Work Item 0809020: A standards developer who’s ANSI-Accredited Procedures includes a DSTU provision associated with the current Annex B as contained in the ANSI Essential Requirements shall revise its procedures to eliminate the DSTU option through ANSI in accordance with the 2009 ANS Compliance Form cycle. That is, developers will have one year from the 2009 Compliance Form deadline date to submit procedures for approval by the ANSI ExSC that eliminate this option.

Source: Anne Caldas - Director, Procedures and Standards Administration; Accreditation Services; American National Standards Institute (ANSI)

Ratified by the EC: Ratification is not required for a work item addressing changes to ANSI Essential Requirements: Due Process Requirements for American National Standards

GOC analysis/rationale: While the elimination of Annex B Draft American National Standards for Trial Use will have no material impact on HL7 process, it is necessary, given the directive above, to remove all reference to or association with Annex B from the GOM.

It is important to note that the elimination of Annex B in no way precludes the use of DSTU by HL7. The notification of elimination includes the following statement: “Deletion of Annex B does not preclude an ANSI-Accredited Standards Developer from developing, approving and disseminating its own draft standards for trial use; however, such documents may not be announced as or otherwise promoted as “Draft American National Standards for Trial Use.”

Proposed revision:

13 Review Ballots

13.02 Draft Standard for Trial Use (DSTU)

13.02.02 Forming the Review Group

All current members shall be notified of the intent to form a review group and ballot the content of a proposed draft standard not less than thirty days prior to the opening of the ballot. This notification shall occur via the various HL7 newsletters and member list servers and shall include the date that enrollment in the review group shall open. Members shall indicate their interest by enrolling in the review group via the HL7 Ballot Desktop during the enrollment period which shall end one week prior to the ballot closing date. The minimum review group shall be ten current individual members or individuals, representing at least three current organizational members.

13.02.04 Handling Comments

[The first paragraph of this section is not affected by this revision]

[The second paragraph of this section is not affected by this revision]

The issue of substantive change shall not be applicable to a proposed draft standard. In the instance of an approved draft standard with substantive change resulting from review, it is left to the discretion of the responsible Work Group to either submit to another ballot or move forward with the revised content and issue a draft standard for trial use.

[The fourth paragraph of this section is not affected by this revision]
The proposed draft standard shall be considered approved if sixty percent (60%) of the combined affirmative and negative votes cast by the review group are affirmative.

Upon approval the proposed draft standard, with the concurrence of the TSC, shall be released for publication as a DSTU.

The front cover of a DSTU shall include the following statement.

“Publication of this draft standard for trial use and comment has been approved by Health Level Seven, Inc. (HL7) Distribution of this draft standard for comment shall not continue beyond [indicate the number of months allocated for evaluation and review, not to exceed 24] months from the date of publication. It is expected that following this [the number of months shown above] month period, this draft standard, revised as necessary, will be submitted to a normative ballot in preparation for approval by ANSI as an American National Standard. This draft standard is not an accredited American National Standard. Suggestions for revision should be submitted at http://www.hl7.org/dstucomments/index.cfm.”

The use of the ANSI logo or trademark on a DSTU is strictly prohibited, and at no time shall the DSTU be referred to as a Draft American National Standard for Trial Use.