Essential Requirements

#	Functional Area	Essential Requirement
1	Admin	Must have system maintenance capabilities that allow the system administrator to: add users, change passwords, disable accounts, define and manage roles (access levels, security, and user experience), manage code lists or phrases that support automation on business rules, provide accessibility on or offline, and archive/restore the configuration and database.
2	Analyses	Must have the ability to create analysis templates that facilitate the creation of common analytical configurations, including: analysis name, analytes, department, method, sample type, instrument type, base and derived units, limits of detection (LOD), limits of quantitation (LOQ), ability to flag individual components (parameters) for reporting, ability to include calculations based on the test and relatable tests, and be able to create multiple components (analytes) per test.
3	Batching	Must allow the user to generate sample batches (Extraction/Metals/Organics/Other). The user must be able to create multiple templates by method and/or analyte, generate batch sequences with multiple types of QC samples (LIMS generates the QC samples which are tied to the batch), pull in the preparation batches into one analytical batch, sort samples by priority or sample type into a batch, close batches or remove or add samples after creation. The batch must comprise the following information: unique identifier, sample IDs, matrix/sample type, dilution factors, spiking traceability to standards, comments, defined intervals for QC in the sequence, and defined batch calculations for QC (recovery, percent error, and relative percent difference).
4	Calculation	Must have the ability to create calculations, including Excel-based calculations with conditional statements and criteria. The calculations can be out of the box or user-defined. The LIMS must be able to allow for all the set-up calculations so the results are based on dry weight (moisture results may come from a different sample aliquot or test).
5	Cargo/Port Data	Must have the ability to capture sample information by allowing the set-up of user-defined fields. The vendor must provide in the comment section the limit of user-defined fields allowed per table. The user must be able to define the fields as Optional, Mandatory, Hidden or Read-Only. The following examples are fields needed for Cargo/Port Data: sample number, sample collection location, site/facility/vessel, tamper resistant seal IDs, sample type, number of aliquots for composite (the LIMS must allow compositing of samples), actual number of aliquots taken, sample date range/time, description, number of containers, container type, sample amount, units, weight, sample analysis requested, sampler ID, courier ID, and inspector personal identifier.

6	COC	Must be able to generate a chain-of-custody (CoC) in LIMS (electronically) that includes the sample IDs, project name/code, sampling information, sample date/time, sampling address, requested analyses for each sample, sample information/description, sample type, number of containers, samples by container, additional comments, custody seal information, and multiple signatures for relinquishing and receiving samples.
7	Containers	Must have the functionality to allow for Container Management, which includes adding an aliquot number/letter to the sample ID, capturing the date and time for aliquoting, capturing who performed the aliquoting, and assigning tests to the aliquots.
8	Data Entry	Must allow for the entry of data such as: multiple results for each analyte, entry in a grid or tabular format, entry based on a pre-defined list of values (phrase list), define/modify standards and QC samples, define calculated fields. The LIMS would allow the user to pre-fill information that is common to each analysis, bar code data entry, supervisors to approve data with additional comments, and to retain and retrieve completed worksheets as calculations and methods change over time (versioning calculations and methods DO NOT impact previously entered data).
9	Data Review	Must allow the review of data on screen, which includes requesting an additional analysis, seeing comments from the analyst, entering reviewer comments, indicating the data is approved (status changed), review of quality control data with the results (batch review), allowing the user to enter a sample ID and seeing all related QC and batch information [batch ID, analyst ID, related QC samples, matrix/sample type, analysis, parameters, results, calculated results for QC (recovery, standard deviation, relative percent difference, average value or replicates)], the approver, and allowing the user to configure flags, colors, etc., to aid in the rapid identification of QC failures (excursions).
10	Data Review	Must have the capability of "flagging" samples with results in exceedance (i.e., falling outside of user-defined acceptance criteria) – this should be based on workflow or business rules.
11	Data Review	Must allow the user to flag a sample for reanalysis.
12	General – ISO 17025	Must support the requirements for meeting ISO 17025 and other laboratory regulations by allowing for retention of records, QC requirements for batching, plating requirements, qualifiers and reporting, limits of detection (LOD) and limit of quantitation (LOQ).
13	General – ISO 17025	Must maintain reagent and standard traceability.
14	Labels	Must be able to generate labels for the sample containers with the program/project name, location, ID, analyses, barcode (2 or 3D), print labels to a specific printer (manual or automatic), print labels with barcodes for samples, aliquots (splits), aggregates, and composites.
15	Microbiology	Must be able to provide location tracking within the department for storage to the location, shelf, tray position, vial, etc., and pull ad hoc data from integrated instruments. Must have plate management, allow multiple steps in a batching process (prep, extractions, sequencing, analysis), allow to add custom fields such as genus, type, strain, etc., and allow the printing of waterproof/freezer labels in variety of sizes.

16	Preparation/Batching	Must capture information for a batch (preparation) such as preparation method, prep analyst, completer (if start and end analyst is applicable), date time started, date time completed, sample amounts (e.g., g, mL) and final sample amount, kits/reagents used in prep, support equipment used, final volumes/weights, units, initials or person who put samples in storage, sample storage date, and free text comments on sample prep process.
17	Preparation/Batching	Must capture sample digestion/extraction information for metals or organics. This includes digestion or extraction method, preparer (start and end or multiple personnel), date time started, date time completed, the analysis method, sample amount (g or mL), pH, spiking solutions, final volume, weights for vessels (before and after), free text comments for batch, sample or result, analysis date, person who stored sample, storage date, and batch reviewer.
18	Program	Must be able to record program information (e.g., research, projects). This includes associating a program with projects and clients, program duration (start and end date), program manager, sampling locations, site/facility/farm, sample point, sampling method, frequency, type of report required, and free text comments.
19	Project	Must be able to record project information. This includes the associated client, name, type, project manager, key personnel, sampling locations, site/facility/elevator/ship, sample point, sample point description, coordinates, geospatial references, sampling type, frequency, analytical methods for project, analytes for project, report details needed, distribution list for report, free text comments, and the ability to create templates that can be copied.
20	Reports	Must meet the following reporting requirements: generating reports such as sample inventory report containing user-specified fields (program, sample location, etc.), daily sample status (backlog with sample information), sample disposition. The user must be allowed to easily search and retrieve information (ad hoc reports) based on client, program, project, location, sample number, sample location, sample type, status, analysis type, priority (turnaround time), overdue samples, reportable versus non-reportable. Must allow the user to define what to report such as target analytes, detected analytes, reporting of dry or weight basis.
21	Reports	Must have reports out of the box or easily made for summary of analytical methods used by queried time periods, LOD/LOQ listing by time period, management reports, backlog by group or lab, emailed reports with a defined frequency to designated personnel or roles, email notifications of excursions of data to a limit, lists samples by client, samples requested but not received, samples pending analysis, samples by analysis type, turnaround reports (program, analysis, method, lab section), sample test count by lab section/program for date range, list of tests by analyst. The reports must be printable.
22	Sample Management	Must provide sample management and tracking capabilities which include the following: automatic creation of a unique sample identifier, format of identifier is configurable by system admin, samples statuses, sample locations, track samples by location electronically, sample received by, received date and time, track samples (aliquots, aggregates, composites), sample size, container type, disposal date, disposal method, sample storage, and sample type. The samples must be able to be received via barcode or keyboard, individually or as batches. The system must allow comments at time of receipt.

23	Samples/Sample Fields	Must allow for sample fields and information (out of box and user-defined). This incudes: allowing for multiple analyses on a sample, supporting grouping a collection of samples into a "sampling event" for tracking and reporting purposes, allowing user to add/remove analyses from samples, allowing for multiple programs/projects per sample, allowing user to specify priority (rush, specific turnaround time), allowing user to add/cancel sample any time during a project, recording comments (at the sample, program, analyte levels), the ability to create user-defined fields and store data in those fields at the sample level, creating pre-configured samples (with projects, testing, locations, other information), sample receipt information, container IDs based on sample ID, and comments on containers.
24	Samples/Sample Fields	Must have sample receiving requirements for recording chain of custody number, sample location, sample identifier, sample type, program ID, project, sample analyses, date/time sample taken and received, and a field to state all samples are present.
25	Schedules/Pre-Login	Must provide for sample scheduling. This includes the ability to schedule collection of samples pending against a project, the capability of building a recurring sample schedule for ongoing or routine sampling and analysis, allowing recurring schedule to repeat without user intervention, the capability of removing non-received samples from the sample schedule when configured to do so, accepting results from analyses performed by an instrument that was not originally scheduled against the sample, allowing subsequent analyses to be automatically scheduled based on analytical results, allowing the user to view tests that are scheduled but not complete, providing a programmatic interface for external programs to schedule samples (e.g., web service, DLL, stored procedure or direct-table access), maintaining templates of sample sets, assigning a unique identifier to a sample set for future recovery, and scheduling multiple sets of samples by filtering sample set templates.
26	Specifications	Must have multiple level specifications (tolerances) for QC data, specifications or known tolerances for sample data, product/grade multilevel specifications, and be able to generate specifications based on historical data. The user must be able to configure the number of points and when the calculations is performed.
27	Integration – Systems	Must be able to import data from Microsoft Excel, Access, text, and CSV. Must be able to export in multiple formats including Excel, CSV, RTF, etc.

Rated Requirements

#	Functional Area	Requirement
1	Batching	The user can define a batch template specifying a sample's order in a batch according to its sample type and location
2	Batching	LIMS batching functionality should allow tare weights (for pre-weighed pans) to be associated with a position in the batch template prior to populating samples in the batch.
3	Calculation	The LIMS has functionality capable to create and perform complex calculations. This would include table look-up capability.
4	Corrective Action/Incidents	Should be able to trigger a corrective action form or checklist for data that has failed QC parameters or specification. This includes triggering a corrective action based on a trending failure, control chart limits, user defined limits (specification), or a quality control (QC) sample failure.
5	Cost	Capable of recording the cost of analysis for a method/standard operating procedure.
6	Cost	Can allow multiple costs of analysis to be associated with a single method/standard operating procedure based on factors such as turnaround time, sample type, and output report type.
7	Integration – Instruments	Should have functionality to allow plates/batch sequences to populate instrument sequence files (create a sequence for the instrument as a batch). The LIMS should have bi-directional communication to send sequences and retrieve data (results and metadata) from instruments. The information that would be transferred both ways would include instrument ID, sample analysis, analysis data, time, identifiers, multiple analysts' information, batch/plate identifier, sample IDs, calibration standards, and sample type.
8	Integration – Instruments	Should capture multiple processing analysts' names for a single analysis, the method name, and version of procedure for the analysis.
9	Integration – Instruments	Instrument integration should allow split samples to be analyzed and their results associated with the original sample.
10	Integration – Instruments	Instrument integration should allow a sample to be reanalyzed and to store the results of the original analysis and the re-analysis.
11	Integration – Instruments	Should report the average of all valid results (e.g., report average of original and re-analysis results, if both are valid) if the user applies this rule to the analysis. This is done via the integration.
12	Integration – Instruments	Should be able to adjust results and limits based on dilution factor.
13	Integration – Systems	Should be able to integrate with internally developed applications.
14	Integration – Systems	Should be able to integrate with invoicing/financial systems.

15	Integration – Systems	Should have capability to integrate with Quality Management Documentation System, which includes functionality for scheduling of maintenance and calibration.
16	Inventory Management	The inventory management system for a reagent or standard should be able to record the analytes, if appropriate (i.e., a standard may have multiple analytes from two sources, Source 1-10 and Source 2-5, the final standard has 15 analytes), and the different concentrations for each analyte (including units).
17	Inventory Management	Should have the capability to create a new reagent/standard by copying an existing record and altering the pertinent information.
18	Inventory Management	Should be able to send an email, at user-defined intervals, to designated analysts indicating that a standard is about to expire (notifications).
19	Inventory Management	The user should be able to create a reagent/standard disposal report (inventory management).
20	Mobile Application	Capability for a mobile/field application which is accessible online or offline. Users should be able to enter data online or offline, be able to create samples (ad hoc) online and offline, and the application must be compatible with Windows, Android, and iOS.
21	Plate Management	Should have the capability to handle PCR and other (plate management multi-well) types of data, which includes creating plate types (templates) for different size and types of plates (96, 144, etc.), allowing creation of difference appearances of the plate (operator aid), and allowing the completed sequences to be transferred to the analyzer and data retrieved (bi-directional integration). In addition, the LIMS should allow the user to define the fill order of the plate.
22	Plate Management	Should allow the user to assign different fill orders to plate based on the laboratory or user process: Bottom to Top Left to Right, Bottom to Top Left to Right Snake, Default (Left to Right), Left to Right Bottom to Top, Left to Right Bottom to Top Snake, Left to Right Top to Bottom, Left to Right Top to Bottom Snake, Right to Left Bottom to Top, Right to Left Bottom to Top Snake, Right to Left Top to Bottom, Right to Left Top to Bottom Snake, Top to Bottom Left to Right, Top to Bottom Left to Right Snake, Top to Bottom Right to Left, Top to Bottom Right to Left Snake, Custom Fill Order, Random Fill Order.
23	Portal	The LIMS can integrate with a customer-facing portal

24	PT	Should be able to handle proficiency testing (PT) information and programs, which includes scheduling and requesting of PT samples, information from PT including values and acceptance ranges associated with the reported results based on the PT provider's evaluations, and Z scores. The LIMS should allow the PT information to be imported (all of the information cited in this requirement). The LIMS should allow the pre-logging or requesting of each PT sample by analyte, method or procedure, report the status of all PTs sorted by analyte, method, and or procedure, and generate reports with the result, analyst, date and time, sample prep, determinative methods (analyses), and analytes.
25	QC	Should have the capability of "flagging" samples that fall out of the historical ranges.
26	QC	Should have the capability of "flagging" samples with marginal exceedances (e.g., non-repetitive exceedances beyond three standard deviations from mean) - use of trending calculations and requirements.
27	QC	Should allow the user to configure trending rules for charting.
28	QC	Should have the capability of "flagging" results from analyses for which CGC Labs are not accredited - ISO 17025.
29	QC-Micro	The LIMS allows the performance and record of autoclave sterility check, variability check for personnel (monthly with criteria of 10%), air monitoring (monthly check with agar plates in different areas – sample points) and lab water sterility checks.
30	QC-Micro	The LIMS can manage and create sterile DI water records: sterility check by lot [these are samples with the appropriate test (micro test) and stock/media], create sample template/test schedule and create sterile buffer solution, sterility check by lot plus positive control [these are samples with the appropriate test (micro test) and stock/media], create sample template/test schedule, plus media checks.
31	QC-Micro	The LIMS can allow recording of temperature checks: refrigerator (1/day) and incubator (2x/day), autoclave temp check (monthly), autoclave record the date, time in and time out, contents, max temp, pressure, two autoclave, batch related, ID autoclave, review if applicable to SM, part of the sterility batch check log, autoclave maintenance, glassware and batches, inhibitory checks on glassware, and dishwasher/detergent checks.
32	Qualifiers	Can support the following data qualifiers and receiving codes (qualifiers would be used to qualify data if there is an issue with QC samples, calibration, spikes, sample composition, matrix effect, etc.). This includes the use of data qualifiers including descriptions for all data qualifiers and codes. For example: "~" means the result is an estimated quantity; the value is above the reported sample level of detection (LOD), but below the reported sample level of quantitation (LOQ). The LIMS would support the creation of user-defined qualifiers, allow recording of specific characters or symbols (<, >, L, H, ND, etc.) and user-defined codes to indicate out of control data.
33	Reports	Allow reporting of historical trending for single locations and/or parameters.

34	Reports	Allow reporting of comparative trending between two or more locations and/or analytes.
35	Reports	Allow reporting of statistical analysis of analytical results.
36	Reports	Should provide summary reports containing contact name, program, sample ID, analyte name, concentration, qualifiers, units, detection limits, comments, and procedure references.
37	Reports	Should have easy ad hoc report generation, cross tabbing (mandatory), drag and drop (preferred).
38	Resources	Should have functionality to manage resources including personnel, qualifications, instruments, and equipment.
39	Resources	The LIMS user can see work schedules/availability of analysts, material resources (inventory management), and consumables (inventory management).
40	Samples/Sample Fields	Should require the user to provide an explanation for voiding or deleting of samples.
41	Schedules/Pre-Login	Planning/scheduling functionality should provide template functionality. This includes: • Ability to create an arbitrary grouping at any level, as building blocks, for potential assembly into higher-level template. • Convert an ad hoc request into a sample set template. • Create provisional templates to explore scheduling options (e.g., to determine if a customer request can be accommodated). • Provisional templates may be discarded or promoted to sample sets. • Scheduler may create a project or request template based on all, or some portion, of an actual request or project. • Scheduler may validate a template with respect to aliquot creation and management of container types. • Scheduler may schedule ad hoc or walk-in requests with a template. • Scheduling field activities automatically schedules any associated lab activities. • Scheduling of collection activities will generate associated worksheets.

42	Training/Certification	The LIMS should be able to track training and certification information for each method. The information includes the following: • Detection limit for instrument and method • Linear calibration range • Quality control sample results • Initial precision and recovery • Calculate the average - including option to select replicate groups and recognize number of sample to average • Calculate the standard deviation • Ability to recognize blanks • Limit of quantitation • Positive and negative controls • Proficiency Test sample • Matrix spike • Method comparison • Send reminders to QA/QC coordinator, program managers, and analysts regarding expiring training pertaining to the topics above • Record the true values associated with the analyst's evaluation • Treat true values as blind to the analyst • Be able to warn or prevent an analyst from running a method without training