PRE-BID CLARIFICATION / AMENDMENT IN RESPONSE TO THE QUERIES RAISED BY THE PROSPECTIVE BIDDERS IN PRE-BID MEETING HELD ON 26.12.2024 AT 4 PM FOR THE TENDER OF ULTRAPORTABLE HANDHELD X-RAY MACHINE

Queries raised by the prospective bidders on the tender terms & conditions, technical specifications etc. were discussed. Based on the written queries by the prospective bidders, the clarification / amendments as decided by the committee in response to the pre-bid queries are mentioned below:

Sl.	Queries Raised by the Prospective Bidders	Original terms & Condition / Technical Specification	Clarification/ Amendment in response to the Pre-bid Queries
A	**Technical Specification**		
1	**X-ray Generator** **Point no 3**. The built-in battery should shoot 200+ images on full charge.	**Point No 3.** The built-in battery should shoot 100 images on full charge.	**No Change**
2	**X-ray Generator: Point No 4.** i)The weight of the X-ray Generator with inbuilt battery should be within 3-4 kg ii) Weight including battery should be under **3.5 Kg** so as to be Ultra-Portable Digital Handheld X-Ray machine. iii)The weight of the X-ray Generator with inbuilt battery should be less than 3 kg	**X-ray Generator:** **Point No 4.** Weight of the unit: The weight of the X-ray Generator with inbuilt battery should be less than **5 Kg**.	**No Change**
3	**X-ray Generator:** **i) Point. No.6** : Voltage Output range in KV: 50-80 KV or More **ii) Point. No. 6** : We recommend Voltage Output range in kV: 40-70 KV **iii) Point No. 6**: Voltage output range to read as Tube Voltage Range. Tube voltage range should be 40 Kv to 70 Kv. It should be variable in 1 Kv step). **iv) Point No.6**: Voltage Output range in kV: 40 to 70 KV	**Point. No.6** - Voltage Output range in KV: **70 KV or More**	**No Change**
4	**Point. No 7.** Tube Current in mA range : 2.0 mA to 5.0 mA or more **Point. No 7** : 3.0mA (Minimum) to 5.0 mA (Maximum) **Point. No 7**: Tube Current in mA: 2.0 mA (Minimum) - 6.0 mA (maximum) is good for better image quality (It should be variable 1mA step**).** **Point No7:** Kindly revise the range to either a fixed value, such as 2mA or 6mA or a narrow range	**Point No.7**. Tube Current in mA: 2.0 mA (Minimum) - 6.0 mA (maximum)	**Amended** Tube Current in mA: It should be **2.0 mA / 3.0 mA / 4.0 mA / 5.0 mA / 6.0 mA**

	within 2 mA-6 mA. A wide range like this allows for varied interpretations, leading to quotations based on individual preferences rather that a consistent standard.		
5	**i) Point no 8.** Exposure time in milli sec: **0.03 sec - 2.0 sec** **ii) Point no 8:** Maximum Exposure time in milli sec should be 0.03 sec to 2 secs (Below 0.03 secs, image clarity is not possible. Also 1.3 sec is insufficient time to get clear image of larger bodied patients. (Exposure time should be variable 0.01 sec step). iii) Maximum Exposure time in milli sec: **0.06-2sec.**	**Point no 8.** Maximum Exposure time in milli sec: **0.01-1.3sec**	**Amended** **Maximum Exposure time in milli sec: 0.03 sec - 1.3 sec**
6	**Point No 10** - Total Filtration of x-ray: should equal to 5.1mm Al.Eq at 70 KV will ensure better quality of image and low radiation dose.	Point No 10. Total Filtration of x-ray: should be in the range of 1.5 mm to 2.5 mm Al.Eq at 70 KV	Amended Total Filtration of x-ray: should be minimum 1.5 mm Al.Eq at 70 KV
7	**Point No 11**. We provide an open collimator**.**	**Point No 11**. Collimator provided: Yes	**No Change**
8	**i) Point No 12 - Type of Collimator:** Laser guided collimator. Better for operation in small spaces**.** **ii) Point No 12:** Type of collimator- Cone collimator is used generally in Dental X-ray machines. It should read only as Collimator for ultra-portable Digital Handheld X-ray machines. It should read only as Collimator for Ultra-Portable Digital handheld X-ray machine. Collimator should have Cross hair laser beam with field of View (FOV) Led Light.	**Point No 12.** Type of Collimator: Cone Collimator with Cross hair Laser	**Amended** **Type of Collimator:** Cone Collimator with Cross hair Laser / Laser guided collimator / Collimator for Ultra-Portable Digital handheld X-ray machine with Cross hair laser beam
	iii) Point No 12: Type of Collimator-Cone Collimator with, square window, Cross hair or any other provision which can clearly define and mark the FOV**.** **iv) Point No 12:** Type of Collimator-Square Collimator with cross hair laser		

9	**i) Point 13.** Automatic exposure control device provided: Yes Please delete this point **ii) Point 13.** No. we recommend exposure with remote and no to Automatic exposure control device required**. Point 13.** Automatic Exposure Device Provided: Should be with Wireless Remote Switch. **iii) Point no 13: delete this point.** AEC functionality is only feasible if the generator is equipped with feedback and fully integrated with the detector. For handheld X-ray systems. AEC is not practical, especially in seenarios like TB camps where mobility is critical. The tender specifications required clarification and adjustment. It is recommended to either modify or delete the AEC requirement and instead specify that an exposure switch and remote exposure capability must be included**.**	**Point 13. Automatic exposure control device provided: Yes**	**Amended** Automatic exposure control device provided: **No**
10	**Point No 15.** Electronic timer supplied: No. We provide wireless remote so timer not required. **Point No 15.** Electronic Timer is not Applicable for Ultra- portable Digital Handheld X-ray machine since the equipment is provided with Wireless Remote switch to take X-ray image when required**.** **Remove this point**	**Point No 15.** Electronic timer supplied: Yes	**Amended** Electronic timer supplied: **No**
11	**CERTIFICATIONS AND REPORTS** Point No 5. Electrical Safety Standards: IEC 60601- IEC is international standard for Imported products. In lieu of this BIS Test report should also be applicable for products under make in India.	Point No 5. Electrical Safety Standards: IEC 60601 (test report of the quoted model should be furnished in the bid)	**No Change**
	USFDA / EU- shall be made compulsory as global regulatory approvals will ensure quality made product	Point No 4 - Additional certification: The model should be USFDA / EU-CE / BIS [IS 7620 (or Latest)] certified.	**No Change**

	Additional certification and Approvals: Since ICMR being a national institute for various infectious and pandemic disease research expertises, they also have ICMR expert committee which evaluates commercially vailable diagnostic solutions and recommend further for use. We kindly request ICMR Approval criteria to be incorporated in technical specification. It will ensure that Indian manufacturers are not at a disadvantage and US FDA / CE is not needed for Indian market sales. CDSCO of course is a must**.**		**Clarification** No additional Certifications **are required.**
12	**Flat Panel Detector** i) **Point No2:** The Scintillator material of the detectors should be made up of latest IGZO technology. ii) **Point No2:** Glass Type should also be acceptable with 1.5 M Drop test report**.** iii) **Point No2:** The Scintillator material of the detectors should be made up of Cesium Iodide or Amorphous Silicon technology with Thin Film Transistor (TFT) with drop resistance certificate of 1 meter fall minimum. For fair participation **non glass word should be removed.** iv) Non Glass TFT is non proven technology and the cost is almost double than the CSI. CSI is the latest and most proven technology today. Hence request to remove Non Glass Type.	**Flat Panel Detector** Point No 2. The Scintillator material of the detectors should be made up of Cesium Iodide or Amorphous Silicon technology with Thin Film Transistor (TFT) Non Glass type.	**Amended** Point No 2. The Scintillator material of the detectors should be made up of Cesium Iodide or Amorphous Silicon / **IGZO technology** with Thin Film Transistor (TFT) with **1 M Drop test report.**
13	**Point No 12**: The offered detector should have load bearing capacity of at least **200 Kg** point weight.	**Point No 12**: The offered detector should have load bearing capacity of 150 kgs or more.	**No Change**

14	i) **Point No 14**: The detector should be protected from dust and liquid. The IP rating should be IP68 or better. ii) **Point No 14**: The detector should be protected from dust and liquid. The IP rating should be IP68 or more.	**Point No 14**: The detector should be protected from dust and liquid. The IP rating should be IP55 or better.	**No Change**
15	**Please delete this points** Certification under flat panel detector: The certificate required in this specification pertains to a manufacturing license for Flat Panel Detector. However to the best of our knowledge, flat panel detectors are not currently manufactured in india. Hence we request the deletion of this requirement**.** 1) CDSCO License to import or manufacturer should be mandatory since the delivery cannot be made without that 2) CDSCO License to import or manufacture should be mandatory**.** 3) CDSCO License to import or manufacturer should be mandatory since the delivery cannot be made without that.	Point no 3: The quoted model must be registered under CDSCO and submit the license to manufacture for sale or for distribution of the medical device. (Copy of the CDSCO License of the quoted model should be furnished in the bid)	**Amended** The certifications under A) X-Ray Generator and Certifications under B) Flat Panel Detector are deleted. **Another clause E)** regarding **Certifications & Reports** is added after clause D) Packing, as mentioned below: **E) <u>Certifications & Reports</u>:** i)The quoted model must be registered under CDSCO and submit the license to manufacture for sale or for distribution of the medical device (Copy of the CDSCO License of the quoted model should be furnished in the bid) ii) The quoted X-ray device should be AERB Type Approved (AERB approval certificate number of quoted Model should be furnished). iii) Manufacturing unit certification : The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB / Nationally Recognized Accreditation Board under IAF MLA. iv) Additional certification: The quoted X-Ray model should be USFDA / EU-CE / BIS [IS 7620 (or Latest)] certified. v) Electrical Safety Standards: IEC 60601(test report of the quoted X-Ray model should be furnished in the bid) vi) Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission as per buyer requirement.

	USFDA / EU - shall be made compulsory as global regulatory approvals will ensure quality made product.	Additional certification: The model should have USFDA Approved / EU-CE / BIS certified.	**No Change**
16	**C) Image Processing Console cum workstation:** i) **Point No 5**. Zooming, ROI, Image Cropping, Windowing and other image processing and annotation features should be available. No bucky operations or grid usage are involved in this project. Since this x-ray system is intended for TB camps where portability and simplicity are key, the inclusion of specifications related to grids or Bucky function is unnecessary. We therefore, request the deletion of the grid-related requirements from the specification. ii) Remove Grid removal function	C) Image Processing Console cum workstation: **Point No 5**. Zooming, ROI, Image Cropping and grid removal function should be available.	**Amended** Point No 5: Zooming, ROI, Image Cropping should be available. *Grid removal function is deleted.*
17	**i) Point No 6 (**Soft tissue processing): Please delete this point**.** ii) Please remove this point	**Point No. 6:** Soft tissue processing must be possible.	**Amended** **Point No 6: Deleted.** *The feature of soft tissue processing unit is deleted.*
18	**i) Point No. 7: Please delete this point as** AI systems are not currently trained to generate reports for bone-suppressed images. Including such a requirement could lead to inaccurate diagnoses due to the AI's limitations in handling bone Suppression effectively. We recommend removing this point from the specifications to avoid potential diagnostic errors**.** **ii) Should be removed** - in most if the reputed flat panel detectors this point does not come as standard. This point (Bone Suppression Imaging) related with a particular company named M/s Konica in most of the reputed FPD this feature is not available so this should be removed from technical specification **iii)** iii) This feature is offered by a specific company and hence restricting a wide participation by	**Point No 7 :** Bone Suppression Imaging (removal of clavicle bone and ribs) should be available so that a clear view of the chest is available which is helpful for the examination of the patients more effectively.	**Amended** **Point No7: Deleted.** *The Bone Suppression Imaging feature is deleted.*

	large no. of suppliers. **It Should be asked as a desirable feature.** Preferably the detector should have Bone Suppression Imaging (removal of calvicle bone and ribs) feature available so that a clear view of the chest is available which is helpful for the examination of the patients more effectively. iv) Please make Bone Suppression Imaging software as optional, since it is restrictive to only a few Detectors companies software.		
19	**Point No 12** "Tissue Equalization": This feature is offered by a specific company and hence restricting a wide participation by large no. of Suppliers. It Should be asked as a **desirable feature.**	**Point No 12** After image acquisition, the software system should have provision, window adjustment, z/ function for image adjustment-clip, contrast, brightness zoom, magnifier, invert, rotate, flip annotations, measurements, digital collimation etc, image view details enhancement and noise suppression, **tissue equalization**).	**Amended** **Point No 12** : After image acquisition, the software system should have provision, window adjustment, z/ function for image adjustment-clip, contrast, brightness zoom, magnifier, invert, rotate, flip annotations, measurements, digital collimation etc, image view details enhancement and noise suppression. *The feature of tissue equalization is deleted.*
20	**Point No 13. Please delete this point** This project is specifically intended for TB diagnosis and is not designed for orthopedic applications. Addressing orthopedic requirements such as imaging the spine and other major bony structures would necessitate specialized software, significantly increasing costs for both the OEM and the tenderer. We therefore request the deletion of this point from the Specifications.	Point No 13: System should be offered with orthopedics measurement tools.	**Amended** **Point No 13 : Deleted** *The requirement of orthopedics measurement tools is delected.*
22	**AI Software for TB Screening**: It helps target abnormalities using Artificial Intelligence with high accuracy. Using Artificial Intelligence, it helps target abnormalities like: Contagious Disease Tuberculosis with an accuracy of more than 90% and specificity of more than 85%. As per the WHO guidelines 90%	AI Software for TB Screening: It helps target abnormalities using Artificial Intelligence with high accuracy. Using Artificial Intelligence, it helps target abnormalities like: Contagious Disease Tuberculosis with an accuracy of more than 95%.	**Amended** AI Software for TB Screening: It helps target abnormalities using Artificial Intelligence with high accuracy. Using Artificial Intelligence, it helps target abnormalities like: Contagious Disease Tuberculosis with an **accuracy of more than 90%.**

	sensitivity and 70 % specificity of AI software is enough to target abnormalities like tuberculosis.		
B	**Eligibility Criteria and Tender Terms & Conditions**		
1	**i) Eligibility Criteria (Section I – Clause A)** 1) Pont No.3a: Currently, the minimum turnover requirement of ₹40 crore is significantly high, which may inadvertently limit the Participation of smaller but equally competent organizations in this tender. In support of this request, I would like to highlight that we are having an average annual turnover of **₹7,91,86,518.70** over the last three years, Demonstrating our solid financial standing and capability to handle such a project. We believe that reducing the turnover criteria to **₹5 crore** would allow a greater number of qualified companies, including emerging players, to compete, thereby fostering more competitive bids and showcasing their expertise. 2) **Point No. 3.a**): In case of a manufacturer / Importer, must have Annual Average turnover of minimum **Rs.30 Crores** (Rupees Thirty Crores) or more during the financial years 2021-22, 2022-23 & 2023-24**.** **ii) Eligibility Criteria (Section I – Clause A, Point No. 3 b)** In case of authorized distributor, must have Annual Average turnover of minimum **Rs.20 Crores** (Rupees Twenty Crores) or more during the financial years 2021-22, 2022-23 & 2023-24**.** Supportive turnover of manufacturer should not be asked. Lead bidder or distributor can submit average turnover.	**3)**a) In case of a manufacturer / Importer, must have Annual Average turnover of minimum Rs.40 Crores (Rupees Forty Crores) or more during the financial years 2021-22, 2022-23 & 2023-24. b) In case of authorized distributor, must have Annual Average turnover of minimum Rs.20 Crores (Rupees Twenty Crores) or more during the financial years 2021-22, 2022-23 & 2023-24.However, in case of distributor, the distributor shall also submit the average annual turnover of the Manufacturer / Importer / Indian Subsidiary of the Manufacturer.	**Amended** **Eligibility Criteria (Section I – Clause A) Point No. 3) a) & 3) b) are amended as:** **Point No. 3) a):** In case of a manufacturer / Importer, must have Annual Average turnover of minimum **Rs.30 Crores (Rupees Thirty Crores)** or more during the financial years **2021-22, 2022-23 & 2023-24.** **Point No. 3) b):** In case of authorized distributor, must have Annual Average turnover of minimum **Rs.15 Crores (Rupees Fifteen Crores)** or more during the financial years **2021-22, 2022-23 & 2023-24.** However, in case of distributor, the distributor shall also submit the average annual turnover of the Manufacturer / Importer / Indian Subsidiary of the Manufacturer.

2	**Eligibility Criteria (Section I – Clause A, Point No. 5 a) & b)** i) 5. a) : In case of Manufacturer / Importer, must have supplied at least 10% of quoted Quantity of the **same model.** ii) 5 (b) : In case of distributor, we would kindly request that this criterion be amended to reflect past performance over the **last five financial years**, as we have successfully supplied X-Ray, C-Arm and DR systems in 2019 and 2020. ii) Also add **Private hospital in the past experience criteria** to any Government organization, PSU Hospitals, / Public Listed Companies in India**.**	**Point No. 5a** In case of Manufacturer / Importer, must have supplied at least 10% of quoted quantity of the same or similar category of products (all type X-Rays / DR / C-Arm / Mammography / Dexa Scan etc.) executed directly by manufacturer through self /importer / distributor to Central / State Govt. Organizations / Public Sector undertakings State Medical Corporations / Govt. Societies / Public Listed Companies during the last three finacial years. Details to be furnished in Format T9 along with Purchase order copies in support of that. **Point No. 5 b:** In case of distributor, must have shown the past performance of at least 10% of quoted quantity of the same or similar category of products (all type X-Rays / DR / C-Arm / Mammography / Dexa Scan etc.) executed directly by manufacturer through self / importer / distributor to Central / State Govt Organizations / Public Sector undertakings / State Medical Corporations / Govt. Societies / Public Listed Companies during the last three financial years. Details to be furnished in Format T9 along with Purchase order copies in support of that. Out of Proof of supply of 10% of Bid quantity, the distributor must have past experience in its own name towards supply of the same or similar Category Products (all type X-Rays / DR / C-Arm /Mammography / Dexa Scan	**No Change**

		etc.) for 2.5 % of 10% of the bid quantity in the last three financial years to any Govt. organization / PSU Hospitals / Public Listed Company in India and should submit the purchase order copies and proof of supply in support of that as per Format T9.	
3	Delivery to be planned in phased ways so that installation can be planned properly and delivery time to be extended to meet quality standards of manufacturing and sufficient time of imports is available.		**No Change**
C	**Other points proposed**		
1	**Please Add:** 1)Preference to Make In India products: Preference should be given to Class 1 local supplier as defined in public procurement (Preference to Make in India), Order 2017 as amended from time to time and its subsequent Orders/Notifications issued by concerned Nodal Ministry for specific Goods/Products. 2) Preference should be given to a "Made in India" solution as per Government of India Public Procurement Company should have a minimum of 10 years of experience in manufacturing and deploying General Radiology x-ray Systems across India**.** 2)Make In India preference should be provided in tender as per Government of India policy of Public Procurement (Preference to Make in India) Order 2017 dated 19-07-2024.		**No Change**
2	**Please Add:** The proposed solution should have seamless integration capabilities with Rapid Molecular Diagnostic platforms (such as TrueNat and CBNAT), ensuring compatibility and readiness for future upgrades.		**No Change**

3	**Page no. 3 Sections IA.** Eligible Tenderers - Preference to Make In India products: Preference should be given to Class 1 local supplier as defined in public procurement (Preference to Make in India), Order 2017 as amended from time to time and its subsequent Orders/Notifications issued by concerned Nodal Ministry for specific Goods/Products.		**No Change**
4	Demonstration of Ultra-Portable Digital handheld X-Ray machine should required before finalization of Purchase order**.**		**Clarification** Yes it is mentioned at point no 4.d under SECTION-II (Terms & Conditions)
D	**Other Terms & Conditions** Section-I, Format of the Tender: Details of EMD is Format T4. By error it is printed as T3. Profile of the Firm (Format T3) instead of T4.		**Amended** Section-I, Format of the Tender (Part A)- Technical Bid is amended as Point No. 5: Details of EMDs (format T4. Point No. 6 : Profile of the Firm (Format T3)
E	**Extension of Bid submission & opening date & time (2nd Extension)**		**Amended** The last date & time of bid submission is extended to **22.1.2025, 3 PM** The date of technical bid opening is rescheduled to **22.1.2025, 4 PM**

N.B: The amendments / clarifications mentioned above are to be treated as amendments / clarifications to the terms & conditions / technical specification of the above tender reference. All other terms & conditions / technical specifications as mentioned in the tender document remain unchanged.

Sd/
Mission Director
NHM, Odisha