

INVITATION OF EXPRESSION OF INTEREST FOR TOT OF MEDICAL ELECTRON LINAC

Ref: SMR/MED2/EOI/01/2021

The clarification for the queries raised by the industry participants in the first pre-bid meeting

S. No.	Point of Clarification	Clarification
1	<p>It will be helpful if the list of tests it has already cleared and the tests which are pending be listed. Also information on time frame within which the final approval will be available may be given for informed decision making at our end.</p> <p>Whether SAMEER will complete the listed pending / to be done technical works before handing over the technology or the manufacturing company will have to complete?</p>	<p>In the first pre-bid meeting detailed presentation was made regarding status of various sub-system developed. It is also mentioned very clearly in the Eol document regarding present status of various sub-systems.</p> <p>As mentioned in the Eol document, SAMEER is transferring the technology "as is where is basis". That means SAMEER will provide know-how to the industry developed as on date and do the hand holding with industry for development of Dual Energy Medical Linac system. Hence it is expected that the industry partner will take-up responsibility of fabricating the 'regulatory approved' commercially deployable Medical Linear accelerator under guidance of SAMEER.</p>
2	<p>Does this mean that bidders who have an existing facility outside the AMTZ` and want to expand the same to undertake manufacture of Linac will not be eligible for this round of Eol.</p> <p>Setting up manufacturing plant in AMTZ is optional or mandatory?</p>	<p>This Eol has been jointly floated by SAMEER and AMTZ. Hence it is mandatory for industry to set up facility in AMTZ campus. However, since SAMEER is transferring this technology on a non-exclusive basis, if any Industry shows interest in the technology of Dual Energy Medical Linac system, but is not interested in setting up a facility in AMTZ, then SAMEER will invite separate Eol independently depending upon feedback from the industry.</p>

3	<p>Will the Type approval taken by SAMEER be valid for the TOT holders or will each ToT holder will have to take individual type approvals.</p> <p>Will SAMEER take responsibility or support in getting type approval of first Linac machine from AERB?</p>	<p>Industry partners have to take responsibility for getting type approval from regulatory body for the machine developed under this ToT. SAMEER will support industry partner in getting type approval.</p>
4	<p>Since various vendors for parts/sub-assemblies have been developed by SAMEER and the same will be recommended as part of TOT by SAMEER, will the bidders be required to sign individual obsolescence management and spares support agreements with them?</p>	<p>SAMEER will provide the list of vendors from whom SAMEER has procured the components for building the prototype. It is not mandatory to procure the components from the same vendors. Industry has freedom to choose different vendors if it suits their requirement.</p> <p>Industry has to take call on modalities suitable for making spares availability for service support of about 15 years.</p>
5.	<p>Kindly elaborate the limit of 66 months. Will the selected bidder be not able to produce the units after 66 months? Or Does it mean that no support will be available after 66 Months? What will be the status of machines under production, produced but not sold? Or Does it mean that SAMEER will provide updates/upgrades till 66 months. Request you to clarify the limitations of 66 months' timeframe.</p>	<p>The time period of technology transfer has been fixed for 66 months to start with. The committee formed by Director General, SAMEER will do periodic review of the progress made on transfer of technology under this EoI. The agreement can be renewed further based on the progress made.</p>
6.	<p>It would be helpful if budgetary price of the tube is provided to enable us to better understand the market positioning of the LINAC.</p>	<p>The cost of Linac tube and other services from SAMEER will be provided to eligible bidders only.</p>

7.	Kindly confirm that the machine fabricated as per the laboratory drawings will meet the specifications listed in the EoI document. Further in order to understand the effort required in generating manufacturing drawings, it is requested that a sample laboratory drawing be provided. Who will confirm accuracy of manufacturing drawing generated by ToT holder? Will SAMEER undertake any audit process before commencing production of individual parts. Can SAMEER provide manufacturing drawings instead of laboratory drawings.	Machine fabricated as per the laboratory drawings will meet the specifications. SAMEER will provide only laboratory drawings. Sample drawing would be provided only to eligible bidders. SAMEER would not undertake any audit of the drawings.
8.	It is requested that a budgetary expense which a ToT holder will have to make in T&M Equipment be provided to enable the bidders to make an estimate of the capital cost of the project.	The list of T&M equipment would be made available to eligible bidders if needed.
9.	Kindly clarify whether any difference in specifications exist for laboratory model and production model? Will the production models have to be within the same tolerance as the laboratory model?	The specification of the laboratory model are mentioned in detail in the section 2.4 of EoI. Industry partner is expected to achieve minimum these specification for the Medical Linac system developed under this ToT.
10	It would be helpful to us in case SAMEER can give a likely date of completion for activities marked Not Tested, Testing in progress and Tested at Low power.	SAMEER is transferring the technology "as is where is basis". Though SAMEER will continue its work on Dual Energy Linac system, it is expected that the industry partner will take-up responsibility to complete the further work under guidance of SAMEER expert and fabricate one model/piece of the 'regulatory approved' commercially deployable Medical Linear accelerator within 30 months from the date of signing the ToT agreement.

11	It will be helpful if SAMEER could provide tentative cost of the machine that has been built so as to enable bidders to accurately estimate the market positioning for the product.	It will be difficult for SAMEER to provide tentative cost of the machine as SAMEER has not developed the machine as commercial activity. SAMEER has developed various technologies required for building the machine under the research program over a long period of time and with large investments and hence the cost of the machine as expected is not available at this point.
12	Kindly clarify whether this royalty is to be paid on perpetual basis on only for machines sold within 66 months of ToT.	Royalty should be paid on perpetual basis.
13	Can dose rate be enhanced to 600MU/ min traditionally at par with other manufacturers or there is limitation?	Industry partner may upgrade the specifications on their own subsequent to making first machine as per specifications given in the EOI document, to make it at par with other manufacturers. However as far as ToT is concerned, SAMEER will provide the knowhow for the specifications mentioned in the section 2.4 of EoI.
14	Which TPS will be incorporated with this Linac. Has it been tested and certified ok?	TPS is bought out item. SAMEER has bought LinaTech make TiGRT TPS. The integration of TPS with system is pending.