DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

October 29, 2012

Dr. Larry Kelly
Chair
International Medical Device Regulators Forum

Dear Dr. Kelly:

DITTA greatly appreciates the opportunity to participate in the recent IMDRF meetings in Sydney. As pointed out in your recent letter, we were particularly grateful for the invitation to join you in a session of the Management Committee meeting.

We could not agree more on the usefulness of this opportunity to set the scene for future relations. As such, we would like to request that DITTA be invited to participate in the next meeting in France on 19 to 21 March 2013 and forthcoming Management Committee meetings. Our view is that engagement at this level is critical to reaching IMDRF's goal to address "the common public health regulatory challenges to convergence due to the globalization of medical device production and the emergence of new technologies."

Industry involvement at the Management Committee level is vital to advance the objectives laid out in IMDRF's terms of reference. Through DITTA, our industries stand ready as your partner to further those objectives. For those reasons we are also happy to directly contribute to two of the five selected work items of utmost importance: UDI and RPS. We were also delighted to hear about the progress IMDRF has made on those as well as on the three other items (Single Audit, Standards and NCAR process). DITTA is currently discussing those matters internally and will probably communicate our comments to the respective conveners.

We also would like to congratulate you for the plans for the new IMDRF website and are looking forward to its completion and the inclusion of GHTF legacy documents. The global imaging community will reap considerable benefit from this work, and we are preparing a statement of support on this topic.

DITTA greatly appreciates the Management Committee's further consideration during their session on 27 September of our proposal for a possible future IMDRF work item on medical software. Reasons which justified our suggested work item to IMDRF are that medical software is playing an increasingly greater role in medical technology in product-embedded software applications or in stand-alone software solutions. This includes but is not limited to aspects of software vulnerability with potential impact on patient safety. Therefore global harmonization of regulations and standards governing medical software is critical for patient safety as well as to the future innovation and prosperity of our industry. We are pleased to know that the Management Committee considers the nomination of "Developing International Harmonized Software Regulatory Environment" to be

both important and desirable. In response to your request, we will be happy to "provide a detailed submission on where you believe there is opportunity for convergence," specifically with regard to where early progress can be made.

We are happy to use the opportunity of this letter to inform you of the progress made within DITTA. Our membership is growing significantly with the recent addition of influential trade associations from Russia, China, Thailand and Brazil. In addition, DITTA recently approved four task forces to address international priorities important to our industries (UDI, RPS, Medical Software and Remanufacturing). This includes a DITTA task force on medical software comprised of industry software experts from around the globe whose mission will be to promote the global harmonization of medical software standards and regulations. This new task force will respond to your request by the end of the year. We look forward to working with the Management Committee as part of their agreement to further consider this proposal.

Finally, we very much appreciate IMDRF's openness to increased industry participation, and DITTA is glad to continue to actively participate in future IMDRF Management Committee meetings. Of course, based on topics of discussions we will nominate the appropriate representatives. DITTA's continued involvement will allow for broad representation of global medical imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers in your important work to accelerate regulatory convergence while maximizing public health and safety, our first priority.

Thank you again for your invitation to participate in the Management Committee meeting and the Stakeholder Session last month in Sydney. Should you have any questions, please feel free to contact us at your convenience.

Sincerely,

Gail Rodriguez	Nicole Denjoy	Mitsuro Tokugawa
DITTA Chair	DITTA Vice-Chair	DITTA Contact
MITA	COCIR	JIRA