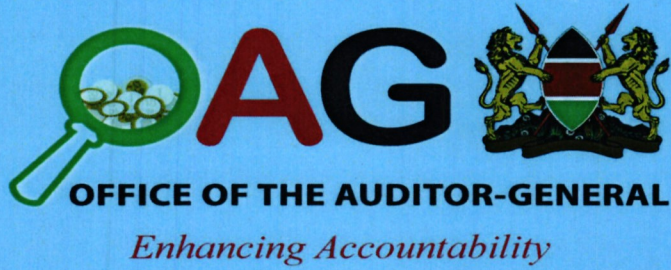


REPUBLIC OF KENYA



REPORT

OF

THE AUDITOR-GENERAL

ON

**NATIONAL QUALITY
CONTROL LABORATORY**

**FOR THE YEAR ENDED
30 JUNE, 2021**

THE NATIONAL ASSEMBLY
PAPERS LAID

DATE: 30 NOV 2022

Wednesday

LOM

Getunde chebet



OFFICE OF THE AUDITOR GENERAL
P. O. Box 30084 - 00100, NAIROBI
REGISTRY
05 JUL 2022
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NATIONAL QUALITY CONTROL LABORATORY

ANNUAL REPORT AND FINANCIAL STATEMENTS

THE NATIONAL ASSEMBLY
PAPERS LAID

DATE: 30 NOV 2022

DAY.

**FOR THE FINANCIAL YEAR ENDING
30 JUNE, 2021**

TABLED

IN THE TABLE:

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



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For the year ended 30 June, 2021
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1. KEY NATIONAL QUALITY CONTROL LABORATORY 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 2021 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



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KEY NATIONAL QUALITY CONTROL LABORATORY INFORMATION AND MANAGEMENT (Continued)

7.	Head, Wet Chemistry Unit	Dr. Peter Ngumo
8.	Head, Instrumentation Unit	Dr. Mathayo Kwena
9.	Head, Biological Analysis & Medical Devices Units	Dr. Khadija Hassan
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








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2. THE BOARD OF DIRECTORS

	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






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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

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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	30
2.		Dr. Pius Wanjala - Snr. Deputy Chief Pharmacist	MPharm, LLB; MPSK	Senior Deputy Director	22
3.		Dr. George Wang'ang'a - Deputy Chief Pharmacist	MSc. Intl. Health, MBA, BPharm; MPSK	Deputy Director Finance & Administration	19
4.		Dr. Serah Muteru - Assistant Chief Pharmacist	Msc, BPharm; MPSK	Deputy Director Quality Assurance Manager	19
5.		Dr. Ernest Mbae - Deputy Chief Pharmacist	MPharm, BPharm; MPSK	Deputy Director Technical Services	19
6.		Dr. Nicholas Mwaura - Assistant Chief Pharmacist	PhD, MPharm, BPharm; MPSK	Deputy Director Research & Technological Development	20

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MANAGEMENT (Continued)

7.		Dr. Mathayo Kwena– Assistant Chief Pharmacist	Msc, BPharm; MPSK	Head Instrumentation Unit	19
8.		Dr. Khadija Hassan- Assistant Chief Pharmacist	Msc; BPharm; MPSK	Head Biological Analysis & Medical Devices Units	19
9.		Dr. Rebecca Manani Assistant Chief Pharmacist	Msc; BPharm; BPharm; MPSK	Head Documentation Unit	17
10.		Dr. Peter Ngumo - Assistant Chief Pharmacist	PhD, MPharm, BPharm; MPSK	Head Wet Chemistry Unit	17
11.		Mr. David K. Yano	B. Com Finance, CPA K,	Head, Finance and Administration	19
12.		Mr. George Ogeto Nyambane	BA. Econ CPA I, Dip. SCM	Head Supply Chain Management Unit	20



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4. CHAIRMAN'S STATEMENT


The Board of Management (BOD) presents the NQCL Annual Reports and Financial Statements for the year ended 30th June 2021.

A new BOD 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 BOD 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 BOD 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 BOD, 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 BOD retreat the highlight of which was to develop a BOD almanac to guide its activities.

The BOD activities were further affected by the emergence of the Covid 19 pandemic, which called for online meetings from mid - March 2020. The BOD followed the guidelines for carrying out meetings as given by the Head of Public Service circulars. Further, the BOD 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 BOD 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 BOD, management and key stakeholders including PPB and MOH.



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CHAIRMAN'S STATEMENT (Continued)

The BOD 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 BOD 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 BOD

Date 20 April, 2022

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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 BOD 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.

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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 BOD. The role of PPB ends at appointment level of the BOD and subsequently, the BOD 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.



20 APR 2022

TEL: 2710073
FAX: 2710073

Prof. Matilu Mwau, D.Phil (Oxon), OGW
Ag. Director,

Date 20 April, 2022

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REVIEW OF NATIONAL QUALITY CONTROL LABORATORY'S PERFORMANCE AGAINST PRE-DETERMINED OBJECTIVES FOR FY 2020/2021

Section 81 Subsection 2 (f) of the Public Finance Management Act, 2012 requires the accounting officer to include in the financial statement, a statement of the national government National Quality Control Laboratory's performance against predetermined objectives. *The Laboratory has some strategic pillars/ themes/issues and objectives within the current Strategic Plan for the FY 2015 FY 2021. These strategic pillars/ themes/ issues are as tabulated below.*

The Laboratory develops its annual work plans based on the below outlined pillars/Themes/Issues. Assessment of the Board's performance against its annual work plan is done on a quarterly basis. The Laboratory achieved its performance targets set for the FY 2020/2021 period for its stated strategic pillars, as indicated in the diagram below:

Under this section therefore, the management has included performance against the strategic objectives of the organisation. The management has outlined the strategic Pillars, activities towards their achievement and outputs under each strategic pillar. The Laboratory also briefly outlined how they have tied achievements to performance contracts.

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;

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- 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.



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REVIEW OF NATIONAL QUALITY CONTROL LABORATORY'S PERFORMANCE FOR FY 2020/2021 (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 BOD'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.	1.1 Review the legal status of the laboratory in consultation with stakeholders –PPB 1.2 Implement the provisions of Cap 244 fully	Not completed SCAC gave directive, MOH and Treasury yet to implement
		b To establish legislation that ensures greater autonomy of the NQCL.	1.3 Establish the office of the corporation secretary (Objective 1) 1.4 Appointment of office holders (Autonomy)	
		c Ensure compliance with legal and regulatory provisions	1.5 Identify the laws and regulations the laboratory should comply with 1.6 Ensure compliance with these laws 1.7 Report to State corporations advisory committee (SCAC). 1.8 Report every quarter to SCAC	
	To ensure Realignment with the constitution on the Bill of rights To decentralize testing services	d Ensure Good governance in line with the Mwongozo code	1.9 Post market surveillance and testing. 1.10 Reporting to stakeholders; PPB, the 47 County and National Governments. 1.11 Create a data bank	On course
		e Ensure provision for quality medicines for all	1.12 Collaborate with stakeholders to set up – minilabs at selected sites	On course
		f To ensure that drugs and medical devices are of good quality.		Awaiting operationalization

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

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Strategic Pillar	Objectives	Key Performance Indicators	Activities	Achievements
4 Financing and Funding	To ensure financial sustainability	<ul style="list-style-type: none"> a To collect and prudently use the available finances b To maximize revenue generation - To advocate for review of the act to appropriate levies are imposed for NQCL operations 	<ul style="list-style-type: none"> 4.1 Maintain mechanisms for raising funds for the Laboratory services from the government, partners and other sources. 4.2 Implement strategies for increased revenue generation and management – Revise analysis fees and offer training 4.3 Identify and implement investment opportunities and other sources of finance, to support the realization of NQCL goals. 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. 4.5 Utilize appropriate technology e.g. computerization, on management of finances. 4.6 Develop and implement mechanisms to reduce loss of revenue and recover debts. 	<p>BOD and management to continue lobbying for AIE funds to come as grants to Lab Account</p> <p>On-going – Reference to policy of 100% upfront payment</p> <p>Continue lobbying for the 0.2% fee from KEBS</p> <p>On-going</p>
5 Corporate image	To improve the corporate image	<ul style="list-style-type: none"> a To develop a corporate image and public awareness plan and strategy b To develop policies and guidelines for improvement of NQCL image and social responsibility to the public 	<ul style="list-style-type: none"> 5.1 Evaluate perceptions of the public and stakeholders on lab and respond as need arises. 5.2 Establish a Good Governance Policy that re-mould the Laboratory’s image. 5.3 Create awareness and educate the public and stakeholders on issues of concern and services in the lab through involvement in public awareness 	<p>To set up a PR department</p> <p>Corporate image improved</p>



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

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Strategic Pillar	Objectives	Key Performance Indicators	Activities	Achievements
8 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)	<p>personnel, which will be maintained and updated by a nominated responsible member of the laboratory personnel.</p> <p>a To attain international accreditation status</p> <p>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.</p>	<p>8.1 Maintain quality assurance and control systems in the laboratory.</p> <p>8.2 Maintain and Establish quality assurance standards for all services.</p> <p>8.3 Regularly update Laboratory quality manuals.</p> <p>8.4 Ensure quality systems are maintained.</p> <p>8.5 Set up research and development unit for standard testing.</p> <p>8.6 Prepare research and training policies and procedures.</p>	<p>Done for Wet Chemistry, Microbiology, CSU and Quality Assurance. Others are on-going.</p> <p>This will be a continuous process</p>
9 Facilities and Equipment	<p>To acquire land and put up physical facilities</p> <p>To acquire adequate and appropriate state of the art equipment</p>	<p>Establish the lab facilities in an independent locality i.e. NQCL owned premises</p>	<p>9.1 Pursue the acquisition of grabbed land and acquire title.</p> <p>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.</p> <p>9.3 Develop key essential physical facilities, equipment and services to</p>	<p>BOD to follow up with Kenya-Re Ltd & KNH for processing of the Title Deeds.</p> <p>Proposal and MOU between the MOH and Sponsor (SYGEC) in-place.</p>

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Strategic Pillar	Objectives	Key Performance Indicators	Activities	Achievements
10 Research and Technological Development	<p>To establish a Research and Technological Development department</p> <p>To Strengthen and deepen research capabilities of the Laboratory.</p>	<p>a To establish a Research and Development department.</p> <p>b Establish, develop and document research findings that address all analytical activities performed at the laboratory.</p>	<p>cater for specialized laboratory, education, training and other services.</p> <p>9.4 Acquire modern equipment and maintain them in order to provide quality services.</p> <p>10.1 Develop and acquire human capacity</p> <p>10.2 Develop secondary standards in collaboration with international bodies.</p> <p>10.3 Develop a Method Development and Validation Unit</p> <p>10.4 Carry out analytical operational research.</p> <p>10.5 Maintain, develop and possibly supply Chemical Reference Standards for use by pharmaceutical manufacturers.</p> <p>10.6 Provide appropriate training and research facilities and services to various stakeholders that use the laboratory.</p>	
11 Collaborations/ Linkages and Partnerships	<p>To establish and strengthen collaborations and partnerships with other institutions, industry and society</p>	<p>To identify potential institutions for collaboration with Laboratory.</p>	<p>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.</p> <p>11.2 Establish and formalise interactive linkages with identified institutions</p> <p>11.3 Develop and maintain sustainable inter-institutional linkages for enhancing the mandate of the laboratory.</p>	

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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.	11.4 Form and maintain alliances with special programs within the MoH (e.g. NASCOP, DOMC, NLTBP). 12.1 Review processes for efficiency and effectiveness. 12.2 Undertake a process mapping. 12.3 Develop clear SOPs for all operations in the NQCL. 12.4 Implement the revised procedures. 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 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 	13.1 Develop procurement policies, guidelines and procedures for all products and services. 13.2 Procure quality goods and services for the laboratory and maintain optimum levels of stock through computerization i.e. e-procurement. 13.3 Monitor and evaluate procurement and tendering procedures of supplies and services in the Laboratory and take appropriate action.	

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Strategic Pillar	Objectives	Key Performance Indicators	Activities	Achievements
14 Information and Communication Technology (ICT)	To increase the use of Information Communication and Technology (ICT) in the development and management of quality control and assurance of medicines	<p>a To establish and maintain an Electronic Service Delivery Strategy.</p> <p>b To offer e-commerce services to cater for speedy procurement</p>	<p>14.1 Establish and maintain ICT infrastructure for the Laboratory.</p> <p>14.2 Recruit qualified and experienced ICT personnel to manage the systems.</p> <p>14.3 Improve data management and record keeping in the Laboratory.</p> <p>14.4 Establish and maintain an integrated data management system.</p> <p>14.5 Maintain LIMS and regularly update the NQCL website.</p> <p>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.</p>	<p>1.1 Electronic service strategy in place</p> <p>1.2 ICT infrastructure in place;</p> <p>1.3 Integrated data management system in place</p>
15 Environment awareness	To promote environmental friendly practices	<p>a To put measures for a clean and safe environment and promote them among staff.</p> <p>b To ensure work environment that is free of biological, chemical and physical hazards.</p> <p>c To ensure proper waste management policies are implemented.</p>	<p>15.1 To develop waste management policy – collaborate with institutions with such policies;</p> <p>15.2 To develop affiliations with waste management/environmental management bodies such as NEMA;</p> <p>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).</p> <p>15.4 To ensure proper waste management</p>	<p>Contract in-place</p> <p>Program on clean and safe environment in place</p> <p>Proper waste management policies in place</p>

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6. CORPORATE GOVERNANCE STATEMENT

Process of Appointment and Removal of Directors

Cap 244 Laws of Kenya Section 35F allows for the creation of a BOD for the Laboratory, which shall consist of (9) nine members to be appointed by the Pharmacy and Poisons Board (PPB). A member of the BOD 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 BOD 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 BOD, 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 BOD to appoint a Director who shall be the chief executive of the Laboratory responsible to the BOD for the day-to-day management of the Laboratory

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

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

Succession Plan

The BOD'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 BOD. We anticipate that in future the Chairperson and the BOD 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 BOD does not have an existing Board Charter and will embark on having a draft ready before the end of quarter

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two (2). BODs will be recruited competitively as governed by SCAC. The BOD 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 BOD 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 BODs. The evaluation shall include ethics, conduct as well as governance audit.

Induction and Training

The BOD 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 BOD are bound by the provisions of Public Officers Ethics Act Cap 183 and the Laboratory's conflict of interest policy. Two core concepts are embodied in these regulations; BOD 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.

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7. 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.

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.

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8. ENVIRONMENT AND SUSTAINABILITY REPORTING

Environment and Sustainability (ESR) is the responsibility of an Laboratory to impacts its Environs through the decisions and activities it carries out in or within the society and the environment, vide transparent and ethical behaviour that:

- Contributes to sustainable development, including the health and the welfare of society,
- Takes into account the expectations of stakeholders or community,
- Is in compliance with applicable law and consistent with international norms of behaviour,
- 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 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 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.

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ENVIRONMENT AND SUSTAINABILITY REPORTING (Continued)

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 BOD 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 grading. In the previous recruitment, the BOD considered gender, regional and ethnic balance. It also considered people living with disabilities in the same recruitment. On training, all the staff continue to be trained on the various techniques as per the requirements of the Laboratory training needs schedule with a significant emphasis on technical skills.

9. REPORT OF THE BOARD OF MANAGEMENT

The Directors submit their report together with the audited financial statements for the year ended 30 June, 2021 which show the state of the National Quality Control Laboratory affairs.

a) Principal activities

The Laboratory continues to;

- Examine and test medicines; on behalf of the Government, locally manufactured and imported medicines or medicinal substances;
- Perform chemical, biological, biochemical, physiological, pharmacological analysis and other pharmaceutical evaluation;
- 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.

b) The Results of the Financial statements and Reports

The results of the Laboratory for the year ended 30 June, 2021 are set out on pages 1 to 5.

c) Directors/Board of Management

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The current BOD 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 BOD was inaugurated on 05th April 2018. The appointment of the entire Board of Management was revoked by the Pharmacy and Poisons Board-the appointing Authority-vide Gazette Notice No. 6599 dated 1st July, 2019. The affected individual Board members filed Petition No. 137 of 2019 (*Mr. Ronoh Sitienei & 4 Others-Vs- Pharmacy and Poisons Board and Cabinet Secretary and 5 interested parties*) in the Employment and Labour Relations Court in their private personal capacities through the firm of Kinyanjui and Njuguna Advocates as they had ceased as Board members as well as having made individual decision to sue at the time of filling the matter.

The NQCL was listed as the 2nd interested party and was represented by its in-house Legal Counsel and did not incur any legal expense in the matter. The Judgment was delivered on 15th November, 2019 in favour of the Petitioners-Board members who were restored as Board members having been out of office between 1st July, 2019 and 15th November, 2019. The financial statements are yet to be reviewed and signed by the Board.

d) Dividends/Surplus remission

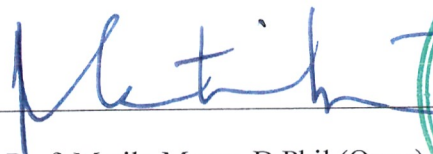
In accordance with Section 219 (2) of the Public Financial Management Act regulations, regulatory entities shall remit into Consolidated Fund, ninety per cent of its surplus funds reported in the audited financial statements after the end of each financial year. The Laboratory did not make any surplus during the year FY 2020-21 and hence no remittance to the Consolidated Fund was done. The Laboratory made a Deficit of Kshs. (30,031,089.8) during the year.

Office of the Auditor General's Responsibility

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

The Office of the Auditor General in compliance with Section 23 of the Public Audit Act, 2015, which empowers the Auditor General to appoint an auditor have carried out the audit of the Laboratory for the year/period-ended 30 June, 2021.

By Order of the Board



Prof. Matilu Mwau, D.Phil (Oxon),
OGW
Ag. Director, Secretary BOD



Ms. Georgina Muchai,
Chairperson, Finance, Administration
& General Purpose Committee of BOD

Date 20 April, 2022

Date 20 April, 2022

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10. 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 2021. 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 National Quality Control Laboratory;
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 2021 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.

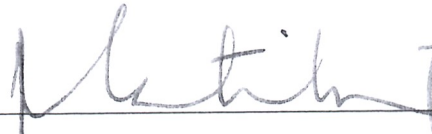
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STATEMENT OF DIRECTORS' RESPONSIBILITIES (Continued)


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, 20 April, 2022 and signed on its behalf by:



Prof. Matilu Mwau, D.Phil (Oxon),
OGW
Ag. Director, Secretary BOD

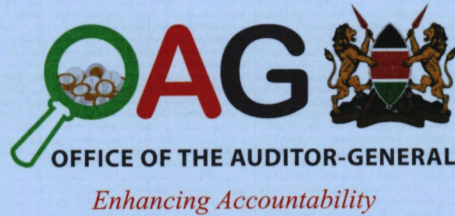

Ms. Georgina Muchai,
Chairperson, Finance, Administration
and General Purpose Committee of
BOD

Date 20 April, 2022

Date 20 April, 2022

REPUBLIC OF KENYA

Telephone: +254-(20) 3214000
E-mail: info@oagkenya.go.ke
Website: www.oagkenya.go.ke



HEADQUARTERS
Anniversary Towers
Monrovia Street
P.O. Box 30084-00100
NAIROBI

REPORT OF THE AUDITOR GENERAL ON NATIONAL QUALITY CONTROL LABORATORY FOR YEAR ENDED 30 JUNE, 2021

PREAMBLE

I draw your attention to the contents of my report which is in three parts:

- A. Report on the Financial Statements that considers whether the financial statements are fairly presented in accordance with the applicable financial reporting framework, accounting standards and the relevant laws and regulations that have a direct effect on the financial statements.
- B. Report on Lawfulness and Effectiveness in Use of Public Resources which considers compliance with applicable laws, regulations, policies, gazette notices, circulars, guidelines and manuals and whether public resources are applied in a prudent, efficient, economic, transparent and accountable manner to ensure Government achieves value for money and that such funds are applied for intended purpose.
- C. Report on Effectiveness of Internal Controls, Risk Management and Governance which considers how the entity has instituted checks and balances to guide internal operations. This responds to the effectiveness of the governance structure, the risk management environment, and the internal controls developed and implemented by those charged with governance for orderly, efficient and effective operations of the entity.

An unmodified opinion does not necessarily mean that an entity has complied with all relevant laws and regulations, and that its internal controls, risk management and governance systems are properly designed and were working effectively in the financial year under review.

The three parts of the report are aimed at addressing the statutory roles and responsibilities of the Auditor-General as provided by Article 229 of the Constitution, the Public Finance Management Act, 2012 and the Public Audit Act, 2015. The three parts of the report, when read together constitute the report of the Auditor-General.

REPORT ON THE FINANCIAL STATEMENTS

Adverse Opinion

I have audited the accompanying financial statements of National Quality Control Laboratory set out on pages 32 to 70, which comprise the statement of financial position

as at 30 June, 2021, 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, 2021, 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 the Pharmacy and Poisons Amendment Act, 1992.

Basis for Adverse Opinion

1. Going Concern

During the year under review, the National Quality Control Laboratory recorded a deficit of Kshs.30,031,090 (2020 - surplus, Kshs.14,667,676) which resulted in depletion of revenue reserves from Kshs.63,320,212 as at 30 June, 2020 to Kshs.33,289,122 as at 30 June, 2021. Further, the statement of financial position reflects current liabilities of Kshs.63,942,578 as at 30 June, 2021 which exceed the current assets balance of Kshs.51,945,827 resulting in a negative working capital of Kshs.11,996,751.

Consequently, the National Quality Control Laboratory is technically insolvent and the financial statements have therefore been prepared on a going concern basis on the assumption of continued financial support from the Government and its creditors.

2. Long Outstanding Debts

The statement of financial position reflects receivables from exchange transactions of Kshs.18,625,714 (2020 - Kshs.26,815,664) which, as disclosed in Note 17 to the financial statements, includes Kshs.6,013,120 owed by the Kenya Medical Supplies Authority (KEMSA) that has been outstanding for more than sixteen (16) years but has not been recognized in KEMSA books of accounts. In addition, Kshs.3,673,547 are debts of one (1) to three (3) years old. No explanation was provided on how the Laboratory Management intends to recover the long outstanding debts from the companies and organizations.

In the circumstances, the accuracy and completeness of receivables from exchange transactions balance of Kshs.18,625,713 as at 30 June, 2021 could not be confirmed.

3. Non - Disclosure of Intangible Asset

As disclosed in Note 14 to the financial statements, the statement of financial performance reflects general expenses balance of Kshs.20,157,453. Included in the balance is Kshs.1,644,689 in respect to professional and consultancy fees, out of which

Kshs.748,473 was expenditure to operationalize the Laboratory Information Management Systems (LIMS) but, there is no evidence LIMS was recognized in the Laboratory books of accounts.

In absence of the disclosure of Laboratory Information Management Systems (LIMS) for the year 30 June, 2021, the accuracy and completeness of the financial statements could not be confirmed.

4. Non-Disclosure of Land - Property, Plant and Equipment

As previously reported, the property, plant and equipment balance of Kshs.60,531,658 as at 30 June, 2021 as disclosed in Note 20A to financial statements excludes an undetermined value of a parcel of land originally measuring four (4) hectares situated in Upper Hill, Nairobi which had been allotted to the National Quality Control Laboratory (NQCL) in 1992 by the Commissioner of Land vide letter Ref:62432/IV/188 dated 15 May, 1992. Information provided by the Management indicate that by 1993, the entire four (4) hectares of land allotted to the Laboratory had either been re-allotted or double allocated to Kenya Times Media Trust Limited and Kenyatta National Hospital by the same Commissioner of Lands. Further information indicate that Kenya Times Media Trust Limited subsequently sold its entire portion of the land to Kenya Reinsurance Company Limited for a consideration. Management has explained that following consultations and on mutual consideration, Kenyatta National Hospital agreed to surrender back 1.35 hectares to the Laboratory while Kenya Reinsurance Company Limited had already surrendered back 1.0 hectares, and the subdivision process is ongoing at the National Land Commission. However, as at the time of the audit, the process had not been concluded.

In absence of the disclosure of land, the accuracy and completeness of property, plant and equipment balance of Kshs.60,531,658 as at 30 June, 2021 could not be confirmed.

5. Unreconciled Inventory

As disclosed in Note 19 to the financial statements, the statement of financial position reflects inventory balance of Kshs.13,253,451 (2020 - Kshs.5,964,091). However, the stock take report dated 17 June, 2021 reflects Kshs.12,663,840 resulting to unreconciled balance of Kshs.589,611.

In the circumstances, the accuracy and completeness of inventory balance of Kshs.13,253,451 as at 30 June, 2021 could not be confirmed.

6. Unrealised Analysis Fees Revenue

As disclosed in Note 8 to the financial statements, the statement of financial performance reflects rendering of services - analysis fees of Kshs.35,838,700 which dropped by Kshs.47,216,925 or 57% from Kshs.83,055,625 in 2019/2020. Despite this drop of revenue, chemicals and reagents disclosed in Note 14 increased by Kshs.5,153,989 (or 102%) from Kshs.5,030,868 in 2019/2020 to Kshs.10,184,857.

In the circumstances, the accuracy and completeness of rendering of services - analysis fees of Kshs.35,838,700 for the year ended 30 June, 2021 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 Matters

1. Budgetary Control and Performance

The summary statement of comparison of budget and actual amount reflects final receipts budget of Kshs.100,368,497 and actual on comparable basis of Kshs.42,532,160 resulting to an under-funding of Kshs.57,836,337 (or 58%) of the budget. Similarly, the actual expenditure on comparable basis was Kshs.62,474,898 against final budget amount of Kshs.154,402,000 resulting to an under-expenditure of Kshs.91,927,102 (or 60%) of the budget. In addition, the Laboratory did not receive any transfers to finance the budget from the Ministry of Health.

The underfunding and underperformance affected the planned activities and may have impacted negatively on service delivery to the stakeholders.

2. Legal Status of National Quality Control Laboratory

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 06 November, 1992. Since inception, the Laboratory has operated as a Division of Pharmacy in the Ministry of Health despite being recognized as a Semi-Autonomous Government Agency (SAGA) in the Ministry of Health in September, 2014. Further, in February, 2016, the State Corporation Advisory Committee after evaluating its capacity categorized the National Quality Control 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, no progress had been made by the Ministry on formation of the Inter-Ministerial Task Force by the time of completion of the audit.

3. Unresolved Prior Year Audit Matters

In the audit report of the previous year, several issues were raised under the Report on Financial Statements and Report on Lawfulness and Effectiveness in Use of Public Resources. However, the Management has not resolved the issues or given any explanation for failure to adhere to the provisions of the Public Sector Accounting

Standards Board templates and the National Treasury's Circular Ref. AG.4/16/2 Vol.3(72) dated 30 June, 2021.

REPORT ON LAWFULNESS AND EFFECTIVENESS IN USE OF PUBLIC RESOURCES

Conclusion

As required by Article 229(6) of the Constitution, because of the significance of the matters discussed in the Basis for Adverse Opinion and Basis for Conclusion on Lawfulness and Effectiveness in Use of Public Resources sections of my report, based on the audit procedures performed, I confirm that public resources have not been applied lawfully and in an effective way.

Basis for Conclusion

Un-Authorized Appropriations-In-Aid and Expenditure

The statement of financial performance reflects rendering of services - analysis fees of Kshs.35,838,700 and comparative balance of Kshs.83,055,625 resulting to unexplained decrease of Kshs.47,216,925 (or 57%). The amounts form part of Appropriations-In-Aid (AIA) for National Quality Control Laboratory and which were expended during financial year 2020/2021. However, there was no evidence of approval by the Board of Directors to spend Appropriations-In-Aid. This contravenes Section 35G of Pharmacy and Poisons Board, Chapter 244 which states that the functions of Board of Management shall be to receive fees, subscriptions of other monies and make disbursements thereof.

In the circumstances, Management was in breach of the law.

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, because of the significance of the matters discussed in the Basis for Adverse Opinion and Basis for Conclusion on Effectiveness of Internal Controls, Risk Management and Governance sections of my report, based on the audit procedures performed, I confirm that internal controls, risk management and overall governance were not effective.

Basis for Conclusion

1. Lack of Board of Directors

During the year under review the National Quality Control Laboratory operated without a Board of Directors as the National Quality Control Laboratory Board of Directors was revoked vide Gazette Notice No.8095 of 16 October, 2020.

Under the circumstances, the functions spelt out in Section 35G of the Pharmacy and Poisons Act Cap 244 were not performed and operations undertaken without a supervisory organ.

2. Audit Committee

The National Quality Control Laboratory has not established an Audit Committee contrary to Section 73(5) of the Public Finance Management Act, 2012, which states that every national government public entity shall establish an Audit Committee whose composition and functions shall be as prescribed by the regulations.

In the circumstances, there was no oversight of Laboratory operations.

3. Weak Internal Controls

During the year under review National Quality Control Laboratory established an Internal Audit Department. However, the following internal control weaknesses were observed:

- a. Inaccuracies and errors in the financial statements;
- b. The petty cash vouches, payment vouchers and local purchase orders were not appropriately authorised and were initiated by only one person;
- c. The cashbook was not examined and bank reconciliations not approved; and
- d. The internal audit reports were not provided for audit and there was no evidence that they were being submitted to oversight body.

In the circumstances and without proper and sufficient supervision by independent internal audit, the Laboratory is exposed to internal control weaknesses.

4. Lack of Accountable Records

During the year under review, the National Quality Control Laboratory used five (5) miscellaneous receipt books to collect various fees. However, there was no evidence of maintaining the Counter Receipt Register (CRBR) to control receipts and issuance of the books and the source of the miscellaneous receipt books was not stated. It was also not possible to confirm the receipts used to collect receipts totalling to Kshs.35,858,700 which was collected as Appropriations-In-Aid during financial year 2020/2021.

In the circumstances, the effectiveness of counter requisition and issue voucher controls over issuance and surrender of miscellaneous receipt books cannot be ascertained.

5. Lack of Key Departments

The National Quality Control Laboratory has not established key departments of human resource, information communication and technology and legal departments among others. As a result, National Quality Control Laboratory lacks technical and professional personnel to run key organisational functions effectively.

In the circumstances, the National Quality Control Laboratory is prone to internal control weaknesses and poor service delivery.

The audit was conducted in accordance with ISSAI 2315 and ISSAI 2330. The standard requires that I plan and perform the audit to obtain assurance about whether effective processes and systems of internal control, risk management and overall 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 the Board of Directors

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 National Quality Control Laboratory's ability to continue to sustain 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, revenue 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 Directors is responsible for overseeing the Laboratory's revenue reporting process, reviewing the effectiveness of how Management 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 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 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 Laboratory 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 revenue 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

22 June, 2022

NATIONAL QUALITY CONTROL LABORATORY
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12. STATEMENT OF FINANCIAL PERFORMANCE FOR THE YEAR ENDED 30 JUNE 2021

	Notes	2020 - 2021	2019 - 2020
		Kshs	Kshs
Revenue from non-exchange transactions			
Public contributions and Donations – Deferred income (GTZ)	6	4,120,587.4	4,393,497.0
Transfers from other GoK – gifts and services-in-kind	7	2,572,873.0	1,503,459.0
Revenue from exchange transactions			
Rendering of services – Analysis fees	8	35,838,700.0	83,055,625.0
Other income - (GMP certification / CoA -certified copies)		-	-
Total Revenue		42,532,160.4	88,952,581.0
Expenses:-			
Use of goods and services -Electricity	9	2,572,873.0	1,503,459.0
Employee costs - Personnel	10	30,381,321.0	27,164,287.0
Remuneration of Directors (BoM)	11	649,026.0	2,743,060.0
Depreciation and Amortization expense	12	9,522,620.9	10,401,720.0
Provision for Bad Debt - ksh. 18,625,713.6 @ 3% Prov.	17B	558,771.4	804,469.9
Provision for Audit fees & Consultancy	21A	348,000.0	696,000.0
Contracted services - Repairs and Maintenance	13	8,241,575.0	13,167,489.0
Grants and subsidies	...	-	-
General expenses (Admin exp & Chemical / Reagents)	14	20,157,453.0	17,652,925.0
Finance costs	15	131,609.9	151,495.0
Total Expenses		72,563,250.2	74,284,904.9
Surplus/(deficit) for the period/year		(30,031,089.8)	14,667,676.1
Total expenses		72,563,250.2	74,284,904.9
Other gains/(losses)		-	-
Gain on foreign exchange transactions		-	-
Surplus before tax		(30,031,089.8)	14,667,676.1
Taxation	27	-	-
Surplus/(deficit) for the period/year		(30,031,089.8)	14,667,676.1
Remission to National Treasury	51	-	-
Net Surplus/(Deficit) for the year		(30,031,089.8)	14,667,676.1

The notes set out on pages 32 to 66 form an integral part of these Financial Statements.

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NATIONAL QUALITY CONTROL LABORATORY
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STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2021

	Notes	2020 - 2021	2019 - 2020
Assets		Kshs	Kshs
Current assets			
Cash and cash equivalents	16	19,823,662.4	32,067,900.0
Receivables from exchange transactions	17	18,625,713.6	26,815,664.0
Receivables from non-exchange transactions staff advances	18	243,000.0	143,000.0
Inventories	19	13,253,451.3	5,964,091.0
Non-current assets		51,945,827.3	64,990,655.0
Property, plant and equipment	20A	60,531,657.5	65,592,651.0
Total assets		112,477,484.8	130,583,306.0
Liabilities			
Current liabilities			
Trade and other payables from exchange transactions		32,449,784.0	23,071,216.0
Deferred income – GTZ Donated Assets (PPE)	20B	25,971,618.1	30,718,966.0
Non-current employee benefit obligation - Gratuity		5,521,175.6	-
		63,942,577.7	53,790,182.0
Non-current liabilities			
Non-current employee benefit obligation - Gratuity	21B	3,791,918.9	2,019,046.0
NHIF MEDICAL SCHEME			-
Total liabilities		67,734,496.6	55,809,228.0
Net assets			
Accumulated surplus B/F		74,774,078.0	48,652,536.0
(Deficit) / Surplus for the year		(30,031,089.8)	14,667,676.1
Asset Restatement / revaluation		0	11,453,865.90
Accumulated surplus C/D		44,742,988.2	74,774,078.0
Total net assets and liabilities		112,477,484.8	130,583,306.0

The Financial Statements set out on pages 32 to 37 were signed on behalf of the Board of Directors by:

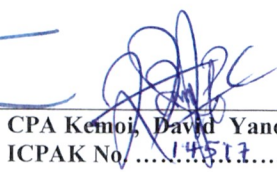
Accounting Officer / Director

Head of Finance

Chairperson of the Board



Prof. Matilu Mwau, D.Phil
(Oxon), OGW



CPA Kemoi David Yano
ICPAK No. 14511



Ms. Georgina Muchai (CPA),
For: Chairperson, Board of Management

Date 20 April, 2022

Date 20 April, 2022

Date 20 April, 2022

NATIONAL QUALITY CONTROL LABORATORY
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STATEMENT OF CHANGES IN NET ASSETS FOR THE YEAR ENDED 30 JUNE 2021

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
Surplus / Deficit for the Year	14,667,676	14,667,676
Balance as at 30 June, 2020	63,320,212	63,320,212
Surplus / Deficit for the Year	(30,031,089.8)	(30,031,089.8)
Balance as at 30 June, 2021	33,289,122	33,289,122

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NATIONAL QUALITY CONTROL LABORATORY
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13. STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30 JUNE 2021


		2020 - 2021	2019 - 2020
		Kshs	Kshs
Cash flows from operating activities			
Receipts			
Rendering of services – A-I-A Income	8	35,838,700.0	83,055,625.0
Other income - (GMP certification)	.	-	-
Other income - (GoK Grants)		2,572,873.0	1,503,459.0
Total Receipts		38,411,573.0	84,559,084.0
Payments			
Compensation of employees (Staff)	10	30,381,321.0	27,164,287.0
Board Expenses	11	649,026.0	2,743,060.0
Goods and services Repairs & Maintenance	13	8,241,575.0	13,167,489.0
Other payments (General / Admin/ office exp)	14	20,157,453.0	19,156,384.0
Finance cost	15	131,609.9	151,495.0
Total Payments		59,560,984.9	62,382,715.0
Net cash flows from operating activities ;		(21,149,411.9)	22,176,369.0
Cash flows from investing activities;			
Property, Plant, Equipment & intangible assets - Purchase	20	(341,040.0)	(190,205.0)
Proceeds from sale of property, plant and Equipment		-	-
(Increase) / Decrease in non-current receivables	17-8	4,920,500.9	(4,057,179.0)
(Increase) / Decrease in inventories	19	(1,239,078.4)	(4,192,168.0)
Increase / (Decrease) in payables	21	13,170,486.9	(1,930,650.0)
(Increase) / Decrease in Payables – staff Gratuity	22	1,772,872.9	(10,866,225.0)
Net cash flows used in investing activities		18,283,742.3	(21,236,427.0)
Cash flows from financing activities;			
(Decrease) Increase in deposits - prepayments	21	(9,378,568.0)	(4,246,493.0)
Net cash flows used in financing activities		(9,378,568.0)	(4,246,493.0)
Net increase/(decrease) in cash and cash equivalents		(12,244,237.6)	26,005,925.0
Cash and cash equivalents at 1 JULY	16	32,067,900.0	6,061,975.0
Cash and cash equivalents at 30 JUNE	16	19,823,662.4	32,067,900.0

Accounting Officer / Director

Head of Finance

Chairperson of the Board


 Prof. Matilu Mwau, D.Phil
 (Oxon), OGW


 CPA Kemoi, David Yano
 ICPAK No.



Ms. Georgina Muchai (CPA),
 For: Chairperson, Board of
 Management

Date 20 April, 2022

Date 20 April, 2022

Date 20 April, 2022

NATIONAL QUALITY CONTROL LABORATORY
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14. STATEMENT OF COMPARISON OF BUDGET AND ACTUAL AMOUNTS FOR THE YEAR ENDED 30 JUNE 2021

PERIOD	2020-2021	2020-2021	2020-2021	2020-2021	2020-2021	2020-2021
	Kshs	Kshs	Kshs	Kshs	Kshs	Kshs
Revenue	4,393,497.00	0.00	4,393,497.00	4,120,587.4	(272,909.6)	
Public contributions and donations	29,271,000	0.00	29,271,000	2,572,873.0	(26,698,127.0)	A* (i)
Government grants and subsidies – AIE, Approved estimates	65,694,000	0.00	65,694,000	35,838,700.0	(29,855,300.0)	F* (ii)
Rendering of services – AJA	1,010,000	0.00	1,010,000	-	(1,010,000.0)	A* (iii)
Rendering of services – GMP certification	100,368,497.00	0.00	100,368,497.00	42,532,160.4	(57,836,336.6)	
Total income		0.00				
Expenses						
Grants and subsidies -	29,271,000	0.00	29,271,000	-	29,271,000.0	F* (iv)
Property Plant & Equipment	0	0.00	0	341,040.0	(341,040.0)	A* (v)
Compensation of Employees ()	25,283,000	0.00	25,283,000	30,381,321.0	(5,098,321.0)	A* (vi)
Remuneration to the Board	3,670,000	0.00	3,670,000	649,026.0	3,020,974.0	F* (vii)
Goods and services (Repairs / Maintenance)	13,426,000	0.00	13,426,000	8,241,575.0	5,184,425.0	A* (viii)
Finance cost – Bank charges	0	0.00	0	131,609.9	(131,609.9)	A* (ix)
General/Admin exp - Other payments (Operating)	53,481,000	0.00	53,481,000	20,157,453.0	33,323,547.0	F* (x)
Electricity Other GoK	29,271,000	0.00	29,271,000	2,572,873.0	26,698,127.0	F* (xi)
Total expenditure	154,402,000.00	0.00	154,402,000.00	62,474,897.9	91,927,102.1	
Surplus (Deficit) for the period	(54,033,503.00)	-	(54,033,503.00)	(19,942,737.52)	(149,763,438.72)	

Note: Source of the data is approved 2020-21 Budget

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.

NATIONAL QUALITY CONTROL LABORATORY
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SURPLUS/ DEFICIT RECONCILIATION

Description	2020-2021	2019-2020
	KShs	KShs
Surplus/ deficit as per statement of financial performance	(30,031,089.8)	14,567,677.0
Donations	4,120,600.0	4,393,497.0
MoH (Electricity and Imprest)	2,572,900.0	1,503,459.0
Finance cost	131,609.9	0
Provision B/DD – 558771, Audit fees - 348000	906,771.0	0
Depreciation	2,356,471.0	0
Total transfers and sponsorships	(19,942,737.52)	20,464,633.0

- (i) **Government Grants and Subsidies - AIE; Kshs. (26,698,127.0) – A* variance**
 We budgeted for Kshs. 29,271,000 which included Electricity but received Kshs. 2,572,873 in payments for Electricity resulting to the difference on account of unabsorbed / unspent funds inversely meaning services budgeted for could not be rendered.
- (ii) **Rendering Services AIA (Internally Generated funds); Kshs. (29,855,300.0) – F* variance**
 During the year our targeted to raise ksh. 62,565,000 in our Budget yet in the year under review, we generated / earned ksh. 35,838,700 hence the variance.
- (iii) **Rendering of services – GMP certification; Kshs. (1,010,000.0) – A* variance**
 There is no GMP certification fee received for the period.
- (iv) **Grants & Subsidies – GoK expenditure Kshs. 29,271,000 – F* variance**
 This arose from null receipt from the Ministry with regards to AIE
- (v) **Property, Plant & Equipment; Kshs. (341,040.) – A* variance**
 There PPE purchased by the laboratory during the financial year.
- (vi) **Compensation of Employee’s Kshs.(5,098,321.0) – A* variance**
 This resulted from an increase recruitment of contracted staff numbers increased as budgeted 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. 3,020,974.0 – F* variance**
 This is due to the reduced number of sittings of the Board members to three (3) in the year under review being fewer than anticipated.
- Goods and Services – Repairs & Maintenance Kshs. 5,184,425 – A* variance**
 This resulted from a reduction in the Laboratory operations hence the adverse variance of repairs and maintenance costs.
- (viii) **Finance Cost Kshs. (131,609.9) A* 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.
- (ix) **General / Administrative Expenses (Other Payments) - Kshs. 33,323,547.0 – 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.
- (x) **Electricity & Other GoK Grants - Kshs. 26,698,127 – F* favorable**
 During the year our budgeted target was ksh. 27,876,000 yet in the year under review, we received ksh. 2,572,873 hence the variance.

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15. NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2021

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 National Quality Control Laboratory is wholly owned by the Government of Kenya and is domiciled in Kenya. The National Quality Control Laboratory'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 2021

Standard	Impact
IPSAS 39: Employee Benefits	Applicable: 1st January 2018 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: 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. This standard has not been applied.

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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:
<p>IPSAS 41: Financial Instruments</p>	<p>Applicable: 1st January 2022: 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 National Quality Control Laboratory’s future cash flows. IPSAS 41 provides users of financial statements with more useful information than IPSAS 29, by:</p> <ul style="list-style-type: none"> • 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; • Applying a single forward-looking expected credit loss model that is applicable to all financial instruments subject to impairment testing; and • Applying an improved hedge accounting model that broadens the hedging arrangements in scope of the guidance. The model develops a strong link between an National Quality Control Laboratory’s risk management strategies and the accounting treatment for instruments held as part of the risk management strategy.
<p>IPSAS 42: Social Benefits</p>	<p>Applicable: 1st January 2022 The objective of this Standard is to improve the relevance, faithful representativeness and comparability of the information that a reporting National Quality Control Laboratory provides in its financial statements about social benefits. The information provided should help users of the financial statements and general purpose financial reports assess:</p> <ol style="list-style-type: none"> (a) The nature of such social benefits provided by the National Quality Control Laboratory; (b) The key features of the operation of those social benefit schemes; and (c) The impact of such social benefits provided on the National Quality Control Laboratory’s financial performance, financial position and cash flows.

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NOTES TO THE FINANCIAL STATEMENTS (Continued)

<p>Amendments to Other IPSAS resulting from IPSAS 41, Financial Instruments</p>	<p>Applicable: 1st January 2022:</p> <ul style="list-style-type: none"> 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. b) Amendments to IPSAS 30, regarding illustrative examples on hedging and credit risk which were inadvertently omitted when IPSAS 41 was issued. c) Amendments to IPSAS 30, to update the guidance for accounting for financial guarantee contracts which were inadvertently omitted when IPSAS 41 was issued. <p>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.</p>
<p>Other Improvements to IPSAS</p>	<p>Applicable: 1st January 2021:</p> <ul style="list-style-type: none"> 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 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 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. 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 National Quality Control Laboratory has to the extent possible adopted some of the effectively maturing new or amended standards in year 2021.

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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 National Quality Control Laboratory 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 National Quality Control Laboratory 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 National Quality Control Laboratory 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 National Quality Control Laboratory 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 2020-2021 was approved by the BOD 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 National Quality Control Laboratory upon receiving the respective approvals in order to conclude the final budget.

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NOTES TO THE FINANCIAL STATEMENTS (Continued)

4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

b) Budget information (Continued)

There were recorded additional appropriations on the 2020-202120 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 National Quality Control 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 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 National Quality Control Laboratory 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

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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 National Quality Control Laboratory 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.

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NOTES TO THE FINANCIAL STATEMENTS (Continued)

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 National Quality Control Laboratory 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 National Quality Control Laboratory 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 National Quality Control Laboratory assesses at each reporting date whether there is objective evidence that a financial asset or an National Quality Control Laboratory of financial assets is impaired. A financial asset or a National Quality Control Laboratory 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 National Quality Control Laboratory of financial assets that can be reliably estimated.

Evidence of impairment may include the following indicators:

- The debtors or National Quality Control Laboratory 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

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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 National Quality Control Laboratory 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.

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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 at 3%.

Contingent liabilities

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

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NOTES TO THE FINANCIAL STATEMENTS (Continued)

4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

a separate National Quality Control Laboratory (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 National Quality Control Laboratory (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 National Quality Control Laboratory, 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

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NOTES TO THE FINANCIAL STATEMENTS (Continued)

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 2020-2021 and projections for 2021-22 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 National Quality Control Laboratory did not record additional adjustments on the 2020-21 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 30 June, 2021.

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

p) Provisions

Provisions were raised and management determined a 3% estimate of Bad and Doubtful Debts –outstanding as at the end of the period under review estimate based on the information available.



NOTES TO THE FINANCIAL STATEMENTS (Continued)

Additional disclosure of these estimates of provisions is included in Note 17. 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 National Quality Control Laboratory'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 National Quality Control Laboratory 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 National Quality Control Laboratory. 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 National Quality Control Laboratory
- 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	2020 – 2021	2019 – 2020
	Kshs	Kshs
GTZ Donations	4,120,600	4,393,497
Total transfers and sponsorships	4,120,600	4,393,497

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.

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NOTES TO THE FINANCIAL STATEMENTS (Continued)

7. TRANSFERS FROM MINISTRIES, DEPARTMENTS AND AGENCIES

Name of the National Quality Control Laboratory sending the grant	Amount recognized to Statement of Financial Performance KShs	Amount deferred under deferred income.	Amount recognised in capital fund.	Total grant income during the year	2020-2021	2019-2020
			KShs	KShs	KShs	KShs
Ministry of Health	2,572,873.0				2,572,873.0	1,503,459
KEMSA Equipment						0
MoH Imprest						0
Total KShs	2,572,873.0				2,572,873.0	1,503,459

Note;

The Laboratory does not receive transfers directly from the Treasury or the Ministry of Health 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	2020-2021	2019-2020
	Kshs	Kshs
Analysis fees	35,838,700	83,055,625
GMP Inspection Certification - fees	0	0
Total revenue from rendering of service	35,838,700	83,055,625

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.

9. USE OF GOODS AND SERVICES

Description	2020-2021	2019-2020
	Kshs	Kshs
Electricity	2,572,873	1,503,459
Total good and services	2,572,873	1,503,459

NQCL consumed electricity paid by MOH for the two (2) Financial years

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NOTES TO THE FINANCIAL STATEMENTS (Continued)

10. EMPLOYEE COSTS

Description	2020-2021	2019-2020
	Kshs	Kshs
Basic Salaries and wages	7,980,616	6,335,625
Extraneous allowance-MOH Staff	4,140,000	4,453,000
Employee related costs, NHIF & NSSF = 365000+117200	482,500	451,600
Employee related costs – PAYE	4,785,900	5,094,064
Travel allowances – Diff. increased staff	1,600,000	1,570,000
Housing benefits and allowances	5,240,200	5,011,500
Risk allow	1,600,000	1,570,000
Overtime	0	417,054
Sub -Total Employee costs	25,829,216	24,902,843
Leave pay 2020-21	162,000	159,000
Employee related costs – NSSF (employer-paid)	64,800	62,800
Employee related costs – Medical scheme	2,756,159	2,039,644
Gratuity, Net – one year contract staff	1,569,146	0
Sub -Total Employee costs	4,552,105	0
Total Employee costs	30,381,321	27,164,287

11. REMUNERATION THE BOARD OF DIRECTORS

Description	2020-2021	2019-2020
	Kshs	Kshs
Lunch	112,000	136,000
Sitting Allowance	502,250	723,500
Accommodation		826,000
Travel	34,776	1,057,560
Chairman’s Honoraria		0
Total Board of Director’s emoluments	649,026	2,743,060

12. DEPRECIATION AND AMORTIZATION EXPENSES

Description	2020-2021	2019-2020
	Kshs	Kshs
Property, plant and equipment - GoK Note 20A	5,402,034	6,008,223
Property, plant and equipment – Donation Note 20B	4,120,587	4,393,497
Total depreciation and amortization	9,522,621	10,401,720

13. REPAIRS AND MAINTENANCE

Description	2020-2021	2019-2020
	Kshs	Kshs
Equipment and Machinery	8,241,575	13,167,489
Total repairs and maintenance	8,241,575	13,167,489

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NOTES TO THE FINANCIAL STATEMENTS (Continued)

14. GENERAL/ADMINISTRATIVE + CHEMICAL/REAGENT EXPENSES

Description	2020-2021	2019-2020
	Kshs	Kshs
Admin fees - Office expenses	3,246,822	2,712,956
Audit fees	0	348,000
Professional & Consulting fees	1,644,689	1,685,126
Legal costs	0	-
Consumables – (Lunches / snacks)	610,030	821,561
Electricity - Note 9 KSH. 2,572,873	0	-
Fuel and oil - Generator.	489,398	86,410
Chemicals & Reagents	10,184,857	5,030,868
Printing and stationery	882,248	836,340
Telecommunication (Telephone, internet & Postage)	965,160	858,927
Training	0	1,525,187
Others - Travelling / Motor vehicle costs	2,134,249	3,129,291
Total general expenses	20,157,453	17,652,925

15. FINANCE COSTS

Description	2020-2021	2019-2020
	Kshs	Kshs
Bank charges	131,609.	151,495
Total finance costs	131,609.9	151,495

16. CASH AND CASH EQUIVALENTS

Description	2020-2021 Kshs	2019-2020 Kshs
Current account	19,823,662.4	32,067,900
Total cash and cash equivalents	19,823,662.4	32,067,900

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

Financial institution - 11711	Account number	2020-2021 Kshs	2019-2020 Kshs
a) Current account			
National Bank of Kenya Ltd	01001031744600	20,283,800.4	32,067,900
Sub- total		20,283,800.4	32,067,900
b) Others (...)			
Cash in transit – Unpresented Cheques		(478,738)	
Cash in hand		0	
Payments in bank statements not in cashbook			
Sub- total			0
Grand total		19,823,662.4	32,067,900

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17. A) RECEIVABLES FROM EXCHANGE TRANSACTIONS

Description	2020-2021 Kshs	2019-2020 Kshs
Current receivables		
Other exchange debtors- AIA fees	10,999,397	16,662,637
Less: impairment allowance		-
Total current receivables		
Non-current receivables		
Non-current receivables – Uncollectable	7,626,317.0	10,153,027
Total non-current receivables		
Sub -Total receivables	18,625,713	26,815,664
Less: impairment allowance		-
Total receivables	18,625,713	26,815,664

Note 17B. PROVISION FOR BAD & DOUBTFUL DEBTS

Description	2020-2021 Kshs	2019-2020 Kshs
Provision For Bad & Doubtful Debts – 18625714	558,771	804,470
Total receivables	558,771	804,470
The laboratory Policy on total Debtors is 3%		

18. RECEIVABLES FROM NON-EXCHANGE TRANSACTIONS.

Description	2020-2021 Kshs	2019-2020 Kshs
Current receivables		
Other debtors - staff advance,	243,000	143,000
Less: impairment allowance		
Total current receivables	243,000	143,000

19. INVENTORIES.

Description	2020-2021 Kshs	2019-2020 Kshs
Consumable stores	8,935,324.00	5,964,091
Medical supplies	5,206,990.00	-
Spare parts and meters - Consumables	-	-
Total inventories at the lower of cost and net realizable value	13,253,451.3	5,964,091.0

20. PROPERTIES, PLANT AND EQUIPMENT.

Tabulated below;

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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	Total computation reported
DEP. METHOD & RATE/ POLICY	Straight Line - 2.5%	Reducing Balance - 12.5%	Straight Line - 12.5%	Straight Line - 30%	Straight Line - 12.5%	F.Y 2016 - 2017 (Kshs)	2015 - 2016 (Kshs)
Net Book Values As at 30 June, 2015	<u>12,563,280</u>	<u>32,199,488</u>	<u>3,011,516</u>	<u>2,241,190</u>	<u>5,806,480</u>	<u>55,821,954</u>	<u>55,821,954</u>
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 July 2015	<u>15,850,595</u>	<u>57,851,723</u>	<u>4,836,891</u>	<u>8,647,464</u>	<u>7,408,283</u>	<u>94,594,956</u>	<u>94,594,956</u>
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	<u>3,774,198</u>	<u>64,945,566</u>	<u>5,221,654</u>	<u>3,842,902</u>	<u>3,103,466</u>	<u>80,887,786</u>	<u>32,788,336</u>
Less: GTZ Donations, Adjusted NBV B/D	(4,178,207)	-	-	-	-	-4,178,207	(3,793,445)
Net Book Values as at 30 June 2016	<u>11,370,556</u>	<u>50,620,258</u>	<u>3,719,275</u>	<u>5,765,072</u>	<u>6,240,311</u>	<u>77,715,472</u>	<u>58,013,176</u>
Additions 2016 - June,17	1,280,000	2,552,000	-	-	-	3,832,000	-
Totals Cost / NBV as at 30 June,2017	<u>12,650,556</u>	<u>53,172,258</u>	<u>3,719,275</u>	<u>5,765,072</u>	<u>6,240,311</u>	<u>81,547,472</u>	-
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	<u>4,108,030</u>	<u>71,592,098</u>	<u>5,221,654</u>	<u>5,765,072</u>	<u>4,271,438</u>	<u>90,958,292</u>	-
Net Book Values - 30 June 2017	<u>12,316,724</u>	<u>46,525,726</u>	<u>3,719,275</u>	<u>5,765,072</u>	<u>5,072,339</u>	<u>73,399,136</u>	-
Additions (Disposal) 2017- June,18	-	-	-	-	-	0	-
Totals Cost / NBV - 30 June,2018	<u>12,316,724</u>	<u>58,186,036</u>	<u>5,765,072</u>	<u>5,765,072</u>	<u>5,072,339</u>	<u>81,340,171</u>	-
Depreciation charge for the year, 2017 - 18	333,832	7,273,254	0	0	800,900	8,407,986	-
Accumm Depreciation -30 June 2018	<u>4,441,862</u>	<u>78,865,353</u>	<u>5,221,654</u>	<u>5,765,072</u>	<u>5,072,339</u>	<u>99,366,280</u>	-

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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
Additions (Disposal) 2020-2021	0	0	0	341,040	0	341,040
Accumm Depreciation - 1st July 2020	5,109,526	11,336,031	5,228,030	5,765,072	5,072,339	32,510,997
Depreciation charge for the year, 2020 -21	333,832	4,959,514	6,376	102,312	0	5,402,034
Accumm Depreciation - 30 June 2021	5,443,358	16,295,545	5,234,406	5,867,384	5,072,339	37,913,031
Net Book Values as at 30 June 2021	10,981,396	34,716,595	3,757,528	6,003,800	5,072,339	60,531,658

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 duly 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.

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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**



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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
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
Charge for the year 2020-21	6,176	-	248,622	1,388,834	2,476,956	4,120,587
NBV B/D 2020-2021	1,545	-	1,740,354	9,721,835	14,507,884	25,971,618

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

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Description	2020-2021	2019-2020
	Kshs	Kshs
International funders		
Public contributions and donations	4,120,587	4,393,497
Total deferred income	4,120,587	4,393,497

The deferred income movement is as follows:

	National government	International funders – GTZ	Public contributions and donations	Total
Balance brought forward	-	30,718,966	-	30,718,966
Additions / Transfers to Capital fund	- (-)	- (-)	- (-)	- (-)
Transfers to income statement	(-)	(4,120,587)	(-)	(4,120,587)
Other transfers	(-)	(-)	(-)	(-)
Balance carried forward	-	25,971,618	-	25,971,618

21. A) TRADE AND OTHER PAYABLES FROM EXCHANGE TRANSACTIONS

Description	2020-2021	2019-2020
	Kshs	Kshs
Trade payables	3,136,714	2,189,535
Electricity =77666+98444+111509	5,653,351	435,369
Payments received in advance – Analysis fees	22,905,331	19,072,884
Employee costs		
PAYE- June, 2021	406,388	444,278
NSSF- Outstanding	10,400	10,400
Unapplied Salary Dr. Khadijah Mohammed	0	222,750
Other payables - OAG	348,000	696,000
Total trade and other payables	32,449,784	23,071,216

21 B. EMPLOYEE BENEFIT OBLIGATIONS

Description	Defined benefit plan	Postemployment medical benefits	Other Provisions	2020-2021	TOTAL 2019-2020
	KShs	KShs	KShs	Kshs	KShs
Current benefit obligation – lot Lot 1 Contracted staff	-	-	-	5521176	9,424,230
Non-current benefit obligation – Lot 2 contracted staff	-	-	-	3791918	-
Total employee benefits obligation gratuity	-	-	-	9,313,094	9,424,230

Gratuity (lot 1 & 2) – Outstanding (3,903,054+5,521,176)

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The National Quality Control Laboratory 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:

	2020-2021	2019-2020
	Kshs	Kshs
Valuation at the beginning of the year	1,951,526.9	2,019,046
Changes in valuation during the year		0
Valuation at end of the year	1,951,526.9	2,019,046

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)	-	5,521,176	-	5,521,176
Additional Provisions gratuity	-	3791918	-	3,903,054
Provision utilised – Audit fees			348,000	348,000
Change due to discount and time value for money (effects)	-	-	(-)	-
Less: Current portion	(-)	(-)	(-)	(-)
Total income (Decrease) / increase in provision		9,313,094	348,000	9,772,230

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

	2020-2021	2019-2020
	Kshs	Kshs
Surplus for the year before tax		
Adjusted for:		
Depreciation (-)	9,522,621	10,401,720
Finance cost	131,431	151,495
Working Capital adjustments		
Increase in inventory	(6,699,360.7)	(4,192,168)
Increase in receivables	(4,986,060.5)	(9,788,770)
Increase in deferred income	4120587	(626,760)
Increase in payables	12,935,777.3	4,408,781
Increase in provision		5,028,556
Net cash flow from operating activities	15,024,995	5,382,854

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25. FINANCIAL RISK MANAGEMENT

The National Quality Control Laboratory'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 National Quality Control Laboratory's financial risk management objectives and policies are detailed below:

i) Credit Risk

The National Quality Control Laboratory 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 National Quality Control Laboratory'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 2021	Kshs	Kshs	Kshs	Kshs
Receivables from exchange transactions	18,868,713.6	16,662,637	10,153,027	-
Receivables from non-exchange transactions	243,000	143,000	-	-
Bank balances	19,822,462	32,067,900	-	-
Total	38,934,176	48,873,537	10,153,027	-
At 30 June 2020				
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.

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NOTES TO THE FINANCIAL STATEMENTS (Continued)
FINANCIAL RISK MANAGEMENT (Continued)

i) Credit risk (Continued)

The National Quality Control Laboratory 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 National Quality Control Laboratory'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 National Quality Control Laboratory 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 2021				
Trade payables	-	-	3,136,714	3,136,714
Provisions - KENAO	-	-	348,000	348,000
Employee benefit obligation	-	-	5,521,176	5,521,176
Total			9,005,890	9,005,890
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 National Quality Control Laboratory on an on-going basis, evaluate and test the design and effectiveness of its internal accounting and operational controls.

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NOTES TO THE FINANCIAL STATEMENTS (Continued)
FINANCIAL RISK MANAGEMENT (Continued)

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 National Quality Control Laboratory'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.

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 National Quality Control Laboratory's exposure to market risks or the manner in which it manages and measures the risk.

a) Foreign currency risk

The National Quality Control Laboratory 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 National Quality Control Laboratory'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 National Quality Control Laboratory 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 2021			
Financial assets (investments, cash ,debtors)	0	0	0
Liabilities			
Trade and other payables			
Net foreign currency asset/(liability)	0	0	0

Foreign currency sensitivity analysis

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NOTES TO THE FINANCIAL STATEMENTS (Continued)

FINANCIAL RISK MANAGEMENT (Continued)

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

iii) Market risk (Continued)

also occur if the Kenya Shilling appreciated with all other variables held constant.

	Change in currency rate	Effect on Profit before tax	Effect on equity
	Kshs	Kshs	Kshs
2021			
Euro	10%	0	0
USD	10%	0	0
2020			
Euro	10%	0	0
USD	10%	0	0
2019			
Euro	10%	0	0
USD	10%	0	0

b) Interest rate risk

Interest rate risk is the risk that the National Quality Control Laboratory'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. We equally, intend to minimise regular withdrawals of cash by executing planned periodic payment of suppliers.

Sensitivity analysis

The National Quality Control Laboratory 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 - (2021: KShs -). A rate increase/decrease of 5% would result in a decrease/increase in profit before tax of KShs - (2021 - 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 National Quality Control Laboratory's market assumptions. These two types of inputs have created the following fair value hierarchy:

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NOTES TO THE FINANCIAL STATEMENTS (Continued)

FINANCIAL RISK MANAGEMENT (Continued)

iv) Capital Risk Management (Continued)

	2020-2021	2019-2020
	Kshs	Kshs
Revaluation reserve	14,667,677	14,667,677
Retained earnings		
Capital reserve	48,635,341	48,635,341
Total funds	63,303,018	63,303,018
Total borrowings	-	-
Less: cash and bank balances	32,067,900	32,067,900
Net debt/(excess cash and cash equivalents)	31,235,118	31,235,118
Gearing	49.5%	49.5%

26. RELATED PARTY BALANCES

Nature of related party relationships

Entities and other parties related to the National Quality Control Laboratory 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 National Quality Control Laboratory, both domestic and external. Other related parties include:

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

NOTES TO THE FINANCIAL STATEMENTS (Continued)

RELATED PARTY BALANCES (Continued)

	2020-2021	2019-2020
	Kshs	Kshs
Transactions with related parties;		
a) Sales to related parties		
Sales of goods / services to a related MDA's - KEMSA	5,030,800	56,958,979
Total	5,030,800	54,675,205
b) Grants from the Government		
Grants from National Gov't – MoH	2,572,873	1,503,459
Donations in kind - GTZ	4,120,600	4,393,497
Total	6,693,473	5,896,956
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	-	-

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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 National Quality Control Laboratory 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	-	-	-	60,531,658
At 30 June 2021				60,531,658
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:

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 National Quality Control Laboratory’s capital risk management is to safeguard the Board’s ability to continue as a going concern. The National Quality Control Laboratory capital structure comprises of the following funds:

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d) Key management compensation		
Directors' emoluments	-	-
Compensation to the CEO	600,000	600,000
Compensation to key management (Directors)	649,026	2,743,060
Total	10,400,426	62,411,762

27. CONTINGENT ASSETS AND CONTINGENT LIABILITIES

Contingent liabilities	2020-2021	2019-2020
	Kshs	Kshs
Court case no against the Laboratory		
Bank guarantees in favour of subsidiary		
Total		

28. CAPITAL COMMITMENTS

Capital commitments	2020-2021	2019-2020
	Kshs	Kshs
Authorised for		
Authorised and contracted for		
Total		

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 National Quality Control Laboratory did not remit any surplus to the Consolidated Fund. [Entities to edit accordingly].

30. TAXATION

	2020-2021	2019-2020
	Kshs	Kshs
At beginning of the year		
Income tax charge for the year (note 27)		
Under/(over) provision in prior year/s (note 27)		
Income tax paid during the year		
At end of the year		

[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 NATIONAL QUALITY CONTROL LABORATORY

The National Quality Control Laboratory 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).

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16. 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	In adequate provision of Bad & doubtful debts. Validity and recoverability of ksh. 7,626,317 for Trade & Other receivables	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 as bad debt using the laid down policy once approved by the BOD	Board of Management	Not Resolved	June, 2019
3.0	Operating without a Board and failure to comply with PPB Act	The BOD has since been appointed vide The Kenya Gazette notice (no. 1940) Vol. CXX- No 29 dated 02 nd March, 2018 and inaugurated on April, 2018 to execute their mandate.	Pharmacy and Poisons Board	Resolved	March, 2018

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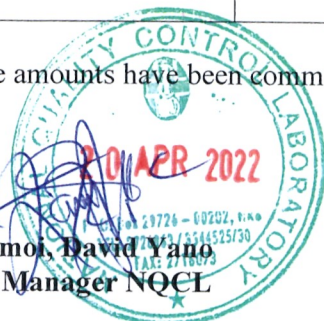
APPENDIX II: INTER-NATIONAL QUALITY CONTROL LABORATORY TRANSFERS

	NATIONAL QUALITY CONTROL LABORATORY NAME:	National Quality Control Laboratory		
Break down of Transfers from the State Department of Health				
	FY 20/21			
a.	Recurrent Grants			
		<u>Bank Statement Date</u>	<u>Amount (KShs)</u>	<u>Indicate the FY to which the amounts relate</u>
		June, 2021	2,572,900	2020-2021
		Total	2,572,900	
b.	Development Grants			
		<u>Bank Statement Date</u>	<u>Amount (KShs)</u>	<u>Indicate the FY to which the amounts relate</u>
		June, 2021	-	2020-2021
		Total	-	
c.	Direct Payments			
		<u>Bank Statement Date</u>	<u>Amount (KShs)</u>	<u>Indicate the FY to which the amounts relate</u>
	NASCOP	As at June, 2021	0	2020/21
	KEMSA	As at June, 2021	4,170,800	2020/21
	PPB	As at June, 2021	860,000	2020/21
		Total	5,030,800	

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


CPA Kemol David Yano
Finance Manager NOCL

Date 20 April, 2022



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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	Statement of Financial Performance	Where Recorded/recognized				Total Transfers during the Year
					Capital Fund	Deferred Income	Receivables	Others - must be specific	
Ministry of Health (DS&R, DoFH)	2020-21	Direct Payment	2,572,873	2,572,873	-	-	5,653,351	0	10,799,097
MoH - KEMSA	2020-21	Recurrent - Equipment	3,353,060	-	-	-	-	-	3,353,060
Pharmacy & Poisons Board - PPB	2020-21	Direct Payment - Analysis	860,000	860,000	-	-	-	-	1,720,000
NASCOP	2020-21	Direct Payment - Analysis	0	0	-	-	0	-	0
KEMSA - Debt	2004	Direct Payment	-	-	-	-	6,013,120	-	6,013,120
Total - Ksh			6,785,933	3,432,873	0	0	11,666,471	0	21,885,277



5005 994 2.5