

IEC SC62A MT 23 Liaison Report to C63® SC8 12 November 2014

Jeffrey L. Silberberg FDA/CDRH

IEC SC62A MT23 Liaison Report

- Edition 4 of IEC 60601-1-2
 - Amendment 1 in progress
- IEC/TR 60601-4-2: Medical electrical equipment
 - Part 4-2: Guidance and interpretation –
 Electromagnetic immunity; performance of medical electrical equipment and medical electrical systems
 - Circulated on October 24 as 62A/971/CD
 - Comments due January 9, 2015
 - Former Annex J of 60601-1-2 Ed 4

- Performance TR
 - Assumption is that IEC 60601-1-2 testing has been performed
 - Extensive references to 60601-1-2 Ed 4
 - Recommends to combine -1-2 and -4-2 testing
 - Scope: This Technical Report applies to the ELECTROMAGNETIC IMMUNITY of the INTENDED USE of ME EQUIPMENT and ME SYSTEMS.
 - No emissions requirements (beyond 60601-1-2)

- Performance TR (cont'd)
 - Whereas immunity test levels in -1-2 are considered to be reasonably foreseeable maximum, immunity test levels in the TR are considered to be typical
 - Immunity test levels for home and hospital are the same
 - Ongoing debate in MT23 regarding the ESD immunity contact discharge test level (4 kV or 6 kV) (Air discharge is 8 kV)

- Performance TR (cont'd)
 - Performance criteria are modified versions of A, B, C

- IEC 61000-4-39: Electromagnetic compatibility (EMC) – Part 4-39: Testing and measurement techniques – Radiated fields in close proximity immunity test (77B/717/CD)
 - At one time a similar test was in the draft IEC 60601-1-2 Ed 4
 - IEC SC62A MT23 requested that TC77 develop this standard
 - MT23 prepared and submitted comments
 - Comments were due 10-10-2014

- MT23 members presented workshops at EMC 2014
 - Introduction to Medical EMC
 - Risk-Managing EMC