

Restricted	Laboratory Information Management System	 IAEA International Atomic Energy Agency	IAEA Specification Dated 17 April 2023
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Laboratory Information Management System Software

1. Scope

This specification describes the requirements for a thick client Laboratory Information Management System (LIMS) with barcode sample tracking to be installed at the State Specialized Enterprise (SSE) “Ecocentre” Central Analytical Laboratory (CAL) (hereinafter referred to as the “End-User”) in Ukraine.

The scope of this specification includes the LIMS software and the barcode tracking software and hardware (hereinafter referred to as the “System”). The scope of supply includes initial configuration of the System in consultation with the laboratory to meet the specification, installation and training of the staff of the End-User, testing of the system, ongoing technical support for a period of three (3) years and warranty service.

The End-User is responsible for the radiation and ecological sampling and monitoring within the Chernobyl Exclusion Zone territory. The CAL is operated by the SSE “Ecocentre” and undertakes laboratory analysis of environmental and waste samples. The CAL performs a wide range of chemical and radiochemical analysis and processes approximately 6 to 14 thousand samples a month. Sample tracking is currently managed using paper ‘passports’ and a LIMS including barcode sample tracking will improve the quality, efficiency and capacity of the CAL.

2. Applicable Documents

The following documents shall be applicable for this Specification to the extent specified hereinafter:

ISO7870-2:2013. Control charts - Part 2: Shewhart control charts. International Standards Organisation, Geneva, Switzerland.

ISO17025:2017. General Requirements for the competence of testing and calibration laboratories. International Standards Organisation, Geneva, Switzerland.

In the event of conflict between the documents listed above and the content of this Specification, the content of this Specification shall take precedence to the extent of the conflict.

3. Definitions, Acronyms, and Abbreviations

The following definitions, acronyms, and abbreviations shall apply throughout this Specification unless defined otherwise hereinafter:

Control point	A location used to record information on LIMS, with a barcode reader installed for scanning samples as they are moved into the location.
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SOP Standard Operating Procedure, the detailed working procedure prepared by the laboratory for each analysis method.

4. Requirements

4.1. Functional and Performance Requirements

The System shall ensure the following:

- 4.1.1. The reception and log in of a sample and its associated customer data;
- 4.1.2. The assignment, scheduling, and tracking of the sample and the associated analytical workload;
- 4.1.3. The processing and quality control associated with the sample and the utilized equipment and inventory;
- 4.1.4. The storage of data associated with the sample analysis; and
- 4.1.5. The inspection, approval and compilation of the sample data for reporting and/or further analysis;

The System shall meet the following functional and performance requirements:

- 4.1.6. Be configurable either through technical support from the supplier or by the laboratory to permit future development of the system;
- 4.1.7. Assign a unique number to each sample received for measurements in CAL;
- 4.1.8. Permit the inputting of user-defined supporting data for each sample (e.g. sampling date, sampling location);
- 4.1.9. Enable the physical tracking of samples through the departments within the laboratory using a bar-code scanning system at control points;
- 4.1.10. Permit the tracking of progress of an analytical programme of work including generation of summary progress reports;
- 4.1.11. Record user-defined details of each analytical procedure performed by the laboratory and include the SOP for the procedure in a downloadable form;
- 4.1.12. Support the recording of details of the types of analyses to be performed on a given sample and any user-defined information associated with the analysis requirements;
- 4.1.13. Support inputting of user-defined analytical information entered manually by the end user including sample masses, chemical recoveries and measurement data arising from analytical instrumentation for a minimum of 100 analytical parameters;
- 4.1.14. Support the recording of user-defined supporting information for each data input (e.g. measurement date, instrument serial number, calibration file reference);
- 4.1.15. Support the recording of quality control data from each analytical instrument and the statistical analysis and display of such data as Shewhart plots in accordance with ISO7870-2:2013;
- 4.1.16. Permit the processing of data using input data and user-defined calculations to convert input data into reportable results;

- 4.1.17. Permit the conversion of results for each analyte into different units based on industry recognized or user-defined conversion factors;
- 4.1.18. Generate analytical reports, using user-defined report templates, summarizing measurement results and supporting data for samples / analyses selected by the user;
- 4.1.19. Maintain the electronic signature system for laboratory personnel;
- 4.1.20. Permit recording of staff training on analytical and supporting procedures,
- 4.1.21. Support the archiving and retrieval of all data in a csv or equivalent format;
- 4.1.22. Incorporate a hierarchy of user-access levels permitting management of the level of access that each user is authorised for;
- 4.1.23. Incorporate security features, such as individual user password-controlled log-in, to restrict and log database access and to log the identity of the user entering input data or modifying database functionality;
- 4.1.24. Store all data in a centralised server accessible over a local area network and support simultaneous multiple-user access from up to 7 separate control points;
- 4.1.25. Support the reporting of statistics on the numbers of samples received and analyses performed for each analysis type within a user-defined timescale;
- 4.1.26. Use Ukrainian or English as the default interface language;
- 4.1.27. Be compliant with any relevant requirements for record keeping and data management in testing and calibration laboratories as specified in ISO17025:2017; and
- 4.1.28. Have been previously installed in a radioanalytical or analytical laboratory and demonstrated to operate effectively – evidenced through supporting statements from existing customers.

4.2. Technical Requirements

The System shall meet the following technical requirements:

- 4.2.1. Operating system for control point computers shall be Microsoft Windows 10; and
- 4.2.2. Include a supply of seven (7) bar-code readers and associated software compatible with the LIMS and Microsoft Windows 10.

5. Marking

The System shall have all safety markings in the Ukrainian language or the English language.

6. Packing

The System, for the shipment by air to the End-User, shall be packed in accordance with international standards that are applicable for the shipment by air of this kind of equipment.

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7. Quality Requirements

7.1. The System shall be manufactured, shipped and installed in accordance with the Contractor's ISO quality assurance system or an equivalent quality assurance system.

7.2. The Contractor shall document the compliance with this quality assurance system.

8. Testing and Acceptance

The System, prior to shipment, shall be configured and tested for conformance of the System with manufacturer's performance specifications and the minimum requirements specified herein.

The System, after installation, shall be tested by the Contractor together with the End-User to demonstrate that the performance meets the manufacturer's performance specifications and the minimum requirements specified herein as determined by the IAEA and the End-User.

The results of the testing of the System shall be documented by the Contractor in an acceptance protocol that shall be signed by the End-User.

9. Installation and Training

The Contractor shall install the System at the End-Users premises or remotely immediately following the delivery of the System on the premises.

The Contractor shall provide three (3) days training for up to eight (8) staff of the End User in the operation and maintenance of the System at the End User's location or remotely immediately after the installation of the System. The spoken language for the trainer shall be Ukrainian or English.

10. Deliverable Data Items

The Contractor shall provide two (2) hard copies and a pdf copy of the manuals to cover use, troubleshooting, servicing, upgrading the software and hardware. Manuals shall in Ukrainian or English language.

11. Warranty and Support

11.1. The System set shall be supplied with a comprehensive warranty, valid for one (1) year from date of the acceptance protocol signed by the End-User;

11.2. The Contractor shall provide a focal point for the End-User, including a valid telephone number with a human response and a valid e-mail address;

11.3. The Contractor shall provide or be able to arrange in-country or regional support to the End-User during the lifespan of the equipment; and

11.4. The Contractor shall Include an ongoing technical support for a period of minimum three (3) years following installation. The spoken language shall for the technical support shall be Ukrainian or English. The technical support shall include as a minimum:

- 11.4.1. a technical helpline where contact can be made for at least 6 hours during the End Users working day (local time Monday 10:00-19:00, Tuesday and Wednesday 08:00-19:00; Thursday 08:00-16:00); and
 - 11.4.2. provision of a services engineer at the End Users premises within one (1) working day for problems that cannot be resolved via the technical helpline.
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