



Cooperation agreement
Between
The International Organization for Standardization (ISO) and
Health Level Seven International (HL7)

1. Purpose

Considering that one of the objectives of the International Organization for Standardization (ISO) is to facilitate the international exchange of goods and services through the development of International Standards, and that ISO Council has adopted a policy of inclusiveness and encourages cooperation between ISO and other standardizing bodies, where such cooperation would serve to ensure effective and efficient use of resources available for standardization activities;

Considering that Health Level Seven International (hereinafter "HL7") is a global, not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery, and evaluation of health services;

Considering that a cooperation agreement between ISO and HL7 would serve to ensure effective and efficient use of resources available for standardization activities;

ISO and HL7 agree to cooperate on projects in the scope of ISO/TC215 Health Informatics where it is mutually beneficial and on a case-by-case basis subject to approval by both organizations and based on the following principles of cooperation.

2. Definition

For the purpose of this agreement, the following definition applies:

Common standard: a standard with technically identical content in ISO and in HL7 specifications.

3. Cooperation in the development of common standards

Participation in each other's work

ISO and HL7 agree that experts from each organization can be nominated to participate in each other's working groups.

Joint development and approval

Where ISO and HL7 wish to develop a common standard jointly such standards will be submitted to the HL7 Chief Standards Development Officer (CSDO) or other HL7 authority designated by the HL7 Board and to the ISO Secretary-General for review and acceptance, in consultation with TC215 or a different relevant ISO committee(s). The project would be developed and approved by establishing a joint working group comprising of experts nominated by ISO and HL7. The joint working group will be responsible for development of the initial draft of the common standard. The standard would then be subject to parallel review and approval within HL7 and ISO in accordance with the rules of each organization. The Secretariats (or appropriate bodies) of the respective ISO and HL7 committees will co-ordinate this work.

DIS fast track

In cases where an HL7 published standard has a particularly high level of global use and acceptance, HL7 may propose to ISO that an existing HL7 standard be submitted as a draft International Standard (DIS).

Such requests shall be submitted to the Secretary-General for review and acceptance, in consultation with the relevant ISO committee(s). Upon acceptance, the HL7 standard shall be circulated to the ISO member bodies for vote (to also allow for national public review and, where necessary, translation). Requirements for acceptance shall be those pertaining to the enquiry stage in the ISO/IEC Directives.

Disagreements in the technical work

In the case of any disagreement arising from the parallel approval process, the leadership of the relevant ISO committee(s) and the HL7 CSDO (or other HL7 authority designated by the HL7 Board) together with the appropriate HL7 project leads shall hold discussions in an attempt to resolve the issues. If no solution is found at the technical level, the matter will be referred to the ISO Secretary-General and the HL7 Chief Executive Officer (CEO). Both ISO and HL7 shall take the utmost care to ensure that conflicting standards are not released into the market.

4. Publication, copyright and exploitation rights

The resulting common standards will be published by ISO as ISO publications subject to ISO policies and by HL7 as HL7 publications. Unless otherwise agreed, ISO and HL7 will publish separate documents with technically identical content.

ISO and HL7 agree to accommodate each other's publication requirements regarding format and to promptly convene to discuss and resolve any issues requiring attention.

ISO and HL7 agree to reflect the common nature of the standards in the introductory parts of the respective publications.

Copyright ownership of ISO publications resulting from the application of this agreement will be held by ISO. Copyright ownership of HL7 publications resulting from the application of this agreement will be held by HL7.

Exploitation and enforcement rights will continue as described in ISO's and HL7 's respective policies. In ISO this includes the right for ISO members to nationally adopt and translate the standard in accordance with the ISO/IEC Directives, Part 1. ISO and HL7 may each sell and distribute the common standards, in accordance with their own rules, without any royalties to the other. This clause shall survive the termination of this agreement.

In the case of any disagreement on copyright, exploitation rights, and publication issues, the matter will be referred to the ISO Central Secretariat and HL7.

5. Maintenance of published common standards

Revisions to common standards produced under this agreement may be proposed at any time by ISO or HL7. Systematic review of the standards produced under this agreement shall occur on a period no longer than every five years.

In case both ISO and HL7 do not reach the same conclusion on the need to revise a common standard, ISO and HL7 may decide to revise the common standard unilaterally. In this case the resultant standard shall not be considered as a common standard.

6. Term of the agreement and cancellation

This cooperation agreement does not affect any other existing agreements between ISO and HL7.

The duration of this agreement shall be 5 years from the date of the latest signature, following which it shall automatically terminate. It may be renewed through the express written agreement from both ISO and HL7.

Notice of intent to cancel this agreement before its expiration may be provided at any time by either party but at least six months prior to the proposed cancellation date. ISO and HL7 shall attempt to resolve issues. If the outstanding issues cannot be resolved to the satisfaction of both parties, cancellation takes place on the date proposed in the notice of intent.



Sergio Mujica
Secretary-General
International Organization for
Standardization

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Vernier, Geneva, Switzerland



Charles Jaffe
Chief Executive Officer
HL7

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Del Mar CA, USA