

AGENDA ITEM 7 STATUS OF US/SDO PILOT PROJECTS AND SECRETARY-GENERAL'S PLANS FOR FURTHER IMPLEMENTING COUNCIL RESOLUTION 14/2001

In line with a set of decisions as consolidated in Council Resolution 12/2000 (attached at Annex 1), Council has approved pilot projects to be processed between ISO and three US Standards Development Organisations (SDO)¹. (A fourth SDO, ASME, was included in the original group of SDOs with which pilot projects were foreseen, but ASME considers the activities of ISO/TC 11 *Boilers and pressure vessels* to be adequate to its needs.)

1 Progress report on the status of the three approved US SDO pilot projects

ASTM

15 standards in the food dosimetry field passed the DIS ballot stage and the FDIS stage; they are due for publication under the ISO/ASTM designation by the end of March 2002. 9 ASTM standards which had previously been adopted by ISO but had not been technically revised were processed as minor revisions (issued for voting as FDIS) and will similarly be published under the ISO/ASTM designation in March 2002. One further ASTM standard was in development at the time the pilot project was initiated: it has now been finalized by ASTM and has been issued for DIS ballot.

API

ISO/TC 67 *Materials, equipment and offshore structures for petroleum and natural gas industries* has established and approved a set of criteria for API to use in selecting standards to be processed under the pilot project. No document to be processed under the project has been formally submitted as yet. In fact, it seems that API have concluded that their standards will in any case need revision and that they are therefore giving preference to the usual ISO process.

IEEE

Most of the activity has involved preparing a detailed implementation process for the pilot project. Having checked the final result of this exercise, the Secretary-General considered that the detailed process was consistent with that approved by Council and that further approval was not required.

IEEE has also indicated that it would like to use the process for a whole series of standards and not just those that were identified in the pilot project description approved by Council. The Secretary-General considered that, while Council would need to be informed, the decision could be left to ISO/TC 215 *Health informatics* which has now approved the extension of the pilot project to cover the other standards. The process has now been initiated for a number of standards, some of which have also been requested by CEN for processing under the Vienna Agreement.

¹ ASTM: American Society for Testing and Materials

API: American Petroleum Institute

IEEE: Institute of Electrical and Electronics Engineers

ASME: American Society of Mechanical Engineers

2 Plans for further implementing Council Resolution 14/2001

A proposal for an ISO pilot project with Health Level 7 (HL7), an ANSI accredited standards development organization, is attached at Annex 2 for consideration by Council.

This proposal is fully endorsed by ANSI and respects the fundamental principles of the ISO system, as approved under Council Resolutions 25/1999 and 12/2000.

Thought is being given to other possible candidates among US SDOs, and international organizations with an interest in standardization.

Any other specific proposals that arise will be submitted to Council in due course.

COUNCIL ACTION

Council is invited to:

- a)** comment on the above report;
- b)** consider the proposed ISO pilot project with HL7, attached at Annex 2, with a view to its approval.

COUNCIL RESOLUTION 12/2000

Council, after a full discussion on the draft pilot project with API, decides to approve the project, based on the following understandings and clarifications, which apply also to the ASTM pilot project:

- the project shall be carried out within the fundamental principles of the ISO system approved by Council under its Resolution 25/1999, and the latter should be referred to in the project;
- the selection of standards to be processed in the framework of the pilot project is and remains the responsibility of the corresponding technical committee in ISO; i.e. by the qualified majority of P-members of ISO/TC 67;
- at DIS level, both initially and during maintenance stages, the procedure ensures that the ISO DIS acceptance criteria are met, which involves a fully transparent handling and disposition of ISO member comments. This process is under the responsibility of the ISO TC Chairman and Secretary. The ISO technical committee remains in charge, to examine how the comments received are to be reviewed;
- the standard's designation shall be consistent with the ISO collection; i.e. for the general designation ISO/API XXXX, the XXXX is the ISO number;

further decides that the elements specified above should be followed in any further pilot project initiatives between ISO and any other Standards Development Organizations (SDOs),

asks the Vice-President (technical management) and the US SDOs negotiating group to take the necessary steps for further negotiations with the API representatives, so as to secure that the above shall be implemented, with due respect for the concerns expressed during the Council meeting in relation to acceptance of the WTO Standards Code and observance of the metric system.

ISO PILOT PROJECT WITH HEALTH LEVEL SEVEN (HL7) – PROPOSAL

1 Scope

Health Level Seven (HL7) is an American National Standards Institute (ANSI) accredited standards developer (ASD) that produces healthcare systems-related standards. The Term HL7 includes both the HL7 US membership and the membership of the HL7 Affiliates. HL7 proposes by this agreement to make certain of its standards, or parts thereof, available to become ISO/HL7 standards. Only ANSI-approved HL7 standards will be submitted to ISO.

2 Parallel processing

HL7 proposes to take responsibility for the development and maintenance of all ISO/HL7 standards through the HL7 Working Group with all rights for participation and input from ISO member bodies through their duly appointed technical experts equal to the members of the HL7 Working Group.

Representatives of the appropriate ISO member bodies will receive all ballots and related technical correspondence concerning the development of ISO/HL7 standards. ISO member bodies are granted limited rights to copy and distribute this information for the sole purpose of gathering greater consensus on the technical content of such standards.

2.1 Approval of ISO/HL7 standards projects

2.1.1 HL7 will propose to TC 215 *Health Informatics* the submission of certain HL7 standards to a process to gain recognition as ISO/HL7 standards. The proposal will include the HL7 standard title, scope, and rationale for using this process as well as the justification of the need for an International Standard and the identification of any liaisons.

2.1.2 The ISO TC secretariat will send a letter ballot to the members of the TC requesting approval to submit the proposed standard to a DIS ballot. A 2/3-majority vote of the P-members of the ISO TC is required for approval.

2.1.3 If the letter ballot is disapproved, HL7 will have the opportunity for further review and discussion with the ISO Technical Management Board.

2.2 DIS ballot

2.2.1 If approved, the ISO Central Secretariat will send a DIS ballot to all ISO member bodies. The ballot shall include a copy of the HL7 standard being considered for approval as an ISO/HL7 standard. The ballot will remain open for five months. (Standards will be distributed electronically wherever possible.)

2.2.2 Votes submitted by ISO member bodies shall be explicit: approval, disapproval, or abstention. An approval vote may be accompanied by editorial or minor technical comments but shall not be conditional on the acceptance of modifications. A disapproval vote shall contain technical rationale and indicate specific technical modifications that will change the disapproval vote to one of approval.

2.2.2a If the DIS ballot receives no disapproval votes from the P-members of the ISO technical committee, then the standard is approved as an ISO/HL7 standard and shall proceed to the publication stage.

2.2.2b If disapproval votes are received, the appropriate HL7 Technical Committee will address all disapprovals in accordance with ANSI-approved HL7 standard procedures. If any disapproval is found persuasive, the HL7 standard will be revised and re-balloted by the HL7 Working Group and, through the ISO Central Secretariat, by the ISO member bodies. The re-ballot will be open for two months.

2.3 FDIS ballot

2.3.1 If the disapprovals are found non-persuasive by the HL7 Technical Committees and the DIS acceptance criteria (see 2.1.2) have been met, HL7 will provide a report of voting and the final text of the standard to the ISO Central Secretariat. The ISO Central Secretariat shall prepare an FDIS ballot that will be distributed to all ISO member bodies. The FDIS ballot will be open for two months.

2.3.2 Votes submitted by ISO member bodies shall be explicit: approval, disapproval, or abstention. A disapproval vote shall contain technical rationale and indicate specific technical modifications.

2.3.3 The FDIS is approved if:

- a) A two-thirds majority of the P-members of the ISO technical committee vote to approve and,
- b) Not more than one-quarter of the total number of votes cast by all member bodies are disapproval. Abstentions are excluded from the count, as are disapproval votes not accompanied by technical rationale. Technical rationales for disapproval are submitted to the appropriate HL7 Technical Committee for consideration at the next review of the standard.
- c) The ISO Central Secretariat shall inform HL7 and the ISO TC of the outcome of the process. (Technical rationales for disapproval shall be appended for information only.) The ISO Central Secretariat shall submit a report to all national bodies showing the result of voting and indicate either the formal approval by national bodies to issue the standard or formal rejection of the standard.
- d) If the FDIS meets approval criteria, it shall proceed to the publication stage.
- e) If the FDIS does not meet approval criteria, the document shall be referred to the appropriate HL7 Technical Committee for reconsideration in light of the technical rationales submitted in support of the disapproval.

2.4 Maintenance

2.4.1 Members of HL7 or the ISO TC may propose changes to the ISO/HL7 standard at any time.

- a) Minor revisions to an ISO/HL7 standard shall be balloted by the HL7 Working Group and by the ISO member bodies as a FDIS with a two-month ballot period.
- b) Major revisions to an ISO/HL7 standard shall be balloted by the HL7 Working Group and by the ISO member bodies as a DIS with a five-month ballot period.

2.5 Periodic review

2.5.1 ISO/HL7 standards without pending ballot actions and whose approval date is four years old shall be reviewed in their entirety by the responsible HL7 Technical Committee and shall be letter balloted for re-approval (confirmation), revision, or withdrawal. Such action shall be initiated within five years of the last approval date.

2.5.2 HL7 will notify ISO TC 215 of HL7's impending action to letter ballot the standard and will request the TC's recommendation regarding the re-approval (confirmation), revision, or withdrawal of the standard prior to the next HL7 meeting where such action will be initiated.

2.6 Logos and document designation(s)

2.6.1 Both the ISO and HL7 logos will appear on the cover pages of ISO/HL7 standards, along with copyright and trademark notices and any appropriate disclaimers in the front matter.

2.6.2 The designation(s) for the documents will be a single designation ISO/HL7 XXXX. HL7 requests ISO to explore a numbering format that incorporates the existing HL7 name and version number in order to retain marketplace identity of the standards.

2.7 Publishing

2.7.1 Publishing (English versions)

2.7.1.1 HL7 will edit, maintain, and publish the English version of the approved standards providing the ISO Central Secretariat with appropriate camera-ready copy and electronic files. The ISO Central Secretariat will provide the cover information to HL7 in a timely manner not to exceed one month from ISO approval. The ISO Secretary-General shall provide fair financial compensation to HL7 for the cost of this work and material, at a level not more than the same would cost were it to be fully done at the ISO Central Secretariat.

2.7.1.2 HL7 will publish the English version in the ISO format.

2.7.2 Publishing (French versions)

For the French versions of the ISO/HL7 standards, the "business as usual" approach will be followed; i.e. AFNOR will, on request, provide the French versions as needed for parallel processing, and for the DIS and FDIS approvals. The ISO Central Secretariat will then handle editing and publication of the final French version of the standards, providing HL7 with copies of the cover and front matter for their records.

2.8 Copyright

2.8.1 Copyright ownership will be held jointly by ISO and HL7. ISO and HL7 will transfer exploitation rights, as is current policy, to those ISO member bodies who either sell the original standard, or adopt it as a national standard.

2.8.2 When ISO and HL7 publish and distribute the ISO/HL7 documents, the copyright notice will include both ISO and HL7.

2.8.3 It is agreed that neither HL7 nor ISO will insist that the other provide accounts of sales or other exploitation results.

2.8.4 As part of the joint copyright ownership, HL7 will retain the right to use material published in ISO/HL7 documents as the basis for subsequent HL7 standards.

2.9 Sales and distribution

2.9.1 ISO members have no geographical restrictions on their rights to sell nationally adopted or original versions of ISO Standards. This right will apply equally to ISO/HL7 standards. Further, there would be no restrictions relevant to the nationally adopted versions of the ISO/HL7 standards, either for HL7 or ISO members, on presentation media (e.g. electronic media), or on the rights to distribute or sell via third parties.

2.9.2 HL7 and ANSI shall have full exploitation and distribution rights and may sell the ISO/HL7 standards anywhere in the world without paying royalties to ISO or its member bodies.

2.9.3 If translations other than French of the published ISO/HL7 standards are made available by the member bodies, HL7 may wish, and is encouraged, to enter into agreements with the member bodies to share rights to those translations, and have the option to co-publish in those other languages.