Questionnaire regarding nomenclatures for concepts related to health technologies

1. **Name of the "nomenclature"**
   
   Medical devices — Coding structure for adverse event type and cause

2. **Name and legal status (Inc, Plc, Ltd, …) of the organization that manages the nomenclature system**
   
   ISO/TC 210. Quality management and corresponding general aspects for medical devices, WG3, Symbols and nomenclature for medical devices

3. **The organization that manages the nomenclature**
   
   a. **Please describe the governance and management of the body responsible for maintaining the nomenclature.**
      
      Standard ISO processes and procedures for technical specifications.

   b. **How is broad stakeholder representation ensured?**
      
      Through international votes and comments on draft documents.

   c. **How is broad geographical representation ensured in governing bodies?**
      
      Global. 31 countries participate/vote on TC210 documents. If interested, additional countries may participate if members of ISO.

4. **Background to the creation of the nomenclature**

   Please outline the scope of the mandate to engage in classification and naming

   Over 10 years ago, Chair of GHTF (Global Harmonisation Task Force) SG2 requested that ISO/TC210 WG3 develop a coding system for regulatory agencies to use for coding device postmarket adverse events.

5. **What is the intended purpose/use of the system?**

   To standardize adverse event information exchange between regulatory agencies and manufacturers submitting reports to regulatory agencies.
6. **Mandatory use of the nomenclature**
   a. Has any country or organization made it mandatory to use the nomenclature for specific purposes? No.

7. **Please comprehensively describe the structure of the system. The structure and format of terms, the relations between terms, design principles for creating terms etc. Current IT implementations by the "management organization" and by users are also of interest.**
   
   Current version (TS19218:2005 Medical devices — Coding structure for adverse event type and cause contains two sets of codes. The first, event type, describes an adverse device event at the time the event occurred as observed by the healthcare provider or other user. The second, adverse event cause code, characterises the conclusions of a cause analysis of the adverse event. Based on input from several regulatory agencies during the development of TS19218:2005, WG3 is in the process of developing a 2 level hierarchical system. The TS has been separated into 19218-1 for event types which is in process of being published by ISO and 19218-2 for evaluation codes (cause codes in current edition of TS19218) which is still under development. The hierarchical system is based on the original edition of ISO 19218 and the USFDA hierarchical structure.

8. **Are the terms used in the classification system generic i.e. non proprietary?**
   
   Generic or based on USFDA terms. USFDA terms are in the public domain and may be used by any party. This also applies to the definitions that are provided for each event and cause code.

9. **Maintenance of the nomenclature system**
   a. **How is the system maintained?**

   Use of ISO process process of periodic review.

   
   b. **Please describe the process for creating or modifying terms in the system.**

   Not currently in place. WG3 wants the new hierarchical TS publications to be in place for a few years before additional codes would be considered.

   
   c. **How is transparency ensured with regard to development and maintenance of the nomenclature?**

   Through ISO standards process of periodic review, new work item proposals and voting requirements. Countries may nominate national experts to participate on work groups.
10. Different language versions of the nomenclature
   a. How is the translation of terms and definitions managed?

   Following ISO translation procedures.

   b. What language versions exist as of February 2011?

   English, French, and Russian.

   c. What language versions are under translation as of February 2011?

   Not aware of any additional translations.

11. Endorsement of the nomenclature system
   a. Has the system been endorsed by stakeholders (healthcare professionals, Ministries of Health, industry, regulatory bodies etc.)?

   ☑ Yes  ☐ No

   Please indicate the names of the entities which have endorsed the system.

   GHTF (Global Harmonisation Task Force) SG2 incorporated code into their post market adverse event reporting device data set that is being used in an electronic submissions pilot.

12. Implementation in IT systems, interoperability and intellectual property
   a. Please outline the intellectual property state of the nomenclature system. Please include reference to the ownership of the terms used.

   Copyrighted by ISO.
b. **Is the system available as a package for integration into user IT systems (maintenance management, adverse event reporting, procurement....) ?** Yes
   - No

c. **Please specify the conditions of agreements for use in user IT systems.**

   There is no system. Codes could be incorporated into IT applications. In process of determining if there are any additional requirements for use of TS content.

13. **Interoperability**

   Please specify compatibilities ensured and mappings to other nomenclatures maintained.

   Intend to map to the USFDA device adverse event coding system.

14. **Model for sustainable financing**

   a. **How is the system financed? I.e. user fees, member fees, subscriptions, one off payments, open source?**

   Administrative support from standards body that supports TC210 (AAMI) and support of expert volunteer members of work group.

   b. **What is the cost of the nomenclature to specific users (governments, industry, health care providers)?**

   Cost of purchasing copy of technical specification.