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

DITTA Liaison Report
To ISO Technical Committee TC 210

The global diagnostic imaging, healthcare IT and radiation therapy industries represented by DITTA would like to share its liaison report with ISO TC 210 at the occasion of the meetings in Stochholm.

DITTA is pleased with its status as Type-A liaison partner to ISO/TC 210 and would like to table the following comments for consideration.

We would like to take the opportunity of this liaison report to kindly ask the ISO TC 210 to amend the full name of DITTA in ISO/TC 210 publications (such as N557) into: "*Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association*". For more information on DITTA, please refer to our website www.globalditta.org and general information given at the end of this document.

1. Comments on standard ISO 14971 for risk management

DITTA considers ISO 14971:2007 a world-class standard that is rightfully appreciated globally. The combination with Technical Report ISO/TR 24971:2013 fulfills adequately the market needs of medical device manufacturers worldwide. Should a question come up whether ISO 14971 must be confirmed, amended or revised, DITTA believes that there is no need for modification, or it is so small that even an amendment would cause more disturbance than benefit.

DITTA has considered the recent "Consensus Paper for the Interpretation and Application of Annexes Z in EN ISO 14971:2012" developed by the European Notified Bodies Recommendation Group (NBRG). This consensus paper identifies certain defects and misinterpretations in EN ISO 14971:2012. Given the major focus of ISO/TC 210 on "providing international standards that can be used as the basis for national or regional regulations",
DITTA suggests ISO/TC 210 to actively reach out to the European Standards Organization CEN to seek improvement of the Annexes Z of EN ISO 14971 as this is creating confusion among the industry and other stakeholders.

2. Comments on standard ISO 13485 for quality system management

DITTA supports the recent disapproval of ISO/DIS 13485. The international standard ISO 13485 is widely accepted and one of the most horizontal standards available in the medical devices area. Because of its wide acceptance, any proposal to change must be well substantiated and of the highest quality. DITTA considers that these conditions are not met for all proposed modifications and, if the absence of such conditions ***is structural***, recommends extension of the validity period of ISO 13485:2003 and discontinuing the revision project.

In addition, DITTA has learned that activities are being set up at national level for "light" versions of a QMS standard, for example, for use with medical apps. DITTA considers such national activities as undesirable, since they may lead to diverging national requirements and barriers to the exchange of products. Especially software and medical apps are not the best suitable products for national regulations. DITTA is a strong supporter of global regulatory convergence and international standards adopted unmodified nationally.

Therefore, DITTA suggests ISO/TC 210 to consider the following:

1. **Identify the most relevant and urgent modifications of ISO 13485 from the current DIS, and make a proposal for an amendment to the 2003 version, rather than pursuing a full revision of the standard;**
2. **If no relevant or urgent modifications are identified, refrain from modifying ISO 13485:2003, reconfirm the standard for a next validity period and discontinue the revision project;**
3. **Study very carefully the implications of adapting ISO 13485 to the new "High-Level Structure" that is currently being implemented by ISO;**
4. **Undertake an enquiry into the national activities for a "QMS light" standard for medical apps, and see whether a new work item for ISO/TC 210 could follow, or perhaps fit into a new revision process of ISO 13485.**

3. Support for the update of standard IEC 62366 for usability engineering

The revision of IEC 62366 is a project of Joint Working Group JWG4 between IEC/SC 62A and ISO/TC 210. DITTA supports the separation of the existing standard into two parts:

- IEC 62366-1, normative requirements;
- IEC/TR 62366-2, informative guidance and reference.

DITTA supports the shortly expected distribution of IEC/FDIS 62366-1, as it is a major improvement in clarity compared to the existing standard. The scope has been refined to emphasize that it is a safety standard, i.e. related to basic safety and essential performance. The relationship between the risk management decision-making process and the usability engineering design and development processes has been clarified. Overall, the new IEC 62366-1 standard is far more "usable" than the present one!

4. Comments on standard ISO 16142-1 for essential principles

DITTA supports the revision of ISO/TR 16142:2006 on Essential Principles (EP) of safety and performance and to split this standard in two parts:

- ISO 16142-1, General EP and additional specific EP for non-IVD medical devices;
- ISO 16142-2, General EP and additional specific EP for IVD medical devices.

DITTA is concerned that the requirements in the currently distributed DIS are insufficiently general at a global level. DITTA suggests ISO/TC 210 to consider carefully reviewing each EP and to determine whether changes are needed to make them appropriately general. It is noted that there has not been any update or maintenance of the Essential Principles after they were published by the GHTF, disbanded in 2012. DITTA recommends ISO/TC 210 to seek close cooperation with IMDRF and possibly also AHWP if the TC considers revising the Essential Principles.

DITTA supports the proposed restructuring, thereby permitting clearer mapping to (portions of) standards that can be used to fulfill the requirement. The current compound requirements are very difficult to map.

Thank you for your consideration.

Best regards,

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More about DITTA:

DITTA is the united global industry voice that represents medical imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers.

DITTA was originally organized in the years 2000 and was officially incorporated in 2012 as a non-profit trade association in the United States. DITTA aims at bringing their expertise to engage with governments and other stakeholders around the globe to promote innovation, improve market access and enhance global competitiveness in the medical imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical industries.