Proposed approach for HL7 endorsement of DICOM PS3.20: Imaging Reports using HL7 Clinical Document Architecture

PS3.20 is the next generation of CDA imaging report template, building on the work of the HL7 [Informative] Basic Imaging Reports in CDA and DICOM Diagnostic Imaging Reports (DIR) Release 1, and the Diagnostic Imaging Report section of the several releases of the HL7 [DSTU] Consolidated CDA Implementation Guide. PS3.20 was developed in close collaboration with HL7 (including a For Comment ballot in December 2014) and with the radiology professional community through RSNA. The PS3.20 imaging report template has been intended as the replacement for C-CDA DIR, although the timing did not allow its incorporation into C-CDA release 2.1.

HL7 endorsement of DICOM PS3.20 will allow the deprecation of the informative universal realm DIR Release 1, and set the stage for incorporation of a US-realm equivalent into a future C-CDA release. A single standard formally endorsed by both HL7 and DICOM will be important to present a unified approach to the worldwide developer community. This operationalizes the commitments of both organizations through the Joint Initiatives Council.

Procedural requirements for endorsement are specified in the HL7 Governance and Operations Manual

18.01 Endorsement

If HL7 elects to endorse an externally developed IG and the developer is an accredited standards development organization, both HL7 and the developer may release their own version of the IG under separate copyright; otherwise the IG will be released by HL7 under joint copyright should the developer prefer to retain copyright. If a previously endorsed IG released under joint copyright is revised, updated, or otherwise changed from the original distribution it shall be resubmitted to HL7 for endorsement.

PS3.20 is a normative part of the DICOM Standard (PS3), with copyright held by NEMA on behalf of the DICOM Standards Committee. NEMA will retain its copyright under this endorsement process. The document is maintained under the DICOM continuous maintenance process of Change Proposals (minor corrections) and Supplements (major enhancements), and is published in PDF, XML, HTML, and Word formats on the DICOM web site. All Parts and formats of the DICOM Standard are available to the public at no cost.

The main organizational point for collaborating on the endorsement process will be the mirror working groups HL7 Imaging Integration Work Group (IIWG) and DICOM WG-20: Imaging Integration (WG-20), which have substantially overlapping membership and meet jointly, in accordance with the IIWG Decision Making Practices.

The endorsement ballot will be sponsored in HL7 by the IIWG in accordance with the HL7 Essential Requirements: Due process requirements for HL7 American National Standards as a Normative standard. Negative ballots and comments will be reconciled by IIWG, in collaboration with DICOM WG‑20 and WG‑06: Base Standard. Agreed changes to the text of PS3.20 will then be further handled through the DICOM Change Proposal (CP) process with a ballot by the DICOM membership. WG-06 may fast-track the CP ballot to ensure timely action on reconciliation. WG-06 will prepare the updated text for publication. HL7 will have the option to also publish the document, or may simply provide pass through from its web site to the DICOM web site.

The HL7 endorsement (upon successful HL7 ballot) will be included on the cover of PS3.20 as follows:

This Part is published with the endorsement of, and under joint copyright with, Health Level Seven® International. Comment or proposed changes to this Part should be sent to the DICOM Secretariat dicom@medicalimaging.org.

Subsequent to the initial endorsement, comments or proposed changes will be received by the DICOM Secretariat and forwarded to WG-06 and WG-20 / IIWG. These will be evaluated by WG-06, with advice from WG-20 / IIWG, and dispositioned as “no change warranted” (with a response to the commenter/proposer), or “for further evaluation” with the proposed change assigned a DICOM Change Proposal (CP) number. The CP will be assigned to an editor (potentially from WG-20), and will go through the standard DICOM CP development and review process. Note that after further consideration, a proposed change may be rejected or substantially modified by the WGs.

When WG-06, with advice from WG-20 / IIWG, determines that the CP is ready for approval, it will be sent to the DICOM membership through a CP Letter Ballot, and to the HL7 membership through an HL7 ballot sponsored by IIWG. Comments received in both ballots will be reconciled jointly by IIWG in accordance with the HL7 Essential Requirements, and by WG-06 in accordance with the DICOM maintenance process. Final Text approval will be done only after reconciliation of both ballots has completed, at which time WG-06 will prepare the updated document for publication.

Major updates to PS3.20, e.g., addition of a new document level template for a different imaging domain, will be handled through the DICOM Supplement process. This requires a New Work Item approval by the DICOM Standards Committee, which will be assigned to a relevant DICOM subject matter expert WG (e.g., WG-08: Structured Reporting, or WG-1: Cardiology) and to WG-20 / IIWG. The Supplement will go through a circulation for Public Comment through the standard DICOM process, as well as an HL7 For Comment ballot sponsored by IIWG. The Supplement as revised following Public Comment will be sent to the DICOM membership through a Supplement Letter Ballot, and to the HL7 membership through an HL7 endorsement ballot sponsored by IIWG. As with CP approval, Final Text approval will be done only after reconciliation of both ballots has completed.