New Work Item Proposal

List of International Standards recognized by IMDRF Management Committee Members
Phase II

March 25, 2015
Background:

– Phase One Final Report issued March 2014
– Standards recognized by majority of MC members listed in Phase I Report
– MC members to update lists on ad hoc basis
– Outcome of September 14 IMDRF meeting: MC members to publish individual list of recognized standards
Phase II Proposal

Goal: To promote regulatory harmonization through greater use and acceptance of international standards:

Identify a core list of horizontal international standards
Core list of standards for consideration

Quality Systems: ISO 13485

Risk management: ISO 14971

Electrical Equipment: IEC 60601

Electrical Equipment for Laboratories: IEC 61010

Software: IEC 62304

Biological evaluation of medical devices (all parts): ISO 10993

Clinical investigation of medical devices: ISO 14155
Core list of standards for consideration

Symbols to be used in medical device labels: ISO 15223

Sterilization: ISO 11135, ISO 11137, ISO 17665, ISO 20857

Usability: IEC 62366

Aseptic Processing: ISO 13408

Use of animal tissues/derivatives: ISO 22442

Packaging (all parts): ISO 11607
Take steps to ensure Management Committee members recognize core standards

• Identify obstacles for not fully recognizing each standard

• Set goals for full recognition of core standards