REPUBLIC OF KENYA

OFFICE OF THE AUDITOR-GENERAL

*Enhancing Accountability*



# REPORT

# OF

# THE AUDITOR-GENERAL

# ON

# NATIONAL QUALITY CONTROL LABORATORY

# FOR THE YEAR ENDED 30 JUNE, 2020

# NATIONAL QUALITY CONTROL LABORATORY

## ANNUAL REPORT AND FINANCIAL STATEMENTS

## FOR THE FINANCIAL YEAR ENDING JUNE 30, 2020

**Prepared in accordance with the Accrual Basis of Accounting Method under the International Public Sector Accounting Standards (IPSAS).**

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## 1. KEY ENTITY INFORMATION AND MANAGEMENT

### (a) Background Information

The National Quality Control Laboratory (NQCL) was established under section 35D of the Pharmacy and Poisons Amendment Act of 1992 (Cap 244, Laws of Kenya) on the 28th October, 1992 and came into operation on 06th November, 1992. The Laboratory is domiciled in Kenya with no branches currently.

### (b) Principal Activities

The Laboratory, under the Pharmacy and Poisons Amendment Act of 1992 (Cap 244, Laws of Kenya), has the following mandate:

1. Examine and test medicines and any material or substance from which or with which and the manner in which medicines may be manufactured, processed or treated and ensure the quality control of medicines and medicinal substances;
2. Perform chemical, biological, biochemical, physiological and pharmacological analysis and other pharmaceutical evaluation;
3. Test, at the request of the Pharmacy and Poisons Board (PPB) and on behalf of the Government, of locally manufactured and imported medicines or medicinal substances with a view to determine whether such medicines or medicinal substances comply with Cap 244;
4. To provide advisory services to the Ministry of Health on medicines quality standard;
5. Carry out Good Manufacturing Practices (GMP) inspections in pharmaceutical manufacturing industry premises and issue certificates of compliance on the same.

### (c) Key Management

The Laboratory's day-to-day management is under the following key organs:

1. Board of Management;
2. Director; and
3. Management Team.

### (d) Fiduciary Management

The key management personnel who held office during the financial year ended 30th June 2020 and who had direct fiduciary responsibility were:

| | Designation | Name |
|---|---|---|
| 1. | Director and Secretary to the Board | Dr. Hezekiah K. Chepkwony, PhD |
| 2. | Senior Deputy Director | Dr. Pius M. Wanjala |
| 3. | Deputy Director, Finance and Administration | Dr. George Wang'ang'a |
| 4. | Deputy Director, Technical Services | Dr. Ernest G. Mbae |
| 5. | Deputy Director, Quality Assurance | Dr. Serah M. Muteru |
| 6. | Deputy Director, Research & Technological Development | Dr. Nicholas Mwaura, PhD |

## KEY ENTITY INFORMATION AND MANAGEMENT (Continued)

| | | |
|---|---|---|
| 7. | Head, Wet Chemistry Unit | Dr. Paul Njaria, PhD |
| 8. | Head, Instrumentation Unit | Dr. Mathayo Kwena |
| 9. | Head, Biological Analysis & Medical Devices Units | Dr. Sarah Mwangi |
| 10. | Head, Documentation Unit | Dr. Rebecca Manani |
| 11. | Head, Finance and Administration | CPA David Yano |
| 12. | Head, Supply Chain Management Unit | Mr. George Ogeto Nyambane |

### (e) Fiduciary Oversight Arrangements

The Statutory fiduciary oversight agencies include;

1. Office of the Auditor-General;
2. Audit and finance committees of the board of management;
3. Parliamentary committees;
4. Development partner oversight; and
5. Other state oversight agencies.

### (f) NQCL Headquarters

National Quality Control Laboratory
P. O. Box 29726 - 00202, KNH, Nairobi, KENYA
Kenyatta National Hospital Complex, Hospital Road,
2nd Floor, School of Pharmacy Building,
College of Health Sciences, University of Nairobi.

### (g) NQCL Contacts

Telephone: 020-3544525/30
E-mail: info@nqcl.go.ke
Website: www.nqcl.go.ke



### (h) NQCL Bankers

National Bank of Kenya Ltd
Hill Plaza Branch, NHIF Building
P. O. Box 45219 – 00100, GPO
Nairobi, KENYA.

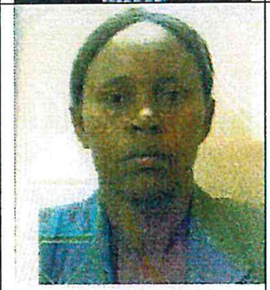
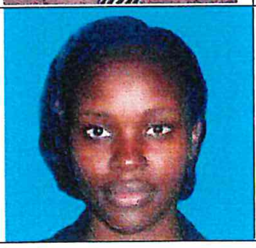
### (i) Independent Auditors

Auditor General
Office of the Auditor General
Anniversary Towers, University Way
P. O. Box 30084 – 00100, GPO
Nairobi, KENYA.

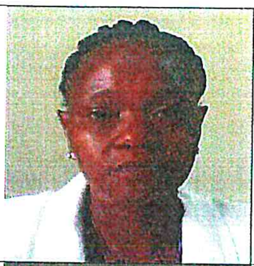
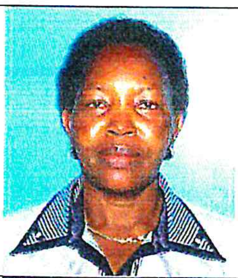
### (j) Principal Legal Adviser

The Attorney General
State Law Office
Harambee Avenue
P.O. Box 40112
City Square 00200
Nairobi, Kenya

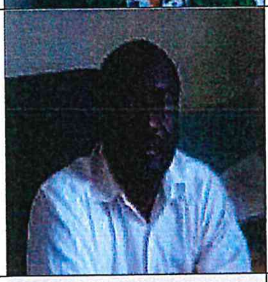
## 2. THE BOARD OF MANAGEMENT

| | Board Member's photo | Name & Designation | Date of Birth | Profession/ Academic Qualification/ Work Experience | Main Responsibility |
|---|---|---|---|---|---|
| 1. |  | William Mwatu (Dr.) | 22nd Nov 1964 | Pharmacist - BPharm, MPSK/ 23 Years Work Experience | Chairperson **(DECEASED)** |
| 2. |  | Irene Thiguku Kamanja (Dr) | 13th Dec 1966 | Veterinary Surgeon – PhD, MSc, BVM/ 23 Years Work Experience | Member & Finance, Administration & General Purpose Committee (FAGPC) Member |
| 3. |  | Paul Munyao Mutua (Mr) | 16th Jan 1974 | Advocate – LLM, LLB, MLSK/ 17 Years Work Experience | Member, Technical & Audit Committees Member |
| 4. |  | John Ronoh Sitienei (Mr) | 25th Nov 1957 | Lecturer – PhD, M.Ed, B.Ed/ 35 Years Work Experience | Member & FAGPC Member |
| 5. |  | Georgina Muchai (CPA) | 1986 | Auditor – CPA (K), BCom/ 13 Years Work Experience | Member, FAGPC Chairperson & Audit Committee Member |

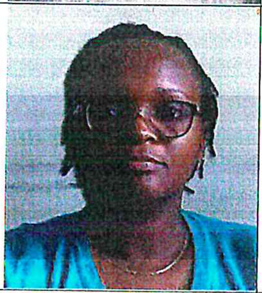
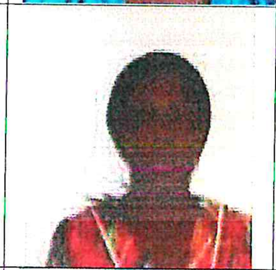
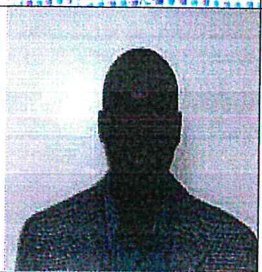
**THE BOARD OF MANAGEMENT (Continued)**

| | | | | | |
|---|---|---|---|---|---|
| 6. |  | Lilian Balusi Makungu Njoroge (Dr.) | 14th Sep 1969 | Pharmacist - BPharm, MPSK/ 25 Years Work Experience | Member& Technical Committee Chairperson |
| 7. |  | Hellen Bosibori Okioma | 03rd May 1953 | Trainer/Management Consultant – B.Ed., MKENAS/ 41 Years Work Experience | Member& Audit Committee Member |
| 8. |  | Simon Njoroge Muigai (Dr.) | 02nd June 1972 | Pharmacist - BPharm, MPSK/ 22 Years Work Experience | Member, Technical & Audit Committees Member |
| 9. |  | Edith Wambui Tanu Wakori (Dr.) | 23rd Dec 1954 | Pharmacist/Lecturer – PhD student, Post Grad., M.Pharm, BPharm, MPSK/ 23 Years Work Experience | Member, Technical & FAGPC Committees Member |
| 10. |  | Hezekiah Kibet Chepkwony (Dr) | 09th Jan 1962 | Director; PhD; MPharm; MSc. Pharm; MPSK/ 29 Years Work Experience | Board Secretary |

## 3. MANAGEMENT TEAM

| | Key manager's passport-size photo | Name – Designation | Professional/ Academic Qualification | Main Responsibility | Experience (Years) |
|---|---|---|---|---|---|
| 1. |  | Dr. H.K. Chepkwony - Snr. Deputy Chief Pharmacist | PhD, MPharm, MSc. Pharm; MPSK | Director | 29 |
| 2. |  | Dr. Pius Wanjala - Snr. Deputy Chief Pharmacist | MPharm, LLB; MPSK | Senior Deputy Director | 21 |
| 3. |  | Dr. George Wang'ang'a - Deputy Chief Pharmacist | MSc. Intl. Health, MBA, BPharm; MPSK | Deputy Director Finance & Administration | 18 |
| 4. |  | Dr. Serah Muteru - Assistant Chief Pharmacist | Msc, BPharm; MPSK | Deputy Director Quality Assurance Manager | 18 |
| 5. |  | Dr. Ernest Mbae - Deputy Chief Pharmacist | MPharm, BPharm; MPSK | Deputy Director Technical Services | 18 |
| 6. |  | Dr. Nicholas Mwaura - Assistant Chief Pharmacist | PhD, MPharm, BPharm; MPSK | Deputy Director Research & Technological Development | 19 |

**MANAGEMENT (Continued)**

| | | | | | |
|---|---|---|---|---|---|
| 7. |  | Dr. Mathayo Kwena– Assistant Chief Pharmacist | Msc, BPharm; MPSK | Head Instrumentation Unit | 16 |
| 8. |  | Dr. Sarah Mwangi- Assistant Chief Pharmacist | Msc; BPharm; MPSK | Head Biological Analysis & Medical Devices Units | 18 |
| 9. |  | Dr. Rebecca Manani Assistant Chief Pharmacist | Msc; BPharm; BPharm; MPSK | Head Documentation Unit | 16 |
| 10. |  | Dr. Paul Njaria - Assistant Chief Pharmacist | PhD, MPharm, BPharm; MPSK | Head Wet Chemistry Unit | 16 |
| 11. |  | Mr. David K. Yano | B. Com Finance, CPA K, | Head, Finance and Administration | 18 |
| 12. |  | Mr. George Ogeto Nyambane | BA. Econ CPA I, Dip. SCM | Head Supply Chain Management Unit | 19 |

## 4. CHAIRMAN'S STATEMENT

The Board of Management (BOM) presents the NQCL Annual Reports and Financial Statements for the year ended 30th June 2020.

A new BOM was appointed by the Chairman of the Pharmacy and Poisons Board (PPB), Dr. Jackson Kioko, in accordance with Cap 244, Section 35 (F) (1) via a gazette notice No. 1940 dated 02nd March 2018 effective from 12th February, 2018 and will serve for a period of three (3) years. The BOM was inaugurated on 05th April 2018 and has since then applied itself to its functions as enumerated at Section 35(G) of Cap 244 Laws of Kenya. The BOM attended the Mwongozo training, the code of governance for state corporations outlined by the Government of Kenya in February 2019. The training was conducted by the State Corporation Advisory Committee (SCAC). In the month of December 2018, after an illness we lost our Chairperson, Dr William Mwatu. May his soul rest in peace.

The appointing authority had in the month of July 2019 de-gazetted this current BOM, which in the view of its membership was an illegality since they had completed their term and had not been found wanting in delivery of their duties. The membership had challenged the de-gazettement in court and was reinstated in November 2019. Thereafter we had a BOM retreat the highlight of which was to develop a BOM almanac to guide its activities.

The BOM activities were further affected by the emergence of the Covid 19 pandemic, which called for online meetings from mid - March 2020. The BOM followed the guidelines for carrying out meetings as given by the Head of Public Service circulars. Further, the BOM made arrangements for the management to ensure all the guidelines issued by the MOH for the Covid 19 pandemic were implemented at the Laboratory.

The BOM has held numerous meetings and would like to thank the management on their commitment towards achievement of the Laboratory's mandate. I look forward to a continued good working relationship between the BOM, management and key stakeholders including PPB and MOH.

**CHAIRMAN'S STATEMENT (Continued)**

The BOM will continue to work on the following issues, which will be paramount in the operations of the Laboratory:

a. Work plan for the 2020/21 FY;
b. Budget plan for 2020/21 FY;
c. Reporting mechanism for the BOM to the appointing authority;
d. Usurpation of the GMP and sample analysis mandate of the Laboratory by the PPB;
e. Court cases that have affected the Laboratory;
f. Collaboration of NQCL and other prequalified Laboratories when and if need to do so arises;
g. The NQCL's engagement with KenTrade, Major Ports of entries and Kenya Revenue Authority on implementation of the GMP compliant certification mandate;
h. The deployment of staff to NQCL by Ministry of Health;
i. Formation of the task force for the operationalization of NQCL as a State Corporation by the Ministry of Health;
j. The construction of the Ultra-Modern Laboratory at the NQCL land in Upper hill Nairobi.
k. The Laboratory's budgetary allocation from The National Treasury is sent to its account as grants to enhance financial independence, accountability and efficiency.

**Ms. Georgina Muchai,**
**Chairperson,**
**Finance, Administration and General Purpose Committee of BOM**

**Date** 16th April, 2021

## 5. REPORT OF THE DIRECTOR.

Since its inception, the NQCL has operated under the Division of Pharmacy in the Ministry of Health. In September 2014, it was recognized as a Semi – Autonomous Government Agency (SAGA) in the Ministry of Health and on 11th February, 2016, SCAC categorized it at category PC 4B and advised the Ministry of Health to embark on the activity of categorization.

The Laboratory continues to receive its budgetary allocation through Ministry of Health under the Vote Head 1081000900. The NQCL generates income from sample analysis fees of drugs for Government institutions as well as private pharmaceutical firms. The income generated supplements the recurrent and development budget the Government gives to the Laboratory through Ministry of Health.

The funds generated and allocated are utilized for the procurement of chemicals, reagents, glassware, related apparatus and additional equipment and also for remuneration of contracted staff members. These items are vital in ensuring the institution continues to meet the current good practices for pharmaceutical quality control laboratories and the relevant parts of the World Health Organization Good Manufacturing Practice guidelines and the ISO 17025 accreditation status for laboratories under the South African National Accreditation System.

The Laboratory has two types of staff among its personnel. The first group comprises of civil servants seconded to the institution by the Ministry of Health. This group includes pharmacists, pharmaceutical technologists, accounts assistant, supply chain management assistant and a medical engineer technician. The second group consists of staff contracted by the BOM for a renewable three-year contract. These include laboratory technicians, accounts assistant, supply chain management assistants, an executive secretary, laboratory assistants and a documentation clerk. The laboratory also engages interns and students on attachment who gain on the job learning as part of the Government policy on training.

In the financial year under review, the laboratory was not able to utilise its allocation for the vote head from The National Treasury through the MOH where the vote head is administered at the headquarters at Afya house. The Director of NQCL has little or no control over this vote head despite being the authorised Authority to Incur Expenditure (AIE) Officer.

**REPORT OF THE DIRECTOR (Continued)**

Previous experience has shown that when approved budgetary allocations are channelled through the Vote Head 108 – 0009 at the Ministry of Health, a number of items requested for procurement as per the approved budget and procurement plan remain as pending bills as a result of lack of compliance with the allocated budget lines. The Laboratory requires budgetary support be channelled directly to its account to continue performing its core functions.

Further, there exists no linkage between the PPB (appointing authority) and the NQCL BOM. The role of PPB ends at appointment level of the BOM and subsequently, the BOM operates on its own with no reporting mechanism or responsibility to the appointing authority (PPB), no financial support from the appointing authority and minimal statutory responsibility and consultation with the Ministry of Health. Consequently, NQCL experiences inadequate funding for its operations.

A proposal has been made for an approved organization structure for the two (2) institutions that should be put in-place to serve the interests of the MOH and in particular support the big 4 agenda of Universal Health Coverage (UHC). It proposed that the PPB uses an approved structure and have a line item for the NQCL in its budget, which will appear as subvention or grant.

The Laboratory further faces challenges in the course of implementing its mandate. PPB the regulator and created under the same law (Cap 244) has usurped the mandate of the NQCL. Recent Judicial decision stated that NQCL and PPB have complementary, but distinctive roles; with NQCL having the mandate of ensuring quality control of medicines through issuance of certificates of analysis and GMP compliance certification, while PPB has regulatory enforcement role partly based on the said NQCL certifications to ensure checks and balances. The mandate of keeping a data bank on quality of medicines should be further, enforced by having all quality control laboratories in the country work under the collaboration of NQCL to ensure a single data stream. This will also steady the stream of analysis samples coming to NQCL which is its current source of income.

16 APR 2021

**Dr. Hezekiah Kibet Chepkwony, PhD**
**Director,**

**Date** 16th April, 2021

## 6. REVIEW OF NATIONAL QUALITY CONTROL LABORATORY'S PERFOMANCE FOR FY 2019/2020

The Government of Kenya has committed itself to providing Universal Health Coverage (UHC) under the Big Four Agenda as part of socio-economic transformation through providing equitable, affordable and quality health care of the highest standard to all Kenyans through the Constitution 2010 under the Bill of Rights. The expectation is that citizens realize increased access to healthcare, especially to the vulnerable groups arising from concerted government efforts. The UHC's goal is to ensure that everyone can access medical services they need without being hindered by finances or suffering economic ruin in the process.

To achieve the UHC, health commodity security is critical because no services can be rendered without the necessary Health Products and Technologies (HPTs) which form the second biggest health budget after human resources. The Laboratory is involved in the HPT key outputs and in particular the second one, to assure quality of all health commodities, which ensures all health commodities in the country are of good quality. The Laboratory working with PPB the other regulatory stakeholder in HPTs, will assure Kenyans of good quality health products by:

i. Conducting GMP inspections for manufacturing sites; both local and external;
ii. Quality control testing;
iii. Intensify Pharmacovigilance (reporting of poor quality commodities and adverse reactions enhanced);
iv. Post market surveillance for selected life-saving commodities including antibiotics on a regular basis;
v. Improving end user storage capacities to support product quality through enhancing storage infrastructure;
vi. Establish Track and Trace mechanisms for HPTs to improve patient safety and eliminate counterfeits, substandard and falsified medicines.

The Laboratory plays a major role in contributing towards the achievement of good health deliverables for people through ensuring that appropriate quality control and assurance of all of health products, vaccines and technologies thus minimizing instances of use of substandard health products, vaccines, and technologies that would be harmful to the people. It has put in place mechanisms for ensuring vigilance in its quality assurance work and adopting risk-based systems of quality control and assurance to minimize incidences of counterfeits.

## REVIEW OF NATIONAL QUALITY CONTROL LABORATORY'S PERFOMANCE FOR FY 2019/2020 (Continued)

The main challenge facing the NQCL is to strategically align itself to external health sector business environment, in Kenya and within the region, and conduct its business in a cost effective manner. It develops its annual work plans based on the strategic pillars highlighted below. Assessment of the BOM's performance against its annual work plan is done on a quarterly basis. From its on-going strategic plan, the Laboratory continues to implement the following strategic issues:

| Strategic Pillar | Objectives | Key Performance Indicators | Activities | Achievements |
|---|---|---|---|---|
| 1 Legal framework for National Quality control Laboratory | To ensure classification of the Laboratory as a parastatal | a To improve or more clearly define the existing legal framework by which the NQCL was created.<br><br>b To establish legislation that ensures greater autonomy of the NQCL. | 1.1 Review the legal status of the laboratory in consultation with stakeholders –PPB<br>1.2 Implement the provisions of Cap 244 fully<br>1.3 Establish the office of the corporation secretary (Objective 1)<br>1.4 Appointment of office holders (Autonomy) | Not completed SCAC gave directive, MOH and Treasury yet to implement |
| | | c Ensure compliance with legal and regulatory provisions | 1.5 Identify the laws and regulations the laboratory should comply with<br>1.6 Ensure compliance with these laws<br>1.7 Report to State corporations advisory committee (SCAC). | On course |
| | | d Ensure Good governance in line with the Mwongozo code | 1.8 Report every quarter to SCAC | On course |
| | To ensure Realignment with the constitution on the Bill of rights | e Ensure provision for quality medicines for all | 1.9 Post market surveillance and testing.<br>1.10 Reporting to stakeholders; PPB, the 47 County and National Governments.<br>1.11 Create a data bank | On course |
| | To decentralize testing services | f To ensure that drugs and medical devices are of good quality. | 1.12 Collaborate with stakeholders to set up – minilabs at selected sites | Awaiting operationalization |

| Strategic Pillar | Objectives | Key Performance Indicators | Activities | Achievements |
|---|---|---|---|---|
| 2 Organisation Structure and Human resource | To attract and retain highly trained and motivated staff<br><br>To optimize efficiency and effectiveness of the available human resources | To realize the goal of the NQCL by coming up with appropriate organization structure and improved scheme of service | 2.1 Lobby for developed scheme of service approval.<br>2.2 Improve terms and conditions of services for all staff.<br>2.3 Facilitate the recruitment of appropriate staff.<br>2.4 Enhance professional management and technical skills of key staff. | BOM to lobby for scheme of service approval by SRC |
| 3 Advocacy on policy issues | To improve advocacy for Laboratory to be involved in coordinating matters of National concern with regards to quality of pharmaceuticals | To create a more enabling environment for the NQCL's functions through a revised NDP derived from the NHP (National Health Policy). | 3.1 Intensify advocacy for the NQCL to be represented in the Drug Registration process possibly through a well-defined linkage with the Pharmacy and Poisons Board.<br>3.2 Intensify advocacy for legislation/ policy that makes the quality testing of all pharmaceuticals a mandatory pre-requisite for their registration.<br>3.3 Outline the NQCL's role in post-market quality surveillance activities.<br>3.4 Continue with Advocacy for all pharmaceutical products sent overseas for analysis to pass through the Director of the Laboratory for clearance. | Continued participation in PMS and BOM intends to start pre-shipment certificates for all imported pharmaceuticals and medical devices<br><br>Finalize enlisting into KENTRADE Single Window System<br><br>(Full -Participation of NQCL in Drug registration/re-registration, Post market surveillance, and all pharmaceutical products should be sent overseas through NQCL for clearance |

| Strategic Pillar | Objectives | Key Performance Indicators | Activities | Achievements |
|---|---|---|---|---|
| 4 Finances and Funding | To ensure financial sustainability | a To collect and prudently use the available finances<br><br>b To maximize revenue generation<br><br>- To advocate for review of the act to appropriate levies are imposed for NQCL operations | 4.1 Maintain mechanisms for raising funds for the Laboratory services from the government, partners and other sources.<br>4.2 Implement strategies for increased revenue generation and management – Revise analysis fees and offer training<br>4.3 Identify and implement investment opportunities and other sources of finance, to support the realization of NQCL goals.<br>4.4 Seek for redefinition of the 0.2% KEBS Levy on Pharmaceutical Industry and have it redirected to NQCL – Treasury approval necessary for this.<br>4.5 Utilize appropriate technology e.g. computerization, on management of finances.<br>4.6 Develop and implement mechanisms to reduce loss of revenue and recover debts. | BOM and management to continue lobbying for AIE funds to come as grants to Lab Account<br><br>On-going – Reference to policy of 100% upfront payment<br><br>Continue lobbying for the 0.2% fee from KEBS<br><br>On-going |
| 5 Corporate image | To improve the corporate image | a To develop a corporate image and public awareness plan and strategy<br><br>b To develop policies and guidelines for improvement of NQCL image and social responsibility to the public | 5.1 Evaluate perceptions of the public and stakeholders on lab and respond as need arises.<br>5.2 Establish a Good Governance Policy that re-mould the Laboratory's image.<br>5.3 Create awareness and educate the public and stakeholders on issues of concern and services in the lab through involvement in public awareness | To set up a PR department<br><br>Corporate image improved |

| Strategic Pillar | Objectives | Key Performance Indicators | Activities | Achievements |
|---|---|---|---|---|
| | | | activities such as Open Days, Public Talks, visits to Industries etc. | Attitude survey<br><br>More awareness of NQCL role |
| 6 Marketing | To promote and create awareness of services among stakeholders. | To intensify marketing efforts to reach the Kenyan public, the region and the international community | 6.1 Use mass media to educate stakeholders on the role and services offered by the Laboratory.<br>6.2 Design and circulate Brochures, Newsletters and regularly update Website to adequately market the lab's activities.<br>6.3 Establish and maintain linkages with larger institutions that may act as major clients for the lab's activities. | To set up a PR department<br><br>Client Service Unit (CSU) to complete exercise by mid-2020<br><br>Improved use of NQCL services and established networks and linkages with clients |
| 7 Analytical Services | To enhance existing capacity for providing effective and quality analytical services | a The Laboratory will establish, implement and maintain a quality system appropriate to the scope of its activities, including type, range and volume of testing and/or calibration, validation and verification activities that it undertakes.<br><br>b The elements of the quality system will be documented in a quality manual, available to the laboratory personnel, which will be | 7.1 Maintain enforcement pre-registration and post-registration regulation on analysis.<br>7.2 Maintain pre-tender regulation on analysis.<br>7.3 Acquire modern equipment and upgrade/maintain existing ones, including ICT.<br>7.4 Acquire adequate materials (books, chemicals and standards).<br>7.5 Build up relevant human capacity.<br>7.6 Develop and document SOPs for all procedures. | BOM to continue Lobbying PPB<br><br>BOM to continue Lobbying KEMSA<br>BOM/Director/Management to discuss and prioritize.<br><br>Management to discuss and Implement.<br>Partially Done.<br>Done for Wet Chemistry, |

| Strategic Pillar | Objectives | Key Performance Indicators | Activities | Achievements |
|---|---|---|---|---|
| | | maintained and updated by a nominated responsible member of the laboratory personnel. | | Microbiology, CSU and Quality Assurance. Others are on-going. |
| 8 Good Laboratory practices and Accreditation | To be organized and operate in such a way as to meet the requirements for good laboratory practices so as to maintain the status as an internationally recognized and accredited institution (WHO Prequalification and ISO 17025 Accreditation Status) | a To attain international accreditation status<br>b To attain role of a secondary accreditation institution that certifies industry QC laboratories and organizes training programs for technical QC staff of such industries. | 8.1 Maintain quality assurance and control systems in the laboratory.<br>8.2 Maintain and Establish quality assurance standards for all services.<br>8.3 Regularly update Laboratory quality manuals.<br>8.4 Ensure quality systems are maintained.<br>8.5 Set up research and development unit for standard testing.<br>8.6 Prepare research and training policies and procedures. | This will be a continuous process |
| 9 Facilities and Equipment | To acquire land and put up physical facilities<br>To acquire adequate and appropriate state of the art equipment | Establish the lab facilities in an independent locality i.e. NQCL owned premises | 9.1 Pursue the acquisition of grabbed land and acquire title.<br>9.2 Put up own physical facilities that can serve both as laboratory, but also as a source of additional income e.g. from rent.<br>9.3 Develop key essential physical facilities, equipment and services to cater for specialized laboratory, education, training and other services. | BOM to follow up with Kenya-Re Ltd & KNH for processing of the Title Deeds.<br>Proposal and MOU between the MOH and Sponsor (SYGEC) in-place. |

| Strategic Pillar | Objectives | Key Performance Indicators | Activities | Achievements |
|---|---|---|---|---|
| | | | 9.4 Acquire modern equipment and maintain them in order to provide quality services. | |
| 10 Research and Technological Development | To establish a Research and Technological Development department<br><br>To Strengthen and deepen research capabilities of the Laboratory. | a To establish a Research and Development department.<br><br>b Establish, develop and document research findings that address all analytical activities performed at the laboratory. | 10.1 Develop and acquire human capacity<br>10.2 Develop secondary standards in collaboration with international bodies.<br>10.3 Develop a Method Development and Validation Unit<br>10.4 Carry out analytical operational research.<br>10.5 Maintain, develop and possibly supply Chemical Reference Standards for use by pharmaceutical manufacturers.<br>10.6 Provide appropriate training and research facilities and services to various stakeholders that use the laboratory. | |
| 11 Collaborations/ Linkages and Partnerships | To establish and strengthen collaborations and partnerships with other institutions, industry and society | To identify potential institutions for collaboration with Laboratory. | 11.1 Review existing memorandum of understanding with various institutions with a view of focusing on issues of concern for mutual benefits and develop new contacts where necessary.<br>11.2 Establish and formalise interactive linkages with identified institutions<br>11.3 Develop and maintain sustainable inter-institutional linkages for enhancing the mandate of the laboratory.<br>11.4 Form and maintain alliances with special programs within the MoH (e.g. NASCOP, DOMC, NLTBP). | |

| Strategic Pillar | Objectives | Key Performance Indicators | Activities | Achievements |
|---|---|---|---|---|
| 12 Operational Management | Enhance operational efficiency within NQCL to satisfy customer demands | Adopt system and reliable approach to all operational activities by developing clear SOPs. | 12.1 Review processes for efficiency and effectiveness.<br>12.2 Undertake a process mapping.<br>12.3 Develop clear SOPs for all operations in the NQCL.<br>12.4 Implement the revised procedures.<br>12.5 Train staff on the quality procedures as per quality manuals/procedures. | |
| 13 Procurement and tendering for services | To improve procurement by ensuring competition, value for money and controls in procurement<br><br>To promote procedures that ensure there is transparency, efficiency and effectiveness in procurement of high quality goods and services, at the right time and right place. | To develop a comprehensive procurement policy | 13.1Develop procurement policies, guidelines and procedures for all products and services.<br>13.2Procure quality goods and services for the laboratory and maintain optimum levels of stock through computerization i.e. e-procurement.<br>13.3 Monitor and evaluate procurement and tendering procedures of supplies and services in the Laboratory and take appropriate action. | |
| 14 Information and Communication Technology (ICT) | To increase the use of Information Communication and Technology (ICT) in the | a To establish and maintain an Electronic Service Delivery Strategy. | 14.1 Establish and maintain ICT infrastructure for the Laboratory.<br>14.2 Recruit qualified and experienced ICT personnel to manage the systems. | 1.1 Electronic service strategy in place<br><br>1.2 ICT infrastructure in place; |

| Strategic Pillar | Objectives | Key Performance Indicators | Activities | Achievements |
|---|---|---|---|---|
| | development and management of quality control and assurance of medicines | b To offer e-commerce services to cater for speedy procurement | 14.3 Improve data management and record keeping in the Laboratory.<br>14.4 Establish and maintain an integrated data management system.<br>14.5 Maintain LIMS and regularly update the NQCL website.<br>14.6 Establish on-line links with clients to enable them submit samples for analysis, query progress of analytical work and receive analysis reports online. | 1.3 Integrated data management system in place |
| 15 Environment awareness | To promote environmental friendly practices | a To put measures for a clean and safe environment and promote them among staff.<br><br>b To ensure work environment that is free of biological, chemical and physical hazards.<br><br>c To ensure proper waste management policies are implemented. | 15.1 To develop waste management policy – collaborate with institutions with such policies;<br>15.2 To develop affiliations with waste management/environmental management bodies such as NEMA;<br>15.3 To re-cycle reagents that may need not to be disposed. This also includes other materials such as paper waste, glass, water (e.g. from distillation).<br>15.4 To ensure proper waste management | Contract in-place<br><br>Program on clean and safe environment in place<br><br>Proper waste management policies in place |

## 7. CORPORATE GOVERNANCE STATEMENT

**Process of Appointment and Removal of Directors**

Cap 244 Laws of Kenya Section 35F allows for the creation of a BOM for the Laboratory, which shall consist of (9) nine members to be appointed by the Pharmacy and Poisons Board (PPB). A member of the BOM appointed shall hold office for three years but shall be eligible for re-appointment, but not for more than 2 terms. A quorum of the BOM shall be five members and the members shall meet not less than four times each calendar year.

**Board Remuneration**

Each member shall receive a sitting allowance of Kshs. 15,000 up effective 01st January 2020, less tax for every meeting and a further allowance for lunch of Kshs. 2,000 when required. The Director shall be the secretary of the Board of Management.

**Roles and Functions of the Board**

Section 35G highlights the functions of the BOM, which include:

a. Administer the property and funds of the Laboratory in such manner and for such purposes as shall, in their opinion, promote its best interests;
b. Receive, on behalf of the Laboratory, grants-in-aid, gifts, donations, fees, subscriptions or other moneys and make disbursements therefrom;
c. Make regulations governing the appointment, conduct and discipline of employees of the Laboratory;
d. In consultation with the Cabinet Secretary (CS) Health, draw up a scheme of service for employees of the Laboratory;
e. Administer the approved terms and conditions of service, including appointments, dismissals, remuneration and retiring benefits of employees of the Laboratory; and
f. Appoint such employees upon terms and conditions to be laid down by them, after consultation with the CS Health, as it considers necessary for the proper and efficient administration of the Laboratory.

Section 35G allows for the BOM to appoint a Director who shall be the chief executive of the Laboratory responsible to the BOM for the day-to-day management of the Laboratory

## CORPORATE GOVERNANCE STATEMENT (Continued)

### NUMBER OF BOARD MEETINGS HELD AND THE ATTENDANCE

The table below shows the number of meetings and attendance held in the financial year under review;

| | Board Member | Normal Meetings (4) | Special Meetings (3) | Emergency Meeting (1) |
|---|---|---|---|---|
| 1. | **William Mwatu (Dr.) - DECEASED** | - | - | - |
| 2. | Irene Thiguku Kamanja (Dr.) | 4/4 | 3/3 | 1/1 |
| 3. | Paul Munyao Mutua (Mr.) | 4/4 | 0/3 | 1/1 |
| 4. | John Ronoh Sitienei (Mr.) | 4/4 | 3/3 | 1/1 |
| 5. | Georgina Muchai (CPA) | 2/4 | 0/3 | 1/1 |
| 6. | Lilian Balusi Makungu Njoroge (Dr.) | 3/4 | 3/3 | 1/1 |
| 7. | Hellen Bosibori Okioma (Ms.) | 4/4 | 3/3 | 1/1 |
| 8. | Simon Njoroge Muigai (Dr.) | 4/4 | 3/3 | 0/1 |
| 9. | Edith Wakori (Dr.) | 4/4 | 3/3 | 1/1 |
| 10. | Hezekiah K. Chepkwony (Dr.) | 4/4 | 3/3 | 1/1 |

The table below shows the number of meetings and attendance held in the financial year under review;

| | Board Member | Committees | | | |
|---|---|---|---|---|---|
| | | Finance, Admin. & General Purpose Meetings (3) | Technical Meetings (2) | Audit Meeting (5) | Adhoc Meetings (2) |
| 1. | **William Mwatu (Dr.) - DECEASED** | - | - | - | - |
| 2. | Irene Thiguku Kamanja (Dr.) | 3/3 | - | - | - |
| 3. | Paul Munyao Mutua (Mr.) | - | 0/2 | 5/5 | - |
| 4. | John Ronoh Sitienei (Mr.) | 3/3 | - | - | - |
| 5. | Georgina Muchai (CPA) | 3/3 | - | - | 2/2 |
| 6. | Lilian Balusi Makungu Njoroge (Dr.) | - | 2/2 | - | - |
| 7. | Hellen Bosibon Okioma (Ms.) | - | - | 5/5 | 2/2 |
| 8. | Simon Njoroge Muigai (Dr.) | - | 2/2 | 5/5 | - |
| 9. | Edith Wakori (Dr.) | 2/3 | 2/2 | - | - |
| 10. | Hezekiah K. Chepkwony (Dr.) | 3/3 | 2/2 | 5/5 | 2/2 |

**Succession Plan**

The BOM's succession plan is to lobby for a review of (Cap 244 Sec) the section of the law that authorises another SAGA (PPB) to appoint its BOM. We anticipate that in future the Chairperson and the BOM will be appointed by the President of the Republic of Kenya or the Cabinet Secretary of the Ministry of Health. The plan is to ensure the BoD's appointment is differentiated so as to allow for continuity. Currently the BOM does not have an existing Board Charter and will embark on having a draft ready before the end of quarter two (2). BOMs will be recruited competitively as governed by SCAC. The BOM will embark on training of its members on the Mwongozo Code of Governance, which is anchored in the Constitution of Kenya, 2010.

**Board and Member Performance**

Each BOM will be evaluated on their performance annually as guided in the Mwongozo code and each member shall be expected to clearly state any conflict of interest that arises in the course of executing their duties as BOMs. The evaluation shall include ethics, conduct as well as governance audit.

**Induction and Training**

The BOM is waiting for training on the Mwongozo Code of Governance, which will be carried out by SCAC. The Laboratory continues to have in place a system of rules, practices and processes based on the same Code of Governance developed by the Government of Kenya, by which it is directed and controlled, which involves balancing the interests of its many stakeholders including but not limited to management, staff, customers, suppliers, donors, government and the community in general. The system in place continues to provide the framework for attaining the Laboratory's objectives and encompasses practically every sphere of management, from action plans and internal controls to performance measurement and corporate disclosures.

**Ethics and Conduct**

Taking cognisance of the fact that the Laboratory is in the process of being categorised as a state corporation, it currently is recognized as Semi – Autonomous Government Agency that performs a regulatory duty on medicines and health technologies control under Ministry of Health. As a testing and inspecting facility, the Laboratory continues to uphold its corporate values of Staff, Environment, Integrity & Patriotism, Technology, Standards, Commitment to customer services, Quality Service and Team & Individual Productivity.

**Conflict of Interest**

To avoid conflicts of interest, pressures and influences, the BOM are bound by the provisions of the Public Officers Ethics Act Cap 183 and the Laboratory's conflict of interest policy. Two core concepts are embodied in these regulations; BOM members shall not use public office for private gain nor act impartially and give preferential treatment to any private organization or individual. A conflict of interest form within the quality management system of the Laboratory is available to document this when necessary.

## 8. MANAGEMENT DISCUSSION AND ANALYSIS

The Laboratory since its establishment has served a variety of clientele that includes government agencies. These include Kenya Medical Supplies Authority, National AIDS & Sexually Transmitted Infections Control Programme, National Tuberculosis, Leprosy and Lung Disease Program, Malaria Control Unit, Division of Vaccines & Immunization, Disease Surveillance and Response Unit, Government & Private Hospitals, Private Agencies & Non-Governmental Organizations, Prequalified Quality Control Laboratories & ISO Certified Institutions, National Drug Regulatory Authorities among others.

Other than testing medicines, the Laboratory, has also expanded its testing capacity to include the testing of medical devices such as male & female latex condoms, gloves, needles and syringes. In an effort to improve the services it offers its clients, the Laboratory has achieved and maintained World Health Organization Prequalification Status since 2008 and attained ISO/IEC 17025:2005 accreditation in 2015. These two worlds acclaimed quality standards guarantee that tests carried out by the Laboratory are recognised internationally. Apart from ensuring that the Kenyan population have medicines of the highest quality, the Laboratory is also a benchmarking institution for local and regional pharmaceutical manufacturers and firms.

The Laboratory housed in the Kenyatta National Hospital (KNH) complex grounds was initially set-up as an upgrade of the Drug Analysis Research Unit of the School of Pharmacy University of Nairobi. It is therefore a squatter and does not pay any rent only incurring a charge for utilities. Over the years, the Laboratory has outgrown its capacity due to the nature of increased analytical services and the number of staff it can accommodate. We are in the process of securing funds for the construction of an ultra- modern Laboratory in the piece of land recovered from Kenya Reinsurance Corporation. This land, originally been allocated to the Laboratory by the Ministry of Lands after initial set-up. An extra piece of the allocated land is currently occupied by the KNH and negotiations are already going on for them to cede this land back to the Laboratory.

## MANAGEMENT DISCUSSION AND ANALYSIS (Continued)

The Laboratory has continually complied with all statutory provisions in discharging its mandate for the Kenya Revenue Authority, National Social Security Fund, National Hospital Insurance fund and The Higher Educations Loan Board among other deductions as and when required.

The major risk facing the organization is the usurping of its mandate by PPB, which as seen from the financial performance has resulted in decreased incomes particularly those from analysis of medicines and health technologies. We hope that this can be mitigated by the new Health Act 2017, which, has proposed the formation of a single regulatory authority in the health sector.

NATIONAL QUALITY CONTROL LABORATORY
16 APR 2021

## 9. CORPORATE SOCIAL RESPONSIBILITY STATEMENT/SUSTAINABILITY REPORTING

Corporate Social Responsibility (CSR) is the responsibility of an organization for the impacts of its decisions and activities on society and the environment, through transparent and ethical behaviour that:

- Contributes to sustainable development, including the health and the welfare of society,
- Takes into account the expectations of stakeholders,
- Is in compliance with applicable law and consistent with international norms of behaviour, and,
- Is integrated throughout the organization and practiced in its relationships.

It can further be elaborated as a form of corporate self-regulation integrated into an organizations business model. It functions as a self-regulatory mechanism whereby the organization monitors and ensures its active compliance with the spirit of the law, ethical standards and national or international norms. For some organizations, it goes beyond compliance and engages in activities that appear to further some social good, beyond the interests of the firm and that which is required by law. The aim is to increase long-term benefits and stakeholder trust through positive public relations and high ethical standards to reduce business and legal risk by taking responsibility for corporate actions. Its strategies encourage the company to make a positive impact on the environment and stakeholders including consumers, employees, investors, communities, and others.

The Laboratory has taken an initiative to assess and take responsibility for the effects on the environment and the kind of impact it has on the society. The Laboratory has made efforts that go beyond what may be required by the Government. The Laboratory has done this by subscribing, to the WHO prequalification guidelines for Good Practices for Pharmaceutical Quality Control Laboratories and the ISO 17025 guidelines all of which clearly define how a quality control Laboratory is meant to dispose of its waste, use of chemicals and reagents and monitoring of environment conditions for sample integrity and staff working conditions.

The Laboratory also engages the society in its activities by allowing students to carry out their attachments in the institutions as a way of gaining experience and work practice. It also donates equipment to teaching institution and also performs demonstrations for students in universities and

## CORPORATE SOCIAL RESPONSIBILITY STATEMENT-SUSTAINABILITY REPORTING (Continued)

colleges that teach pharmaceutical sciences. We have also engaged interns under the Public Service Internship Programme (PSIP) being run by the Public Service Commission for one (1) year. In the year under review, we have engaged a total of eleven (11) interns in the following units: Biological Analysis, Wet Chemistry, Client Services, Procurement, Accounts and Information Communication Technology Units. This is in-line with the Government policy of engaging the youth in productive activities and in also reduce unemployment.

In procurement, we have ensured that the Laboratory has put in place the Access to Government Procurement Opportunities (AGPO) to allow for 30 per cent of contracts to be given to the youth, women and persons with disability without competition from established firms.

Going into the future the Laboratory intends to devote real time system on its activities to enhance environmental sustainability programs, alternative/clean energy, and various social welfare initiatives to benefit staff, customers, and the society at large. The Laboratory has a vibrant Environment & Health Safety Committee, which ensures the members are trained annually on first aid and fire marshalling services.

The Laboratory continues to be responsive to the changes in employment welfare requirements All the BOM and the contracted staff are under a signed contract with National Health Insurance Fund (NHIF) which caters for their medical needs as per their job classification. In the previous recruitment, the BOM considered gender, regional and ethnic balance. It also considered people living with disabilities in the same recruitment. On matters training, all the staff continue to be trained on the various techniques as per the requirements of the Laboratory training schedule with a significant emphasis on technical skills.

## 10. REPORT OF THE BOARD OF MANAGEMENT

The Directors submit their report together with the audited financial statements for the year ended June 30, 2020, which show the state of the National Quality Control Laboratory affairs.

**Principal activities**

The Laboratory continues to;

- Examine and test medicines;
- Perform chemical, biological, biochemical, physiological and pharmacological analysis and other pharmaceutical evaluation;
- Test, on behalf of the Government, locally manufactured and imported medicines or medicinal substances;
- Provide advisory services to the Ministry of Health on medicines quality standards; and
- Carry out Good Manufacturing Practices (GMP) inspections in pharmaceutical manufacturing industry premises and issue certificates of compliance on the same.

The Laboratory has also expanded its testing capacity to include the testing of medical devices such as male & female latex condoms, gloves, needles and syringes.

**Results**

The results of the entity for the year ended June 30, 2020 are set out on pages 1 to 5.

**Directors/Board of Management**

The current BOM was appointed by the appointing authority via a gazette notice No. 1940 dated 02nd March 2018 effective from 12th February, 2018 and will serve for a period of three (3) years. The BOM was inaugurated on 05th April 2018. There is an on-going matter in court on the membership of the Board of Management. The financial statements are yet to be reviewed and signed by the Board.

**Dividends/Surplus remission**

In accordance with Section 219 (2) of the Public Financial Management Act regulations, regulatory entities shall remit into Consolidated Fund, ninety per centum of its surplus funds reported in the audited financial statements after the end of each financial year. The entity did not make any surplus during the year (FY 2018-19) and hence no remittance to the Consolidated Fund was done.

The entity made a surplus of Kshs. 13,412,335 during the year.

## REPORT OF THE BOARD OF MANAGEMENT (Continued)

### Auditors

The Auditor General is responsible for the statutory audit of the National Quality Control Laboratory in accordance with Article 229 of the Constitution of Kenya and the Public Audit Act 2015.

The officers from the Office of the Auditor General Office have been nominated to carry out the audit of the Laboratory for the year/period-ended June 30, 2020 in accordance to section 23 of the Public Audit Act, 2015, which empowers the Auditor General to appoint an auditor to audit on his behalf.

By Order of the Board

| | |
|---|---|
| **Dr. Hezekiah Kibet Chepkwony, PhD**<br>**Director, Secretary BOM** | **Ms. Georgina Muchai,**<br>**Chairperson, Finance, Administration and General Purpose Committee of BOM** |
| **Date** 16th April, 2021 | **Date** 16th April, 2021 |

## 11. STATEMENT OF DIRECTORS' RESPONSIBILITIES

Section 81 of the Public Finance Management Act, 2012; require the Board to prepare financial statements in respect to the Laboratory, which give a true and fair view of the state of affairs and the operating results at the end of the financial year. The Board is also required to ensure that the Laboratory keeps proper accounting records, which disclose with reasonable accuracy the financial position of the Laboratory. The Board is also responsible for safeguarding the assets of the Laboratory.

The Board is responsible for the preparation and presentation of the Laboratory's financial statements, which give a true and fair view of the state of affairs of the Laboratory for and as at the financial year ended on 30 June 2020. This responsibility includes:

1. Maintaining adequate financial management arrangements and ensuring that these continue to be effective throughout the reporting period;
2. Maintaining proper accounting records, which disclose with reasonable accuracy at any time the financial position of the entity;
3. Designing, implementing and maintaining internal controls relevant to the preparation and fair presentation of the financial statements, and ensuring that they are free from material misstatements, whether due to error or fraud;
4. Safeguarding the assets of the Laboratory;
5. Selecting and applying appropriate accounting policies; and
6. Making accounting estimates that are reasonable in the circumstances.

The Board accepts responsibility for the Laboratory's financial statements, which have been prepared using appropriate accounting policies supported by reasonable and prudent judgements and estimates, in conformity with International Public Sector Accounting Standards, and in the manner required by the Public Finance Management Act and the State Corporations Act.

The Board asserts that the financial statements give a true and fair view of the state of the Laboratory's transactions during the financial year ended 30 June 2020 and of its financial position as at that date. The Board further confirms the completeness and accuracy of the accounting records maintained by the Laboratory, which have been relied upon in the preparation of the financial statements as well as the adequacy of the internal control systems.

## STATEMENT OF DIRECTORS' RESPONSIBILITIES (Continued)

Nothing has come to the attention of the Board of Management indicating that the Laboratory will not remain a going concern for at least the next twelve (12) months from the date of this statement.

### Approval of the Financial Statements

The Laboratory's financial statements are approved by the Chairperson of the Board on, 30th September, 2020 and signed on its behalf by:

| | |
|---|---|
| **Dr. Hezekiah Kibet Chepkwony, PhD**<br>**Director, Secretary BOM** | **Ms. Georgina Muchai,**<br>**Chairperson, Finance, Administration and General Purpose Committee of BOM** |
| **Date** 16th April, 2021 | **Date** 16th April, 2021 |

# REPUBLIC OF KENYA

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OAG
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## REPORT OF THE AUDITOR-GENERAL ON NATIONAL QUALITY CONTROL LABORATORY FOR THE YEAR ENDED 30 JUNE, 2020

REPORT ON THE FINANCIAL STATEMENTS

### Adverse Opinion

I have audited the accompanying financial statements of National Quality Control Laboratory set out on pages 1 to 39, which comprise the statement of financial position as at 30 June, 2020, and the statement of financial performance, statement of changes in net assets, statement of cash flows and statement of comparison of budget and actual amounts for the year then ended, and a summary of significant accounting policies and other explanatory information in accordance with the provisions of Article 229 of the Constitution of Kenya and Section 35 of the Public Audit Act, 2015. I have obtained all the information and explanations which, to the best of my knowledge and belief, were necessary for the purpose of the audit.

In my opinion, because of the significance of the matters discussed in the Basis for Adverse Opinion section of my report, the financial statements do not present fairly, the financial position of the National Quality Control Laboratory as at 30 June, 2020, and of its financial performance and its cash flows for the year then ended, in accordance with International Public Sector Accounting Standards (Accrual Basis) and do not comply with the Public Finance Management Act, 2012 and Section 35D of the Pharmacy and Poisons Amendment Act, 1992.

### Basis for Adverse Opinion

### 1.0 Unbalanced Trial Balance

The trial balance reflects debit balances totalling to Kshs.260,811,339 and credit balances totalling to Kshs.138,637,838 resulting in unexplained variance of Kshs.122,173,501. No explanation was provided for failure to reconcile the balances.

Under the circumstances, the accuracy and validity of the financial statements could not be confirmed.

### 2.0 Inaccuracy of the Statement of Cash Flows

The statement of cash flows reflects a decrease in payables-staff gratuity of Kshs.4,408,781 and an increase in deposits-prepayments of Kshs.9,878,270. However, the two balances are not supported by movements in the statement of financial position as at 30 June, 2020. In addition, the statement of cashflow reflects purchase of property plant and equipment of Kshs.190,205 under investing activities. However, the fixed assets movement schedule reflects additions of Kshs.51,005 resulting in un-reconciled difference of Kshs.139,200.

Under the circumstances, the accuracy and completeness of the statement of cash flows for the year ended 30 June, 2020 could not be confirmed.

### 3.0 Property, Plant and Equipment

### 3.1 Inaccuracy of the Property, Plant and Equipment Balances

The statement of financial position reflects comparative property plant and equipment figure of Kshs.60,042,741 which differs with the comparative balance in the property plant and equipment movement schedule of Kshs.71,410,669 resulting in unexplained difference of Kshs.11,367,928. Further, the fixed assets movement schedule reflects net book value for lab equipment of Kshs.45,344,123 but the movement cast to Kshs.45,204,923 resulting in unexplained difference of Kshs.139,200.

### 3.2 Land

As disclosed in Note 20A to the financial statements, the statement of financial position reflects property, plant and equipment balance of Kshs.65,592,651. However, as previously reported, the balance excludes an undetermined value of a parcel of land measuring four (4) hectares situated in Upper Hill, Nairobi which was allotted to the Laboratory in 1992. The parcel of land was re-allocated to the National Quality Control Laboratory in 1995 but was reduced from 4 hectares to 2.61 hectares. Available information indicated that out of 2.61 hectares, 1.26 was sold to Kenya-Re by the Kenya Media Trust and the remaining 1.35 hectares was taken over by Kenyatta National Hospital. However, a total of 2.35 hectares has since been surrendered back leaving Kenya-Re with 1.0 hectares and Kenyatta National Hospital with 1.35 hectares.

Further, the National Land Commission has repossessed part of 1.35 hectares surrendered by Kenyatta National Hospital and reallocated it to the Kenya Urban Road Authority for construction of road without the consent of the National Quality Control Laboratory. Available information indicated that the 1.35 hectares parcel of land surrendered by Kenyatta National Hospital is under survey process while Kenya-Re has since surveyed the 1.0 hectare for purposes of subdivision for the property. The laboratory has not obtained any ownership documents for the remaining 1.65 hectares and no evidence was provided that the processing of the same was on course.

Under the circumstances, the accuracy and completeness of property, plant and equipment balance of Kshs.65,592,651reflected in the statement of financial position as at 30 June, 2020 could not be confirmed.

### 4.0 Cash and Cash Equivalents

The statement of financial position reflects a cash and cash equivalents balance of Kshs.32,067,900 as at 30 June, 2020. However, the current account bank reconciliation statement reflects a balance as per bank statement of Kshs.32,249,655 while the bank confirmation certificate reflects an amount of Kshs.31,355,655 resulting to an unexplained variance of Kshs.894,000.

Consequently, the accuracy of the cash and cash equivalents balance of Kshs.32,067,900 as at 30 June, 2020 could not be confirmed.

### 5.0 Receivables from Exchange Transactions

As disclosed in Note 17A to the financial statements, the statement of financial position reflects receivables from exchange transactions balance of Kshs.26,815,664 as at 30 June, 2020. The balance includes analysis fees totalling Kshs.6,013,120 reflected as owed by Kenya Medical Supplies Authority (KEMSA), which has been outstanding for more than fifteen (15) years. However, this balance has not reflected as a payable in the Authority's financial statements.

Further, the receivables balance includes other receivables from United Nations Development Programme-Southern Sudan of Kshs.1,476,930 and Government of South Sudan of Kshs.136,267 which have been outstanding for more than six (6) years and other debtors amounting to Kshs.4,111,507 which have been outstanding for more than three (3) years. A provision for bad and doubtful debts of Kshs.804,470 equivalent to 3% of total outstanding debtors has been made in respect of the outstanding receivables.

Consequently, the accuracy and validity of the receivables from exchange transactions balance of Kshs.26,815,664 reflected in the statement of financial position as at 30 June, 2020 could not be confirmed.

### 6.0 Inventories

The statement of financial position reflects a balance of Kshs.5,964,091 in respect of inventories while the approved annual stock take report reflects an amount of Kshs.18,385,027 resulting to an unexplained variance of Kshs.12,420,936.

Consequently, the accuracy of the inventories balance of Kshs.5,964,091 as at 30 June, 2020 could not be confirmed.

### 7.0 Restatement/Assets Revaluation

The statement of financial position reflects accumulated surplus carried forward balance of Kshs.74,774,078 which includes restatement/assets revaluation of Kshs.11,453,865 whose supporting documents including journal entries were not provided for audit review.

Consequently, the accuracy and validity of the restatement/assets revaluation of Kshs.11,453,865 for the year ended 30 June, 2020 could not be confirmed.

### 8.0 General Expenses

The statement of financial performance reflects general expenses of Kshs.17,652,925 for the year ended 30 June, 2020. However, the corresponding Note 14 to the financial statements cast to Kshs.17,034,666 resulting in an unexplained difference of Kshs.618,259.

Under the circumstances, the accuracy of general expenses of Kshs.17,652,925 for the year ended 30 June, 2020 could not be confirmed.

The audit was conducted in accordance with International Standards of Supreme Audit Institutions (ISSAIs). I am independent of the National Quality Control Laboratory

Management in accordance with ISSAI 130 on Code of Ethics. I have fulfilled other ethical responsibilities in accordance with the ISSAI and in accordance with other ethical requirements applicable to performing audits of financial statements in Kenya. I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my adverse opinion.

## Key Audit Matters

Key audit matters are those matters that, in my professional judgment, are of most significance in the audit of the financial statements. There were no key audit matters to report in the year under review.

## Other Matter

### 1.0 Legal Status of National Quality Control Laboratory (NQCL)

As previously reported, the National Quality Control Laboratory was established under Section 35D of the Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya on 28 October, 1992 and came into operation on 6 November, 1992. Since inception, the Laboratory has operated under the Division of Pharmacy in the Ministry of Health. However, in September, 2014, it was recognized as a Semi-Autonomous Government Agency (SAGA) in the Ministry of Health. Subsequently, in February, 2016, the State Corporation Advisory Committee after evaluating its capacity categorized the Laboratory at category PC 4B and advised the Ministry of Health to proceed to form an Inter-Ministerial Task Force to advise on attainment of full parastatal status. However, as at the time of audit, no progress had been made by the ministry on formation of the Inter-Ministerial Task Force.

### 2.0 Budgetary Control and Performance

During the year under review, the National Quality Control Laboratory actual receipts amounted to Kshs.88,952,581 against budgeted receipts of Kshs.91,405,000 resulting in revenue shortfall of Kshs.2,452,419. Further, the Laboratory actual expenditure amounted to Kshs.74,284,904 against budgeted expenditure of Kshs.106,141,000 resulting in an overall under absorption of Kshs.31,856,096. The revenue shortfall and the under expenditure adversely affected the planned activities and may have impacted negatively on service delivery to the public.

REPORT ON LAWFULNESS AND EFFECTIVENESS IN USE OF PUBLIC RESOURCES

## Conclusion

As required by Article 229(6) of the Constitution, based on the audit procedures performed, I confirm that, nothing has come to my attention to cause me to believe that public resources have not been applied lawfully and in an effective way.

## Basis for Conclusion

The audit was conducted in accordance with ISSAI 4000. The standard requires that I comply with ethical requirements and plan and perform the audit to obtain assurance about whether the activities, financial transactions and information reflected in the financial statements are in compliance, in all material respects, with the authorities that govern them. I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my conclusion.

REPORT ON EFFECTIVENESS OF INTERNAL CONTROLS, RISK MANAGEMENT AND GOVERNANCE

**Conclusion**

As required by Section 7(1)(a) of the Public Audit Act, 2015, based on the audit procedures performed, I confirm that, nothing has come to my attention to cause me to believe that internal controls, risk management and overall governance were not effective.

**Basis for Conclusion**

The audit was conducted in accordance with ISSAI 2315 and ISSAI 2330. The standards requires that I plan and perform the audit to obtain assurance about whether effective processes and systems of internal control, risk management and governance were operating effectively, in all material respects. I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my conclusion.

**Responsibilities of Management and Board of Management**

Management is responsible for the preparation and fair presentation of these financial statements in accordance with International Public Sector Accounting Standards (Accrual Basis) and for maintaining effective internal control as Management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error and for its assessment of the effectiveness of internal control, risk management and overall governance.

In preparing the financial statements, Management is responsible for assessing the Laboratory's ability to continue to sustain its services, disclosing, as applicable, matters related to sustainability of services and using the applicable basis of accounting unless Management is aware of the intention to terminate the Laboratory or to cease operations. Management is also responsible for the submission of the financial statements to the Auditor-General in accordance with the provisions of Section 47 of the Public Audit Act, 2015.

In addition to the responsibility for the preparation and presentation of the financial statements described above, Management is also responsible for ensuring that the activities, financial transactions and information reflected in the financial statements are in compliance with the authorities which govern them, and that public resources are applied in an effective way.

The Board of Management is responsible for overseeing the financial reporting process, reviewing the effectiveness of how the Laboratory monitors compliance with relevant legislative and regulatory requirements, ensuring that effective processes and systems are in place to address key roles and responsibilities in relation to overall governance and risk management, and ensuring the adequacy and effectiveness of the control environment.

**Auditor-General's Responsibilities for the Audit**

The audit objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes my opinion in accordance with the provisions of Section 48 of the Public Audit Act, 2015 and submit the audit report in compliance with Article 229(7) of the Constitution. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISSAIs will always detect a material misstatement and weakness when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

In addition to the audit of the financial statements, a compliance audit is planned and performed to express a conclusion about whether, in all material respects, the activities, financial transactions and information reflected in the financial statements are in compliance with the authorities that govern them and that public resources are applied in an effective way, in accordance with the provisions of Article 229(6) of the Constitution and submit the audit report in compliance with Article 229(7) of the Constitution.

Further, in planning and performing the audit of the financial statements and review of compliance, I consider internal control in order to give an assurance on the effectiveness of internal controls, risk management and overall governance processes and systems in accordance with the provisions of Section 7(1)(a) of the Public Audit Act, 2015 and submit the audit report in compliance with Article 229(7) of the Constitution. My consideration of the internal control would not necessarily disclose all matters in the internal control that might be material weaknesses under the ISSAIs. A material weakness is a condition in which the design or operation of one or more of the internal control components does not reduce to a relatively low level the risk that misstatements caused by error or fraud in amounts that would be material in relation to the financial statements being audited may occur and not be detected within a timely period by employees in the normal course of performing their assigned functions.

Because of its inherent limitations, internal control may not prevent or detect misstatements and instances of non-compliance. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate.

As part of an audit conducted in accordance with ISSAIs, I exercise professional judgement and maintain professional skepticism throughout the audit. I also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Management.

- Conclude on the appropriateness of the Management's use of the applicable basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Laboratory's ability to continue to sustain its services. If I conclude that a material uncertainty exists, I am required to draw attention in the auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify my opinion. My conclusions are based on the audit evidence obtained up to the date of my audit report. However, future events or conditions may cause the Laboratory to cease to continue to sustain its services.

- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

- Obtain sufficient appropriate audit evidence regarding the financial information and business activities of the Laboratory to express an opinion on the financial statements.

- Perform such other procedures as I consider necessary in the circumstances.

I communicate with the Management regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that are identified during the audit.

I also provide Management with a statement that I have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on my independence, and where applicable, related safeguards.

**CPA Nancy Gathungu, CBS**
**AUDITOR-GENERAL**

**Nairobi**

**28 January, 2022**

## 13. STATEMENT OF FINANCIAL PERFORMANCE FOR THE YEAR ENDED 30 JUNE 2020

| | Notes | 2019 - 2020 | 2018 - 2019 |
|---|---|---|---|
| | | Kshs | Kshs |
| **Revenue from non-exchange transactions** | | | |
| Public contributions and donations – Deferred income (GTZ) | 6 | 4,393,497 | 5,020,257 |
| Transfers from other governments – gifts and services-in-kind (26,149,766+400,000) | 7 | 1,503,459 | 26,549,766 |
| **Revenue from exchange transactions** | | | |
| Rendering of services – Analysis fees | 8 | 83,055,625 | 59,586,750 |
| Other income - (GMP certification / CoA -certified copies) | | - | 916,234 |
| **Total Revenue** | | **88,952,581** | **92,073,007** |
| **Expenses;-** | | | |
| Use of goods and services -Electricity | 9 | 1,503,459 | - |
| Employee costs - Personnel (66000+1095379+4828744+18037388=24027511) | 10 | 27,164,287 | 22,932,132 |
| Remuneration of Directors (BoM) | 11 | 2,743,060 | 3,329,461 |
| Depreciation and Amortization expense | 12 | 10,401,720 | 14,147,170 |
| Provision for Bad debt (3% x 26,815,664) | 17B | 804,469 | 1,098,133 |
| Provision for Audit fees (2018/19 & 2019/20) | | 696,000 | 348,000 |
| Contracted services - Repairs and Maintenance | 13 | 13,167,489 | 11,911,815 |
| General expenses (Admin exp & Chemical / Reagents) | 14 | 17,652,925 | 48,635,091 |
| Finance costs | 15 | 151,495 | 136,714 |
| **Total Expenses** | | **74,284,904** | **102,538,516** |
| **Surplus/( deficit) for the period/year** | | **14,667,677** | **(10,465,509)** |
| **Total expenses** | | **74,284,904** | **102,538,516** |
| **Other gains/(losses)** | | - | - |
| Gain on foreign exchange transactions | | - | - |
| **Surplus before tax** | | **14,667,677** | **(10,465,509)** |
| Taxation | 30 | - | - |
| **Surplus/( deficit) for the period/year** | | **14,667,677** | **(10,465,509)** |
| **Net Surplus for the year** | | **14,667,677** | **(10,465,509)** |

The notes set out on pages 7 to 30 form an integral part of these Financial Statements.

## 14. STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2020

| Assets | Notes | 2019 - 2020 | 2018 - 2019 |
|---|---|---|---|
| | | Kshs | Kshs |
| **Current assets** | | | |
| Cash and cash equivalents | 16 | 32,067,900 | 6,061,975 |
| Receivables from exchange transactions | 17A | 26,815,664 | 36,604,434 |
| Receivables from non-exchange transactions staff advances | 18 | 143,000 | 232,500 |
| Inventories | 19 | 5,964,091 | 10,156,259 |
| **Non-current assets** | | | |
| Property, plant and equipment | 20A | 65,592,651 | 60,042,741 |
| **Total assets** | | **130,583,306** | **113,097,909** |
| **Liabilities** | | | |
| **Current liabilities** | | | |
| Trade and other payables from exchange transactions | 21A | 23,071,216 | 27,020,912 |
| Deferred income – GTZ Donated Assets (PPE) | 20B | 30,718,966 | 35,112,462 |
| | | **53,790,182** | **62,133,374** |
| **Non-current liabilities** | | | |
| Non-current employee benefit obligation - Gratuity | 21B | 2,019,046 | 2,311,999 |
| **Total liabilities** | | **55,809,228** | **64,445,373** |
| **Net assets** | | **74,774,078** | **48,652,536** |
| Accumulated surplus B/F | | 48,652,536 | 59,118,045 |
| (Deficit) / Surplus for the year | | 14,667,677 | (10,465,509) |
| Restatement / Revaluation Assets | 20A - i | 11,453,865 | - |
| **Accumulated surplus C/F** | | **74,774,078** | **48,652,536** |
| **Total net assets and liabilities** | | **130,583,306** | **113,097,909** |

The Financial Statements set out on pages 1 to 6 were signed on behalf of the Board of Directors by:

| **Director** | **Head of Finance** | **Chairman of the Board** |
|---|---|---|
| **Dr. Hezekiah Kibet Chepkwony, PhD** | **Mr. David K. Yano (CPA)** ICPAK No 14517 | **Ms. Georgina Muchai (CPA), For Chairperson, Board of Management** |
| **Date** 16th April, 2021 | **Date** 16th April, 2021 | **Date** 16th April, 2021 |

NATIONAL QUALITY CONTROL LABORATORY
16 APR 2021

## 15. STATEMENT OF CHANGES IN NET ASSETS FOR THE YEAR ENDED 30 JUNE 2020

| Details | Accumulated Surplus | Totals |
|---|---|---|
| | Kshs | Kshs |
| **Balance as at 30 June, 2015** | **32,224,428** | **32,224,428** |
| Surplus / Deficit for the Year - Restated | 26,712,041 | 26,712,041 |
| Restatement of property plant and equipment NBV and Depreciation | 21,326,844 | 21,326,844 |
| **Balance as at 30 June, 2016** | **80,263,313** | **80,263,313** |
| Surplus / Deficit for the Year | 6,428,141 | 6,428,141 |
| **Balance as at 30 June, 2017** | **86,691,454** | **86,691,454** |
| Surplus / Deficit for the Year | **(27,573,409)** | **(27,573,409)** |
| **Balance as at 30 June, 2018** | **59,118,045** | **59,118,045** |
| Surplus / Deficit for the Year | **(10,465,509)** | **(10,465,509)** |
| **Balance as at 30 June, 2019** | **48,652,536** | **48,652,536** |
| Restatement / Revaluation Assets | 11,453,865 | 11,453,865 |
| (Deficit) / Surplus for the year | 14,667,677 | 14,667,677 |
| **Balance as at 30 June, 2020** | **74,774,078** | **74,774,078** |

## 16. STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30 JUNE 2020

| | | 2019 - 2020 | 2018 - 2019 |
|---|---|---|---|
| | | Kshs | Kshs |
| **Cash flows from operating activities** | | | |
| **Receipts** | | | |
| Rendering of services – A-I-A Income | 8 | 83,055,625 | 59,586,750 |
| Other income - (GMP certification / CoA -certified copies) | | - | 916,233 |
| Other income - (GoK Grants) | | 1,503,459 | 26,549,766 |
| **Total Receipts** | | **84,559,084** | **87,052,749** |
| **Payments** | | | |
| Compensation of employees (Staff ) | 10 | 27,164,287 | 22,932,132 |
| Board Expenses | 11 | 2,743,060 | 3,329,461 |
| Goods and services Repairs & Maintenance | 13 | 13,167,489 | 11,911,815 |
| Other payments (General / Admin/ office exp) | 14 | 17,652,925 | 48,635,091 |
| Finance cost | 15 | 151,495 | 136,714 |
| **Total Payments** | | **60,879,256** | **86,945,213** |
| **Net cash flows from operating activities ;** | | **23,679,828** | **107,536** |
| | | | |
| **Cash flows from investing activities;** | | | |
| Purchase of property, plant, equipment and intangible assets (139200+51005) | 20 | (190,205) | (749,988) |
| Proceeds from sale of property, plant and Equipment | | - | - |
| (Increase) / Decrease in non-current receivables | 17 | (9,878,270) | (14,808,565) |
| (Increase) / Decrease in non-current receivables | 18 | | |
| (Increase) / Decrease in inventories | 19 | (4,192,168) | 10,222,228 |
| Increase / (Decrease) in payables | 21 | (3,949,696) | (7,528,301) |
| (Increase) / Decrease in Payables – staff Gratuity(3680781+728000) | 22 | 4,408,781 | 2,311,999 |
| **Net cash flows used in investing activities** | | **(13,801,558)** | **(10,552,627)** |
| | | | |
| **Cash flows from financing activities;** | | | |
| (Decrease) Increase in deposits - prepayments | 21 | (9,878,270) | **12,299,969** |
| **Net cash flows used in financing activities** | | **(9,878,270)** | **12,299,969** |
| **Net increase/(decrease) in cash and cash equivalents** | | **26,005,925** | **(1,854,878)** |
| | | | |
| Cash and cash equivalents at 1 JULY | 16 | **6,061,975** | **7,916,853** |
| **Cash and cash equivalents at 30 JUNE** | 16 | **32,067,900** | **6,061,975** |

## 17. STATEMENT OF COMPARISON OF BUDGET AND ACTUAL AMOUNTS FOR THE YEAR ENDED 30 JUNE 2020

**Note;** Source of the data is approved 2019/20 Budget

| | Original budget | Adjustments | Final budget, AIE & Approved Estimates | Actual on Comparable basis | Performance difference | status |
|---|---|---|---|---|---|---|
| | 2019-2020 | 2019-2020 | 2019-2020 | 2019-2020 | 2019-2020 | |
| **Revenue** | Kshs | Kshs | Kshs | Kshs | Kshs | |
| Public contributions and donations | 0 | - | 0 | 4,393,497 | (4,393,497) | F (i) |
| Government grants and subsidies – AIE, Approved estimates | 27,878,000 | - | 27,878,000 | 1,503,459 | 26,374,541 | A* (ii) |
| Rendering of services – AIA | 62,565,000 | | 62,565,000 | 83,055,625 | 20,490,625) | F* (iii) |
| Rendering of services – GMP certification | 962,000 | - | 962,000 | - | 962,000 | A* (iv) |
| **Total income** | **91,405,000** | **0** | **91,405,000** | **88,952,581** | 2,452,419 | |
| **Expenses** | | | | | | - |
| Electricity | 0 | | 0 | 1,503,459 | (1,503,459) | A* (v) |
| Medical Equipment's () | 0 | | 0 | - | - | |
| Compensation of employees () | 24,079,000 | - | 24,079,000 | 27,164,287 | (3,085,287) | A* (vi) |
| Remuneration to the Board | 3,495,000 | | 3,495,000 | 2,743,060 | 751,940 | F* (vii) |
| Goods and services (Repairs / Maintenance) | 12,787,000 | - | 12,787,000 | 13,167,489 | (380,489) | A* (viii) |
| Finance cost – Bank charges | 0 | - | 0 | 151,495 | (151,495) | A* (ix) |
| General/Admin exp - Other payments () | 50,934,000 | - | 50,934,000 | 17,652,925 | 33,281,075 | F* (x) |
| Provision for Depreciation, Audit fee & Bad D/D ksh. (10401720+348000+348000+804469) | 14,846,000 | | 14,846,000 | 11,902,189 | 2,943,811 | F* (xi) |
| Grants and subsidies - Other GoK | 0 | - | 0 | | - | |
| **Total expenditure** | **106,141,000** | **0** | **106,141,000** | **74,284,904** | 31,856,096 | |
| **Surplus for the period** | **(14,736,000)** | - | **(14,736,000)** | **14,667,677** | (29,403,677) | (29,403,677) |

**Budget notes denoted with the asterisk mark ***

1. Provide explanation of differences between actual and budgeted amounts (if 10% over/ under) IPSAS 24.14
2. Provide an explanation of changes between original and final budget indicating whether the difference is due to reallocations or other causes. (IPSAS 24.29)
3. Where the total of actual on comparable basis does not tie to the statement of financial performance totals due to differences in accounting basis (budget is cash Basis, statement of financial performance is accrual) provide reconciliation.

## SURPLUS RECONCILIATION

| Description | 2019-2020 |
|---|---|
| | KShs |
| Surplus/ deficit as per statement of financial performance | 14,667,677 |
| Donations | 4,393,497 |
| MoH (Electricity and Imprest) | 1,503,459 |
| **Total transfers and sponsorships** | **20,564,633** |

(i) **Public Contributions and Donations Kshs. 4,393,497– F* variance**
This favourable difference resulted from a grant not budgeted for as shown

(ii) **Government Grants and Subsidies; Kshs. (26,374,541) -A* total variance**
We budgeted for Kshs. 27,878,000 but received Kshs.1, 503,459 for Electricity resulting to the favourable difference on account of unabsorbed / unspent funds inversely meaning services budgeted for could not be rendered.

(iii) **Rendering Services AIA (Internally Generated funds); Kshs. 20,490,625 - F* variance**
During the year our budgeted target was ksh. 62,565,000 yet in the year under review, we earned ksh. 83,055,625 hence the variance. There is no GMP certification fee received for the period.

(iv) **Good Manufacturing Practices - GMP Kshs.(962,000) –A* variance**
This resulted from unrealized income from one of the source of revenues for activities and services not carried out in the year under review, to enable us earn

(v) **Compensation of Employee's Kshs.(1,503,459) –A* variance**
This resulted from the expenditure not budgeted for but paid in the financial year due to an editing typo that removed the entry.

(vi) **Compensation of Employee's Kshs.(3,085,287) –A* variance**
This resulted from an increase in contracted staff numbers recruited at the end of the period under review and the previous pay as projected due to increased work recruited staff.

(vii) **Remuneration to the Board Kshs. 751,940 – F* variance**
This is due to the reduced number of sittings of the Board members in the year under review being fewer than anticipated.

(viii) **Goods and Services – Repairs & Maintenance Kshs. (380,489) - A variance**
This resulted from an increment in the Laboratory operations hence the adverse variance of repairs and maintenance costs.

(ix) **Finance Cost Kshs. (151,495) F* variance**
This item was not factored in the budgeting although the Bank charges increased due to the numerous cash transactions in the year under review compared to the previous years anticipated transactions.

(x) **General / Administrative Expenses (Other Payments) - Kshs. 33,281,075 - F* variance**
The Management had budgeted for activities which would have resulted to more spending for equivalent planned services to the citizens, but the AIE allocation was not received hence the favorable variance in expenditure on general /administrative/ office expenses overall.

(xi) **Government Grants - Kshs. 2,943,811 – F* variance**
The indicated amount is as in our approved estimates by the Government for the Laboratory vote for – AIE as in our previous year's amounts

## 18. NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2020

### 1. GENERAL INFORMATION

The National Quality Control Laboratory is established by and derives its authority and accountability from Section 35D of the Pharmacy and Poisons Act Cap 244 of the Laws of Kenya. The entity is wholly owned by the Government of Kenya and is domiciled in Kenya. The entity's principal activity is to examine and test medicines for quality and carrying out Good Manufacturing Practices inspections in pharmaceutical manufacturing industry premises.

### 2. STATEMENT OF COMPLIANCE AND BASIS OF PREPARATION

The financial statements have been prepared on a historical cost basis except for the measurement at re-valued amounts of certain items of property, plant and equipment, marketable securities and financial instruments at fair value, impaired assets at their estimated recoverable amounts and actuarially determined liabilities at their present value. The preparation of financial statements in conformity with International Public Sector Accounting Standards (IPSAS) allows the use of estimates and assumptions. It also requires management to exercise judgement in the process of applying the Laboratory's accounting policies. The areas involving a higher degree of judgment or complexity, or where assumptions and estimates are significant to the financial statements, are disclosed in the notes. The financial statements have been prepared and presented in Kenya Shillings, which is the functional and reporting currency of the NQCL.

The financial statements have been prepared in accordance with the PFM Act, the State Corporations Act and IPSAS. The accounting policies adopted have been consistently applied to all the years presented.

### 3. ADOPTION OF NEW AND REVISED STANDARDS

**i. Relevant new standards and amendments to published standards effective for the year ended 30 June 2020**

| Standard | Impact |
|---|---|
| **IPSAS 39:** Employee Benefits | **Applicable: 1st January 2018**<br>The objective to issue IPSAS 39 was to create convergence to changes in IAS 19 Employee benefits. The IPSASB needed to create convergence of IPSAS 25 to the amendments done to IAS 19. The main objective is to ensure accurate information relating to pension liabilities arising from the defined benefit scheme by doing away with the corridor approach. This has been effected through. |
| **IPSAS 40:** Public Sector Combinations | **Applicable: 1st January 2019:**<br>The standard covers public sector combinations arising from exchange transactions in which case they are treated similarly with IFRS 3 (applicable to acquisitions only) Business combinations and combinations arising from non-exchange transactions which are covered purely under Public Sector combinations as amalgamations.<br>This standard has not been applied. |

NOTES TO THE FINANCIAL STATEMENTS (Continued)

ii. **New and amended standards and interpretations in issue but not yet effective in the year ended 30 June 2018-19.**

| Standard | Effective date and impact: |
|---|---|
| **IPSAS 41:** Financial Instruments | **Applicable: 1st January 2022:**<br>The objective of IPSAS 41 is to establish principles for the financial reporting of financial assets and liabilities that will present relevant and useful information to users of financial statements for their assessment of the amounts, timing and uncertainty of an entity's future cash flows.<br>IPSAS 41 provides users of financial statements with more useful information than IPSAS 29, by:<br>• Applying a single classification and measurement model for financial assets that considers the characteristics of the asset's cash flows and the objective for which the asset is held;<br>• Applying a single forward-looking expected credit loss model that is applicable to all financial instruments subject to impairment testing; and<br>• Applying an improved hedge accounting model that broadens the hedging arrangements in scope of the guidance. The model develops a strong link between an entity's risk management strategies and the accounting treatment for instruments held as part of the risk management strategy. |
| **IPSAS 42:** Social Benefits | **Applicable: 1st January 2022**<br>The objective of this Standard is to improve the relevance, faithful representativeness and comparability of the information that a reporting entity provides in its financial statements about social benefits. The information provided should help users of the financial statements and general purpose financial reports assess:<br>(a) The nature of such social benefits provided by the entity;<br>(b) The key features of the operation of those social benefit schemes; and<br>(c) The impact of such social benefits provided on the entity's financial performance, financial position and cash flows. |

**NOTES TO THE FINANCIAL STATEMENTS (Continued)**

| | |
|---|---|
| Amendments to Other IPSAS resulting from IPSAS 41, Financial Instruments | **Applicable: 1st January 2022:**<br>a) Amendments to IPSAS 5, to update the guidance related to the components of borrowing costs which were inadvertently omitted when IPSAS 41 was issued.<br>b) Amendments to IPSAS 30, regarding illustrative examples on hedging and credit risk which were inadvertently omitted when IPSAS 41 was issued.<br>c) Amendments to IPSAS 30, to update the guidance for accounting for financial guarantee contracts which were inadvertently omitted when IPSAS 41 was issued.<br>Amendments to IPSAS 33, to update the guidance on classifying financial instruments on initial adoption of accrual basis IPSAS which were inadvertently omitted when IPSAS 41 was issued. |
| Other Improvements to IPSAS | **Applicable: 1$^{st}$ January 2021:**<br>a) Amendments to IPSAS 13, to include the appropriate references to IPSAS on impairment, in place of the current references to other international and/or national accounting frameworks<br>b) IPSAS 13, Leases and IPSAS 17, Property, Plant, and Equipment. Amendments to remove transitional provisions which should have been deleted when IPSAS 33, First Time Adoption of Accrual Basis International Public Sector Accounting Standards (IPSASs) was approved<br>c) IPSAS 21, Impairment of Non-Cash-Generating Assets and IPSAS 26, Impairment of Cash Generating Assets. Amendments to ensure consistency of impairment guidance to account for revalued assets in the scope of IPSAS 17, Property, Plant, and Equipment and IPSAS 31, Intangible Assets.<br>d) IPSAS 33, First-time Adoption of Accrual Basis International Public Sector Accounting Standards (IPSASs). Amendments to the implementation guidance on deemed cost in IPSAS 33 to make it consistent with the core principles in the Standard |

**iii. Early adoption of standards**

The entity has to the extent possible adopted some of the effectively maturing new or amended standards in year 2020.

NOTES TO THE FINANCIAL STATEMENTS (**Continued**)

## 4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### a) Revenue recognition

#### i. Revenue from non-exchange transactions

**Fees, taxes and fines**

The entity recognizes revenues from fees, taxes and fines when the event occurs and the asset recognition criteria are met. To the extent that there is a related condition attached that would give rise to a liability to repay the amount, deferred income is recognized instead of revenue. Other non-exchange revenues are recognized when it is probable that the future economic benefits or service potential associated with the asset will flow to the entity and the fair value of the asset can be measured reliably.

**Transfers from other government entities.**

Revenues from non-exchange transactions with other government entities are measured at fair value and recognized on obtaining control of the asset (cash, goods, services and property) if the transfer is free from conditions and it is probable that the economic benefits or service potential related to the asset will flow to the entity and can be measured reliably. Recurrent grants are recognized in the statement of comprehensive income. Development/capital grants are recognized in the statement of financial position and realised in the statement of comprehensive income over the useful life of the assets that has been acquired using such funds.

***Rendering of services***

The entity recognizes revenue from rendering of services by reference to the stage of completion when the outcome of the transaction can be estimated reliably. The stage of completion is measured by reference to labour hours incurred to date as a percentage of total estimated labour hours. Where the contract outcome cannot be measured reliably, revenue is recognized only to the extent that the expenses incurred are recoverable.

**Interest income**

Interest income is accrued using the effective yield method. The effective yield discounts estimated future cash receipts through the expected life of the financial asset to that asset's net carrying amount. The method applies this yield to the principal outstanding to determine interest income each period.

### b) Budget information

The original budget for FY 2019-2020 was approved by the BOM and forwarded to the MOH. Subsequent revisions or additional appropriations were made to the approved budget in accordance with specific approvals from the appropriate authorities. The additional appropriations are added to the original budget by the entity upon receiving the respective approvals in order to conclude the final budget.

## 4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

### b) Budget information (Continued)

There were recorded additional appropriations on the 2019-2020 budgets following the governing body's approvals. The Laboratory did not consume the funding as proposed in the budget since the funds were being discharge under the MOH.

The entity's budget is prepared on a different basis to the actual income and expenditure disclosed in the financial statements. The financial statements are prepared on accrual basis using a classification based on the nature of expenses in the statement of financial performance, whereas the budget is prepared on a cash basis. The amounts in the financial statements were recast from the accrual basis to the cash basis and reclassified by presentation to be on the same basis as the approved budget. A comparison of budget and actual amounts, prepared on a comparable basis to the approved budget, is then presented in the statement of comparison of budget and actual amounts.

In addition to the Basis difference, adjustments to amounts in the financial statements are also made for differences in the formats and classification schemes adopted for the presentation of the financial statements and the approved budget.

A statement to reconcile the actual amounts on a comparable basis included in the statement of comparison of budget and actual amounts and the actuals as per the statement of financial performance has been presented under section 1 of these financial statements.

### c) Taxes

**Current income tax**

Current income tax assets and liabilities for the current period are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted, at the reporting date in the area where the Entity operates and generates taxable income.

Current income tax relating to items recognized directly in net assets is recognized in net assets and not in the statement of financial performance. Management periodically evaluates a position taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

NQCL is exempted from paying corporate tax by virtue of being a SAGAs

**Sales tax**

Expenses and assets are recognized net of the amount of sales tax, except:

- When the sales tax incurred on a purchase of assets or services is not recoverable from the taxation authority, in which case, the sales tax is recognized as part of the cost of acquisition of the asset or as part of the expense item, as applicable

NOTES TO THE FINANCIAL STATEMENTS (Continued)

4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

b) Taxes (Continued)

- When receivables and payables are stated with the amount of sales tax included

The net amount of sales tax recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the statement of financial position.

**d) Property, plant and equipment**

All property, plant and equipment are stated at cost less accumulated depreciation and impairment losses. Cost includes expenditure that is directly attributable to the acquisition of the items.

When significant parts of property, plant and equipment are required to be replaced at intervals, the entity recognizes such parts as individual assets with specific useful lives and depreciates them accordingly. Likewise, when a major inspection is performed, its cost is recognized in the carrying amount of the plant and equipment as a replacement if the recognition criteria are satisfied. All other repair and maintenance costs are recognized in surplus or deficit as incurred. Where an asset is acquired in a non-exchange transaction for nil or nominal consideration the asset is initially measured at its fair value.

**e) Research and development costs**

The Laboratory's research costs/ expenses as incurred. Development costs on an individual project are recognized as intangible assets when the Laboratory can demonstrate:

- The technical feasibility of completing the asset so that the asset will be available for use or sale
- Its intention to complete and its ability to use or sell the asset
- How the asset will generate future economic benefits or service potential
- The availability of resources to complete the asset
- The ability to measure reliably the expenditure during development.

Following initial recognition of an asset, the asset is carried at cost less any accumulated amortization and accumulated impairment losses.

Amortization of the asset begins when development is complete and the asset is available for use. It is amortized over the period of expected future benefit. During the period of development, the asset is tested for impairment annually with any impairment losses recognized immediately in surplus or deficit.

## 4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

### f) Financial instruments

**Financial assets**

**Initial recognition and measurement**

Financial assets within the scope of IPSAS 29 Financial Instruments: Recognition and Measurement are classified as financial assets at fair value through surplus or deficit, loans and receivables, held-to-maturity investments or available-for-sale financial assets, as appropriate. The Entity determines the classification of its financial assets at initial recognition.

**Loans and receivables**

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. After initial measurement, such financial assets are subsequently measured at amortized cost using the effective interest method, less impairment. Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. Losses arising from impairment are recognized in the surplus or deficit.

**Held-to-maturity**

Non-derivative financial assets with fixed or determinable payments and fixed maturities are classified as held to maturity when the Entity has the positive intention and ability to hold it to maturity. After initial measurement, held-to-maturity investments are measured at amortized cost using the effective interest method, less impairment. Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The losses arising from impairment are recognized in surplus or deficit.

**Impairment of financial assets**

The Entity assesses at each reporting date whether there is objective evidence that a financial asset or an entity of financial assets is impaired. A financial asset or a entity of financial assets is deemed to be impaired if, and only if, there is objective evidence of impairment as a result of one or more events that has occurred after the initial recognition of the asset (an incurred 'loss event') and that loss event has an impact on the estimated future cash flows of the financial asset or the entity of financial assets that can be reliably estimated.

Evidence of impairment may include the following indicators:

- The debtors or entity of debtors are experiencing significant financial difficulty
- Default or delinquency in interest or principal payments
- The probability that debtors will enter bankruptcy or other financial reorganization

NOTES TO THE FINANCIAL STATEMENTS **(Continued)**

4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES **(Continued)**

**f) Financial instruments (Continued)**

- Observable data indicates a measurable decrease in estimated future cash flows (e.g. changes in arrears or economic conditions that correlate with defaults)

**Financial liabilities**

**Initial recognition and measurement**

Financial liabilities within the scope of IPSAS 29 are classified as financial liabilities at fair value through surplus or deficit or loans and borrowings, as appropriate. The Entity determines the classification of its financial liabilities at initial recognition.

All financial liabilities are recognized initially at fair value and, in the case of loans and borrowings, plus directly attributable transaction costs.

**Loans and borrowing**

After initial recognition, interest bearing loans and borrowings are subsequently measured at amortized cost using the effective interest method. Gains and losses are recognized in surplus or deficit when the liabilities are derecognized as well as through the effective interest method amortization process. Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate.

**Inventories**

Inventory is measured at cost upon initial recognition. To the extent that inventory was received through non-exchange transactions (for no cost or for a nominal cost), the cost of the inventory is its fair value at the date of acquisition.
Costs incurred in bringing each product to its present location and conditions are accounted for, as follows:
Raw materials: purchase cost using the weighted average cost method.
Finished goods and work in progress: cost of direct materials and labour and a proportion of manufacturing overheads based on the normal operating capacity, but excluding borrowing costs
After initial recognition, inventory is measured at the lower of cost and net realizable value.
However, to the extent that a class of inventory is distributed or deployed at no charge or for a nominal charge, that class of inventory is measured at the lower of cost and current replacement cost.
Net realizable value is the estimated selling price in the ordinary course of operations, less the estimated costs of completion and the estimated costs necessary to make the sale, exchange, or distribution.

**NOTES TO THE FINANCIAL STATEMENTS (Continued)**

**4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

Inventories are recognized as an expense when deployed for utilization or consumption in the ordinary course of operations of the Laboratory

**f) Financial instruments (Continued)**

**Provisions;**

Provision are recognized when the Laboratory has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits or service potential will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation.

Where the Laboratory expects some or all of a provision to be reimbursed, for example, under an insurance contract, the reimbursement is recognized as a separate asset only when the reimbursement is virtually certain.
The expense relating to any provision is presented in the statement of financial performance net of any reimbursement.

**Contingent liabilities**

The Entity does not recognize a contingent liability, but discloses details of any contingencies in the notes to the financial statements, unless the possibility of an outflow of resources embodying economic benefits or service potential is remote.

**Contingent assets**

The Entity does not recognize a contingent asset, but discloses details of a possible asset whose existence is contingent on the occurrence or non-occurrence of one or more uncertain future events not wholly within the control of the Entity in the notes to the financial statements. Contingent assets are assessed continually to ensure that developments are appropriately reflected in the financial statements. If it has become virtually certain that an inflow of economic benefits or service potential will arise and the asset's value can be measured reliably, the asset and the related revenue are recognized in the financial statements of the period in which the change occurs.

**g) Nature and purpose of reserves**

The laboratory maintains retained earnings (Surplus / deficits) as its reserves in general.

**h) Changes in accounting policies and estimates**

The Entity recognizes the effects of changes in accounting policy retrospectively. The effects of changes in accounting policy are applied prospectively if retrospective application is impractical.

**i) Employee benefits**

**Retirement benefit plans**

The Entity provides retirement benefits for its employees and directors. Defined contribution plans are post-employment benefit plans under which an entity pays fixed contributions into

NOTES TO THE FINANCIAL STATEMENTS (Continued)

4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

a separate entity (a fund), and will have no legal or constructive obligation to pay further contributions if the fund does not hold sufficient assets to pay all employee benefits relating

**i) Employee benefits (Continued)**

to employee service in the current and prior periods. The contributions to fund obligations for the payment of retirement benefits are charged against income in the year in which they become payable.
Defined benefit plans are post-employment benefit plans other than defined-contribution plans. The defined benefit funds are actuarially valued tri-annually on the projected unit credit method basis. Deficits identified are recovered through lump sum payments or increased future contributions on proportional basis to all participating employers. The contributions and lump sum payments reduce the post-employment benefit obligation.

The Laboratory does not maintain a defined contributory plan or a defined benefit plan as it is yet to adopt its scheme of service which provides for the employees retirement benefits as half of the employees are public service commission officers posted through the Ministry of Health while the other half are contracted, interns or casuals This is due to challenges on the status of the Laboratory, its financial arrangements with the parent Ministry (Health) and the Board of Managements appointing entity (Pharmacy and Poisons Board).

**j) Foreign currency transactions**

Transactions in foreign currencies are initially accounted for at the ruling rate of exchange on the date of the transaction. Trade creditors or debtors denominated in foreign currency are reported at the statement of financial position reporting date by applying the exchange rate on that date. Exchange differences arising from the settlement of creditors, or from the reporting of creditors at rates different from those at which they were initially recorded during the period, are recognized as income or expenses in the period in which they arise.

**k) Related parties**

The Laboratory regards a related party as a person or an entity with the ability to exert control individually or jointly, or to exercise significant influence over the Entity, or vice versa. Members of key management are regarded as related parties and comprise the Directors, the CEO and senior managers.

**l) Cash and cash equivalents**

Cash and cash equivalents comprise cash on hand and cash at bank, short-term deposits on call and highly liquid investments with an original maturity of three months or less, which are readily convertible to known amounts of cash and are subject to insignificant risk of changes in value. Bank account balances include amounts held at the Central Bank of Kenya and at various commercial banks at the end of the financial year. For the purposes of these financial statements, cash and cash equivalents also include short term cash imprest and advances to authorised public officers and/or institutions which were not surrendered or accounted for at the end of the financial year.

## 4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

### m) Budget information

The original budget for FY 2019-2020 covering 2018-19 as per the procurement plan was approved by the Board of Management. Subsequent revisions or additional adjustments were made to the approved budget in accordance with specific approvals from the appropriate Managements. The additional adjustments are effected to the original budget by the Laboratory upon receiving the respective approvals in order to conclude the final budget. Accordingly, the entity did not record additional adjustments on the 2017-2018 budgets following the Board's approval.

The Laboratory's budget is prepared on a different basis to the actual income and expenditure disclosed in the financial statements. The financial statements are prepared on accrual basis using a classification based on the nature of expenses in the statement of financial performance, whereas the budget is prepared on a cash basis. The amounts in the financial statements were recast from the accrual basis to the cash basis and reclassified by presentation to be on the same basis as the approved budget. A comparison of budget and actual amounts, prepared on a comparable basis to the approved budget, is then presented in the statement of comparison of budget and actual amounts. In addition to the Basis difference, adjustments to amounts in the financial statements are also made for differences in the formats and classification schemes adopted for the presentation of the financial statements and the approved budget.
A statement to reconcile the actual amounts on a comparable basis included in the statement of comparison of budget and actual amounts and the actuals as per the statement of financial performance has been presented under section necessary of these financial statements.

### n) Comparative figures

Where necessary comparative figures for the previous financial year have been amended or reconfigured to conform to the required changes in presentation.

### o) Subsequent events

There have been no events subsequent to the financial year end with a significant impact on the financial statements for the year ended June 30, 2020.

- Availability of funding to replace the asset
- Changes in the market in relation to the asset

**Provisions**

Provisions were raised and management determined an estimate based on the information

NOTES TO THE FINANCIAL STATEMENTS (Continued)

Provisions were raised and management determined an estimate based on the information available. Additional disclosure of these estimates of provisions is included in Note 22. Provisions are measured at the management's best estimate of the expenditure required to settle the obligation at the reporting date, and are discounted to present value where the effect is material.

## 5. SIGNIFICANT JUDGMENTS AND SOURCES OF ESTIMATION UNCERTAINTY

The preparation of the Entity's financial statements in conformity with IPSAS requires management to make judgments, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and the disclosure of contingent liabilities, at the end of the reporting period. However, uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of the asset or liability affected in future periods. State all judgements, estimates and assumptions made as shown below;

**Estimates and assumptions**

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below. The Entity based its assumptions and estimates on parameters available when the consolidated financial statements were prepared. However, existing circumstances and assumptions about future developments may change due to market changes or circumstances arising beyond the control of the Entity. Such changes are reflected in the assumptions when they occur. IPSAS 1.140

**Useful lives and residual values**

The useful lives and residual values of assets are assessed using the following indicators to inform potential future use and value from disposal:

- The condition of the asset based on the assessment of experts employed by the Entity
- The nature of the asset, its susceptibility and adaptability to changes in technology and processes
- The nature of the processes in which the asset is deployed

## 6. PUBLIC CONTRIBUTIONS AND DONATIONS

| Description | 2019 - 2020<br>Kshs | 2018 - 2019<br>KShs |
|---|---|---|
| GTZ Donations | 4,393,497 | 5,020,257 |
| **Total transfers and sponsorships** | **4,393,497** | **5,020,257** |

The charge for the year is derived from computations of depreciating GTZ Assets left when the donor left the Laboratory to the Kenyan Government in 1994.

NOTES TO THE FINANCIAL STATEMENTS (Continued)

## 7. TRANSFERS FROM MINISTRIES, DEPARTMENTS AND AGENCIES

| Name of the Entity sending the grant | Amount recognized to Statement of Financial Performance KShs | Amount deferred under deferred income. | Amount recognised in capital fund. KShs | Total grant income during the year KShs | 2019-2020 KShs | 2018- 019 KShs |
|---|---|---|---|---|---|---|
| Ministry of Health | 1,503,459 | | | | 1,503,459 | 26,149,766 |
| KEMSA Equipment | | | | | | 0 |
| MoH Imprest | | | | | | 400,000 |
| **Total KShs** | **1,503,459** | | | | **1,503,459** | **26,549,766** |

**Note;**
The Laboratory does not receive transfers directly from the Treasury or the Ministry of Heath but conducts procurement processes then forwards the documents to the Ministry of Health for payments. This has led to pending bills as the payment process mostly concludes by the year end. But in 2017-18 FY we received supplies worth ksh. 7,251,408. The breakdown for the above transfers from KEMSA for equipment are as follows; LAL reader 237,800 Zone reader 2,186,310 Polarimeter 733,294.84 UV+VIS 1,326,228.8 D. Tester 1,583,400 Ph-conductivity meter 302,516.8 Ultrasonic bath 245,456 digital hygrometer 1,455,104 Bulk filing system 1,450,000.

## 8. RENDERING OF SERVICES

| Description | 2019-2020 Kshs | 2018 - 2019 KShs |
|---|---|---|
| Analysis fees | 83,055,625 | 59,586,750 |
| GMP Inspection Certification - fees | 0 | 916,234 |
| **Total revenue from rendering of service** | **83,055,625** | **60,502,984** |

This reflects pharmaceutical testing services (analysis fees) for pharmaceuticals products where a certificate of analysis is issued against samples submitted by clients and the GMP inspection certifications.

NOTES TO THE FINANCIAL STATEMENTS (Continued)

## 9. USE OF GOODS AND SERVICES

| Description | 2019-2020 | 2018 - 2019 |
|---|---|---|
| | Kshs | KShs |
| Electricity | 1,503,459 | - |
| **Total good and services** | **1,503,459** | - |

NQCL consumed electricity paid by MOH

## 10. EMPLOYEE COSTS

| Description | 2019-2020 | 2018 - 2019 |
|---|---|---|
| | Kshs | KShs |
| Basic Salaries and wages | 6,335,625 | 2,891,625 |
| Extraneous allowance-MOH Staff | 4,453,000 | 4,180,000 |
| Employee related costs - NHIF & NSSF =388800+62,800 | 451,600 | 279,800 |
| Employee related costs – PAYE | 5,094,064 | 4,610,484 |
| Travel allowances | 1,570,000 | 960,000 |
| Housing benefits and allowances | 5,011,500 | 3,273,900 |
| Risk allow | 1,570,000 | 960,000 |
| Overtime | 417,054 | 0 |
| **Sub -Total Employee costs** | **24,902,843** | **17,155,809** |
| Leave pay 2017-18 | 159,000 | 66,000 |
| Employee related costs – NSSF (employer-paid) | 62,800 | 33,000 |
| Employee related costs – Medical scheme | 2,039,644 | 848,579 |
| Gratuity | 0 | 4,828,744 |
| **Sub -Total Employee costs** | 0 | **5,776,323** |
| **Total Employee costs** | **27,164,287** | **22,932,132** |

## 11. REMUNERATION THE BOARD OF DIRECTORS

| Description | 2019-2020 | 2018 - 2019 |
|---|---|---|
| | Kshs | KShs |
| Lunch | 136,000 | 286,000 |
| Sitting Allowance | 723,500 | 917,000 |
| Accommodation | 826,000 | 270,849 |
| Travel | 1,057,560 | 1,480,612 |
| Chairman's Honoraria | 0 | 375,000 |
| **Total Board of Director's emoluments** | **2,743,060** | **3,329,461** |

NOTES TO THE FINANCIAL STATEMENTS (Continued)

## 12. DEPRECIATION AND AMORTIZATION EXPENSES

| Description | 2019-2020<br>Kshs | 2018 - 2019<br>KShs |
|---|---|---|
| Property, plant and equipment – GoK | 6,008,223 | 9,126,913 |
| Property, plant and equipment - Donation | 4,393,497 | 5,020,257 |
| **Total depreciation and amortization** | **10,401,720** | **14,147,170** |

## 13. REPAIRS AND MAINTENANCE

| Description | 2019-2020<br>Kshs | 2018 - 2019<br>KShs |
|---|---|---|
| Equipment and Machinery | 13,167,489 | 11,911,815 |
| General | - | - |
| **Total repairs and maintenance** | **13,167,489** | **11,911,815** |

## 14. GENERAL/ADMINISTRATIVE + CHEMICAL/REAGENT EXPENSES

| Description | 2019-2020<br>Kshs | 2018 - 2019<br>KShs |
|---|---|---|
| Admin fees - Office expenses | 2,712,956 | 3,390,139 |
| Audit fees | 348,000 | 150,000 |
| Professional & Consulting fees | 1,685,126 | 2,268,145 |
| Legal costs | - | - |
| Consumables – (Lunches / snacks) | 821,561 | 1,527,612 |
| Electricity - Note 9 | - | - |
| Fuel and oil - Generator. | 86,410 | 93,826 |
| Chemicals & Reagents | 5,030,868 | 27,430,480 |
| Printing and stationery | 836,340 | 8,385,019 |
| Telecommunication (Telephone, internet & Postage) | 858,927 | 1,438,297 |
| Training | 1,525,187 | 854,600 |
| Others - Travelling / Motor vehicle costs | 3,129,291 | 3,096,973 |
| **Total general expenses** | **17,652,925** | **48,635,091** |

## 15. FINANCE COSTS

| Description | 2019-2020<br>Kshs | 2018 - 2019<br>KShs |
|---|---|---|
| Bank charges | 151,495 | 136,714 |
| **Total finance costs** | **151,495** | **136,714** |

NOTES TO THE FINANCIAL STATEMENTS (Continued)

## 16. CASH AND CASH EQUIVALENTS

| Description | 2019-2020 | 2018 – 2019 |
|---|---|---|
| | Kshs | KShs |
| Current account | 32,067,900 | 6,061,975 |
| **Total cash and cash equivalents** | **32,067,900** | **6,061,975** |

## 16 B). DETAILED ANALYSIS OF THE CASH AND CASH EQUIVALENTS

| Financial institution 11711 | Account number | 2019-2020 Kshs | 2018 – 2019 KShs |
|---|---|---|---|
| a) **Current account** | | | |
| National Bank of Kenya Ltd | 01001031744600 | 32,067,900 | 6,061,975 |
| **Sub- total** | | **32,067,900** | **6,061,975** |
| b) **Others (….)** | | | |
| Cash in transit – Unpresented Cheques | | | |
| Cash in hand | | | |
| Payments in bank statements not in cashbook | | | |
| **Sub- total** | | **0** | **0** |
| **Grand total** | | **32,067,900** | **6,061,975** |

## 17. A) RECEIVABLES FROM EXCHANGE TRANSACTIONS

| Description | 2019-2020 | 2018 - 2019 |
|---|---|---|
| | Kshs | KShs - Restated |
| **Current receivables** | | |
| Other exchange debtors- AIA fees | 16,662,637 | 30,591,314 |
| **Less:** impairment allowance | - | - |
| **Total current receivables** | | |
| **Non-current receivables** | | |
| Non-current receivables – Uncollectable | 10,153,027 | 6,013,120 |
| **Total non-current receivables** | | |
| **Sub -Total receivables** | **26,815,664** | **36,604,434** |
| **Less:** impairment allowance | - | - |
| **Total receivables** | **26,815,664** | **36,604,434** |

## 17. B) PROVISION FOR BAD & DOUBTFUL DEBTS OF 3%

| Description | 2019-2020 | 2018 - 2019 |
|---|---|---|
| | Kshs | KShs - Restated |
| | | |
| Provision For Bad & Doubtful Debts | 804,470 | 1,098,133 |
| **Total receivables** | **804,470** | **1,098,133** |

NOTES TO THE FINANCIAL STATEMENTS (Continued)

## 18. RECEIVABLES FROM NON-EXCHANGE TRANSACTIONS.

| Description | 2019-2020<br>Kshs | 2018 - 2019<br>KShs |
|---|---|---|
| **Current receivables** | | |
| Other debtors - staff advances | 143,000 | 232,500 |
| Less: impairment allowance | | |
| **Total current receivables** | **143,000** | **232,500** |

## 19. INVENTORIES.

| Description | 2019-2020<br>Kshs | 2018 - 2019<br>KShs |
|---|---|---|
| Consumable stores | 5,964,091 | 3,124,232 |
| Medical supplies | - | 7,032,027 |
| Spare parts and meters - Consumables | - | - |
| **Total inventories at the lower of cost and net realizable value** | **5,964,091** | **10,156,259** |

## 20. PROPERTIES, PLANT AND EQUIPMENT.

Tabulated below;

NATIONAL QUALITY CONTROL LABORATORY
16 APR 2021
P. O. Box 29726 – 00202,
TEL: 2726963 / 3544525/30
FAX: 2718073

NATIONAL QUALITY CONTROL LABORATORY
**Annual Reports and Financial Statements**
**For the year ended June 30, 2020**



## NOTES TO THE FINANCIAL STATEMENTS (Continued)

## 20. A) PROPERTIES, PLANT AND EQUIPMENT

| ASSETS/ ITEMS HEAD | Buildings - Renovation | Lab. (Electronic) Equipment | Furniture & Fittings | Office Electronic/ Equipment | Auto motives | **Recomputed Totals / Adjusted** F.Y 2016 – 2017 (Kshs) | **Total computation reported 2015 – 2016 (Kshs)** |
|---|---|---|---|---|---|---|---|
| DEP. METHOD & RATE/ POLICY | Straight Line - 2.5% | Reducing Balance - 12.5% | Straight Line - 12.5% | Straight Line – 30% | Straight Line - 12.5% | | |
| Net Book Values As at 30 June, 2015 | 12,563,280 | 32,199,488 | 3,011,516 | 2,241,190 | 5,806,480 | **55,821,954** | **55,821,954** |
| Additions 2015-16 | 3,287,315 | 25,652,235 | 1,825,375 | 6,406,274 | 1,601,803 | **38,773,002** | 38,773,002 |
| **Cost / NBV as at 01 July2015** | **15,850,595** | **57,851,723** | **4,836,891** | **8,647,464** | **7,408,283** | **94,594,956** | **94,594,956** |
| Accumm Depreciation - 1st July 2015 | 3,472,366 | 57,714,101 | 4,104,038 | 960,510 | 1,935,494 | **68,186,509** | 21,711,607 |
| Depreciation for the year, 2015 - 16 | 301,831.98 | 7,231,465 | 1,117,616 | 2,882,392 | 1,167,972 | **12,701,277** | 11,076,729 |
| Accumm Depreciation -1st July 2016 | 3,774,198 | 64,945,566 | 5,221,654 | 3,842,902 | 3,103,466 | **80,887,786** | **32,788,336** |
| Less: GTZ Donations, Adjusted NBV B/D | (4,178,207) | | - | | - | **-4,178,207** | (3,793,445) |
| Net Book Values as at 30 June 2016 | 11,370,556 | 50,620,258 | 3,719,275 | 5,765,072 | 6,240,311 | **77,715,472** | **58,013,176** |
| Additions 2016 - June,17 | 1,280,000 | 2,552,000 | - | | | **3,832,000** | |
| **Totals Cost / NBV as at 30 June,2017** | **12,650,556** | **53,172,258** | **3,719,275** | **5,765,072** | **6,240,311** | **81,547,472** | |
| Accumm Depreciation - 1st July 2016 | 3,774,198 | 64,945,566 | 5,221,654 | 3,842,902 | 3,103,466 | **80,887,786** | |
| Depreciation charge for the year, 2016 - 17 | 333,832 | 6,646,532 | 0 | 1,922,170 | 1,167,972 | **10,070,506** | |
| Accumm Depreciation - 30 June 2017 | 4,108,030 | 71,592,098 | 5,221,654 | 5,765,072 | 4,271,438 | **90,958,292** | |
| Net Book Values - 30 June 2017 | 12,316,724 | 46,525,726 | 3,719,275 | 5,765,072 | 5,072,339 | **73,399,136** | |
| Additions (Disposal) 2017- June,18 | - | | | | | **0** | |
| **Totals Cost / NBV - 30 June,2018** | **12,316,724** | **58,186,036** | | **5,765,072** | **5,072,339** | **81,340,171** | |
| Depreciation charge for the year, 2017 - 18 | 333,832 | 7,273,254 | | 0 | 800,900 | **8,407,986** | |
| Accumm Depreciation -30 June 2018 | 4,441,862 | 78,865,353 | 5,221,654 | 5,765,072 | 5,072,339 | **99,366,280** | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Net Book Values as at 30 June 2018 | 11,982,892 | 50,912,781 | 3,719,275 | 5,765,072 | 5,072,339 | **77,452,359** |
| Additions 2018-19 | - | | | | | **0** |
| **Totals Cost / NBV as at 30 June, 2019** | **11,982,892** | **51,662,769** | | **5,765,072** | **5,072,339** | **74,483,072** |
| Accumm Depreciation - 1st July 2018 | 4,441,862 | 78,865,353 | | 5,765,072 | 5,072,339 | **94,144,626** |
| Depreciation charge for the year, 2018 -19 | 333,832 | 6,457,846 | | 0 | 0 | **6,791,678** |
| Accumm Depreciation -30 June 2019 | 4,775,694 | 85,323,199 | 5,221,654 | 5,765,072 | 5,072,339 | **106,157,958** |
| Net Book Values as at 30 June 2019 | 11,649,060 | 45,204,923 | 3,719,275 | 5,765,072 | 5,072,339 | **71,410,669** |
| Additions 2019- June,20 | - | | 51,005 | | | **51,005** |
| **Cost / Net Book Values as at 30 June 2020** | **11,649,060** | **45,344,123** | **3,770,280** | **5,765,072** | **5,072,339** | **71,600,874** |
| Accumm Depreciation - 1st July 2019 | 4,775,694 | 85,323,199 | 5,221,654 | 5,765,072 | 5,072,339 | **106,157,958** |
| Depreciation charge for the year, 2019 -20 | 333,832 | 5,668,015 | 6,376 | 0 | 0 | **6,008,223** |
| Accumm Depreciation - 30 June 2020 | 5,109,526 | 11,336,031 | 5,228,030 | 5,765,072 | 5,072,339 | **32,510,997** |
| **Net Book Values as at 30 June 2020** | **11,315,228** | **39,676,108** | **3,763,904** | **5,765,072** | **5,072,339** | **65,592,651** |

**Note;** The 2015-16 figures have been recomputed and restated in 2016-17 due to errors as shown. In 2015-16 the NBV relating to renovations by GTZ in 1994, which was erroneous treated as an asset (always attracting audit query) has now been reconciled from the assets register and an income (donation) recognized and dully expensed in compliance with the double entry concept and auditor general's advice, ref; NQCL/2015-2016/(9). The furniture and fittings computation 2015-16 gives a discarded negative net book value computations figure of (384,762) while the accumulated depreciation for equipment of ksh 57,714,101 which had been derived at by including ksh. 38,633,848 donated assets now transferred to note 04 where it should be adjusted. Going forward the management will seek the help of Government valuers to ascertain the Assets' Net Realisable Values for purposes of correcting and re-stating the assets register.

NOTE 20A – i **THE RESTATEMENT EXPLANATIONS FOR OF KSH. 11,453,865**

In 2016-17 the Accumulated Depreciation **for Automotive is ksh. 4,271,438 added to the charge for the year is ksh. 1,167,972** which sums up to ksh. 5,439,410 which value exceeds the computed Net Book Value for the year ksh. 6,240,311 less ksh. 1, 167, 972 which results to ksh. 5,072,339. **The NBV of ksh. 5,072,339 is therefore less than the accumulated Depreciation of ksh. 5,439,410 by ksh. 367,071**

In the same way Office Electronic Equipment Accumulated Depreciation computation would be ksh. 5,765,072+2882392 = 6,725,294 against NBV of ksh. 5,765,072 which exceeds it by ksh. 960,222. This has been reduced from the charge for the year ksh. 2,882,392 to get ksh. 1,922,170 as the charge for the year. Therefore, effectively the Accumulated Depreciation equals NBV at ksh. 5,765,072 which has been carried down since 2017 as NBV / disposal value. **The ksh 5,072,339 and ksh. 5,765,072** with the difference of (ksh **367,071) and ksh. 960,222 could Accounts for the ksh. 11,453,865 in the Note 20A – i** in the SOFP

## NOTES TO THE FINANCIAL STATEMENTS (Continued)

### 20 B) PROPERTY, PLANT AND EQUIPMENT - DONATED ASSETS, GTZ (Deferred income computation / tabulation).

| | Furniture & fittings 2008/09 Straight line 2.5% | Office equipment 2012/13 Straight line 30.0% | Plant and Equipment – B/D 2012/13 Reducing Balance 12.5% | Plant and Equipment – HPLC 2013/14 Reducing Balance 12.5% | Plant and Equipment – Isolator 2014/15 Reducing Balance 12.5% | Total |
|---|---|---|---|---|---|---|
| | Shs | Shs | Shs | Shs | Shs | Shs |
| Cost as at Stated date | 635,998 | 73,767 | 10,419,395 | 33,008,867 | 38,633,848 | 82,771,875 |
| Balance B/D 2012/2013 | 49,409 | 73,767 | 5,170,446 | 22,882,759 | - | 28,176,381 |
| Charge for year 2013/2014 | 6,176 | 22,130 | 646,306 | 3,610,345 | - | 4,284,957 |
| Balance B/D 2013/2014 | 43,233 | 51,637 | 4,524,140 | 25,272,414 | - | 29,891,424 |
| Charge for the year 2014/2015 | 6,176 | 22,130 | 565,518 | 3,159,052 | 4,829,231 | 8,582,107 |
| Balance B/D 2014/2015 | 38,601 | 29,507 | 3,958,623 | 22,113,362 | 33,804,617 | 59,944,710 |
| Charge for the year 2015/2016 | 6,176 | 22,130 | 494,829 | 2,764,170 | 4,225,577 | 7,512,882 |
| Balance B/D 2015/2016 | 32,425 | 7,377 | 3,463,795 | 19,349,192 | 29,579,040 | 52,431,829 |
| Charge for the year 2016-2017 | 6,176 | 7,377 | 432,974 | 2,418,649 | 3,697,380 | 6,562,556 |
| NBV B/D 2015/2017 | 26,249 | - | 3,030,821 | 16,930,543 | 25,881,660 | 45,869,273 |
| Charge for the year 2017-2018 | 6,176 | - | 378,853 | 2,116,318 | 3,235,208 | 5,736,554 |
| NBV B/D 2015/2018 | 20,073 | - | 2,651,968 | 14,814,225 | 22,646,453 | 40,132,719 |
| Charge for the year 2018-2019 | 6,176 | - | 331,496 | 1,851,778 | 2,830,807 | 5,020,257 |
| NBV B/D 2018 -19 | 13,897 | - | 2,320,472 | 12,962,447 | 19,815,646 | 35,112,462 |
| Charge for the year 2019-2020 | 6,176 | - | 290,059 | 1,620,306 | 2,476,956 | 4,393,497 |
| NBV B/D 2019-2020 | 7,721 | - | 2,030,413 | 11,342,141 | 17,338,690 | 30,718,966 |

Note: the Autoclave equipment valued at Kshs. 749,998 will be depreciated in the Financial Year 2019/20 after undergoing operational and performance qualifications which is our practice at the Laboratory

## NOTES TO THE FINANCIAL STATEMENTS (Continued)

| Description | 2019-2020 | 2018 - 2019 |
|---|---|---|
| | Kshs | KShs |
| International funders | | |
| Public contributions and donations | 4,393,497 | 5,020,257 |
| **Total deferred income** | **4,393,497** | **5,020,257** |

**The deferred income movement is as follows:**

| | National government | International funders – GTZ | Public contributions and donations | Total |
|---|---|---|---|---|
| **Balance brought forward** | - | **35,112,462** | - | **35,112,462** |
| Additions / Transfers to Capital fund | - (-) | - (-) | - (-) | - (-) |
| Transfers to income statement | (-) | (4,393,497) | (-) | (4,393,497) |
| Other transfers | (-) | (-) | (-) | (-) |
| **Balance carried forward** | - | **30,718,966** | - | **30,718,966** |

## 21. A) TRADE AND OTHER PAYABLES FROM EXCHANGE TRANSACTIONS

| Description | 2019-2020 | 2018 - 2019 |
|---|---|---|
| | Kshs | KShs |
| Trade payables, DLA -2189535 | 2,189,535 | 3,313,093 |
| Electricity =77666+98444+111509 | 435,369 | - |
| Payments received in advance – Analysis fees | 19,072,884 | 22,569,171 |
| Employee costs<br>Gratuity – Outstanding<br>PAYE- June, 2020<br>NSSF- Outstanding<br>Unapplied Salary – Dr. Khadijah Mohammed Oct, 2018 – June | <br>-<br>444,278<br>10,400<br>222,750 | <br>-<br>492,765<br>59,828<br>10,800 |
| Other payables - OAG | 696,000 | 348,000 |
| **Total trade and other payables** | **23,071,216** | **27,020,912** |
| | | |

## 21 B. EMPLOYEE BENEFIT OBLIGATIONS

| Description | Defined benefit plan | Post-employment medical benefits | Other Provisions | TOTAL 2019-2020 | TOTAL 2018-2019 |
|---|---|---|---|---|---|
| | KShs | KShs | KShs | | KShs |
| Current benefit obligation – | - | - | - | 2,019,046 | - |
| Non-current benefit obligation | - | - | - | - | 2,311,999 |
| **Total employee benefits obligation gratuity** | - | - | - | **2,019,046** | **2,311,999** |

NOTES TO THE FINANCIAL STATEMENTS (Continued)

The entity operates a defined benefit scheme for all full-time employees from July 1, 2015. The scheme is based on **31% percentage** of basic salary of an employee at the time of retirement. During the year, No actuarial valuers were engaged to value the scheme. The liability at the end of the year is as follows:

| | 2019-2020 | 2018 - 2019 |
|---|---|---|
| | Kshs | Kshs |
| Valuation at the beginning of the year | 2,019,046 | 0 |
| Changes in valuation during the year | 0 | 2,311,999 |
| Valuation at end of the year | **2,019,046** | **2,311,999** |

The company also contributes to the statutory - National Social Security Fund (NSSF). This is a defined contribution scheme registered under the National Social Security Act. The company's obligation under the scheme is limited to specific contributions legislated from time to time and is currently at Kshs.200 per employee per month.

## 22. NON-CURRENT PROVISIONS

| Description | Long service leave | Gratuity | Other Provisions | Total |
|---|---|---|---|---|
| | KShs | KShs | KShs | KShs |
| Balance at the beginning of the year (5294554/3) | - | 5,294,554 | - | 1,764,851 |
| Additional Provisions gratuity | - | 2,019,046 | - | 2,019,046 |
| Provision utilised – Audit fees | | 696,000 | | 696,000 |
| Change due to discount and time value for money (effects) | - | - | (-) | - |
| Less: Current portion | (-) | (-) | (-) | (-) |
| **Total income (Decrease) / increase in provision** | | **8,009,600** | - | **4,479,897** |

## 23. SERVICE CONCESSION ARRANGEMENTS

Fair value of service concession assets recognized under PPE, Accumulated depreciation to date, Net carrying amount, Service concession liability at beginning of the year, Service concession revenue recognized, Service concession liability at end of the year.

## 24. CASH GENERATED FROM OPERATIONS

| | 2019-2020 | 2018 - 2019 |
|---|---|---|
| **Surplus for the year before tax** | Kshs | KShs |
| **Adjusted for:** | | |
| Depreciation (6008223+4393497) | 10,401,720 | 14,147,170 |
| Finance cost | 151,495 | 136,714 |
| **Working Capital adjustments** | | |
| Increase in inventory | (4,192,168) | 10,222,228 |
| Increase in receivables | (9,788,770) | (14,808,565) |
| Increase in deferred income | (626,760) | (716,297) |
| Increase in payables | 4,408,781 | 7,528,301 |
| Increase in provision | 5,028,556 | 3,009,510 |
| **Net cash flow from operating activities** | **5,382,854** | **19,519,061** |

## 25. FINANCIAL RISK MANAGEMENT

The entity's activities expose it to a variety of financial risks including credit and liquidity risks and effects of changes in foreign currency. The company's overall risk management programme focuses on unpredictability of changes in the business environment and seeks to minimise the potential adverse effect of such risks on its performance by setting acceptable levels of risk. The company does not hedge any risks and has in place policies to ensure that credit is only extended to customers with an established credit history. The entity's financial risk management objectives and policies are detailed below:

### i) Credit Risk

The entity has exposure to credit risk, which is the risk that a counterparty will be unable to pay amounts in full when due. Credit risk arises from cash and cash equivalents, and deposits with banks, as well as trade and other receivables and available-for-sale financial investments.

Management assesses the credit quality of each customer, taking into account its financial position, past experience and other factors. Individual risk limits are set based on internal or external assessment in accordance with limits set by the directors. The amounts presented in the statement of financial position are net of allowances for doubtful receivables, estimated by the company's management based on prior experience and their assessment of the current economic environment.

The carrying amount of financial assets recorded in the financial statements representing the entity's maximum exposure to credit risk without taking account of the value of any collateral obtained is made up as follows:

| | Total amount | Fully performing | Past due | Impaired |
|---|---|---|---|---|
| **At 30 June 2020** | **Kshs** | **Kshs** | **Kshs** | **Kshs** |
| Receivables from exchange transactions | 26,815,664 | 16,662,637 | 10,153,027 | - |
| Receivables from non-exchange transactions | 143,000 | 143,000 | - | - |
| Bank balances | 32,067,900 | 32,067,900 | - | - |
| **Total** | **59,026,564** | **48,873,537** | **10,153,027** | - |
| | | | | |
| **At 30 June 2019** | | | | |
| Receivables from exchange transactions | 36,604,434 | 36,604,434 | 6,013,120 | - |
| Receivables from non-exchange transactions | 232,500 | 232,500 | - | - |
| Bank balances | 6,137,074 | 6,137,074 | - | - |
| **Total** | **42,974,008** | **42,974,008** | **6,013,120** | - |

The customers under the fully performing category are paying their debts as they continue trading. The credit risk associated with these receivables is minimal and the allowance for uncollectible amounts that the company has recognised in the financial statements is considered adequate to cover any potentially irrecoverable amounts.

NOTES TO THE FINANCIAL STATEMENTS **(Continued)**

FINANCIAL RISK MANAGEMENT **(Continued)**

**i) Credit risk (Continued)**

The entity has significant concentration of credit risk on amounts due from receivables

The board of directors sets the company's credit policies and objectives and lays down parameters within which the various aspects of credit risk management are operated.

**ii) Liquidity risk management**

Ultimate responsibility for liquidity risk management rests with the entity's directors, who have built an appropriate liquidity risk management framework for the Management of the Laboratory's short, medium and long-term funding and liquidity management requirements. The entity manages liquidity risk through continuous monitoring of forecasts and actual cash flows.

**The table below represents cash flows payable by the company under non-derivative financial** liabilities by their remaining contractual maturities at the reporting date. The amounts disclosed in the table are the contractual undiscounted cash flows. Balances due within 12 months equal their carrying balances, as the impact of discounting is not significant.

| | Less than 1 month | Between 1-3 months | Over 5 months | Total |
|---|---|---|---|---|
| | Kshs | Kshs | Kshs | Kshs |
| **At 30 June 2020** | - | - | 3,176,154 | 3,176,154 |
| Trade payables | - | - | 348,000 | 348,000 |
| Provisions - KENAO | - | - | 2,019,046 | 2,019,046 |
| Employee benefit obligation | - | - | 5,543,200 | 5,543,200 |
| | | | | |
| **Total** | | | **11,086,400** | **11,086,400** |
| | | | | |
| **At 30 June 2019** | - | - | 3,313,093 | 3,313,093 |
| Trade payables | - | - | 348,000 | 348,000 |
| Provisions | - | - | 2,311,999 | 2,311,999 |
| Employee benefit obligation - Gratuity | - | - | 5,973,092 | 5,973,092 |
| **Total** | - | - | **11,946,184** | **11,946,184** |

**iii)Market risk**

The board has put in place an internal audit function to assist it in assessing the risk faced by the entity on an on-going basis, evaluate and test the design and effectiveness of its internal accounting and operational controls.

Market risk is the risk arising from changes in market prices, such as interest rate, equity prices and foreign exchange rates which will affect the entity's income or the value of its holding of financial instruments. The objective of market risk management is to manage and control market risk exposures within acceptable parameters, while optimising the return. Overall responsibility for managing market risk rests with the Audit and Risk Management Committee.

## NOTES TO THE FINANCIAL STATEMENTS (Continued)

### FINANCIAL RISK MANAGEMENT (Continued)

**iii) Market risk (Continued)**

The company's Finance Department is responsible for the development of detailed risk management policies (subject to review and approval by Audit and Risk Management Committee) and for the day to day implementation of those policies.

There has been no change to the entity's exposure to market risks or the manner in which it manages and measures the risk.

a) Foreign currency risk

The entity has no transactional currency exposures. Such exposure arises through purchases of goods and services that are done in currencies other than the local currency. Invoices denominated in foreign currencies are paid after 30 days from the date of the invoice and conversion at the time of payment is done using the prevailing exchange rate. The carrying amount of the entity's foreign currency denominated monetary assets and monetary liabilities at the end of the reporting period are as follows:-

| | Ksh | Other currencies | Total |
|---|---|---|---|
| | Kshs | Kshs | Kshs |
| **At 30 June 2019** | | | |
| Financial assets(cash ,debtors) | - | - | - |
| Liabilities | | | |
| Trade and other payables | - | - | - |
| Net foreign currency asset/(liability) | - | - | - |

The entity manages foreign exchange risk form future commercial transactions and recognised assets and liabilities by projecting for expected sales proceeds and matching the same with expected payments.

| | Ksh | Other currencies | Total |
|---|---|---|---|
| | Kshs | Kshs | Kshs |
| **At 30 June 2020** | | | |
| Financial assets (investments, cash ,debtors) | | | |
| Liabilities | | | |
| Trade and other payables | | | |
| **Net foreign currency asset/(liability)** | | | |

**Foreign currency sensitivity analysis**

The following table demonstrates the effect on the company's statement of comprehensive income on applying the sensitivity for a reasonable possible change in the exchange rate of the three main transaction currencies, with all other variables held constant. The reverse would also occur if the Kenya Shilling appreciated with all other variables held constant.

NOTES TO THE FINANCIAL STATEMENTS (Continued)

FINANCIAL RISK MANAGEMENT (Continued)

**iii) Market risk (Continued)**

| | Change in currency rate | Effect on Profit before tax | Effect on equity |
|---|---|---|---|
| | Kshs | Kshs | Kshs |
| **2019** | | | |
| Euro | 10% | - | - |
| USD | 10% | - | - |
| **2020** | | | |
| Euro | 10% | - | - |
| USD | 10% | - | - |

b) Interest rate risk

Interest rate risk is the risk that the entity's financial condition may be adversely affected as a result of changes in interest rate levels. The company's interest rate risk arises from bank deposits. This exposes the company to cash flow interest rate risk. The interest rate risk exposure arises mainly from interest rate movements on the company's deposits.

*Management of interest rate risk*
To manage the interest rate risk, management has endeavoured to bank with institutions that offer favourable interest rates.

*Sensitivity analysis*
The entity analyses its interest rate exposure on a dynamic basis by conducting a sensitivity analysis. This involves determining the impact on profit or loss of defined rate shifts. The sensitivity analysis for interest rate risk assumes that all other variables, in particular foreign exchange rates, remain constant. The analysis has been performed on the same basis as the prior year.
Using the end of the year figures, the sensitivity analysis indicates the impact on the statement of comprehensive income if current floating interest rates increase/decrease by one percentage point as a decrease/increase of KShs - (2018: KShs - ). A rate increase/decrease of 5% would result in a decrease/increase in profit before tax of KShs - (2018 – KShs -)

**Fair value of financial assets and liabilities**

a) Financial instruments measured at fair value

Determination of fair value and fair values hierarchy

IFRS 7 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources; unobservable inputs reflect the entity's market assumptions. These two types of inputs have created the following fair value hierarchy:

**NOTES TO THE FINANCIAL STATEMENTS (Continued)**

**FINANCIAL RISK MANAGEMENT (Continued)**

**iii) Market risk (Continued)**

- Level 1 – Quoted prices (unadjusted) in active markets for identical assets or liabilities. This level includes listed equity securities and debt instruments on exchanges.
- Level 2 – Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly (that is, as prices) or indirectly (that is, derived from prices).
- Level 3 – inputs for the asset or liability that are not based on observable market data (unobservable inputs). This level includes equity investments and debt instruments with significant unobservable components. This hierarchy requires the use of observable market data when available. The entity considers relevant and observable market prices in its valuations where possible.

| | Level 1 Kshs | Level 2 Kshs | Level 3 Kshs | Total Kshs |
|---|---|---|---|---|
| **Non- financial Assets** | | | | |
| Land and buildings | - | - | - | - |
| Property, plant and equipment | - | - | - | 65,592,651 |
| **At 30 June 2020** | | | | **65,592,651** |
| **Non- financial Assets** | | | | |
| Land and buildings | - | - | - | - |
| Property, plant and equipment | - | - | - | 60,042,741 |
| Restatement/ Revaluation -2020 | | | | 11,558,233 |
| **At 30 June 2019** | | | | **71,600,974** |
| | | | | |

Fair value of financial assets and liabilities

The following table shows an analysis of financial and non- financial instruments recorded at fair value by level of the fair value hierarchy:

**Fair value of financial assets and liabilities**

Disclosures of fair values of financial instruments not measured at fair value have not been made because the carrying amounts are a reasonable approximation of their fair values.

**iv) Capital Risk Management**

The objective of the entity's capital risk management is to safeguard the Board's ability to continue as a going concern. The entity capital structure comprises of the following funds:

NOTES TO THE FINANCIAL STATEMENTS (Continued)

FINANCIAL RISK MANAGEMENT (Continued)

**iv) Capital Risk Management (Continued)**

| | 2019-2020<br>Kshs | 2018 - 2019<br>Kshs |
|---|---|---|
| Revaluation reserve | 14,667,677 | (12,222,294) |
| Retained earnings | | |
| Capital reserve | 48,635,341 | 59,118,045 |
| **Total funds** | **63,303,018** | **46,895,751** |
| Total borrowings | - | - |
| Less: cash and bank balances | 32,067,900 | 6,137,074 |
| Net debt/(excess cash and cash equivalents) | **31,235,118** | |
| **Gearing** | 49.5% | 26.2% |

## 26. RELATED PARTY BALANCES

**Nature of related party relationships**

Entities and other parties related to the entity include those parties who have ability to exercise control or exercise significant influence over its operating and financial decisions. Related parties include management personnel, their associates and close family members.

**Government of Kenya.**

The Government of Kenya is the principal shareholder of the Laboratory, holding 100% of the Laboratory's equity interest. The Government of Kenya has provided full guarantees to all long-term lenders of the entity, both domestic and external. Other related parties include:

i) The National Government;
ii) The Parent Ministry;
iii) Key management;
iv) Board of directors;

NATIONAL QUALITY CONTROL LABORATORY
16 APR 2021
P. O. Box 29726 - 00202, ...
TEL: 2726963 / 3544525/34
FAX: 2718073

NOTES TO THE FINANCIAL STATEMENTS (Continued)

**RELATED PARTY BALANCES (Continued)**

| | 2019-2020 Kshs | 2018 - 2019 Kshs |
|---|---|---|
| **Transactions with related parties;** | | |
| **a) Sales to related parties** | | |
| Sales of goods / services to a related MDA's | 56,958,979 | 26,427,529 |
| **Total** | **54,675,205** | **26,427,529** |
| **b) Grants from the Government** | - | |
| Grants from National Gov't – Through KEMSA | 0 | 26,549,766 |
| Donations in kind - GTZ | 4,393,497 | 5,020,257 |
| **Total** | **4,393,497** | **31,570,023** |
| **c) Expenses incurred on behalf of the laboratory by related party** | | |
| Payments of salaries and wages for - employees | - | - |
| Payments for goods and services for a related party | - | - |
| **Total** | - | - |
| **d) Key management compensation** | | |
| Directors' emoluments | - | 375,000 |
| Compensation to the CEO | 600,000 | |
| Compensation to key management (Directors) | 2,743,060 | 2,954,461 |
| **Total** | **62,411,762** | **34,899,484** |

## 27. CONTINGENT ASSETS AND CONTINGENT LIABILITIES

| Contingent liabilities | 2019-2020 Kshs | 2018 - 2019 Kshs |
|---|---|---|
| Court case no …… against the company | | - |
| Bank guarantees in favour of subsidiary | | - |
| **Total** | | - |

## 28. CAPITAL COMMITMENTS

| Capital commitments | 2019-2020 Kshs | 2018 - 2019 Kshs |
|---|---|---|
| Authorised for | | - |
| Authorised and contracted for | | - |
| **Total** | | - |

NOTES TO THE FINANCIAL STATEMENTS (Continued)

## 29. DIVIDENDS/SURPLUS REMISSION

In accordance with Section 219 (2) of the Public Financial Management Act regulations, regulatory entities shall remit into Consolidated Fund, ninety per centum of its surplus funds reported in the audited financial statements after the end of each financial year. The entity did not remit any surplus.to the Consolidated Fund

## 30. TAXATION

| | 2019-2020 | 2018-2019 |
|---|---|---|
| | Kshs | Kshs |
| At beginning of the year | | |
| Income tax charge for the year (note 27) | | 0 |
| Under/(over) provision in prior year/s (note 27) | | 0 |
| Income tax paid during the year | | (0) |
| | | |
| At end of the year | | 0 |
| | | ===== |

[Provide short appropriate explanations as necessary]

## 31. EVENTS AFTER THE REPORTING PERIOD

There were no material adjusting and non- adjusting events after the reporting period.

## 32. ULTIMATE AND HOLDING ENTITY

The entity is a State Corporation/ or a Semi- Autonomous Government Agency under the Ministry of Health. Its ultimate parent is the Government of Kenya.

## 33. CURRENCY

The financial statements are presented in Kenya Shillings (Kshs).

## 19. APPENDICES

### APPENDIX I: PROGRESS ON FOLLOW UP OF AUDITOR RECOMMENDATIONS

The following is the summary of issues raised by the external auditor, and management comments that were provided to the auditor. We have nominated focal persons to resolve the various issues as shown below with the associated time frame within which we expect the issues to be resolved.

| Reference No. external audit Report | Issue / Observations from Auditor | Management comments | Focal Point person to resolve the issue (Name and designation) | Status: (Resolved / Not Resolved) | Timeframe: (Put a date when you expect the issue to be resolved) |
|---|---|---|---|---|---|
| 1.0 | Undetermined value of Land included in Property plant & Equipment | The laboratory was allocated 4.0 hectares in 1992 vide Ref; 62432/IV/188. Kenya-Re has ceded back 1.0Ha and KNH has promised to cede 1.35 Ha of which the National Land Commission has donated part of it to KURA for road construction without our consent. We are following up the matter with NLC to value the land and acquire a title deed for the whole parcel. | Dr. Pius Wanjala | Not Resolved | June, 2019 |
| 2.0 | Understatement of ksh. 507,896 in Cash & Cash Equivalent | Cash book balance reflects Kshs. 10,276,389 while cash and cash equivalent shows ksh.9,768,493 The Kshs . 507,896 differences being reconciliation oversights resulting from previous years balances brought forward, due to lack of effective internal audit function. This has since been corrected. | Mr. Naphtaly Ogolah | Resolved | June, 2018 |
| 3.0 | In adequate provision of Bad & doubtful debts. Validity and recoverability of ksh. | KEMSA is yet to responded to our requests and efforts to recover the Kshs .6,013,120 from them and neither have UNDP (Kshs 1,476,930) and Gov't of South Sudan (Kshs .136,267). We shall be recommending a write off | Board of Management | Not Resolved | June, 2019 |

| | | | | | |
|---|---|---|---|---|---|
| | 7,626,317 for Trade & Other receivables | as bad debt using the laid down policy once approved by the BOM | | | |
| 4.0 | Operating without a Board and failure to comply with PPB Act Cap 244 and ISSAI 30 on code of ethics | The BOM has since been appointed vide The Kenya Gazette notice (no. 1940) Vol. CXX- No 29 dated 02nd March, 2018 and inaugurated on April, 2018 to execute their mandate. | Pharmacy and Poisons Board | Resolved | March, 2018 |
| Other Matters | 70% Under absorption Budgetary Control and performance. Budgeted ksh. 255, 057, 000 while Actual for the year is ksh. 75,922,326 | 30% absorption indicates we could not implement plans hence service delivery suffered due to diversion of our allocations to other departments and Agencies by the parent Ministry We request treasury to directly send allocated funds to our account to avoid reallocations. | The National Treasury | Not Resolved | June, 2019 |

**Guidance Notes:**

(i) Use the same reference numbers as contained in the external audit report;

(ii) Obtain the "Issue/Observation" and "management comments", required above, from final external audit report that is signed by Management;

(iii) Before approving the report, discuss the timeframe with the appointed Focal Point persons within your entity responsible for implementation of each issue;

**(iv)** Indicate the status of "Resolved" or "Not Resolved" by the date of submitting this report to National Treasury.

**Dr. Hezekiah Kibet Chepkwony, PhD**
**Director, Secretary BOM**

**Date** 16th April, 2021

**Ms. Georgina Muchai (CPA),**
**Chairperson, Finance, Administration and General Purpose Committee of BOM**

**Date** 16th April, 2021

## APPENDIX II: INTER-ENTITY TRANSFERS

| | | | | |
|---|---|---|---|---|
| | **ENTITY NAME:** | National Quality Control Laboratory | | |
| | **Break down of Transfers from the State Department of Health** | | | |
| | **FY 19/20** | | | |
| a. | Recurrent Grants | | | |
| | | Bank Statement Date | Amount (KShs) | Indicate the FY to which the amounts relate |
| | | June, 2020 | 1,503,459 | |
| | | **Total** | **1,503,459** | |
| b. | Development Grants | | | |
| | | Bank Statement Date | Amount (KShs) | Indicate the FY to which the amounts relate |
| | | June, 2020 | - | |
| | | **Total** | - | |
| c. | Direct Payments | | | |
| | | Bank Statement Date | Amount (KShs) | Indicate the FY to which the amounts relate |
| | NASCOP | June, 2020 | 42,732,380 | 2019/20 |
| | KEMSA | June, 2020 | 11,047,900 | 2019/20 |
| | PPB | June, 2020 | 1,675,240 | 2019/20 |
| | | **Total** | **56,958,979** | |

The above amounts have been communicated to and reconciled with the parent Ministry

ICPAK 4517.

16 APR 2021

**Dr. David Kemoi Yano (CPA),**
**Finance Manager NQCL**

**Date** 16th April, 2021

## APPENDIX III: RECORDING OF TRANSFERS FROM OTHER GOVERNMENT ENTITIES

| Name of the MDA/Donor Transferring the funds | Date received as per bank statement | Nature: Recurrent/ Development /Others | Total Amount - KES | Where Recorded/recognized | | | | | Total Transfers during the Year |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Statement of Financial Performance | Capital Fund | Deferred Income | Receivables | Others - must be specific | |
| Ministry of Health (DS&R, DoFH) | 2019-20 | Direct Payment | 1,503,459 | 1,503,459 | - | - | 1,503,459 | 0 | 1,503,459 |
| MoH - KEMSA | 2019-20 | Recurrent - **Equipment** | - | - | - | - | | | - |
| Pharmacy & Poisons Board - PPB | 2019-20 | Direct Payment - **Analysis** | 1,675,240 | 1,675,240 | - | - | - | | 1,675,240 |
| NASCOP | 2019-20 | Direct Payment - **Analysis** | 42,732,380 | 35,976,380 | - | - | 6,756,000 | | 42,732,380 |
| KEMSA | 2019-20 | Direct Payment - **Analysis** | 6,013,120<br>5,034,780 | 6,013,120<br>5,034,780 | - | - | 6,013,120<br>5,034,780 | | 11,047,900 |
| **Total** | | | **56,958,979** | **50,202,979** | **0** | **0** | **19,307,359** | **0** | **56,958,979** |

NATIONAL QUALITY CONTROL LABORATORY
16 APR 2021
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