

**SCORED TECHNICAL SPECIFICATIONS
ATTACHMENT #6**

4.2.2 All items listed in the following table are Scored Technical Specifications. Contractor should carefully follow the directions provided when providing Ratings and Descriptions within the table.

Instructions

Contractor Rating - Contractor must numerically rate each functional specification listed using the following scale:

0 = no existing functionality in LIMS product or currently under development

1 = currently available in LIMS

2= available, implemented and is currently used in a laboratory

3 = available, implemented, and is currently used in an agricultural testing laboratory

| | Contractor Rating (Enter 0, 1, 2, or 3 for each row) | DESCRIPTION COLUMN Within EACH of the following (23) listed categories, (starting with PROJECTS category), Contractor should provide a narrative description of how their system delivers the specifications listed. |
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| <p>PROJECTS The LIMS application software shall be able to create and use projects. The tasks may include, but are not limited to, the following list.</p> | | 1-PROJECTS In addition to a narrative description of PROJECTS, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed. |
| Ability to associate a single or multiple samples together to form a project. | | |
| Ability to create templates for projects, samples, and tests via customer configuration. | | |
| Ability to add, edit, or archive created templates | | |
| Ability to include project-level notes or narratives. | | |
| Ability to invoice at the project level. | | |
| Ability to search for projects. | | |
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| <u>Project Identifying Information</u> | | |
| Information that must be associated with a project, at minimum, includes: Customer Name Each sample in the project Unique Identifier | | |
| Tests required | | |
| SAMPLES The LIMS application software shall track all samples from initiation to disposal. The tasks may include, but are not limited to, the following list. | | 2-SAMPLES In addition to a narrative description of SAMPLES, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed. |
| Ability to add, edit, remove, and cancel samples. | | |
| Ability to add, edit, remove, and cancel samples either one at-a-time or all-at-once if multiple samples are selected. | | |
| Ability to login samples with a spreadsheet like functionality. | | |
| Ability to pre-log routine samples that have yet to be submitted. | | |
| Ability to perform login of samples ad-hoc. | | |
| Ability to associate samples with each other as duplicates. | | |
| Ability to associate samples with each other as an un-spiked and spiked duplicate. | | |
| Ability to associate a sample dilution with the original sample. | | |
| Ability to assign a sample as internal quality control (i.e., a representative negative blank, positive blank, media, for a "lot" or "batch" of associated samples). | | |
| Ability to trigger an event upon sample receipt. | | |

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| Ability to record sample condition upon receipt data for each sample (i.e., temperature, chemical preservation, etc.). | | |
| Ability to add, edit, or remove sample condition upon receipt information on multiple samples at one time. | | |
| Ability to have sample condition upon receipt criteria for evaluating sample validity with automatic flag when criteria are not met. | | |
| Ability for sample condition flag to trigger automatic sample cancelling or automatic flagging of associated data (ability to have one or the other depending on assigned tests). | | |
| Ability to add, edit, or remove sample condition evaluation criteria via customer configuration. | | |
| Ability to choose a sample collection location from an established list. | | |
| Ability to add, edit, or remove sample collection locations from the list via customer configuration. | | |
| Ability to filter sample collection locations available for choice by lab section. | | |
| Ability to have sample descriptors associated with each sample including, at minimum, sample category, sample type, and sample matrix as separate fields in the LIMS. | | |
| Ability to add, edit, or remove sample descriptors on multiple samples at one time. | | |
| Ability to choose a sample descriptor from established lists. | | |
| Ability to filter sample descriptors available based on laboratory section. | | |
| Ability to add, edit, or remove descriptors from lists via customer configuration. | | |
| Ability to have default sample descriptor associations such that they can be assigned to a sample all at one time. | | |
| Ability to designate samples as for regulatory compliance or not for compliance and as official or unofficial. | | |
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| Ability to designate sample priority (e.g., routine, high, urgent, etc.). | | |
| Ability to limit sample priority designation based on user role. | | |
| Ability to assign a unique sample identification that is never repeated. | | |
| Ability to have a sample serial/tag number (submitted by customer) that can be tracked over time. | | |
| Ability to login samples using the serial/tag number for reference. | | |
| Ability to find a sample using the lab sample unique ID by the end user. | | |
| Ability to find a sample using the sample serial/tag number by the end user. | | |
| Ability to find a sample using Laboratory Section, Project, Test, Customer name, Customer sample identification number, sample collection date, sample receipt date, or sample storage location by the end user. | | |
| Ability to track samples down to the individual container level. | | |
| Ability to track sub-samples. | | |
| Ability to track sample disposal or return to customer. | | |
| Ability to track the sample container each time the storage location changes. | | |
| Ability to track receipt, storage locations, and disposal/return as part of the sample's chain of custody. | | |
| Ability to choose storage location from a predefined list. | | |
| Ability to add, edit, or remove storage locations from the list via customer configuration. | | |
| Ability to restrict possible sample storage locations based on sample category, type, matrix, or assigned test and by laboratory section. | | |
| Ability to manually override restrictions and choose a storage location (with audit trail comment required). | | |

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| Ability to log environmental conditions and associate log with storage locations. | | |
| Ability to track storage of separate containers of the same sample in different locations. | | |
| Ability to restrict samples available for disposal/return to only those designated as completed or cancelled. | | |
| Ability to assign sample retention schedules by sample type, project, lab section, etc. | | |
| Ability to track sub-contracted or split samples. | | |
| Ability to enter data for sub-contracted or split samples with unambiguous designation for which data were sub-contracted. | | |
| Ability to configure workflow of sample login procedures to suit needs of several different laboratory sections. | | |
| Ability to automatically designate samples as hazardous (e.g., test positive for a human or animal health hazard, test above an action limit, contain hazardous chemicals, etc.) | | |
| Ability to manually designate samples as hazardous (e.g., test positive for a human or animal health hazard, test above an action limit, contain hazardous chemicals, etc.) | | |
| Ability to add customer specific sample fields to support ongoing projects. | | |
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| <u>Sample Identifying Information</u> | | |
| Each item listed below (on this & next page) must be a separate datum in the LIMS and should be available for data mining/searching by that item without requiring the end-user to program LIMS code or database queries. | | |
| Information that is associated to a sample includes: Laboratory sample unique identification number Customer sample identification number Laboratory section | | |

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| <p>Sample priority (e.g., routine, high, urgent, etc.)</p> <p>Sample serial number (mandatory for Bureau of Standards section, optional for other sections)</p> <p>Sample category</p> <p>Sample type</p> <p>Sample matrix</p> <p>Test or tests assigned to sample</p> <p>Sample collector's name</p> <p>Sample collection date</p> <p>Sample collection time</p> <p>Sample collection location</p> <p>Sample receiver's name</p> <p>Sample receipt date</p> <p>Sample receipt time</p> <p>Sample storage location</p> <p>Preservation type /storage condition</p> <p>Sample relinquisher's name (for sub-contracted/split samples)</p> <p>Sample relinquish date (for sub-contracted/split samples)</p> | | |
| <p>Sample relinquish time (for sub-contracted/split samples)</p> <p>Review status</p> <p>Review date and time</p> <p>Sample container type</p> <p>Number of sample containers</p> | | |
| <p>Sample designation as for regulatory compliance or not for compliance</p> <p>Customer chain-of-custody number</p> <p>Complaint number</p> <p>Note or narrative (a non-reportable intra-lab note field)</p> | | |

| TESTS The LIMS applications software shall be able to manage test assignments. The tasks may include, but are not limited to, the following list. | | 3-TESTS In addition to a narrative description of TESTS, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed. |
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| Ability to assign one and assign multiple tests to one sample. | | |
| Ability to add, edit, remove, and cancel tests assigned to a sample. | | |
| Ability to add, edit, remove, and cancel tests either one at-a-time or all-at-once if multiple sample are selected. | | |
| Ability to add tests at sample login and at any time before disposal/return. | | |
| Ability to associate tests with other tests (as a "test package") and assign them to a sample together. | | |
| Ability to choose a test or tests from an established test list. | | |
| Ability to associate non-reportable supporting tests. | | |
| Ability to add, edit, or remove tests from the established list via customer configuration. | | |
| Ability to filter possible test assignments based on laboratory section, sample category, sample type, and sample matrix. | | |
| Ability to manually override test assignment restrictions (with audit trail comment required). | | |
| Ability to automatically assign a test based on sample collection location and sample type. | | |
| Ability to manually override automatic test assignment. | | |
| Ability to version tests. If an established test is changed, analysis that has been submitted but has not been initiated shall be updated to reflect the test changes, and analysis that has been initiated or completed shall not reflect the test changes. | | |
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| Ability to have sample condition upon receipt criteria for evaluating test validity with automatic flag when criteria are not met. | | |
| Ability for sample condition flag to trigger automatic test cancelling or automatic flagging of associated data (ability to have one or the other depending on assigned test). | | |
| Ability for holding time (the date and time of collection to the date and time analysis was initiated) to trigger automatic test cancelling or automatic flagging of associated data (and the ability to have one or the other depending on assigned test). | | |
| Ability to manually override default test cancellation (with audit trail comment required). | | |
| Ability to include one and more than one preparation/extraction information as part of a test. | | |
| Ability to designate one and more than one analyst as authorized to perform a test. | | |
| Ability to automatically and manually assign tests to authorized analysts and sample preparation/extractionists. | | |
| Ability to automatically and manually assign sample preparation/extraction to a secondary analyst other than the assigned primary analyst. | | |
| Ability to add, edit, or remove authorized analysts via customer configuration. | | |
| Ability to designate one and more than one instrument as authorized for use with a test. | | |
| Ability to automatically and manually assign tests to authorized instruments. | | |
| Ability to add, edit, or remove authorized instruments via customer configuration. | | |
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| <u>Test Identifying Information</u> | | |
| <p>Each item listed below must be a separate datum in the LIMS and should be available for data mining/searching by that item without requiring the end-user to program LIMS code or database queries.</p> <p>Information that is associated with a test includes:</p> <ul style="list-style-type: none"> Test unique name Reference method name Parameter(s) assigned to the test Preparation/Extraction start date Preparation/Extraction start time Preparation/Extraction completion date Preparation/Extraction completion time Preparation/Extraction reference method (if separate from reference method for analysis) Preparer/Extractor's name(s) Analysis/Prep batch ID | | |
| <ul style="list-style-type: none"> Note or narrative Analysis start date Analysis start time Analysis completion date Analysis completion time Analyst's name(s) | | |

| PARAMETERS The LIMS applications software shall be able to manage test parameters. The tasks may include, but are not limited to, the following list. | | 4-PARAMETERS In addition to a narrative description of PARAMETERS, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed. |
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| Ability to associate one and up to 300 parameters to a test. | | |
| Ability to have default test parameters. | | |
| Ability to add, edit, remove, or cancel default parameters from a test and create a new default version. | | |
| Ability to add, edit, remove, or cancel default parameters from a test and not create a new default version, i.e., change parameters one time/ad-hoc. | | |
| Ability to add, edit, remove, or cancel ad-hoc parameters on selected samples one-at-a-time or all-at-once. | | |
| Ability to choose parameters to add from an established list. | | |
| Ability to add, edit, or remove parameters on the established list via customer configuration. | | |
| Ability to filter/restrict parameter choice from list based on laboratory section, sample descriptors, or test. | | |
| Ability to manually override restrictions to parameter choice (with audit trail comment required). | | |
| <u>Parameter Identifying Information</u> Each item listed below must be a separate datum in the LIMS. Information that is associated with a parameter includes: <ul style="list-style-type: none"> Parameter name Expected result assigned to the parameter (e.g., ability to assign label guarantee information) Observed result (i.e., initially a blank field for data entry) Calculated result Quality control criteria/acceptable values | | |

| RESULTS The LIMS applications software shall be able to manage test results. The tasks may include, but are not limited to, the following list. | | 5-RESULTS In addition to a narrative description of RESULTS, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed. |
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| Ability to associate one and more than one result to a parameter. | | |
| Ability to track results of the same parameter over multiple tests (of the same sample). | | |
| Ability to support qualitative results. | | |
| Ability to support quantitative results. | | |
| Ability to support tests with label guarantees and specification checking. | | |
| Ability to associate quality control (QC) criteria with a parameter. | | |
| Ability to set default QC acceptable values for a parameter and test. | | |
| Ability to add, edit, or remove default QC acceptable values for a parameter and test via customer configuration. | | |
| Ability to support acceptable QC values/criteria including positive/negative, percent difference from expected result, and standard deviation from an expected result. | | |
| Ability to assign an expected result (e.g., for a label guarantee) at the time of login and at any time prior to initiating analysis. | | |
| Ability to automatically compare observed results with expected results and QC criteria and trigger an event. | | |
| Ability to add, edit, or remove an event trigger via customer configuration. | | |
| Ability to automatically compare observed results with expected results or QC criteria and trigger either cancelling or flagging that parameter (choice of trigger depending on parameter and/or test). | | |

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| Ability to automatically login a repeat test for the parameter that was cancelled due to failing variance from expected result or QC criteria. | | |
| Ability to set the automatic login of a repeat test to a specific number of iterations per parameter or test. | | |
| Ability to automatically login a second, different test based on the results of the first test (e.g., first testing for a negative/positive result, then automatically logging a quantitative test upon a positive result). | | |
| Ability to establish minimum detection level (MDL) or minimum reporting limit (MRL). | | |
| Ability to compare results to minimum detection level (MDL) or minimum reporting limit (MRL) and, for a observed result below an MDL or MRL, to automatically report the MDL or MRL value. | | |
| Ability to establish action limits. | | |
| Ability to compare results to action limits and trigger an event. | | |
| Ability to calculate results based on other results (e.g. sums) as well as test or sample level information (e.g. dry weights or dilutions) | | |
| Ability to track sample disposal/return such that automatic login of tests is not performed for disposed/returned samples. | | |
| Ability to control automatic login so that multiple failing parameters associated with a single test do not cascade into multiple retests being logged. | | |
| Ability to add or remove automatic retest login functionality via customer configuration. | | |
| Ability for results to be expressed as significant figures. | | |
| Ability for results to be expressed as text. | | |
| Ability to set and change a default number of significant figures for each parameter. | | |

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| Ability to establish custom rounding/reporting rules, (e.g., limit significant figures for results close to RL) by program, section, sample type, etc. | | |
| Ability for results to be expressed as a percentage. | | |
| Ability to set a result as reportable or non-reportable. | | |
| Ability to set more than one result as reportable. | | |
| Ability to specify which result(s) will be reported for samples with multiple results of the same parameter. | | |
| Ability to prevent multiple results for the same parameter from being reported (if this is undesirable.) | | |
| Ability to add an analyst comment to a result. | | |
| Ability to track results of multiple instrument components (e.g., columns and detectors). | | |
| Ability to set default values for results. | | |
| Ability to cut-and-paste or fill-down upon selection of data entry for multiple results. | | |
| Ability to copy result of one test to paste to other samples with the same test one-at-a-time or all-at-once for multiple selected samples. | | |
| Ability to import and export data with statistics software (such as NWA). | | |
| <u>Result Units</u> | | |
| Ability to support the absence of units for parameters. | | |
| Ability to require a unit for a parameter. | | |
| Ability to associate a default unit to a parameter. | | |
| Ability to change a default unit. | | |
| Ability to choose a unit from a list of units. | | |
| Ability to automatically recalculate results if units are changed after result entry | | |
| Ability to filter list of units to choices based on laboratory section. | | |
| Ability to add, edit, or remove units from the list via customer configuration. | | |

| CALCULATIONS The LIMS applications software shall be able to perform calculations. The tasks may include, but are not limited to, the following list. | | 6-CALCULATIONS In addition to a narrative description of CALCULATIONS, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed. |
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| Ability to perform one and more than one calculation on a result parameter. | | |
| Ability to perform calculations inter-test and intra-test. | | |
| Ability to perform calculations inter-sample and intra-sample. | | |
| Ability to automatically calculate correct minimum detection level (MDL) or minimum reporting limit (MRL) with dilutions. | | |
| Ability to use comparison operators in calculations. | | |
| Ability to use common mathematical formulas in calculations (e.g., average, sum, standard deviation, etc.). | | |
| Ability to use logical functions in calculations (e.g., =if (logical_test, value_if_true, value_if_false) in Excel). | | |
| Ability to have user generated and modifiable Excel templates for calculations on results. The LIMS must support easy setup of calculations based on vendor or user supplied Excel worksheets. | | |
| Ability to natively export data to Microsoft Excel so further result calculations may be performed. | | |
| Ability to natively import a calculated result from Excel | | |
| Ability to automatically export and import result calculations to and from Excel without user intervention. | | |
| Ability to track result data before and after each calculation. | | |
| Ability to add, edit, or remove calculations on a result via customer configuration. | | |

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| <p>Ability to support versions. If a calculation is added, edited, or removed, all data acquired prior to the calculation change must not be altered.</p> | | |
| <p>FLAGS/QUALIFIERS The LIMS applications software shall be able to flag results. The tasks may include, but are not limited to, the following list.</p> | | <p>7-FLAGS/QUALIFIERS In addition to a narrative description of FLAGS/QUALIFIERS, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed.</p> |
| <p>Ability to use flags on samples, tests, parameters, and results. Flags should be visible to users and, when applicable, on reports.</p> | | |
| <p>Ability to establish a list of possible flags and their associated definitions/information.</p> | | |
| <p>Ability to add, edit, or remove flags from the list via customer configuration.</p> | | |
| <p>Ability to filter available flags from list based on laboratory section, sample, test, parameter, and result.</p> | | |
| <p>Ability to set automatic triggers so that a flag is automatically applied to an item when an event occurs via customer configuration.</p> | | |
| <p>Ability to set automatic triggers than automatically run an event when a flag is applied via customer configuration.</p> | | |
| <p>Ability to manually override automatic flag triggers (with audit trail comment required).</p> | | |
| <p>Ability to automatically flag a sample, test, parameter, or result associated with a QC sample that was outside acceptable values.</p> | | |

| DATA REVIEW The LIMS application software shall have the ability to review and approve data. The tasks may include, but are not limited to, the following list. | | 8-DATA REVIEW In addition to a narrative description of DATA REVIEW, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed. |
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| Ability to review data for approval with, at minimum, approval at a result level, test level, and sample level. | | |
| Ability to review data for approval at a project level. | | |
| Ability to assign sets of data (e.g. batches or projects) to specific users for review either automatically or manually. | | |
| Ability to restrict approval of a higher review level unless the lower level review is approved. | | |
| Ability to redirect a sample, test, or parameter for additional analysis as part of approval/review process. | | |
| Ability to view flags and comments with a sample, test, or result at time of review. | | |
| Ability to view MDLs, MRLs, and other QC information associated with a sample or test at time of review. | | |
| Ability to set a requirement for data approval at all levels or none before a customer report can be generated. | | |
| Ability to change requirements for data approval based on test type, sample type, project type, customer, or laboratory section. | | |
| Ability to limit permission to approve data based on user roles. | | |
| Ability to add comments to samples, tests, parameters, and results during review. | | |
| Ability to trigger generation of final report upon approval of a project or sample. | | |
| Ability to use electronic signature. | | |
| Ability to use more than one electronic signature when a sample is shared by different lab sections. | | |
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| Ability for approval by more than one user when a sample is shared by different lab section. | | |
| Ability to review and approve data from a read-only view type user license. | | |
| QUALITY ASSURANCE/QUALITY CONTROL The LIMS application software shall manage all aspects of quality control. The tasks may include, but are not limited to, the following list. | | 9-QUALITY ASSURANCE/QUALITY CONTROL In addition to a narrative description of QUALITY ASSURANCE/QUALITY CONTROL, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed. |
| Ability to perform trend analysis/control charting. | | |
| Ability to automatically use the most recent 30 QC samples for control charting. | | |
| Ability to automatically update QC acceptance criteria applied to results from control charting information. | | |
| Ability to designate which type of QC sample will be used for control charting including positive controls, matrix spiked, and PTs. | | |
| Ability to generate control charts by instrument, test, parameter, and analyst and with the ability to specify date ranges. | | |
| Ability to automatically determine outliers, flag outliers, and remove them from the control chart (with audit trail comment required). | | |
| Ability to manually choose which samples are to be included and excluded for control charting. | | |
| Ability to use QC sample information to calculate statistical representations of data (such as method and instrument detection limits, quantitation limits, etc.). | | |
| Ability to track data reported for performance evaluation programs (check samples, PTs). | | |
| Ability to track data for performance evaluation programs by test, parameter, analyst, and instrument. | | |
| Ability to view statistical information for results and QC samples. | | |

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| Ability to support CAPA process and documentation. | | |
| BATCHING The LIMS application software shall have the ability to create and use batches. The tasks may include, but are not limited to, the following list. | | 10-BATCHING In addition to a narrative description of BATCHING, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed. |
| Ability to add, edit, and remove sample batch templates via customer configuration. | | |
| Ability to assign unique batch numbers to a group of samples processed together for extraction/preparation. | | |
| Ability to assign unique batch numbers to a group of samples processed together for analysis. | | |
| Ability to select samples from different preparation/extraction batches to group as an analytical batch. | | |
| Ability to configure batch number format via customer configuration. | | |
| Ability to automatically assign QC samples to be run in a batch. | | |
| The system will natively provide the ability to add, edit, or remove QC sample assignments. | | |
| Ability to designate mandatory order and frequency of QC samples in a batch. | | |
| Ability to auto-populate batch list with samples based on priority. | | |
| Ability to manually change the order of samples in a batch. | | |
| Ability to associate equipment/reagents with batches. | | |

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| <p>INSTRUMENTATION</p> <p>The LIMS application software shall have the ability to track instrument use and maintenance and have the ability to interface directly with instruments. The tasks may include, but are not limited to, the following list.</p> | | <p>11-INSTRUMENTATION</p> <p>In addition to a narrative description of INSTRUMENTATION, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed.</p> |
| <p>Ability to log instrument analytical batches.</p> | | |
| <p>Ability to log instrument maintenance.</p> | | |
| <p>Ability to schedule instrument maintenance with or without automatic re-occurrence.</p> | | |
| <p>Ability to export data electronically via instrument interface.</p> | | |
| <p>Ability to allow analyst to review and approve instrument data before sending to LIMS.</p> | | |
| <p>Ability to configure instrument interfaces for the specific tests analyzed with the instrument and not a generic .dll parser.</p> | | |
| <p>Ability to interface bi-directionally, with the LIMS populating sample sequence tables/sample file information at the instrument workstation (for all software that will accept such file transfers).</p> | | |
| <p>Ability to automatically match tests to instrument data files.</p> | | |
| <p>TRACEABILITY</p> <p>The LIMS application software shall have the ability to associate standards, media, reagents, containers and other supplies to projects, batches, samples, or tests. The tasks may include, but are not limited to, the following list.</p> | | <p>12-TRACEABILITY</p> <p>In addition to a narrative description of TRACEABILITY, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed.</p> |
| <p>Ability to associate standards, media, reagents, containers and other supplies to projects, batches, samples, or tests.</p> | | |
| <p>Ability to restrict use of these items based on predefined criteria (e.g. expiration date) and/or identify questionable items during review.</p> | | |

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| Ability to maintain an inventory of chemicals, standards, media, etc. Information must include, at minimum: assigned unique ID, date received, expiration date, date discarded, chemical name, manufacturer, lot, amount received, and a link to its certificate of analysis. | | |
| Ability to associate chemical inventory with a purchase order or PO number. | | |
| Ability to use inventory to maintain a constant level of supplies (reordered due to low quantity or nearing the expiration date). | | |
| Ability to use inventory to log working standard preparation. Information must include, at minimum: assigned unique ID, date prepared, date discarded, test method, final solvent/matrix, final concentration, a link/reference to the unique ID of each standard and reagent used in the preparation, and a expiration date for the working standard based on the expiration date of the first to expire standard or reagent used in its preparation. | | |
| Ability to generate inventory logs/reports. | | |
| Ability to generate working standards logs/reports. | | |
| Ability to print labels for chemicals and working standards that must include their unique identification. | | |
| Ability to link/attach MSDSs to inventory that is retrievable by users. | | |
| AUDIT TRAIL The LIMS application software shall protect information and data with respect to authorization rules and include an audit trail. The tasks may include, but are not limited to, the following list. | | 13-AUDIT TRAIL In addition to a narrative description of AUDIT TRAIL, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed. |
| Ability to provide an audit trail for any addition to, change to, removal of, or cancellation of projects, samples, tests, parameters, or results, and the minimum amount of information that must be logged in the audit trail includes: date, time, user, original value, new value, and reason for change. | | |

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| Ability to provide an audit trail for approval of projects, samples, or tests and for designating a result as reportable, and the minimum amount of information that must be logged in the audit trail includes: date, time, and user. | | |
| Ability to provide an audit trail for changes to user roles and permissions. | | |
| Ability to add and view audit trail comments. | | |
| Ability to run queries against audit trail data. | | |
| DOCUMENT TRACKING The LIMS application software shall have the ability to support versioning of documents and worksheets. Any change requires permission limited by user role. Once approved, the new version is the only version available for viewing and any outstanding tests should be updated to the new version. The tasks may include, but are not limited to, the following list. | | 14-DOCUMENT TRACKING In addition to a narrative description of DOCUMENT TRACKING, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed. |
| Ability to link/attach documents and worksheets to a project, sample, test, or parameter. | | |
| Ability to limit document retrieval to a read-only version for users. | | |
| Ability to support versioning of documents and worksheets. Any change requires permission limited by user role. Once approved, the new version is the only version available for viewing and any outstanding tests should be updated to the new version. | | |
| Ability to archive previous versions of documents and worksheets. | | |
| Ability to schedule document review and approval. | | |

| REPORTS The LIMS application software shall generate reports for samples, quality control, and management purposes. The tasks may include, but are not limited to, the following list. | | 15-REPORTS In addition to a narrative description of REPORTS, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed. |
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| Ability to create and configure templates for all documents produced by the LIMS (COCs, work lists, sample reports, invoices, etc.) via customer configuration. | | |
| Ability to generate a template for Microsoft Word, Excel, Access, and Crystal Reports. | | |
| Ability to include multiple tests and parameters on a sample report. | | |
| Ability to include multiple tests from different sections on a sample report. | | |
| Ability to use multiple sample report formats for a test with the test result automatically triggering which report format is generated. | | |
| Ability to report associated QC results with sample results. | | |
| Ability to include and exclude statements on reports for lab accreditation or certification, disclaimers, etc. based on test performed. | | |
| Ability to report results before all levels of verification/review are complete and distinguish results as preliminary. | | |
| Ability to report partial results of a sample and distinguish results as incomplete. | | |
| Ability to re-issue customer reports and re-issues are unambiguously designated as such. Re-issues must have unique report ID and a reference to the superseded report ID. | | |
| Ability to retain all versions of final sample reports. | | |
| Ability to create new reports ad-hoc. | | |
| Ability to restrict report creation, modification, and printing capabilities based on user roles, most current version of report, and project, sample, and tests status. | | |

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| Ability to create worksheets and associate them with tests. | | |
| Ability to add, edit, and remove worksheets associated with tests via customer configuration. | | |
| Ability to generate reports for quality control samples. | | |
| Ability to print a chain-of-custody form for pre-logged samples. | | |
| Ability to print a chain-of-custody form ad-hoc. | | |
| Ability to print reports with a consistent format on a variety of printers. | | |
| Ability to distribute reports via email and facsimile. | | |
| Ability to export reports in multiple file formats, including but not limited to CSV, XLS, XML, TXT, and DOC formats. | | |
| Ability to print labels for samples prior to or after collection. | | |
| Ability to generate reports (work lists) that analysts can use to identify samples waiting for analysis. | | |
| Ability to generate reports of sample priority, sample status/lifecycle, and turn-around times filterable by user, test, parameter, and holding time. | | |
| Ability to generate reports of sample counts filterable by laboratory section, user, sample type, sample category, sample matrix, test, repeated tests, and holding time. | | |
| Ability to generate lists for samples available for disposal/return. | | |
| Ability to generate a report for all parameters, tests, and samples that did not pass QC criteria. | | |
| Ability to group queries/reports based on user/lab section. | | |
| <u>Sample Reports</u> | | |
| Ability to generate sample reports. Sample reports must include, at minimum (listed on this page & next page): | | |
| <ul style="list-style-type: none"> Unique report ID Report title ODAFF LSD address and contact information Customer name and address | | |

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| <p>Sample collector/submitter</p> <p>Project name</p> <p>Complaint number, when applicable</p> <p>Lab sample ID</p> <p>Customer sample ID</p> <p>Sample category</p> <p>Sample type</p> <p>Sample matrix</p> <p>Received date</p> <p>Completed date</p> <p>Tests</p> <p>Test method name</p> <p>Reference to test certification, when applicable (e.g., ISO 17025 or ODEQ Lab 9927)</p> <p>Test start date</p> <p>Test start time</p> <p>Test completion date</p> <p>Test completion date</p> <p>Parameters</p> <p>Expected Results (for label guarantees)</p> <p>Results</p> <p>Units</p> <p>Flags and their associated definitions</p> <p>Analyst's comments</p> <p>Approver's signature</p> <p>Report ID/Document control</p> <p>Number of current page and total number of pages</p> | | |
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| <p>DATA EXCHANGE The LIMS application software shall have the ability to electronically exchange data with other databases (e.g. ELEXNET). The tasks may include, but are not limited to, the following list.</p> | | <p>16-DATA EXCHANGE In addition to a narrative description of DATA EXCHANGE, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed.</p> |
| <p>Ability to automatically or manually, electronically exchange all chemical and microbiological data related to food safety that is generated by the laboratory with the FDA's eLEXNET (Electronic Laboratory Exchange Network) database.</p> | | |
| <p>Ability to import any relevant sample information from internal and external agency databases (CPS ARID, CPS PID, CAFO, and OCC) for pre-logging samples. Once imported, the information may be added to or changed as needed in the LIMS.</p> | | |
| <p>Ability to allow user to define and customize imports and exports via customer configuration.</p> | | |
| <p>Ability to import files of different types, including but not limited to, CSV, XLS, and TXT formats.</p> | | |
| <p>Ability to export files of different types, including but not limited to, CSV, XLS, and TXT formats.</p> | | |
| <p>WORKFLOWS The LIMS application software shall manage workflows. The tasks may include, but are not limited to, the following list.</p> | | <p>17-WORKFLOWS In addition to a narrative description of WORKFLOWS, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed.</p> |
| <p>Ability to filter workflow views for samples by LIMS user, role, and/or laboratory section and must be able to be prioritized by holding time.</p> | | |
| <p>Ability to filter workflow views for samples by sample category, type, matrix, regulatory compliance, test, and/or parameter and should be able to be prioritized by a user-designated priority status (e.g., "urgent").</p> | | |

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| Ability to filter workflow view based on the status of a project, sample, or test and should include stages (when appropriate) of: received, assigned, in progress, in review, approved, reported, returned/discarded, and cancelled (or however so named). | | |
| Ability to automatically assign work based on user roles. | | |
| Ability to manually override work assignment (ability limited by user role). | | |
| Ability to set due dates and prioritize samples close to or past the due date. | | |
| Ability to track the status of a project, samples within the project, and tests assigned to those samples. | | |
| Ability to track the project status through, at minimum, the following stages: project pre-logged/scheduled (when applicable) and completion of all samples grouped in the project. | | |
| Ability to track the sample status through, at minimum, the following stages: receipt at laboratory, sample condition upon receipt verification, customer report authorization, customer report sent. | | |
| Ability to track the test status through, at minimum, the following stages: preparation/extraction (when applicable), analysis, result entry into LIMS, each level of verification of results, test result authorization (which may be synonymous with the last level of result verification). | | |

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| <p>SCHEDULER The LIMS application software shall manage scheduling. The tasks may include, but are not limited to, the following list.</p> | | <p>18-SCHEDULER In addition to a narrative description of SCHEDULER, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed.</p> |
| <p>Ability to schedule one-time and reoccurring events with choice of frequency (e.g., daily, weekly, monthly, etc.).</p> | | |
| <p>Ability for scheduled event to trigger notification to user(s) and ability to designate which user(s).</p> | | |
| <p>Ability to use scheduler for sample scheduling, instrument maintenance, personnel training, and document review.</p> | | |
| <p>CUSTOMERS The LIMS application software shall manage customer information. The tasks may include, but are not limited to, the following list.</p> | | <p>19-CUSTOMERS In addition to a narrative description of CUSTOMERS, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed.</p> |
| <p>Ability to maintain a list of customers with lab assigned customer IDs.</p> | | |
| <p>System will natively provide the ability to add, edit, and remove customers from the list.</p> | | |
| <p>Find customers and view customer information from various fields in the customer record.</p> | | |
| <p>Ability to validate entered customer information (e.g. verifying that email addresses and phone numbers are in the correct format).</p> | | |
| <p>Ability to automatically check for similar records when creating new customer records to prevent unintentional duplication.</p> | | |
| <p>Ability to associate multiple contacts with each customer (billing, sample kits, reports may need to go to different people, or a customer may have multiple project managers, etc.)</p> | | |

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| Ability to choose a customer from the list at sample login and have customer information automatically fill sample receiving information. | | |
| Ability to choose one or multiple samples with which to have customer information automatically fill. | | |
| Ability to add a customer at sample login ad-hoc. | | |
| Ability to add customer information at any time in a sample's lifecycle. | | |
| Ability to associate default customers with project or sample templates. | | |
| Ability to change the default customer via customer configuration. | | |
| Ability to log customer correspondence. | | |
| INVOICING/BILLING The LIMS application software shall generate reports for invoicing purposes. The tasks may include, but are not limited to, the following list. | | 20-INVOICING/BILLING In addition to a narrative description of INVOICING/BILLING, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed. |
| Ability to generate invoices based on sample type and test performed. | | |
| Ability to use customer information stored in LIMS to generate invoices. | | |
| Ability to add, edit, and remove cost factors to tests and samples. | | |
| Ability to create unique customer price lists. | | |
| Ability to associate prices with applicable date ranges and to retain previous pricing to allow re-invoicing past work. | | |
| Ability to flag customers not in good financial standing in order for lab operations to modify their interaction with those customers (e.g. not accepting work, not releasing results). | | |
| Ability to support different invoice workflows based on lab section. | | |
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| Ability to invoice all services and samples including sub-contracted work. | | |
| Ability to format invoices to comply with state accounting system requirements. | | |
| Ability to interface with existing accounting system software (AMS Advantage). | | |
| LIMS DESIGN/ARCHITECTURE The tasks may include, but are not limited to, the following list. | | 21-LIMS DESIGN/ARCHITECTURE In addition to a narrative description of LIMS DESIGN/ARCHITECTURE, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed. |
| Ability to design a Lab section module where the workflow and project, sample, test, parameter, and result associations can serve as a template to "copy and paste" and create a new Lab section module (that is also modifiable). | | |
| Ability for multiple users to access data simultaneously for data entry and functions that require data retrieval (queries). | | |
| Ability to run multiple processes concurrently. | | |
| Ability to interface and enter data (e.g., consistent use of screen layouts, keyboard/mouse functions, navigation, etc.). | | |
| Ability to natively support menu customization. | | |
| Ability to archive data using user defined retention schedules. | | |
| Ability to restore archived data. | | |
| Ability to insure data integrity (information is not corrupted during communication, transfer, manipulation, storage, and recall functions) and recovery after fault. | | |
| Ability to provide maintenance tools to change domain data. | | |
| Ability for user to define tables without recourse to the vendor. | | |

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| Ability for user to define fields and field without recourse to the vendor. | | |
| Ability for user to change the order of the records being viewed. | | |
| Ability for user to define field expressions without recourse to the vendor. | | |
| Ability to perform ad-hoc queries via customer configuration. | | |
| Ability to link/attach objects to a project, sample, test, or parameter. | | |
| Ability to provide version control on applications and objects. | | |
| Ability for the LIMS and the backend database to be upgraded and maintained without major disruption to the system. | | |
| Ability to provide all secured users access to data via the internet or LAN. | | |
| Ability to have user-level security based on the user's login into LIMS system as an integral part of the LIMS. | | |
| Ability to support at least 50 concurrent users and allow an unlimited number of named users. | | |
| Ability to add, edit, or remove users via customer configuration. | | |
| Ability to configure permissions for each user based on roles. Roles must be able to control authority to delegate and assign work; to add, edit, or remove data from lists and templates; to enter or view data; to print documents and reports; and to add, edit, or remove report forms and templates. | | |
| Ability to override role-based permissions to add or restrict certain permissions for specific users. | | |
| Ability to support the State of Iowa Lab's compliance with 21 CFR Part 11. | | |
| Ability to support the State of Iowa Lab's compliance with ISO 17025:2005. | | |

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| All system software is designed to allow growth. | | |
| LIMS DOCUMENTATION/SUPPORT The LIMS product shall have supporting materials. The tasks may include, but are not limited to, the following list. | | 22-LIMS DOCUMENTATION/SUPPORT In addition to a narrative description of LIMS DOCUMENTATION/SUPPORT, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed. |
| System documentation available including design, setup, and maintenance information. | | |
| User documentation available. | | |
| User and training documentation describes how to use each component in non-technical terms (e.g., functional description). | | |
| Documentation available in electronic format (e.g., CD-ROM). | | |
| Documentation regularly updated and distributed to customers. | | |
| On-line help provided including: features to assist in locating a function or feature, descriptions of how each function works, and descriptions of fields, their contents, and acceptable formats. | | |
| Multiple support package options available depending on the changing needs of the laboratory. | | |
| Multiple training options available (on-site, training site, online, etc.) | | |

| BARCODES The LIMS application software shall have the ability to generate, print, and read barcodes. The tasks may include, but are not limited to, the following list. | | 23-BARCODES In addition to a narrative description of BARCODES, for any line items that Contractor either cannot provide or provides a deviation from the line item please explain why and explain what the Contractor does provide that may meet the ability listed. |
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| Ability to generate labels with barcodes. | | |
| Ability to select from common barcode formats (including Code 39 and Code 128). | | |
| Ability to generate a unique barcode for each sample (to the container level), reagent, and working solution/standard. | | |
| Ability to set a default number of labels to print with the ability to manually change the number of copies. | | |
| Ability to use bar code labels and scanners for sample tracking from receipt to disposal/return. | | |
| Ability to use bar code labels and scanners for entering sample ID and other information. | | |