Request for Information (RFI) for a Prospective LIMS implementation for the South Carolina Public Health Laboratory

Amendment #1

Following is a complete list of questions received from vendors which may respond to the RFI, followed by answers from the agency. To reiterate, this Request for Information is not a solicitation for purchase and no contract will result from this RFI. Rather, the intent is to gather information, including technical and cost information, which will inform the future development of a solicitation for the purchase of a Laboratory Information Management System. Please submit electronic copies of RFI responses to the following email addresses no later than 4pm EST on Friday, July 7 2023: clarkhc@dhec.sc.gov. Please use the email subject "LIMS RFI Response"

Questions from Vendors

Vendor #1

Question 1 - If this RFI greenlights a solicitation, what is the estimated timeframe for procurement?

Answer: We anticipate that it will be at least 6 months after we review the RFI responses before a solicitation would be issued. Recent legislation that divides the agency into two agencies, one for Public Health and one for Environmental Services is to go into effect July 1, 2024. Our desire is that the solicitation will be issued prior to this date.

Question 2 - What is the anticipated contract value?

Answer: The final budget for this project remains unknown. A significant goal in the RFI process is to determine the budgetary requirements and to match that against available funds and potential funds.

Question 3 - Is there a current vendor providing these services? If so, how may I obtain copies of any incumbent contract documents?

Answer: The current LIMS is OpenElis and provided by the OpenElis Foundation. It was first acquired by DHEC in 2017. The initial cost on the first PO issued, for years 2017 – 2022, was $1,336,649. This includes, but is not limited to, training, implementation, cloud hosting, and maintenance. Payments have been made to OpenElis Foundation against a total of 11 purchase orders related to the LIMS since 2017. Total payments since 2017 are $4,324,785.91.

Vendor #2

Question 1 - Whether companies from Outside USA can apply for this (like from India or Canada)?

Answer: There are no international restrictions for responding to this RFI. It is anticipated that this RFI will likely lead to a future RFP. The specifications and requirements for that RFP are not yet determined. There may be limitations on what work can be performed outside of the U.S. and all data must be stored within the U.S.

Question 2 - Whether we need to come over there for meetings?

Answer: There are no anticipated meetings for this RFI. It is anticipated that this RFI will likely lead to a future RFP, and that RFP and the resulting contract could have some on-site requirements.

Question 3 - Can we perform the tasks (related to RFP) outside USA (like from India or Canada)?

Answer: See response above to question 1, vendor 2.

Question 4 - Can we submit the proposals via email?

Answer: Responses to this RFI should be submitted by email. Please submit electronic copies of responses to the following email addresses no later than 4pm EST on Friday, July 7, 2023, to clarkhc@dhec.sc.gov. Please use the email subject "LIMS RFI Response". It is anticipated that this RFI will likely lead to a future RFP and those proposals may not be submitted by email and the RFP will contain instructions for submittal.

Vendor #3

Question 1 - On page 2 of the RFI document it states: "Staff: The PHL employs 120 personnel who require concurrent access to the proposed LIMS." Can you confirm for me the total number of staff members who require access to the LIMS? And can you clarify for me how many of the total users on staff will need access to the LIMS at the same time?

Answer: The daily users of the LIMS would be accessioning, testing personnel, their managers, the quality assurance and LIMS team. We expect that the number of concurrent users would never exceed 90% of the 120 total users (maximum of 108 concurrent users).

Vendor #4

Question 1 - I would like to clarify the definition of the term SAAS used in Minimum Technical Requirement #8: Cloud based SAAS. Based on the pricing details requested in the RFI my assumption is that DHEC is not looking for a SAAS (Software as a service where a monthly fee is paid to access the LIMS) solution but rather DHEC want to purchase a LIMS that is hosted by the vendor and accessed via web by the users. Thank you for any additional information you can provide. Thank you!

Answer: You are correct, that was incorrectly worded in the RFI document. DHEC would like to purchase a LIMS hosted by the vendor and accessed via web by users.

Vendor #5

Question 1 - Does the South Carolina Public Health Laboratory have a preferred LIMS vendor?

Answer: No.

Question 2 - Who will be our key contacts throughout this process?

Answer: Communications in response to this RFI are addressed to Tripp Clark, Procurement Director, at clarkhc@dhec.sc.gov. Following the RFI, DHEC anticipates developing a formal Request for Proposals. That document, once issued, will contain details regarding communications and submission of both questions and proposals.

Question 3 - Can we coordinate a needs assessment visit with at the South Carolina Public Health Laboratory?

Answer: A site visit may be a part of the future RFP but is not a part of this initial RFI.

Question 4 - Where does the South Carolina Public Health Laboratory see itself going or growing within the next 5 years (i.e., are there areas of growth being explored, additional testing possibilities, or even just looking to maintain etc.?)

Answer: Some of the current capacity we expect to grow would be advanced molecular detection and sequencing workflows and wastewater surveillance. We would want an LIMS that is easily configurable and flexible as these methods undergo significant changes in relation to targeted analytes/organisms.

Question 5 - What results are you hoping your next LIMS will achieve that you are not finding with your current solution?

Answer: we would like a LIMS that has all the features of a modern public health information system as defined by the CDC namely, LIMS should be: scalable, flexible, interoperable, reusable, intuitive, and sustainable.

Question 5.a - How do you envision your next LIMS solution fitting into your overall business strategy?

Answer: We would like a system that is highly automated and interoperable between information systems (e.g Cerner EHR, AIMS, CDC, EDSS), easily interfaces with all automated instrumentation in real time, and flexibility in sending out or not sending out reports to different groups of providers (e.g CDC vs providers).

Question 5.b - What are some of the pain points with your current LIMS?

Answer: Current LIMS has limitations in scalability, flexibility, interoperability, and is not intuitive to learn.

Question 5.c - Is the intent to consolidate your lab systems to a single vendor solution wherever possible?

Answer: yes, we currently have a separate LIMS system for newborn screening. Preferably we would like a one vendor one product solution but is not required.

Question 6 - Do you have any commitments with your current vendors/ solutions that need to be considered when outlining a solution for the South Carolina Public Health Laboratory (i.e., open contracts/timelines, systems being sunset, etc.)?

Answer: No

Question 7 - Should you move to a new LIMS, by when would you like to be LIVE? Are you looking to go LIVE in a big bang model, or would the South Carolina Public Health Laboratory consider a phased approach?

Answer: If we are able to proceed with the solicitation, we would like to go live with all sections of the laboratory at the same time within 2-3 years of choosing a vendor.

Question 8 - Can you describe the South Carolina Public Health Laboratory's decision-making process and who else would be involved?

Answer: This RFI process is to assist in market research and to gather information for budgeting and for developing a future RFP. The responses to the RFI will be reviewed by multiple staff, both at the lab and other areas of DHEC, with information gathered helping in the development of the RFP. For the RFP, there will be an identified set of evaluation criteria that will be published in the solicitation and a panel of several employees that will independently review all

responsive proposals submitted and score them against the published evaluation criteria. The combined scores, including a score for price, will determine the selected solution.

Question 9 - What will be the South Carolina Public Health Laboratory's key decision factors when selecting its next LIMS?

Answer: This has yet to be finalized. When the RFP is developed, there will be an identified set of evaluation criteria that will be published in the solicitation.

Question 10 - Does the State of South Carolina prefer a Capital purchase of the LIMS for Subscription model?

Answer: We would prefer to purchase the solution outright, the reference to SAAS was an oversight.

> Question 10.a. - Are there any grant funding and/or purchase details LIMS vendors should be aware of as it relates to a potential purchase/ subscription?
>
> Answer: No

Question 11 - Please provide an integration diagram outlining how your current Systems are connected.

Answer: The main aim of this RFI is to obtain a reasonable estimate about the cost of a replacement system; if an RFP were approved such details would be provided at that stage.

> Question 11.a. - Please provide an overview of your current workflows from order request through testing and report delivery.
>
> Answer: The main aim of this RFI is to obtain a reasonable estimate about the cost of a replacement system; if an RFP were approved such details would be provided at that stage.
>
> Question 11.b. - Please provide details of the Chemistry and Newborn screening workflows noted in the RFI.
>
> Answer: The main aim of this RFI is to obtain a reasonable estimate about the cost of a replacement system; if an RFP were approved such details would be provided at that stage.

Question 12 - Please confirm which analyzers on the instrument list require interfaces. If possible, please provide a list of instruments by location.

Answer: All the instruments on the list require interfaces.

Question 13 - How will the LIMS be utilized in the support sections?

Answer: Data entry uses LIMS to accession samples, Quality Assurance teams uses LIMS to pull reports related to non-conformances (e.g # corrected reports, # unsatisfactory specimens, turn-around times), LIMS team also pull information on users with access to ensure security is maintained as well as operational indicators through ad-hoc reports.

Question 14 - Are there other interfaces desired (e.g., EMRs, reference labs, etc.)?

Answer: yes Interfaces to Cerner, AIMS, or Electronic Disease Surveillance system and to CDC are necessary.

Question 15 - What QA step(s) are most important to maintain within the System?

Answer: That level of detail has not been defined yet at this stage.

Question 16 - What % of your orders are received electronically (web portal or host system interface) versus paper (fax or mail)?

Answer: Based on a 2022 assessment, 25% of lab orders are received electronically.

Question 17 - Do you send requisitions, kits, supplies to your clients? How is this process managed currently?

Answer: We do send out kits to submitters based upon need. Submitters contact the lab via phone and lab prepares and mails the collection kit; no tracking process within current LIMS for this function.

Question 18 - Please provide examples of your current report formats. Are there any modifications you want to make within the reports?

Answer: The main aim of this RFI is to obtain a reasonable estimate about the cost of a replacement system; if an RFP were approved such details would be provided at that stage.

Question 19 - Are you currently offering a patient portal? What functionality is supported? Will the new LIMS vendor need to provide this functionality?

Answer: We do not currently have a patient portal. If a new LIMS vendor offers a patient portal it would be considered a desirable but not required feature.

Question 20 - What state department of health integrations are currently in place and/or required as part of a new LIMS implementation?

Answer: See answer to question 14.

Question 21 - For the minimum requirement “capable of supporting complete whole genome sequencing workflow,” please clarify the types of testing you support (e.g., hereditary, other).

Answer: We expect that the LIMS would manage WGS specimen tracking of workflow from accessioning to nucleic acid extraction to library prep to reporting to electronic disease surveillance system. If an inventory and or equipment module is available that can track the kit numbers of reagents and equipment used for processing specific specimen, those features would be highly desirable.

Question 22 - Do you expect the LIMS solution to store whole gene sequencing data?

Answer: We would not store WGS data in the LIS.

Question 23 - Please confirm that for final NGS resulting, your intent is to use a final PDF report from Color to attach to the patient order.

Answer: We do not intend to report NGS results to patients. LIMS should be configurable to prevent reporting of NGS results to patients while enabling reporting to our disease surveillance system used for epidemiological follow up.

Question 24 - The RFI indicates the need for 120 concurrent users. Please confirm how many concurrent users will be needed for laboratory tasks (e.g., reviewing/approving results, Quality Control, etc.) versus administrative functions and accessioning?

Answer: We believe that 90% of our total staff is sufficient, so 108 concurrent user licenses would be needed.

Question 25 - How many Web-Portal concurrent users are needed?

Answer: Our current LIMS does not limit number of concurrent users on Web Portal. We have over 350 users active.

Question 26 - What is your definition of Software-as-a-Service (SaaS)?

Answer: Please see the answer above to question 1 from vendor 4.

Question 27 - Regarding migrating legacy data into new system, what format(s) can the data be exported in? How much data needs to be migrated (specifically the number of records)?

Answer: The data from current LIMS would be exported in a format that enables transfer,but has not been stipulated ahead of time. We estimate that if 2 yrs of lab records and 13 yrs of Newborn screening records were to be migrated, this would total about 2-3 million records.

Question 28 - What Microbiology culture types are you testing for?

Answer: We aren't clear on the meaning of the question. PHL participates in the following surveillance programs: PulseNet, WHO collaborating lab for Flu, NREVSS (National Respiratory and Enteric Virus Surveillance System), NARMS (National Antimicrobial Resistance Monitoring

System, FoodCORE (CDC Foodborne Centers for Outbreak Response Enhancement), CaliciNet (National Molecular Subtyping Network for Foodborne Disease Surveillance), and LRN-B/C (CDC Laboratory Response Laboratory)

Question 29 - What Molecular assays do you perform? What panels are performed?

Answer: We perform the following single agent PCR (flu, COVID-19, measles, mumps, ettc), HIV diagnostic and viral load test, STI testing on Panthers (GC/CT, TC), BioFire respiratory panel, BioFire GI panel, Illumina Viral Surveillance Panel

Question 30 - How is Molecular interpretation done?

Answer: Some instruments directly interpret and output results (e.g Panther) while others are interpreted by the analyst (e.g Flu testing on ABI 7500). An LIMS where in interpretations for molecular tests can be automated would be desirable.

Question 31 - Are you pooling?

Answer: We do not currently pool any samples for diagnostic tests.

Question 32 - What is your pipetting strategy (manual or robotics)?

Answer: We use both liquid handlers and manual Pipettes for library preparation of NGS samples.

Vendor #6

Question 1 - Does the State invoice for tests? If so, is there more than one version of the price list or can fees be added as needed?

Answer: We do need billing for tests. Currently billing system is distinct from LIMS system. Currently there is one version of the price list that is typically updated on annual basis but it would be desirable to have billing controlled by lab within LIS.

Question 2 - Are SpecimenGate Screening Center and Patient Center deployed in the Newborn Screening Laboratory?

Answer: Yes currently SpecimenGate and Patient Center is being used for newborn screening.

Question 3 - Does the lab have field collectors?

Answer: We do not currently have that capacity but would find that feature highly desirable.

Question 4 - Will Procurement permit purchase directly from the GSA Schedule 70 for IT after thorough assessment of vendor software and support?

Answer: No. South Carolina Procurement Law does not provide for GSA Schedules to be an available purchasing method for state agencies.

Question 5 - Since an RFI does not guarantee an RFP, will the lab be permitted to invite demonstrations before an RFP is issued?

Answer: There is not a prohibition on demonstrations before the RFP, but it is more likely that we will include demonstrations after the RFP has been issued and as a part of the review and selection process.

Vendor #7

Question 1 - Please provide the following metrics:

This information will be included

> # of annual General Laboratory (GL) Procedures
>
> Answer: This information will be included in the resulting solicitation but is not immediately available now.
>
> # of annual Microbiology (MB) Procedures
>
> Answer: This information will be included in the resulting solicitation but is not immediately available now.
>
> # of annual Molecular Procedures
>
> Answer: This information will be included in the resulting solicitation but is not immediately available now.

Question 2 - Is it accurate the 120 personnel accessing the new LIMS will be leveraging the existing public health domain/environment?

Answer: See answer to quest 24 listed under vendor 5 above.

Question 3 - Are any specimens being sent to another reference lab? If so, which reference labs?

Answer: We do send out specimens to reference labs at CDC and regional state health department and some private labs. Currently reference testing results is attached to Samples as a pdf.

Question 4 - Regarding technical requirement #1, what is needed for the client management and reagent supply inventory components? Please elaborate on what this involves.

Answer: This information will be included in the resulting solicitation but is not immediately available now.

Question 5 - Is there a need for a billing system to support the lab or is there an existing system that needs to be interfaced to?

Answer: Please see the answer to question #1 from vendor 6 above.

Question 6 - Regarding the HL7 interface to Electronic Disease Surveillance System and AIMS:

Between the LIMS and the Electronic Disease Surveillance System or AIMS, what type of transactions will be passed to and from systems?

Answer: Laboratory results or ELRs will be reporting out to EDSS or AIMS.

Are there specification documents available for these interfaces?

Answer: This information will be included in the resulting solicitation but is not immediately available now.

What are the responsibilities of the quality assurance team? What systems do they utilize to do their daily work? What is their monthly QA volume?

Answer: The Division of Quality Assurance is an essential part of the quality assurance team and PHL leadership and ensures that the laboratory provides reliable test results to our providers and the epidemiologists. The Division's activities include quality monitoring, quality control, preventative maintenance monitoring, and compliance with accreditation agencies CLIA, the FDA, and the CDC. The QA Division ensures validation of staff credentials, training and competency through standardized forms and QA office

audits, office reports and follow-ups for non-compliance. The LIMS system is critical to their responsibilities so a LIMS with built in quality management features is highly desirable. Monthly QA volumes will be made available in the future solicitation.

Question 7 - Regarding technical requirement #13, attached is Oracle Cerner's discovery document to assist determining what's in scope for the data migration. What datasets are in scope? If possible, please fill out the grid in the discovery document. Additionally, is there only one instance or database of OpenELIS where lab solutions are housed?

Answer: We estimate that if 2 yrs of lab records and 13 yrs of Newborn screening records were to be migrated, this would total about 2-3 million records. These are stored in two different LIMS systems, one for main lab with 4 instances and another for Newborn screening with 3 instances. We are unable to fill out the discovery document at this time.

Question 8 - Please clarify what the 'support sections' are and what they do per the program overview description: "The PHL is comprised of 11 specialty laboratories and 6 support sections"

Answer: Please see the answer to question 13 from vendor 5 above.

Question 9 - What is the number of lab document scanners in scope?

Answer: This information will be included in the resulting solicitation but is not immediately available now. We estimate approximately 7 document scanners and 20 or more hand scanners.

Question 10 - Given the 4th of July holiday upcoming, would DHEC consider extending the July 7th RFI response submission deadline by 2 weeks?

Answer: Unfortunately, because of an external deadline related to this project and beyond our control, we need to keep the July 7 deadline in place.