Question 1: ***The delivery time mentioned in the tender documents is 3-4 weeks after contract signature.***
This is a very short delivery time, especially since this is an international tender and companies will have to ship the goods from all over the world. Therefore we would like you to clarify if a longer delivery time is acceptable, for an international tender like this, with these amounts and this kind of equipment, a delivery time of at least 90 days after signing of contract is common practice.

Answer 1: Pursue to Section II. Bid Data Sheet (BDS), clause ITB 34.6, and Section III. Evaluation and Qualification Criteria, paragraph 2.1. Evaluation Criteria (ITB 34.6), Deviation in Delivery schedule/ Delivery Schedule is not a factor of the evaluation. On the other hand, the delivery time is calculated based on the successful previous experience of the Ministry of Health in the last 3 years where medical equipments of the same nature including MRI and angiograph are purchased and successfully delivered within the period of 3 until to 4 weeks from the date of contract signature.

Question 2: ***The tender documents mention that all bidders are required to be licensed. Our question is, if it is also acceptable to include an authorized local representative with this license in our offer, without having the license ourselves.***

Answer 2: With reference to the Bidding Document, Bidding Section, GCC 8.1 "The governing law shall be the law of*:* **Republic of Albania"** , hence According to the Albanian Law 89/2014 "On medical devices", all items required under this Bidding Documents should be registered in the National Agency for Drugs and Medical Devices (http://www.akbpm.gov.al/urdheri.pdf). This requirement is mandatory only for the successful bidder, who will be selected for contract award. Furthermore the above mentioned Albanian law is based on the European directives on medical devices and has been notified by World Trade Organization (WTO).

All vendor bidders, who choose to submit their bid, are required to be licensed by the Ministry of Health for wholesale trade of medical equipment in Albania. Authorization for wholesale trade of medical equipment in Albania is issued from the responsible department of Ministry of Health within a period of 15 days, from the moment of application as consequence all bidders are required to be licensed from the Ministry of Health for wholesale trade of medical equipment in Albania. If a bidder is joint venture where the authorized local representative is a member of JV, then this is acceptable. All bidders located outside the purchaser country and having authorization for wholesale of medical devices in their country of origin are accepted. **(Provision Amended from MoH)

Question 3: **In relation to ITB 11.1 (j) and the requirement for "The authorization for wholesale of medical devices issued by the Ministry of Health, according to the law 89/2014 "On medical devices" – could you please confirm that a bidder located outside the purchaser country and having authorization for wholesale of medical devices in its country of origin will**

be applicable at the time of tendering and it will be allowed to obtain further authorization from the Ministry of Health in the country of Albania in case of being chosen for a contractor?

Question 6 (2): ITB 11.1.(j) - Point h) The authorization for wholesale of medical devices issued by the Ministry of Health, according to the law 89/2014 "On medical devices".
We understanding that the above authorization is mandatory for the participation in this bid.
Please advise whether the license of our national representative is sufficient to address this requirement or whether the bidder (i.e. our company) has to obtain this license directly.
In this latter case, please let us have information on the procedure to be followed (documents required and instructions) and on any costs to be borne for licensing release.

Answer 3 and 6(2):

With reference to the Bidding Document, Bidding Section, GCC 8.1 "The governing law shall be the law of*:* **Republic of Albania"** , hence According to the Albanian Law 89/2014 "On medical devices", all items required under this Bidding Documents should be registered in the National Agency for Drugs and Medical Devices (http://www.akbpm.gov.al/urdheri.pdf). This requirement is mandatory only for the successful bidder, who will be selected for contract award. Furthermore the above mentioned Albanian law is based on the European directives on medical devices and has been notified by World Trade Organization (WTO).

**All vendor bidders, who choose to submit their bid, are required to be licensed by the Ministry of Health for wholesale trade of medical equipment in Albania. Authorization for wholesale trade of medical equipment in Albania is issued from the responsible department of Ministry of Health within a period of 15 days, from the moment of application as consequence all bidders are required to be licensed from the Ministry of Health for wholesale trade of medical equipment in Albania. If a bidder is joint venture where the authorized local representative is a member of JV, then this is acceptable. All bidders located outside the purchaser country and having authorization for wholesale of medical devices in their country of origin are accepted.

The procedure to be followed for receiving the authorization for wholesale of medical devices (documents required and instructions), are detailed prescribed in the Bidding Document, page 38 up to page 42 (Albanian and English version). Additional and detail information on this issue , you may receive by clicking: http://www.akbpm.gov.al/urdheri.pdf (provided in the ITB 16.4 provision). **(Provision Amended from MoH)**

Question 4: In relation to ITB 11.1 (j) and the requirement for: "The Bidder should demonstrate average annual turnover of at least a minimum amount of 1.5 time of the lot/s price/s he is quoting for, in one of the last five (3) years. Copies of its audited financial statements for the past three fiscal years (2015, 2014,2013) should be submitted to support this requirement. "

Answer 4: According to Section III. Evaluation and Qualification Criteria, paragraph **3.1 Post qualification Requirements (ITB 36.1), part** (iii) The Bidder shall also submit the following additional documentations:

(b) The Bidder should demonstrate average annual turnover of at least a minimum amount of 1.5 time of the lot/s price/s he is quoting for, in one of the last three (3) years. Copies of its audited financial statements for the past three fiscal years (2015, 2014,2013) should be submitted to support this requirement.
Consequently the same requirement is applicable in the **ITB 11.1 (j) paragraph (d).**

Question 5: **ITB 11.1 (j): point i – bidder must be certified ISO9001 for the import, marketing, installation maintenance of medical equipment.** With reference to the ISO9001 certification requested for the Bidder, could you please confirm that the ISO certification related to the ***"Design and provision of operation and maintenance services in global management services"*** is accepted?

Answer 5:
The purpose of the requirement that the economic operator must be equipped with ISO 9001 certificate will ensure the system quality management, this certification is accepted globally despite the size of the organization or the services it provides. For this reason it is important that bidders should be equipped with such certificate which will assure a quality management system, that in relation to the type of the organization that owns it might be for import, marketing, installation maintenance of medical equipment or design and provision of operation and maintenance services in global management services etc., according to the scope of the organisation.

Question 6(1):

ITB 11.1.(j) - Point a) Manufacturer's Authorization
please let us know whether pdf. or scanned versions of the Manufacturer's Authorizations are acceptable.

Answer 6(1)- Manufacturer's Authorization should be submitted in original version, as per the form included in Section IV, Bidding Forms.

Question 7: ITB 11.1.(f) - Point (ii) The bid documents states that "the Bidder has been duly authorized by the manufacturer of the Goods that meets the criteria under (i) above to supply the Goods in the Purchaser's country".
Please confirm whether the above requested authorization corresponds to the Manufacturer's Authorization as per format attached to the bid documents.

Answer: 7. The requested authorization under ITB 11.1.(f) - Point (ii) corresponds to the Manufacturer's Authorization as per format attached to the bid documents, which should be submitted in original version only.