing of Drugs, Vaccines & Biologicals as per the International and WHO guidelines, so as to meet and satisfy the needs of the ultimate customers i.e. the user population, the regulatory authorities or organization's providing recognition. The laboratory expects to ensure the testing standards of international level.

7.3. Location of the Laboratory and its Testing Facilities

NDCL is located in Mohakhali, Dhaka beside icddr,b and IPH

Address of NDCL:

National Drug Control Laboratory (NDCL)

Mohakhali, Dhaka-1212, Bangladesh.

Tel : 880-2-222261021,222299315

Website: http://www.dgda.gov.bd

In 2010, as per WHO recommendation, MOH&FW placed NDCL under DGDA as per orders No. 45.160.116.00.00.003.2010-166 dated 07.06.2010 which previously was under the administrative control of Directorate General of Health Services (DGHS). Since August 2017, NDCL's employees were moved to DGDA as per Ministry Order and all employees has been getting their salary and other logistics support including lab activities from DGDA budget.

7.4. Independent Judgment on Quality of Drugs, Vaccines & Biologicals

The laboratory is a Third party testing laboratory and has independent opinion on the quality of the Drugs, Vaccines & Biologicals, according to Drug and Cosmetics Act 2023, Drugs acts 1940 and BenDAI Drugs Rules 1946. The laboratory has complete, independence of judgment because of its legal status. It is ensured that the laboratory is independent from any commercial, financial, or other pressures which might adversely affect the quality of tests and resulting reports.

7.5. Accreditation

Accreditation of a laboratory by ~~the~~ an internationally recognized Accreditation Body is essential. Accreditation is an approved procedure by the Accreditation Body, which is competent enough to function as a regulatory authority to accord formal recognition to a laboratory to undertake specific task, provided that the laboratory meets predefined standards. Bangladesh Accreditation Board (BAB), ANAB and ISO/IEC 17025 defines the standards of accreditation of a laboratory. It is a process of inspection of laboratories and their license documents. NDCL had to ensure conformity to predefined criteria pertaining to various aspects of infrastructure and function.

7.6. Minimization of Departures from the Laboratory and Management System

The laboratory has the trained human resource, working in the laboratory for a reasonable period of time. This is evident from the list of the trained staff and their service in the laboratory. The status of the laboratory and its responsibility for the society imparts job satisfaction, which helps in minimization of departure from the laboratory. The personnel working in the laboratory are free from any internal or external pressures and are committed for work of high quality.

7.7. Organizational Chart

7.7.1. The organization and management structure of the laboratory and the relationships between management, technical operations, support services, and the QMS is defined through the Organizational chart as-

Annexure – 01 A (Organizational Chart of NDCL)

Annexure – 01 B (Position of NDCL in DGDA Organizational Chart)

Annexure – 01 C (Functional Organogram of LT)

Annexure – 01 D (Functional Organogram of LR)

7.7.2. The laboratory maintains regular communications for QMS with its entire staff through an effective communication procedure as per SOP No.- NC-QA-GNL-042.

7.8. Responsibilities

Director General (DG) of the DGDA is the top management of NDCL. DC of NDCL as the Head of the laboratory, and Head of the QA is responsible for overall quality of laboratory activities. Head of QA is appointed by DG, DGDA and has direct access to the DG in case of any need for resources, decisions, consultations etc. Deputy is appointed for key managerial personnel to continue laboratory work uninterrupted during the absence of main managers. It is ensured that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system. Job descriptions of the key laboratory staff are as follows:

7.8.1. Deputy Chief (Head of NDCL)

7.8.1.1. Responsible to take administrative and managerial decisions & implementation follow-up.

7.8.1.2. To assure the availability and allocation of all kinds of necessary resources for testing, analysis & quality management system.

7.8.1.3. To give approval of sample for release in LIMS software

7.8.1.4. Oversees the development and implementation of laboratory strategic plan & crafts strategic direction of the laboratory

7.8.1.5. Ensures that the ISO/IEC 17025 and/ or WHO-PQ programs comply with the regulations and government requirements

7.8.1.6. Co-ordinate with DG and other stakeholders to arrange and provide resources required for testing and quality assurance activities in the laboratory

7.8.1.7. Implements managerial decisions on behalf of DG of DGDA

7.8.1.8. Ensures the smooth running of day -to-day operations of the laboratory

7.8.1.9. Assure that staff are trained and competent to undertake tasks in the laboratory related to their roles

7.8.1.10. Organizes & participates in Laboratory Management Review Meetings

7.8.1.11. Issues the lot release certificate for biologicals and vaccines and approve the release of laboratory certificates to clients

7.8.1.12. Authorizes the use ~~or archive~~ of laboratory Standard Testing Procedures (STPs)

7.8.1.13. Participates in Marketing Authorization related documents review.

7.8.1.14. Inspects the manufacturing facilities as a member of DGDA Inspection Team.

7.8.1.15. Any other assignment given by higher authority.

Supervisory Responsibilities: To supervise & monitor the activities of all the employees of NDCL

7.8.2. Deputy Chief (DC) for the Key Managerial Function

DC looks after the duties of all officers and staffs of NDCL. All the personnel in the laboratory are made well aware of their duties, its importance and their contribution for continual improvement of the laboratory's performance at the time of induction into the laboratory. Every person in the laboratory is free to approach to DC for any kind of suggestion/guidance. The management is committed for satisfactory resolution of the situation.

7.8.3. Head of Quality Assurance (QA)

7.8.3.1. Acts as the overall lead for Quality Assurance across all technical and supports departments of the laboratory.

7.8.3.2. Designs and implements policies and procedures in compliance with the requirements of international standard ISO/IEC 17025, BAB and WHO-PQ.

7.8.3.3. Assures the implementation of Laboratory Quality Management Systems (QMS) as per international standard's requirements.

7.8.3.4. Leads the planning and ensuring internal and external quality assurance audits in all laboratory departments.

7.8.3.5. Leads the review of technical and QMS-related documents and procedures to assure compliance to international standards.

7.8.3.6. Coordinate management review meetings, oversees corrective and preventive actions and assures laboratory procedures are of standard quality.

7.8.3.7. Ensures staff are adequately trained for their role and continuously monitor performance, training needs and continuous improvements in the laboratory.

7.8.3.8. Prepares annual progress report, trending and timelines related to QMS.

7.8.3.9. Conduct and analyze customer satisfaction survey data and complaints related issues received in NDCL.

7.8.3.10. Inspects manufacturing facilities as a member of DGDA Inspection Team if require.

7.8.3.11. Participates in the Lot release of Vaccines if require.

7.8.3.12. Approves the use, changes and archive of laboratory standard operating procedures (SOPs), Standard Testing Procedures (STPs), Protocols, Reports and other quality documents.

7.8.3.13. To give approval of different forms (CAPA, Deviation, Change Control, etc.,) for release in LIMS software

7.8.3.14. Any other assignment given by higher authority.

Supervisory Responsibilities:

To supervise & monitor the activities of the employees related to testing and analysis in NDCL.

7.8.4. Drug Analyst (DA) (Drug and Cosmetics Act 2023, Section 51, Rule-45)

7.8.4.1. Performs all duties associated with testing and analysis (i.e. organize testing & analysis,

analytical report review & signing, handling of legal issue regarding test results) as Drug Analyst.

7.8.4.2. DA shall cause to be analyzed or tested such sample of Drugs, Vaccine and Biologicals, Medical Devices, Cosmetics as may be sent to him/her by Superintendent of Drugs (SDs) & Drug Inspectors or other persons under the provisions of Drugs Acts 1940 and Bengal Drugs Rules 1946, Drug and Cosmetics Act 2023.

7.8.4.3. DA is responsible for ultimate opinion and interpretation of all tests and analyses and authorized person to sign the final report of such testing and analysis.

7.8.4.4. DA shall, from time to time, forward reports to the Government giving the result of analytical work and research with a view to their publication at the discretion of Government.

7.8.5. Deputy Head of QA

7.8.5.1. To attain works complying with ISO/IEC 17025 and WHO International Standard.

7.8.5.2. Involved in Lot Release activities if required.

7.8.5.3. Performs laboratory managerial activities assigned by Deputy Chief

7.8.5.4. Assists Head of QA in all quality assurance matters as 'Deputy Head of QA'

7.8.5.5. Conducts annual reviews &/or re-analysis of each analyst.

7.8.5.6. Supports the internal audit processes, and continuous training of analysts to achieve international recognition – ISO/IEC 17025 and WHO-PQ.

7.8.5.7. Provides training on Root Cause Analysis and CAPA, if applicable.

7.8.5.8. Inspects local manufacturing facilities as a member of DGDA Inspection Team if required

7.8.5.9. Responsible for control of Documents and Records used and generated in NDCL

7.8.5.10. To give approval of different forms (CAPA, Deviation, Change Control, etc.,) for release in LIMS software in absence of Head QA

7.8.5.11. Reports to Head of QA.

7.8.5.12. Any other assignments given by higher authority.

7.8.6. Technical Manager (Drug Wing and Vaccine Wing)

7.8.6.1. To attain work complying with ISO/IEC 17025 and WHO International Standard.

7.8.6.2. Develops daily, weekly and / or monthly laboratory work plan for technical staff within the laboratory, NDCL

7.8.6.3. Assures that all testing equipment in the department are properly serviced, maintained and calibrated to assure the accuracy and reliability of analytical testing

7.8.6.4. Assures the implementation of laboratory SOP's, quality manual, safety procedure after approval of competent authority.

7.8.6.5. Develop, monitor and reports Key Performance Indicators (KPIs) of the department to laboratory managemert.

7.8.6.6. Develop and validate or verify analytical testing method, when required.

7.8.6.7. Participates in laboratory management review meetings.

7.8.6.8. Signs off on CoA in his technical area only for release of data

7.8.6.9. Determines technical training needs & conducts training of new & existing staff.

7.8.6.10. Review the data for Inter-Laboratory comparison and Proficiency Testing

7.8.6.11. Ensures that health and safety regulations are followed & maintained compliance with ISO/IEC 17025 & WHO Guideline

7.8.6.12. To supervise the procurement activities.

7.8.6.13. Any other assignment given by higher authority.

7.8.7. Responsibilities of NDCL

7.8.7.1. NDCL is responsible for making an accurate conclusion on the samples received in NDCL from the Post Marketing Surveillance (PMS) and from its customers.

7.8.7.2. Involved in evaluation of drugs, vaccines, biologics, medical device, cosmetics, APIs etc. from production, storage, distribution to registration, marketing authorization and export.

7.8.7.3. Lot Release of vaccines for both locally produced and imported vaccines.

7.8.7.4. Participates in GMP inspection of pharmaceuticals

7.8.7.5. Quality control of government procured drugs

7.8.7.6. Partakes in Marketing Authorization, AEFI, Pharmacovigilance and Clinical Trial oversight

7.8.7.7. Organize training and retraining to QC staff

7.8.7.8. Involved in identification of SF drugs thereby participated in preventing SF drugs in Bangladesh

7.8.7.9. Participates in the SEARN Network (Working Group – 1, Quality) in prevention of SF drugs in the region.

7.8.8. Authority of NDCL

7.8.8.1. NDCL is the organization in the scope of activities, functions, responsibility and authority granted by Ministry of Health & Family Welfare (MOH&FW) and NDCL is accountable for its activities

7.8.8.2. NDCL has the authority to demand the pharmaceutical and cosmetic manufacturers, importers, distributors, and exporters to supply necessary documents including test procedures, reference standards, formulary, method validation documents, manufacturing processes, specifications, analytical records and related drug information.

7.8.8.3. Making annual and general reports on testing/analyzing activities of drugs, vaccines, biologicals, medical devices and cosmetics, etc.

7.8.8.4. Providing test reports of drugs, vaccines, biologicals, medical devices and cosmetics, etc.

7.8.8.5. Receive complaints / appeals and handling complaints for corrective actions and preventive actions

7.8.8.6. Retention or destruction of samples as per law and procedure

7.8.8.7. Retention of documents as per the national law and NDCL procedures

7.8.9. Responsibilities of Drug Wing

7.8.9.1. Testing and Analysis of Allopathic Drugs and conclusion of results

7.8.9.2. Testing and Analysis of Active Pharmaceutical Ingredient (API)

7.8.9.3. Testing and Analysis of Medical Devices

7.8.9.4. Testing and Analysis of Traditional Medicines like Ayurvedic, Unani and Herbal Medicines

7.8.9.5. Testing and Analysis of Homoeopathic and Biochemical Medicines

7.8.9.6. Shoulders other assignment given by Directorate General of Drug Administration (DGDA), MOH&FW in relation to test and analysis

7.8.10. Responsibilities of Vaccine Wing

7.8.10.1. Testing and Analysis of Vaccines and Biologicals.

7.8.10.2. Shoulders other assignment given by DGDA, MOH&FW in relation to test and analysis

7.8.11. Responsibilities of Cosmetic Lab

7.8.11.1. Testing and Analysis of Cosmetic sample and conclusion of results.

7.8.11.2. Shoulders other assignment given by DGDA, MOH&FW in relation to test and analysis

7.8.12. Responsibilities of Physico-chemical Department

7.8.12.1. Perform physical tests in NDCL

7.8.12.2. Performs Chemical Tests of drug and cosmetic samples

7.8.12.3. Implement method validation for chemical tests

7.8.12.4. Ensures technology transfer procedures

7.8.12.5. Shoulders other assignment given by DGDA, MOH&FW in relation to test and analysis

7.8.13. Responsibilities of Microbiology Department

7.8.13.1. Responsible for microbiological testing of sterile and non-sterile samples

7.8.13.2. Performs Sterility test, Antibiotic Assay Tests. Total Aerobic Microbial Count (TAMC) and Total Combined Yeast and Mold Count (TYMC), Bioassay, Potency by Cell-culture, RT-PCR

7.8.13.3. Performs Growth Promotion Test (GPT)

7.8.13.4. Tests for microbial contamination

7.8.13.5. Other test using microbiological techniques

7.8.13.6. Manages standard strain, cultivating and collecting microbial strains for quality control tests

7.8.13.7. Shoulders other assignment given by DGDA, MOH&FW in relation to testing and analysis.

7.8.14. Responsibilities of Pharmacology Department

7.8.14.1. Responsible for Endotoxin tests (LAL) by Gel-Clot method and Kinetic method

7.8.14.2. Shoulders other assignment given by DGDA, MOH&FW in relation to testing and analysis.

7.8.15. Responsibilities of Animal Testing Laboratory

7.8.15.1. Testing of vaccines and biological on animals

7.8.15.2. Pyrogen Testing of Parenteral

7.8.15.3. Ensure proper receive, quarantine and bio-security of animal

7.8.15.4. Management of animal wastage by proper incineration

7.8.15.5. Shoulders other assignment given by DGDA, MOH&FW in relation to test and analysis

7.8.16. Responsibilities of Metrology Department

7.8.16.1. Responsible for In-house calibration of equipment

7.8.16.2. Planning and execution of equipment by third party calibrating agency

7.8.16.3. Maintains current calibration status of equipment

7.8.16.4. Arrange qualification of premises

7.8.16.5. Ensure Qualification of HVAC system

7.8.16.6. Maintains log book of in-house and third party calibration records

7.8.16.7. Shoulders other assignment given by DGDA, MOH&FW in relation to testing and analysis.

7.8.17. Responsibilities of Engineering Department

7.8.17.1. Responsible for maintenance of Engineering works in all laboratories

7.8.17.2. Maintain access control and close circuit camera

7.8.17.3. Maintain HVAC System

7.8.17.4. Implement preventive and breakdown maintenance

7.8.17.5. Maintain and operate Generators

7.8.17.6. Assist in maintenance of equipment

7.8.17.7. Ensure to maintain environmental condition in NDCL

7.8.17.8. Maintain log book of all physical assets of NDCL

7.8.17.9. Ensures training on safety and fire-related issues

7.8.17.10. Ensure safety, security and maintenance of laboratory premises

7.8.17.11. Prepare, maintain and update the laboratory lay-out

7.8.17.12. Operation and maintenance of ETP

7.8.17.13. Shoulders other assignment given by DGDA, MOH&FW.

7.8.18. Responsibilities of Finance and Administrative Department

7.8.18.1. Maintains financial budgets as per government budget rules

7.8.18.2. Manages assets receipt and delivery log books, annual inventory records, handling of consumables, its storage, distribution and destructions records

7.8.18.3. Asset management as per current government rules

7.8.18.4. Generate reports on receipts, expenses, existing assets

7.8.18.5. Prepare requirements for finances and assets

7.8.18.6. Plan for purchase of logistics, laboratory equipment, chemical/reagents on demand and on quarterly and annual basis

7.8.18.7. Prepare document for contracts for procurement

7.8.18.8. Evaluate and enlist vendors

7.8.18.9. Set acceptance criteria for purchases

7.8.18.10. Ensure receipt of supplies as per requirement

7.8.18.11. Arrange tender document for procurement

7.8.18.12. Shoulders other assignment given by DGDA, MOH&FW.

7.8.19. Responsibilities of Quality Assurance Department

7.8.19.1. Responsible for planning, implementation and improvement of Quality Control activities of NDCL

7.8.19.2. Monitor consistency of quality activities in testing and analysis

7.8.19.3. Ensures implementation of GLP

7.8.19.4. Prepare, revise, approve, control, archive and disposal of documents (SOPs, STPs, Protocols, CAPA, Deviations, Change Control, etc,) of NDCL.

7.8.19.5. Assures easy availability of documents

7.8.19.6. Perform training need assessment and arrange training for NDCL staff and others when necessary

7.8.19.7. Performs Internal Audit

7.8.19.8. Performs Management Review

7.8.19.9. Periodically evaluates effectiveness (KPI) of QC activities

7.8.19.10. Prepare competency matrix of laboratory personnel

7.8.19.11. Ensures activities related to continual improvement of NDCL

7.8.19.12. Monitors the plan, implementation, calibration and maintenance activities

7.8.19.13. Manages analytical equipment and other devices for proper service in testing and analysis with accuracy and reliability.

7.8.20. Lot Release of Vaccines

7.8.20.1. NDCL is responsible for Lot Release of Vaccines, locally produced and imported

7.8.20.2. NDCL Vaccine Wing is responsible for testing of vaccines as part of Lot Release activities.

8. Resource Requirements

8.1. General

NDCL has adequate qualified staff, spacious facilities, enough equipment, necessary systems and support services to manage and perform laboratory activities.

8.2. Personnel

8.2.1. Laboratory staff is selected for employment based on professional qualifications, including education, training, technical knowledge, skills and relevant experience. Class-1 & 2 Employees are recruited directly through Public Service Commission on the basis of framed recruitment rules. Other employees including technical staff is recruited through DGDA on the basis of written examination and interview following an initial screening process.

8.2.2. DA, appointed by the MOH&FW, is authorized for making opinions and interpretations of test report. DA, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have:

8.2.2.1. relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service;

8.2.2.2. knowledge of the general requirements expressed in the legislation and standards;

8.2.2.3. an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned. (Ref.: The Drug and Cosmetics Act 2023, The Drugs Acts and Rules 1940, Page-44-45)

8.2.3. Staffing is just sufficient to maintain the timely processing of workload, laboratory internal monitoring, quality control, and traceability activities required for accreditation.

8.2.4. Adequately trained staff is a key factor in performing the tests. Laboratory personnel have the necessary background in the life sciences to ensure comprehension of the laboratory tests and operations. There is a provision for external and on-the-job training through WHO, USP-PQM, KOICA and other Developing Partners for the scientific and technical staff.

8.2.5. DC and DA utilizes staff resources to meet following policy goals:

8.2.5.1. Implement and apply the procedures contained in the referenced documents

8.2.5.2. Provides ongoing training to ensure proficiency in testing

8.2.5.3. Develops work plan schedules and requires that the staff follow the procedures in day-to-day operations;

8.2.5.4. Assign tasks based on personnel training and verified competence.

8.2.6. All staff of NDCL act impartially, with competence and in accordance with the laboratory's management system.

8.2.7. NDCL management assigns appropriate duties, responsibilities and authority to its staff.

8.2.8. The Laboratory maintains procedures and records for determination of competence, selection, training, supervision, authorization of personnel and their competence monitoring.

8.2.9. NDCL authorizes personnel to perform specific laboratory activities, including but not limited to, the following:

8.2.9.1. Development, modification, verification and validation of methods

8.2.9.2. Analysis of results, including statements of conformity or opinions and interpretations

8.2.9.3. Report review and Authorization of results.

8.2.10. Training Requirements

8.2.10.1. NDCL requires and provides training to all staff and personnel from both inside and outside of NDCL. Laboratory staff meets the training requirements of NDCL and all training is documented and maintained in the laboratory. Laboratory staff conducting experiments in the specific areas has successfully completed the noted courses and assignments as per the training requirements of the department. Training is imparted as per Training Plan. (Ref.: SOP No. - NC-QA-GNL-002)

8.2.11. Job Descriptions

Current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations are maintained centrally in the QA. Minimum contents of job descriptions include:

8.2.11.1. the duty of performing tests and/or calibrations

8.2.11.2. key responsibilities of personnel

8.2.11.3. common responsibilities as per function

8.2.11.4. specific responsibilities

8.2.11.5. supervisory responsibilities

8.2.11.6. the act of planning tests and/or calibrations and evaluation of results

8.2.11.7. the responsibility of developing and validating new methods as / when requested expertise and experience

8.2.11.8. qualifications and training programs

8.2.11.9. managerial duties (Ref. SOP No. - NC-QA-GNL-039)

8.3. Facilities and Environmental Conditions

8.3.1. The laboratory facilities, test areas, energy sources, lighting, heating, and ventilation facilitate proper performance of estimations and tests.

8.3.2. The laboratory facilities are maintained, where applicable, in accordance with GLP. The design of the laboratory does not adversely affect the assay results and supports GLP.

8.3.3. The laboratory ensures that dust, electromagnetic interference, humidity, line voltage, temperature, sound and vibration levels or temperature changes that adversely affect the estimations are appropriate for specific results.

8.3.4. The environment in the laboratory where testing is performed does not invalidate results nor adversely affect the accuracy or uncertainty of the measurement. Laboratory staff ensures adequate conditions in the facility by checking items listed below:

8.3.4.1. Verify that lighting, humidity and heating are controlled and monitored.

8.3.4.2. Maintain good housekeeping practices to promote a clean, uncluttered laboratory according to procedures.

8.3.4.3. Have sufficient space to minimize the risk of injury to staff and/or damage to standards or equipment due to activities around test setup.

8.3.4.4. Bench tops and floors are made of impervious, smooth, easily cleaned materials. Walls and ceilings are made of materials that are smooth and easily cleaned. In the Microbiology area, critical work surfaces are monitored for pathogens pertinent to the scope of the laboratory.

8.3.4.5. Effective separation between neighboring areas is made when the activities are incompatible. Measures are taken to prevent cross-contamination.

8.3.4.6. Controlled use of cleaning and pest control materials is exercised. The laboratory complies with the local health and safety requirements.

8.3.4.7. Access to the laboratory is restricted to authorized personnel and Microbiology Lab No.: NC-MB-LST/118/17-00). The authorized personnel are made aware of the following items:

- the intended use of the area
- the restrictions imposed on working within such areas
- the reasons for imposing the restrictions

8.3.5. HVAC System in NDCL

NDCL has well established HVAC system in microbiology lab, vaccine chemical, animal lab as well as drug lab for continual consistent environmental condition. Environmental conditions of the microbiology laboratory is monitored on regular intervals by exposing Agar plates for Colony Forming Units (CFUs) and by air sampling. Monitoring of temperature and humidity of the laboratory is done on regular basis (SOP No.–NC-MB-GNL-017). In addition, pressure differentials are also monitored regularly as per SOP No.: NC-MB-GNL-017).

8.3.6. Waste Disposal System

8.3.6.1. NDCL establishes waste disposal system for effective operation of the laboratory for its intended use. It operates contracts with external agency for disposal of solid wastes

8.3.6.2. NDCL also has established Effluent Treatment Plant (ETP) for liquid waste disposal.

8.3.6.3. SOP No.: NC-QA-GNL-034 is implemented for effective waste disposal system of NDCL.

8.3.7. LIMS Software and Server Set Up

NDCL has developed LIMS software for upgrading the laboratory system which follow SOP No.- NC-QA-ENG-016. NDCL has central server system for data security and data backup which follow SOP No.- NC-QA-ENG-015. Secondary server for additional backup and security of data is also established in NDCL.

8.3.8. Archive Setup

NDCL has well established archival facility for archiving documents and raw data, closed logbook, reports, old documents, legal documents, etc. All documents are archived there according to SOP No.- NC-QA-GNL-052

8.3.9. Sample Receiving and Storage Setup

NDCL has well established facility for receiving and storage of sample and retention sample by maintaining proper temperature, humidity and access control which follow SOP No.- NC-QA-GNL-036.

8.3.10. Chemical/Reagent Storage Setup

NDCL has well established facility for storage of received chemical and reagents by maintaining proper temperature, humidity and access control which follow SOP No.- NC-QA-GNL-014.

8.4. Equipment

8.4.1. Required Equipment

8.4.1.1. NDCL is furnished with all items for measurement and test equipment required for the correct performance of the tests and/or calibrations (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) and that can influence the results.

8.4.1.2. Laboratory does not have any use of equipment outside its permanent facility; however, if such use is warranted, it will ensure that the requirements of this QM are met.

8.4.1.3. Equipment is used in an environment appropriate to its proper performance. All equipment required by a test is described in each method, including the equipment's tolerances and standards operating procedures(SOP).

8.4.2. Accuracy of Equipment

8.4.2.1. Equipment and software used for testing and/or calibration are capable of achieving the accuracy required and comply with specifications relevant to the tests and/or calibrations concerned.

8.4.2.2. Calibration programs are established for key quantities or values of the instruments where these properties have a significant effect on the results.

8.4.2.3. When received, equipment is checked by performing IQ, OQ and PQ whichever required to establish that it meets the laboratory's specification requirements, complies with the relevant standard specifications before use.

8.4.2.4. Quarterly Calibration programs are established to check the performance of equipment by metrology team.

8.4.2.5. The procedures for checking newly received equipment are as determined by manufacturers' specification and/or those determined by the laboratory during procurement.

8.4.3. Authorized Access to Equipment

8.4.3.1. Equipment is operated by authorized personnel whose have specific training on that equipment. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) are readily available for use by the appropriate laboratory personnel.

8.4.3.2. Access to laboratory equipment is controlled by individual User Name and Password to ensure that only authorized personnel use equipment.

8.4.4. Unique Identification

8.4.4.1. Each item of equipment used for testing and calibration is uniquely identified as appropriate and identification label is attached on every equipment.

8.4.4.2. Measuring and testing equipment is uniquely identified through asset identification number.

8.4.4.3. Components that can be interchanged between various instruments are tracked in equipment logbooks but are not assigned individual asset identifications. (Ref. : SOP No. – NC-QA-ENG-009)

8.4.5. Inventory and Maintenance Records

8.4.5.1. Records are maintained for each item of equipment significant to the tests and/or calibrations performed. The records include the following:

- identity of the item of equipment (and its software and firmware version)
- manufacturer's name, type identification, and serial number and/or other unique identification
- checks that equipment complies with the specification
- current location, where appropriate
- the manufacturer's instructions, if available, or reference to their location
- dates, results and copies of reports and certificates of all calibrations, adjustments,
- acceptance criteria, and due date of next calibration
- maintenance carried out to date and the maintenance plan (includes calibration)

- damage, malfunction, modification or repair to the equipment

8.4.5.2. A database is used to capture the above inventory information. The above information related to service and maintenance is kept in individual equipment files and/or binders.

8.4.5.3. Other information kept in these files and/or binders may include:

- date received and date placed in service
- condition when received (e.g., new, used, refurbished)
- dates and results of calibration and/or verification and date of next calibration and/or verification
- performance history, where appropriate (e.g., response time, drift, noise level)

(Ref.: SOP No. – NC-QA-ENG-001)

8.4.6. Procedures Related to Equipment

8.4.6.1. Procedure for safe handling, transport, storage, use and maintenance (including calibration) of measuring equipment, and appropriate use of correction factors to ensure proper functioning and to prevent contamination or deterioration is followed in NDCL (SOP No. – NC-QA-GNL-043).

8.4.6.2. NDCL does not have scope to use measuring equipment outside the permanent laboratory for tests

8.4.6.3. The procedures for each piece of measuring equipment are in the appropriate room where the equipment is located.

8.4.7. Out of Service Equipment

8.4.7.1. Equipment giving suspected results or has been shown to be defective or outside specified limits, is taken as out of service, clearly marked/labeled, and appropriately stored or segreDAted until it has been repaired, performance checked and shown by calibration or test to perform correctly.

8.4.7.2. Routine testing work is completely discontinued on equipment that even shows minor nonconformances.

8.4.7.3. The laboratory examines the effect of the defect or departure from specified limits on previous test and/or calibrations.

(Ref.: SOP No. – NC-QA-ENG-001)

8.4.8. Calibration of Equipment

8.4.8.1. NDCL maintains an internal calibration program for yearly third-party calibration and is supported by an accredited equipment calibration provider, which is reviewed and adjusted as necessary to maintain confidence in the status of calibration.

8.4.8.2. Equipment requiring calibration is labeled to indicate the calibration status and/or operational status and the date when re-calibration is due when appropriate.

8.4.8.3. Calibration labels have a write-on surface and a pressure sensitive adhesive.

8.4.8.4. Calibration label include the person who performed the calibration, the date it was performed, the date it is due for re-calibration, and the equipment's identification number. (Ref.: SOP No. – NC-QA-ENG-003)

8.4.9. Return to Service

8.4.9.1. When equipment goes outside the direct control of the laboratory for a period, the laboratory ensures that the function and calibration status of the equipment are checked and validated and shown to be satisfactory before the equipment is returned to service.

8.4.9.2. The procedures used to check and ensure that the function and calibration status of the equipment are satisfactory before the equipment is returned to service are outlined in the manufacturer's equipment manual.

8.4.10. Periodic Checks

8.4.10.1. When intermediate checks are needed to maintain confidence in the calibration status of equipment, these checks are carried out periodically according to defined procedure and Intermediate Check Plan. (Ref.: SOP No. – NC-QA-ENG-003)

8.4.11. Correction Factors

Calibrations that give rise to a set of correction factors are updated along with all copies of this data (e.g., in computer software).

8.4.12. Adjustment Security

8.4.12.1. Test and calibration equipment, including hardware and software, are safeguarded from adjustments that invalidate test and/or calibration results/status.

8.4.12.2. Safeguards against adjustment for laboratory equipment include:

- detailed SOPs and manufacturer's manuals on the operation of the equipment
- policies permitting only fully trained and competent personnel to operate equipment
- access to the laboratory is restricted to authorized personnel

8.4.12.3. Safeguards against adjustment for software Includes:

- password protection for important files and packages
- access to the laboratory is restricted to authorized personnel

8.5. Metrological Traceability – Please see at Clause 11.

8.6. Externally Provided Products and Services

8.6.1.1. NDCL ensures that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

- Are intended for incorporation into the laboratory's own activities
- Are used to support the operation of the NDCL
- Product may be measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services include – calibration services, testing services and equipment maintenance services, proficiency testing, Interlaboratory comparison, assessment and auditing services.

8.6.1.2. NDCL has procedures and retain records for:

- defining, reviewing and approving the laboratory's requirements for externally provided products and services
- defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers
- ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer
- taking any actions arising from evaluations, monitoring of performance and re-evaluation of the external providers.

8.6.1.3. NDCL communicates with its external providers for:

- Products and services to be provided
- The acceptance criteria
- Competence, including any required qualification of personnel
- Activities that NDCL wants to perform at external provider's premises.

9. Process Requirements

9.1. Review of Requests, Tenders and Contracts

9.1.1. NDCL has procedures to review requests, tenders and contracts where requirements are adequately defined and documented.

9.1.2. Any work pertaining to the testing of samples is carried out according to ISO 17025 Standard and WHO Guidelines.

9.1.3. The laboratory has the capability and resources to meet the clients' requirements.

9.1.4. Records of reviews, including any significant changes, are maintained. Records of any discussions or meeting with the clients are also maintained.

9.1.5. Any contract made by NDCL for any laboratory activities should be acceptable both to the customer and to NDCL.

9.1.6. The requirements, including the methods to be used, are adequately defined and documented.

9.1.7. If the method requested by customer is inappropriate or out of date, NDCL decides appropriate methods for testing and informs the customer.

9.1.8. Decision rule applied for conformity (Pass/Fail, In-tolerance/Out-of-tolerance) is clearly defined in the report and communicated to, and agreed with, the customer.

9.1.9. Differences in the requests, tenders and contracts, if any, are resolved before laboratory activity commences. Any amendment to contracts if required after work has commenced, contract is reviewed and possible impact because of that amendment is communicated to all stakeholders.

9.1.10. NDCL allows reasonable access of customers into NDCL to witness any laboratory activity specific to the customer's need; however, confidentiality of the NDCL is protected by signing confidentiality agreement by such customers.

9.2. Selection, Verification of Vendors/Suppliers

NDCL has established procedure for selection of vendors/suppliers for externally provided product and services. After .selection of vendors/suppliers, they are enlisted in a logbook and verification of vendors/suppliers also done according to SOP No.- NC-QA-GNL-033.

9.3. Selection, Verification and Validation of Methods

9.3.1. Selection and Verification of Methods

9.3.1.1. Laboratory shall use appropriate (Standard) methods and procedures for the test and analysis and for evaluation of measurement uncertainty and statistical analysis.

9.3.1.2. All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory work kept up to date and readily available to the laboratory personnel.

9.3.1.3. These compendial methods are mentioned in the approved pharmacopoeia of respective countries in which the product is manufactured. NDCL uses the current version of pharmacopoeia available.

9.3.1.4. In the absence of compendial methods, NDCL uses methods published in international, national and regional standards, or by reputable technical organizations, or in relevant scientific texts or journals or as specified by the manufacturer.

9.3.1.5. These procedures are also in the form of technical guidelines of WHO or in some cases national guidelines.

9.3.1.6. The laboratory verifies compendial methods and validates other methods, if used in NDCL.

9.3.1.7. The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.

9.3.1.8. Any deviation from the methods is well documented, technically justified, authorized and accepted by the customer.

9.3.2. Validation of Methods

9.3.2.1. The laboratory shall validate non-standard methods, laboratory developed methods (if any), and standard methods used outside their intended scope, and amplification and modification of standard methods to confirm that the methods are fit for the intended use.

9.3.2.2. In case, validation is already done by the sample sender or any other party, NDCL will review validation data for its authenticity and scientific soundness. If the review is satisfactory, NDCL uses that test procedure after proper verification.

9.3.2.3. In case, any changes or modification done to any validated method, influence of such changes/modification on the original validation will be evaluated. If significant impact is found, the method will be validated and considering it a new method.

9.3.2.4. The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs.

9.3.2.5. Validation records include:

- Validation procedure/protocol used
- Specification of the requirements
- Determination of the performance characteristics of the method
- Result obtained
- A statement as to whether the method is fit for the intended use.
- Methods are validated as per SOP No.- NC-QA GNL-062 and NC-QA GNL-075

9.4. Sampling

9.4.1. NDCL does not have any sampling system for drugs, vaccines, biologicals, medical devices and cosmetics, etc.

9.4.2. Sampling plan for submitting samples to laboratory is dependent on the source of sampling (e. g. NRA, Legal sources & others, etc.)

9.4.3. In the case of imported consignment, respective SDs designated by DGDA of Bangladesh draw the samples and send it to laboratory through courier services

9.4.4. Survey samples of drugs, vaccines, biologicals, medical devices and cosmetics, etc. are drawn by concerned officer of DGDA as per rules and are referred to laboratory for complete analysis / specific test request

9.4.5. Legal samples are also referred by Drugs Administration authorities, judiciary or police for opinion

9.4.6. Samples for cold chain monitoring from field are referred by concerned officer of DGDA

9.4.7. Samples are also drawn by manufacturers and referred to laboratory for testing

9.4.8. Samples once received in the laboratory are allotted a laboratory identification No. and stored in prescribed conditions handling testing. For testing, samples are picked-up randomly and all details of samples are entered in the relevant testing protocol or register as the case may be (Ref.: SOP No. – NC-QA-GNL-006, 035).

9.5. Handling of Test or Calibration Items

9.5.1. Samples received for test are recorded in a laboratory work log and assigned a number which uniquely identifies the item during its stay in the laboratory. Work logs are maintained in the laboratory. A receipt is completed which includes:- the sample or samples received for test, name of company submitting the test samples, and date of receipt. Testing orders are taken on the receipt proforma.

9.5.2. Incoming test samples are stored under prescribed conditions as specified in SOP by appropriate laboratory staff to ensure proper storage of the samples.

9.5.3. Prior to testing incoming samples, the laboratory communicates to the manufacturer any significant abnormalities including:

9.5.3.1. Departures from required standard transportation conditions and necessary preparations

9.5.3.2. Doubt as to the item's suitability for test

9.5.3.3. Nonconformance of the test sample with the description provided on the label and unspecified test requirements.

9.5.4. NDCL maintains records of such communication in the Communication logbook. Disclaimers are made in the report indicating possible effect of any deviation when customers request NDCL to continue testing items against which deviation was raised by NDCL.

9.5.5. The laboratory handles, prepares, and stores test items in its custody in a safe manner to protect them from loss, contamination, deterioration, damage, and destruction of required chains of evidence.

9.5.6. A portion of the sample usually sufficient for duplicate repeat testing is stored as 'Retention Sample' and another part is distributed to the Unit for Testing. Test Request Form is provided to the Unit with details of samples, necessary testing details, any special instruction for handling based on the risk category, any special storage condition to be maintained. Such instructions with samples are followed-up for proper implementation during storage, testing and disposal of those samples. Documented procedures for the receipt and retention of the test samples are maintained in the laboratory files.

9.5.7. Upon completion of testing, the leftover sample is disposed as per disposal SOP.

9.5.8. NDCL does not practice movement of samples to outside laboratory and does not accept remaining sample after test from units to the storage system. After test, the remaining samples are disposed as per SOP. (Ref.: SOP No. -. NC-MB-GNL-027, NC-QA-GNL-006 & NC-QA-GNL-036)

9.6. Technical Records

9.6.1. The laboratory ensures that its technical records for each laboratory activity:

9.6.1.1. Contains the results, reports and sufficient information to facilitate, if possible, to identify factors affecting the measurement results and its associated measurement uncertainty.

9.6.1.2. Contains enough information in such way to enable repetition of the activity under condition as close to the original.

9.6.1.3. Shall include date and identity of the personnel responsible for the activity as well persons checking data and results

9.6.1.4. Original data, observation and calculations which are recorded at the time they are made and identifiable to the specific task.

9.6.1.5. Any amendments to the technical records are made traceable to previous version or to original observations.

9.6.1.6. Both amended and original data and files are retained indicating the persons amended, area/issue altered and date of alteration.

9.7. Evaluation of Measurement Uuncertainty

9.7.1. When estimating the uncertainty of measurement, all uncertainty components that are of importance in the given situation are taken into account using accepted methods of analysis.

9.7.2. Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, the environmental conditions, the item being tested or calibrated and the operator.

9.7.3. NDCL determines measurement uncertainties of its major equipment and procedures as per SOP- NC-QA-GNL-067.

9.7.4. The laboratory has implemented procedures to control environmental conditions which has critical impact on the measurement uncertainties like, dust, temperature, humidity, pressure differentials, electromagnetic interference, line voltage, sound and vibration levels etc.

9.7.5. Where Uncertainty is measured from outside agency, NDCL will review and authorize the Uncertainty Report and document it. In addition, NDCL will perform its own uncertainty. (Ref.: NC-QA-GNL-067).

9.8. Ensuring the Validity of Results

The testing laboratory has a system for monitoring the validity of tests undertaken. The resulting data is recorded in a way that trends are detectable, where practicable, statistical techniques are applied to the reviewing of results. The monitoring shall be planned and reviewed and may include the following:

9.8.1. Regular use of certified reference materials and/or internal quality control using secondary standard to check the validity of assay

9.8.2. Use of alternative instruments which is calibrated to provide traceable results

9.8.3. Functional checks of measuring and testing equipment

9.8.4. Replicate tests using the same or different methods

9.8.5. Use of check or working standards with control charts, where applicable

9.8.6. Intermediate checks of measuring equipment

9.8.7. Retesting from retained samples

9.8.8. Correlation of results for different characteristics of an item e.g. trend analysis of testing results and reference standard.

9.8.9. Comparison of results with that of manufacturer's results.

9.8.10. Testing of blind sample(s)

9.8.11. Intra-laboratory comparison

9.8.12. Participation in proficiency testing program

9.8.13. Participation in Inter-laboratory Comparison

9.8.14. Reported data from the monitoring activities shall be analyzed, used to control and improve the laboratory's activities. Appropriate actions will be undertaken for any data outside pre-defined criteria to prevent incorrect results from being reported. (Ref.: SOP No. – NC-QA-GNL-040)

9.9. Reporting of Results

The results of each test, calibration, or series of tests or calibrations are reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

The results are reported, normally in a test report, and include all the information requested by the customer and necessary for the interpretation of the test results and all information required by the method used. Test reports are issued as per SOP meant for reporting of samples received for testing under different categories (Ref.: SOP No. – NC-QA-GNL-036).

9.9.1. General

9.9.1.1. The UH/Supervisor looking after a particular case shall examine/review the documents, Analytical Worksheet, Laboratory Note Book received from the Analyst to ensure that testing was done as per testing order, calculation and other information provided was accurate and documented properly. The reviewed analytical worksheet will be signed and submitted to DA for approval and authorization.

9.9.1.2. DA shall approve and authorize the report after complete review against raw data and order for typing.

9.9.1.3. The typed report will aDAin be checked by UH/Supervisor for any topographic mistakes before sending to DA for final signature and authorization.

9.9.1.4. After thorough review of each report after typing, reports are sent to DC of laboratory for final approval.

9.9.1.5. Required no. of copies are made and checked and signed by DA.

9.9.1.6. NDCL controlled dispatch no. are issued on each report and necessary endorsement be made.

9.9.1.7. Reports are then sent to the sending Drug Inspectors in triplicate as per The Drug and Cosmetics Act 2023 and to other senders as required.

9.9.1.8. All reports shall be issued upon approved by DC. Template of reports for drugs, vaccines, biologicals, medical devices and cosmetics, etc. are available at Annexure-2 (A to C).

9.9.1.9. All reports shall be addressed to the sample sender, indicating subject, batch no. of the product, manufacturing date, expiry date, name of manufacturer, presentation and status (i.e. standard or not of standard quality) along with parameters of lot release (i.e. scrutiny of protocols, testing) followed by NDCL No.

9.9.1.10. Copy of the Non-compliant report shall always be endorsed to DGDA of Bangladesh.

9.9.1.11. The report shall be dispatched under registered cover by postal services to sample sender.

9.9.1.12. One copy of the Noncompliant/Substandard report will be retained within the DA for future reference leDAI purposes.

9.9.1.13. The office copies after dispatch shall be marked and finally be preserved as technical record for future reference.

9.9.2. Common Requirements for Test Reports

9.9.2.1. A title (e.g. "Test Report")

9.9.2.2. Name and address of the laboratory

9.9.2.3. Location of the Laboratory, if laboratory activities are performed away from NDCL's permanent facility including at customer's facility.

9.9.2.4. Unique identification of the test report, and on each page an identification in order to ensure that the page is recognized as a part of the test report, and a clear identification of the end of the test

9.9.2.5. Reference to Drugs Acts used as leDAI basis for testing and reporting of the sample

9.9.2.6. Name and Contact information of the Customer (Sample Sender)

9.9.2.7. Test methods are used as per SOP of GTP (SOP No:NC-QA-GNL-063) and compendia, where applicable. For non-compendial products, the test parameters which are not available in GTP can be taken from the manufacturers' supplied method.

9.9.2.8. Description of, the condition of, and unambiguous identification of the item(s) tested

9.9.2.9. Date of receipt of sample and date of sampling, when required

9.9.2.10. Date(s) of performance of the test/laboratory activity

9.9.2.11. Date of issue of the report

9.9.2.12. Reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results. NDCL does not have Sampling activity.

9.9.2.13. A statement to the effect that "Certified that the result relates only to the items tested. This report shall not be reproduced except in full, without written approval of the laboratory authority. Directorate General of Drug Administration (DGDA) makes no opinions or interpretations derived from the documentation and the data generated".

9.9.2.14. Test results with, where appropriate, the units of measurement

9.9.2.15. Information on addition to, deviations, or exclusion from method

9.9.2.16. Name and signature of DA

9.9.2.17. A statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory

9.9.2.18. NDCL shall be responsible for all the information provided in the report; however, the laboratory will not be responsible for any information provided by the customer. In such case, any data / information provided by the customer shall be clearly marked and mentioned in the report as 'disclaimer'.

9.9.2.19. In special cases, reporting may be done in simplified way as per agreement with the customer. In such case, all the required information mentioned in ISO/IEC 17025:2017 from clause 7.8.2 to 7.8.7 will be readily available with NDCL for future reference.

9.9.2.20. As NDCL does not do sampling, all samples tested in NDCL will be treated as 'as received'.

9.9.3. Specific Requirements for Test Reports

In addition to the common requirements listed above, test reports shall include following information, if necessary for interpretation of results:

9.9.3.1. Details of any environmental conditions during sampling that may affect the interpretation of the test results

9.9.3.2. A statement of conformity with requirements or specifications

9.9.3.3. Where applicable, Measurement Uncertainty –if it is relevant to the validity or application of the test results, a customer's instruction so requires, or — the measurement uncertainty affects conformity to a specification limit(s)

9.9.3.4. where appropriate, opinions and interpretations

9.9.3.5. Any additional information required by the customer or methods

9.9.4. Specific Requirements for Calibration Certificates

9.9.4.1. NDCL does only internal calibrations of its non-critical equipment and does not have any services for Customers on calibration activities; however, it receives calibration certificates from the third party calibration laboratory and needs to be familiarized with calibration certificate and its contents.

9.9.4.2. Calibration certificate should have following additional information included:

- the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results
- the uncertainty of measurement (as same unit to the measurand or relative to it like, %) and/or a statement of compliance with an identified metrological specification or clauses thereof evidence that the measurements are traceable.
- In case any repair or adjustment, result before and after adjustment/repair should be reported.
- A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the NDCL or it is to be used by the laboratory itself. (Ref. :SOP No. – NC-QA-ENG-003)

9.9.5. Reporting Statement of Conformity

9.9.5.1. NDCL reports statement of conformity as per the decision rule provided by the respective pharmacopoeia and customers' information.

9.9.5.2. Test Reports clearly mention which results statement of conformity applies and which specifications, standards or parts thereof are met or not met.

9.9.6. Reporting Opinions and Interpretations

9.9.6.1. In some cases, as per legal requirements, when reporting on prescribed Form, details of results or analysis with protocols of test applied has it be specified, a statement has to be given that the sample is of standard or is not of standard quality as defined in the Drug and Cosmetics Act 2023.

9.9.6.2. Such opinions and interpretations is made by designated DA appointed by the Ministry of Health & Family Welfare (MOHFW).

9.9.6.3. Opinions and Interpretations made by DA should be based on the test results and it should be identifiable.

9.9.6.4. Records of opinions and interpretations, if communicated verbally with the customer, will be recorded.

9.9.7. Amendments to Reports

9.9.7.1. If an issued report needs to be changed, amended or re-issued, any changes in the information is clearly marked with reason of such change or amendment included.

9.9.7.2. Amendment to a test report after issue shall be made only in the form of a new report, which includes the statement:

- Amendment to Report, serial number....
- That previous report No. ..... dt. ..... will be treated as cancelled. or
- "Supplement to Test Report (serial number). or
- "To be replaced in the same Memo and Date". Or
- an equivalent form of wording.

9.9.7.3. Amendments should meet all the requirements of ISO 17025.

9.9.7.4. New report shall be uniquely identified and shall contain a reference to the original that it replaces.

9.9.8. Testing and Calibration Results Obtained from Subcontractors

9.9.8.1. NDCL accepts results of Vaccine potency and toxicity testing from external laboratories. NDCL also contracts the calibration of its critical equipment by third party accredited calibration laboratory.

9.9.8.2. NDCL maintains contracts with such laboratories and shoulder responsibility of such reports

9.9.8.3. When the test report contains results of tests performed by external laboratories these results shall be clearly identified.

9.9.8.4. Such report should be in writing or electronically.

9.9.8.5. When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the NDCL.

9.9.8.6. NDCL does not have any subcontracting testing service for its Chemical and Microbiological Tests.

9.9.9. Electronic Transmission of Results

9.9.9.1. In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this International Standard shall be met.

9.9.10. Format of Reports and Certificates

9.9.10.1. The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.

9.9.10.2. The layout of the test report is such that the presentation of the test data facilitates ease of assimilation by the reader.

9.9.10.3. The headings are standardized as far as possible. (Ref.: SOP No. – NC-QA-GNL-035)

9.10. Complaints / Suggestions

9.10.1. Complaints/Suggestions are received from the customers or other departments in the form of letter, fax, email, direct contact, phone, customer survey response, audit result, media news etc.

9.10.2. In addition, a complaint and Suggestion dropping box is established to receive any complaints, suggestions, and opinions from the customers.

9.10.3. The box is opened twice a month for any complaint available. All complaints/suggestions are immediately checked for any issue that needs to be addressed instantly. Regular meeting to review the content of complaint and corrective actions to be taken to settle such is held by QA as per SOP - NC-QA-GNL-027.

9.10.4. All activities like opening of the box, complaints/suggestions received and actions taken are dealt with by NDCL and recorded in the designated file.

9.10.5. The QA Head communicates with the complainants or customers about the result of the review and actions taken by NDCL.

9.10.6. Anonymity and confidentiality of the information and the person involved are strictly maintained.

9.11. Nonconforming Works

If any activity of NDCL, do not conform to its procedure or agreed requirement of the customer, NDCL has a procedure to implement to address those nonconformance. The procedure will contain:

9.11.1. Responsibility and authorities for management of nonconforming works are defined

9.11.2. Actions for management of nonconformance work which may include halting or repetition of work or withholding of reports

9.11.3. An evaluation of the significance of the nonconforming work including its impact on the previous results is made

9.11.4. Correction is taken immediately, together with any decision about the acceptability of the nonconforming work

9.11.5. Where necessary, the customer is notified and work is recalled

9.11.6. DA is authorized for giving permission for resumption of work

9.11.7. Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures shall be promptly followed.

9.11.8. NDCL retains records of all records of nonconforming works and actions taken or planned.

9.12. Control of Data and Information Management

9.12.1. Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

9.12.2. When the LIMS are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory ensures that:

9.12.2.1. Software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use

9.12.2.2. If there is any changes or modifications in the software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation

9.12.2.3. procedures are established and implemented for protecting the data; such procedures include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing, measures against data tampering, loss and unauthorized access.

9.12.2.4. computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

9.12.3. All LIMS related documents including instructions, manuals and reference data are readily available to the concerned personnel.

9.12.4. In case, LIMS is managed and maintained through external provider / operator, it will be ensured that requirements of this manual are maintained.

9.12.5. Computer Software Procedures

9.12.5.1. Where computers are involved in data recording, retrieval, processing, calculation, analysis, or reporting, the laboratory ensures that:

- Computer software has been documented and verified for use.
- Procedures are established to:
  - ⊃ Protect the integrity of stored data
  - ⊃ Provide limited access to maintain security of the programs in use
  - ⊃ Back-up programs and records and
  - ⊃ Provide information for revising the software if updates occur
  - ⊃ Record system failure and initiate immediate and corrective actions, where appropriate.

10. Management System Requirements

10.1. General

NDCL establishes documents, maintains and implements a management system that is capable of supporting and demonstrating consistent achievement of requirements of ISO 17025 and assures quality of test results. NDCL maintains option A of ISO 17025 clause 8.1.2 for its management system which addresses the following:

10.1.1. Management System Documentation

10.1.2. Control of Management System Documents

10.1.3. Control of Records

10.1.4. Actions to Address Risks and Opportunities

10.1.5. Improvement

10.1.6. Corrective Actions

10.1.7. Internal Audits

10.1.8. Management Reviews

10.2. Management System Documentation

10.2.1. Policy and Procedures

10.2.1.1. The purpose of our QMS is to ensure that all services and products satisfy the customer's requirements and have been designed, manufactured, and delivered under controlled conditions.

10.2.1.2. All policies, systems, programs, procedures and instructions are documented to the extent necessary to enable the laboratory to assure the quality of results generated. These documents are communicated to, understood by, available to, and implemented by the appropriate personnel.

10.2.1.3. The effectiveness of the QMS is assessed in several ways:

- by a program of planned internal audits, covering all aspects of the operation of the QMS
- by regular management reviews of the suitability and effectiveness of the QMS
- by analysis of potential and actual problems as shown by customer complaints and supplier and subcontractor assessments
- by other methods approved from time to time by the QA Head and DC

10.2.2. Quality Policy

10.2.2.1. National Drug Control Laboratory (NDCL) shall ensure strict compliance with ISO 17025:2017 and WHO cGMP and GLP standards and local regulatory norms in every phase of sourcing & procuring quality materials, analysis, quality assurance and delivery of services to the customers.

10.2.2.2. NDCL shall ensure all activities through documented effective QMS complying International Standard requirements of ISO 9001 and WHO through continuously developing Human Resources by regular training and participation. NDCL's motto is to familiarize its staff with documentation required for ensuring quality and implementation of the policies and procedures in its working arena.

10.2.2.3. The laboratory management's commitment is to good professional practice and quality of testing, calibration, validation, verification and compliance with the content of these guidelines. The management is also committed to undertake appropriate review, evaluation and performance

measurement of processes, business activities and QMS for continual improvement to ensure highest standard, customer satisfaction, developing human resources and institutional growth.

10.2.3. Quality Objectives

NDCL is committed to complying with ISO/IEC 17025 and WHO international standards and to continually improve the effectiveness of the management system: the principal objective of the NDCL is to document and implement the compliant policies and associated procedures that are integrated into our daily activities. Continual improvements are established, implemented, and locked into the management system. To protect the health of people of Bangladesh by ensuring easy access to useful, effective, safe and good quality Drugs including Vaccines, Biologicals, Medical Devices and Traditional Medicines, NDCL's quality objectives are as follows:

10.2.3.1. To improve laboratory performance through reducing non-conformity/deficiencies and using validated test procedures

10.2.3.2. To provide genuine and timely result with highest quality, impartiality and ethical standards along with instant reporting of results

10.2.3.3. To ensure scientific evaluation of quality through regular evaluation & skill upgradation of quality of services

10.2.3.4. To maintain strict confidentiality, privacy and restricted access to customer's data

10.2.3.5. To ensure availability of quality chemicals/reagents and other materials from registered vendors and maintain minimum stock

10.2.3.6. To provide flawless sample & data processing, handling, distribution, transfer and management

10.2.3.7. To improve housekeeping services of the laboratory

10.2.3.8. To reduce breakdown time of equipment

10.2.3.9. To ensure safety and security of the laboratory and staff

10.2.3.10. To ensure loyalty, integrity and commitment of the laboratory staff towards effectiveness of the QMS

10.2.3.11. To ensure that all personnel are trained and competent to a level of familiarity with the QMS appropriate to the individual's degree of responsibility

10.2.3.12. To impart training to the employees for upgradation knowledge and skill through assessment of training needs of each staff related to their assigned job

10.2.3.13. To participate in Inter-laboratory Comparison Testing schemes, Proficiency Testing (PT) or quality evaluation programs with peer laboratories.

10.2.4. Assuring the Quality of Tests

10.2.4.1. The laboratory conducts tests for the parameters in accordance with the procedures, practices, and conditions required, recommended, and/or approved as per pharmacopeias and WHO

Technical Report Series and/or its affiliated documents. The techniques utilized for specific tests ensure the accuracy, tolerance, precision, traceability and are within the applicable guidelines.

10.2.4.2. Lot Release of each batch of Vaccines is done as per WHO criteria of NRA function of Lot Release and testing is done as per criteria of Laboratory Access. (Ref: SOPs No. – NC-QA-GNL-013, 009 & 010)

10.2.4.3. The guidelines for the accurate performance of the tests are available in the form of controlled/active copies of SOPs. These are available with the concerned department, unit and Head, QA. The DA and DC are responsible for ensuring that testing is carried out by only the competent and trained personnel. Every test method is authenticated by DA and DC of NDCL. They are also responsible for ensuring that the resources are made available for high quality of laboratory operations. (Ref.: SOP No. – NC-QA-GNL-040)

10.2.5. Accessibility of NDCL Staff to QM and QMS

10.2.5.1. This QM (along with appendices and references) is available to all concerned laboratory staff and those staff familiarizes themselves and complies with the policies and procedures established in the manual and associated documents.

10.2.5.2. All NDCL staff who are involved in laboratory activity have access to Management System up to the extent of their involvement in that part of QMS.

10.2.6. Delegation of Authority / Management Substitutions

10.2.6.1. Management is responsible for ensuring that current and/or increased workload requirements are met. This includes making adjustments as a result of employee absence. Only fully trained employees are utilized to fulfill the duties of personnel who are absent.

10.2.6.2. In the absence of the DC, the QA Head will secure his/her duties. Similarly, in the absence of QA Head, the Deputy Head of QA will assume his/her responsibilities. In the absence of the Technical Manager (TM) / Supervisor, the senior analyst for that department will assume his/her responsibilities. One DA will replace another DA during his/her absence. In case, no alternative staff is available, Management will find ways for best possible solutions.

10.2.7. Conflict of Interest

Staff working in NDCL will not have any bias, financial or any other interest which might compromise the integrity and credibility of NDCL. All the staff working in NDCL will disclose any private financial interests that are related to NDCL activities. All staff are governed by BSR. (Ref.: SOP No. – NC-QA-GNL-021). Every staff are encouraged and monitored to maintain utmost impartiality in all laboratory activities. Every staff is required to sign declare, in a prescribed form, if any of their close relatives are related to any of its stakeholders through financial or any other means which may be a conflicting factor for accomplishing his/her duties in NDCL.

10.2.8. Operation Control

DC of the Laboratory keeps track of all the activities going on in the various sections including safety, security, training, testing, interpretation and assessment of test results.

10.2.9. Deviations

From time to time it may be necessary to authorize deviations from the requirements stated in this manual. Such deviations must be authorized by Head, QA and DC of NDCL.

10.2.10. Structure of Documentations in QMS

10.2.10.1. This QMS is structured in three tiers of documentation. The tiers are as follows:

- Quality Manual and Standard
- SOPs and Standard Test Procedures
- Forms and Records

10.2.10.2. The following records and directive documents (Not exhaustive) are referenced in the QM, but maintained separately:

- Organizational Chart
- Copies of the Quality Policy Statement posted in the laboratory
- Copies of Quality Objectives Statement posted in the Laboratory
- Copies of Safety Policy Statement posted in the Laboratory
- Copies of Impartiality Policy Statement posted in the Laboratory
- Confidentiality Agreements
- Job Descriptions
- Test Reports
- Identification of the Laboratory's Approved Signatures (and initials) and ID of Staff.
- Equipment Inventory, Maintenance Records and Calibration Status and Plan
- Chemical, Reagent and Reference Standards/Materials Inventory
- Corrective Action Records
- Preventive Action Records
- Customer Complaint Records
- Audit Schedule and Records
- Procurement Records
- Training Records and Plans
- Master List of Documentation

10.2.11. Maintenance (Changes in the Management System)

Top management ensures that the integrity of the management system is maintained when changes to the management system are planned and implemented. (Ref.: SOP No. – NC-QA-GNL-041))

10.3. Control of Management System Documents

10.3.1. Document means any information or instructions including policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, and plans. These may be in various media, whether hard copy or electronic and they may be digital, analog, photographic or written.

The documents to be controlled include:

10.3.1.1. Quality Manual

10.3.1.2. Standard

10.3.1.3. Standard Operating Procedures and Standard Test Procedures

10.3.1.4. Forms and Records

10.3.1.5. Any other documents mentioned in the NDCL's Master Document List, internally generated or collected from the external sources.

10.3.2. The SOPs No. NC-QA-GNL- 003 & 011 are used to control all QMS documents (internally generated and from external sources). These include documents of external origin, such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, specifications, instructions, and manuals.

10.3.3. This document control system should ensure that –

10.3.3.1. authorized editions of appropriate documents are available at all locations where operations are performed

10.3.3.2. documents are periodically reviewed by personnel knowledgeable in the documented activity and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements

10.3.3.3. invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use

10.3.3.4. obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

10.3.4. A Master List of all Documents identifying the current revision status and revision due date is maintained.

10.3.5. Identification of Documents:

All QMS documentation is identified by:

10.3.5.1. date of issue and/or revision number

10.3.5.2. page numbering

10.3.5.3. total number of pages (e.g., page 05 of 05)

10.3.5.4. a mark signifying the end of the document.

10.3.5.5. issuing authority (i.e., approval signature)

10.3.6. Controlled Copies

Controlled/active copies of this QM, all SOPs, and checklists are made available to all Technical and Administrative staff as per distribution list. All controlled/active copies are numbered and updated by the Deputy Head, QA whenever changes are made. Recipients of controlled/active copies are issued the revised QM with a cover sheet identifying updates made to the manual. It is the responsibility of the Head, QA to ensure that the most current QM is issued and followed by all laboratory and administrative staff. A list of the names, control numbers, and locations of all controlled/active copies are maintained in QA Department.

10.3.7. Document Changes

10.3.7.1. Any changes or revisions and approval in the documents will be made by the same function who did it in the original documents.

10.3.7.2. Changes in the document in the computerized system will be marked by highlighting the text.

10.3.7.3. Revision history will be added after every revision of any document.

10.3.8. Changes in QM

Head, QA has the designated authority to modify or update the QM. The QM will be reviewed and updated every 3 (Three) years. However, if needed, it may be done earlier. The DC of the laboratory is responsible for final approval of all changes made to the QM and the revised document takes effect when authorized by DG, DGDA.

10.3.9. Changes in the Other Documents

10.3.9.1. The documents will be reviewed at least once in three years. The reason for altering any document will be recorded in the history sheet available with every document.

10.3.9.2. The altered or the new document will be given a new version number.

10.3.9.3. Hand-pending corrections are made to data by drawing a single line through the entry and initialing the change and dated, with a note as to why the change was made. The change is made in all the controlled/active copies also. With the three-yearly revision of the document, a new version number will be given to the whole document in which correction has been made. A revised document shall be formally re-issued as soon as practicable. (Ref.: SOP No. – NC-QA-GNL-011)

10.4. Control of Records

10.4.1. The laboratory shall establish and maintain control procedures for identification, collection, archiving, access, filing, storage, protection, back-up, retrieval, retention time and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.

10.4.2. All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

10.4.3. Retention times of records shall be established with consideration of National Guideline and its contractual obligation.

10.4.4. The laboratory ensures the safety and security of records.

10.4.5. Records include those with information required by regulation, or associated with original test observations, calculations, and reported results.

10.4.6. Test results in the form of raw data are recorded in permanent form, in bound note books, or on standard forms on file.

10.4.7. Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

10.4.8. Permanent ink is used to record the actual data and no erasures or white-outs are made. Corrections are made to data by drawing a single line through the entry and initialing the change.

10.4.9. Test records contain sufficient detail to, if necessary, permit the estimation of sources of uncertainty and repetition of test.

10.4.10. Records, including those in computer files, are accessible to authorized personnel only. Computer files are backed-up for protection against loss or unauthorized access or amendments. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

10.4.11. Access to the records shall be consistent with confidentiality commitments and records shall be readily available.

10.4.12. All records are retained for at least twenty years.

(Ref.: SOP No. NC-QA-GNL-022 & NC-QA-GNL-044)

10.5. Documents Archival System

NDCL has well established document archival systems for archiving the documents like- test reports, obsolete documents, finished logbook, legal documents, lot release documents, etc. by following Archive Management SOP No.- NC-QA-GNL-052.

10.6. Actions to Address Risks and Opportunities

10.6.1. NDCL considers risk and opportunities associated with its activities to assure that management achieves its expected results, enhance opportunities to fulfill purpose and objectives of NDCL, prevent / reduce undesired impacts and potential failures in the laboratory activities thereby achieves improvements.

10.6.2. Actions necessary are integrated and implemented into management system. The effectiveness of such activities is evaluated at the same time.

10.6.3. NDCL has procedures to identify and avoid threats, to find opportunities for better and wider scope of activities of NDCL. Actions are taken based on the magnitude of risks and its possible consequences.

10.6.4. NDCL has risk management plan which includes all these activities, and also to address when to share and retain risks for further improvement of NDCL's activities (Ref. SOP NO: NC-QA-GNL-065).

10.7. Improvement

10.7.1. NDCL identifies opportunities for improvements through review of operational procedures, using policy and objective of NDCL, internal and external audit, CAPA follow-up, management review and through suggestions from personnel.

10.7.2. NDCL partakes in the Inter-laboratory Comparison Test (ILT), Proficiency Testing (PT) Scheme to explore scope of improvements. (Ref.: SOP No. – NC-QA-GNL-045)

10.8. Subcontracting of Tests and Calibrations

10.8.1. NDCL may require subcontracting a competent subcontractor for increasing its expertise, temporary short of capacity to do certain procedure etc. A competent subcontractor is one that, for example, complies with the International Standard for the work in question like ISO/IEC 17025:2017.

10.8.2. NDCL will make a written agreement with the subcontractor after thorough review of their capacity.

10.8.3. However, in all cases, NDCL will shoulder the responsibility of the results of the subcontractors if such subcontractor is selected by NDCL; however, in case, when such subcontractor will be decided by customer or regulatory agency, responsibility will not be borne by NDCL.

10.8.4. The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question.

10.8.4.1. NDCL does not have any plan for subcontracting chemical and microbiological testing as it has capacity to conduct all types of microbiological tests.

10.8.4.2. In case, subcontracting is inevitable, specific laboratory activities will be shared and agreed with the customer.

10.9. Purchasing Services and Supplies

10.9.1. NDCL purchase and procure services and supplies as per SOP No: NC-QA-GNL-014.

10.9.2. DG, DGDA also provide full financial supports for services and supplies needed.

10.9.3. Developing partners like, WHO, USP-PQM also provides substantial supports in the form of supplies and services.

10.9.4. NDCL maintains list of qualified vendors with ISO 9000/ 9001 or ISO/IEC 17025 certification. (Ref.: SOP No. – NC-QA-GNL-033).

10.9.5. Purchased/procured materials undergo rigorous inspection for its quality, appropriateness for its intended use, compliance to specific test/procedure and to international standards. Records of such inspection and action taken in case of non-compliance preserved in the archive.

10.9.6. Irrespective of source of procurement, NDCL will verify related documents which includes type, class, grade, precise identification, specifications, drawings, inspection instructions, and other technical data including approval of test results, the quality required and the management system standard under which they were made. These documents should be reviewed for its technical content and be approved before release for use.

10.9.7. The NDCL evaluates suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.

10.9.8. Where the supplies do not meet the specifications provided by the NDCL, the items are rejected.

10.9.9. All purchased / procured items are documented in the registers meant for the purpose and stored under conditions that will not affect the quality of the materials.

10.10. Services to Customers

10.10.1. Having ensuring utmost confidentiality, NDCL cooperates with its customers or their representatives in clarifying customer's request and in monitoring laboratory's performance in quality and reliable testing.

10.10.2. In case of any unusual delay in reporting, NDCL communicates and informs the customer about the amount of and reason for the delay. In the event of any dispute or major deviation in any test-related matters, customers are welcomed to have a free and open free discussion to settle it. NDCL has SOP of seeking feedback from the customers in the designated template to assess their satisfaction. Such feedback is reviewed by QA at regular interval according to SOP to improve management of NDCL and to increase customer's satisfaction. (Ref.: SOP No. – NC-QA-GNL-038)

10.11. Corrective Actions

10.11.1. General

NDCL maintains SOP (NC-QA-GNL-008) for any corrective and preventive actions to be taken in case of nonconforming work or departures from the policies and procedures in the management system or technical operations identified through a variety of activities, such as control of nonconforming work,

internal or external audits, management reviews, feedback from customers and from staff observations.

10.11.2. Root Cause Analysis

Prior to initiate a Corrective action, investigation is done to explore the root cause of the problem by carefully reviewing and analyzing the nonconformities. Careful investigation of all potential causes like, customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration is done when root cause is not obvious. Investigations are also done to find out whether similar nonconformities could potentially occur elsewhere or recurs.

10.11.3. Selection, Implementation and Monitoring of Corrective Actions

10.11.3.1. Selection of an appropriate corrective action will eliminate the problem and its recurrence. So, it should be proportionate to the magnitude and risk of the problem. NDCL monitors and documents any required changes resulting from taken corrective action.

10.11.3.2. The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

10.11.3.3. If identification of a non-conformance is because of some weakness, lacking in the policy and/or procedure of NDCL, the laboratory will undertake additional audit in the relevant area to improve it.

10.11.3.4. If nonconformity is because of some weakness in the management system, NDCL will make required changes in the management system.

10.11.3.5. NDCL will assess identify and update any risks and opportunities during planning.

10.11.3.6. NDCL shall maintain records of the nature of nonconformities, actions taken and subsequent results of such corrective actions

10.12. Preventive or Risk Mitigation Actions

10.12.1. NDCL has procedures (SOP No: NC-QA-GNL-008) to identify potential sources of non-conformance and areas needing improvement. An action plan will be developed, implemented and monitored to reduce likelihood of recurrence and to improve the situation.

10.12.2. Review of the operational procedures, analysis of data including trend and risk analyses and proficiency-testing results will be evaluated to find the possible source of non-conformance.

10.12.3. The QA will review suggested actions and will record the conclusions reached as per SOP.

10.12.4. Procedures for preventive actions shall include the initiation of such actions and the application of controls to ensure that they are effective.

10.13. Internal Audits

10.13.1. Internal audits (self-assessments) are conducted at least once a year to verify that operations continue to comply with the quality system of NDCL as well as ISO 17025 Standard. Auditors are trained in auditing techniques, have technical insight concerning the laboratory's functions, and are (wherever possible) independent of the activity to be audited. When audit findings cast doubt on the correctness or validity of the laboratory's test results or some observations are made, DC investigate further and, if warranted, directs immediate remedial measures. A compliance report is given to Head, QA.

10.13.2. The laboratory has established and maintains a quality system supporting the tests conducted by the laboratory. The quality system is described in these QM, annexures, and applicable sections of the references named therein. These documents are readily available to all laboratory staff and serve as the basis for evaluating the tests and associated reports. The laboratory conducts internal audits or periodic checks carried out by or on behalf of management to ensure that the laboratory's policies and procedures and other aspects of management systems as set out in the QM are being implemented and maintained.

10.13.3. The area of activity audited, the audit findings and corrective actions that arise from them are recorded.

10.13.4. Follow-up audits are undertaken to verify and record the implementation and effectiveness of the corrective action taken. (Ref.: SOP No. – NC-QA-GNL-012)

10.14. External Audits

External audits (on-site assessments) are performed by WHO and/or any other organization to verify that the laboratory's operations, facilities, equipment, standards, and staff continue to comply with the standard, guidelines and this QM. All external and internal audit and accreditation review findings, and any corrective actions that arise from them, are promptly settled within the agreed time, documented by QA, and maintained in the laboratory files. Compliance report is sent to the concerned authority.

10.15. Management Reviews

10.15.1. Top Management periodically conducts a review of laboratory's management system and testing and / or calibration activities to ensure their continuing suitability and effectiveness and to introduce necessary changes or improvements. The review looks into:

10.15.1.1. Changes in the internal and external issues that are relevant to the laboratory

10.15.1.2. Fulfillment of objectives

10.15.1.3. Suitability of policies and procedures

10.15.1.4. Status of actions from previous management reviews

10.15.1.5. Outcome of recent internal audits

10.15.1.6. Corrective actions

10.15.1.7. Assessment by external bodies

10.15.1.8. Changes in the volume and type of work or in the range of laboratory activities

10.15.1.9. Customers' and personnel feedback

10.15.1.10. Complaints

10.15.1.11. Effectiveness of any implemented improvements

10.15.1.12. Adequacy of resources

10.15.1.13. Results of risk identification

10.15.1.14. Outcomes of the assurance of the validity of results; and

10.15.1.15. Other relevant factors, such as monitoring activities and training. The outputs from the management review shall record all decisions and actions related to at least:

- the effectiveness of the management system and its processes
- improvement of the laboratory activities related to the fulfilment of the requirements of this document
- provision of required resources
- any need for change

10.15.2. Management Review frequency will be at least once a year. The decisions taken in the management review meeting are implemented in the predetermined/targeted time schedule for effective functioning of the laboratory.

10.15.3. Findings from management reviews and the actions that arise from them are recorded and will be fed into the action plan for the coming year.

10.15.4. The management ensures that those actions are carried out within an appropriate and agreed timescale. (Ref.: SOP No. – NC-QA-GNL-037)

10.16. Key Performance Indicator (KPI)

NDCL has procedure to assess the performance of the relevant staffs and also as an institute for NDCL based on the target set and achievement against that target by following SOP No.- NC-QA-GNL-074

11. Metrological Traceability

11.1. NDCL has procedures of calibrating critical equipment, glassware, HVAC system etc. by third party which has traceability of calibration through an unbroken chain to International System of Units (SI) including measurement uncertainty.

11.2. For internal calibration, Laboratory uses trained Analysts and certified reference materials procured from competent producer with stated metrological traceability.

11.3. In case, Metrological Traceability is not technically possible, NDCL ensures metrological traceability to an appropriate reference, e.g.:

11.3.1. certified values of certified reference materials provided by a competent producer

11.3.2. results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fir for intended use and ensured by suitable comparison.

11.4. Standards and test equipment significantly affecting the test results conducted by the laboratory are monitored for stability. Standards and equipment are calibrated and/or verified before use to ensure the recall or removal from service of any equipment or standards that are unreliable or that have exceeded the calibration interval, if established. All measurement and test equipment having an effect on the accuracy or validity of tests is calibrated and/or verified before being put into service.

11.5. An established program for the maintenance of equipment and calibration includes a system for selecting, using, calibrating, checking, controlling, and maintaining:

11.5.1. measurement standards

11.5.2. reference standards used as measurement standards

11.5.3. measuring and test equipment used to perform tests and calibrations

11.5.4. All measurements that play a defining role in testing accuracy are based directly or indirectly on reference standards, reference materials, certified reference materials, or other standards or materials having appropriate traceability.

11.5.5. Records are maintained for each standard. These records include, as applicable:

11.5.5.1. supplier, grade, batch#

11.5.5.2. dates of preparation or verification

11.5.5.3. measurement of weights, volumes, time intervals, temperatures, and pressures and related calculations

11.5.5.4. relevant processes (e.g., pH adjustment, sterilization)

11.5.5.5. verification results

11.5.5.6. identification of personnel involved

11.5.6. Records are maintained for each lot/batch of test organisms. These records include, as applicable:

11.5.6.1. species and ATCC

11.5.6.2. maintenance history

11.5.7. Disposal of test organisms is carried out humanely and conforms to applicable leDAI requirements.

11.5.8. Reagents prepared in the laboratory are labeled to identify substance, strength, solvent (where not water), any special precautions or hazards, restrictions of use, and date of preparation and/or expiry. The person responsible for the preparation of the reagent is identified either from the label or from records.

11.6. Specific Requirements

11.6.1. Calibration and Testing

11.6.1.1. NDCL maintains program for calibration of equipment which is designed and operated to ensure that calibration measurements are traceable to the SI units of measurement.

11.6.1.2. Traceability of measurement is assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability.

11.6.1.3. The calibration certificates issued by these laboratories show that there is a link to a primary standard or to a natural constant realizing the SI unit by an unbroken chain of calibrations.

11.6.1.4. The calibration certificates contain the measurement results including the measurement uncertainty and/or a statement of compliance with an identified metrological specification

11.6.1.5. Calibration laboratories accredited to ISO 17025 are considered competent to provide the appropriate calibration services.

11.6.1.6. Maintains certificates of all reference standards, measuring equipment, or certified reference material used in ensuring traceability.

11.6.1.7. Reference standards, such as thermometers and weights, are traceable to a national or international standard (e.g., NIST).

11.6.1.8. Frequency of calibration is based on a review of calibration, maintenance, and repair history.

11.6.1.9. The laboratory participates in proficiency testing and/or check sample programs. The list of programs is maintained by the QA Head. (Ref.: SOP No. – NC-QA-ENG-003)

11.6.2. Reference Standards, Reference Materials and Reference Cultures

11.6.2.1. Reference standards and Reference Materials used in NDCL are traceable to SI Units of Measurement.

11.6.2.2. Certified reference cultures are traceable to a national or internationally recognized type culture collection. Reference cultures from laboratory sources must be identified to standard reference sources.

11.6.3. Intermediate Checks

11.6.3.1. Checks needed to maintain confidence in the calibration status of reference, primary, secondary or working standards and reference materials shall be carried out according to defined procedures and schedules. (SOPs No. – NC-QA-GNL-059 & NC-MB-GNL-009)

11.6.4. Transport and Storage

11.6.4.1. NDCL has procedures for safe handling, transport, storage and use of reference standards reference materials and reference cultures in order to prevent contamination or deterioration and in order to protect their integrity.

11.6.4.2. NDCL does not use reference materials outside the laboratory. (Ref.: SOP No. NC-QA-GNL-059 & NC-MB-GNL-009).

12. Laboratory Safety

12.1. Safe working conditions are prerequisite to GLP. Laboratory personnel are instructed on safe working practices and are encouraged to look for hazardous conditions as well as recommend and implement accident prevention.

12.2. The laboratory maintains training of safety and security for its staff and also training on how to use emergency exit, fire extinguisher and how to respond to emergency notification in the form of whistle/fluting.

12.3. Management provides safe working conditions, complies with safety issues and, along with supervisors, assures that the staff comply with these issues.

12.4. It is the responsibility of all staff to be familiar with and comply with all safety requirements. The laboratory staff takes proper precautions in the laboratory.

12.5. Required Personal Protective Equipment (PPE) are available in the laboratory. All staff are trained and supervised about the proper use of PPEs based on the type of risks.

12.6. Emergency shower bath and eye showers are available and staff are trained on how to use it.

12.7. Risky chemicals / reagents and other items are segregated and labeled properly to avoid accidents.

12.8. List of all hazardous and non-hazardous material is maintained.

12.9. Laboratory staff is trained on not to work in the laboratory alone.

12.10. Unauthorized access to laboratory is controlled through digital access system.

12.11. 24/7 monitoring the important and sensitive areas are done closed circuit cameras.

12.12. Minors are not allowed to enter the laboratory except under proper guidance.

12.13. Laboratory Safety Policy (Annexure – 4) is displayed on the entrance of the laboratory and all laboratory safety related activities are undertaken as per SOP No.: NC-QA-GNL-043.

13. Reference Documents

13.1. WHO. Quality systems requirements for national good manufacturing practice inspectorates. Technical Report Series No.902 (Annex No.8). 2002

13.2. ISO/IEC 17025:2017. International Standard. General requirements for the competence of testing and calibration laboratories. 3rd. Edition, 2017.

13.3. ISO 9001:2008. Quality management systems — Requirements. 2nd Edition, 2008.

13.4. The Drug Acts and Rules 1940 to 2006. Reprinted by Directorate General of Drug Administration, Ministry of Health and Family Welfare, Government of the People's Republic of Bangladesh. April, 2008.The Constitution of the People's Republic of Bangladesh. Part II Fundamental Principles of State Policy. Section 18(1): Public health and morality. Available at: http://bdlaws.minlaw.gov.bd/sections_detail.php?id=367&sections_id=24566

13.5. ISO GUM. Guide to the Expression of Uncertainty in Measurement, ISO, Geneva, Switzerland, 1993 (Reprinted 1995).

13.6. EU GMP Annex 1- Basic Elements Clean Room Classification, 2008. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2009/12/WC500017886.pdf

13.7. Bangladesh Service Rules (BSR). Classification of Records for preservation and Disposal. 53rd. Edition, 2014; Page-319.

13.8. WHO. Good Laboratory Practice (GLP) - Quality Practices for Regulated Non-clinical Research and Development. 2nd Edition, 2009.

13.9. WHO. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO TRS No. 1052, Annex 3, 2024.

13.10. WHO-Quality Manual Template. Supplement to the Laboratory Quality Management System Training Toolkit, Module 16 - Documents and records. 2013

13.11. National Drug Policy 2016. Public Health Branch, Ministry of Health & Family Welfare, Dhaka, Bangladesh. Published in : Bangladesh Gazette – March 23, 2017.

13.12. BAB. Management Review for CABs. Revision 2, January 2012.

13.13. ICH-GCP. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH Harmonised Tripartite Guideline Guideline for Good Clinical Practice E6(R1). Version 4. pp-8, 1996.

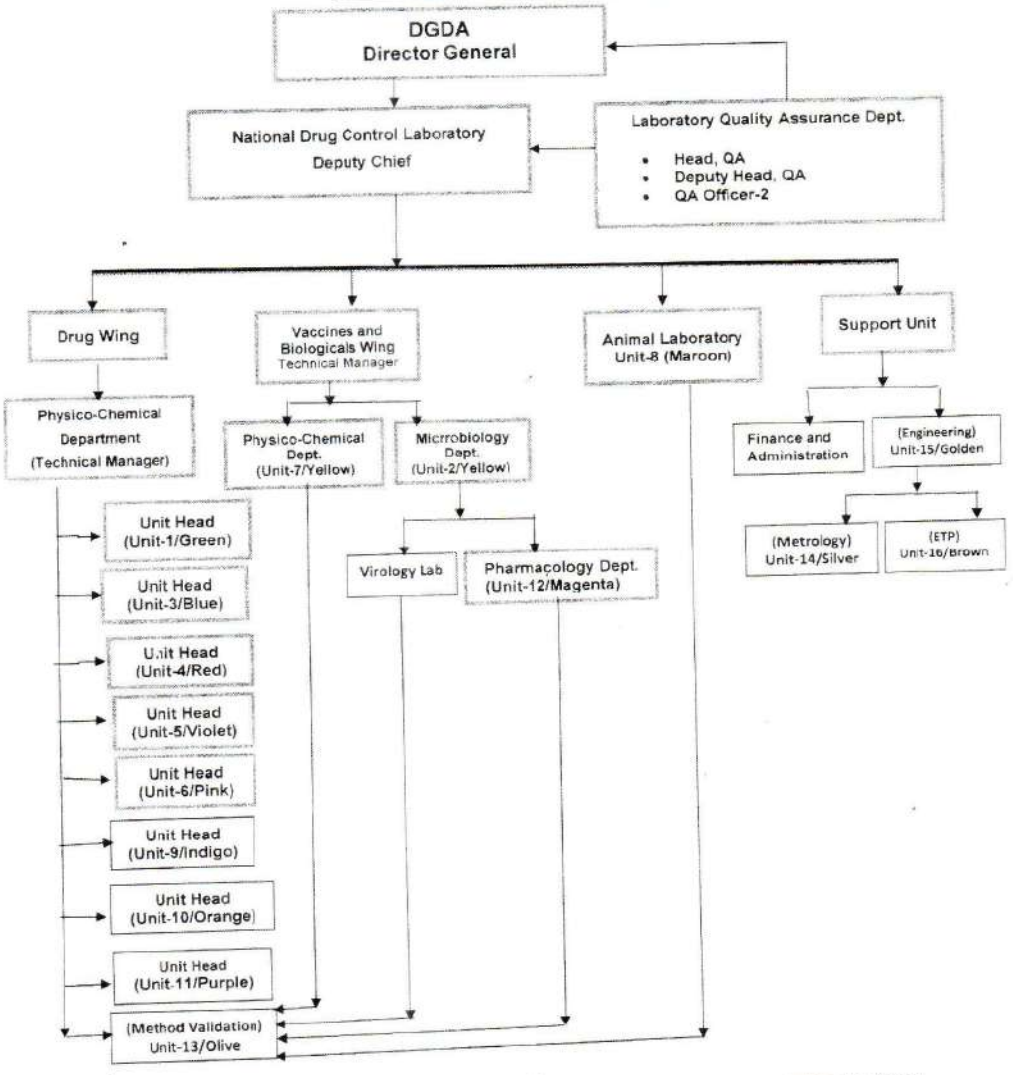
Annexures

Annexure – 01A: -

Organizational Chart of National Drug Control Laboratory (NDCL)

National Drug Control Laboratory (NDCL), DGDA	
Directorate General of Drug Administration (DGDA), Mohakhali, Dhaka-1212.	
Form No.: NC-QA-FRM-952/24-01	Effective Date: 21.08.2024

Organizational Chart of NDCL



Prepared By: 21.08.24
Hamida Begum
QA Head
National Drug Control Laboratory
DGDA, Dhaka

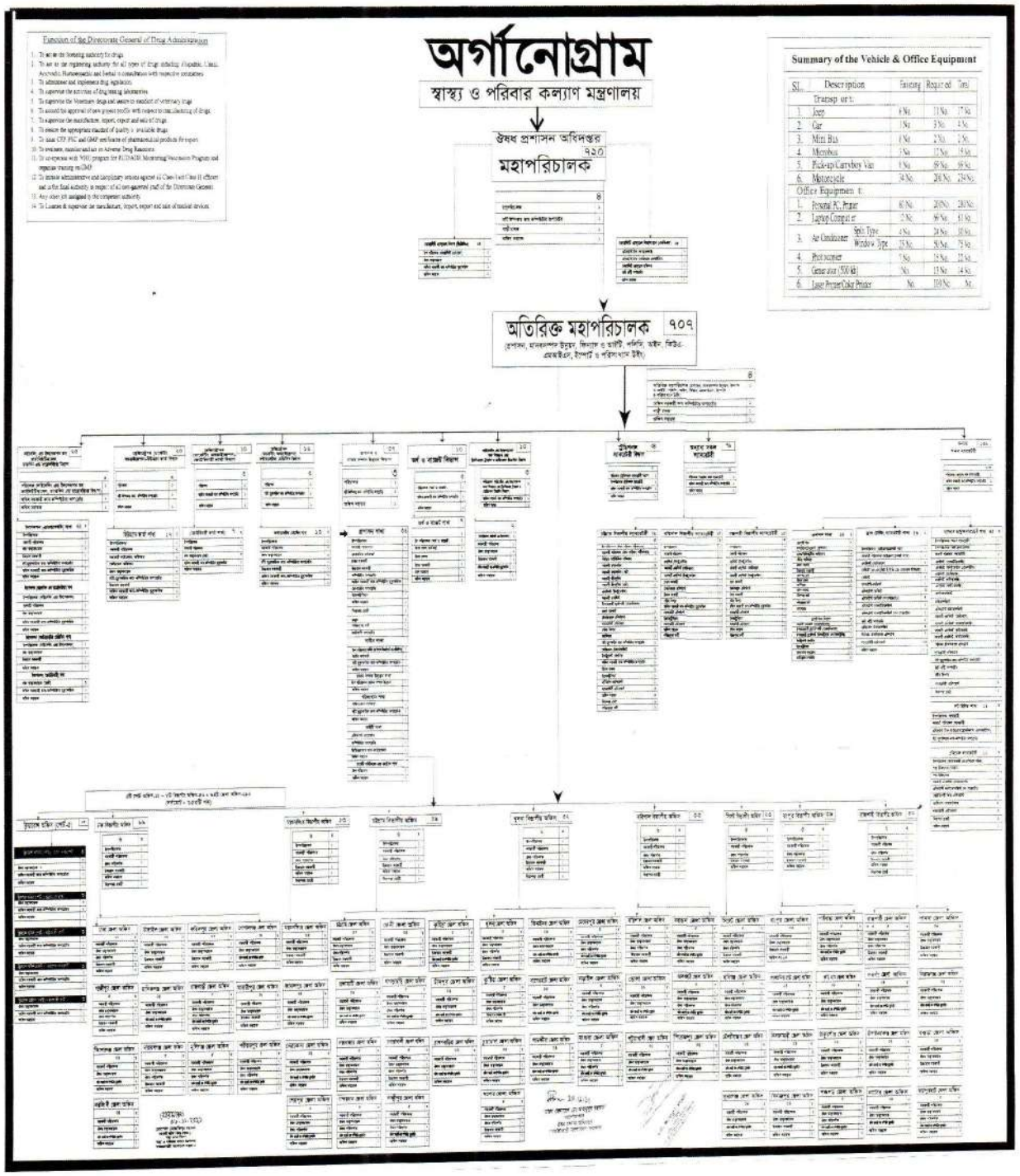
Approved By: 21.08.24
Dr. Md. Harun-Or-Rashid
Deputy Chief
National Drug Control Laboratory (NDCL)
Mohakhali, Dhaka-1212

Authorized By: 21.08.24

End of the Document

Annexure - 01B: -

Position of NDCL in DGDA Organizational Chart



Annexure – 01C: -

Functional Organogram of LT

DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

Annexure-2

Document Title: Format of functional Oorganogram

Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-RS-027/F02-00	00	DEC'2021	DEC'2026			01 of 01

Function/Department: Laboratory Access & Testing	Version No: 02	Page No. 1 of 1

Organogram

Terms and Reference/Activities:

- NDCL is responsible for making an accurate conclusion on the samples received in NDCL from the Post Marketing Surveillance (PMS) and from its customers.
- Involved in evaluation of drugs, vaccines, APIs from production, storage, distribution to export.
- Issued lot release certificate for both locally produced and imported vaccines.
- Participates in GMP inspection of pharmaceuticals
- Quality control of government procured drugs
- Partakes in Marketing Authorization, AEFI, Pharmacovigilance and Clinical Trial oversight
- Organize training and retraining to QC staff
- Involved in identification of SF drugs thereby participated in preventing SF drugs in Bangladesh
- Participates in the SEARN Network in prevention of SF drugs in the region.

Prepared by (Sign & Date):	Reviewed by Head of the Function (Sign & Date):	Approved by Head of QMS (Sign & Date):	Authorized by Director General (Sign & Date):
Name: Dr. Sarwat Jahan Pita Designation: Assistant Director (lab)	Name: Dr. Md. Harun-Or-Rashid Designation: Deputy Chief	Name: Hossain Mohammad Imran Designation: Assistant Director	Name: Major General Mohammad Yousuf Designation: Director General

IF THIS DOCUMENT IS SIGNED BY BLUE INK, IT IS A MASTER DOCUMENT AND CANNOT BE USED

Annexure – 01D: -

Functional Organogram of LR

DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

Annexure-2

Document Title: Format of functional Oorganogram

Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-RS-027/F02-00	00	DEC'2021	DEC'2026			01 of 01

Function/Department: NRA Lot Release Function | Version No: 02 | Page No. 1 of 1

Organogram

Government of the People's Republic of Bangladesh
Directorate General of Drug Administration
Mohakhali, Dhaka-1212

Functional Organogram of DGDA for Performing NRA Lot Release (LR) Function

Terms and Reference/Activities:

- NDCL is responsible for Lot Release of Vaccines, locally produced and imported
- NDCL Vaccine Wing is responsible for testing of vaccines as part of Lot Release activities.

Prepared by (Sign & Date):	Reviewed by Head of the Function (Sign & Date):	Approved by Head of QMS (Sign & Date):	Authorized by Director General (Sign & Date):
20.03.24	20.03.24	20.03.24	20.03.24
Name: Dr. Nasima Pervin	Name: Dr. Md. Harun-Or-Rashid	Name: Hossain Mohammad Imran	Name: Major General Mohammad Yousuf
Designation: Assistant Director (lab)	Designation: Deputy Chief	Designation: Assistant Director	Designation: Director General

Annexure – 02 (A): -

Test Report Form

GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
NATIONAL DRUG CONTROL LABORATORY (NDCL)
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MOHAKHALI, DHAKA-1212, BANGLADESH
Phone: +880-2-222299315, 222261021

TEST REPORT

Memo / Id. No. **Date:**

Test/Analysis Report of Drug sample by Drug Analyst according to the Drug and Cosmetics Act 2023 Section 52(1) Section 53.

1. Date of Sample Receive :
2. Purpose/Background of Investigation / Testing :
3. Sender's Memo No. & Date :
4. Name & Contact Information of the Sample Sender :

5. **Description of Claimed Drugs in the Sample:**

(A) Brand Name :
(B) Generic Name :
(C) Batch No. / Code No. :
(D) Manufacturer's Name :
(E) Name of Repacker/ Trader :
(F) Quantity Received :
(G) Condition of the Seal of the Package :
(H) Date of Manufacture :
(I) Date of Expiry :

6. **Detailed Description of Test/Analyses:**

Sl. No.	Physical / Qualitative / Quantitative Tests' Details	Test Result(s)	Declared Claim	Acceptable Limit (Ref.: Mfg.)	Test's Date	Test Method
01						
02						
03						
04						
05						
06						
07						
08						
09						

NB: Test Methods applied for this sample is accreditated by: BAB on ISO 17025:2017 Standard

Remarks (If any):

Opinion(s) of Drug Analyst:

Drug Analyst

Caution: Certified that the result relates only to the items tested. This report shall not be reproduced except in full, without written approval of the laboratory authority. Directorate General of Drug Administration (DGDA) makes no opinions or interpretations derived from the documentation and the data generated.

End of the Document

Annexure – 02 (B)

Lot Release Certificate

Government of the People's Republic of Bangladesh
National Drug Control Laboratory
Directorate General of Drug Administration
Ministry of Health & Family Welfare
Mohakhali, Dhaka-1212

Lot Release Certificate

Certificate Number: NCL/ **Date:**

To
M/s.----------

In reference to your letter No. ----------Dated: -------/------/------, this is to certify that the following lot of ----------(product name) manufactured by ----------, has been released whose lot number appear on the labels of the final containers meet National, WHO summary protocol requirement(s) and or complies with the relevant specification in the marketing authorization of vaccine producing country.

Lot No.	Manufacturing Date	Expiry Date

As a minimum, this certificate is based on review of the Summary Lot Protocol which includes the following information:

- Name and address of manufacturer :
- Marketing Authorization Holder (MAH) :
- Name of Local agent/Organization :
- Name of the distributor :
- Trade Name :
- Common Name of the product :
- Marketing authorization number :
- Lot number (s) (including sub-lot number, packaging lot number if necessary) :
- Type of container :
- Number of doses per container :
- Number of containers released :
- Storage condition :
- Presentation :

(Name ----------)
Deputy Chief
(Head of the Laboratory)
National Drug Control Laboratory (NDCL)

(Ref. No.-SOP No. NC-QA-GNL-013/F2-08)

End of the Document

Annexure – 02 (C)

Non-compliance Certificate (Vaccine)

Government of the People's Republic of Bangladesh
National Drug Control Laboratory
Directorate General of Drug Administration
Ministry of Health & Family Welfare
Mohakhali, Dhaka-1212

Notification for Non-Compliance of Lot Release

Certificate Number: NCL/ **Date:**

To
M/s.----------

In reference to your letter No. ----------Dated: -------/------/-------, this is to certify that the following lot/lots of ----------(product name) manufactured by ----------, has been rejected whose lot number appear on the labels of the final containers, does not meet National, WHO summary protocol requirement(s)) and or does not comply with the relevant specification in the marketing authorization of vaccine producing country.

Reason for Rejection:

(Name ----------)
Deputy Chief
(Head of the Laboratory)
National Drug Control Laboratory (NDCL)

(Ref. No.-SOP No. NC-QA-GNL-013/F3-08)

End of the Document

Annexure – 3 Impartiality Policy

Impartiality Policy

The National Drug Control Laboratory (NDCL), under the Directorate General of Drug Administration (DGDA), Ministry of Health & Family Welfare (MOH&FW), Bangladesh is committed to the fulfillment of its responsibility for assuring the impartiality in relation to testing and analytical work carried out here. To ensure utmost impartiality by all NDCL personnel during their laboratory activities, the following principles are strictly ensured.

1. NDCL and DGDA top management always show strong commitment to impartiality
2. NDCL staff do not offer consultancy services to clients on matters relating to quality of medicines
3. NDCL personnel declares ownership and interest (financial or in other forms) in the client company/organization to which the laboratory is providing analytical services, if any, in the declaration form used for the purpose. Accordingly, NDCL management takes necessary measures to avoid any conflict or breach of impartiality matters by related staff.
4. Laboratory personnel do not share any incentive (financial, non-monetary gifts, confidential data or in other forms) or any other resources from the clients.
5. NDCL personnel do not engage in any private work with the clients.
6. NDCL identifies all risks to impartiality based on random monitoring on an ongoing basis.
7. NDCL personnel failing to be transparent or communicate their engagement, secondary employment, consulting or receiving incentive (financial, non-monetary gifts or in other forms) from the clients, can be investigated for violating this policy. If objective evidence is found during an investigation that would jeopardize the trust, validity, integrity or unbiased authority of NDCL, DGDA, the organization may choose to suspend and or terminate that personnel.

DGDA and NDCL top management will ensure that all necessary support is provided so that the entire process of analytical testing and data review can be performed in a credible, independent and non-discriminatory manner while complying to international standards (Such as ISO 17025, 9000, WHO-PQ) and the laws of the People's Republic of Bangladesh.

Approval Details:

Prepared By:	Checked & Approved By:	Agreed & Authorized By:
13.08.24	13.08.24	13.08.24
Hamida Begum Head QA, NDCL	Dr. Md. Harun-Or-Rashid Deputy Chief, NDCL	Major General Quazi Md Rashid-Un-Nabi Director General, DGDA

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End of the Document

Annexure – 4: Laboratory Safety Policy

Safety Policy

NDCL is committed to ensure the safety of all its staff, visitors as well as of internal and external environments through efficient applications of all safety measures in laboratory operations including waste management through strict adherence to all applicable national, international, environmental regulatory, health and safety requirements.

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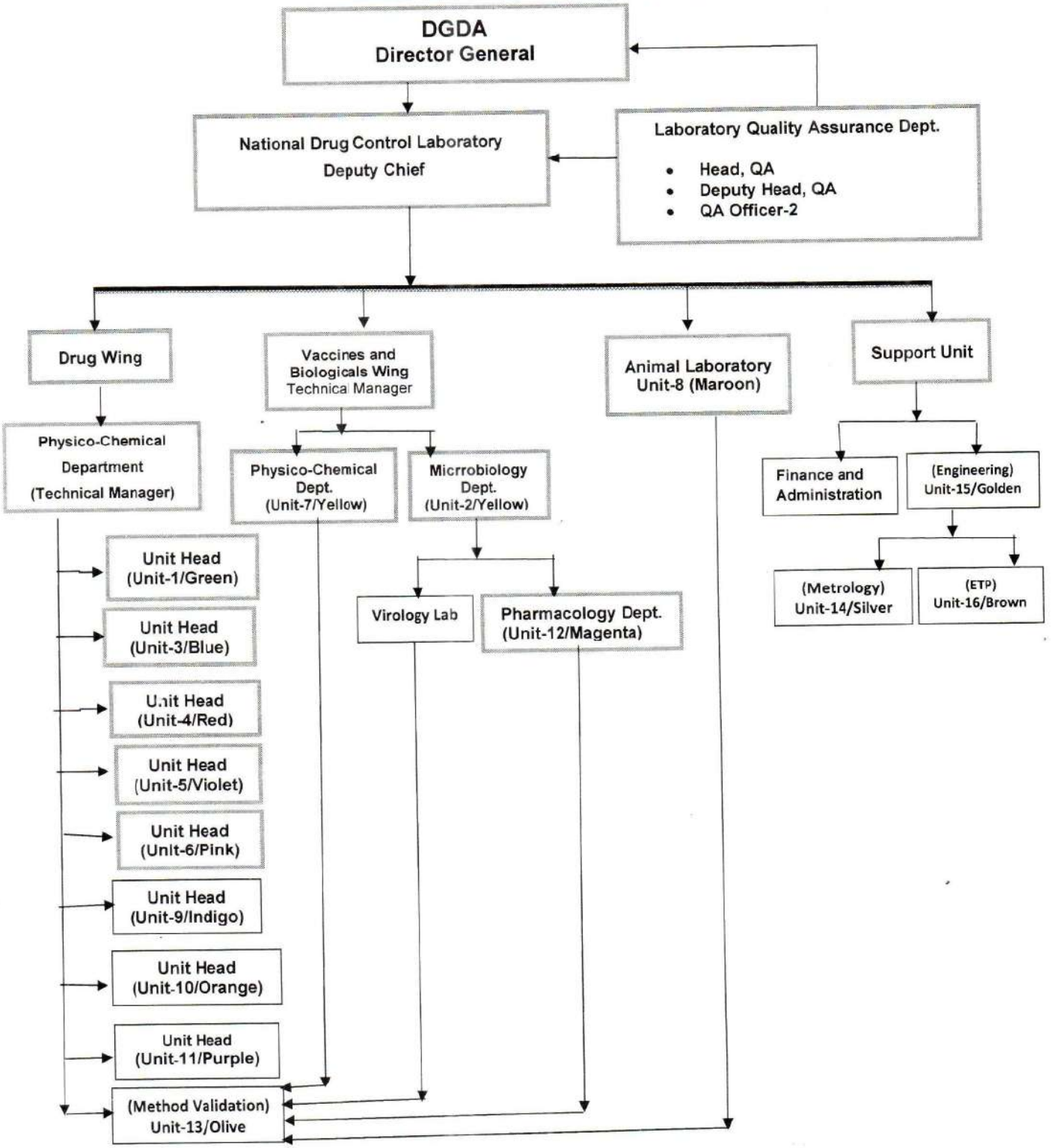
Organizational Chart of NDCL



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QA Head
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Dr. Md. Harun-Or-Rashid
Deputy Chief
National Drug Control Laboratory (NDCL)
Mohakhali, Dhaka-1212

Authorized By: 21.08.24

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Quality Policy

1. National Drug Control Laboratory (NDCL) shall ensure strict compliance with ISO 17025:2017 and WHO cGMP and GLP standards and local regulatory norms in every phase of sourcing & procuring quality materials, analysis, quality assurance and delivery of services to the customers.

2. NDCL shall ensure all activities through documented effective QMS complying International Standard requirements of ISO 9001 and WHO through continuously developing Human Resources by regular training and participation. NDCL's motto is to familiarize its staff with documentation required for ensuring quality and implementation of the policies and procedures in its working arena.

3. The laboratory management's commitment is to good professional practice and quality of testing, calibration, validation, verification and compliance with the content of these guidelines. The management is also committed to undertake appropriate review, evaluation and performance measurement of processes, business activities and QMS for continual improvement to ensure highest standard, customer satisfaction, developing human resources and institutional growth.

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Impartiality Policy

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Quality Objectives

NDCL is committed to complying with ISO/IEC 17025 and WHO international standards and to continually improve the effectiveness of the management system, the principal objective of the NDCL is to document and implement the compliant policies and associated procedures that are integrated into our daily activities. Continual improvements are established, implemented, and locked into the management system. To protect the health of people of Bangladesh by ensuring easy access to useful, effective, safe and good quality Drugs including Vaccines, Biologicals, Medical Devices and Traditional Medicines, NDCL's quality objectives are as follows:

1. To improve laboratory performance through reducing non-conformity/deficiencies and using validated test procedures
2. To provide genuine and timely result with highest quality, impartiality and ethical standards along with instant reporting of results
3. To ensure scientific evaluation of quality through regular evaluation & skill upgradation of quality of services
4. To maintain strict confidentiality, privacy and restricted access to customer's data
5. To ensure availability of quality chemicals/reagents and other materials from registered vendors and maintain minimum stock
6. To provide flawless sample & data processing, handling, distribution, transfer and management
7. To improve housekeeping services of the laboratory
8. To reduce breakdown time of equipment
9. To ensure safety and security of the laboratory and staff
10. To ensure loyalty, integrity and commitment of the laboratory staff towards effectiveness of the QMS
11. To ensure that all personnel are trained and competent to a level of familiarity with the QMS appropriate to the individual's degree of responsibility
12. To impart training to the employees for upgradation knowledge and skill through assessment of training needs of each staff related to their assigned job
13. To participate in Inter-Laboratory Comparison Testing schemes, Proficiency Testing (PT) or quality evaluation programs with peer laboratories.

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Hamida Begum **Head QA, NDCL**	**Dr. Md. Harun-Or-Rashid** **Deputy Chief, NDCL**	**Major General Quazi Md Rashid-Un-Nabi** **Director General, DGDA**

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