

Clarifications regarding queries from prospective Selection of Agencies for the Supply, Installation, Testing and Commissioning of Equipment for TB Laboratories across India under International Competitive Bidding (ICB)

ITB No.: SAMS - FIND- EQUIPMENT – PROCT - ICB - 03/2014

Pre-Bid Meeting on- 11th Mar 2014

Sl. No.	Tender Specifications	Query	Suggestions from Bidders	Clarifications provided by SAMS / FIND
1.	Schedule I: Biosafety cabinet Class II Type A2 with UPS			
1		<u>Main Specification:-</u> Integrated (V –) shaped air grill is asked which no reputed manufacturer offers. It should be amended.	-----	The text is being amended through Amendment 1 of ITB with the provision of the following- “with suitable design of front window to reduce user fatigue”
2		<u>Filter and Flow Conditions:-</u> (i) Pre filter is asked whereas in Type A2 cabinet pre-filter is not required. It should be deleted. (ii) You have asked for HEPA filter only whereas this cabinet is used for TB Lab and for this purpose you must asked for ULPA filter. HEPA filter rated 99.99% efficient with particle 0.3 micron whereas ULPA (Ultra Low Penetration Air) filters rated 99.999% efficient with particle 0.12 microns.	-----	i No amendment is needed in specs. This is desired requirement-not mandatory. ii) No amendment to specs is needed. If a vendor offers ULPA, it may be accepted.
3		It should be either EN 12469 or NSF 49. NSF 49 Biosafety cabinets are tested with 24 parameters whereas EN 12469 Biosafety Cabinets are tested with only with 13 parameters . It is always advisable to have Biosafety Cabinets with NSF standard . Please amend it accordingly.	-----	Compliance to either NSF 49 or EN 12469 would be acceptable
4		The specification mentions EN 12469 / NSF 49 with 10° front slope. Only one manufacture in Europe have both 10° slope and EN Certificate.	-----	The text is being amended through Amendment 1 of ITB with the provision of the following- “Suitable slope for effective functioning”
5		The scope includes supplying and installation of ducting. Can we quote Biosafety Cabinet in foreign currency and ducting in INR ? Can you place two orders,		Yes, two POs can be issued. As regards the ducting work, vendors can quote unit rates for a)15 feet ducting

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		one on our foreign principles and another on the local vendor for providing local components and services?	-----	b) 25 feet ducting and each should include following items: Ducting, reducer if required as per suppliers specs, 90 ⁰ bend, blower and motor of suitable size, holding clamp, louver flaps any other item that may be needed
6		Ducting length of each location is to inform us in advance. Up to 3 Biosafety Cabinets can be hooked on to one blower, if they are located next to each Other. The blower capacity shall depend on the running length of the ducting and no. of bends and no. of Biosafety Cabinets hooked on the same blower.	-----	Please refer Sl. No. 5.
7		Maximal lifting height of front window >500mm	NSF49 BSC in markets are in the range of 200- 400mm	The text is being amended through Amendment 1 of ITB with the provision of the following- Maximal lifting height of front window >400mm
8		Ability to lock hermetically for gaseous disinfection for the filter decontamination	In Bio-safety cabinet class A2 (NSF49)– for safety glass sash can be closed fully but not hermetically!!!	The text is being amended through Amendment 1 of ITB by deleting “hermetically”
9		Noise pressure level ≤60db(A)	The noise level range between ≤60dB(A) to ≤65dB(A) and not exactly ≤60dB(A)!!!!	No amendment is needed.
10		1000 lux warm colored light	The range is between 800 to 1000 lux	No change is required
11		Filter and flow conditions: Pre-filer and HEPA filter – metal framed	Pre-filter and HEPA filters are just framed – it could be metal or non-metal	The text is being amended through Amendment 1 of ITB by deleting “metal framed”
12		Air circulation volume flow For BSC120cm (4 feet version): 700-1200 m ³ /h	In Class A2 the minimum air circulation volume flow should be in the range of 465 - 956 m ³ /h	This is as per WHO guidelines. No amendment is needed.
13		According to NSF49: the average airflow velocity at front aperture should be 0.51m/s for Class A2	Actual airflow velocity at front aperture should be in the range of 0.51m/s to 0.53 m/s for class A2	The text is being amended through Amendment 1 of ITB with the provision of the range 0.51 m/s to 0.53 m/s
14		Lead fuse T16 A(slow blow) or circuit breaker B16	A standard fuse with ‘slow blow’ is recommended	No amendment is needed

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15		Power consumption for cabinet of BSC 120cm (4 feet version):600W	Recommended is between 600 W to 1200 W	These are desired figures- do not need amendment
16		Power consumption for plugs inside: approx 1000W	It should be up to 1200W	These are desired figures- do not need amendment
17		NSF 49 or EN 12469 You have nowhere asked for the Certification. You have just asked that the BSC should meet the Inflow(page 45) and downflow (page 46) requirements of the above standards. We just wish you to reconfirm that NSF 49 or EN12469 certification is not required. Only the specs should be met.	-----	Compliance to Standards had to be supported by third party certification
18		Protection class in accordance with EN 60529 (page 47) Again, you just need the specs to be met, not the EN 60529 certificate? Or a certificate issued by the manufacturer is good enough ?	-----	Manufacturer's certificate in such cases would be acceptable
19		Accessories (page 47) You have asked for support stand adjustable at least at three feet (points) This is not clear whether the requirement is adjustment at three points (may be every 6 or 7 cm totalling to 2 cm) or it should be adjustable from 78 cm to three feet ?	-----	It is clear that height has to be adjustable between 76-80 cm at three points effectively managed through provided feet.
20	Fully closing, clear 1/4" tempered safety glass sash with two sash handles, counterbalanced anti racking mechanism ;and 10°slope	Specifications seems to be specific to a particular brand, you should make it broad-based like there is no need of two handles ,one handle can make it, no need of anti racking system and slope is not required with our Daihan Labtech's system as glass used is anti-glared so no reflection.	-----	The text is being amended through Amendment 1 of ITB with the provision of the following- "Fully closing, clear 1/4" tempered safety glass sash with sash handles, counterbalanced with suitable mechanism ;and a suitable slope for effective functioning"
21	The supplier would carry out IQ/OQ/PQ as per laid down protocols and provide documentationsat	Some of the vendors wanted to know more about IQ/OQ/PQ laid down protocols.	-----	IQ/OQ/PQ helps in validation of equipment including principal systems and sub systems as claimed in technical specification. These are required to be carried out at the time of commissioning on the

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	the time of installation/ commissioning.			basis of pre-defined protocols set out by the manufacturers. These are covered under CFR 21 Part 11
22		Filter and flow conditions: mentioned “ pre-filter construction preferred”. Please be advised a pre-filter construction can be provided; however, it will increase cabinet amperage due to increased filter resistance.	-----	It is not a mandatory requirement
23		Mentioned “filter change without tools preferred”. Please note the Baker bio-safety cabinet requires a socket wrench to fix 3/4” Hex Head. We hope this would an acceptable deviation to the stated specification	-----	The specifications are self explanatory
24		Stated “Air down flow velocity: NSF49-2002 and EN12469”. We would like to clarify here that the Baker model complies with the updated NSF standard NSF49-2011, and is compliant with (though not listed with) EN standards. Appropriate supporting documentation for the same would be provided with our bid	-----	It has been clearly stated that BSC has to be compliant to either NSF 49 or EN12469
25		Regarding the UPS, it would be provided free of charge . However, pre-dispatch inspection will have to be carried out in India as it would be sourced locally, or alternatively could be waived off. Kindly clarify	-----	It is up to the supplier how he builds up the cost. Providing and maintenance of a compatible UPS is the responsibility of the supplier
26			Delivery schedule on page 43 requires delivery time to all consignees within 60 days from the date of issue of the purchase order. Kindly note this cannot be met . Manufacturer lead time for the product is 60 days plus transit time to India. Local delivery time would be 60 days. Therefore the total delivery time we propose is 120 days plus transit to India	The text is being amended through Amendment 1 of ITB .
27			Regarding shipment into India, would all goods be required to arrive at only 1 port, or is it possible to break the	It is advisable to have one port of entry as it would facilitate quicker custom clearance since only one CDE certificate for each product

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			consignment into 2 separate lots. The container will arrive in 1 port (Mumbai) but part of the consignment will be cleared in Mumbai, and the remaining in Delhi to ensure efficient logistics. We would therefore require 2 duty exemption certificates. We hope this would be acceptable	would be arranged
28			The payment terms as specified on page 106 states that 80% of the contract price shall be paid within 30 days of submission of documents, with the balance 20% to be paid within 30 days of satisfactory installation and commissioning of the goods. We wish to inform you that this would NOT BE ACCEPTABLE to our international Principal. Please clarify whether terms of 90% payment upon shipment and 10% on successful installation through letter of credit would be fine. Also, as stated by you in the pre-bid meeting, custom duties would be nil . We would require a written confirmation of the same. Also, from our past experience with such tenders, consignees show reluctance in issuing installation certificate. We therefore require assurance from you that this would not happen	90% payment would be released upon submission of invoice and receipt and acceptance certificate. Balance 10% payment would be released after installation, commissioning of equipment and training on site. No LC will be opened in case of foreign supplier. (To be read with the Amendment No1 to ITB) The supplier would be provided Custom Duty Exemption Certificate with zero % Customs Duty. . In case there are problems in getting installation/ commissioning certificates, SAMS/ FIND will facilitate in obtaining such certificate (s) from Labs.
29			There is an ambiguity as regards the inspection. Please refer to Page 91 (Clause 8.2 and 8.4): would the inspection be twice or only once at the supplier's premises? Kindly elaborate on how, when and where inspection	There is absolutely no ambiguity in Claus 8.2 and 8.4.. Even if predespatch inspection is carried out, the responsibility of performance of equipment lies with the supplier.

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			would be carried out	
30			As regards the CMC would it acceptable if the same is submitted in the name of local agent/ dealer of a principal foreign supplier?	Yes provided the principal supplier provides full technical back up and spares to the local agent/ dealer
2.	Schedule II : Bacteriologic Incubator			
31	Temperature range +10 °C (at least 5 °C above ambient temperature) to +60 °C	Please clarify temperature range if need a refrigerated or non-refrigerated system	-----	There is no amendment - The technical specification included in ITB would remain as such incubator will be a non refrigerator system.
3.	Schedule III : Refrigerated centrifuge			
32		<p>1. Aerosol tight - should be certified by international agency, we suggest.</p> <p>2. Rotor recognition should be automatic, we suggest.</p> <p>3. Equipment should be IVD approved i.e. EC direct 98/79/EG</p>	-----	<p>1. We have included under title 'Manufacturer's Certificate' which inter alia reads as "----- Quality and safety standards met by the product offered have to be listed and copies of the certificates issued by the authorized agencies to be enclosed for verification". Accordingly requirement of aerosol tightness is included in the specification.</p> <p>2. The text is being amended through Amendment 1 of ITB.</p> <p>3. No such requirement is included</p>
4.	Schedule V: Autoclaves (Horizontal)			
33		<p><u>Main Specification</u></p> <p>(i) As per your specs vessel should be as per ASME, EN 13445 and EN 12953 for steam boiler with class B sterilization, whereas it should be ASME & EN13445 or EN 12953. ASME is must.</p> <p>(ii) Double walled construction is asked whereas this should be deleted. No Lab Autoclave are double walled.</p>	-----	<p>i) Compliance to any of these standards would be acceptable.</p> <p>ii) Our requirement is for double walled autoclave</p>
34	Automatic water	Automatic water feed and connection to a		The text is being amended through

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	feed, connection to a demineralised water supply	demineralised water supply will unnecessary increase the cost to the equipment as a distillation unit have to be installed for autoclave. If lab/Hospital is established already it may have a distillation unit already and manually autoclave can be feeded.	-----	Amendment 1 of ITB .
35	Integrated pump to equalize pressure variations in external supply lines	This is really specific to a particular brand and not possible to do with most of the manufacturers. We request to delete it.	-----	No change in specification is required
36	Autoclave equipped for pre-vacuum and flash cycles and post vacuum through vacuum pump	Pre-vaccum and post vaccum thru vaccum pump- please mention that vaccum pump should be inbuilt-Integrated. (some manufacturers supply vaccum pump as external device, not a part of autoclave)	-----	No change in specification is required
37	Validation: The supplier would carry out IQ/OQ/PQ as per laid down protocols and provide documentations at the time of installation/ commissioning	Please specify what are the IQ/OQ/PQ laid down protocols.	-----	IQ/OQ/PQ helps in validation of equipment including principal systems and sub systems as claimed in technical specification. These are required to be carried out at the time of commissioning on the basis of pre-defined protocols set out by the manufacturers. These are covered under CFR 21 Part 11
5.	Schedule VI: Autoclaves (Vertical)			
38		(i) As per your specs vessel should be as per ASME, EN 13060-2 / EN-13445:2009 and EN 12953, whereas it should be ASME, EN 13060-2 or EN 13445:2009 and EN 12953. ASME is must. (ii) Double walled construction is asked whereas this should be deleted. No Lab Autoclave are double walled.	-----	i) Compliance to any of these standards would be acceptable. ii)Our requirement is for double walled autoclave
39	Automatic water feed, connection to a demineralised water supply	Automatic water feed and connection to a demineralised water supply will unnecessary increase the cost to the equipment as a distillation unit have to be installed for	-----	The text is being amended through Amendment 1 of ITB .

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		autoclave. If lab/Hospital is established already it may have a distillation unit already and manually autoclave can be feeded.		
40	Autoclave equipped for pre-vacuum and flash cycles and post vacuum through vacuum pump	Pre-vacuum and post vacuum thru vacuum pump- please mention that vacuum pump should be inbuilt-Integrated. (some manufacturers supply vacuum pump as external device, not a part of autoclave)	-----	No change in specification is required
41	Accessories: Steel stand, appropriately coated for corrosion protection or made from stainless steel SS304	Autoclave Vertical is a bulky equipment and is fitted with castor wheels for movability so stand for autoclave is not required. Kindly amend the specs. Also clarify if you need stand to put items those are to be autoclaved.	-----	The text is being amended through Amendment 1 of ITB.