

1. Can you expand on the Joliet location for me? I am of the belief this is one of the 13 that you and your VISN are keeping as an option only? In other words, you may or may not buy them instruments. The line item for CLINS 1023, 1025, 3025, 4025 address instrumentation for option years. Since this is a purchase RFQ (I think), I do not understand the Joliet carve out.

ANSWER: The Joliet CLIN for equipment may or may not be purchased throughout the term of the proposed contract. There are multiple option CLINs for the Joliet Clinic to allow for difference in pricing covering the base and all option years.

2. If we do not make a test of two that need to be purchased from another company (likely not a prospective bidder to this RFQ) can this contract allow for that. For instance, the BNP test is run on our instruments but is sold by Alere. Please comment about this example.

ANSWER: In this example it would be allowed as long as the equipment and testing meets all the requirements set forth in the solicitation and your company is providing and supporting the tests for use on your equipment.

3. My understanding this RFQ is for a purchase award of all hardware with a warranty period. What happens with service and presumed service contracting after the warranty period? Will there be follow up service contracts sent out toward the end of the one year warranty period (for example).

ANSWER: Any service required after the warranty period will be acquired under a separate service contract.

4. Comments were made that back up testing requirements are listed in Attachment B. Why can't I find any designated back-up test requirements? I see the list of tests per site and I am now thinking you want back up platforms for ALL TESTS highlighted. Correct?

ANSWER: Section 3.2.3 references Back-up Testing Analyzer(s). The attachment was inadvertently omitted from the RFP and will be incorporated as Attachment C. Attachment C indicates which tests have the requirement for a Back –up analyzer (the designated tests are highlighted). The outpatient clinic laboratories at Appleton, Green Bay, Rockford, Crown Point, Joliet and Red Rover **DO NOT** require the back-up equipment. All remaining medical centers require the backup testing. There is space in for each of the medical center CLINs (Attachment B) to indicate back up equipment and pricing required for the items listed in Attachment C.

5. To our knowledge, the Green Bay and Rockford sites are under construction currently. When will they be done and able to accept instruments for performing their own lab work? What happens to the work volumes at Iron Mountain or Appleton when Green Bay comes on line?

ANSWER: The Green Bay OPC is expected to open in the June/ July 2013 time frame. Delivery for the instrumentation could be as early as April 2013. The Rockford CBOC is currently open and has the ability to accept delivery. Once the Green Bay OPC begins performing lab work the test volumes at the Iron Mountain VAMC and Appleton CBOCs may vary but is unknown at the present time at what level.

6. On the note about Green Bay and Rockford, when would you expect delivery of instruments to begin. I understand this is your best guess only, knowing what you know today.

ANSWER: See the above answer.

7. I saw no growth factor built into the test volume lists. It appears the base year and option years 1-4 all have the same volumes.
Is this intended or am I missing something here relative to projected growth.

ANSWER: This is intentional. There is no projected growth built into the testing volumes.

8. It is our experience to provide reagent credits for any interfacing costs. For example, if the interface for our equipment is 10,000.00, we would reduce the first invoice by that amount. That would mean the VA would contract with DI or Dawning individually to make sure the facilities and LIS are all working together. Can you expand on your expectations of each vendor here?

ANSWER: For the 1st year of each of the equipment and instrumentation CLINs the vendor shall purchase the hardware and provide the interface support through either Dawning or Data Innovations as required. After the first year the VA will contract with Dawning or Data Innovations for the interface.

9. Phosphorus and Potassium not listed in volumes. What is the volume for these?

ANSWER: These tests are addressed in Amendment A00002.

10. VA Tomah only has 1 DAT assay listed; cocaine. – volume listed is 1,800
- Should the rest of the DAT panel be included?
 - Or maybe they made a mistake and accidentally put Iron Mountain's cocaine volume in Tomah's.

ANSWER: Attachment A has been corrected to reflect the appropriate DAT testing volumes.

11. VA Iron Mountain's menu doesn't include cocaine and PCP.
- Should these be included to complete the panel?
 - Each DAT test listed has a volume of 1,800.

ANSWER: Attachment A has been corrected to reflect the appropriate DAT testing volumes. PCP is not performed at VA Iron Mountain.

12. Can you ask how many days a week the clinics are open? (Crown Point, Joliet, Red Rover, Rockford, Appleton, Green Bay)?
- e. It will be important, so we don't build in too much usage volume for QC ect...
 - f. And also shifts per day?

ANSWER: The clinics are open five (5) days per week, Monday through Friday, for one shift.

13. Can you ask him to clarify: "Additional Training Slots, Optional Clin"? for both Hospitals and Clinics? It states the estimated QTY is 3.

ANSWER: The Additional Training Slots are included as an option in the instance a facility has new personnel that may require training during the term of the contract. The requirements for Hospitals and Clinics have been removed and are now based on training per model of equipment.

14. We were a little unsure on how you were going to acquire the instruments. We assumed you were going to purchase them outright, but we want to be certain.

ANSWER: Yes, the instrumentation will be purchased on separate delivery orders.

15. Are you looking for us to provide 24/7 service for all your sites and equipment for the duration of the agreement?

Answer: Section 3.5 **GENERAL REQUIREMENTS –WARRANTY MAINTENANCE AND REPAIR SERVICE** indicates "The Contractor shall provide a one (1) year warranty period covering emergency equipment repair and preventative maintenance services that is no less than what is offered to other commercial customers." Any service after this time period will be acquired under a separate service contract.

16. Can you please define up time for us?

ANSWER: Refer to the response to Question 24.

17. We have noticed there are no test totals for Potassium and Phosphorus at any testing site. We will need these volumes to proceed.

ANSWER: These tests are addressed in Amendment A00002.

18. It is our understanding that control materials for any analyte being tested are NOT included in this RFQ, Can you please confirm.

ANSWER: This is correct. Control materials for any analyte being tested are not included in this RFP.

19. Training: We understand that each year you requested (3) additional training slots. (See CLINS 0027 and 0028 for example and then each additional year CLINS). We could use some more clarity. Suppose we propose 5 instruments at a medical center site along with connected automation. With the purchase comes 2 training slots per analyzing instrument for year one and two automation training slots per site. For year one, do you want 3 additional training slots per site or per instrument or for automation only or what. Please clarify for us.

This same discussion needs clarification for specific training slots for option years 1-4.

ANSWER: VISN12 is asking for pricing in the event additional operator training is required beyond what is offered in the basic purchase package of the equipment. Additional training CLINS have been established to allow the vendor to submit pricing, per equipment model. These CLINS are located in the Supplies or Services And Price/Costs: section of the RFP document and in Attachment B.

20. The RFQ (page 23 of 54) mentions interface costs using middleware for your Dawning sites at \$ 6,750 per site. What is the cost for using middleware with DI? If you do not have that cost from DI, what process do we use to get it?

ANSWER: The RFP states in section 3.4.8.6 that the pricing indicated is only an estimate of the potential cost for interfacing equipment to VistA and it should only be used as a guide. It further states that it is “the sole responsibility of the Contractor to obtain current costs for the components to establish the interface(s)”. VISN12 does not have in-depth knowledge of the requirements for interconnectivity associated with each Contractor’s equipment. Therefore, it is incumbent on the contractor to pursue this information with Dawning and/or Data Innovations.

21. How will the VISN assess and rank the vendor proposals that do not meet the sole source orientation of these specifications?

Example: It is quite apparent that only one instrument mix in the world can meet some of these specifications. For example, page 17 of 54 (chart #4) states Milwaukee must have a throughput of no less than 3240 Total Tests per hour. The 3240 is exactly the stated throughput of two Siemens Vista 1500’s and a Siemens Centaur. We believe the preferred specification is stated on page 16 of 54 - 3.4.5.1: “50% of testing is processed between 0700 and 1300 hours” and the real question is, can a vendor meet that criteria. In chart #4, the CBOC’s are stating no less than 1000 tests per hour. Based on the test volumes in attachment B, they do not perform 1000 tests in a day. Why the minimum of 1000 tests per hour. The Siemens Vista 500 performs exactly 1000 tests per hour. We understand the phrase “no less than”. If the spirit of this process is an open opportunity

for all vendors to compete with “reasonable” responses of similar ranges of throughput, again the question is, how are the vendors evaluated that do not meet exactly the written specifications?

Example: Page 17 of 54, 3.4.5.5.1. and .2: Only Siemens Vista meets this requirement. All vendors have some variation of calibration that accomplishes calibration of testing with arguably various degrees of ease of use. All vendors have successful clients calibrating tests successfully. Just not exactly like Siemens does as shown in the specifications on page 17. What is the impact of not meeting the sole source orientation of these specs?

ANSWER: The RFP has been revised changing specifications. Charts 3, 4, 5 and 7 have been removed.

The evaluation for this procurement is Lowest Price Technically Acceptable. Items being offered in a vendor’s proposal must be technically acceptable in accordance with the factors set forth in the RFP in order to be considered.

22. Please define calibrations per year in chart #5. For example, if a drug of abuse test has a 5 level calibration and this one “calibration event” calibrates that test for some extended period of time, does that count as 1 or 5 calibrations?

ANSWER: One calibration event. However, this specification has been deleted.

23. Page 41 of 54 item c. Contractors shall report the mean failure rate of the equipment offered. Also referred to page 21 of 54 - 3.4.7.10.

The reliability of the instrument system shall be no less than 98% of total annual operation time. No more than 7.5 days per year of down time.

Question: Can you better define 98% and 7.5 days per year? Is that 8 instances of down time per instrument per year? Is that 180 hours of time when no testing can be performed per instrument? How about some testing is performed but not all testing. How is failure rate measured.

Example: In Q2 2012, one VISN site directed us to review their current downtime log. 36 service calls were identified per instrument, per the last one year. Does this example meet or exceed the 98% requirement or meet or exceed the requirement of no more than 7.5 days per year requirement? If not, and in the spirit of this RFQ, what are the vendor ramifications for not meeting 98% or 7.5 days of down time requirement?

ANSWER: The specification of 98% reliability inversely correlates to 180 hours of complete down time per instrument, where the instrument is not reporting any tests at all.

24. On page 21, 3.4.7.10 (Reliability) the RFP talks about downtime being no more than 7.5 days per year. This assumes uptime is 357.5 days per year. Can you please define uptime and downtime.

ANSWER: Up time is when the instrument is either fully operating or is ready to perform its intended function. It is the opposite of downtime where the instrument is not available for use due to an instrument or system malfunction.

25. VA69D-12-R-0986

- a. Which facilities (if any) are currently utilizing BioRad Unity Real Time QC?

ANSWER: All facilities are using BioRad Unity Real Time QC.

- b. What are the VISN's vendor expectations for the inclusion of service and materials to support the Data Innovations interface?

ANSWER: VISN12 has no expectation for the inclusion of service and materials beyond the purchase of the interfacing equipment.

- c. FSS contracts generally provide for an allowance (or credit against invoice) for incremental water systems. Please clarify that this is acceptable for the VISN facilities and what, if any, other requirements for water systems is expected.

ANSWER: This is not acceptable. If a water filtration system is required for the operation of the Contractor's equipment, the Contractor must purchase and install the device(s).

26. Attachment B

- d. Each individual item listed in this document (e.g., Acetaminophen and Albumin) shows a "Quantity" and "Unit Price". We understand "Unit Price" to mean the reagents, consumables, and calibration materials required to create the "Unit Price" for each item.

ANSWER: True

- e. Extended service, beyond the warranty period, is not covered in any of the CLINs beyond the Base Year. We presume the VISN 12 facilities will require service support for the years beyond the Base Year and that it should be included in the "Unit Price" as defined above in 1.a.

ANSWER: This is incorrect. As indicated in the answer to question 3. "Any service required after the warranty period will be acquired under a separate service contract".

- f. Training is called out under the Base Year Consumables section, however if additional training slots are provided, it is unclear where this should be included. Please provide clarification on where you would like this information provided.

ANSWER: Additional training CLINS have been established to allow the vendor to submit pricing, per equipment model. These CLINS are located in the Supplies or Services And Price/Costs: section of the RFP document and in Attachment B.

- g. Are Quality Control (QC) materials included in the solicitation or will they be purchased separately from the responding vendor or from a third party

ANSWER: Quality Control materials are not included in the solicitation and will be purchased separately from a third party vendor. However, if your company manufactures/distributes quality control material and wishes to offer a price for these items, please do so. The procurement of these items will be considered 'Optional' and not included in the evaluation of the cumulative cost of the acquisition.

- h. Does the "Quantity" reflect the "Patient Reportable Result"?

ANSWER: Yes. The 'Quantity' reflects the "Patient Reportable Result".

27. Attachment A

- i. Will new equipment for Iron Mountain be installed at their current location or the new location? To that end, do we presume all systems being proposed are for the new locations only? If not, please clarify by facility.

ANSWER:

Iron Mountain: The tentative laboratory relocation date will be no earlier than July 9, 2013. There is a possibility that the move will be delayed. If the contract award is made by January 1, 2013 with a 90 day delivery timeframe, the new equipment will be installed and validated in the existing Lab. The RxL without the RMS will be replaced with the new equipment. The new equipment will be validated against the MAX with RMS. Once this is complete, the MAX with RMS will be replaced with the 2nd new chemistry analyzer. The 2nd new chemistry analyzer will be validated against the first new chemistry analyzer. The delivery of front end automation will need to be postponed until after the relocation to the new laboratory.

Tomah: The renovation of the Tomah Laboratory will not begin until January 2013 with an expected completion date of 1.5-2 years. The new equipment will need to be installed in and validated in the existing Lab and then relocated to the new Lab upon completion of the renovation. The delivery of front end automation will need to be postponed until after the relocation to the new laboratory. If this is not possible the equipment should be delivered and the facility will store until the renovation is complete.

Madison: Madison will not be able to validate new instrumentation within the laboratory. They will have a room available to perform validations one floor

above the laboratory. Due to the size of the analyzers, they would more than likely only be able to validate one instrument at a time. It may be possible to have both instruments shipped at the same time if they can find a location to temporarily store one of the instruments while the other is being validated.

Milwaukee: The equipment will be installed and validated in the Research Room adjacent to the current Lab. The equipment will then be relocated to the existing Lab after successful completion of the validation studies.

Appleton: The new equipment will be delivered to the current existing Laboratory space. The instrument will be installed next to the current instrument until validation studies are complete. The new instrument will be relocated to its permanent location after validation is completed.

Jesse Brown: The new equipment will be installed and validated in the Laboratory supply room, immediately adjacent to the Laboratory. Upon completion of the validation studies, the new equipment will be relocated to the existing laboratory.

Joliet: The task order for the new equipment will not be issued until the laboratory space at the new facility is completely renovated. The new equipment will be delivered to and installed at its final destination. Validation studies will be performed at that location.

Hines: The equipment will be installed and validated one at a time in the Special Coagulation Laboratory across the hall from the current General Diagnostics Laboratory. As the validation studies on each piece of equipment are completed, the unit will be relocated to the Laboratory hallway. When all of the equipment is completely validated, the existing equipment will be dismantled and the new equipment will be installed at its final destination.

Crown Point: The new equipment will be delivered to the current existing Laboratory space. The instrument will be installed next to the current instrument until validation studies are complete. The new instrument will be relocated to its permanent location after validation is completed.

FHCC: The new equipment will be installed and validated at their final destination point, after the current equipment is relocated.

Red Rover: The new equipment will be validated at the FHCC medical center laboratory. Upon completion of the validation, the new equipment will be relocated to the Red Rover Bldg 1523 clinic.

Green Bay: The task order for the new equipment will not be issued until the laboratory space at the new facility is completely renovated. The new equipment

will be delivered to and installed at its final destination. Validation studies will be performed at that location.

- j. Tobramycin test volumes at Iron Mountain are very low and seems as if it may be discontinued (4 patient reportable test per year). Should this test be included in the solicitation?

ANSWER: Yes. Tobramycin will be performed at Iron Mountain regardless of the volume of testing.

- k. In general, what is the lowest testing volume we should consider a VISN facility will actually perform testing on site?

ANSWER: If a 'Test Volume' quantity is listed on the Attachment A, the testing will be performed on-site at the indicated VISN facility. Testing will not be performed on-site, if the test volume is listed as zero (0).

- l. How does VISN 12 want us to respond to facilities who will not be ready for implementation at the time of contract award due to construction or relocation?

ANSWER: Separate Delivery Orders will be placed for those facilities when it is necessary to order the required items.

28. Does the ABJ Clinic currently have 208 VAC dedicated in place?

ANSWER: No. The electrical connection is currently 120V/20 amp dedicated. The electrical system will be updated, based on the requirements of the new system.

29. What is the current Di H2O output in L/ph for the ABJ Clinic?

ANSWER: The deionized water output at the ABJ Clinic is 8 liters per hour.

30. What are the turnaround times for tests?

ANSWER: Minimum specifications for turnaround times have not been defined in this solicitation.

31. Chart #7 indicates 144 assays on board Attachment A indicate 39 assays for the ABJ Clinic in Crown Point. Please clarify which is correct.

ANSWER: The specification has been rewritten to read as follows:

3.4.7.4.8 sufficient on-board reagent capacity to meet one average day of testing.

32. The RFP requires 1,000 test p/hr for the Crown Point Clinic per Chart #4. How is this number determined? What is the basis for the required number?

ANSWER: The observations of the vendors represented the workload of one 24 hour period. This one day sample is not to be construed as the average maximum throughput or the specifications of future performance needs. Having said this, specification 3.4.2 and specification 3.4.5.4 have been rewritten as follows:

3.4.2 The models of equipment offered shall be identical at the VISN locations as follows:

3.4.2.1 Hines, Milwaukee and the Federal Health Care Center (Large facilities)

3.4.2.2 Madison and Jesse Brown (Medium facilities)

3.4.2.3 Iron Mountain, Tomah, Appleton, Green Bay, Rockford, Crown Point, Joliet and Red Rover (Small facilities)

3.4.5.4 The combined instrument system including back-up instrumentation (as applicable) must have a minimum test throughput as follows:

3.4.5.4.1 Large facilities – 3000 tests per hour

3.4.5.4.2 Medium facilities – 2000 tests per hour

3.4.5.4.3 Small facilities – 1000 tests per hour

33. The onboard Reagent Stability indicates 30days or 7 days. Which one is correct?

ANSWER: Both. VISN12 has made a distinction between a ‘high throughput testing analyzer’ (refer to Definition in section 3.2.5) and other analyzers that may be offered in response to this solicitation. The high throughput testing analyzer requires a minimum of 30 day reagent stability. The minimum requirement on other offered analyzers only requires a reagent stability of 7 days.

34. Is the measurement of 300SF at the Joliet CBOC reasonable to expect?

ANSWER: Unfortunately, no. The specifications have been revised to reflect an available space of 85 square feet.

35. Are there CAD drawings of floor plans available for the individual labs?

ANSWER: Drawings are issued with this amendment. Vendors are asked to submit a CAD drawing for each laboratory proposing the location and orientation of their equipment based on the maximum foot print detailed in the solicitation. In addition, the vendor is asked to detail any infrastructure modifications that are required, i.e. utilities, to house their instrumentation. These are detailed in ADDENDUM TO FAR 52.212-1 INSTRUCTIONS TO OFFERORS

36. Where will validation studies for the individual labs be located?

ANSWER: Refer to the response to Question 27h above

37. I have heard that Tomah has doubts/challenges/concerns about having automation installed in the lab they are currently in. Comments about the possibility of them getting front end automation or not based on space? Can you elaborate for me what the intentions are here with Tomah and front end automation? Automation in 2-3 years maybe after a move to a new lab?

ANSWER: Although their current Lab space could not support automation, their new lab can, so we do want to proceed with automation at Tomah as originally planned. We believe that the site can store this equipment for future use in the new lab.

38. Section 3.4.7.6 states that a refrigeration system to store reagents at 2-6° C is required. We understand that refrigeration facilities are likely already in place at most, if not all, of the facilities participating in this solicitation. Would you please provide what the current refrigeration facilities are and their capacity by location? Also, what are your expectations regarding refrigeration given our reagents and consumables may take less space than is currently required, and would allow for storage of other lab consumables?

ANSWER: Section 3.4.7.6 refers to on-board, refrigerated reagent storage on the primary testing automation.

VISN 12 Questions

FOR CONTRACTING:

39. We understand that this solicitation is for a Firm Fixed price agreement, would you please verify that all pricing should be based upon calculations for a Cost Per Test format and that there is no requirement to provide Cost Per Reportable Result options.

ANSWER: Pricing is to be based on a Cost per Test format.

40. According to Section 3.5.1 and subsections, the Warranty and Service requirements are for the term of one (1) year. Attachment B indicates that there are Warranty and Service requirements for Joliet CBOC. However, we are unable to locate any other requirement for Warranty and Service for Option Years within the solicitation. Please verify that Service and Warranty pricing for Option Years is not required for this solicitation.

ANSWER: Service and Warranty pricing for Option Years are not required. The exception is if/when equipment/instrumentation is ordered for the Joliet CBOC which of course the service /warranty period will be effective for one year after the acceptance of those line items.

41. Please define the specific scope of requirements of Relocation/Reinstallation of Equipment After Validation on pricing Appendix B.

ANSWER: The vendor will be required to relocate and reinstall the new equipment, as necessary, based on the validation and installation plan described in the previous Question 27h.

ENTIRE VISN:

42. Since the RFP defines Service Calls for Warranty requirements as noted below, do you require Service Calls metrics from each vendor for each instrument model offered as proof of reliability? (Mean time between failures is open to vendor interpretation of the definition of “failure,” many VISN solicitations use Service Calls per Year.)

- a. 3.5.1.9 In determining the mean failure rate for the equipment the VA will consider each notification for an emergency repair service call as a separate and new service call.

ANSWER: Your published mean failure rate is to be provided.

43. There are no requirements to verify or submit FDA Notifications information. Do you require vendor’s recent (2011 & 2012) FDA Notifications regarding Instruments and Reagents as an indication of their quality and reliability? Typical language included with VISN RFPs as:

- b. Contractor to include copies (or listing) of any active FDA Product Corrections or Recalls for Instrument and Reagents with submission.

ANSWER: No

44. Please indicate which specific personnel from IT/ISO will review the RFP for LIS/Interface capability so that we may align our response language to that required by the VA IT/ISO Network team.

ANSWER: Members of the Technical Evaluation Committee will not include an IT/ISO subject matter expert. It is required that a summary of the interconnectivity be provided to describe how the interface to VistA and CHCS will occur and the hardware and software that will be utilized in accordance with 52.212-1 Instructions to Offerors.

45. Are there any costs incurred by the Vendor associated with a “direct” interface to CHCS and VISTA, vice a “universal” interface? Please indicate the costs.

ANSWER: The only cost associated with interfacing is the middleware connection. In theory, if the vendor uses a middleware that can be directly interfaced to VistA or CHCS

without the use of a generic interface manager, they would not incur a Dawning or Data Innovations interface cost.

46. Is the "Bomar" software and acceptable secure software tool for remote connectivity?

ANSWER: The RFP does not require remote diagnostics connectivity (as a minimum requirement).

47. The requirement for maintaining calibrators on the analyzer is unique and exclusive to Siemens. We request removal of this specification.

3.4.5.5.1 the ability to store and maintain the calibrators on the analyzer.

ANSWER: This specification has been deleted.

48. The "on-board reagent slot storage" requirement (noted below) is not an indication of adequate reagent on-board test capacity for daily reagent usage. Every vendor's on-board slots and capacity will be unique. This criteria appears to be based upon the current vendor's reagent slot capacity versus the actual requirements for meeting each site's daily inventory needs. Other VISN RFP's have required a vendor to validate that their test capacity needs can be met for each unique site with interaction no more than once daily. Would you please amend the question to reflect actual reagent capacity needs for each?

3.4.7.4.8 an on-board reagent slot storage capacity that is no less than the criteria indicated in Chart# 7

ANSWER: The specification has been rewritten to read as follows:

3.4.7.4.8 sufficient on-board reagent capacity to meet one average day of testing.

SITE SPECIFIC:

VA Tomah:

49. Your facility requires 2000 test per hour throughput, what is the basis for that value?

Observed data indicates this is nearly 6 times the required throughput. Our observation noted a maximum of 1,125 tests PER DAY.

ANSWER: The observations of the vendors represented the workload of one 24 hour period. This one day sample is not to be construed as the average maximum throughput or the specifications of future performance needs. Having said this, specification 3.4.2 and specification 3.4.5.4 have been rewritten as follows:

3.4.2 The models of equipment offered shall be identical at the VISN locations as follows:

3.4.2.1 Hines, Milwaukee and the Federal Health Care Center (Large facilities)

3.4.2.2 Madison and Jesse Brown (Medium facilities)

3.4.2.3 Iron Mountain, Tomah, Appleton, Green Bay, Rockford, Crown Point, Joliet and Red Rover (Small facilities)

3.4.5.4 The combined instrument system including back-up instrumentation (as applicable) must have a minimum test throughput as follows:

3.4.5.4.1 Large facilities – 3000 tests per hour

3.4.5.4.2 Medium facilities – 2000 tests per hour

3.4.5.4.3 Small facilities – 1000 tests per hour

50. You require 288 reagents on board, yet only run 46 assays. Please indicate the technical need for exactly 288 reagents minimum on board?

ANSWER: The specification has been rewritten to read as follows:

3.4.7.4.8 sufficient on-board reagent capacity to meet one average day of testing.

51. You specified the requirement for 200 tubes per hour throughput, but observed data indicates a maximum requirement of 68. Please indicate the technical need for exactly 200 tubes per hour minimum requirement.

ANSWER: The observations of the vendors represented the workload of one 24 hour period. This one day sample is not to be construed as the average maximum throughput or the specifications of future performance needs. Having said this, specification 3.4.2 and specification 3.4.5.3 have been rewritten as follows:

3.4.2 The models of equipment offered shall be identical at the VISN locations as follows:

3.4.2.1 Hines, Milwaukee and the Federal Health Care Center (Large facilities)

3.4.2.2 Madison and Jesse Brown (Medium facilities)

3.4.2.3 Iron Mountain, Tomah, Appleton, Green Bay, Rockford, Crown Point, Joliet and Red Rover (Small facilities)

3.4.5.3 The combined instrument system including back-up instrumentation (as applicable) must have a minimum specimen throughput as follows:

3.4.5.3.1 Large facilities – 200 specimens per hour

3.4.5.3.2 Medium facilities – 175 specimens per hour

3.4.5.3.3 Small facilities – 100 specimens per hour

52. We observed only one floor water drain, it is our understanding that your location is listed as a National Historic site and may not accept utility work to accommodate relocation of plumbing. Would you please state the limits of the utility work available to your location?

ANSWER: The “historical site” designation does not affect plumbing or any other type of utility work – any required work can be done in the buildings.

53. What is the basis for the calculation and requirement for no more than 500 calibrations per year? Every vendor's calibration requirements will be unique and this criteria appears to be based upon the current vendor's calibration process. Would it be helpful for each Vendor to instead detail the calibration process for each instrument offered (i.e. vendors may require reconstitution of calibrators vice ready to use, some vendors require the instrument to be placed in standby, etc.)

ANSWER: Specification 3.4.5.5.5 has been deleted.

VA Madison:

54. Your facility requires 2000 test per hour throughput, what is the basis for that value? Observed data indicates this is nearly 2 times the required throughput. Maximum observed tester PER DAY was 4,131.

ANSWER: Refer to the response to Question 49.

55. You require 288 reagents on board, yet only run 60 assays. Please indicate the technical need for exactly 288 reagents minimum on board?

ANSWER: Refer to the response to Question 50.

56. You specified the requirement for 200 tubes per hour throughput, but observed data indicates a maximum requirement of 123. Please indicate the technical need for exactly 200 tubes per hour minimum requirement.

ANSWER: Refer to the response to Question 51.

57. What is the basis for the calculation and requirement for no more than 500 calibrations per year? Every vendor's calibration requirements will be unique and this criteria appears to be based upon the current vendor's calibration process. Would it be helpful for each Vendor to instead detail the calibration process for each instrument offered (i.e. vendors may require reconstitution of calibrators vice ready to use, some vendors require the instrument to be placed in standby, etc.)

ANSWER: Refer to the response to Question 53.

VA Milwaukee:

58. Your facility requires 3240 test per hour throughput, what is the basis for that value? Observed data indicates this is nearly 2.5 times the required throughput. Our observation noted a maximum of 8,720 tests PER DAY.

ANSWER: Refer to the response to Question 49.

59. You require 332 reagents on board, yet only run 87 assays. Please indicate the technical need for exactly 332 reagents minimum on board?

ANSWER: Refer to the response to Question 50.

60. You specified the requirement for 400 tubes per hour throughput, but observed data indicates a maximum requirement of 173. Please indicate the technical need for exactly 400 tubes per hour minimum requirement.

ANSWER: Refer to the response to Question 51.

61. What is the basis for the calculation and requirement for no more than 1 500 calibrations per year? Every vendor's calibration requirements will be unique and this criteria appears to be based upon the current vendor's calibration process. Would it be helpful for each Vendor to instead detail the calibration process for each instrument offered (i.e. vendors may require reconstitution of calibrators vice ready to use, some vendors require the instrument to be placed in standby, etc.)

ANSWER: Specification 3.4.5.5.5 has been deleted.

VA Hines:

62. Your facility requires 3,840 test per hour throughput, what is the basis for that value? Observed data indicates this is nearly 2.5 times the required throughput. Our observation noted a maximum of 12,130 tests PER DAY.

ANSWER: Refer to the response to Question 49.

63. You require 332 reagents on board, yet only run 98 assays. Please indicate the technical need for exactly 332 reagents minimum on board?

ANSWER: Refer to the response to Question 50.

64. You specified the requirement for 400 tubes per hour throughput, but observed data indicates a maximum requirement of over double the current need. Please indicate the technical need for exactly 400 tubes per hour minimum requirement.

ANSWER: Refer to the response to Question 51.

65. What is the basis for the calculation and requirement for no more than 1500 calibrations per year? Every vendor's calibration requirements will be unique and this criterion appears to be based upon the current vendor's calibration process. Would it be helpful for each Vendor to instead detail the calibration process for each instrument offered (i.e. vendors may require reconstitution of calibrators vice ready to use, some vendors require the instrument to be placed in standby, etc.)

ANSWER: Specification 3.4.5.5.5 has been deleted.

VA Jesse Brown:

66. Your facility requires 3000 test per hour throughput, what is the basis for that value? Observed data indicates this is nearly 4 times (823) the required throughput. Our observation noted a maximum of 5,966 tests PER DAY.

ANSWER: Refer to the response to Question 49.

67. You require 288 reagents on board, yet only run 59 assays. Please indicate the technical need for exactly 288 reagents minimum on board?

ANSWER: Refer to the response to Question 50.

68. You specified the requirement for 400 tubes per hour throughput, but observed data indicates a maximum requirement of less than ½ that total. Please indicate the technical need for exactly 400 tubes per hour minimum requirement.

ANSWER: Refer to the response to Question 51.

69. What is the basis for the calculation and requirement for no more than 500 calibrations per year? Every vendor's calibration requirements will be unique and this criterion appears to be based upon the current vendor's calibration process. Would it be helpful for each Vendor to instead detail the calibration process for each instrument offered (i.e. vendors may require reconstitution of calibrators vice ready to use, some vendors require the instrument to be placed in standby, etc.)

ANSWER: Specification 3.4.5.5.5 has been deleted.

FHCC Lovell:

70. Your facility requires 3240 test per hour throughput, what is the basis for that value? Observed data indicates this is more than 3 times the required throughput (951). Our observation noted a maximum of 3,790 tests PER DAY.

ANSWER: Refer to the response to Question 49.

71. You require 332 reagents on board, yet only run 79 assays. Please indicate the technical need for exactly 332 reagents minimum on board?

ANSWER: Refer to the response to Question 50.

72. You specified the requirement for 400 tubes per hour throughput, but observed data indicates a maximum requirement of over double the current need. Please indicate the technical need for exactly 400 tubes per hour minimum requirement.

ANSWER: Refer to the response to Question 51.

73. What is the basis for the calculation and requirement for no more than 1500 calibrations per year? Every vendor's calibration requirements will be unique and this criterion appears to be based upon the current vendor's calibration process. Would it be helpful for each Vendor to instead detail the calibration process for each instrument offered (i.e. vendors may require reconstitution of calibrators vice ready to use, some vendors require the instrument to be placed in standby, ect.)

ANSWER: Specification 3.4.5.5.5 has been deleted.

74. Attachment B – Pricing

On the Equipment worksheets, for example “Base Period Equipment”, the Qty field for the automation pieces is locked. In some instances our proposal may include a different configuration than the amount included in this field. Is it possible to obtain a version of Attachment B with the Qty field unlocked? If not, how would you propose this information is included in our pricing proposals?

ANSWER: Attachment B –Pricing is updated in this amendment and allows vendors to increase the quantities of the automation equipment.