Terms of Reference for the Establishment of a Laboratory Data Management Information System

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1. List of abbreviations

DEM	Department of Environmental Monitoring under the Ministry of Natural Resources, Ecology and Technical Supervision of the Kyrgyz Republic
UIS	The Unified Identification System of the Kyrgyz Republic, the functions of which are defined by the Regulation on the Unified Identification System of the Kyrgyz Republic, approved by Resolution No. 748 of the Government of the Kyrgyz Republic dated December 31, 2019. One of the main goals of the Unified Identification System is to ensure proper identification, authentication, and authorization of information about participants in information interactions while providing state and municipal services.
KAC	The Kyrgyz Accreditation Center was established by the Kyrgyz Government Resolution No. 795 of November 15, 2006, "On the Accreditation of Conformity Assessment Bodies in the Kyrgyz Republic" as an independent organization with the legal status of "state institution." DEM is an accredited organization of the KCA and is obligated to regularly submit reports to the KCA.
CBES	A cloud-based electronic signature is an electronic equivalent of a handwritten signature, containing digital symbols with the necessary information about its owner. The state-owned cloud-based electronic signature is provided by Infocom.
LIMS, IS, LIS	Laboratory Information Management System.
ToR	Terms of Reference
API	Application Programming Interface
SDATE	State Classifier - System of Designations of Administrative-Territorial and Territorial Entities (SDATE), available on the website of the National Statistics Committee of the Kyrgyz Republic
DB	Database
JSON	JavaScript Object Notation is a data interchange format.
JWT	JSON Web Token - JSON format web token
KML	Keyhole Markup Language is an XML format for representing geographic data developed for Google Earth. It is used to create building outlines, routes, points of interest (POIs), and boundaries. File extension: .kml
KMZ	Compressed KML is a compressed version of a KML file (a ZIP archive with the .kmz extension) that can include images and other supporting files. This format has the same functionality as KML, but with the ability to include media files (icons, images). File extension: .kmz
HTTP	HyperText Transfer Protocol
HTTPS	HyperText Transfer Protocol Secure
SaaS	Software as a Service
SSL certificate	A digital certificate that verifies the authenticity of a website and provides an encrypted connection between the server and the user
SQL	Structured Query Language
UI	User Interface
UX	User Experience
XML	Extensible Markup Language

2. General information

These Terms of Reference for the Establishment of the Laboratory Data Management Information System were prepared in accordance with the Interstate Standard GOST 34.602–2020 “Information Technology. Set of Standards for Automated Systems. Terms of Reference for the Creation of an Automated System,” introduced on January 1, 2022.

Full name of the system: **Laboratory Research Management Information System**

Conventional designation of the system (abbreviated name): LIMS

LIMS is an automated information system for managing laboratory research, which will be used in the Department of Environmental Monitoring under the Ministry of Natural Resources, Ecology and Technical Supervision of the Kyrgyz Republic and is intended DEM employees to work with laboratory data.

The beneficiary and owner of the LIMS is the Department of Environmental Monitoring under the Ministry of Natural Resources, Ecology and Technical Supervision of the Kyrgyz Republic.

The Customer for the implementation of the LIMS is the Climate Resilient Water Services Project Implementation Unit of the Water Resources Service under the Ministry of Water Resources, Agriculture and Processing Industry of the Kyrgyz Republic.

The Developer of the LIMS will be a software development company with which a contract will be concluded for the provision of services for the development and implementation of the automated information system.

Planned start and end dates for work on the development and implementation of the LIMS:
July 2026 - January 2028

Sources of funding
The development and implementation of the LIMS will be financed by the Climate Resilient Water Services Project Implementation Unit of the Water Resources Service under the Ministry of Water Resources, Agriculture and Processing Industry of the Kyrgyz Republic.

Regulatory framework
When developing and implementing the LIMS, the Beneficiary and the Developer shall ensure compliance with the following regulatory legal acts governing the development and implementation of information systems for state bodies of the Kyrgyz Republic, as well as DEM:

- Law of the Kyrgyz Republic "On Electronic Governance" dated July 19, 2017, No. 127
- Law of the Kyrgyz Republic "On Personal Information" dated April 14, 2008, No. 58
- Law of the Kyrgyz Republic “On the Right of Access to Information” dated December 29, 2023, No. 217
- Requirements for the procedure for the creation, development, commissioning, operation and decommissioning of state information systems, approved by the Resolution of the Government of the Kyrgyz Republic dated December 31, 2019, No. 744
- Requirements for the protection of information contained in the databases of state information systems, approved by the Resolution of the Government of the Kyrgyz Republic dated November 21, 2017, No. 762

- Requirements for ensuring the security and protection of personal data when processing them in personal data information systems, the implementation of which ensures the established levels of protection of personal data, approved by the Resolution of the Government of the Kyrgyz Republic dated November 21, 2017, No. 760
- Requirements for the interaction of information systems in the interdepartmental electronic interaction system "Tunduk", approved by the Resolution of the Government of the Kyrgyz Republic dated April 11, 2018, No. 200
- Resolution of the Government of the Kyrgyz Republic "On certain issues of the implementation of electronic governance in the Kyrgyz Republic" dated December 31, 2019, No. 748;
- Resolution of the Government of the Kyrgyz Republic "On certain issues related to basic state information resources" dated February 6, 2020, No. 66.
- GOST ISO/IEC 17025–2019 - General requirements for the proficiency of testing and calibration laboratories.

Procedure for registration and presentation of work results

LIMS is a multifunctional automated information system for laboratory research management.

The Developer shall develop specifications for the functional modules of the LIMS; after the specifications have been agreed upon, all functional modules shall be developed and tested by the Developer within the timeframes established by the contract in accordance with these Terms of Reference.

The Developer must carry out commissioning work on the placement of the LIMS on the equipment provided by DEM, and then conduct preliminary tests of the information system.

After completing initial testing, the Developer is required to provide training for all user groups of the responsible employees at the DEM, focusing on how to use the system based on the developed methods and training programs. A minimum of five training sessions should be provided to each user group.

Following user training, the LIMS must be launched in trial mode for at least six (6) months. During this period, all identified inaccuracies, errors, and bugs in the system's functional modules must be resolved. Based on the results of the trial, a trial report and a statement of the identified inaccuracies, errors, and bugs must be prepared.

Acceptance and commissioning of the system shall be planned and carried out by the Developer and the Beneficiary after the trial operation period.

The Developer shall provide guaranteed technical support for the LIMS for 12 (twelve) months after commissioning.

All listed stages of the creation and commissioning of the LIMS into trial operation must be carried out and documented in accordance with the Requirements for the creation, development, commissioning, operation and decommissioning of state information systems, approved by the Resolution of the Government of the Kyrgyz Republic dated December 31, 2019 No. 744.

3. Objectives and purpose of the LIMS development

LIMS is a specialized information system designed to automate and manage laboratory activities related to sampling, testing, processing and storing obtained data, and managing laboratory equipment and resources.

The system covers the entire laboratory testing cycle—from registering a test request to generating a protocol and transmitting results to interested organizations, including government agencies and customers.

The main objectives of the LIMS creation include:

- Digitalization and standardization of laboratory processes
  Implementation of a unified digital platform that ensures standardized execution of procedures, from sample receipt to Protocol issuance, in accordance with the regulatory requirements of GOST ISO/IEC 17025–2019.
- Transparency and traceability of data at all stages
  Maintaining a complete history of each sample's processing: from registration to archiving, including all intermediate steps, personnel, methods used, and instrument calibrations.
- Automatic management of resources and consumables
  Keeping track of reagent usage, expiration dates, and remaining stock, as well as automatic notification of the need for replenishment or disposal.
- Equipment inventory and management
  Streamlining the tracking of equipment, maintenance schedules, inspections, calibrations, and service life.
- Providing a knowledge management system and staff training
  Maintaining an electronic log of training, instruction, course completion, equipment operation permits, and employee certifications.
- Quality control of laboratory tests
  Automation of deviation control, re-analysis, statistical assessments of accuracy/error, and maintenance of internal quality control documentation.
- Ensuring compliance with international accreditation standards
  Support for ISO/IEC 17025 requirements, including the ability to automatically generate logs, report forms, and records required for external and internal audits.
- Integration with laboratory equipment and automatic data collection
  Implementation of mechanisms for direct interaction with analytical instruments for automatic transfer of measurements to the LIMS, eliminating manual input and reducing the risk of errors.
- Flexibility and scalability of the system
  Developing an architecture that allows for easy adaptation of the system to different laboratories (including regional ones), customization of methods, reference books, and processes without the need for significant modifications.
- Reduced time to obtain results and elimination of paperwork
  Minimizing the time between sample collection and receipt of the final protocol by automating all links in the supply chain and transitioning to electronic documents certified with an electronic digital signature.
- Integration with government information systems
- Analytical support for decision making

Implementation of mechanisms for analyzing trends, deviations, quality and workload statistics, and generation of visual reports for management and decision-makers.

- Improving the security and reliability of data storage
  Implementation of backup, encryption, access rights control and compliance with information security requirements for government information systems.
- Support for remote work and mobile devices
  Implementation of a web interface and mobile modules for field staff and sample monitoring in transit.
  - GIS map for pollution sources to be developed
  - Possibly use of remote sensing for water quality monitoring. Open source satellite imagery.

4. Characteristics of the automation object

Currently, DEM uses home-grown research automation methods to manage laboratory data. Specifically, it has a web application developed between 2015 and 2016.
Access to the system is provided via a web browser, with user authorization using login and password.
The application is developed in the SaaS solution format, which allows connecting users from several laboratories, providing each of them with:

- Individual access rights settings.
- Setting up parameters depending on the specifics of the laboratory.

Tech stack:

- Programming language: PHP
- Framework: Symfony 5.4.2
- Database: MySQL

The current application has the following functionality:

- Order request management
- Sample Registration Management
- Test results management
- Monitoring
- Claims management
- Settings management
- Administrative panel

The current application is not a fully functional laboratory management system (LIMS) and, as stated above, is a home-grown development aimed at automating certain processes and simplifying employee workflows. A fully functional LIMS needs to be developed using new technologies, redesigned, improved, and new functionality created, including interfaces for user convenience. Maximizing the automation of laboratory processes is especially important. The LIMS also needs to be integrated with government services and systems, including the Unified Identification System (USI), the Infocom cloud-based electronic signature service for electronic document processing, and the Infocom state electronic document management system (EDMS) for efficient electronic interaction with government and other organizations. In addition to the LIMS itself, a mobile app needs to be developed for field operations.

5. Requirements for the LIMS functions

5.1 General description of the system functionality

LIMS should be a centralized system; data should be stored centrally on a server.
LIMS should be a multi-layered application that includes:

- The presentation layer, which includes components related to the user interface and web services that interact with the business logic layer. The presentation layer must function through the users' computer browsers.
- The business logic layer, which defines the rules for processing requests, application logic, data access logic, access logic to third-party information systems, and the layer that connects the presentation layer and the data layer.
- A data access layer that stores all the data required for the application to function—the database and documents. Data should be stored in a database management system, while files and documents should be stored in file storage.

The LIMS should consist of modules/subsystems that implement specific application functions listed in the system's functional requirements. Each module should also include the data set necessary to perform its function.

5.1.2 Requirements for the operating modes of the LIMS

The LIMS must operate in the following modes:

- normal mode, which ensures the performance of tasks in the scope of functions provided for in these Terms of Reference;
- service mode required for maintenance and system reconfiguration;
- emergency mode of system operation.

In normal operation, the LIMS must function uninterruptedly 24/7, provided that the equipment comprising the set of technical means is in good working condition and the system's core and application software is functioning properly. Round-the-clock operation of the system should not require the 24-hour presence of personnel servicing the system and should allow users to work in accordance with the staffing schedule.

In service mode, the system must provide the ability to perform the following work:

- technical maintenance;
- modernization of the hardware and software complex;
- elimination of emergency situations.

The system must switch to emergency mode when an abnormal situation occurs and normal operation is impossible. If the system switches to emergency mode due to the failure of one or more software and/or hardware components, or if the internet connection is interrupted, it must be possible to restore the system after technical issues are resolved and data is restored from backups in the event of failures, first in service mode and then in normal mode. Instructions for restoring system operation must be provided in the LIMS administrator's manual.

5.1.3 System diagnostic requirements

In the event of emergency situations or software errors, diagnostic tools must be available that allow the developer to save a complete set of information necessary for identifying the problem (screenshots, current state of memory, file system, log files with errors).

5.1.4. Requirement to the technical support

At the system analysis phase, the Consultant determines the specifications for the server hardware (processor, RAM, disk space). The necessary resources will be provided through the infrastructure of the Ministry of Natural Resources, Environment and Technical Supervision of the Kyrgyz Republic prior to the start of the development phase.

5.2 Requirements for the LIMS functions

5.2.1 General description of the system functionality

LIMS is a laboratory data management information system designed to automate all stages of laboratory operations: from order requests, sample collection and registration, and test planning to storage, processing, approval, and transmission of research results in the form of a Protocol.

LIMS should operate on a centralized basis, providing laboratories with the ability to work with the software through a web browser application.
The LIMS will operate in the Department of Environmental Monitoring (hereinafter DEM) in Bishkek, as well as in regional divisions that are currently engaged in sampling and should also be connected to the LIMS - the Osh-Batken regional unit, the Jalal-Abad regional unit, and the Issyk-Kul-Naryn regional unit.
Some of the system's directories should be general, while some of the directories and settings will relate to a specific subdivision (DEM or units).

Each subdivision and each unit should be able to customize their settings, as well as ensure separate document registry management, equipment inventory, consumables, methods, personnel records, etc.
Access control for the program within the LIMS is available to users with the administrator role. Within a department/unit, authorized users should be able to independently manage users within the subdivision.
The subdivisions that conduct tests in LIMS are called laboratories.

Below is a sample traceability diagram for the DEM. One of the main tasks of the LIMS is to ensure traceability according to this diagram, which is achieved through functional modules.

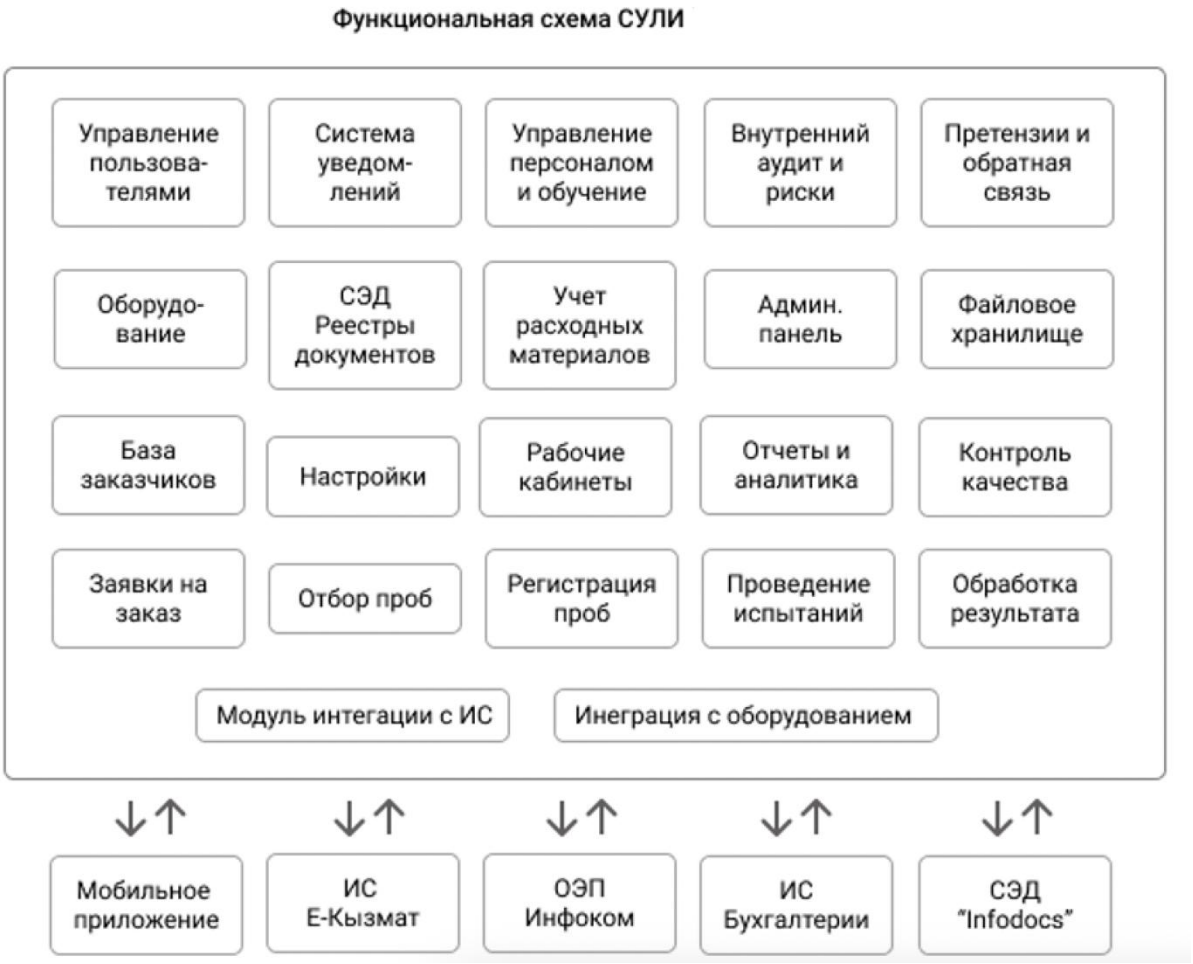
The following functional modules must be implemented in the LIMS:

No.	**Module**	**Functional purpose**
1	Settings	Management of sample types, ingredients, testing methods, methods of sample preparation and collection, maximum permissible concentrations, documents (methods), reference books
2	Test Requests Management	Maintains records of incoming requests from clients, as well as planned research activities within environmental monitoring. Includes a client database.
3	Sampling	Recording of sampling, sealing, filling out sampling passports and labels, transporting samples, preparing sample submissions for testing.
4	Registration of samples	Accounting for incoming samples, generating barcodes, registering samples and transferring samples for testing
5	Conducting tests	Distribution of samples among Developers, control of deadlines
6	Integration with equipment	Automatic data acquisition from instruments, linking to a sample and method, monitoring the status of instruments.
7	Processing results	Entering and checking results, automatic checking for maximum permissible concentrations, history of changes, generating reports, preparing test protocols.

8	Quality control and method validation	Includes control measurements and uncertainty calculation
9	Electronic document management system (EDMS)	The processes of preparation, processing, coordination and approval of documents - incoming, outgoing, internal.
10	Inventory and equipment	Accounting of devices, calibrations, checks, maintenance schedules, equipment condition.
11	Accounting for reagents and consumables	Warehouse accounting, expiration dates, balances, purchase requests, notifications.
12	Human Resources Management and Training	Accounting of roles, qualifications, permits, briefing and certification logs.
13	Internal audit and risk management	Manages internal audit and risk management activities, as well as risk mitigation measures.
14	Claims management and customer surveys	A unit for recording complaints received from customers, as well as anonymous customer satisfaction assessments.
15	Reports and analytics	Generation of statistical reports, loading graphs, dashboards, measurement dynamics, including report constructs.
16	User access management	A module for managing access to system functions, to data from conducted tests, and managing user rights and roles.
17	Integration with external systems	Data exchange between information systems
18	File storage	Provides secure and reliable file storage.
19	Notification system	A system for sending notifications and reminders within the system and via email.
20	Administration subsystem	Management of settings, reference information, system failure logging module
21	User workspaces	Availability of functions depending on the user's role and access level

A mobile application should also be developed.

Below is the functional diagram of the LIMS



5.2.1.1 Architectural and functional diagrams of the system

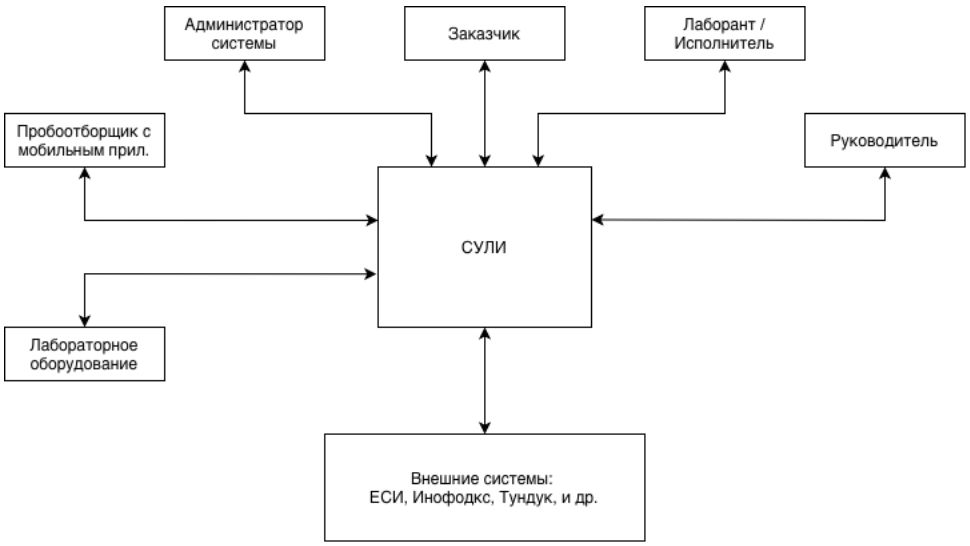
In accordance with the requirements of GOST 34.602–2020, clause 6.1.3, diagrams are presented below that clarify the structure, main functional processes and principles of interaction of the components of the control system.

Data Flow Diagram (DFD). Level 0 (Context Diagram)
The diagram displays the LIMS as a single module (the system as a whole) and defines its boundaries, as well as the main external entities and data flows between them.

- **External entities:**
    - **Customer:** An individual or legal entity initiating an application to conduct testing.
    - **Lab Assistant/Developer:** A laboratory worker conducting sample testing.
    - **Sampler:** An employee who carries out sampling in the field (including via a mobile application).
    - **System Administrator:** An employee who performs setup and maintenance of the LIMS.
    - **Supervisor:** An employee who approves protocols and analyzes reports.
    - **External systems (UIS, EDMS "Infodoks", "Tunduk", etc.):** State and departmental information systems with which LIMS is integrated.

- **Laboratory equipment:** Analytical instruments transmitting measurement data.

- **Main data flows:**
  - From the Customer to LIMS: Applications, contracts, details.
  - From LIMS to the Customer: Test reports, invoices, notifications.
  - From the Sampler to the LIMS: Sampling data (including geotags, photos, sample passports).
  - From LIMS to Sampler: Sampling tasks, methods, routes.
  - From Lab Technician to LIMS: Test results entered manually.
  - From LIMS to the Laboratory Assistant: Sample registration cards, testing assignments.
  - From Laboratory Equipment to LIMS: Measurement Data in Automatic Mode.
  - From LIMS to External Systems: Authentication requests (UIS), registration documents (EDMS), reporting data ("Tunduk").
  - From External Systems to LIMS: Responses with data, receipts for document acceptance.



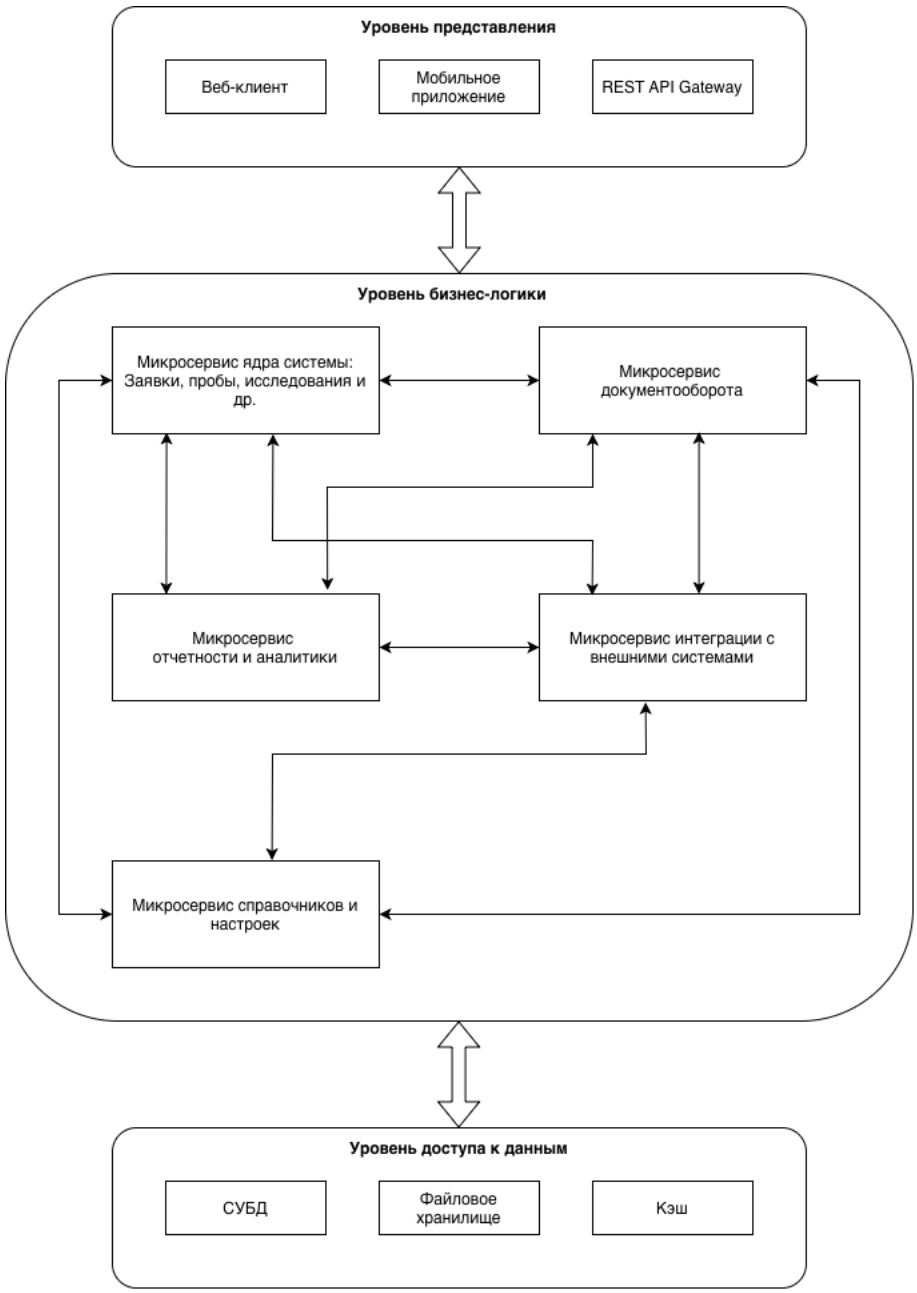
Logical architecture of the system

The logical architecture describes the main components (subsystems) of the LIMS and the key interactions between them without reference to the physical implementation.

- **Presentation Layer:**
  - **Web client:** The main user interface (browser-based SPA application). Provides functionality for all user roles.
  - **Mobile application:** Simplified interface for field samplers.
  - **REST API Gateway:** A single-entry point for all external integrations. Provides authentication, authorization, routing, and request logging.
- **Business logic layer (Application/Business Layer):**
  - **Core Services:** Application and sample management, testing, quality control, uncertainty calculation.

- **Document Management Microservice (SED Services):** Document workflow management (coordination, signing, registration), routing, assignments.
- **Reporting and analytics microservice (Reporting Services):** Generation of standard reports, report designer, dashboards.
- **Integration Services:** Orchestration of interaction with external systems (UIS, “Infodok”, “Tunduk”, “E-Kyzmat”, “Infokom”, accounting, equipment).
- **Reference Data Services:** Centralized management of all regulatory and reference information.

- **Data Access Layer:**
  - **Database (DBMS):** Storage of structured data (applications, samples, results, users, directories).
  - **File Storage (Object Storage):** Storage of unstructured data (documents, scans, photos, method files).
  - **Cache (In-Memory Cache):** To improve performance (caching of directories, sessions, frequently requested data).

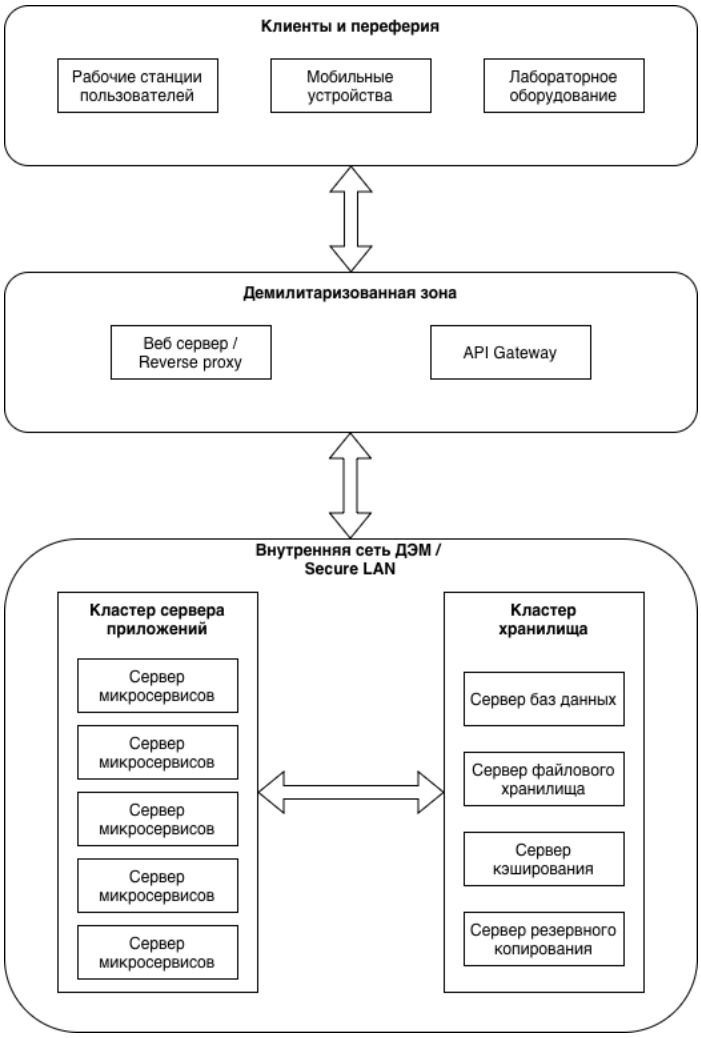


Physical architecture of the system (Deployment diagram)

The physical architecture determines on which servers and hardware the LIMS components will be deployed.

- **Peripherals and client access:**
  - **User workstations:** Personal computers with web browsers to access the Web Client.
  - **Mobile devices:** Smartphones and tablets with the Mobile application installed.
  - **Laboratory equipment:** Devices connected to the DEM Local Area Network.
- **Edge-network/Demilitarized Zone (DMZ):**
  - **Web Server / Reverse Proxy:** Accepts incoming HTTPS requests, serves static Web Client content, and redirects API requests to the internal network.

    - **API Gateway:** Placed in DMZ for secure communication with external systems.
- **Internal network of DEM (Secure LAN):**
    - **Application Servers:** A cluster of servers on which business logic microservices are deployed.
    - **Database Server:** A high-performance server for running the DBMS. A failover cluster configuration is recommended.
    - **File Storage Server:** Dedicated server or data storage system (DSS) for file storage.
    - **Cache Server:** A server for deploying an in-memory cache (e.g. Redis).
    - **Backup Server:** Provides regular backup of database and file storage data.



5.2.2 Settings management

Settings can be managed by users who have this right.

In this module of the system the user should be able to control:

- types of samples;
- ingredients;

- documents (methods);
- testing methods (including maximum permissible concentrations);
- methods of sample preparation and collection;
- quality control methods
- reference books (units of measurement, etc.)

This option in LIMS is implemented in the “Settings” section.
The fields specified in this module can be added or changed at the system design stage.

5.2.2.1 Sample types

Currently, DEM laboratories are testing the following samples:

- surface waters
- wastewater
- atmospheric air
- industrial emissions
- soil
- bottom sediments
- coal

The ability to conveniently add new samples and methods needs to be implemented.

When launching, add to existing samples and methods: radiation and ND measurement, testing methods, unit of measurement (conversion of units of measurement) (μSv/hour; μR/hour).

Each sample has its own documentation requirements. Further in the description of the system's functionality, whenever there is a reference to something depending on the sample type, these specific sample types are meant.

The system should have a unified directory for all organizations and laboratories, but each laboratory should be able to select or hide specific samples for testing. It should also be possible to add new sample types to the shared directory.

5.2.2.2 Parameters

A parameter or ingredient is a controlled or measured component, physicochemical characteristic, or substance determined in a sample as part of environmental monitoring.

Examples of parameters:

- pH;
- water temperature;
- content of heavy metals (lead, mercury, cadmium, etc.);
- ammonia concentration;
- petroleum product content.

The user must be able to:

- Add new parameters (analyzed components/substances);
- Specify the properties of ingredients:
    - Parameter name
    - International name of the parameter
    - International code value

- Link parameters to sample types. This is necessary for creating correct research protocols and improving the accuracy of analytical method selection.

This directory should be uniform across all organizations and laboratories, but each laboratory should be able to configure whether it conducts analysis of these parameters for each sample individually. New parameters should be able to be added to the general directory.

The section should include a feature for searching by name;

Filtration by sample type (water, soil, air, etc.).
Filtration by location (GIS map should be developed and maintained)
By type of enterprises
By type of sources

5.2.2.3 Management of methods and regulatory documents

It is necessary to ensure centralized storage and management of regulatory documentation on the basis of which all types of testing, sampling and quality control procedures are carried out. The LIMS must contain a Register of Regulatory Documents. The following data must be stored for each document:

- Document title
- Document identification number
- Number/Standard number (for example: GOST 31957–2012);
- Edition No.
- Date of publication
- Approval date and validity period (if limited);
- The developer or source organization (for example, the Interstate Council for Standardization, Metrology and Certification) - for external documents;
- Number of pages
- Confidential (yes, no)
- Document type (test method, internal regulatory document, sampling method, etc.)
- Group of documents (personnel, testing methods, equipment, consumables, etc.)
- Sample types regulated by the document (for methods)
- Status (active, expired).
- Document file

A document's edition history must be maintained so that it is possible to see during what period of time which edition of the document was relevant.
It should be possible to search the register of regulatory documentation by number, name, as well as filter by status, group, document type, and sample type.

Document types:

- Internal regulatory document
- Test methods (for example, GOST 33045–2014 “WATER. Methods for determining nitrogen-containing substances”);
- Methods of sampling and sample preparation;
- Quality control methods;
- General regulatory documents: GOSTs, SanPiNs, MU, TU, RD, etc.

5.2.2.4 Validation of test methods

Testing methodology is an organizational and methodological document that includes **testing methods**, testing equipment and conditions, sampling, algorithms for performing operations to determine one or more interrelated characteristics of an object's properties, data presentation formats, accuracy and reliability assessment, safety and environmental protection requirements.

According to the test methods (type of document), a Test Method Validation Plan and Test Method Validation Reports must be developed and stored.

The Plan must contain the following activities:

- Definition of basic testing requirements
- Selecting an appropriate test method
- Determining the required degree of validation
- Drawing up an action plan
- Conducting validation experiments or evaluating already collected data
- Calculation of measurement uncertainty
- Evaluation of validation data (while, if necessary, improving the method to meet customer requirements, if any)
- Preparation of documents for method validation with its details
- Periodic confirmation of the laboratory's ability to comply with the established requirements of the method

With filling for each type of work:

- Responsible executors
- Completion date
- Notes (optional)

It must be possible to generate a document in accordance with the approved document F.PR-2021-08-01. Upon Plan completion, a completion mark must be issued.

The system must also store Test Method Validation Reports - prepared documents in the form F.PR-2021-08-01.

Validation reports should contain data on:

- Name and identification of the method
- Persons responsible for conducting tests/research
- Verification period
- Object and indicator
- Overall assessment of the method
- Conclusions regarding compliance/non-compliance of performance characteristics with the acceptance criteria
- File with scanned original report
- Links to records in electronic journals about the tests carried out.

Validation plans and reports should be available when reviewing test methods.

5.2.2.5 Method Management

This module of the LIMS system enables the creation, editing, and structural management of methods used in laboratory operations. Methods are used in sample analysis, preparation and selection, and for quality control. All methods must be linked to regulatory documentation, parameters, and the laboratory equipment used.

Test methods

A test method describes a method for determining a parameter in a sample of a certain type, according to an approved methodology.

Mandatory attributes of the test method:

- Name of the method (for example: photometric, titrimetric, etc.);
- Short names of methods (for ease of use);
- Type of method (testing method, sampling, quality control);
- The parameter to be determined (e.g. pH, lead concentration, COD);
- The type of sample to which the method is applied (e.g. water, air, soil);
- Related regulatory document (for example: GOST, MU, SanPiN);
- Unit of measurement (for example: mg/dm³, μg/m³);
- Range of acceptable values:
    - Minimum acceptable value;
    - Maximum allowable value;
    - The detection limit is the smallest amount or concentration of analyte in a test sample that can be reliably distinguished from zero for a given measurement system;
    - Limit of quantification is the lowest concentration or amount of an analyte in a sample that can be quantitatively determined with an acceptable level of accuracy and precision.
- MPC (Maximum Permissible Concentration) (if applicable) - the maximum permissible concentration of a substance at which it does not pose a danger to human health or the environment, according to regulations.
    - Meaning;
    - Conditions of use (according to regulations, type of environment);
- Period of validity of the method;
- Percentage of uncertainty;
- Calculation formula, if the method involves calculating the result based on intermediate data;
- Equipment used:
    - List of devices (related to the laboratory equipment register);
    - Requirements for calibration and verification.

Additionally:

- Method execution time;
- Required operator qualifications;
- Conditions of implementation (temperature, humidity, lighting);
- Possibility of multiple measurements (for example, triple measurement);
- Quality control within the method (repeatability, reproducibility, standard samples).

Sampling methods

A sampling method describes the procedure for extracting material from the environment, ensuring that it is representative and suitable for further analysis.

Key attributes of the selection method:

- Method name;
- Short names of methods (for ease of use);
- Type of method (testing method, sampling, quality control);
- The type of sample to which the method is applied (e.g. water, air, soil);
- Related regulatory document (for example: GOST, MU, SanPiN);
- Unit of measurement (for example: mg/dm³, μg/m³);
- Selection conditions (depth, temperature, time of day, location/altitude);
- Containers and tools used;
- Requirements for transportation and storage;
- Requirements for personnel and personal protective equipment (PPE);
- Selection control (duplicates, control samples);
- Period of validity of the method;
- Possibility of photo documentation or geotagging (mark (coordinate) used on maps.

Each sampling method must also provide the ability to specify which additional fields must be filled in when collecting a sample in the test order, in the sample passport, and on the label form.

Using the example of sampling industrial emissions for the sampling method GOST 33007–2014, 17.2.4.06-90, there should be additional fields to fill in the test request:

- Gas analyzer readings (KASKAD-N 62.2)
    - CO- NO- NO2 - SO2 -
- Pipe diameter:
- Input No. of cartridge case:
- Output No. of sleeve:
- Gas flow rate, m/sec; liter/min
- Sampling time:
- Atmospheric pressure mm Hg:
- t°C before the aspirator (Temperature of the air (or gas mixture) before entering the aspirator - a device that creates draft/air flow through the system).
- t°C of the flue gas duct (the channel through which the gases move)
- t°C of a riometer (a device for measuring the density of a gaseous medium).

There must be additional fields in the sample passport:

- Temperature before the aspirator
- Atmospheric pressure

The user will need to enter this data for industrial air samples if the selected sampling method is used.

For example, for soil, these could be fields of sampling depth, soil type, terrain, and intended purpose.

Quality control methods

The quality control method allows to evaluate the accuracy and reliability of the results obtained.

Key attributes of quality control:

- Method name;
- Short names of methods (for ease of use);
- Type of method (testing method, sampling, quality control);
- Related regulatory document (for example: GOST, MU, SanPiN);
- Test Method (Quality Control applies to a specific test method);
- Type of control (intra-laboratory, inter-laboratory, etc.)
- Frequency of control;
- Reference standards or standard solutions used;
- Criteria for acceptable discrepancy;
- Calculation of deviations, formulas;
- Period of validity of the method;
- Mechanism for re-validation of results when control thresholds are exceeded.

The section should include search options by title, short title, date, and other attributes.

Filtering by sample type (water, soil, air, etc.), method type, and parameter.

5.2.2.6 Pricing Management

Users should be able to set the cost for testing depending on the test methods.

5.2.2.7 Application and sample logs

The LIMS should have the ability to configure application and sample logs, in addition to configure the algorithm for assigning a number when registering applications and samples.
If there are several laboratories in one department, for example, as in the Department of Electromedical Engineering, and there is a need to maintain separate application and sample logs for each laboratory, a function that allows for this capability must be included in the settings.

For example, there may be either single application logs or application logs for each laboratory, as well as for sample logs, or separate ones.
If journals are maintained for each laboratory separately, it is necessary to provide the ability to indicate the name (full and short) and code for each laboratory journal.

For example, for order logs for a laboratory conducting water research:
- Logbook of requests for water sample analysis
- Short name - Water.

And so, for each laboratory.

For each application log, you can specify the algorithm for assigning an application number in the settings, for example:
- just a serial number;
- Journal code, dash, serial number, dash, year. For example, applications in the “Water” journal would be generated as 01-001-25;
- numbering by sample type (so that applications are numbered separately for each sample type.

The same settings should be for sample logs.

This issue must be agreed upon at the design stage. The system for assigning numbers when registering applications and samples must be sufficiently flexible.

5.2.2.8 Directories management

The LIMS must use reference books for convenience, information standardization, and data integrity control. The following reference books are mandatory in this section:

- Units of measurement;
- Types of methods;
- Status of documents;
- Type of control (intra-laboratory, inter-laboratory, etc.)
- Frequency of control
- Types of sample processing (filtration, preservation, etc.) depending on the sample type
- Application type (custom, scheduled, complaint)
- Application status (draft, planned, in progress, completed, cancelled, archived).

The list of reference books should be supplemented at the design stage and the development stage.

5.2.2.9 Document templates

Settings should also include the ability to manage document templates (contract, invoice, order request, etc.) that are generated while working in the program.

5.2.2.10 Module "Administration of Regulatory Reference Books"

The module is designed for centralized management of all regulatory and reference materials in the system, ensuring their relevance, version control, and differentiation of access rights.

Functional requirements:

1. Centralized register of regulatory documents:

- Storage of a single catalog of all regulatory documents: GOST, SanPiN, guidelines, technical regulations, internal organization standards.
- For each document, the following details must be stored: name, designation, date of entry into force, validity period, status (current/cancelled), area of application.
- Possibility of attaching document files in various formats (PDF, DOC, XLS).

2. Version control:

- Maintaining revision history for regulatory documents. When changes are made to a document, a new version must be created, preserving previous revisions.
- For each version, the following are recorded: the start date, the end date (if any), and the reason for the change.
- Automatic warning to users when using outdated versions of documents.

3. Centralized update mechanism:

- The ability to bulk import regulatory framework updates from approved external sources (XML, JSON, XLSX formats).
- Interface for batch adding and updating groups of related documents.

- Maintaining a log of updates, recording the date, scope of changes, and the person responsible.

4. Communication with other system modules:

- Integration with test methods, equipment and quality control modules to ensure referential integrity.
- Automatic verification of the methods used in work for compliance with current versions of regulatory documents.
- The ability to generate a report on the applicable versions of regulatory documents by laboratory and test type.

5. Differentiation of access rights:

- Multi-level system of rights:
  - **View** - available to all users
  - **Editing** - appointed responsible specialists
  - **Approval/commissioning** - to heads of departments
  - **Administration** - full access to module settings
- Change control with mandatory approval for critical regulatory documents.

6. Notifications and reporting:

- Automatic notification of responsible persons about the upcoming expiration of documents.
- Formation of registers of current regulatory documents in accordance with established forms.
- Reports on the history of changes to the regulatory framework for any period.

7. Backup and Restore:

- Regular automatic backup of the regulatory documents database.
- Ability to restore previous states of directories in case of erroneous updates.

Interface requirements:

- Tree structure of categories and subcategories for systematization of regulatory documents
- Advanced search by document details and full-text search by content
- Visual highlighting of new and modified documents
- Intuitive interface for comparing different versions of documents
- Quick access toolbar for frequently used documents

This module must ensure that the regulatory framework of the LIMS complies with the requirements of current legislation and standards, as well as promptly communicate changes to all users of the system.

5.2.3 Application Management

The module is designed for registering, processing, and supporting all types of requests for laboratory testing, including:

- Requests from external customers (under contract)
- Scheduled applications (environmental monitoring)
- Applications for complaints (unscheduled, at the request of supervisory authorities)

When creating planned requests, there should be an option to specify their frequency. For example, scheduled requests can be added at the beginning of the year with their frequency specified. For example, if the user specifies that a scheduled request should be performed once per quarter, then scheduled tests will be performed each quarter according to the plan.

Main application fields:

Field	**Description**
Application number	Assigned automatically (unique, according to a template, for example: 2025–000123)
Date and time of registration	Specified automatically or manually
Application type	Custom / Scheduled / Upon complaint
Frequency of requests	One-time (default), monthly, quarterly, annually, etc.
Start and end dates of validity	For periodic applications
Date of first performance	For periodic applications
Request`s status	Draft / Registered / In progress / Completed / Cancelled / Archive etc.
Customer	Select from the customer database if the application is under a contract or a complaint
Contact person	Name, phone number, email
Agreement	Link to contract (if applicable). Contracts with customers must be stored in the system.
Project	Link to project (if applicable). Projects allow testing to be grouped together if it is being conducted as part of a project.
List of samples	Sample types (selected from the directory)
Number of samples	The quantity for each sample type is indicated.
Analysis parameters	Select from the parameter directory
Sampling method	Selection from the methods directory, indicated for each sample
Method of analysis	Selection from the method directory is specified for each parameter

Sampling location (point)	Geolocation, address, object. Select from the database or enter information directly in the application.
Purpose of the request	Text description
Justification	Text description
Preservation (if necessary)	Text description
Confidential access	Yes, no (for requests that are strictly confidential)
Priority	Normal / Urgent / Critical
Notes / documents	Ability to attach scanned copies of applications, cover letters, etc.
Completion deadlines	standard for each type of sample (from 1 day to 4 weeks)
Sample storage period	Specified for each sample type (from 5 days to 1 year)
Complaint acceptance period	Specified for each sample type (from 1 day to 4 weeks)
Selection criteria	Independently or laboratory for each sample
Responsible employee	Person responsible for the application process within the laboratory

When an application is registered, it is assigned a number according to the settings. As soon as a sample is registered for this application, the status will automatically be set to “in progress”. The application keeps a history of status changes, as well as logging changes made to the application after its status becomes “in progress”.

Payment information
For paid orders, information on receipt of payment for order fulfillment must be stored, along with payment document details.

Creating a single request with specified frequency

For periodic requests, such as scheduled identical requests that are made once a month, you must specify:

- Frequency (monthly, quarterly, annually, etc.)
- Start and end dates of validity
- First execution date (e.g. beginning of month)
- Status “active” or “planned”/

When created, such a request receives the status “scheduled”, as soon as a new request is created within this request, the request status will become “active”, when all requests are completed, this request will also become “completed”.

In this case, the system should automatically create new requests for the main request for each month or other period, based on the specified frequency.

For example, when a new month begins, a new request will be created at the beginning of the month for the monthly request.

Request templates

LIMS enables the development of request templates that simplify the creation of future requests. Users can choose a template for recurring requests, enabling them to efficiently generate new requests.
Each template will contain all critical request details, including research criteria, deadlines, and sampling locations, making it easy to access this information during the creation of new requests.

Sampling point database

For convenience, users can add sampling points to the system's database. To do so, they must enter the name, address, including the SDATE code, coordinates, and select the water body from the water body directory. It should be possible to either select a sampling point from the database or enter it in a text field.

For contract requests, it should be possible to generate a contract on request in accordance with the template provided by the Beneficiary, with the ability to make changes to the template in the settings, as well as the ability to generate an invoice for payment and transfer data to the accounting department.
The invoice should be generated automatically based on:

- List of declared analyses and number of samples;
- Price list
- Tariffed services
- Discounts/contractual terms

It should be possible to export to PDF/Excel

The request should include the ability to maintain a payment history.

At the design stage, it is necessary to work out the possibility of integrating the LIMS with the accounting information system.

The system should display a log of all requests with the ability to search, filter, edit, delete (for drafts), and send to the archive.

The search should be available by request number, full name, or customer name.
There should be filters by date, customer, request/application type, status, responsible employee, sample type, and parameters being studied.
There should be the ability to manage group requests (e.g. mass execution, export, etc.)

Printing documents

It should be possible to export the list of requests (request/application log) in Word, Excel, and PDF formats for subsequent printing.

Requests must be generated based on templates for each sample type in Word, Excel, and PDF formats. The system settings must allow for modifications to request print templates. Request templates for each sample will be provided by the Beneficiary.

5.2.3.1 Customer database

The module must be linked to the customer database, which stores:

- Name of organization or full name
- Legal entity or individual
- Organizational and legal form
- Legal and actual address
- Tax Identification Code, OKPO
- Contact persons with contact information
- Availability of discounts
- Contracts (list of contracts with the option to attach a scanned copy of the contract)
- Status (active/suspended/archived)

The LIMS should maintain a Register of Contracts with Customers with the ability to generate data in Excel and Word formats for transferring data on concluded contracts and costs to the accounting department.

The LIMS must maintain a **log of negotiations** with customers on work
It should contain:

- Record number;
- Date of negotiations;
- Customer ID;
- Position, full name of the person with whom negotiations were conducted
- Phone number
- Subject of negotiations
- Request number (if applicable)
- Decision based on the results of negotiations
- Note

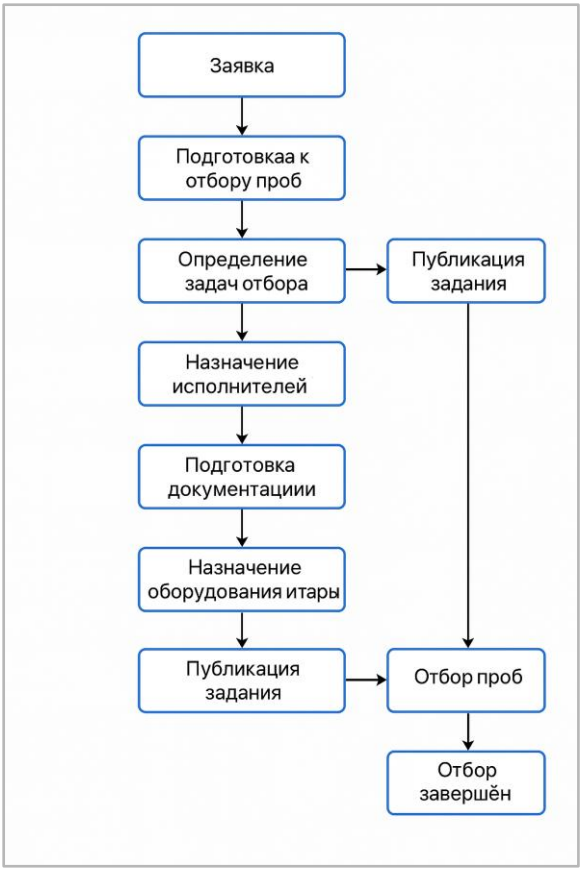
It should be possible to print the log for a given period in Word and PDF formats.

5.2.4 Sampling

Sampling – organizing, planning, conducting, and documenting sampling procedures in accordance with regulatory documents, methods, and procedures. Ensuring traceability and data reliability from the moment of sampling until the sample arrives at the laboratory.

5.2.4.1 Sampling

The sampling plan must be drawn up before any sampling is carried out. The sampling plan must be prepared on the basis of completed request forms. The sampling process is illustrated in the diagram below.



Sampling process diagram

Sampling tasks must be generated by the user based on a registered request.

The user completes or confirms:

- Place of sampling (there may be several sampling points);
- Date/time or period (if the selection is to be repeated, a schedule is set);
- Sample type (included in the request);
- Parameters to be tested (included in the request)
- Selection method (selected from the reference book)
- Required equipment (selected from the list)
- The required container
- Responsible persons

Preparation of documentation for sampling

The following are generated automatically:

- Sampling assignment (memo or route sheet)
- **Sample passport** to be filled in on site
- **Referral for testing** for filling in the laboratory
- Print labels for on-site filling
- Route plan for selection (if several points are specified)
- Document with a list of equipment, reagents, containers

Documents can be downloaded as PDF/Word and printed or sent to a mobile device.

A connection must be made with the inventory module, which will allow reserve the necessary equipment, consumables, and containers.

After confirmation, a sampling card is created in the LIMS (there may be one or more, if there are multiple points). The sampling task becomes available in the executor's interface (and/or mobile app).

The following statuses are set: Planned → In progress → Selection completed
The system must record the history of status changes.

Executor:

- receives a notification with a task in LIMS, as well as in the mobile application

- has access to the route, methods, and necessary documents
- At the sampling site, the following can be recorded:
    - Actual time and coordinates
    - Environmental conditions
    - Field measurements (from the device)
    - Fillings, photos, comments
    - Enter measured data depending on the selection methodology.
- Upload scanned, manually completed documents
- After selection, it sends the data to LIMS (synchronization)

The executor must be able to enter data into the sample passport and the test referral.

The following data is entered into the electronic sample passport:

- Serial number
- Name, address of the object
- Basis for selection (order request)
- Sample type
- Containers
- Quantity
- Volume
- Place of selection
- Purpose of selection
- Nature of the samples collected
- Environmental conditions
- Sampling method
- Samples were taken by (DEM representative)
- Attendees:
- State Inspector (position, full name, contact information)
- Company representative (position, full name, contacts)

5.2.4.2 Transportation of samples

After the samples have been collected, they need to be transported.
Sample transport data is an important part of sample traceability and should be recorded in the sample management system immediately after sampling and before registration in the laboratory.
The data must be entered into electronic systems:

- Sealing: seal/label number
- Date and time of dispatch
- Person responsible for transportation (employee or representative of the customer)
- Means of transportation (car, thermal container, courier etc.)
- Storage and transportation conditions (temperature, humidity, light, etc.)
- Equipment used during transportation
- Arrival time at the laboratory
- Violations of storage conditions
- Photo of the packaging
- Notes

The data can be entered both in the program and in the mobile application.

5.2.4.3 Preparation of sample submission for testing

The following data shall be entered into the electronic referral for testing:

- Sample name
- Sample code
- Determined indicators
- Date/time of sample submission/reception to the laboratory
- Sample volume (from label)
- Type of container
- Submitted by (employee ID or full name of the customer's representative)
- Accepted by (employee ID)

The available data (filled in the sample passport or transport data) is automatically entered into the referral.

Furthermore, the fields that must be completed based on the chosen selection method are populated (these are set up in the Settings).

When completing the sampling and sample transportation, LIMS checks that all required fields are filled in.

This module should generate documents in Word/PDF format in accordance with document F.PR-2021-09-06:

- Referral for atmospheric air sample testing
- Referral for water sample testing
- Referral for industrial emissions testing
- Referral for testing of coal and soil samples

In accordance with document F.PR-2021-09-02:

- sample passport (atmospheric air)
- sample passport (industrial emissions)
- sample passport (wastewater)
- sample passport (surface water)
- soil sample passport
- sample passport (coal)
- passport (radiation measurement),

  shall be prepared.

Labels for sample stamping should also be generated for each sample.

It should be possible to add new passports, referrals, labels.

5.2.5 Registration and transfer of samples for testing

This module must ensure accurate, controlled, and traceable registration of all samples received by the laboratory based on requests. This is a crucial step, determining the accuracy of testing, traceability, and compliance with regulatory requirements.

5.2.5.1 Registration of receipt of samples

The sample is registered based on a request (the requests can be selected from a list or pulled up automatically), as well as data received as a result of the sample collection and transportation processes.

It should be possible to register one or more samples for one request.

Each sample is assigned a unique registration number (with the option of automatic numbering according to a template defined in the settings).

A sample card is maintained for each sample.

There must be a separate sample registration block for each sample:

Field	Description
Sample number	Assigned automatically according to the template in the settings
Request number	Recorded automatically
Date and time of sample receipt	Specified automatically or manually
Sample type	From the sample passport
Sample quantity and volume	The ability to choose units of measurement
Sample volume required for testing	Sufficient or not - indicated for each sample
Nonconformities detected during sample acceptance	Description if any discrepancies are found Condition of the sample upon receipt (e.g. sealed, damaged)
Sample processing	Select from a sample type directory for each sample type (filtration, preservation, cooling, drying, etc.)
Sample passport	Connection with the sample passport
Referral for testing	Connection with the directory of the sample for testing
Test parameters and methods	From the request
Sample statuses	Awaiting registration, registered, submitted to laboratory, being examined, examined

Sample storage data. After receiving and before transferring the sample for testing, there must be information about the place and time of storage of the sample. For example, refrigerators, cabinets, etc. (link to data on the inventory of laboratory equipment).

The LIMS must record the history of changes in the sample status - date, time, user, who changed the status.

It should be possible to print labels for sticking on samples with a QR code, which can be used to quickly find information about the sample in the LIMS.

Depending on the settings in the system, sample registration logs are maintained, and numbers are assigned according to specified algorithms.

The log should allow searching for samples by number. Filtering samples by time period, status, sample type, and other parameters should be possible.

It must be possible to print Test Logs in accordance with document requirements in Word, Excel and PDF format.

5.2.5.2 Submitting the sample for testing

Once registered, the sample is transferred to the laboratory for testing. The date the sample was received for testing is recorded in the log:

- Sample name
- Sample code
- Determined indicators
- Date/time of sample submission/reception to the laboratory:
- Passed
- Accepted

A specialist shall be appointed to conduct the tests.

5.2.6 Conducting tests

The person assigned to conduct the test enters the test start date and time into the system. During the test, the user enters the data into the system according to the test method. The LIMS settings should allow for specifying which data should be entered into the system during the test.

If there is a possibility of receiving data from equipment, this should also be configured in the system.

The data received along with the test referral must be displayed to the user.

5.2.6.1 Processing of test results

The LIMS settings for each method must store algorithms for calculating test results according to the test procedure. This way, the user will enter the data obtained during the tests, and the LIMS will perform the required calculations for the results independently using pre-configured formulas. Uncertainty will be calculated in the same manner.

5.2.6.2 Integration with equipment

It is necessary to explore the possibility of obtaining data from laboratory equipment in the LIMS, this will allow:

- reduce manual data entry;

- increase data processing speed;
- reduce errors in data transmission.
- ensure control.

Many laboratory instruments (spectrophotometers, analyzers, scales, etc.) operate using the RS-232 interface, an outdated but still widely used serial data transfer interface. Modern equipment has ports for USB or RJ-45 integration.
It is necessary to develop an intermediate application (driver/desktop agent/script) that will receive data from devices on these ports and transmit it to the LIMS.

[Hardware] --(any port) --> [Application] ↓ [HTTP request to the LIMS API]

This must be a local application or script that:
- reads data from any RS-232, USB or RJ-45 port;
- processes or parses this data;
- sends them via HTTP request (REST API) to LIMS.

As part of the work, it is necessary to study the possibility of connecting laboratory equipment to the LIMS and implement the acquisition of data from laboratory equipment devices (up to 20 devices).

In the future, it is also planned to purchase a mobile laboratory for the Department of Environmental Monitoring (DEM). This will be a vehicle equipped with equipment for measuring the quality of atmospheric air, water, soil, and other parameters, which will be used by specialists from the Department of Environmental Monitoring of the Ministry of Natural Resources, Ecology and Technical Supervision of the Kyrgyz Republic in the field. It is necessary to provide the ability to exchange data between the LIMS and the mobile laboratory software. Data should be transferred from the mobile laboratory to the LIMS after testing.

5.2.6.3 Requirements for the equipment calibration module

The equipment calibration module is designed to automate the planning, accounting and control of metrological support for laboratory equipment used in testing, and should be closely integrated with the equipment register (Section 5.2.10).

Module functionality requirements:

1. **Accounting of measuring instruments (MI):**
    - Maintaining a register of measuring instruments subject to calibration/verification, indicating: type of measuring instrument, factory and inventory numbers, measurement range, accuracy.
    - Linking measuring instruments to specific test methods and laboratory equipment in the register.
2. **Calibration planning:**
    - Formation of a schedule of planned calibration/verification based on the frequency established for each measuring instrument.
    - Automatic calculation of the next calibration dates based on the date and result of the previous one.
3. **Calibration process management:**

- Registration of the fact of sending measuring instruments for calibration/verification (date, performing organization, accompanying documents).
- Entering calibration results: date, results, certificate number, validity period.
- Possibility of attaching an electronic copy of the calibration certificate/verification certificate to the file storage.
- Recording of measuring instrument statuses: “Ready for work”, “In calibration”, “Expired”, “In write-off”.

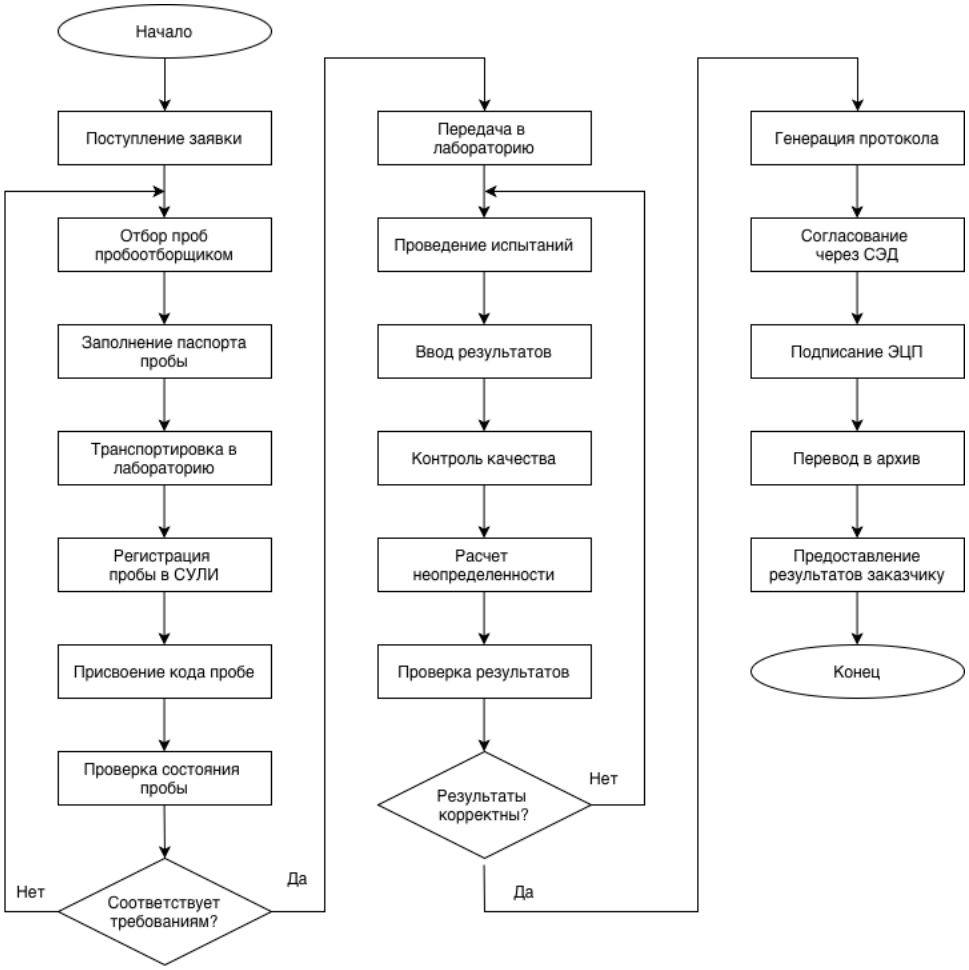
4. **Control and notifications:**
    - Automatic verification of the relevance of the measuring instrument calibration before starting tests.
    - Generate warnings and notifications for responsible persons about approaching calibration deadlines (e.g. 30, 14 and 7 days).
    - Blocking the possibility of using measuring instruments with expired calibration in tests.
5. **Reporting:**
    - Formation of the “Schedule for conducting intermediate equipment checks and equipment calibrations” (F.PR-2021-05-02).
    - Reports on the calibration status of the entire fleet of measuring instruments, reports on expired measuring instruments.

5.2.6.4 BPMN diagram of the sample life cycle

To visually describe the entire sample lifecycle from receipt to results archiving, BPMN (Business Process Model and Notation) is used. The diagram displays key stages, process participants, decisions made, and integration points with other LIMS modules.

Description of the main stages of the process:

- **Start:** The process is initiated based on a request received from the Customer or as part of scheduled monitoring.
- **Selection and transportation:** The sampler collects samples according to the procedure, completes the electronic sample passport and labels. Data can be entered via a mobile app. The transportation process is recorded.
- **Registration and acceptance:** The sample is received by the laboratory, where it is registered in the LIMS system and assigned a unique barcode. The sample's condition and accompanying documents are verified.
- **Tests:** The sample is distributed among the laboratory departments. A laboratory technician conducts tests, entering results manually or receiving them automatically from the equipment. The system performs automatic quality control (QC) and uncertainty calculation.
- **Verification and approval:** The results are reviewed by the responsible person (the laboratory manager). If necessary, the sample is sent for reanalysis.
- **Formation of the protocol:** Based on the verified results, a Test Report is automatically generated.
- **Coordination and signing:** The protocol undergoes the approval and signing procedure through the electronic document management system module using an electronic digital signature.
- **Archiving:** The signed protocol and all initial sample data are transferred to a version-controlled archive. The final document is provided to the client.



5.2.6.5 Requirements for the archive of test reports and version control

The system must ensure reliable, long-term storage of test reports and associated data in an archive with mandatory version control.

Archive functionality requirements:

1. **Formation of an archive copy:**
    - Automatic archiving of the entire data package after signing and registering the test protocol.
    - The archive copy must include: the final protocol (PDF), initial test data, quality control results, electronic signature, memos and comments that arose during the approval process.
2. **Version control:**
    - Recording all changes to the protocol after its initial creation. Each change should create a new version of the document.
    - For each version the following must be stored: date and time of change, author of change, comment on the change (reason).
    - It must be possible to view the change history and compare any previous version of the protocol with the current one.
    - Access to previous versions should be restricted (only for audit and responsible persons).

3. **Archive immutability:**
    - Data placed in the archive must be protected from any changes and deletion.
    - The integrity of archived data must be ensured using hashing mechanisms (checksums).
4. **Storage periods and indexing:**
    - Setting up storage policies in accordance with the regulatory requirements of the DEM (at least 5 years).
    - Providing a powerful search and filtering system for archived protocols: by protocol number, customer, date, sample type, and parameters.
5. **Export and upload:**
    - The ability to download archived protocols and related data in standard formats (PDF, XML, JSON) for provision upon request to regulatory authorities or for migration purposes.

5.2.7 Preparation of test reports

Based on the results of the tests, the test staff members - who conducted the tests - prepare test reports. An approved test report form is available for each sample type. The system must generate the Test Report automatically. After generating the report, the employee must submit it to the Laboratory Director for approval via the electronic document management system (EDMS). The Laboratory Director must review the report, either return it for revision, or sign it. The signed report is then forwarded to the staff members who interact with the Customer. These staff members, using the report received from the laboratory, prepare a Test Report with the Customer's details for delivery to the Customer. This report is also generated by the system and signed electronically or by an authorized representative.

The final test report is registered in the EDMS and can be sent directly to the Customer if they are connected to the Infodocs EDMS. The system must contain a test report registry. It must be accessible both from the EDMS and through the order request.

5.2.8 Quality control and method validation

The quality control module is responsible for ensuring and documenting the validity of laboratory test, analysis, and calibration results. This module helps control and maintain the quality of work performed, in accordance with the requirements of ISO/IEC 17025:2019 (clauses 7.7 and 7.5).

5.2.8.1 Control measurements

Main functions of the module:

1. Control measurements management
    - Planning and automation of control tests (internal quality control). Maintaining lists of control samples (reference materials, standard samples): separate accounting of control samples or reference samples. These may include: standard samples, duplicate analyses, or interlaboratory comparisons.

- Automatic verification of results according to specified tolerances and rules (according to Shewhart's rules).

The results of control measurements must be automatically entered into the quality control module. Control measurements must be linked to the method/equipment, and the measurement time, and the employee performing the measurement must be recorded.

2. Control schedules and reminders
   - Setting up the frequency of control tests for each method or device.
   - Reminders about the need to carry out control measures.

3. Recording and analysis of control results
   - Storage of all control measurement results.
     LIMS must:
     - Store historical data (for example, for the last 30 measurements).
     - Calculate:
       - Average (CL),
       - Standard deviation (σ),
       - Upper/lower control limits (±3σ),
       - Update boundaries as data accumulates (or on a schedule).

   - Automatic generation of control charts (X-diagrams, control charts). The LIMS system should generate a Shewhart chart. An interactive chart should be implemented in the LIMS interface.
   - It should be possible to add rules for evaluating deviations.
   - Highlighting deviations from the norm.
   - History of changes to results, including the reason for the adjustment.

4. Responding to deviations
   - Recording deviations and describing corrective actions. If a value exceeds the specified limits, the system should record a deviation. It should be possible to specify the reason for the deviation and the corrective actions.
   - Automatic notifications to responsible specialists about rejections.

5. Audit and traceability
   - Maintaining a history of changes to quality control results and records.
   - Recording: who, when, what changed and why (in accordance with clause 7.5 of ISO/IEC 17025).
   - Possibility to export data for analysis, auditing and reporting.

6. Statistical analysis
   - Calculation of average values, standard deviations, trends.
   - Integration with statistical data processing modules.
   - Comparison of interlaboratory results.

This module should be integrated with the equipment module, the methods module and the personnel module.
This module will allow to:
   - ensure compliance with ISO/IEC 17025 requirements for data quality control and reliability.

- increase the transparency and reliability of the results.
- simplify preparation for internal/external audits.

5.2.8.2 Calculation of uncertainty

According to clause 7.6 Evaluation of uncertainty of measurement of ISO/IEC 17025–2019, the laboratory shall evaluate the uncertainty of measurement when:

- Calibrations,
- Methods that give quantitative results,
- And also, in cases where it is important for the reliability of the results.

Calculating uncertainty helps ensure the reliability of measurements, which is used when:

- Validation and verification of methods
- Equipment calibration
- Evaluation of analytical quality control

It is necessary to develop a function for calculating uncertainty with configuration by methods and templates.
The following features should be available:

- Support for various methods of calculating measurement uncertainty
- Configuring calculation templates for different types of studies
- Storage and management of uncertainty budgets
- Integration with other LIMS modules
- Generating Measurement Uncertainty Reports

The function must support the following methods:

- Type A (statistical approach)
- Type B (assessment based on a priori information)
- Combined method (types A and B)
- Expanded uncertainty with coverage factor

Configuring templates

- Creating calculation templates for various research methods
- Setting up uncertainty components for each template
- Assignment of sensitivity coefficients
- Setting coverage rates
- Determination of degrees of freedom

Uncertainty budget (needed to calculate expanded uncertainty):

- Formation of a full uncertainty budget
- Accounting and classification of sources of uncertainty
- Quantitative assessment of the contributions of each source
- Visualization of component contributions to overall uncertainty

User interface development required:

- Form for creating and editing calculation templates
- Data entry form for uncertainty calculation
- Presentation of calculation results in tabular and graphical form
- Calculation parameters settings interface

This function is needed to register measurement results, to calculate uncertainty for test methods, and to generate test protocols and reports.

It is necessary to implement basic algorithms:

Calculation of Type A standard uncertainty
- Sample mean
- Standard deviation
- Standard uncertainty of the mean

Calculation of Type B standard uncertainty
- According to the characteristics of measuring instruments
- According to reference data
- According to calibration data
- According to expert estimates

Calculation of combined standard uncertainty
- Taking into account correlations between input values
- Application of the law of propagation of uncertainty

Calculation of expanded uncertainty
- Determining the coverage rate
- Taking into account the effective number of degrees of freedom

Requires storage in LIMS:
- Uncertainty Calculation Templates
- Parameters of uncertainty sources
- Calculation results
- Change history

Based on the results of the uncertainty calculation, the following reports should be generated:
- Measurement uncertainty budget
- Summary of uncertainty for a series of measurements
- Statistical information on uncertainty components
- Graphical representations

Export formats for obtained values: PDF, Excel, XML, JSON

At the design stage, the Developer must obtain detailed consultations from the Beneficiary's experts on this module, develop technical specifications and agree them with the Beneficiary.

5.2.9 Electronic document management system (EDMS)

The LIMS must include a separate module for the Electronic Document Management System (EDMS), which is designed to automate the registration, storage, approval, execution, control, and signing of documents used in the DEM activities. The EDMS must support the full cycle of processing internal and external documents, including the use of a cloud-based electronic signature for signing electronic documents, including protocols.

The LIMS system must be integrated with the Infodocs electronic document management system (EDMS), a government system also used for document exchange between organizations. The integration will allow the LIMS system to automatically receive documents from organizations participating in the EDMS and send signed electronic documents to organizations participating in the EDMS.

The EDMS must support document typing:

- Incoming (external) - letters, acts, orders, requests, orders from external organizations;
- Outgoing - responses, acts, reports sent to external organizations;
- Internal - orders, instructions, protocols, methods, reports, memos, instructions, etc.
- Procedural documents - Standard operating procedures (SOP), instructions, regulations;
- Project documents are documents on projects, contracts, and assignments.

Each document is assigned a unique registration number, and its registration date, source/recipient, type, responsible employee, etc. are recorded.

Automatic document numbering must be implemented during the registration process, according to the numbering rules that are managed in the settings.

For each document, there should be the option to attach scans or electronic files, which should be stored in the file storage.

It should be possible to link a document to a request, project, sample, or methodology.

After registration, the user must create a document flow - prepare a resolution, indicate the document executors, select a document reviewer and controller, indicate the document execution deadlines, and whether the document is under control.

After issuing a resolution, the head of the department to which the resolution is addressed can also issue their own resolution, appointing executors and a finalizer. The finalizer prepares a response regarding the resolution's implementation. If an outgoing document is required, this is also prepared, a document file is attached, and the outgoing document then undergoes the approval process. Once the document is implemented, the user marks it in the EDMS. The system should allow for posting final and interim responses, as well as comments. Approval should be available for both internal and outgoing documents. It should be possible to reject or return the document for revision.

It should be possible to create instructions for employees and issue memos within the framework of document execution.

For certain types of documents, such as test result reports, it should be possible to set up standard document flow paths. For example, from the test Developer to the laboratory manager, and from the laboratory manager to the person responsible for signing the report. Once signed, the document should be registered and then sent to the organization that commissioned the test.

In LIMS, templates must be prepared for all types of documents.

The history of all actions on a document, including date, time, and user, must be recorded in the system.

Document signing must be accomplished using a cloud-based electronic signature provided by the Infocom State Enterprise certification authority. To achieve this, integration with this certification authority is required.

Completed documents must be submitted to the closing and, after closing, after a certain period of time, must be transferred to the archive.

The LIMS system should have a user-friendly dashboard for monitoring current document assignments. Users should be able to see which documents or assignments are currently being processed and how many days they have to complete them without delay.

The LIMS must implement control over access rights to documents.

Internal documents approved in the LIMS EDMS, which underpin the work of the DEM, must be stored in a separate registry, with the ability to retrieve data from the EDMS on the procedure for their preparation, approval, and signing. For convenience, current documents in the registry can be stored in various categories, such as contracts with customers, internal audit, methodologies, etc.

For example, it is important for the DEM to store the following documents:

- F.PR-2021-06-01 Journal of receipts, incoming inspection and supplier assessments
- F.PR-2021-06-02 Supplier Assessment Card
- Quarterly information on the movement of precursors that are not drugs subject to control in the territory of the Kyrgyz Republic for submission to the Department of Drug Control and Monitoring of the Ministry of Health of the Kyrgyz Republic
- F.PR-2021-11-03 Schedule of internal laboratory quality control of tests
- F.PR-2021-11-04 Protocol for in-laboratory quality control of tests
- F.PR-2021-11-05 Interlaboratory Comparison Report
- F.PR-2021-16-01 Quality objectives for 2025
- F.PR-2021-17-07 Risk Passport
- F.PR-2021-18-01 Plan for the implementation of corrective actions to eliminate non-conformities/eliminate (minimize) risks
- F.PR-2021-18-02 Report on the implementation of corrective actions to eliminate non-conformities
- F. PR-2021-19-03 Internal Audit Plan
- And others.

The EDMS should have a convenient system for searching and filtering by various document attributes.

At the design stage, the Developer must develop technical specifications for this module, prepare prototypes and agree them with the Beneficiary.

5.2.10 Inventory and equipment

The Inventory and Equipment module includes functions for accounting of laboratory equipment and its maintenance.

Equipment register
The LIMS must have a register of all laboratory equipment with unique identification numbers.

The following characteristics must be stored for each piece of equipment:

- Identifier
- Name and model
- Serial number
- Inventory number
- Country of origin
- Manufacturer
- Date of purchase
- Date of commissioning
- Price
- Warranty period
- Technical documentation (possibility of file attachment)
- Location (laboratory, office, room)
- Responsible person
- Equipment status (in operation, under maintenance, undergoing calibration, written off)
- Equipment category (analytical, auxiliary, measuring, etc.)
- Metrological characteristics (for measuring equipment)

Equipment condition monitoring

It is necessary to maintain a history of equipment condition monitoring:

- Registration of the current status of each piece of equipment
- Maintaining a history of changes in equipment statuses, indicating the date, time, and reason for the change
- Possibility of attaching photographs and documents confirming the condition of the equipment

The LIMS should have the ability to record the temperature regime in the refrigerator, as well as record the environmental conditions.

Maintenance management

- Formation of scheduled maintenance schedules (document - F.PR-2021-05-04)
- Registration of unscheduled maintenance
- Record of completed maintenance work indicating:
    - Dates and times of work
    - Developer (in-house specialist or third-party organization)
    - Type of work performed
    - Used spare parts and materials
    - Service results
    - Cost of work (for external Developers)
    - Storage of documents confirming the performance of technical maintenance

Calibration and verification management

- Formation of schedules for planned calibration/verification
- Notification of upcoming calibration/verification dates
- Registration of calibration/verification results with the ability to attach supporting documents
- Control of validity periods of calibration/verification certificates

Accounting of faults and repairs

- Registration of identified faults indicating:
    - Date and time of discovery
    - Description of the malfunction
    - The person who discovered the malfunction
    - Impact on workflow
- Maintaining a log of repair work indicating:
    - Start and end dates of repairs
    - Repair Developer
    - Replaced parts
    - Repair costs
    - Warranty period for the work performed

The following documents in Word and PDF format must be generated using templates:

- Equipment Registration Card F.PR-2021-03-01
- Equipment Maintenance Schedule (F.PR-2021-05-04)
- Refrigerator Temperature Recording Card F.PR-2021-04-01/02
- Environmental Conditions Registration Card F.PR-2021-04-01/01
- Schedule of intermediate equipment checks and equipment calibrations F.PR-2021-05-02
- Logbook for recording the results of intermediate inspections of the drying oven F.PR-2021-05-03
- Equipment inventory list
- Maintenance log
- Log of malfunctions and repairs

At the design stage, the Developer must develop technical specifications for this module, prepare prototypes and agree them with the Beneficiary.

5.2.11 Accounting for reagents and consumables

The LIMS must implement the ability to maintain a nomenclature of consumables:

- Name and article number
- Unit of measurement
- Manufacturer/supplier
- Best before date
- Storage conditions
- Minimum stock
- Storage location

- Accounting for current balances for each item
- Accounting for batches of consumables indicating:
    - Dates of admission
    - Batch numbers
    - Expiration date
    - Quality certificate (possibility of attachment)

In LIMS it should be possible to form:

- Act on write-off of reagents
- Report for the Ministry of Health “Quarterly information on the movement of precursors that are not drugs subject to control in the territory of the Kyrgyz Republic”

- Journal of Chemical Reagent Life Extension F. PR-2021-06-03

Inventory control
The inventory control system must perform the function of inventory control:
- Automatic minimum stock control with alerts when threshold is reached
- Expiry date monitoring with expiration date alerts
- Generating reports on current balances

Procurement management
- Generating requests for the purchase of consumables
- Tracking the status of applications
- Registration of receipt of consumables
- Maintaining a register of suppliers with contact information, delivery and payment terms
- Maintaining a log of receipts, incoming inspections and supplier assessments
- Supplier evaluation cards must be maintained

Generation of standard reports in PDF and Excel formats:
- Journal of receipts, incoming inspection, and supplier assessments F.PR-2021-06-01
- Report on current balances of consumables
- Report on material consumption for the period
- Equipment Utilization Efficiency Report
- Supplier Evaluation Card F.PR-2021-06-02

At the design stage, the Developer must develop technical specifications for this module, prepare prototypes and agree them with the Beneficiary.

5.2.12 Personnel management and training

In accordance with clause 6.2.2 of ISO/IEC 17025–2019, the Laboratory shall document the requirements for the competence of personnel for each function that affects the results of laboratory activities, including requirements for education, qualifications, professional training, technical knowledge, skills, and experience.

To achieve this, a special module must be developed within the laboratory's management system (LIMS) that contains information on the education, retraining, certification, and work history of personnel. Its purpose is to ensure systematic recording, monitoring, and confirmation of the competence of laboratory staff who influence the reliability of results, in accordance with the standard's requirements.

If the system is integrated with the E-Kyzmat information system, the data must be linked.

The LIMS must contain competency profiles - these are the competence requirements for each position and function:
- Education
- Qualification
- Professional training (education, workshops)
- Technical knowledge and skills
- Experience
- Relationship of functions with methods/operations of laboratory activities

According to the form “Criteria (requirements) for the competence of personnel to perform laboratory activities” F. PR-2021-03-01.

An employee card must be maintained for each employee:

- Full name, position, department
- Date of admission, length of service, experience
- Education (higher, additional professional education, certifications)
- Completed trainings and courses
- Knowledge assessment protocols
- Retraining/Reassessment Deadlines
- Uploading and storing scanned copies of diplomas, certificates, and work record books

Internal auditors must maintain a Personal Card of the Internal Auditor F.PR-2021-19-02.

Competency assessment

- Comparison of the actual employee data with the required data for the position
- Competency Status Reporting (Personnel Competency Monitoring Report F.PR-2021-03-0)
- The opportunity to take the F.PR-2021-03-04 Learning Effectiveness Test at LIMS with assessment of test results, as well as saving the test results.
- Possibility of conducting a staff survey using the Staff Satisfaction Questionnaire F.PR-2021-20-01 with saving the survey results.
- Possibility of conducting a survey of internal auditors using the Auditor Assessment Questionnaire F.PR-2021-19-05 with the preservation of the survey results.
- Possibility of evaluating internal auditors using the internal auditor's assessment sheet F.PR-2021-19-06
- Possibility of storing the Minutes of the meeting of the certification committee to summarize the results of the internship F.PR-2021-03-02
- Generation of competency reports for auditors (including PDF/Excel format)

Planning and monitoring of training

- Training and Certification Schedule for Employees - Laboratory Personnel Training Plan for the Year F.PR-2021-03-03
- Reminders and notifications about the need for recertification
- Internal training log

The LIMS must store a history of all changes to employee profiles and cards, as well as signatures and approvals for access from responsible persons.

At the design stage, the Developer must develop technical specifications for this module, prepare prototypes and agree them with the Beneficiary.

5.2.13 Internal audit and reporting module of the KAC

This module should ensure the planning, execution, documentation, control and evaluation of internal audits, automate the generation of all related documents and the management of corrective actions.

It should be possible to form an annual audit program:

- Selection of processes, departments, methods
- Appointment of auditors (taking into account independence)

- Possibility of editing and adding unscheduled audits

The generation of the Internal Audit Program must be implemented according to form F.PR-2021-20-01.

Upon implementation of the Audit Plan (F.PR-2021-19-03), it should be possible to create a plan for each audit:
- Purpose, scope, criteria, documents
- Schedule (date, time, stages)
- Assigning team members
- Attaching files and links to documents

The Audit Plan must be generated using form F.PR-2021-19-03.

After the audit, it should be possible to generate an internal audit report in the form F.PR-2021-19-04.

The LIMS must record non-conformities and identified risks:
- registration of all identified non-conformities and risks
- assignment of priority and category
- binding to regulatory requirements
- link to corrective actions

The LIMS should provide the ability to create a corrective action plan for each identified non-conformity:
Create and maintain a plan for each identified non-conformity:
- Events
- Responsible persons
- Execution deadlines
- Evaluation of effectiveness
- Report on the results of implementation
- Notifications of late deliveries

The system must generate a Corrective Action Plan and it must be implemented according to form F.PR-2021-18-01.

It should be possible to automatically generate a report based on data from all audits for the period:
- Number of audits
- Frequency of nonconformities
- Repeated comments
- Results of corrective actions

The system must generate a Report on the analysis and evaluation of the activity process for the year in the form F.PR-2021-20-02.

It should be possible to create and maintain a laboratory improvement plan and generate a document in the form of the Laboratory Improvement Plan F.PR-2021-20-03.

All internal audit documents must undergo the signing procedure through the electronic document management system and be stored in the document register in the internal audit document category.

At the design stage, the Developer must develop technical specifications for this module, prepare prototypes and agree them with the Beneficiary.

5.2.13.1 Module for KCA reporting

During the analysis and design phase, the Developer, in collaboration with the Beneficiary, must analyze the laboratory procedures and reporting forms that, in accordance with the requirements of GOST ISO IEC 17025-2019, the DEM must submit to the Kyrgyz Accreditation Center (KCA). The Developer must also develop technical specifications for automating the forms and procedures, coordinate them with the Beneficiary, and implement processes for collecting procedures and reporting forms from various departments within the DEM to generate documents for subsequent reporting to the KCA. Some data for the reports must be generated automatically from existing automated blocks and then approved in the EDMS. For some forms and procedures, it will be necessary to develop data entry forms for document generation, followed by approval through the EDMS.

Below are the forms and procedures that need to be analyzed and automated.

No	Reporting block	Form/document
1	Laboratory passport	Form 1 Form 2 Form 3 Form 4 Form 5 Form 8 Form 9.1 Form 9.2 Form 10 Form 11 Form 12
2	PC/MLS Participation Plan and PC/MLS Participation Information	
	According to GOST ISO IEC 17025-2019	Laboratory procedures
3	4.1 Impartiality	PR-2021-01
4	4.2 Confidentiality	PR-2021-02
5	6.2 Personnel	PR-2021-03
6	6.3 Premises and environmental conditions	PR-2021-04
7	6.4 Equipment 6.5 Metrological traceability	PR-2021-05
8	6.6 Products and services provided by external suppliers	PR-2021-06
9	7.1 Review of requests, tenders and contracts	PR-2021-07
10	7.2 Selection, verification and validation of methods 7.6 Evaluation of measurement uncertainty	PR-2021-08
11	7.3 Sampling 7.4 Handling of test objects	PR-2021-09
12	7.5 Technical Records 8.4 Records Management	PR-2021-10
13	7.7 Ensuring the reliability of results	PR-2021-11

14	7.8 Reporting of Results	PR-2021-12
15	7.9 Complaints (claims)	PR-2021-13
16	7.10 Control of nonconforming work	PR-2021-14
17	7.11 Data and Information Management	PR-2021-15
18	8.2 Management system documentation 8.3 Management of management system documents	PR-2021-16
19	8.5 Actions Related to Risks and Opportunities	PR-2021-17
20	8.7 Corrective actions	PR-2021-18
21	8.8 Internal audits	PR-2021-19
22	8.9 Management Review 8.6 Improvements	PR-2021-20

5.2.14 Claims management and customer surveys

The LIMS should have the ability to store the history of claims received from customers and the results of their consideration.

The following information must be kept for each claim:

- Incoming number
- Date of registration
- Customer
- Request (test results)
- The essence of the claim
- Result of the review
- Measures taken
- Status
- Uploading a document file
- Outgoing response number
- Uploading the response document file
- Details of the personnel who reviewed the complaint

At the design stage, the Developer must develop technical specifications for this module, prepare prototypes and agree them with the Beneficiary.

Anonymous customer survey

After receiving the test reports, the program should send a link to the anonymous survey form to the email address specified by the customer.

The questionnaire must be completed in accordance with the Customer Satisfaction Questionnaire F.PR-2021-07-03.

The LIMS should provide the ability to analyze the survey results over a period, as well as by sample type:

- number of questionnaires sent;
- number of completed questionnaires;
- minimum, average, maximum scores for answers to questions.

At the design stage, the Developer must develop technical specifications for this module, prepare prototypes and agree them with the Beneficiary.

5.2.15 Reports and Analytics

It is necessary to create a user-friendly module so that one can quickly obtain the required standard reports based on the results of the tests carried out.

At the design stage, the Developer, together with the Beneficiary, must define and design the reports that the LIMS must generate for each module and implement their generation for different periods of time, including monthly, quarterly, semi-annual, and annual reports:

- upon request for order
- for sampling
- for registration of samples
- based on test results
- according to scheduled tests
- for testing under contracts
- for testing based on complaints, including those conducted jointly with inspectors
- for exceeding the maximum permissible concentration
- separately by sample types and objects (atmospheric air, water bodies, Lake Issyk-Kul, the Chui River, the Talas River, etc.)
- by personnel (qualifications, training, employee workload)
- according to documents in the electronic document management system
- upon receipt of funds
- according to questionnaires
- and others.

Report generation should be available for viewing for the selected period in HTML format with the ability to search, filter and sort, with the ability to export summary reports in Excel and PDF format.

5.2.15.1 Report Designer

The Report Designer is a tool used to create and customize various reports and documents according to user needs. It's designed to create custom reports without the need for additional software coding. This tool provides a convenient way to customize and format reports, allowing users to generate customized reports based on their specific needs. The Report Designer facilitates the process of creating and customizing reports, making it a useful tool for data analysis.

In LIMS, for analytical purposes, it is necessary to develop a special module for generating statistical reports based on various criteria.

The Report Designer should include:

- Visual Interface. An intuitive visual interface that allows users to easily add and customize report elements.
- Selectable data types. Support for various data types, such as numbers, lines, dates, and more.
- Grouping and sorting: Ability to group data by specific fields and sort them for easier analysis.
- Filters. Apply filters to limit the data in your report and improve its relevance.
- Export: Ability to export reports in PDF, Excel, CSV formats.
- Graphs and Charts: Ability to generate graphs and charts to visualize data in a report.

- The ability to save templates of designed reports for each specific user;
- In the administrative panel: the possibility to add criteria for generating reports.

As part of this ToR, the Developer is required to study the data collected by the system, gather user requirements for this module, develop a specification for this module, and develop module prototypes. The specification and prototypes must be submitted to and approved by the Beneficiary.

5.2.16 User Access Management

The user rights and roles management system should allow a specific role to be assigned to a user. User roles should include individual rights, the combination of which should allow new roles to be created or existing ones to be expanded, as well as individual rights to be added to a particular user in addition to the assigned role. Rights are granted to users to a certain extent. For example, the right to view test data within a single laboratory.

Assignment of roles and rights in the system will be performed through the LIMS administration subsystem.

User roles that must be implemented in the system:
- Director of Division/Unit
- Quality Manager
- Management Specialist
- Head of the laboratory
- Lab assistant
- Application Manager
- Sampler
- Administrator

The user rights and role management system must allow the termination or suspension of a user's access to the system.

The following data must be stored for each user:
- Surname
- Name
- Patronymic name
- Job title
- Taxpayer Identification Number (INN)
- Department
- Email
- Telephone

If the system is integrated with the E-kyzmat IS, a link must be established between the employee data from the E-kyzmat IS and the user in the LIMS.

The system must store a history of granting, suspending, and terminating user access to the system, indicating roles, rights, and reasons - “Access Log”.
The system of user rights and roles must be finalized and agreed upon with the Beneficiary at the design stage.

5.2.17 Integration with external systems

5.2.17.1 General Provisions

The LIMS provides for integration with external government and departmental systems through unified data exchange interfaces. Information exchange is performed in automatic and semi-automated modes in accordance with approved interaction regulations. Generated reports should be shared with the National Water Information System under the Water Service. List of reports to be shared with the National Water Information System should be agreed with the Water Service under MWRAPI. The LIMS should consider report transmission to the Water Services in close consultations.

5.2.17.2 Data exchange architecture

- Message formats: JSON (main) and XML (when interacting with SOAP services).
- Interaction type: RESTful API (primary), SOAP 1.2 – if compatibility is required.
- Encoding: UTF-8.
- All exchanges are carried out through secure communication channels using the HTTPS protocol (TLS 1.2 and higher).
- Messages that contain:
    - transaction metadata (ID, date, source);
    - payload (data in JSON/XML);
    - electronic signature or JWT token, if required by the security policy.

5.2.17.3 Frequency and synchronization methods

- Real time (online) — for critical interactions (e.g., UIS and Tunduk).
- Periodic synchronization - for directories and service data (once per hour or day, according to the cron-schedule).
- Asynchronous exchange - via message queues (e.g. RabbitMQ / Kafka) or push notifications (webhook).
- All exchanges have transaction identifier (UUID) control to ensure idempotency and tracing.

5.2.17.4 Exchange logging requirements

- The system is required to maintain a log of integration exchange, including:
    - date and time of request and response;
    - source and addressee;
    - type of operation;
    - execution status (success/error);
    - error code and description (if any).
- Logs are stored for at least 12 months and are only accessible to system administrators.
- It is possible to export logs in CSV or JSON format for analysis and auditing.
- A mechanism for tracing correlation identifiers (traceId, spanId) is implemented to link logs between subsystems.

5.2.17.5 Requirements for the protection of transmitted data

- Data transfer is carried out only via secure channels (TLS 1.2+).
- The following are used for authorization and access control:

    - OAuth 2.0 (when integrated with UIS);
    - JWT tokens (for REST API interactions);
    - Electronic certificates (when exchanged through the “Tunduk” system).
- All data containing personal information is encrypted during transmission and stored in accordance with the requirements of the legislation of the Kyrgyz Republic on the protection of personal data.
- At the transport protocol level, integrity control and protection against replay attacks (nonce + timestamp) are implemented.
- API access logs are protected and signed with the administrator's electronic signature.

5.2.17.6 Integration API (REST API Gateway)

To ensure centralized and secure interaction with external information systems, the development of an integration API gateway (REST API Gateway) is envisaged.

Purpose:

- Providing a single point of access to all services and data of the DigiLab 2.0 information system.
- Unification of exchange formats and routing of requests to internal microservices.
- Enhance security through centralized authentication, authorization, and traffic filtering.
- Monitoring and logging of integration calls.

Main features of REST API Gateway:

1. Access control via OAuth 2.0 and JWT tokens.
2. Support for JSON and XML formats.
3. API versioning (v1, v2, etc.).
4. Support for cross-domain requests (CORS) when accessing external systems.
5. Logging of all requests, recording the time and status of responses.
6. Possibility of limiting the number of requests (rate limiting) and protection against overload.
7. Support for standard REST methods: GET, POST, PUT, PATCH, DELETE.
8. Ensuring fault tolerance and horizontal scalability.

Implementation requirements:

- Implementation language and framework: Python (FastAPI / Django REST Framework) or equivalent.
- Must support interaction with internal microservices via a secure internal API.
- All external requests go through a gateway with mandatory data schema validation.
- API documentation must be formatted in OpenAPI 3.0 / Swagger format.

5.2.17.7 Integration with the Unified Identification System (USI)

Purpose: To ensure authentication and authorization of users of the information system using the state Unified Identification System (USI), which is a component of the infrastructure of the State Enterprise “Tunduk”.

Description of interaction:

- The OAuth 2.0 / OpenID Connect protocol is used.
- LIMS redirects the user to the UIS page for authentication.
- After successful authorization, the UIS returns an access token (access_token) and a user identifier (sub) to the system.
- Based on the token, the system receives basic information about the user (full name, TIN/PIN, role) via the Unified Information System (UIS) API.
- All operations are performed over a secure HTTPS connection (TLS 1.2 and higher).

Main scenarios:

1. The user selects to log in via the Unified Information System (UIS).
2. The system redirects it to the UIS gateway for authentication.
3. UIS returns a token and profile data.

4. LIMS registers the session and assigns access rights.

5.2.17.8 Integration with the Infodox electronic document management system

Purpose: To ensure the exchange of documents and official correspondence between the LIMS and the state electronic document management system (EDMS) “Infodox”, used in state and municipal bodies of the Kyrgyz Republic.

Description of interaction:

- The REST API of the Infodox electronic document management system is used.
- Data transfer is via HTTPS protocol.
- Exchange formats: JSON / XML.
- Authentication is performed using JWT tokens or credentials issued by the EDMS administrator.
- Bilateral exchange of document metadata is supported: registration numbers, statuses, executors, registration and approval dates.

Main scenarios:

1. Sending documents from LIMS to the Infodox electronic document management system for registration.
2. Obtaining information about the document processing status.
3. Obtaining the registered number and date.

4. Receive notifications about new incoming documents (via webhook or periodic API polling).

5.2.17.9 Integration with the interdepartmental electronic interaction system “Tunduk”

Purpose: Ensuring interdepartmental data exchange between the LIMS and other state information systems through the state integration platform “Tunduk”, operated by the State Enterprise “Tunduk” under the Ministry of Digital Development of the Kyrgyz Republic.

Description of interaction:

- SOAP 1.2 and REST API protocols are supported.
- Interaction is carried out through the Interdepartmental Interaction Gateway (IIG).

- Authentication and identification - using an electronic certificate (EDS) or API key issued by the operator of the State Individual Entrepreneurship Service “Tunduk”.
- Data transfer is carried out via a secure communication channel (HTTPS, TLS 1.2+).
- Exchange formats are XML (for SOAP services) and JSON (for REST services).
- Logging of requests and responses is implemented to audit interdepartmental exchanges.

Main scenarios:

1. Initiating a request to an external government system (via the “Tunduk” API).
2. Receiving response data from an external system.
3. Transfer of information on laboratory tests and results (if necessary, according to regulations).

4. Receipt for acceptance and results of request processing

Compatibility with the state system of interdepartmental interaction “Tunduk”

The LIMS must be fully compatible with the state system of interdepartmental electronic interaction “Tunduk”, functioning under the management of the State Enterprise “Tunduk” under the Ministry of Digital Development of the Kyrgyz Republic.

Compatibility requirements:

1. The system must use standardized data exchange interfaces supported by the State Enterprise “Tunduk”:
    - SOAP 1.2 and REST API;
    - XML and JSON message formats.
2. Support for authentication and authorization mechanisms stipulated by the regulations of the State Enterprise “Tunduk”:
    - using an electronic certificate (EDS) for SOAP interactions;
    - Support for API keys and JWT tokens for REST interfaces.
3. Data transfer must be performed exclusively via secure communication channels (TLS 1.2+).
4. The system must ensure the correct registration and processing of all incoming and outgoing requests received through the Tunduk gateway, with the preservation of exchange logs.
5. The implementation must comply with the regulations for interdepartmental interaction of the State Enterprise “Tunduk” and be tested on the platform's test environment (sandbox) before being put into commercial operation.

When changing formats or versions of the API, Tunduk must ensure backward compatibility and the ability to adapt without data loss.

5.2.17.10 Integration with the E-Kyzmat information system

The LIMS must ensure integration with the state service platform “E-Kyzmat” to provide the population and organizations with electronic government services in terms of submitting requests, receiving environmental monitoring results, and exchanging documents.

Key integration features with E-Kyzmat:

1. Reception of applications and requests from citizens and organizations
2. Transfer of environmental research results
3. User authorization and identification
4. Data exchange in the following format:

    - JSON (REST API);
    - XML (as required by the regulator);
    - use of approved data schemas.

Data exchange architecture with “E-Kyzmat”:

- interaction is carried out via API Gateway;
- For protection the following is used:
    - TLS 1.2+,
    - OAuth 2.0 / JWT,
    - digital signature (when transmitting protocols);
- each interaction is recorded in a log:
    - time,
    - request,
    - answer,
    - user ID.

Frequency and synchronization methods:

- online mode (real-time),
- confirmation of message delivery,
- retry on failure (retry/queue).

5.2.17.11 Integration with the Infocom certification center

Key features of integration with Infocom:

1. Verification of individuals
2. Verification of legal entities
3. Biometric verification (optional)
4. Working with digital signatures

Exchange formats and protocols:

- SOAP or REST (depending on the provided Infocom interface);
- XML/JSON messages;
- using official Infocom XSD schemas.

Data protection and information security requirements:

- TLS secure channel;
- digital signature of requests (if required by the service);
- logging of all actions:
    - Full name/TIN of the operator,
    - request type,

- check result,
- lead time.

Sync frequency:

- online mode (upon request),
- caching data with a limited period of time (if permitted by the regulator).

5.2.17.12 Integration with the accounting information system.

It should be possible to transfer data on concluded contracts and invoices to the accounting information system, as well as automatically confirm receipt of payment for customer requests from the accounting system to the LIMS.

5.2.18 File storage

In LIMS, file storage must be used to store files, which must ensure:

- secure long-term storage of documents
- the ability to manage access and version control
- support for integration with LIMS
- scalability
- compliance with information security requirements.

There should be support for storing files in any common format: .docx, .pdf, .xlsx, .xml, .csv, .jpg, .png, .zip, as well as files with spatial data .kml .kmz, etc.

Files are stored without changing their original format. Support for PDF and image previews in the interface would be desirable.

The repository must support hierarchical or metadata storage organization (for example, by folders or by attributes: project, date, type, author, etc.).

Each file or document must be linked to a specific object in the system (document, application, sample, method, report, etc.).

There should be a flexible system of access rights at the level of folders, file types and individual documents.

File encryption must be ensured during storage and transmission.

All operations must be recorded: who, when, and what was uploaded, deleted, or changed.

The repository must be integrated through the use of API to interact with other LIMS.
There should be the ability to customize automatic backups, as well as support for external storage: local disk, NAS, S3-compatible storage.

5.2.19 Notification system

The LIMS must implement a block system of notifications in the system and via e-mail.

The system must generate different types of notifications:

- notifications of receipt of samples/documents/instructions/memos;
- notifications about the need to register samples, enter test results, and execute a document (reminders).

The system should allow users to see new notifications, view them, and mark them as read. Notifications should be stored in the system.

The user should be able to enable email notifications in the settings. If this feature is enabled, the user will receive all system notifications via the specified email address.

This module must be designed and agreed with the DEM.

5.2.20 Requirements for the administration subsystem

The LIMS administration subsystem must contain the main functional blocks for system management.

Functions for administering the locked part of the system:

- management of users, roles, rights, access logging;
- managing system settings;
- notification management;
- management of business processes in the system;
- system backup;
- management of system reference information;
- view user actions in the system.

The settings section should allow management of all settings available in the system. The admin panel should also include a section for managing notifications.

Section on business process management in the electronic document management system.

5.2.20.1 Log file

A user action log should be available in the admin panel.

The LIMS must have a logging system, and the following data must be recorded in the log file:

- Username
- Date and time of action
- Action
- Object of action
- Additional action data
- IP address

The system should also have a history of changes to the data in these fields. The list of fields for which a history of changes should be kept needs to be decided during the design phase.

5.2.20.2 Error handling system

An error handling system must be implemented in the LIMS.

The data entered by the user must be checked for validity, and mandatory fields must be filled in. If errors are detected, the system must display an error message asking for the correct data to be entered so that the user of the LIMS understands what he/she did incorrectly or did not fill in.

A system for handling known system errors and exceptions must also be implemented to inform the user about the problem that has occurred.

5.2.20.3 Organization of reference books

All reference information used in the LIMS is stored in reference books and classifiers and is used in system modules. The system must implement the ability to add new values to all reference books and classifiers, recording the date of value addition, as well as edit values, recording the date of value modification. It must also be possible to designate a value as "inactive" to exclude it from value selection when filling in data. The LIMS must not allow values to be deleted from reference books. When the "Delete" button is clicked, the reference book entry must be assigned the "deleted" status and no longer appear in the system, but the value is not deleted from the database. These same requirements apply to new system modules.

5.2.20.4 Registration of system failures and corrective actions

The LIMS must ensure that measures to eliminate system failures that affect the reliability of results are recorded and monitored, with mandatory recording of corrective actions.

The administration subsystem must have the ability to enter data and receive reports on system failures.

1. Registering a system failure
Electronic form for registering failures:

- Date/time
- Department/responsible person
- Description of the failure
- Impact on results (yes/no + comment)
- Detection source (audit, user, quality assurance, etc.)
- Category assignment: critical / moderate / minor
- Attaching screenshots, files, logs, instrument readings, etc.

2. Temporary measures to minimize the consequences:

- Appointment of a responsible person
- Steps taken
- Implementation period
- Suspension of work in LIMS (optional) - if yes, then for how long.

3. Corrective actions:

- Assessing the cause of the failure
- Creating a corrective action plan (with a description of the activities)
- Events
- Responsible
- Deadlines
- Documentation of completed actions
- Result

- Verifying the effectiveness of corrective measures

Reports must be generated for each failure and for failures over a period.

Administration functions must be agreed upon at the design stage.

5.2.21 Requirements for the organization of work offices in LIMS

The LIMS must ensure that each user has access only to those functions, modules, and information that correspond to his/her role, access level, and area of responsibility, and also guarantee the traceability, security, and confidentiality of data in the system.

Authorization and authentication

LIMS is a closed system; access is only possible through an individual user account.

Authentication must be through the Unified Information System (UIS) and PIN entry, as well as user verification through the E-Kyzmat information system.
The session should be automatically blocked if there is no activity (for example, 15 minutes).
All logins and login attempts must be logged, IP address, time, and device must be recorded.

Upon logging into LIMS, each user sees a personalized dashboard, including:

- Only those modules that are allowed by his/her role (e.g. “Order Requests”, “Sample Registration”)
- Only those records that are allowed to him/her (for example, by department or laboratory)
- Work only with those documents in which he/she is an executor, or to which he/she has access to view.

The following must be implemented in the LIMS:
- Quick actions related to user functions
- To-do list, reminders, notifications
- History of own operations
- Selection of documents in progress, etc.

5.2.22 Mobile application

To improve the convenience and efficiency of the employees of the Department of Analytics, Metrology and Coordination, it is necessary to develop a mobile application that ensures the prompt collection and transmission of data.

A cross-platform application compatible with Android and iOS must be developed to ensure its use on various devices, including smartphones and tablets.

Key features of the mobile app

SAMPLING
- Receiving a sampling assignment
- Obtaining a sampling plan

- Display of the current plan indicating sampling locations, sample types and required parameters
- Possibility of filtering and searching for the required sampling points.
- Interactive map with routing to sampling locations.

Entering sampling data
- Recording of environmental parameters (temperature, humidity, pressure).
- Filling in the data in the Sample Passport
- Filling in the data in the Test Referral Form
- Ability to add text comments and additional data

Geolocation recording
- Automatic recording of GPS coordinates of the sampling location.
- Display of geo-points on the map with the ability to view the selection history.

Recording the exact time of sampling
- Automatic recording of sample collection time with the possibility of manual adjustment.
- Synchronize time with the server if there is Internet access.

Photographing the sample
- Ability to take pictures of the sample and surrounding environment.
- Automatic attachment of photographs to the registered sample.
- Storing photos in the application until they are transferred to LIMS.

TRANSPORTATION
- Entering sample transportation data

REGISTRATION
- Filling out the registration card and assigning a registration number

SUBMITTING A SAMPLE FOR TESTING
- Submitting a sample to the laboratory for testing
- Confirmation of transfer by the responsible employee.

OBTAINING INFORMATION
- Search for sample status data by scanning a QR code and track the sample status in the laboratory (in progress, completed, re-sampling required).

Offline mode of operation

The application must support operation without internet access. In this mode, data is stored in the device's local storage and is automatically uploaded to the LIMS when the connection is restored.

Additional features for user convenience
- Intuitive interface for quick data entry.
- Notifications and reminders about the need to complete tasks.
- Transaction history available in the app.
- Integration with the corporate system for user authorization and access management.

Mobile application development will ensure:

- Prompt data collection without the use of paper media.
- Improving the accuracy of information recording (automatic recording of time, geolocation).
- Speeding up the process of transferring samples to the laboratory.
- Reducing the likelihood of errors when filling out data.
- Implementation of this solution will significantly optimize the sampling process, improve data quality control, and provide convenience for department employees.

5.3 Requirements for types of security of the LIMS

5.3.1 Requirements for mathematical support

The system's software must support the functions of all its modules, implemented using programmable hardware. Algorithms must be operative for all input and processed data values.

5.3.2 Requirements for information support

The composition, structure and methods of organizing data in the system modules must be determined at the design and specification stage.

All necessary documents, reference books, regulations, questionnaires, reports, etc. must be provided to the Developer by the DEM.

The database structure must be organized in a rational way that excludes a one-time complete download of the information contained in the system database.

5.3.3 Requirements for linguistic support

All user interface elements (forms, controls, reference values, modal windows, etc.) of the system must use both Kyrgyz and Russian. Language switching must be supported. Exceptions are permitted only for system messages.

The method of organizing dialogue with the user must ensure:

- reducing the likelihood of the operator making random errors;
- provide logical control of data input.

5.3.4 Software requirements

The system software must be sufficient to implement all its functions.

The client part of LIMS must be a cross-browser application, working correctly in popular browsers - Google Chrome, Mozilla Firefox, Safari in supported versions no older than 3 years from the year of release.

The development of the LIMS requires the use of open-source software that does not require additional licensing costs. The developer is free to choose the technology independently.

5.3.5 Requirements for organizational support

The LIMS is being developed for all employees of the Department of Environmental Monitoring and regional laboratories. To develop a functional system that will ensure compliance with all requirements, the Beneficiary must establish a working group that will focus on the development, pilot implementation, and commercialization of the LIMS.

The DEM must also identify officials responsible for:

- representation of the DEM in the process of developing the LIMS (participation in development, provision of documentation, information, approval of the technical project, design layouts, versions, etc.);
- consulting the Developer on the subject area;
- introduction of the LIMS into trial operation;
- documentary registration of the LIMS (instructions, procedure for interaction with the personnel who service the LIMS, regulations for interaction with the Developer, etc.);
- for the integration of LIMS with other information systems;
- LIMS maintenance (providing user and technical support for LIMS and equipment).

Only employees who have completed training in using the system in accordance with the training methodology and who have successfully passed the test based on the training results must be allowed to work with the system.

The Beneficiary must develop documents on the use of the system in work - instructions, regulations for interaction with the Developer, etc.

5.3.6 Requirements for methodological support

When developing and implementing new modules of the information management system, the Beneficiary and the Developer are jointly required to ensure compliance with the following regulatory legal acts governing the area of development and implementation of information systems for government agencies of the Kyrgyz Republic, listed in Section 2 of this technical assignment.

The DEM must prepare and transfer to the Developer all approved internal documents, required reference books and classifiers, reports, forms and other documents.

5.4 General technical requirements

5.4.1 Requirements for the number and qualifications of personnel and users of the LIMS

All employees of the Department of Environmental Monitoring and regional laboratories must work with the LIMS in real time. Currently, there are approximately 50 such employees.

All users of the system can be divided into the following groups:

- Director of Department/Unit
- Quality Manager
- Management Specialist
- Head of the laboratory
- Lab assistant
- Application Manager
- Sampler

- Administrator

Director of Department/Unit— This is the department manager who must have access to the electronic document management system, inventory and equipment, requests, customers, reagent and consumables accounting, personnel management and training, the "Reports and Analytics" module, etc. The manager must have access to view data and work with documents in the electronic document management system.

Quality Manager— This is the employee responsible for quality assurance. He/she has access to modules for quality control, settings, personnel management, inventory, customers, customer surveys, internal audit, order requests and contracts, working with the electronic document management system, reports, and analytics.

Management Specialist— is an employee who has access to settings, personnel management, user management, and documents in the electronic document management system, where he/she has the role of a general department employee.

Head of the laboratory— This is the head of the department responsible for conducting tests. The laboratory director has access to the analysis unit, the electronic document management system, and the right to approve test results. He/she doesn`t have access to order requests or to customers.

Lab assistant— This is the employee who conducts the tests. He/she has access only to his/her own tests, as well as to the EDMS system and documents to which they have access. They do not have access to order requests or customers.

Application Manager - an employee who handles order requests and customer contracts, plans sample collection, and prepares final protocols. He/she also has access to the electronic document management system.

Sampler - an employee who collects samples. He/she has access to the "Sampling" module, the electronic document management system, and the mobile app.
Administrator – a superuser with full access to the administrative panel, settings management, backups, etc.

To work with the LIMS, users must have computer skills, internet experience, and have successfully completed training on the system and passed the training course. Access to system functions and data must be determined according to job responsibilities and the level of access to information and data.

At the design stage, the Developer, together with the Beneficiary, must determine the rights available to a particular role and the system for assigning them.

5.4.2 Requirements for target indicators

The LIMS system can accommodate up to 100 concurrent users, with aimed response times of no more than 3 seconds for navigation, 5 seconds for data saving, and 15 seconds for generating standard reports. Meanwhile, complex report generation should not exceed 60 seconds.

5.4.3 Reliability requirements

Provided the hardware and basic software are functioning properly, the number of users does not exceed the stated maximum, the data center and client's internet bandwidth, and the user computer specifications meet the minimum specifications in the technical documentation, the LIMS with additional modules should operate reliably and perform all required functions. In the event of technical failures, it should be possible to restore the LIMS from backup copies.

5.4.4 Requirements for protecting information from unauthorized access

LIMS is a closed system, accessible to users after authorization.

The storage and transmission of passwords must be carried out in a secure manner, excluding the possibility of their viewing by OS and applications (DBMS).
Logging into the system and working with data and system functions shall only be available to authenticated and authorized users. It shall not be permissible for a situation to arise in which it is possible to access a system component or function without authorization.

The information security system must comply with the “Requirements for the protection of information contained in databases of state information systems”, approved by the Decree of the Government of the Kyrgyz Republic dated November 21, 2017, No. 762.

The components of the subsystem for protecting the LIMS from unauthorized access must ensure:

- user identification via the Unified Information System;
- checking user permissions when working with the system;
- delimitation of user access at the level of functions and information (user roles and rights);
- control of the integrity of uploaded documents.

To ensure the protection of transmitted data, the following methods must be provided:

- Protection against unauthorized access to the system servers is carried out using standard security tools of the operating system and DBMS by granting access rights to data only to server applications and accounts;
- Control of received information for the absence of malicious software code and control sequences;
- Protection of communication channels, including provision of an SSL certificate for data exchange using the HTTPS protocol.
- At the DBMS level, access control to data in the database must be implemented;
- Logging of individual user actions related to working with data determined by the Beneficiary.

5.4.5 Requirements for ergonomics and technical aesthetics

The interface languages must be Kyrgyz and Russian. The design of the system modules must be consistent, formal, and business-like, and must fit within the overall design of the web application without compromising its integrity.

The interface elements of the modules must be logically ordered and visually understandable.

The user interface of the system must provide the following capabilities:

- convenient input, editing and viewing of data, including documents;
- receiving input prompts;
- performing all operations listed in the functional requirements in an intuitive manner;
- displaying error messages when the input data is formatted incorrectly or contains invalid values, or when mandatory fields are not filled in.

An intuitive interface means that any system function can be accessed with no more than five mouse clicks on interface elements. Ease of use means that users refer to the User Manual no more than once every 15 minutes during training, and no more than once every two hours while using the system after training.

5.4.6 Requirements for operation, maintenance, repair and storage of LIMS components

To implement the DEM LIMS, an IT infrastructure must be provided, including both server and communication equipment, as well as user computers with Internet access

During the warranty period, the Developer shall provide technical maintenance of the LIMS and shall eliminate all identified discrepancies and defects.

Subsequently, maintenance must be carried out periodically in accordance with the developer's technical documentation. The technical documentation must contain procedures for providing technical support to the Developer and for interactions with the Developer. These procedures must ensure that the system operates in accordance with the operating modes described in the ToR.

Periodic maintenance and testing of technical equipment should include servicing and testing of all equipment used, including workstations, servers, cabling systems, network equipment, and uninterruptible power supplies. Based on the results of technical testing, the causes of any detected defects should be analyzed and measures taken to eliminate them.

When commissioning a system for trial operation, a backup plan for software and processed information must be developed. During system operation, personnel responsible for system operation must implement the developed plan.

It must be possible to organize automatic and manual backup of system data using the system and basic software (OS, DBMS) included in the LIMS hardware and software complex.

5.4.7 Requirements for patent purity and patentability

When developing a LIMS, only those intellectual property assets for which rights have been acquired and are used without infringing the intellectual property rights of third parties must be used. This requirement ensures compliance with copyright, related, patent, and other rights. The LIMS should be developed primarily on the basis of open-source software products that do not require the purchase of licenses, including DBMS and file storage.

In the event that third-party software components developed by other companies are used in the software and require the purchase of licenses, the Developer shall provide the Beneficiary with the required number of licenses that meet the requirements specified in these Terms of Reference at its own expense for the duration of the system for at least 3 years.

5.4.8 Requirements for standardization and unification

All pages, screen forms, and work areas must be designed taking into account the requirements of unification:

- All pages and screen forms of the user interface must be designed in a uniform graphic style, have the same graphic layout with the same arrangement of the main control and navigation elements;
- Similar graphic icons, buttons and other control (navigation) elements should be used to indicate similar operations;
- The external behavior of similar interface elements (reaction to mouse hover, focus switching, button pressing) should be implemented in the same way for the same type of elements.

When developing the LIMS, it is necessary to use state classifiers of the Kyrgyz Republic or international classifiers, if applicable.

5.5 Requirements for security and protection of information

5.5.1 General Provisions

The LIMS must ensure the protection of processed data and personal data in accordance with:

- Resolution of the Government of the Kyrgyz Republic No. 762 of December 29, 2017 "On approval of requirements for ensuring the security of state information systems";
- Law of the Kyrgyz Republic "On Personal Data" No. 58 of April 14, 2017;
- GOST 34.602–2020, section 5.7;
- ISO/IEC 27001:2022 - Information Security Management Systems (ISMS).

5.5.2 Data Security Levels

- Personal data of users and employees is classified as confidential information and is subject to "high" level of protection (in the terms of Resolution No. 762).
- Technical and system data (logs, configurations, metadata) - "medium" level.
- Open reference data (regulatory and reference information, classifiers) – "low" level.
- For each level, appropriate mechanisms for access control, encryption and integrity control must be implemented.

5.5.3 Authorization and role management mechanism

- Role-based access control (RBAC) is used with the ability to assign hierarchical roles: Administrator, Lab Assistant, Registrar, Auditor, etc.
- User authorization is carried out:
    - via UIS (OAuth 2.0 / OpenID Connect) for external users;
    - via the internal DigiLab 2.0 role management module for staff.
- The system must support multi-factor authentication (password + one-time code / electronic certificate).
- Each user action is performed only within the limits of his/her role and rights.

5.5.4 Logging user actions

- All user actions (authentication, viewing, changing, deleting data, administration) are subject to mandatory logging.
- The journal should include:
  - user ID;
  - event time (UTC+6);
  - IP address and source of the request;
  - description of the operation;
  - result (success / error).
- Logs are protected from unauthorized modification and stored for at least 12 months.
- It should be possible to export logs for internal audit and external verification.

5.5.5 Data backup and recovery

- Backups are performed daily (incremental) and weekly (full).
- Copies are stored in an isolated secure storage facility for at least 30 days.
- The recovery procedure must ensure that the system is returned to a working condition within 4 hours of the incident.
- All backup and recovery procedures must be documented and tested at least quarterly.

Additionally:

The LIMS infrastructure must include a separate backup server, designed not only for storing backup copies of the system's databases and file storage, but also for centralized storage of backup copies of the software distributions for laboratory analyzers and auxiliary specialized software used in the DEM laboratories.

The specified server must provide:

- storage of current and archived versions of laboratory equipment software distributions;
- the ability to restore analyzer software in the event of failures, equipment failures, or loss of original installation files;
- storage of backup copies of the internal data of the DEM, including configuration files, methods, reference books, documents and other critical data not included directly in the LIMS databases.

The backup server must be logically and/or physically isolated from the main production environment, and access to it must be limited and regulated. The procedure for backing up, storing, updating, and restoring these distributions and data must be documented and included in the overall system backup and recovery plan.

5.5.6 Data integrity control and protection

- All critical files and databases must be protected by hashing mechanisms (SHA-256 or higher) and/or electronic digital signature (EDS).
- Data transfer is performed via encrypted channels (TLS 1.2 and higher).
- At the application level, data integrity is verified for each exchange via the API (by verifying checksums/signatures).
- All personal data in the storage must be encrypted (AES-256 or similar algorithm).

- A notification mechanism for data changes or corruption (Integrity Monitoring) must be implemented.

6. Composition and content of work on the creation and implementation of the LIMS

The work on the development and implementation of the LIMS is divided into the following stages:

- system analysis and design stage - 1 month;
- system development and testing stage - 9 months;
- trial operation stage - operation of the system in trial operation mode - from 3 months (at the discretion of the Beneficiary);
- technical support period: 12 months.

At the stage of system analysis and design

The Developer must clarify all questions and obtain all required documents, materials, and consultations. At this stage, the following documents must be prepared:

- The project charter, which should specify the parties involved in the project, their roles in the project, the procedure for interaction, the procedure for coordinating project documents, the procedure for considering issues that arise during development, requests for changes to the system, and the procedure for accepting the system into pilot and industrial operation.
- A detailed Technical Project for the creation of the system, which must contain the specification of the LIMS with a detailed description of the functional modules of the system and a general description of all the system blocks;
- A detailed plan and schedule of work for the development and commissioning of the system into trial operation.

These documents must be prepared by the Developer and submitted to the Beneficiary for review, amendment and approval.

At the stage of development and testing of the system

All system modules must be developed in accordance with the approved Technical Design and tested by the Developer. The Developer must categorize the functional modules into versions and propose a release schedule to the Beneficiary.

The Developer shall carry out commissioning work on the placement of the information system on the equipment provided by the Beneficiary, and then conduct preliminary tests of the functioning of the information system in accordance with the Requirements for the procedure for the creation, development, commissioning, operation and decommissioning of state information systems, approved by Resolution No. 744 of the Government of the Kyrgyz Republic dated December 31, 2019.

Following preliminary testing, the Developer must develop a user training methodology and program for all user roles and then conduct training for all user groups of the Beneficiary's responsible employees on the available system functions using the developed methodology and training programs for each user group, with at least two training sessions for each group. Following user training, the LIMS must be launched in trial mode.

Documents that must be prepared and agreed upon with the Beneficiary at the stage of system development and testing:

- Teaching methodology;
- Training program;
- Protocol of preliminary tests of the system, including test methodology and test documentation;
- Report on the trainings conducted;
- Regulations for the provision of technical support for the system;
- Technical documentation of the system.

The result of this stage should be a fully functional system developed in accordance with the Terms of Reference, launched on equipment provided by the Beneficiary, prepared technical documentation for the program, as well as conducted training for the Beneficiary's employees.

At the trial operation stage: Within a period of three months, determined by the Beneficiary, all identified inaccuracies, errors, and bugs in the system and its functionality must be identified and corrected. At this stage, technical documentation for the system shall be developed.

Documents that must be prepared and agreed upon at this stage:

- Technical documentation of LIMS, revised if necessary;
- A report on completed work, which should include a list of identified and corrected inaccuracies, errors, and bugs;
- Program and methodology for acceptance testing of the system for commissioning;
- Report on the trial operation mode.

The program and methodology of acceptance tests must necessarily include testing of the information system for compliance with the Terms of Reference for its creation, as well as the requirements for information protection in accordance with the current regulatory framework and standards for the protection of information and personal data of the Kyrgyz Republic, specified in Section 2 of these Terms of Reference.

All listed stages of the creation and commissioning of the information management system into industrial operation must be carried out and documented in accordance with the Requirements for the procedure for the creation, development, commissioning, operation and decommissioning of state information systems, approved by the Resolution of the Government of the Kyrgyz Republic dated December 31, 2019, No. 744.

7. Requirements for development and design stages

According to these Terms of Reference, system development must be carried out in stages and iterations. The Developer must propose and agree with the Beneficiary on the key stages of software development, the number of product versions, the functionality to be developed in each iteration, and the system development milestones. This information must be included in the Technical Project for the system's creation.

Before implementing the functional blocks, the Developer must develop and provide prototypes of the functional modules for approval by the Beneficiary.

The Developer shall provide a report on the work performed to the Beneficiary at least once every two weeks.

The Developer is obliged to demonstrate the Beneficiary's software from the moment of creation of the first version of the system in accordance with the agreed Work Plan and schedule in order to receive feedback from the Beneficiary during the course of the work and make changes to the system, if necessary.

Changes may be made to the Technical Project for the creation of the system after its approval during the system development process, if such changes are justified, made for objective reasons, subject to the agreement of both parties—the Beneficiary and the Developer—and provided that the required changes do not increase the scope of work to be performed by the Developer by more than 15% (fifteen percent).

7.1 Work schedule and project stages

The development of the LIMS information system should be carried out in stages, in accordance with GOST 34.601-90 “Automated systems. Stages of creation” and GOST 34.602-2020.

The work schedule must include the following main stages and phases of work execution:

7.1.1 Stage “Draft Design”

Objective: development of conceptual architecture and key design solutions.

Stage results:

- logical architecture of the system;
- high-level physical architecture;
- integration schemes (UIS, Infodox, Tunduk);
- top-level data models;
- process diagrams (DFD Level 0/1, BPMN).

Document: “Draft Design” (DD).

7.1.2 Stage “Technical design”

Objective: detailed development of architecture and design solutions.

Stage results:

- detailed software architecture (levels, modules, interfaces);
- detailed data structures and database schemas;
- API models, request/response structures;
- technical solutions for information security and data protection;
- interaction diagrams with laboratory equipment;
- integration schemes and exchange logic.

Document: “Technical design” (TP).

7.1.3 Stage "Working documentation"

Objective: to create documentation necessary for the development, implementation and operation of the system.

Stage results:

- working specifications of modules;
- description of algorithms and business logic;
- administrator instructions;
- user manual;
- deployment and upgrade documentation;
- test scenarios for pilot and acceptance testing.

Document: “Working documentation” (WD).

7.1.4 Implementation Stage

Objective: to launch the LIMS into operation at the facilities of the Department of Environmental Monitoring.

Stage results:

- installation and configuration of the system;
- user training;
- User Manual in Russian/Kyrgyz;
- data migration (if necessary);
- conducting preliminary, pilot and acceptance tests;
- correction of identified defects;
- signing of the Commissioning Certificate.

Document: “Certificate of commissioning of the EMIS information system”.

7.1.5 Work schedule

The work schedule is developed by the Developer and agreed upon with the Customer.

The schedule should contain:

- list of stages and phases;
- deadlines;
- checkpoints (milestones);
- dependencies between tasks;
- information about resources and Developers.

The form of the graph is a Gantt chart or a table of stages.

8. Quality and testing requirements

This section defines the procedure for conducting quality control, types of tests, criteria for testing success and requirements for the presentation of results carried out as part of the readiness check of the environmental monitoring information system (EMIS) for operation.

8.1 Types of tests

The compliance of the developed system with the requirements of these Terms of Reference is monitored by conducting the following types of tests:

8.1.1 Preliminary tests

Conducted by the Developer before the system is handed over to the Customer. The purpose of preliminary tests:

- confirmation of the implementation of the functions;
- checking the correctness of the main modules;
- identifying errors at early stages;
- determination of readiness for trial operation.

The result is presented in an internal report by the Developer.

8.1.2 Experimental tests

Conducted jointly by the Developer and the Customer at a test or pilot site.

Pilot tests include:

- checking the functionality of the system's business processes;
- testing of functional modules (sample reception, laboratory processing, analysis of results, standards, archives);
- checking integrations with external systems (UIS, Infodok's electronic document management system, Tunduk platform, e-Kyzmat, Infokom services);
- checking the correctness of data exchange with laboratory equipment;
- checking the settings of access rights and roles;
- testing notification and logging mechanisms.

The result is recorded in the Protocol of experimental tests.

8.1.3 Acceptance tests

Conducted by the Customer to confirm the compliance of the information system with the requirements of these Terms of Reference and its readiness for industrial operation.

Acceptance tests include:

- checking the completeness of the implemented functionality;
- testing the correctness of sample life cycle operations;
- verification of security and data protection mechanisms;
- checking the functionality of integrations with all external systems;
- performance testing;
- verification of documentation;
- checking recovery and backup procedures.

The result is formalized in the Acceptance Test Report.

8.1.4 Test success criteria

The system is considered to have successfully passed the tests if the following criteria are met:

1. All requirements of the ToR have been implemented and verified.
2. The number of critical errors is 0.
3. Non-critical errors have either been corrected or agreed upon in the form of a list of improvements.
4. Functional modules work correctly in all test scenarios.
5. Integrations with government systems function reliably.
6. The system provides the required performance.
7. The security mechanisms comply with the established requirements.
8. Backup and restore operations are performed correctly.
9. System and user documentation has been provided and verified.

8.2 Liability of the Parties

8.2.1 The Developer shall ensure

- conducting preliminary tests;
- elimination of identified defects;
- participation in pilot and acceptance tests;
- provision of necessary documentation;
- testing support and consultations.

8.2.2 The Customer shall ensure

- provision of test environment and data;
- participation of specialists in pilot and acceptance tests;
- organization of working groups;
- verification of test results;
- signing of protocols and acts.

8.3 Forms of reporting documents

Based on the test results, the following documents are issued:

1. **Preliminary Test Report**— internal document of the Developer.
2. **Protocol of experimental tests**— a joint document of the Customer and the Developer.
3. **Acceptance Test Certificate**— a document confirming the system's compliance with the requirements of the ToR.
4. **List of identified errors and comments**, containing deadlines for their elimination.
5. **Defect Elimination Protocol** (if necessary).

8.4 Mandatory types of specialized tests

In accordance with GOST 34.603-92, as well as safety and quality requirements, the following mandatory types of tests are additionally performed when checking the system.

8.4.1 Functional testing

Objective: to confirm that the implemented EMIS functionality fully complies with the current ToR.

This includes checking:

- registration and accounting of samples;
- laboratory analysis procedures;
- formation of protocols and regulatory checks;
- mechanisms for storing, archiving and managing document versions;
- correctness of calculations and reference data;
- integration with external government systems;
- user roles and access.

Result - Functional Test Protocol.

8.4.2 Security Testing

Conducted to confirm compliance with information security and data protection requirements.

The following should be checked:

- authentication and authorization;
- role-based access control;
- data encryption and secure channels;
- logging of user actions;
- integrity control;
- correct operation of backup mechanisms;
- API protection.

Result - Security Test Report.

8.4.3 Performance testing

Conducted to confirm the system's ability to operate under specified loads.

The following should be checked:

- interface response time;
- processing time for registration and sample analysis operations;
- speed of report generation;
- stability under load;
- use of resources.

The result is a Performance Test Protocol.

8.4.4 Testing integration with laboratory equipment

The correctness of the reception, processing and verification of data from measuring instruments is checked, including:

- correctness of data formats;
- processing of erroneous or incomplete data;
- comparison of data with methods and standards;
- accounting for the verification status of devices;
- stability of equipment connection.

Result - Equipment Integration Test Protocol.

9. Operation and maintenance requirements

This section defines the procedure for operation, maintenance and technical support of the LIMS, including incident management, service level parameters (SLA) and requirements for decommissioning the system.

9.1 Technical support procedure

Technical support for the LIMS must be provided within the framework of the established service regulations and include:

- reception and registration of user requests;
- classification of incidents;
- troubleshooting;
- infrastructure maintenance and updates;
- user consultations.

Technical support is provided by the authorized support service of the Developer or Customer (depending on the operating model).

9.1.1 Incident Categories

Incidents are classified according to their level of criticality:

9.1.1.1 Category A - Critical Incident

- Complete unavailability of the system or its key functions (sample registration, loading measurements, generating protocols).
- Security breach (data leak, account compromise).

Requirements:

- Response time: no more than 1 hour;
- Time of elimination: no more than 8 hours.

9.1.1.2 Category B - Significant Incident

- Incorrect operation of individual modules, affecting production processes (calculation errors, incorrect standards/maximum permissible concentrations, failure to unload devices).

Requirements:

- Response time: up to 4 hours;
- Time of elimination: no more than 24 hours.

9.1.1.3 Category C - Non-critical error

- Interface errors, reporting issues, non-critical defects.

Requirements:

- Response time: up to 1 business day;
- Time of elimination: up to 5 working days.

9.1.1.4 Category D - Consultations and requests for improvements

- instructions, questions about functionality, suggestions for improvements.

Requirements:

- Response time: up to 2 business days;
- Deadlines for implementing changes are subject to separate agreement.

9.1.2 Channels for contacting technical support

Users can contact technical support through the following channels:

1. Service desk system (recommended channel) is a web portal for registering requests.
2. Support service email.
3. Hotline telephone number (for critical incidents).
4. Integrated feedback module in LIMS (optional).

All requests are recorded in the incident registration system with the following information:

- date and time,
- incident categories,
- Developer,
- deadlines for the decision,
- comments and measures taken.

9.2 Update and Maintenance Requirements

1. System updates should include bug fixes, new features, and regulatory changes.
2. All updates undergo preliminary testing in a test environment.
3. Updates are performed during a scheduled maintenance window agreed upon with the Customer.

4. A rollback mechanism must be implemented to allow returning to a previous version of the system.
5. All updates must be accompanied by release notes.

9.3 Requirements for decommissioning the system

In accordance with the Decree of the Government of the Kyrgyz Republic No. 744, paragraph 13, the decommissioning of the state information system must be accompanied by a regulated process, including:

9.3.1 Grounds for decommissioning

- implementation of a new information system to replace the existing one;
- termination of the unit's activities;
- loss of need for the functionality of the LIMS;

9.3.2 Mandatory measures during decommissioning

When decommissioning the LIMS, the following actions must be performed:

1. Data inventory

- accounting of all data contained in the system (archives of protocols, analysis results, standards, journals).

2. Data migration

- data migration to a new system or centralized storage;
- export of data in CSV/XML/JSON formats or in the format required by the regulator;
- checking the correctness of data transfer.

3. Terminate all active processes

- completion of sample processing;
- completion of all audit operations.

4. Saving archives

- archiving:
  - test reports,
  - regulatory information,
  - audit logs.
- storage period - at least 5 years or in accordance with the Law of the Kyrgyz Republic on State Archives.

5. Decommissioning of software components

- disabling services;
- deleting accounts;
- destruction of copies of data on workstations;
- stopping integrations with UIS, Infodox, Tunduk.

6. Documentation

Based on the results of decommissioning, the following is drawn up:

- Act of decommissioning an information system;
- Data Transfer Protocol;
- Protocol for the destruction of confidential information.

10. Documentation requirements

The following types of documents must be developed and submitted:

- System passport;
- General description of the system, its functionality and how to use it;
- Technical project for software development;
- User manual for each individual user role;
- Mobile application user manual;
- System Administrator's Guide;
- System Developer's Guide;
- System Administrator's Guide;
- Methodology and program for user training;
- Report on the training sessions and lists of training participants;
- Database structure;
- Source code of the system.

A system passport is a document containing the main characteristics of the system required for its operation, installation, and development.

The general description of the system should include general information about the LIMS, its functional capabilities, integration capabilities, etc.

A technical project for software development is a document or package of documents that describes in detail the final design decisions for the development of a software system.

The user manual for each role should provide detailed instructions on how to use the program, including screenshots to describe the functionality.

The administrator's guide should provide a general description of the system and describe the functionality for administering the LIMS through the administrative panel.

The system developer's guide should describe the technologies used in the system, list all the libraries used, describe the software structure, the relationship between the system modules, etc. A separate developer's guide should be provided for the mobile application.

The system administrator's guide must include: a description of the system, hardware requirements, a description of the required system software, instructions for installing and configuring the information system and its components, instructions for backing up the system and restoring system operation after failures.

All documentation developed must be in Russian or Kyrgyz and submitted to the Beneficiary electronically.

11. Sources for the development of the Terms of Reference

In the process of developing these Terms of Reference, an analytical stage was first carried out, which included the following work:

- Analysis of the current information system
- Research of the requirements of the DEM
- Evaluation of the technical equipment and usability of the existing system
- Analysis of information and technical capabilities
- Identifying deficiencies and causes of problems
- Evaluation of the equipment available to DEM
- Analysis of hardware limitations
- Documentation Review
- Study of existing analog systems

Meetings and consultations were held with DEM employees; all approved internal documents, standards, reporting forms, and classifiers were received and analyzed.

Contract type - Lump sum.

Timing – 30 months

Annex A: Qualification Criteria

1. Qualification requirements

1.1. Qualification requirements for the Consulting Company

To be selected consulting company shall meet the following qualification requirements:

- At least 5 (five) years of overall experience in the field of information systems development;
- At least two (2) successfully completed contracts for information systems of similar complexity within the last three years;
- Experience in developing information systems for government agencies in the Kyrgyz Republic;

1.2. Consultant company staff

The Consultant's team shall consist of an acceptable number of qualified and experienced specialists with relevant proven experience:

1. **Systems Architect**

a) Experience in designing multi-layered distributed information systems;
b) Knowledge of modern architectural patterns (microservices, SOA, event-driven);
c) Experience in integrating with external systems, including government information systems.
d) Higher education in the field of information technology
e) Fluency in spoken and written Kyrgyz and Russian.

The System Architect is a key position, and it is essential that the company has this Consultant among its staff.

2. **Software developers**

Backend Developer 1:

- Experience with SQL/NoSQL, APIs (REST/GraphQL), data security, backup, and high availability.
- Holds a higher education degree in Information Technology.
- Fluent in both spoken and written Kyrgyz and Russian.

Backend Developer 2:

- Experience with SQL/NoSQL, APIs (REST/GraphQL), data security, backup, and high availability.
- Holds a higher education degree in Information Technology.
- Fluent in both spoken and written Kyrgyz and Russian.

Frontend Developer 1:

- Experience creating web interfaces using modern frameworks (React, Angular, Vue) and responsive design.
- Holds a higher education degree in Information Technology.
- Fluent in both spoken and written Kyrgyz and Russian.

Frontend Developer 2:

- Experience creating web interfaces using modern frameworks (React, Angular, Vue) and responsive design.
- Holds a higher education degree in Information Technology.
- Fluent in both spoken and written Kyrgyz and Russian.

Mobile Developer:

- Experience developing applications for iOS and Android, working with REST APIs, and integrating with external hardware.
- Holds a higher education degree in Information Technology.
- Fluent in both spoken and written Kyrgyz and Russian.

Software developers are key positions, and their availability among the Consultant's staff is mandatory.

3. Integration engineer and DevOps engineer

a) Experience in integration with external systems (EDMS, ESIS, laboratory equipment);
b) CI/CD configuration, deployment and testing automation;
c) DevOps Engineer must have the skills to deploy and administer server infrastructure, as well as to set up and maintain data backup and recovery systems
d) Higher education in the field of information technology
e) Fluency in spoken and written Kyrgyz and Russian.

Integration and DevOps engineers are key positions, and their availability within the Consultant's staff is mandatory.

4. Business Analyst

a) Experience in gathering and documenting requirements;
b) Skills in developing terms of reference, process diagrams, and user stories;
c) Interaction with the customer at all stages of development.
d) Higher education in the field of information technology
e) Fluency in spoken and written Kyrgyz and Russian.

Business Analyst is of high importance, and it is mandatory for the Company to have at least one Business Analyst in its staff.

5. Information Security Specialist

a) Knowledge of ISO/IEC 27001 requirements and other security standards;
b) Experience in security auditing, data encryption, access management, and user activity logging.
c) Higher education in the field of information technology
d) Fluency in spoken and written Kyrgyz and Russian.

6. Tester / QA Engineer

a) Experience in functional, integrative, and load testing;
b) Skills in working with automated testing tools;
c) Verification of the system's compliance with regulatory requirements and internal terms of reference.
d) Higher education in the field of information technology
e) Fluency in spoken and written Kyrgyz and Russian.

7. UX/UI Designer

a) Experience in developing user-friendly interfaces for different user groups;
b) Creating responsive designs for web and mobile applications;
c) Conducting user experience testing and making adjustments.

d) Higher education in the field of information technology
e) Fluency in spoken and written Kyrgyz and Russian.

8. User Training and Support Specialist

a) Conducting training sessions and webinars for different user groups;
b) Preparation of training materials and documentation;
c) Support for users during the trial operation phase.
d) Higher education in the field of information technology
e) Fluency in spoken and written Kyrgyz and Russian.

2.3. Criteria for evaluating the Consultant's company and its employees

The proposal submitted by the consulting company will be evaluated based on the following qualification criteria:

- Methodology and work plan for completing the assignment - 40%
  - Proposed high-level system architecture
  - Approach to integration with external systems and laboratory equipment
  - System deployment model
  - Implementation and scaling strategy for the solution
- Experience and qualifications of key staff - 60%

Evaluation criteria for key staff:

- General qualifications (general experience in the IT industry) - 20%
- Relevance to the assignment (relevant experience in a similar assignment) - 70%
- Knowledge of languages – 10%

2.4. Development Process

- The Consultant shall provide a detailed development schedule including the following project stages:

Terms of Reference → Preliminary Design → Technical Design → Working Documentation → Implementation → Trial Operation → Commissioning.

- Preliminary, trial, and commissioning tests of the system must be conducted, and the results must be documented.
- Provision of training for all user groups (at least 5 training sessions for each group) and support during the trial period for at least 6 months.

2.5. Technical Support

- The Consultant shall provide warranty technical support for the system **for 12 months** after its launch into commercial operation.
- Availability of an incident classification system and communication channels for contacting support services.
- Ensuring rapid response to critical errors and the ability to remotely fix problems.
- Provision of updates, patches, and system support during the warranty period.

2.6. The Consultant will ensure:

- The ability to interact fully remotely during development and implementation.

- Guarantee of patent infringement-free status and no violation of third-party rights during software development.
- Provision of comprehensive documentation for all stages of development and implementation.
- Compliance with ergonomic and UX requirements, ease of use for different user groups (web and mobile application).
- The possibility of scaling the system and upgrading it in the future without completely redesigning the architecture.

Annex B: Payment schedule and expected Deliverables

#	Deliverable	Documents to be provided by the Consultant	Timeframe	Payment terms
1	Approved technical documentation, including: - Terms of Reference - Technical design - Preliminary design -Test Plan and Methodology (TPM), containing detailed acceptance criteria and test plans		2 months	20% of a total cost
2	System development: Phase 1, including: - Progress report - Product presentation		5 months	20% of a total cost
3	System development: Phase 2, including: - Approved Progress report on phase 2 - Product presentation - Agreed Administrator's Guide - Agreed User manual		5 months	20% of a total cost
4	System deployment, is completed, trial operation is completed, and bug fixes, including, Report on the results of trial operation.		6 months	20% of a total cost
5	Technical support	Final project report, technical support results	12 months	20% of a total cost