

MedBiquitous Response to ANSI Findings of January 2009 Audit

May 21, 2009

This document outlines ANSI audit findings from its January 2009 audit and proposes corrective actions to address those findings as well as timelines for their implementation.

FINDING

i. The auditor recommends that, in accordance with clause 2.5 of the *ANSI Essential Requirements*, MedBiq submit a PINS form at the initiation of the project to develop or revise an American National Standard (including the national adoption of ISO and IEC standards as American National Standards). In the opinion of the auditor project initiation begins when the MedBiq Executive Committee votes to authorize the project. Registration of projects using the PINS form is designed to provide a central databank of information relative to voluntary consensus standards. It is useful for providing direct information to all interested parties and is a key element in planning and coordination. It is therefore crucial that submission of a PINS form be timely. In addition, a timely notice published in Standards Action based on a PINS form submitted at the time a decision is made to review and revise a standard may result in greater participation in the development of a standard. The auditor noted that the June 1, 2005 minutes of the Executive Committee indicated initiation of the project, and the PINS form was filed on July 19, 2005.

PROPOSED ACTION

MedBiquitous proposes the development of internal guidelines for the implementation of the standards program operating procedures. The guidelines will clarify that PINS forms must be submitted within 30 days of approval by the Executive Committee. Staff will check to confirm that the PINS form is submitted in a timely manner.

TIMELINE

Guidelines will be developed by October 31, 2009.

FINDING

ii. The auditor recommends that, when a recirculation ballot is conducted for the approval of a draft standard, all consensus body be given the opportunity to vote. Clause 2.6 of the *ANSI Essential Requirements* states that “any substantive change made in a proposed American National Standard shall be reported to the consensus body in order to afford **all members** of the consensus body an opportunity to respond, reaffirm, or change their vote.” (emphasis added) The auditor noted that the email sent to the consensus body for the recirculation ballot stated “[f]or those of you that voted in the Healthcare LOM and Professional Profile, you have the opportunity to change your vote based on the changes made to the specifications as a

result of the comments received.” The auditor noted that this statement does not appear to allow those consensus body members who did not vote on the first ballot to vote on the recirculation ballot.

PROPOSED ACTION

MedBiquitous has changed the ballot language to ensure that from now on it is clear to the consensus body that everyone on it will have the opportunity to respond, reaffirm or change their vote regardless of whether or not they returned the original ballot.

TIMELINE

The change has been implemented.

FINDING

iii. The auditor recommends that, in accordance with Section 8.4 of MedBiq’s Procedures, MedBiq provide all consensus body members with the six-week voting period. The auditor noted that when MedBiq extended the ballot due to the fact that nine organizations initially had not received the ballot, those voters only had a ballot period of 23 days.

PROPOSED ACTION

MedBiquitous is committed to affording all members of the Standards Committee opportunity and time to vote on standards. Internal guidelines for the implementation of the standards program operating procedures will specify measures to ensure that the ballot pool is up-to-date before balloting begins. Guidelines will also specify appropriate action to take in the event of Standards Committee members being inadvertently omitted from ballot communications. Staff will ensure that this takes place.

TIMELINE

Guidelines will be developed by October 31, 2009.

FINDING

iv. The auditor recommends that, MedBiq revise its procedures to comply with the *ANSI Essential Requirements*:

- a. That in accordance with clause 2.7 of the *ANSI Essential Requirements*, MedBiq revise its procedures to include a method by which MedBiq will document and consider as new proposals timely comments that are not related to the proposal under consideration. The policy should include notification to the commenter.
- b. That MedBiq add the words “in writing” to Section 8.6 of MedBiq’s Procedures for informing unresolved objectors of the right to appeal.

- c. That MedBiq revise the MedBiq Appeals Policy to comply with the *ANSI Essential Requirements*, in particular, by removing Section 12.7.

PROPOSED ACTION

MedBiqitous will revise its standards program operating procedures to comply as noted.

TIMELINE

Procedures will be revised and approved by October 31, 2009.

FINDING

v. The auditor recommends that, in accordance with clauses 3.0 and 3.3 of the *ANSI Essential Requirements*, MedBiq revise its Policy on Evidence of Compliance (Records Retention Policy) and provide ANSI with a copy. Clause 3.3 regarding records retention requires, as a minimum, that records concerning new, revised or reaffirmed American National Standards be retained for one complete development cycle or until the standard is revised. Records concerning withdrawn standards shall be retained for at least five years from date of withdrawal. The auditor finds that the MedBiq Records Retention Policy, in Section 14.0 of the MedBiq Procedures, does not meet the requirements of clauses 3.0 and 3.3 of the *ANSI Essential Requirements* because not all records relating to the development of the standard are required to be kept by MedBiq for at least one records cycle.

PROPOSED ACTION

MedBiqitous will revise its standards program operating procedures to comply as noted.

TIMELINE

Procedures will be revised and approved by October 31, 2009.