USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

PROCUREMENT AND SUPPLY MANAGEMENT

ANSWERING SUPPLIER QUESTIONS REGARDING THE WAVE 2 RFP

Thank you for all your thoughtful questions. We have grouped the questions and answers in the following sections:

CONNECTIVITY AND REPORTING

1.Q: Will cloud based systems be acceptable to all countries in the second wave RFP?

A: Cloud-based systems are considered by PSM to be acceptable in general as a reporting system offering. Data sharing agreements will need to be agreed by PEPFAR with each individual country to confirm acceptability at a country level. Some countries may have requirements that data remain within a country's borders; in those cases, PSM will need to confirm whether a cloud-based solution can be implemented for those countries.

2.Q: What data is Chemonics expecting to be passed to the country program managers?

A: Data to be passed to country program managers and the PSM global dashboard team includes the following operational data. Absolutely no patient data would be reported.
- Machine serial number
- Machine placement location
- Number of runs per machine each day
- Time stamp of each run
- Number of samples in each run
- Errors, timestamp of each error, error type and code, and machine they correspond to
- Instrument outages, the timestamp of each outage, and the machine it corresponds to
- Maintenance efforts, the timestamp of each maintenance, the maintenance type and code, and the machine it corresponds to

3.Q: Are suppliers expected to link to local LIS systems?

A: Suppliers are expected to connect new machines to the country's local LIS system, assuming such a system is available at the relevant lab.

4.Q: "*Data automatically transmitted to country LIS, i.e., instruments have the capability to allow bidirectional communications with LIS to allow testing order automation*".
- What are the LIS capabilities for each country? Will a supplier be excluded if they cannot provide bidirectional communications?

A: PEPFAR expects supplier instruments should be able to communicate electronically with a country's LIS (e.g., to provide electronic reporting of test outcomes). If bi-directional communication is not supported, this will not result in an automatic exclusion. In such a case, suppliers should note the instrument's communication abilities: what instructions/data can be sent to the instrument and reported back by the instrument. Given the varying LIS capabilities across countries, PSM will evaluate this capability on a global basis.

5.Q: Who will secure the permission to share data from labs? Will Chemonics obtain this permission?

A: PSM is working with USAID, CDC and OGAC to put in place data sharing agreements at a national level, so that suppliers may meet the reporting requirements on operational data as specified in the RFP.
PSM recognizes that remote data sharing may require for some instrument servicing activities (e.g., remote maintenance). Suppliers should independently pursue data sharing agreements with the labs/MoH if necessary to maintain their instruments.

CONTRACTING

6.Q: Chemonics states that Wave 2 is a "3-year term" and that even if Chemonics is no longer the procurement agency, the contract will be assigned to a new procurement partner of USAID (based on USAID's intention)?

A: Correct. USAID and PSM have agreed that the contract would be assigned to the Diagnostics PSA awardee under the NextGen GHSC suite of contracts once that awardee has been confirmed and transition activities are completed. The expectation is that such a transition would occur in the next 18-24 months. Until that time, or if Chemonics is chosen as the NextGen Diagnostics PSA provider, the contract would continue to be administered by Chemonics.

7.Q: Can a vendor bid on any country volumes, even if they do not have a current service setup or platform registered, so long as they anticipate they could start providing tests within 18 months of RFP submission? I.e., can they submit a conditional pricing offer?

A: Yes, suppliers may submit a conditional pricing offer for countries in which they could start providing tests within 18 months of RFP submission. The pricing submitted will inform country decision making around future supplier mix and potential volume commitments.

COUNTRY TESTING DATA

8.Q: Please confirm that the volumes presented in Annex 4, Sheet A1 reflect programmatic testing volumes, rather than procured volumes. Are the testing volumes agnostic to the mechanism by which the tests were procured?

A: The volumes presented in Annex 4, Sheet A1 reflect an aggregated estimate of national testing volumes performed in 2021. The associated tests were procured through multiple procurers/channels. The approximate breakdown across procuring entities (e.g., USG, GFATM, MoH) is provided where available. In some countries, USG may procure through more than one agency or mechanism (e.g., through both USAID and CDC).

9.Q: Please confirm if DBS volumes are expected and whether data will be made available on current/anticipated volumes.

A: Data on DBS programs for many Wave 2 programs was limited. Where available, we have added information on anticipated DBS volumes in the updated Annex 4.

10.Q: a) Can Chemonics provide a breakdown of volumes per site as this will dictate system configuration? For example, Angola is doing 38k tests in total at 9 sites. Is it 4.5k tests per site? This applies to all countries
b) How can we figure out the number of systems that would be required? Are we allowed to submit a price without any system placement? What if some of the systems already installed is more than 5y old?

A: We are not able to provide a breakdown of volumes by site.
Pricing can be submitted without system placement. Based on country interest in pursuing a supplier's offer, PSM will initiate discussions of instrument placement.
For systems already installed that are over 5 years old, PSM or the MoH may request replacement, but this will usually occur only if the instrument has poor maintenance performance / uptime availability.

11.Q: The data for Benin looks incorrect. Should it not be 41k viral load tests and 2k EID and not vice versa?

A: The data for Benin was incorrect. We have updated that information in the updated Annex 4. As noted, the correct volumes are 41k viral load tests and 2k EID tests

12.Q: a) Will Chemonics provide testing volumes by lab (if yes, when)?
b) How many low volume labs are anticipated (below 10 thousand annual tests)?
c) What is the actual TAM for the Wave 2 tender? Is there any data analysis or background information from USAID?

A: Testing volume by lab will not be provided as part of this RFP, only national testing volume which can be found in Annex 4.

13.Q: Can Chemonics clarify and provide the volumes of tests and labs for all non-African countries? Currently the A1 Data tab only shares data for limited APAC (Indonesia) and LATAM countries (Haiti) – please send more information for balance of 10+ countries.

A: For the remaining 10+ countries, PEPFAR procurements are sporadic and under 20k tests per year. No regular volume information is available.

INCOTERMS AND DELIVERY

14.Q: "*Suppliers to be held accountable for the performance of their distributors, and their adequacy to meet good storage practices/good distribution practices*".
a) Are Suppliers, and where they are not direct within a country their distributors, expected to warehouse testing kits and be responsible for distributing them to the HIV laboratories within the country?
b) Will shipment not be to the medical stores in country for distribution?

A: For all countries, we are requesting suppliers provide a price for delivery to Central Medical Store. Where suppliers are currently delivering to labs, the pricing for that should be noted on the "currently offered freight" pricing line item. Given the need for careful cold chain management of some products, suppliers will likely need to work with local distributors/partners to manage in-country distribution, especially where delivery is to individual labs. Local cold storage is likely required.

15.Q: Will Chemonics limit the number of orders per year?

A: PSM's preference is to minimize the number of orders and shipments, and we will work with suppliers to attempt to optimize them. However, PSM is not providing limits on the number of orders per year.

16.Q: "For the modified DDP incoterm, suppliers shall be responsible for clearing the goods for export, facilitating shipping documentation, managing transportation, importing and customs clearance at destination, delivering the goods."
- Will Chemonics be supplying tax waivers for each country to help facilitate importing and customs clearance? If not will Chemonics be supplying order details and quantity guarantees for each delivery to enable costs to be calculated?
- Will Chemonics be responsible for paying taxes and be the consignee for Products?
- Current suppliers do not obtain duty and import waivers for the products (reagents and instruments) – is this a change? Please clarify the process, responsible parties, action owners.

A: Under the modified DDP incoterms:
1) Suppliers would manage the overall import and customs clearance process except for provision of the tax waiver
2) PSM would arrange with MoHs in each country for provision of a tax waiver for each shipment. This is the one aspect of import and customs clearance that the supplier would not manage directly
3) No importation taxes or duties would be paid by supplier. Supplier shall be responsible for all costs and risks related to payment of duties, taxes and other official charges assessed on exportation from the country of manufacture and shipment. Importation duties will be covered by the tax waiver arranged by Chemonics. In the exceptional case where a tax waiver cannot be obtained for a specific order, or is delayed, any import duties or other costs assessed by the government of the country of destination, as well as container demurrage/detention and comparable charges will be payable by Chemonics after approval by USAID, except for container demurrage/detention and other charges levied in those instances where the supplier fails to comply with the shipping document delivery schedule or has otherwise caused the delays giving rise to the demurrage/detention or comparable charges. If a late waiver is the direct cause of goods to no longer be compliant with remaining shelf-life requirements at time of importation approval, Chemonics will work with the MoH to gain acceptance import for the

goods. The consignee for products will be chosen to meet the requirements of the duty waiver. In general, this will be the Ministry of Health.

17.Q: Was the intention to request suppliers' price for DAP and not DDP modified, as is the case for Wave 1 (DDP has constraints for implementation as discussed under Wave 1)?
Can suppliers quote with either CIP/CPT or FCA instead of modified DDP?

A: Our preference is for suppliers to bid per the modified DDP incoterm and will give preference to those incoterms during evaluation. If suppliers prefer not to provide a bid under modified DDP incoterms for any given country, we request that suppliers make the reasons for doing so clear in the optional section of the country bid, and price according to DAP incoterms as the best alternative, and as least preferred CIP/CPT or FCA.

Where today suppliers are operating under a DAP incoterm but are also managing the customs clearance (except for tax waiver), this is considered to be equivalent to modified DDP.

18.Q: For countries where the supplier has no presence but would like to submit a bid, what flexibility is there around the accuracy of the Incoterms price (acknowledging that discussions ongoing with distribution partners and some level of estimation required)? For example, can a ceiling price be bid due to the uncertainty? Fuel costs and shortages in many countries listed may heavily impact the distribution cost, making this difficult to calculate.

A: Suppliers may bid a ceiling price for distribution of reagents and consumables. However, in comparing pricing bids between suppliers, PSM will need to use the price provided as an indication of actual pricing expected.

19.Q: "*Supplier provides delivery of reagents and consumables to the country's preferred point of delivery*"
- Will Chemonics be providing preferred delivery points for each country?

A: Delivery points for each country are specified in final row of each of the individual pricing grids in Annex 4-tab P2. For most countries, the delivery point is the central medical store.

20.Q: "*Target is at least 80% of shelf life remains when reagents clear customs*"
- This does not take into consideration variation in dating from suppliers. A kit with 2 years shelf life would be deemed unacceptable if received in country with 18 months left. Should Chemonics not specify a minimum shelf life in terms of months?

A: Shelf-life requirements are set by countries and are not under the control of PSM or PEPFAR. We have indicated a % target given the approach taken by countries but note that specific requirements for orders will be subject to country specification and client acceptance of remaining shelf life. PSM will continue to work with country offices and suppliers to agree on modified requirements for orders where required.

INSURANCE

21. Q: Is insurance to be considered in pricing?

A: Insurance should be provided by suppliers and included in pricing. There is a row for insurance pricing in the services pricing grid in Annex 4-tab P2.

Q: "*Supplier provides comprehensive instrument insurance, including force majeure*" - What guarantees will be provided by each country regarding the security of system placements? Will every facility be guarded?

A: PEPFAR expects country labs to have appropriate security measures in place, but PSM is not in a position to confirm that every facility is guarded. In their response, suppliers may note any specific requirements, including security requirements, for insurance provision.

NEW COUNTRY ENTRANCE

22. Q: Can GHSC-PSM delete subsection (iii) of Section 1.7.a, General Requirements, as it conflicts with Section 1.3. RFP structure and scope:
- "*Companies or organizations must have a local presence in the countries for which they submit proposals at the time the subcontract is signed*" (Section 1.7.a, page 10)
- "*We understand that not all suppliers have platforms that are currently verified in all countries, and suppliers may lack an existing service network in specific countries. However, we are taking a longer-term strategic view through this RFP process and encourage suppliers to bid in any countries in which they could start providing services within 18 months from the time of submission*". (Section 1.3, page 8)

A: PSM confirms deletion of subsection (iii) of Section 1.7.a, General Requirements. At time of contracting, suppliers do NOT need to have a local presence in all the countries for which they have submitted proposals. The requirement at time of contracting is that, where a local presence is not already established, suppliers must have demonstrated a clear plan to be operational in all such countries within the next 18 months.

POC

23.Q: This paragraph about POC testing says that "*Many countries' point-of-care (POC) diagnostic strategies for delivery of same-day results are still under development, of limited size, or lack committed funding, so POC volumes will not be addressed in this RFP*". How is the procurement of POC tests supposed to take place?

A: Procurement of tests for POC instruments will continue to be undertaken by PSM under current ordering procedures with applicable pricing.

PRICING APPROACH

24.Q: Can GHSC-PSM further identify the Integrated Diagnostics Consortium (IDC) referenced in Section 1.11.d – Application of pricing to other buyers?
a) With which organizations will pricing be shared?
b) Shouldn't additional buyers be extended collaboratively and by mutual agreement?

A: A full list of partners on the IDC can be found at: https://aslm.org/what-we-do/idc/. Consistent with Section 1.11.d, pricing from this RFP would not be shared with all organizations on IDC, only those organizations that procure tests for the countries involved in this Wave 2 RFP. Aside from the US Government and its implementing partners, the other main procurer on the IDC is GFATM. Smaller volumes of tests may be procured by Unitaid, EGPAF, UNICEF, MSF. Where one of these organizations uses an implementing partner to procure in a given country (e.g., GFATM typically works through implementing partners in each country), country-specific pricing and terms would be shared with the implementing partner managing the procurement.

25.Q: RFP states two (2) types of pricing needs to be offered – (1) based on PEPFAR volume commitments and (2) other based on total country volume (PEPFAR/All other funders/Govt purchases). Can Chemonics clarify that the RFP means total volumes per country will affect the following year's pricing or how a tiered pricing will take effect?

A: For pricing approach (2), referred to in the RFP as volume incentive pricing, the volumes used in this pricing scheme are total volumes per country. To illustrate how this would work and how volume tiers would be applied, we use the following hypothetical situation. Suppose in a given year in Country X the following volumes are procured from a particular supplier:
- PEPFAR: 60,000 tests (some through PSM and some through a CDC implementing partner)
- GFATM: 50,000 tests through its Principal Recipient
- MoH: 10,000 tests

The total number of tests procured for the country from that supplier in the given year are 120,000. This falls into the 100,000 - 200,000 volume tier. For the following year, the pricing accessible to PEPFAR (and to other procurers should they opt to take it up) from that supplier is the pricing under the 100,000-200,000 tests column in the volume incentive pricing table.

26.Q: "*Offerors will be asked to provide service pricing information in two (2) different ways*"
- Will suppliers be excluded if they provide neither option but just a fixed all-inclusive price?

A: Suppliers may bid a fixed all-inclusive price. Suppliers could indicate this approach by filling out the pricing tables with all columns showing the same price. However, this pricing approach may not encourage PSM and countries to place large volumes with the supplier.

27.Q: Please confirm if surcharges will be applicable for difficult to serve/hard to reach labs (Tier 2). Have labs been pre-identified or classified as Tier 2?

A: The lab locations can affect pricing of reagent and consumable delivery and of installation and maintenance. For most countries, delivery will be to central medical store, so this issue would largely impact suppliers in terms of maintenance costs only.
A surcharge to serve hard-to-reach labs was used in Wave 1 of the Global RFP. Here we would like to remove that complexity and have suppliers bid a single price for each country. For this reason, PSM has not pre-identified which labs are hard to reach. If suppliers wish to provide a bid with a surcharge, and clearly specify exactly which labs they consider hard-to-reach, we would consider such a bid but prefer a standardized pricing approach with no surcharge. We will evaluate bids on a single price basis and would convert any surcharge approach into an average price for the country in terms of evaluation.

28.Q: Our understanding is that pricing will apply to both new placements as well as installed base, although for installed base it would exclude the placement, lease and equipment removal/relocation components. Will a supplier have to replace country owned instruments without surcharge or other payment?

A: For installed base, the placement, lease, and equipment removal/relocation components are excluded only for equipment owned by the Ministry or other in-country stakeholders. If that equipment is owned by the supplier, those components would still apply (since the lease cost is assumed to be the largest cost in this service area).
As country-owned equipment reaches end of life, suppliers would replace this equipment with equipment that is owned by the supplier and leased to countries. From that point, the placement, lease, and equipment removal/relocation component of service pricing would apply.

29.Q: - Is separate or blended pricing for installed base and new instruments expected?
- What other options could suppliers consider as alternatives to weighted surcharge / install base surcharge calculations, with the goal of further simplifying this item for customers/ donors?

A: We propose to use blended pricing based on the proportion of owned vs. leased instruments (weighted by instrument capacity) in the same way as adopted for Wave 1 countries.
The blended pricing approach allows the application of a single price to all orders for that country. However, the percentage of owned vs. leased instruments must be updated as new leased instruments are placed. We are open to suggestions from suppliers of alternative approaches, but request bids assuming the blended pricing model.

30.Q: Who will be responsible for providing the non-PEPFAR volume to PSM?

A: For the purpose of managing the volume incentive pricing, we request that suppliers provide the non-PSM volume to PSM.

31.Q: Could you confirm what services are included under '*Current services included in current service price*'?

A: Here we are requesting that, if suppliers are currently serving a country, that they briefly outline the services they currently supply (e.g., maintenance with response within 24 hours, annual end-user training, leasing of instruments, connectivity, logistics for reagents and consumables). Current agreements with countries often do not reflect the exact set of services that suppliers provide, and we want to ensure assessment of bids is informed by an accurate view of what suppliers currently provide.

32.Q: For countries that are not bid by the supplier, could orders still be placed if needed (e.g., in an emergency situation)?

A: In an emergency, PSM would likely seek to place volume with a contracted supplier for that country. However, if that is not possible, there may be need to place volume with a supplier who has not bid on a country.

33.Q: A company submitting an all-inclusive price by definition will include all service prices. Greater transparency will therefore not be provided. Would this exclude a bidder?

A: When developing an all-inclusive price, suppliers will need to determine the appropriate cost contribution from each service. PSM is asking suppliers to provide that high-level breakdown. This is important to us in terms of being able to benchmark service pricing across countries and suppliers, but also to be able to adjust contract price based on exact services contracted. For instance:
1) If most instruments in a country are owned rather than leased, we would not expect to pay the leasing cost.
2) If a country MoH is unwilling to sign a data sharing agreement with PSM and suppliers, then we would not require connectivity and would not expect to pay the connectivity fee
3) If the incoterms or delivery location needed to be changed in the future (e.g., if the MoH requested to change delivery location from Central Medical Store to individual labs), we would seek to renegotiate the freight cost separate from the rest of the service pricing
Bids that do not provide this transparency may still be considered by PSM but may be disadvantaged during evaluation when compared to other bids that provide the requested service price breakdown.

PRICING BASIS (PER TEST VS PER PATIENT TEST)

34.Q: "*For country services, we require suppliers to bid a price per patient test*"
- With respect to control inclusion, can you confirm "effective price per patient test." reflects not charging for controls but tests that link to a patient result?
- Will companies be excluded from bids if they do not bid on a per patient basis?

A: PSM has requested per-patient test pricing as the default pricing basis. However, suppliers are encouraged to bid in the pricing basis (either per patient test or per test) that they prefer and which they typically use in contracting - either will be considered equally. Therefore, bids

on a per-test basis will be considered without penalty but must be clearly marked as such and an appropriate conversion factor provided for each instrument. When converting between pricing per test and pricing per patient test, we assume full utilization of the well plate or modules of an instrument. The conversion factor is the proportion of tests that are available for patient samples. For instance:
1) Assume an instrument uses a well plate of 96 tests with 3 wells used for controls/calibrators. We would define the price per patient test as (96/93) x price per test.
2) Assume an instrument uses a modular cartridge-based system, with each cartridge used for one patient sample and no cartridges used for controls/calibrators. Then price per patient test would be the same as price per test.

35.Q: Request for a Price per Patient test – will this also apply to new sales for Wave 1 countries?
Some platforms will have estimated pricing until volumes/testing days per week are confirmed. How will Chemonics review these variances?

A: We are requesting pricing per patient test to enable consistent comparison across suppliers when evaluating bids. The conversion between price per patient test and price per test is outlined above and assumes full utilization of a well plate (where relevant); hence it does not involve any estimations or adjustments based on testing days. For current suppliers, we anticipate final contracting being done on the same pricing basis as adopted for Wave 1.

QUALITY

36.Q: Quality documents for relevant systems and assays have previously been submitted to FHI 360. Can the supplier reference these documents instead of resubmitting?

A: We are requesting information that is current and as such we require that offerors provide the following information in accordance with instructions on submission specified in Annex 5:
- Current operational manuals (version controlled) for each instrument and model offered. Offeror shall commit to provide updated operational manuals upon updates.
- A list of instrument-generated error codes/flags/messages with instructions for interpretation and troubleshooting.
- A list of each product offered, that includes the product name, variant identification number, manufacturing site, regulatory version offered.
- Copies, for the last 3 years, of the (1) post-market surveillance report (2) trend report, and 3) performance evaluation report for each IVD/EID/VL.

SUBMISSION REQUIREMENTS

37.Q: For the cover letter, does a separate form need to be filled out for each separate entity that has a unique identifier number?

A: No - a single cover letter on behalf of all relevant operating units, using the unique identifier of the largest relevant operating unit for the supplier will be sufficient.

TECHNICAL REQUIREMENTS AND EVALUATION

38.Q: What will be the criteria for assessment for in-country partner quality? What are the standard service levels, and will these vary by country? What are the standard supply levels? What are the standard service levels for connectivity and data reporting? What are the standard training service levels?

A: In-country partner quality will be assessed on several criteria, including:
- Track record of proven ability to deliver similar services
- Sufficient staff available to perform the services
- Appropriate training/certification of partner staff to perform the services
- Ability to provide service to all labs/geographic locations in the country
- Access to any infrastructure (e.g., a cold room with available storage space) that improves partner's ability to deliver product consistently at required lead times

Standard service levels are specified in Annex 3 tabs T1 and T3.

39.Q: How will value added maintenance offerings, trainings and potential value add of likely upgrades, planned enhancements etc. be scored above baseline levels? How will this be standardized?

A: Value added offerings will be assessed on several criteria, including:
- Potential value of offering to PEPFAR
- Indicative cost of offering
- Likelihood of uptake by PEPFAR

Offerings that could provide high value, are cost-effective and for which PSM sees a strong rationale for PEPFAR adoption will contribute to a higher technical evaluation score. Value added services that do not add significant value for PEPFAR, that are unaffordable or for which adoption is unlikely will not contribute any significant points. The maximum number of points that can be awarded for value added services will be the same for all suppliers.

40.Q: Will the scores for Distributors be provided to the suppliers?

A: PSM does not have plans to release RFP evaluation scores to suppliers, although clarifications and feedback on specific distributors may be addressed with the supplier prior to or during negotiations.

41.Q: Wave-2 KPIs will mirror the 10 KPIs that we use in Wave 1?

A: Wave 2 KPIs are specified in Annex 3-tab T3 and mirror those used in Wave 1.

42.Q: In cases where the lab has never run molecular testing or basic training is needed, who is responsible for covering the cost of training?

A: For such labs, a new instrument would presumably need to be placed. We request in Annex 3-tab T1 cell E29 that all new placements come with initial end-user training, the cost of such training to be covered by supplier.

43.Q: Please confirm a local presence can mean a Vendor affiliated/managed/trained Distributor.

A: Confirmed. Local presence can mean a vendor-affiliated/managed/trained distributor.

44.Q: In case a proposed site is deemed unsuitable, the request will be put on hold until the rehabilitation or improvement works at the site have been completed:
a) What is the timeline for Chemonics or End User to make the Lab suitable after Vendor has provided the installation, calibration, and commissioning report?
b) Who is responsible for payment of the rehabilitation/renovation, improvement, parts, or items to make a Lab suitable for molecular testing?

A: It is the End User's responsibility for ensuring that each testing site satisfies the infrastructure requirements and the associated costs, with support from country stakeholders as appropriate. With respect to renovations required to specific labs, the schedule for completion will be determined by the End User with support from country stakeholders. .

TEMPERATURE MONITORING

45.Q: "*We are also requiring suppliers to provide bids for distribution of reagents and consumables from supplier port to country (with delivery to either central medical store or individual labs); inclusive of temperature monitoring during shipping and handling*" - What is meant by temperature monitoring during handling?

A: Temperature monitoring during handling refers to the set of processes required to confirm cold-chain products are kept within appropriate temperature limits. Suppliers will be responsible for assuring that all products reach their destination without having temperature excursions that could compromise their efficacy. Typically, this would include some form of temperature monitoring (e.g., electronic temperature loggers that can confirm appropriate cold chain integrity).

46.Q: Requirement for Vendors to bids for distribution from port to country AND inclusive of temperature controls.
a) Are data loggers necessary?
b) Are incoterms DDP? Will Chemonics consider alternate Incoterms where applicable? Will Chemonics consider DAP incoterms, as long as the consignee is the central medical warehouse?
c) What happens in cases where countries do not allow Vendor to do delivery to lab/central medical office?

A: a) PSM requires that suppliers ensure that products requiring cold chain arrive at the destination with assurance that they have not been temperature-compromised during transport. A simple approach to do this is to use temperature loggers. If a supplier has an alternative approach that provides such assurance, we are open to this.
b) PSM is requesting suppliers bid according to a modified DDP incoterm in which suppliers are responsible for all activities and costs to deliver to destination EXCEPT for provision and application of a duty waiver. This could also be described as a DAP incoterm but with supplier

managing the importation and customs clearance process EXCEPT for provision of the duty waiver.
c) We do not anticipate any countries denying the supplier the ability to deliver to the specified location (either Central Medical Store or lab) and suppliers should bid assuming that delivery will be permitted to the specified location.

47.Q: "The temperature monitoring device data that is required to be included in cold chain shipment shall be downloadable, readable, and interpretable at point of delivery by GHSC-PSM staff"
a) Is GHSC-PSM staff able to read all commercially available data loggers?
b) If our assays are stored at room temperature, does that mean that temperature monitoring is not required?
c) If a company does not utilize data loggers for shipments will they be excluded from bidding. Does the use of data loggers apply to kits able to be shipped at ambient temperatures up to 35C?

A: a) In principle GHSC-PSM staff should be able to read all commercially available data loggers, If for some reason additional training is required for GHSC-PSM or other in-country staff, GHSC-PSM will work with suppliers to facilitate such a training.

b) Suppliers need to ensure all products are transported within temperature guidelines. For assays stored at room temperature (~24C), there may still be maximum allowable temperatures (e.g., max of 35C) that should be met.
c) As above

48.Q: For Certificates of Analysis will a company be excluded from bidding if limit of detection, linearity, precision, accuracy, and error rate on each batch are not available. What would be the minimum criteria for a C of A?

A: The unavailability of the detailed Certificate of Analysis requirement should not preclude suppliers from offering products as part of this RFQ. GHSC preference is to receive a certificate of analysis that incorporates descriptive lot release testing criteria on each batch. Supplier shall make all efforts toward providing a certificate of analysis.