

ISO/TC 194 – Biological evaluation of medical devices

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Material Characterization

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Overview of Current 'Nanotech' Standards Program (1)

- Material Characterization; Risk Management; Biological Evaluation (Safety) and Biological Evaluation Tests
- Program drivers – Nanotechnology materials (Nanoparticles) were starting to be used in medical devices; Awareness that physico-chemical and biological properties, body distribution and elimination, chemical reactivity and toxicological effects of nanoparticles may be different to particle materials of larger dimensions
- Customers/stakeholders - Patients, Healthcare Professionals, Carers, Consumers
- Pertinent work completed – ISO TS 10993-19, Physico-chemical, morphological and topographical characterization of materials

Overview of Current 'Nanotech' ISO 10993 Standards Program (2)

- Work underway - Ongoing review of all parts of ISO 10993 (20 parts) for potential modifications necessary
- Ongoing review of toxicological, tissue distribution, potential accumulation and fate data on Nanoparticles and other Nanomaterials in biological models and man. Incorporation of new data into Risk Management of Medical Devices (ISO 14971 and ISO 10993-1)
- Liaison with ISO/TC 229 Nanotechnologies
- Challenges and obstacles – Very limited characterization and toxicological data so far available in public domain

Overview of Current 'Nanotech' ISO 10993 Standards Program (2)

- Part 1: Evaluation and Testing (2003, DIS approved)
- Part 2: Animal Welfare Requirements (2006)
- Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity (2003, CD vote)
- Part 4: Selection of Tests for Interactions with Blood (2002, amendment 1, 2006, NWIP)
- Part 5: Tests for Cytotoxicity: In-Vitro Methods (1999, DIS vote)

Overview of Current 'Nanotech' ISO 10993 Standards Program (2)

- Part 6: Tests for Local Effects After Implantation (2007)
- Part 7: Ethylene Oxide Sterilization Residuals (1995, DIS approved)
- Part 8?: PDTS 29741 for Development of Tolerable Intake values for DEHP (diethyl hexyl phthalate) (NWI)
- Part 9: Framework for the Identification and Quantification of Potential Degradation Products (1999, DIS approved)

Overview of Current 'Nanotech' ISO 10993 Standards Program (2)

- Part 10: Tests for Irritation and delayed-type hypersensitivity (2002, CD vote)
- Part 11: Tests for Systemic Toxicity (2006, NWIP)
- Part 12: Sample Preparation & Reference Materials (2002, FDIS approved)
- Part 13: Identification and Quantification of Degradation Products from Polymeric Medical Devices (1998, CD approved)

Overview of Current 'Nanotech' ISO 10993 Standards Program (2)

- Part 14: Identification and Quantification of Degradation Products from Ceramics (2001, confirmed in 2006)
- Part 15: Identification and Quantification of Degradation Products From Metals and Alloys (2000, confirmed in 2006)
- Part 16: Toxicokinetic Study Design for Degradation Products and Leachables (1997, NWI)
- Part 17: Establishment of Allowable Limits for Leachable Substances (2002)

Overview of Current 'Nanotech' ISO 10993 Standards Program (2)

- Part 18: Chemical Characterization of Materials (2005)
- Part 19: Physico-chemical, Morphological and Topographical Characterization of Materials (TS, 2006)
- Part 20: Principles and Methods for Immunotoxicology Testing of Medical Devices (TS, 2006)

Documentary Standards Needs/Gaps

- Prioritization challenges – Risk management standard ISO 14971 does not refer to potential Nanotechnologies hazards
- Fundamental knowledge issues – very little data available on characterization, exposure and effects of engineered nanoparticles
- Measurement and characterization needs - Yes
- Supporting reference materials - needed
- Market need/demand – Public, patients and healthcare professionals expect/demand technology applications to be safe during manufacture, in use and in disposal.