

User Requirements Document

Divisional Support Services
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User Requirements Document

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Project:	Electronic Result Management System
Module:	LIMS Result Interfacing – Microbiology
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1. Terms and Definitions

Term	Definition
Acute health parameters	<i>Determinand that poses an immediate unacceptable health risk if present at concentrations exceeding the acceptable limits.</i>
ISO	<i>International Organisation for Standardisation</i>
Operation parameters	<i>Determinand that is essential for assessing the efficient operation of treatment systems and risks to infrastructure</i>
QC	<i>Procedures intended to ensure that analyses adhere to a defined set of quality criteria or meets the requirements of the client or customer</i>
SANAS	<i>South African National Accreditation System</i>
System	<i>System in this case refers to the LIMS and ELN modules performing as one, coherent and inter-linked system</i>

2. Introduction

As per the South African National Standard for Drinking Water Quality, i.e. the SANS 241, Rand Water tests for a spectrum of microbial water quality indicators to not only meet the specified legal requirements but also to ensure consumer safety. As very few opportunities exist to modernise the traditional microbial testing methods to digital systems, focus is usually placed on reducing the amount of paper-based data as well as the manual methods of analysing data and its transfer to electronic database management systems.

3. Background

The Microbiology Laboratory is responsible for testing a variety of indicator microbes that are linked to acute health outcomes from a safety standpoint or the operational efficiency from a water treatment perspective. In a week, hundreds of samples are analysed using six different methods targeting specific microorganisms. These microorganisms consist of heterotrophs, total coliforms (including faecal coliforms), *Escherichia coli*, pathogenic *Vibrio cholerae* as well as *Cryptosporidium* and *Giardia*. As an ISO 17025 accredited laboratory, quality control (QC) is an integral aspect of the testing process. This process does not only ensure that the results produced are true and accurate but also comparable to that of international testing standards. Unfortunately, this process is also dependent on a great deal of data associated with each item (i.e. consumable, equipment, analysis parameters) linked to the method. This is in addition to the reading and subsequent recording of all methodological results thereof.

Moving towards a “paperless” laboratory will increase productivity by tracking paperless workflows on an electronic workbench. In doing so, other significant benefits will result in increased traceability and reliability, greater efficiency and shorter turnaround times. Therefore, as the Microbiology Laboratory has already developed and implemented an electronic batch QC and results Excel worksheet for each method, it aims to replace the

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existing worksheet with an Electronic Laboratory Notebook (ELN) directly linked to the Laboratory Information Management System (LIMS).

4. Current Laboratory Workflow

Each method follows a specific process when samples are analysed in the Microbiology Laboratory according to details provided in the method documents and associated work instructions as per Table 1 below.

Table 1 Documents related to the detailed methodological procedure for sample analysis, quality assurance and the recording of final, reportable results.

No.	Document Number	Document Title	Microbial Parameters Investigated
1	1.2.2.01.1	Heterotrophic plate count	Total heterotrophs
2	1.2.2.02.1	Detection and enumeration of faecal coliforms and <i>Escherichia coli</i> using the Colilert®-18/Quanti-Tray® 2000 method	<i>Escherichia coli</i> and faecal coliforms:
3	1.2.2.05.1	Determination of coliphages	Somatic coliphages
4	1.2.2.06.1	Isolation and detection of <i>Cryptosporidium</i> and <i>Giardia</i>	<i>Cryptosporidium</i> and <i>Giardia</i> species [(oo)cysts]
5	1.2.2.09.1	Detection and enumeration of <i>Escherichia coli</i> and coliform bacteria using the Colilert®-18/Quanti-Tray® and Colilert®-18/Quanti-Tray® 2000 method	<i>Escherichia coli</i> and coliforms (total)
6	1.2.2.10.1	Real time polymerase chain reaction assay for the <i>ctxA</i> gene of <i>V. cholerae</i>	Pathogenic <i>Vibrio cholerae</i>

A brief description of the general but complex process flow for each Microbiology method is shown in Figure 1 below. The process may be segregated into two stages, i.e. the analysis stage where the samples are collected and analysed according to the pre-determined schedule of work; and the interpretation and data transfer stage where the results are read, verified by an independent analyst and recorded prior to transfer to LIMS.

At these stages, the electronic batch QC and results Excel worksheet is utilized to record all information associated with the procedure. The worksheet is therefore a complex electronic form intended to provide all pertinent information to the user, management or independent bodies such as SANAS for ease of reference and traceability to the accuracy of the results generated. These data are then manually entered into LIMS for subsequent long term storage, management and accessibility to all authorized personnel. The manual data transfer process between the electronic worksheet and LIMS is therefore a tedious, time-consuming and error-prone process. The Microbiology Laboratory therefore intends to remove the intermediary transfer process to improve turnaround times and reduce human error.

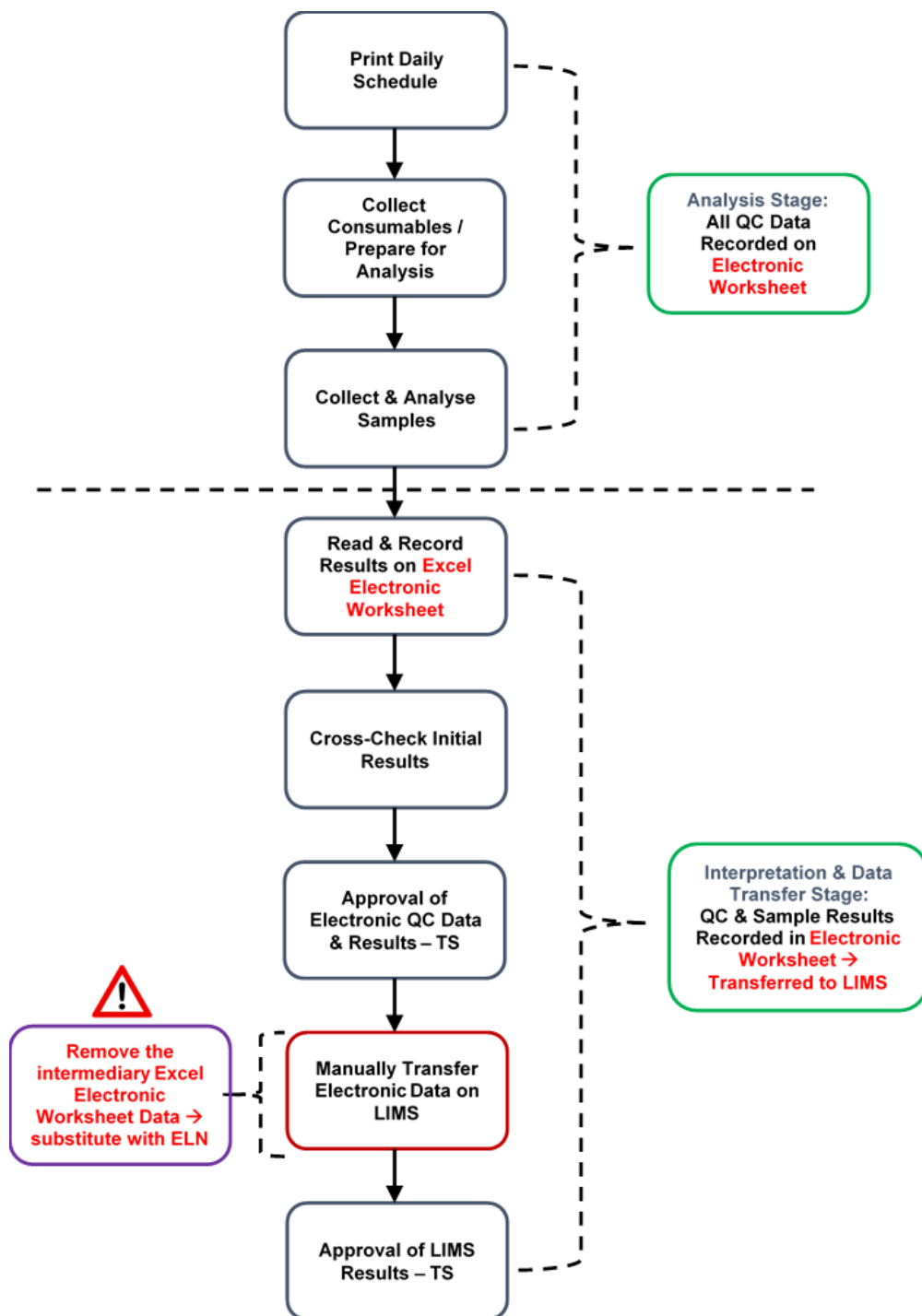
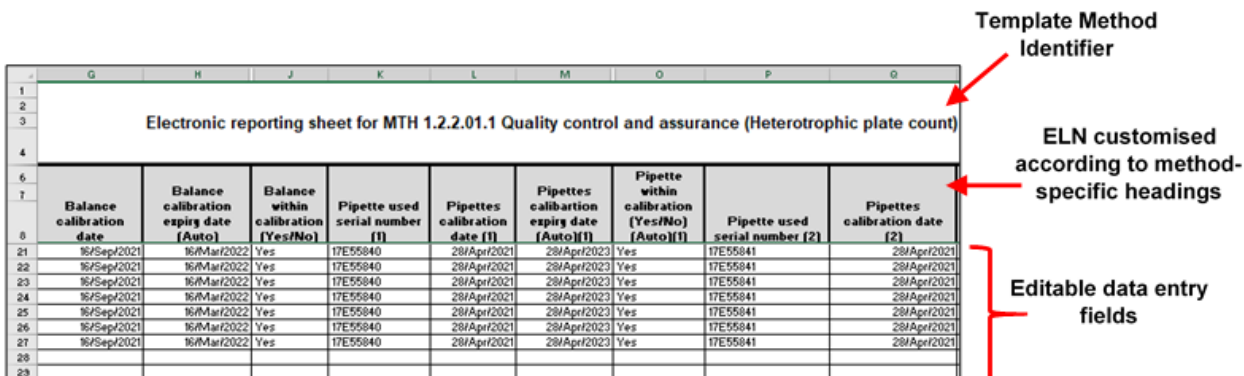


Figure 1 Schematic diagram of the general process flow for conducting analyses, recording QC data and results as well as its approval in the Microbiology Laboratory.

5. User-Defined Requirements

5.1 Development of Electronic Laboratory Notebooks (ELNs) Linked to LIMS

1. The current electronic QC and result worksheets must be evaluated for each of the six technical methods in the Microbiology Laboratory.
2. Development of customized ELN templates specific to each analytical method and according to the requirements of the current electronic Excel worksheets.



Electronic reporting sheet for MTH 1.2.2.01.1 Quality control and assurance (Heterotrophic plate count)

	Balance calibration date	Balance calibration expiry date (Auto)	Balance within calibration (Yes/No)	Pipette used serial number (1)	Pipettes calibration date (1)	Pipettes calibration expiry date (Auto)(1)	Pipette within calibration (Yes/No) (Auto)(1)	Pipette used serial number (2)	Pipettes calibration date (2)
21	16/Sep/2021	16/Mar/2022	Yes	17E55840	28/Apr/2021	28/Apr/2023	Yes	17E55841	28/Apr/2021
22	16/Sep/2021	16/Mar/2022	Yes	17E55840	28/Apr/2021	28/Apr/2023	Yes	17E55841	28/Apr/2021
23	16/Sep/2021	16/Mar/2022	Yes	17E55840	28/Apr/2021	28/Apr/2023	Yes	17E55841	28/Apr/2021
24	16/Sep/2021	16/Mar/2022	Yes	17E55840	28/Apr/2021	28/Apr/2023	Yes	17E55841	28/Apr/2021
25	16/Sep/2021	16/Mar/2022	Yes	17E55840	28/Apr/2021	28/Apr/2023	Yes	17E55841	28/Apr/2021
26	16/Sep/2021	16/Mar/2022	Yes	17E55840	28/Apr/2021	28/Apr/2023	Yes	17E55841	28/Apr/2021
27	16/Sep/2021	16/Mar/2022	Yes	17E55840	28/Apr/2021	28/Apr/2023	Yes	17E55841	28/Apr/2021
28									
29									

3. The ELN worksheets must be directly linked to LIMS – form ELN-LIMS system.
4. Where available, the system must parse data from reports produced by specific instruments to the method-specific ELN worksheets.
5. The ELN worksheets must supersede the current laboratory batch QC and results modules in LIMS.
6. Each module in the ELN-LIMS system must operate under the following conditions:
 - The ELN module operates as a recording medium for all laboratory analyses and data.
 - LIMS operates as a control and report module for all data produced in the Microbiology Laboratory.
7. The ELN worksheets must provide compliance limit checkpoints according to specific criteria as developed by the Microbiology Laboratory. Where a compliance limit is exceeded, the workbook must flag the data point according to a user-defined classification system.
8. The ELN must allow for compartmentalization of the methodological sections referenced in the Microbiology Laboratory's technical method documents. Where user-defined criteria has been developed, auto-filling of specific fields of interest must be completed by the ELN worksheets.

For example, pipette calibration is conducted at two (2) year intervals. If the data field requires the calibration expiry date or date of next calibration, then the value entered at the current calibration date should automatically calculate and autofill the date of next calibration or calibration expiry date by a period of two (2) years:







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Date of calibration = 28/04/2022
Calibration expiry = 28/04/2024

5.2 ELN-LIMS System Requirements

1. All data linked to LIMS must be accessible by ELN and vice versa. Therefore, the ELN must provide a compounded interface between the two (2) modules.
2. Where possible, the system should allow for the attachment of supporting documentation and/or intrinsic information related to the methodological process.
3. The system must allow specific (i.e. selective), identifiable report data to be parsed to the ELN. Therefore, string components must be analysed for specific and correct syntax and then attached to the specific and correct tag in the ELN worksheet.
4. The system must provide a platform for continuous additions to the ELN module for new methods, parsing of instrument data, procedural amendment, etc.

5.3 Excel reporting sheet

Method Number	Method Name	Excel
MTH 1.2.2.01.1	Heterotrophic plate count	 Copy of 06-02-2023 to 12-02-2023 Electro
MTH 1.2.2.02.1	Detection and enumeration of faecal coliforms and Escherichia coli using the Colilert®-18/Quanti-Tray® 2000	 Copy of 06-02-2023 to 10-02-2023 Electrc
MTH 1.2.2.05.1	Coliphages	 Copy of 06-02-2023 to 10-02-2023 Electro
MTH 1.2.2.06.1	Isolation and detection of Cryptosporidium and Giardia	 Copy of 06-02-2023 to 10-02-2023 Electro
MTH 1.2.2.09.1	Escherichia coli and coliform bacteria using the Colilert®-18/Quanti-Tray® and Colilert®-18/Quanti-Tray® 2000	 Copy of 06-02-2023 to 10-02-2023 Electro
MTH 1.2.2.10.1	Real-Time Polymerase Reaction Assay for the ctxA gene	 Copy of 06-02-2023 to 10-02-2023 reporti

6. User Acceptance**a) User Acceptance**

Acknowledge that the contents of this document, is correct as understood by IM.

Role	Name	Signature	Date