Re: MITA Letter for Smart Dose Created on May 21st 2015

To Whom it May Concern:

Zetta Medical Technologies appreciates the clarifications presented by MITA in their letter authored by Mr. Thaddeus Flood and created on 2015-05-21. The details MITA offered in this letter gave guidance to our customer's understanding of the difference between products that comply with XR-29 standards and the ones that do not. Zetta Medical Technologies prepared answers to the questions presented. Our Dose Monitoring solution, Z-Dose[29],was developed to make CT scanners compliant with XR-29. These CT scanners are usually classified by the OEMs as non-compliant. **Z-Dose[29] makes your CT scanner compliant with the four attributes of XR-29 Smart Dose standards without the need to replace the scanner**. Z-Dose[29] is also vendor neutral so it can be transferred to other scanners you decide to purchase.

Zetta's responses to the MITA letter are below in Blue.

MITA Letter: Appendix A: Independent Vendor Evaluation Guide:

Vendors may offer modifications or solutions about dose management including some that claim will

make your CT equipment compliant with the Smart Dose Standard. We suggest you approach the

decision to purchase a solution with caution and consider the following factors:

1. Does the vendor provide a certification that the four required attributes have been integrated on

a particular piece of equipment? YES, after the installation of your Z-Dose[29] on your system, Zetta will perform training for your staff and demonstrate the performance of the Z-Dose[29] product on your scanner. Also Zetta will provide you with a certificate that the four required attributes have been integrated on your piece of equipment.

2. Assess the upgrade solution as it relates to each of the four attributes. Ask the vendor for detailed information on how their product meets each attribute.

a. Are invasive modifications to the CT system required? No invasive modifications to your CT scanner is needed or required.

b. Will an invasive modification be designed and performed by a vendor who is regulatory registered to do so. No invasive modification is needed to be installed on your scanner.

c. DICOM SR: Is a complete DICOM Structured Report generated (not just CTDIvol & DLP)? Yes, a detailed Structured Dose Report includes more than CTDIvol & DLP. It also provides accession number, patient name, facility name, CT model and type, CT serial number, Acquisition Protocol, Exposure Time,

Scanning Length in mm, Collimation Width, Number of X-Ray Sources, Study number, Physician name, CTDIvol, Number of Series, DLP per Series, Total DLP for the Study, etc… Data in this RDSR is transferable to the Patient's Records.

d. Dose Check: Do alerts and notifications appear on the operating console of the CT scanner prior to starting a scan? Yes, prior to scanning a Dose Alert and Notification appears in the Operating Console informing the operator of the exact value of the CTDI and confirming if the value is within the predetermined threshold dose range or not.

Does the system prompt the user to enter their name, diagnostic reason for exceeding the predetermined threshold, reconfirm the chosen protocol, and in some cases provide a password before proceeding to the scan? If the CTDI value is outside the predetermined threshold, the system prompts the user to provide a reason for exceeding the predetermined threshold and enter their name. The user also has the opportunity to modify the protocol parameters to reduce the dose and reconfirm prior to scanning.

e. AEC: Does the system use patient-specific parameters obtained during the scan setup process and/or continuously during the scan to modulate the X-Ray tube output? If not, can this feature be implemented without invasive modifications to the system? Your system must have AEC installed. Most CTs manufactured after 2002 should have AEC already installed. We will evaluate your system and inform you of the details and features including AEC.

f. Reference Protocols: Are reference protocols pre-loaded onto the CT system and developed with detailed knowledge of the system's specific performance characteristics and input from clinical collaborators? Yes, the scanner usually comes with preloaded protocols developed by the manufacturer. In addition our certified clinical applications specialists can help developed tailored protocols for your specific site and scanners.

3. If invasive modifications are required, will this modification void the OEM warranty? No invasive modifications are required. Either way, in most cases OEM warranty is only valid for one year after installation of the scanner.

4. Smart Dose Standard compliance requires these four, and only these four, attributes. There are no substitutes (e.g. iterative reconstruction) for any one or all of them that can make your equipment compliant or render any one or more of these four attributes unnecessary. Yes, Z-Dose[29] is a Smart Dose Monitoring solution and it covers these four attributes. Iterative Reconstruction is associated with CT Dose Reduction which is totally a different product.

5. Review the vendor product information and specifications.

a. Do you understand clearly how the product effectively upgrades your system to meet each of the four attributes? Zetta will give its customers all the details explaining how Z-Dose[29] installed on your scanner complies with the four attributes of the XR-29 standard.

b. Does this meet your understanding of how your system operates? No change to your system operations will take place with the integration of Z-Dose[29].   The added Dose notification and alert messages are self-explanatory but our Clinical Applications Specialists will demonstrate the product and can always be reached via our technical support toll free telephone number.

c. Does it sound possible and technically accurate? Our product will be demonstrated to assure you of full accuracy and compatibility with your scanner.

d. Does the vendor's response confuse you by referring to various other features not specifically related to the Smart Dose Standard? Only the four attributes of XR-29 standard (Smart Dose) will demonstrated and discussed.

Please ask us for additional detail, pictures and web-based demos.