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Caisse Nationale de Sécurité Sociale- CNSS

REFERENCE HOSPITAL PROJECT: SAINT PEREGRIN

Tender Specifications

ACQUISITION, INSTALLATION AND MAINTENANCE OF OPHTALMOLOGY EQUIPMENT

TECHNICAL SPECIFICATIONS

CONSTRUCTION PROJECT OF THE SAINT PEREGRIN REFERENCE HOSPITAL

OPHTHALMOLOGY EQUIPMENT

DC N°____/
Date:.....

This scope statement takes place during the creation of the new Saint Pérégrin hospital in Lomé, Togo. This hospital will bring healthcare solutions of great quality at an affordable price for the local population. The ambition of this hospital is to become a reference in Togo with occidental standards of quality thanks to the best training of the medical team and the accreditation of the staff and equipment.

The hospital, which constructions have started, is in Lomé in the Agoenyive district at the intersection of the "nationale 1" road and the main ring road. Therefore, the road access is excellent from the harbour.

The healthcare offer of this new hospital of reference will be deployed on the whole Lomé agglomeration (1,500,000 inhabitants). The planned activity in ophthalmology is 13 consultations per day mostly for the following reasons: infectious diseases (conjunctivitis), routine consultations and aging pathologies. As for the ophthalmological surgeries, it will mostly consist of cataract treatments and glaucoma.

In that regard, this specifications document's goal is to present to the different suppliers of ophtalmology equipment the needs of the hospital and its expectations. As the opening of the hospital is planned to be during the first trimester of 2020, every supplier who will receive this document will have to emit an offer in the six (6) weeks following the receipt of these specifications.

This document presents the technical specifications of the expected solutions. This document will be attached to the administrative specifications document.

1. The needs

1.1. The different lots

Hereafter is a non-detailed list of the lots included in this document:

- One (1) slit lamp,
- One (1) auto-kerato-refractometer,
- One (1) ophthalmic operating microscope.

Every lot described hereafter represent an **inseparable** lot. Every supplier will be able to apply for all or a part of the lots. Furthermore, each supplier will be able to make more than one offer for each need which will be evaluated separately. The lots are going to be described more in detail below.

1.2. Lot n°1: slit lamp

As listed above, this lot includes one (1) slit lamp which will be used during ophthalmic consultations. The device offered shall be fixed, composed of converging binocular tubes, a light source and a chinrest for the patient. It will be mandatory to describe the following elements in each offer:

- The maximal and minimal slit lengths and widths,
- The light source (LED or halogen for example),
- The different magnification factors available,
- The available filters,
- The available movement (horizontal, vertical, longitudinal, ...).

Option: possibility to include a motorised table with the device in the offer.

The expected device is not a digital one, however, each supplier will be able to make a variant including a digital slit lamp and a screen.

1.3. Lot n°2: auto-kerato-refractometer

As listed above, this lot includes one (1) auto-kerato-refractometer which will be used during ophthalmic consultation. This device shall be able to make measures of refractometry and keratometry with at least the following measurement modes: K/R mode, REF and KER.

For the refractometry, shall be detailed:

- The spherical refractive power range (0,25D steps maximum),
- The cylindrical refractive power range (0,25D steps minimum),
- Axial angle measurement range (1mm steps maximum),
- The maximum and minimum pupil distance measurement (in mm),
- The minimum pupil diameter measured (in mm).

For the keratometry, shall be detailed:

- The corneal curvature radius measurement range and its steps (in mm),
- The corneal astigmatism measurement range and its steps (in D),
- The corneal refractive power measurement range and its steps (in D).

Also, in each offer will be detailed the following elements:

- The size and weight of the device,
- The screen category and its size,
- The voltage,
- Any other option or parameter judged as essential.

1.4. Lot n°3: ophthalmic operating microscope

As listed above, this lot includes one (1) ophthalmic operating microscope. The microscope offered must be appropriate mostly for manual cataract surgeries. The expected microscope must be a floor standing type with lockable wheels. In every offer the following parameters will be detailed:

- The binocular inclination (at least 45°),
- The magnification of the binocular tubes (minimum 12,5x),
- The working distance of objective lens F (at least F=200mm),

- The total magnification range,
- The available fields of view,
- The light source,
- The available filters (at least UV filter and heat absorbing filter),
- The possible horizontal and vertical movements,
- The sizes and weight of the device,
- The voltage.

Options: the following options can be **added** in the offer:

- A foot switch for motorized step zoom and focusing,
- An assistant binocular microscope,
- A video recording system with a screen to see the surgery,
- Any other option judged as necessary by the supplier can be detailed.

2. Acquisition, implementation and maintenance

The handling, delivery and installation of the devices are part of this call for tender. Every chosen supplier will have to deliver, install and set-up its devices on-site.

2.1. Delivery modalities

For every device, the on-site delivery will be included in the offer and in the incoterm used (Incoterms® 2010 version), therefore, the supplier shall take care of it. This delivery will have to be made during the first trimester of 2020, the exact date will be determined with the architect in charge of this project. The supplier will give every information about the shipment process, the delivery time and the customs clearance modalities in Lomé, Togo. The reception modalities will also have to be described. It is important to remind that the Purchaser (CNSS of Togo) is exonerated of taxes and customs clearance thanks to its status.

2.2. Implementation

Every supplier is committed to give with each offer an implementation project of the equipment and will take care of the installation upon delivery of the devices. Every offer will include all the necessary devices for an optimal use of the solution, including the installation accessories.

It will be the supplier's missions to:

- receipt on-site the delivery, unload the equipment, check and install them;
- restore any goods deteriorated during the installation process,
- ensure the various informatic and electric interfaces between the newly installed devices and those already installed,
- coordinate the whole operation and manage the potential subcontractor working on behalf of the supplier.

The Purchaser's duty will be to:

- prepare the appropriate electrical alimentations,
- ensure that the site is ready to install the devices according to the supplier's information.

Every supplier will make an appointment with the hospital's biomedical engineer before the implementation date. During the implementation, the supplier will give a list of trials or quality controls which will have to be made and he will train the future users of the device(s). Each supplier will make a delivery, implementation and training planning.

2.3. Formation

The supplier will include in its offer the method, place and cost of the formation of two engineers or technicians, employed by the Purchaser, so they can be able to realise maintenance and repairs of first level. A formation onsite will be preferred. The intervention of an engineer or technician from the Purchaser's team does not exonerate the supplier from its duties.

The supplier shall also include an appropriate training of the devices to the future users in order to ensure their proper use.

A training on the appropriate cleaning and disinfection procedures will also be given to the hospital's staff.

2.4. Warranties and maintenance

Important point in the evaluation of the different offers and turning point for the hospital. Hereafter a non-exhaustive list of information that will have to be given in that regard:

- the warranty period,
- the existence of a hotline for the technical team and its availabilities,
- the amount of annual preventive maintenance,
- the amount of quality controls planned,
- the presentation of the potential subcontractors or technical partners that could intervene on behalf of the supplier,
- the location of the technical(s) team(s) and the **warranted** intervention time on-site,
- the details on where the spare parts will come from and the **warranted** delivery time (including shipment, delivery to Togo, customs clearance and delivery on-site),
- the warranted time to put back to work a device,
- the possibility to have a stock of usual spare parts on-site or some spare devices,
- the annual availability time warranted for each device,
- the potential warranty extension after a curative intervention,
- etc.

For each device included in an offer, the supplier will include a warranty which will last at least one year, starting at the first use of the device. During this warranty period, the devices will be under a **total** warranty from the supplier and he will take care of everything if an intervention is needed (spare parts, workforce, travel, ...). The preventive maintenance will also be included in the warranty.

A lending modality will be discussed in order to ensure the service continuity of the hospital in case of failure. The possibility to have a stock of spare parts/devices on-site which will be used only for that purpose will also be considered.

The preventive maintenance frequency will also be specified for each device. Every supplier will be responsible of the maintenance, whether he takes care of it himself or he delegates it to a subcontractor. After any intervention, the device will be able to accomplish the same initial functions in the same initial safety conditions.

2.5. Penalties if the commitments are not respected

If any of the commitments taken by the supplier is not respected (delivery time, intervention time, time to bring back to work, annual availability, ...) then penalties shall be applied. These penalties will consider the loss of activity related to the impossibility to use the equipment and the impossibility to take care of patients in a critical situation. In that regard, every supplier will mention its usual penalty policy. These policies are going to be discussed independently for each device.

2.6. Presentation of local partners or distributors

If any of the missions described before were to be realised by one of the supplier's partner or distributor, he will be identified and presented in the offer. The supplier will prove that his partners/distributors have the necessary skills to complete their tasks and he is also responsible of the quality of their interventions. If it turns out that one of his partners/distributors were not qualified to complete their tasks, then the supplier is committed to complete those tasks and he will take care of any resulting extra costs.

3. Expected characteristics of the devices

3.1. Accreditations: CE, FDA, other

In order to ensure the quality of the devices and to ease the future accreditation strategy of the hospital, priority will be given to the devices which have recognized accreditations such as CE marking or the FDA approval. The suppliers will precise, for each device and each disposable in the offer, every marking, norms, agreements and certifications it has, and he will provide these documents in his answer.

3.2. Available interfaces and communication processes

3.2.1. User interface

In order to ensure an optimal use of the equipment, the following criteria must be considered:

- ergonomics and ease of use of the solution,
- interfaces in French or in English,

• user manual in French or in English.

3.2.2. Electronic interfaces

It is agreed that all electronic interface and various ports should be listed:

- Ethernet (norm and output detailed), Wi-fi, Bluetooth, RS232, USB, etc.;
- electrical alimentation from solar panels and batteries through an inverter.

3.2.3. Data transfer protocols

The supplier will precisely define the available data transfer protocols between the device, the different acquisition or treatment systems and the central information system. These protocols will be open source and available.

4. Evaluation criteria

Every offer submitted will be evaluated with the following criteria:

- the quality of the commitments taken for the maintenance and warranty,
- the global cost of the solution (devices, maintenance, disposables, ...),
- the technical and functional characteristics of the solution,
- the user friendliness of the solutions,
- the available certifications,
- the supplier's presence in Western Africa and in Togo,
- the respect of Saint Pérégrin's opening planning.

Every supplier who will emit an offer will receive an answer, whether it is a positive or negative one. The suppliers whose offer have been selected will be invited to present their solutions in front of the team in charge of implementing the hospital.

5. Expected answer

Every offer presented by a supplier shall contain:

- information about the supplier and the constructor (if different),
- the extend of the offer,
- the total cost of the solution over 8 years including the equipment, the transport, the installation, the maintenance and the disposables;
- a complete description of the associated software,
- the technical documentation of all devices included in the offer,
- the environmental limits (hygrometry, temperature, air treatment, ...),
- the maintenance contract and the warranty,
- a list of spare parts which could be stocked on-site and their amount,
- references of similar project realised by the supplier in Africa and Western Africa with similar devices and possibility to contact those clients,
- general sell conditions,
- delivery and installation time of the solution,
- official document of CE mark, FDA accreditations and any other accreditations available;
- user manuals,
- cleaning and disinfection procedures,
- any other technical and commercial document the supplier wants to share.

By default, all these documents shall be given in French. If these documents are not available in that language or cannot be translated, they can be given in English. Any document in another language will not be considered.