

Nota van inlichtingen "EA Micro CT - Erasmus MC"

Nr.	Uw vraag heeft betrekking op	Verwijzing naar tekst in aanbestedingsdocumenten (bijlage en paginanummer, tekstpassage)	Concrete vraag	Antwoord
1	Excel sheet "Programma van Eisen"	#1 "Gantry based X-ray tube and flat pannel detector" is requested.	Question: would another X-ray specific detection method that is not flat panel based be considered as meeting the minimal criteria if this detector would secure the same applications as requested in the overall tender like lung or cardiac gating?	The "Eis" is based on state of the art configurations for the intended equipment as defined based on the previous market consultation. Alternative configurations that are proven better than or equivalent to the requested configurations will also be considered. The equivalence must be demonstrated by the Tenderer
2	Excel sheet "Programma van Eisen"	#5 "High speed flat panel detector" (up to 100 fps).	Question: As in request #1 this seems the same request again for a flat panel detector. Again, would an alternative detection solution that would secure proven lung and cardiac applications be considered as equal solutions?	The "Eis" is based on state of the art configurations for the intended equipment as defined based on the previous market consultation. Alternative configurations that are proven better than or equivalent to the requested configurations will also be considered. The equivalence must be demonstrated by the Tenderer
3	Excel sheet "Programma van Eisen"	#8 "Built-in shielding and interlocks to meet cabinet X-ray systems 21 CFR 1020.40"	Question: As the FDA/21 CFR 1020.40 is valid for the US and the FDA even makes the statement that "...it does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. ..." Thus, we would asked if the tenderer is willing to consider alternative but similar certifications likewise from the NFC, TUV, IEC/EN, etc. as equally valuable as long as those fulfilling the requirements of being a built-in shielded X-ray system with security interlocks that meet fully shielded X-ray cabinet conditions and thus meet European X-ray laboratory standards?	The "Eis" is based on state of the art configurations for the intended equipment as defined based on the previous market consultation. Alternative configurations that are proven better than or equivalent to the requested configurations will also be considered. The equivalence must be demonstrated by the Tenderer

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4	Excel sheet "Programma van Eisen"	#10 "Integrated image acquisition and reconstruction computer with local area network connection".	Question: does by "integrated image acquisition and reconstruction computer" being meant that it would be physically integrated or would it be allowed to have this integrated in form of an software integration; i.e. the workstation would be provided but would not be part of the main scanner to secure easy serviceability, fast and reliable swop options but would still be deeply integrated within the overall workflow via an integration in the scanner by driving its acquisition and reconstruction. If an physical /in-system integration is meant, would it be allowed to offer an alternative via a frontend-integration and remote/LAB based backend that would enable users to operate the scanner in a BSL or SPF environment but would keep the benefits available for the end user like office access to DVD/CD-ROM, USB ports without having the need to enter the SPF area. Next to this it would allow fast swops and immediate serviceability without SPF-required decontamination procedures and thus extend the overall lifetime of such a backend workstation.	In this "eis" integration refers mainly to functional integration than to fysical integration. It is however mandatory that users can reconstruct and view data by the scanner in order to, if needed, adjust acquisition parameters for a next scan.
5	Excel sheet "Programma van Eisen"	#38 Complete system complies with CE and TUV standards.	Question: Would next to the European CE certification instead of the TUV certificate another similar/equal certificate likewise from the NFC, IEC/EN, etc. be considered as fully equally?	Alternative certificates that are proven better than or equivalent to the requested certification will also be considered. The equivalence must be demonstrated by the Tenderer.
6	Excel sheet "Programma van Wensen"	#7: "Removable and cleanable gantry covers".	Question: We understand that the user likes to protect the X-ray source, detector and system from contaminations. However, we would asked if an alternative solution would be considered as equally valuable and fulfilling the needs that would secure the previous mentioned concerns?	The "Eis" is based on state of the art configurations for the intended equipment as defined based on the previous market consultation. Alternative configurations that are proven better than or equivalent to the requested configurations will also be considered. The equivalence must be demonstrated by the Tenderer
7	Excel sheet "Programma van Wensen"	#12 "Number of user removable X-ray Al/Cu filters."	Question: we consider that the removable means that the filters can be selected i.e. exchanged? Can you confirm.	In deed we meant to express that filters can be exchanged by the users as required for the specific purpose
8	Excel sheet "Programma van Wensen"	#14 "Max detector frame rate (frames per sec)"	Question: As already mentioned previously: Would it be allowed to offer a detector that would fulfill the same in vivo analysis performance and would be ranked equally valuable that would not be founded on a flat panel and thus would have slightly different frame rates. While having different frame rates we would prove by example that with this offering there would be no limitation vs a >100 fps flat panel detector and thus could be considered absolutely equivalent. Pls confirm.	The "Eis" is based on state of the art configurations for the intended equipment as defined based on the previous market consultation. Alternative configurations that are proven better than or equivalent to the requested configurations will also be considered. The equivalence must be demonstrated by the Tenderer

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9	Excel sheet "Programma van Wensen"	#18: "Max sample/animal weight (g)"	Question: Here up to 5 kg are requested which not really reflects a small animal micro-Ct anymore as the normal range for rodents is in between 20-30 g (mouse) or 400-500 g for rat micro-CT imaging; If here samples with >2 kg are requested pls confirm.	Because of the function of the machine in the imaging Core Facility we need to ensure that as many as possible small animal imaging can be accommodated. And small animal imaging is not limited to mice and rats but also includes e.g. guinea pigs, ferrets and rabbits. Therefore we included this in the "wensen".
10	Excel sheet "Programma van Wensen"	#19: "Direct animal observation through a X-ray protective transparent window."	Question: A direct observation window would require that the user is always focused on the window. Would an alternative, more integrated indirect solution be considered as valuable that was approved by e.g. an ethics committee recently and that would allow to instantly monitor the animal's welfare?	The "Eis" is based on state of the art configurations for the intended equipment as defined based on the previous market consultation. Alternative configurations that are proven better than or equivalent to the requested configurations will also be considered. The equivalence must be demonstrated by the Tenderer
11	Excel sheet "Programma van Wensen"	#25: "Reconstruction GPU NVIDIA with CUDA cores"	Question: Would it be allowed to offer a more advanced graphic card solution?	The "Eis" is based on state of the art configurations for the intended equipment as defined based on the previous market consultation. Alternative configurations that are proven better than or equivalent to the requested configurations will also be considered. The equivalence must be demonstrated by the Tenderer
12	Excel sheet "Programma van Wensen"	#26: "Computer integration into the scanner cabinet".	Question: Would it be considered also as advantageous if the computer would not be implemented in the scanner, however its functionality would be accessible from the scanner itself without having the need to leave the room? Please note that this would improve also the serviceability as well as non-SFP/BSL access to such a workstation vs an integrated solution?	In this "eis" integration refers mainly to functional integration than to physical integration. It is however mandatory that users can reconstruct and view data by the scanner in order to, if needed, adjust acquisition parameters for a next scan.
13	Bijlage 5 AIV - Algemene Inkoopvoorwaarden NFU 2016		Would it be possible to have the "Algemene Inkoopvoorwaarden NFU 2016" in an English version?	Yes, see Annex "AIV - General Terms and Conditions NFU 2016.pdf"