



Name of Contract: Supply, Delivery, Installation, Testing, Commissioning, Room Preparation and Finish, and Licensing of One (1) Lot Brand New Whole Body Digital PET-CT Scanner and Accessories for the Nuclear Medicine Research and Innovation Center (NMRIC) Located at the Department of Science and Technology – Philippine Nuclear Research Institute Compound.

Location of the Contract: PNRI Compound, Commonwealth Avenue, Diliman, Quezon City

BID BULLETIN/SUPPLEMENT NO. 2
March 05, 2025

This Bid Bulletin/Supplemental No. 2 is issued to inform of the following amendments/changes in the Bid Documents and to clarify and address queries of the prospective bidders. This shall form an integral part of the Technical Documents.

A. PNRI response to the clarifications of prospective bidders.

I. Medilines Distributors – SIEMENS Digital PETCT System

Concern	Request or Clarification	Reason	PNRI Response
Terms of Reference, General Conditions and Technical Specifications IV. QUALIFICATIONS OF PROSPECTIVE SUPPLIER/ MANUFACTURER 5. The supplier/ manufacturer must have a US-FDA license, FDA clearance, and CE marked.	Clarification on whether the FDA Clearance mentioned is the PH FDA certification. In case also that the registration of the model to be offered is expired and is ongoing renewal, may we request if we can submit the expired license together with the Official Receipt from the Philippine FDA.		FDA Clearance refers to the Philippine FDA certification. Local distributors must have an active License-To-Operate (LTO) and Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) of the Digital PET-CT pursuant to FDA-Circular-No.2017-013-A. The proposed equipment should have US-FDA clearance/certification AND appropriate Philippine FDA certification/ evidence of lodgement/ Philippine FDA approval of equipment/ model proposed.

<p>Terms of Reference, General Conditions and Technical Specifications IV. QUALIFICATIONS OF PROSPECTIVE SUPPLIER/ MANUFACTURER 6. The PET-CT supplier shall be an authorized installer by the manufacturer and must have at least seven (7) years of work experience in the installation, testing and commissioning, operation, maintenance, and training on the PET-CT brand it is supplying. The PET-CT supplier shall at least have completed one (1) similar project of the specific PET-CT System and its accessories locally.</p>	<p>Request to add "supplier <u>or</u> manufacturer".</p>	<p>The installation, testing, commissioning, operation, maintenance, and training of the PET-CT system are typically performed by the machine manufacturer.</p> <p>Furthermore, we request that the manufacturer's completed project be taken into account, as they are the primary responsible for the overall project execution. This will serve as a testament to their reliability, which is a result of their extensive experience and established track record.</p>	<p>6. The PET-CT manufacturer shall have at least six (6) years of experience in PET-CT System manufacturing, installation, testing and commissioning, operation, maintenance, and training. The PET-CT supplier/distributor shall have at least five (5) years' related experience in commissioning and licensing of medical equipment and have completed at least one (1) similar project related to PET-CT System installation and its accessories locally.</p>
<p>Terms of Reference, General Conditions and Technical Specifications VI. SCOPE OF WORKS B. Preparation for PET-CT Site Readiness Furthermore, the SUPPLIER/ MANUFACTURER shall ensure the adequacy of structural integrity of the site area for the PET-CT installation. The SUPPLIER/ MANUFACTURER modification or corrective actions shall be submitted for PNRI's review and approval before execution. The SUPPLIER/ MANUFACTURER shall be responsible for implementing the approved design on-site, ensuring compliance with all technical and regulatory requirements for a PET-CT area.</p>	<p>Request for identification of the possible area of installation within the Nuclear Medicine Research and Innovation Center (NMRIC).</p>	<p>Identifying the potential area will enable us to precisely calculate the expenses that will be incurred during the rigging in of the equipment and the preparation of potential costs, should a structural retrofit be necessary during the final phase of the planning process.</p>	<p>The location of installation will be in one of the four (4) rooms on the second floor of the Nuclear Medicine Research and Innovation Center at the PNRI compound. Previous plans have been provided.</p>

<p>Terms of Reference, General Conditions and Technical Specifications</p> <p>XIII. WARRANTY</p> <p>The SUPPLIER/ MANUFACTURER shall include in the warranty scope of services for five (5) years from the date of acceptance, the once a month regular and systematic maintenance of the PET-CT system. Its report will be submitted to PNRI, through the Isotope Techniques Section, upon completion of each regular service.</p>	<p>Request to change from the once a month regular and maintenance of the PET-CT system to "<u>manufacturer's recommendation of regular and systemic maintenance of the PET- CT system</u>".</p>		<p>Quarterly regular maintenance of the PET-CT system or as recommended by the manufacturer, whichever is more frequent.</p>
<p>Terms of Reference, General Conditions and Technical Specifications</p> <p>IV. QUALIFICATIONS OF PROSPECTIVE SUPPLIER/ MANUFACTURER</p> <p>7. The supplier's manufacturer must have an authorized local service center, and that the supplier/manufacturer has the engineer/s trained and capable for corrective and preventive maintenance for the model being offered. Service engineer/s should be presently employed by the supplier or authorized by the manufacturer.</p>	<p>Request to add "authorized local service center <u>or office</u>"</p>	<p>Siemens Healthcare is legally represented in the Philippines through an office located at 10F M1 Tower, 141 H.V. Dela Costa St., Salcedo Village, Makati City 1227. This office also functions as the home base for Siemens Healthineers' service engineers.</p>	<p>Authorized local service center <u>or office</u> is acceptable.</p>

<p>Terms of Reference, General Conditions and Technical Specifications</p> <p>V. GENERAL NOTES AND CONDITIONS</p> <p>23. 95% uptime of the equipment is guaranteed within the warranty period and that any accumulated downtime in excess of 5% shall be added to the warranty period.</p> <p>UPTIME – The total time in hours in which the equipment and its accessories are operational and reckon from the time the service provider is officially notified.</p>	<p>Please provide clarification regarding the inclusion of all third-party items, such as pulse oximeters and glucometers, in the term "its accessories." In the event of a malfunction, are these items also subject to the warranty period extension computation?</p>		<p>The third-party equipment is not subject to the 95% uptime rate. However, all third-party equipment/items should also have a five (5) year warranty on parts and services per undertaking.</p>
<p>Technical Specification PET GANTRY</p> <p>2. Axial Field of View (AFOV):</p> <p>≥ 24 centimeters or ≥ 240 millimeters</p>	<p>Request to add the option of "<u>≥ 24cm, but with continuous bed motion</u>".</p>	<p>With continuous bed motion the AFOV can be disregarded. This is different from the conventional method where PET images are acquired with sequential bed positions (where AFOV is a significant factor), alternating between image acquisition and patient table motion.</p> <p>Continuous bed motion scanning enables:</p> <ul style="list-style-type: none"> • Personalized exam protocols based on patient anatomy • Definition up to four distinct scanning regions, each with a different bed speed 	<p>Technical Specification PET GANTRY</p> <p>2. Axial Field of View (AFOV):</p> <p>≥ 24 centimeters or ≥ 240 millimeters</p> <p>Note: Continuous bed motion (CBM) can be an add-on with no cost on the procuring entity. NOT required.</p> <p>As is.</p>

		<ul style="list-style-type: none"> • High-resolution reconstructions and respiratory gating • Simple protocol setup so the technologist can spend more time with the patient 	
<p>Technical Specification PET GANTRY 4. ToF timing resolution: ≤ 400 picosecond (ps)</p>	<p>Request to update the TOF resolution requirement from ≤ 400 picosecond (ps) to "<u>≤ 250 picosecond (ps)</u>".</p>	<p>When we compare a scanner with a 400ps TOF resolution to one with a 250ps TOF resolution, while the other parameters remain the same, the following are the distinctive values:</p> <p>Image Quality and Precision The scan-to-noise ratio of 250 ps scanner is about 26.5% better than of a 400 ps scanner, a 250 ps scanner produces sharper, clearer images, making it easier to spot small or subtle abnormalities as detecting tiny tumors or metastases earlier in Oncology.</p> <p>Scan Time and Patient Dose The 250-ps scanner can achieve the same image quality as the 400-ps scanner using fewer detected signals (counts). This allows for:</p>	<p>Technical Specification PET GANTRY 4. ToF timing resolution: ≤ 400 picosecond (ps)</p> <p>As is.</p>

		<p>Shorter Scan Times: Scans could be up to 37% faster with the 250-ps scanner while maintaining image quality. Faster scans enhance comfort, especially for patients who struggle to stay still or feel anxious during imaging</p> <p>Lower Radiation Doses: Alternatively, the same image quality could be achieved with a 37% lower radiotracer dose (saving cost), reducing radiation exposure. Lower doses improve safety, which is critical for pediatric patients or those needing repeated scans.</p> <p>For an LSO system paired with SiPM, a TOF of less than 250ps should be the average.</p>	
<p>Technical Specification CT GANTRY</p> <p>1. CT slice: At least 64 slices</p>	<p>Request to change to "<u>64 acquired slices</u>".</p>	<p>A higher number of acquired CT slices will result in more detailed and accurate imaging.</p> <p>Higher resolution: higher acquired slices will capture more anatomical detail by generating thinner, more closely spaced image slices compared to lower acquired slices. This allows for better visualization of small structures and improved detection of subtle abnormalities.</p>	<p>Technical Specification CT GANTRY</p> <p>1. CT slice: At least 64 slices</p> <p>As is.</p>

		<p>Faster scan times: The increased number of detector rows enables faster volumetric image acquisition. This reduces the total scan time required, which can be beneficial for patients who have difficulty holding their breath or staying still for long periods.</p> <p>Reduced radiation exposure: The faster scan times will allow lower radiation doses per scan compared slower scanners, while still maintaining high image quality.</p> <p>Better 3D reconstruction: The large number of thin slices provided allows more accurate three-dimensional reconstruction of anatomical structures, which can be valuable for surgical planning and other clinical applications.</p>	
<p>Technical Specification F. Quality Control (QC) 3. Must provide necessary test tools.</p> <ul style="list-style-type: none"> a. PETCT system phantoms b. NEMA phantoms c. ACR phantoms d. Jaszczak phantoms e. Check sources as appropriate f. CT ion chamber with reading or data logging unit compliant with applicable IEC standards for CTDI measurements. 	<p>Request to remove "<u>d. Jaszczak phantoms</u>"</p>	<p>This is specifically used in SPECT systems.</p>	<p>Technical Specification F. Quality Control (QC) 3. Must provide necessary test tools.</p> <ul style="list-style-type: none"> a. PETCT system phantoms b. NEMA phantoms c. ACR phantoms d. Esser Flangeless Deluxe PET Phantom e. Check (sealed) sources as appropriate f. CT ion chamber with reading or data logging unit compliant with applicable IEC standards for CTDI measurements

<p>Technical Specification</p> <p>I. WARRANTY AND SUPPORT SERVICE</p> <p>Five (5) years warranty on parts and labor including CT XRAY tube. Must perform quarterly proactive maintenance within the warranty period.</p> <p>24/7 availability of service engineer for onsite/remote support during operation, repair and maintenance. In case that the equipment is faulty, repair should be done within 24 to 48 hours.</p> <p>Supplier shall be liable to monetary losses for every day that the equipment is not working/ unrepaired. Calculation of the losses will depend on the average number of scans per day.</p>	<p>Request to update repair should be done within 24 to 48 hours "<u>to 2 days to 7 days</u>".</p>	<p>System will be visited and checked within 24 to 48 hours upon receipt of service call but in cases that the part required to fulfill the repair will be coming from the US of A, which will be shipped and requires local custom clearance, we respectfully request for a longer fulfillment time.</p>	<p>In case that the equipment is faulty, repair should be done to 2 - 5 days only.</p>
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II. Assurance Controls Technology – United Imaging Digital PETCT System

Page #	Tender Requirement	Concerns & Suggested Revision/Request	PNRI RESPONSE
Section VII. Terms of Reference, General Conditions and Technical Specifications:			
Page 29	IV. Qualification of Prospective Supplier/Manufacturer 2. The supplier/ manufacturer shall have a Registration certificate or Equivalent Document	- Clarification on what specific Registration Certificate or Equivalent Document is required.	PhilGEPS registration certificate is required
Page 29	The supplier/manufacturer must have a US- FDA license, FDA clearance, and CE marked.	- Consider the submission of payment receipt for the local FDA clearance. It takes time for FDA to release the actual certificate of registration. Payment of the registration fee is only allowed for approved applications.	FDA Clearance refers to PH FDA certification. Local distributors must have an active LTO and Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) of the Digital PET-CT pursuant to FDA-Circular- No.2017-013-A. The proposed equipment should have US-FDA clearance/certification AND appropriate PH FDA certification/ evidence of lodgement/ PH-FDA approval of equipment/

<p>Page 30</p>	<p>6. The PET-CT supplier shall be an authorized installer by the manufacturer and must have at least seven (7) years of work experience in the installation, testing and commissioning, operation, maintenance, and training on the PET-CT brand it is supplying. The PET-CT supplier shall at least have completed one (1) similar project of the specific PET-CT System and its accessories locally.</p>	<p>- Consider revising as follows: "The PET-CT supplier and/or manufacturer is/are authorized installer" by the manufacturer and must have "at least five (5) years of work experience" in the installation, testing and commissioning, operation, maintenance, and training on the PET-CT brand it is supplying. The PET-CT supplier shall at least have completed one (1) similar project of the "specific" PET-CT System and its accessories locally.</p>	<p>model proposed.</p> <p>6. The PET-CT manufacturer shall have at least six (6) years of experience in PET-CT System manufacturing, installation, testing and commissioning, operation, maintenance, and training.</p> <p>The PET-CT supplier/distributor shall have at least five (5) years' related experience in commissioning and licensing of medical equipment and have completed at least one (1) similar project related to PET-CT System installation and its accessories locally.</p>
<p>Page 32</p>	<p>V. GENERAL NOTES AND CONDITIONS</p> <p>21. After completion and acceptance of the project, there shall be a five (5) year warranty/retention or defects liability period for all activities implemented and delivered by the SUPPLIER/ MANUFACTURER or as stated in the technical specifications and general conditions of the project. The parts and labor, including CT X-ray tube and accessories of the equipment shall be available for the next five (5) years after expiration of the warranty period.</p>	<p>- Clarification on the scope of warranty for the site construction works. Request is to follow standard practice for construction works – 6 months to a maximum of 12 months from site turnover.</p>	<p>The location of installation will be in one of four (4) rooms on the second floor of the Nuclear Medicine Research and Innovation Center at the PNRI compound. Previous plans have been provided.</p> <p>The warranty for the site construction works is 12 months after completion and acceptance of the project, against workmanship.</p>

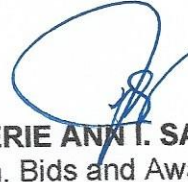
Page 33	<p>23. 95% uptime of the equipment is guaranteed within the warranty period and that any accumulated downtime in excess of 5% shall be added to the warranty period.</p> <p>UPTIME – The total time in hours in which the equipment and its accessories are operational and reckon from the time the service provider is officially notified.</p>	<p>- Clarification if the 3rd party equipment is also subject to the 95% uptime rate. If so, which ones?</p>	<p>The third-party equipment is not subject to the 95% uptime rate. However, all third-party equipment/items should also have a five (5) year warranty on parts and services per undertaking by the bidder/supplier</p>
Page 38	<p>X. ORIENTATION AND FAMILIARIZATION</p> <p>The trainings for the PET-CT system must have:</p> <ol style="list-style-type: none"> a. One (1) month off-site clinical training for two (2) clinical staff on PET-CT applications for oncology, neurology and cardiology viewing/reading and analyses. b. One (1) month off-site training for eight (8) technical staff on PET-CT operation, periodic Quality Control tests, maintenance, and troubleshooting. c. One (1) month on-site training for ten (10) technical staff and two (2) clinical staff. 	<p>- Request to make point "b. One (1) month off-site training" to be more specific.</p> <p>Example:</p> <ol style="list-style-type: none"> a. Biomed – 5 days – system trouble shooting b. Technologist – 10 days – PET-CT operations observer 	<p>The trainings for the PET-CT system must have:</p> <ol style="list-style-type: none"> a. One (1) month off-site clinical training for two (2) clinical staff on PET-CT applications for oncology, neurology and cardiology viewing/reading and analyses. b. One (1) month off-site training for eight (8) PET-CT technical staff. <ol style="list-style-type: none"> i. Four (4) Technologists - 10 days on PET-CT operations ii. Two (2) Medical Physicists - 10 days on Dosimetry and QA/QC tests iii. Two (2) Engineers- 10 days on maintenance and troubleshooting c. One (1) month on-site training for ten (10) technical staff and two (2) clinical staff.
Page 44	<p>D. SOFTWARE PACKAGES</p> <ol style="list-style-type: none"> 1. Must provide free lifetime updates and upgrades 	<p>- A certification that is issued by the manufacturer to this effect should be submitted</p>	<p>A certification or undertaking that is issued by the manufacturer to this effect should be submitted</p>

<p>Page 46</p>	<p>E. WORKSTATION/SERVER</p> <p>1. Minimum of five (5) workstations with concurrent access and have optimum hardware specifications as recommended by the manufacturer inclusive of DVD writer with appropriate government license for archiving of images.</p> <p>a. Four (4) workstations with dual monitors (medical grade) for Physicians</p> <p>b. One (1) workstation with medical grade monitor for Technologists</p> <p>c. Each workstation with Uninterrupted Power Supply (UPS)</p>	<p>- Please confirm the following:</p> <p>a. All 5 workstations can be used at the same time</p> <p>b. All 5 workstations can use the same application / program / post-processing at the same time.</p> <p>- A certification that is issued by the manufacturer to this effect should be submitted</p>	<p>a. All 5 workstations can be used at the same time;</p> <p>b. All 5 workstations can use the same application / program / post-processing at the same time.</p> <p>- A certification that is issued by the manufacturer to this effect should be submitted</p>
<p>Page 46 C 47</p>	<p>F. QUALITY CONTROL (QC)</p> <p>3. Must provide necessary test tools.</p> <p>a. PETCT system phantoms</p> <p>b. NEMA phantoms</p> <p>c. ACR phantoms</p> <p>d. Jaszczak phantoms</p> <p>e. Check sources as appropriate</p> <p>f. CT ion chamber with reading or data logging unit compliant with applicable IEC standards for CTDI measurements</p>	<p>- Please consider replacing Jaszczak with Esser Flangeless Deluxe PET Phantom</p>	<p>F. QUALITY CONTROL (QC)</p> <p>3. Must provide necessary test tools.</p> <p>a. PETCT system phantoms</p> <p>b. NEMA phantoms</p> <p>c. ACR phantoms</p> <p>d. Esser Flangeless Deluxe PET Phantom</p> <p>e. Check (sealed) sources as appropriate</p> <p>f. CT ion chamber with reading or data logging unit compliant with applicable IEC standards for CTDI measurements</p>

Page 47	<p>G. ACCESSORIES</p> <p>1. Uninterrupted Power Supply (UPS) for the PETCT system with a battery run-time of ≥ 30 mins. There should be a separate UPS system for each PET AND CT system.</p>	<p>- We suggest considering a one (1) unit UPS that can support both CT and PET Gantries</p>	<p>The proposal to use a single UPS unit, with a battery run-time of ≥ 30 mins, for both the CT and PET gantries is acceptable, provided that its capacity and specifications fully support the total power requirements (electrical load) of both PET and CT systems.</p>
Page 48	<p>4. One (1) Unit Dual Barrel Automatic Contrast Injector</p> <p>a. With contrast dose management software and workstation</p> <p>Must be delivered with at least 100 pcs Syringe set</p>	<p>- Please clarify on what is expected for the "contrast dose management software and workstation"</p>	<p>4. One (1) Unit Dual Barrel Automatic Contrast Injector</p> <p>a. With integrated workstation for contrast dose management (enterprise software/application)</p> <p>b. Must be delivered with at least 100 pcs Syringe set</p> <p>Note: Automated functions of the contrast dose management application can be an add-on with no cost on the procuring entity.</p>
Page 48	<p>H. TRAINING</p> <p>Off-site training for one (1) month for eight (8) technical staff on PETCT operation, periodic Quality Control tests, maintenance, troubleshooting, and onsite local training for at least ten (10) technical staff.</p>	<p>- Request to be more specific</p> <p>Example:</p> <p>a. Biomed – 5 days – system trouble shooting</p> <p>Technologist – 10 days – PET-CT operations observer</p>	<p>The trainings for the PET-CT system must have:</p> <p>a. One (1) month off-site clinical training for two (2) clinical staff on PET-CT applications for oncology, neurology and cardiology viewing/reading and analyses.</p> <p>b. One (1) month off-site training for eight (8) PET-CT technical staff:</p> <p>i. Two (4) Technologists - 10 days on PET-CT operations</p> <p>ii. Two (2) Medical Physicists - 10 days on Dosimetry and QA/QC tests</p> <p>iii. Two (2) Engineers - 10 days on maintenance and troubleshooting</p> <p>c. One (1) month on-site training for ten (10) technical staff and two (2) clinical staff.</p>

Bid Bulletin/Supplement No 1:			
Page 51	<p>Section VIII. Checklist of Technical and Financial Documents</p> <p>Financial Documents (1) The Supplier's audited financial statements, showing, among others, the Supplier's total and current assets and liabilities, stamped "received" by the BIR or its duly accredited and authorized institutions, for the preceding calendar year which should not be earlier than two (2) years from the date of bid submission (2023 and 2024)</p>	<p>- Consider reducing the documents to be submitted - 2022 and 2023's Financial Statements only. Since the filing for 2024 audited financial statement for the private will only be in April 2025, the 2024 FS will not be available before the submission of bids.</p>	<p>Agree with the proposal below and will be accepted.</p> <p>2022 and 2023's Financial Statements are acceptable.</p>
Bidding Forms:			
Page 53 to 63	Bidding Forms	<p>- Please clarify if we will use the sample bidding forms template of "Name of the Project" on each form or stick the Name of the Project stated in Section II. Instructions to Bidders No. 1 Scope of Bid which is the - <u>"SUPPLY, DELIVERY, INSTALLATION, TESTING, COMMISSIONING, ROOM PREPARATION AND FINISH, AND LICENSING OF ONE (1) LOT BRAND NEW WHOLE BODY DIGITAL PET-CT SCANNER AND ACCESSORIES FOR THE NUCLEAR MEDICINE RESEARCH AND INNOVATION CENTER (NMRIC) LOCATED AT THE DEPARTMENT OF SCIENCE AND TECHNOLOGY – PHILIPPINE NUCLEAR RESEARCH INSTITUTE COMPOUND"</u> to</p>	<p>Use this project title on each forms which is the – "SUPPLY, DELIVERY, INSTALLATION, TESTING, COMMISSIONING, ROOM PREPARATION AND FINISH, AND LICENSING OF ONE (1) LOT BRAND NEW WHOLE BODY DIGITAL PET-CT SCANNER AND ACCESSORIES FOR THE NUCLEAR MEDICINE RESEARCH AND INNOVATION CENTER (NMRIC) LOCATED AT THE DEPARTMENT OF SCIENCE AND TECHNOLOGY – PHILIPPINE NUCLEAR RESEARCH INSTITUTE COMPOUND"</p>

For guidance and information of all concerned.



VALLERIE ANN T. SAMSON, Ph.D.
Chairman, Bids and Awards Committee